Current Topics in Otolaryngology – Head and Neck Surgery

Middle Ear Surgery

Recent Advances and Future Directions

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Klaus Jahnke

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Middle Ear Surgery

Recent Advances and Future Directions

Editor

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Preface

The papers presented at the annual meeting of the German Society of Otorhinolaryngology, Head and Neck Surgery represent important contributions to clinical research. On the threshold of a new century, some of the most important chapters in middle ear surgery will be explored as the keynote topic for the first time in 43 years. It was then that Wullstein and Zöllner presented their ground-breaking concepts and results of tympanoplasty. In the decades following, individual topics in middle ear surgery were repeatedly presented at the annual meetings, including Plester's lecture on the surgical treatment of cholesteatoma. Because of our limited format, we cannot fully explore the topic at hand. It is our intent, rather, to emphasize key points, address questions that are still unresolved, and provide an impetus for future research.

The function of the eustachian tube plays a key role in the pathogenesis and resolution of many diseases of the middle ear and in its successful reconstruction. Dr. Pahnke reviews current knowledge on the anatomy of the eustachian tube, to which he has made important contributions. He details the physiology and pathophysiology of the eustachian tube and reviews current diagnostic methods. He closes with a critical look at the limited possibilities of influencing eustachian tube function and takes note of recent developments.

Dr. Hüttenbrink, reviews what is currently known about the biomechanics of the reconstructed sound conduction apparatus. His paper is a fascinating look at the numerous factors that determine the functional outcome of a middle ear reconstruction. Many studies confirm the validity of clinical developments such as cartilage techniques that are used to reinforce the plane of the tympanic membrane, even in classic type III and IV cases. In other cases, basic research in recent years has contributed greatly to the refinement of tympanoplastic techniques. Of course, clinical realities often require making trade-offs between, say, the stability of a reconstructed tympanic membrane and its ability to vibrate. Compromises may also have to be made regarding the stable attachment of implants in patients with eustachian tube dysfunction. The technological advances described in the last section of Dr. Hüttenbrink's paper suggest that new discoveries will be forthcoming.

Until a few decades ago, biomaterials research had yielded almost nothing of practical value. The first international biomaterials conference was held in 1980. Until quite recently, new implants were being introduced that had not previously been tested at analogous sites in laboratory animals. Dr. Dost and I undertook the formidable task of reviewing the principal classes of biomaterials. Our paper deals with the requirements that must be met for various indications. Examples from our own studies are given to document the importance of preclinical animal trials and cell culture studies. We also emphasize the need for further research. Based on our experience with new titanium stapes implants, we stress the need for controlled clinical studies.

Techniques of cholesteatoma surgery continue to stir controversy, as the most recent international cholesteatoma conferences have shown. Drs Hildmann and Sudhoff and I address this topic by first discussing the various forms of cholesteatoma and their pathogenesis, which significantly influences surgical management. Our discussion takes into account the results of recent studies in molecular biology. The focal point of our paper is the concept of tailoring the cholesteatoma surgery to the individual patient. This concept is based on clinical experience and study results at two training centers, which have already supplied material for numerous national and international courses in otologic surgery. A number of refinements in operative technique are also described. We were unable to review the very extensive international literature in this area, and we could only touch upon some important aspects such as specific complications.

Stapes surgery has a predictably high success rate in experienced hands with a very low incidence of complications. Even so, innovations in operative technique have still been presented in recent years. Dr. Häusler has written a comprehensive paper dealing with all aspects of stapes surgery. He describes numerous technical refinements in detail and presents his own innovations in their clinical applications and results, giving special attention to improved instruments and various laser techniques. He analyzes the extensive world literature and discusses methods of evaluation. Dr. Häusler answers almost all questions pertaining to stapes surgery based on his wealth of otosurgical experience.

The development of partially and completely implantable hearing aids has been fascinating in recent years and has included important pioneering work by Dr. Zenner and his group. His paper deals with all types of hearing aids in current use and also describes developments that have not proven successful. With convincing clarity, he proposes a new nomenclature for active hearing aids based not on the implantation site but on the function that the device replaces. He reviews the indications for hearing aid implantation and the clinical results that have been reported thus far. Dr. Zenner suggests that these technical developments will help to achieve a balance between the further optimization of conventional hearing aids and cost containment issues.

I express thanks to all the contributors for their tireless efforts. May this collection of articles bear witness to the high standards and innovative power of middle ear surgery at the start of the new century, and may it provide a valuable reference work for every otologic surgeon.

Essen, Spring 2003 Klaus Jahnke

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1 Morphology, Function, and Clinical Aspects of the Eustachian Tube

J. Pahnke

Abstract

Morphology, Function, and Clinic of the Eustachian Tube. Diagnostics and treatment of diseases of the Eustachian tube are difficult due to the deep position underneath the skull base and its oblique course. Several theories exist explaining the normal and disturbed function. Few sufficient tests for functional evaluation exist. Gross anatomical and microscopical features of the Eustachian tube gained from 30 sectional series were correlated with radioanatomical findings of high resolution magnetic resonance tomography (MRT) of 29 adult persons without ear disease. Differences to MRT of 31 patients with tubal disease or disturbed ear ventilation were evaluated. Tubal cartilage (TC), musculus tensor veli palatini (MTVP), and Ostman's fat pad have a characteristical shape, that ist correlated to normal function. The zone of physiological tubal closure ist found in the vicinity of the isthmus. For precise imaging of these anatomical tubal structures using of special simple or double angulation of MRT-planes is necessary. Open tube disease often shows a typical atrophy of the Ostman's fat pad in the physiological closing zone. Causes of obstruction are found in different parts of the tube. Atrophy and hypertrophy of mucous membrane are also shown as a pathogenetic factor. In many cases disturbed function of the Eustachian tube is correlated to impaired anatomical structures which may be identified by MRT. Treatment should be planned according to afflicted structures. A synopsis of anatomy, physiology, and clinical characteristics ist presented.

Introduction

As early as 500 BC, Alkmaeon of Sparta knew of the existence of the eustachian tube. In the 16th century, the Italian anatomist Eustachio believed that the tube was normally patent [1].

The position, course, and parts of the eustachian tube have been described in numerous publications and evaluated with regard to their medical significance. The eustachian tube consists of a bony part and a cartilaginous part, which comprise the basic elements of its wall. In the bony part, the temporal bone provides a stable, rigid framework for the tubal mucosa, while the cartilaginous part retains some degree of mobility and flexibility throughout life.

Although the individual components of the eustachian tube and the muscles that act on the tube have been known for many years, the interpretation of its overall structure has always been a matter of controversy. For example, while Henle [2] believed that the tensor veli palatini muscle compressed the tubal lumen, Luschka [3] called that muscle the dilator tubae.

Proctor [4] emphasizes that the eustachian tube is one of the most complicated regions in the human body and that tubal abnormalities are difficult to interpret. Honjo et al. [5] note that we still know few details about the processes of tubal opening and closure.

Several authors have explored the topographic relationships of the eustachian tube [4, 6, 7], but few have presented quantitative data on its spatial relationships.

Because of its complex course, the eustachian tube is not routinely visualized in standard imaging procedures. Another difficulty is that the bony part of the tube is defined better by computed tomography (CT), while its cartilaginous part is defined more clearly by magnetic resonance imaging (MRI).

Because the eustachian tube is angled in relation to both the horizontal and median planes and does not lie in a single plane, it cannot be completely visualized in one standard sectional image [8]. Generally, one imaging procedure alone cannot define all of the structures and tissue types in one body region. Thus, it is particularly important in the skull base region to know the forms and dimensional features of structures that are being looked for or interpreted.

With the modern image processing systems that are available in CT and MRI, the examiner can reconstruct images in arbitrary planes from a 3D data set [9]. When this type of system is used, it is not difficult to generate detailed cross-sectional images of the eustachian tube and its surroundings.

From a therapeutic standpoint, it is important to consider not just the dimensional parameters of the eustachian tube and its muscles but also the relationship of the tube to neighboring structures. Numerous studies of this kind have already been done on the bony part of the tube [10, 11], but relatively little information has been published on its cartilaginous part.

In this paper we shall review various anatomical, functional, and clinical features of the eustachian tube and attempt to apply a uniform interpretation to all of its aspects.

Spatial Orientation and Length of the Eustachian Tube

The eustachian tube is angled in relation to both the midsagittal and horizontal planes [12]. It runs medially downward from the middle ear toward the nasopharynx (Fig. 1.**1**).

The angles formed by the cartilaginous part of the tube with the midsagittal plane (MS) and with the orbitomeatal plane (DH) were measured in 50 heads that had been sectioned in the midsagittal plane [13]. An average angle of 35.6° was measured between the DH and the long axis of

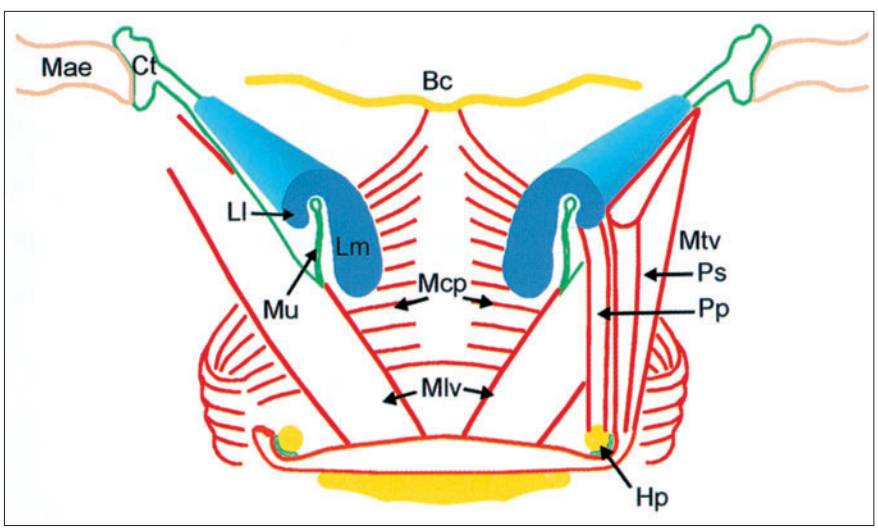

Fig. 1.**1** Schematic representation of both eustachian tubes, viewed from the anterior aspect.
Bc = skull base, Mae = external auditory canal, Ct = tympanic cavity, Ll = lateral lamina of tubal cartilage, Lm = medial lamina of tubal cartilage, Mu = mucosa, Mcp = constrictor pharyngis superior muscle, Mlv = levator veli palatini muscle, Mtv = tensor veli palatini muscle with superficial part (Ps) and deep part (Pp), Hp = pterygoid hamulus

the cartilaginous part. The side-to-side difference was 3°, and the gender difference was 1.8°. Neither difference is statistically significant.

Schwalbe [14] defined the angle between the eustachian tube and the horizontal plane as the inclination, which averaged 30° in his measurements. Graves and Edwards [6] reported a range of 30–40°, noting that the pharyngeal orifice of the tube is 15 mm lower than the tympanic orifice. The fact that the angle with the DH is smaller on the right side than on the left can be attributed to side-to-side difference in the orientation and position of the petrous bone, for according to Lang [15] the middle cranial fossa is lower on the right side than on the left. Schwalbe [14] called the angle between the eustachian tube and the sagittal plane the declination, stating that it averaged 45–50°. According to Warwick and Williams [7], the longitudinal axis of the eustachian tube forms a 45° angle with the sagittal plane. Kubik [16] states that it forms a 45° angle with each of the three cardinal planes. An average value of 43° (29–52°) was found in the Würzburg specimens (see below) for the angle between the eustachian tube and the midsagittal plane. The presence of smaller angles on the right side than on the left is consistent with the findings of Putz [17], who described smaller "sinus peak angles" on the right side. Lang [15] found that the anterior angle between the petrous ridge and MS plane averaged 128.7° on the right side and 127.0° on the left side, representing a statistically significant difference between the two sides.

The angles between the eustachian tube and the cardinal planes are of key importance in diagnostic imaging studies, for when these angles are known, the examiner can match the scan plane to the anatomical course of the tube [8]. The angles also have practical importance with regard to the placement of tubal catheters and endoscopes.

Todd and Muller [18] tried to correlate the position of the eustachian tube with signs of prior middle ear inflammation. They could not find a significant relationship for either the bony or cartilaginous portion of the tube. They claim, however, that short tubes have a significantly higher association with signs of previous otitis than longer tubes.

The pharyngeal origin of the eustachian tube has been localized to the anterior surface of the posterior tubal eminence. Starting from that point, the length of the tube can be reconstructed in serial sections. Its total length averages 36.2 mm (range of 31.2–42.4 mm), which is consistent with the findings of other authors. Thorton [19]: 1.5–1.75 in, Bezold [20]: 36.4 (34–40) mm, Graves and Edwards [6]: 31–38 mm. The eustachian tube is approximately half as long in newborns as in adults [7]. The length of the tubal cartilage in the Würzburg specimens averaged 31.5 mm. This means that the total length of the tube is only about 15 % greater than that of the tubal cartilage. The end of the tubal cartilage is always located posterolateral to the tubal isthmus. As will be shown later, the length of the cartilage is not equivalent to the length of the cartilaginous part of the tube. Zöllner [21] measured a distance of 24–28 mm between the pharyngeal orifice and the tubal isthmus. Other authors found that the cartilaginous part was approximately 25 mm long [4, 6]; it averaged 26 mm (22.4–31.6) in the Würzburg specimens. Precise values are rarely stated for the origin and endpoint of the cartilaginous part, as there is no single standard for defining that segment of the tube. The length of the eustachian tube is an important consideration, for example, in the positioning of MR imaging volumes.

Components of the Eustachian Tube

We obtained our anatomical data from series of sawed sections taken from 30 hemicrania at the Department of Anatomy of Würzburg University [13]. All the specimens had been prepared for academic use by standard methods using formalin- and alcohol-containing solutions. Some of the specimens had been injected with intra-arterial and intravenous dye-containing gelatin solutions for enhanced contrast. Twenty specimens were sectioned perpendicular to the long axis of the eustachian tube, five in the sagittal plane, and another five in the transverse plane.

Lumen

The diameter of the tubal lumen decreases from the pharyngeal orifice toward the middle ear, but not steadily. The tube often shows slight expansions in its posterior course. The maximum luminal diameter averages 7.3 (6.0–10.0) mm and is located approximately 6–7 mm behind the pharyngeal orifice. As a rule, therefore, the eustachian tube does not steadily widen from the tympanic cavity to form a trumpet-like lumen at its pharyngeal end (Fig. 1.**2**). The shape of the lumen in the pharyngeal third is highly variable, due in part to the presence of mucosal folds in the floor of the tube. These folds are always visible and provide the redundant tissue that is necessary for tubal opening. Usually the medial and lateral mucosal surfaces are apposed except in the area of the inlet funnel, which is expanded to about 7 mm. The walls increasingly diverge at the junction of the bony and cartilaginous parts. Rüdinger [22] states that the lumen measures 6.2 mm. In the upper part of the tube located in the cartilaginous groove, he describes a space 0.4–0.5 mm in diameter that is constantly patent and is occupied by air or mucosa. This area, known as Rüdinger's safety canal, could be positively identified in the upper portion of the tube in 85 % of the Würzburg specimens. It had an average diameter of 0.4 mm and commenced about 10 mm behind the pharyngeal orifice. It could not always be traced for the entire length of the cartilaginous part of the tube [13].

Persistent, valve-like protrusions of tubal mucosa are believed to divide the upper portion of the tubal lumen from the lower portion. Honjo et al. [5] claim to have identified Rüdinger's safety canal in two contrast radiographs. In endoscopic procedures on the eustachian tube, attention should be given to possible accessory lumina or local dilatations in the tubal lumen. No true diverticula were found in any of the Würzburg specimens. Our measurements indicate a slight expansion in the pharyngeal third of the tube (Fig. 1.**2**), which Siebenmann [23] depicted in an illustration but did not describe. The local expansion of the tubal lumen behind the pharyngeal orifice may form a site of

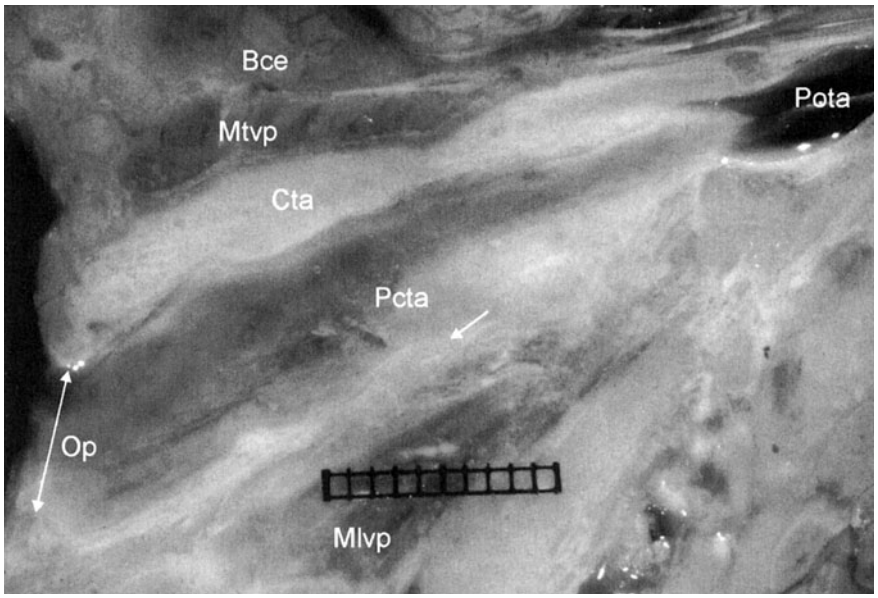

Fig. 1.**2** Longitudinal section through the right eustachian tube of an adult. The plane of the section is angled 45° from the midsagittal plane, giving a view of the lateral tubal wall.
Bce = external skull base, Mtvp = tensor veli palatini muscle, Cta = cartilage of eustachian tube, Pcta = cartilage part of eustachian tube, arrow = inferior mucosal border, Pota = bony part of eustachian tube, Mlvp = levator veli palatini muscle, Op = pharyngeal orifice of eustachian tube.

predilection for Kirchner diverticula. Functionally significant narrowing of the tube by lymphatic tissue is rare. Histologic studies of fetal and postnatal stages have confirmed that the tubal tonsil does not occur as an anatomical entity [24]. Lymphatic tissue in the nasopharynx does not extend into the tube itself. It may extend as far as the pharyngeal orifice and deform it, but this does not cause eustachian tube dysfunction [25].

Kamimura and colleagues investigated histopathologically the mucosa-associated lymphoid tissue (MALT) in middle ear and eustachian tube in 99 vertically cut temporal bone–eustachian tube specimens. MALT did not appear in 21 neonates under the age of 1 month, but among the specimens from infants between 1 month and 7 years of age MALT was found in 50 %. In 26 adults over 18 years it appeared in 7.7 %. The presence of MALT was significantly higher in specimens with otitis media (43.9 %) than in cases without (13.8 %) [145].

Urbantschitsch [26] found that the distance from the anterior nasal spine to the pharyngeal orifice ranged from 5.3 to 7.5 cm. Mangiaracina [27] measured a distance of 7.9 (6.9–8.8) cm.

According to von Tröltsch [28] and Proctor [29], the pharyngeal orifice is 9 mm in height and 5 mm in width. According to Bryant [30], the long diameter measures 7 mm, and on tubal opening the orifice assumes the shape of an equilateral triangle 6 mm in height and width. Moos [31] states that the depth of the inlet funnel is 5–6.5 mm. The orifice normally undergoes distinct shape changes during swallowing and other muscular contractions (e.g., phonation) [32, 33].

Tubal Cartilage

The tubal cartilage can often be traced into the roof portion of the osseous part of the eustachian tube. Thus, its total length of 31.2 (27.2–36.7) mm is considerably greater than the length of the cartilaginous part of the tube. Occasionally it may extend into the roof portion of the tympanic orifice [13]. In the Würzburg specimens, the medial lamina has a maximum width of 5.1 (3.2–8.0) mm. This site is located 6.6 (2.5–11.6) mm behind the pharyngeal orifice. The maximum width of the lateral lamina is 1.8 (1.1–2.6) mm. Numerous morphological variants in the tubal cartilage can be recognized in the serial sections. It is common to find deep notches that may contain seromucous glands, fatty tissue, vessels, and even nerves (Fig. 1.**3**) [34].

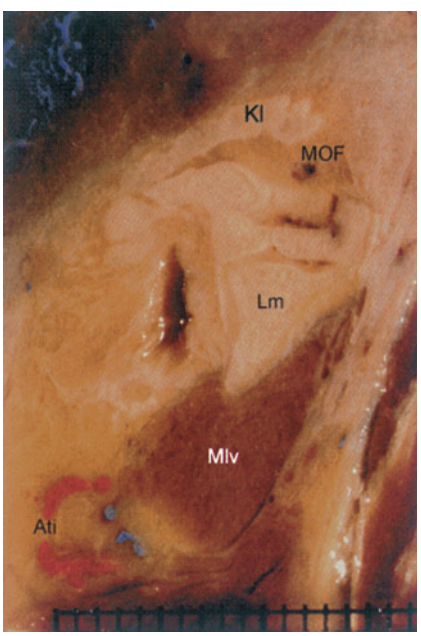

Fig. 1.**3** Cartilaginous part of the eustachian tube, parasagittal section. The cartilaginous ridges (Kl) may appear as isolated cartilage fragments in transverse section.
Lm = medial lamina of tubal cartilage, Mlv = levator veli palatini muscle, Ati = inferior tubal artery, MOF = medial Ostmann fat pad. Male age 71 years.

In some cases this appears to produce cartilage fragments that are separate from the main cartilage mass, but scrutiny of adjacent sections shows that the "fragments" are continuous with the rest of the cartilage [24]. It is also common to find islets of fatty tissue and vessels. Apparently these discontinuities serve to increase the mobility of the cartilage, especially in the medial lamina. Deep clefts are consistently found in the pharyngeal portion of that structure. In one-fourth of cases, hooklike processes from the medial lamina curve around the inferior portion of the lumen. In almost all specimens, small additional cartilage fragments are found near the floor of the lumen. At the temporal end of the cartilaginous part, the lumen is occasionally completely surrounded by cartilage. As the resolution of MRI improves, isolated cartilage fragments and morphologic variants assume increasing importance.

Rüdinger [22] believed that the tubal cartilage was avascular. This is true as far as the actual cartilaginous tissue of the tube is concerned. Examination of the Würzburg material consistently revealed areas with fatty tissue, vessels, and occasionally even nerves within the cartilage. Henle [2] discovered vascularized processes of perichondrium that extended into the cartilage. Elastic fibers are particularly abundant in the zone of attachment between the medial and lateral laminae [24, 35].

According to Proctor [37], the tubal cartilage is composed of three or four segments that are derived from an equal number of chondrification centers. Between the segments are gliding joints that supposedly promote mobility during swallowing. We could find no signs of this gliding mechanism in our own material, although the deep, fluid-filled notches could perform such a function. The arrangement of the tubal muscles and the numerous clefts in the cartilage are apparently designed to allow bending movements of the cartilage. The medial lamina has the most notches in its pharyngeal portion. Urbantschitsch [26] found splits in the tubal cartilage with such frequency that he considered them normal.

Near the pharynx, the laminae are directed more or less at right angles to each other. Further posterolaterally, the laminae show a typical "shepherd's crook" pattern in cross section. On average, the cartilage extends approximately 5 mm into the roof portion of the bony eustachian tube. The tubal cartilage stopped just behind the isthmus in only one of 20 series of transverse sections. Although Kubik [16] states that the cartilage may often extend into the floor of the bony part, we did not see this in any of our specimens.

At the inferior border of the medial lamina is a notch called the tubal incisure [38]. It gives attachment to the levator veli palatini muscle.

Cartilaginous fragments located at the convexity of the cartilage were connected to the main cartilage in more than 80% of cases and were part of a cartilage ridge that attached to the superior ligament apparatus. The zone of attachment with the main cartilage is generally located near the pharyngeal end.

Accessory cartilage elements located between the superior circumference of the levator veli palatini muscle and the floor of the lumen may exert slight pressure on the tubal lumen. In this way they facilitate relaxation of the membranous part of the tube by the levator veli palatini muscle.

Suspensory Fibers

In all segments of the cartilaginous part of the eustachian tube, thin bundles of collagen fibers project to the tubal cartilage and hold it in place. They arise from bony prominences on the petrous temporal bone or sphenoid bone, from the sphenopetrosal suture, and from the basilar fibrocartilage. Most of the fibers run in two tangential groups to the medial and lateral laminae, where they attach to the perichondrium or project radially into the cartilage after making a right-angle bend. As suggested by Zöllner [21], these fibers may be termed the lateral and medial suspensory ligaments (Fig. 1.4). A particularly constant feature in almost all segments is the lateral ligament, which runs tangentially to the lateral lamina. It also gives origin to several fibers belonging to the superficial part of the tensor veli palatini muscle. Structurally, the lateral ligament is not a discrete band but a ligamentous plate. If the fiber tract is not in direct contact with the cartilage, a small fat pad is consistently interposed between the fibers and the cartilage. Lateral to the fat pad, it is common to find additional fatty tissue that permeates the origin of the superficial part of the tensor veli palatini muscle close to the pharynx.

Near the pharynx the fibers arise directly from the skull base. About 1 cm posterolaterally, the fibers arise mostly from the basilar fibrocartilage and may be reinforced by additional fibers from the lateral side.

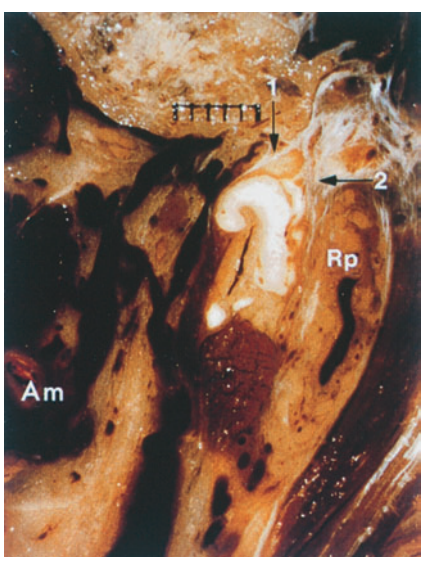

Fig. 1.4 1 = Lateral tubal suspensory ligament, 2 = fibers passing from the basilar fibrocartilage to a process on the medial lamina, the medial suspensory ligament, and to the pharyngeal recess (Rp). Am = maxillary artery. Section perpendicular to the long axis of the tube. Female age 59 years.

In all of the specimens examined, we could identify the salpingopharyngeal fascia on the medial aspect of the tensor veli palatini muscle. Attachments to the lateral lamina of the tubal cartilage and to the membranous part are consistently present. Citelli [39] identified the structure as an aponeurotic fascia of the muscles. Based on its connections with the tensor veli palatini muscle and the eustachian tube, it appears to assist in the opening action of the muscle on the tube.

In the literature that we have reviewed, the superior ligament apparatus is not subdivided into individual fiber tracts. In all of the Würzburg specimens, we found that the apparatus was consistently differentiated into a medial and lateral fiber system. The fibers that project to the lateral lamina typically show a tangential mode of contact with the cartilage surface. This mode of attachment not only fixes the lateral lamina to the skull base but also allows for mediolateral movement of the lateral cartilage lamella, following the action of the tensor veli palatini muscle [40]. Other functional aspects are discussed in the section on the tensor veli palatini. The fiber systems for the medial lamina also show a predominantly tangential attachment to the cartilage in the pharyngeal third, again allowing for unrestricted mediolateral movements by the levator veli palatini while simultaneously acting as a checkrein against downward displacement. The central 80% of the cartilaginous part of the tube is not in direct contact with the skull base, but is separated from it by connective tissue and small fat pads (Fig. 1.**4**). This provides a degree of protection for the cartilaginous tube in the event of skull base injury. The fat pads and superior ligament apparatus allow for slight tubal mobility in relation to the inferior surface of the skull base.

According to some biomechanical concepts, the lateral lamina acts as a lever for the tensor veli palatini muscle in moving the medial lamina in the medial direction. This theory is weakened by the considerable size difference between the two cartilage plates and by the fibrous attachment of the medial lamina to the levator veli palatini and pharyngeal wall by fasciae and the salpingopharyngeal ligament.

Membranous Part and Fatty Tissue of the Tube

The lateral, noncartilaginous wall of the eustachian tube is called the membranous part. Besides the Ostmann fat pad, which is always present, additional fatty tissue is found at characteristic locations along the tube:

1. Medial to the medial lamina, where it may be permeated by numerous fiber bundles from the basilar fibrocartilage and the medial suspensory ligament: the "medial Ostmann fat pad" (Fig. 1.**3**).
2. Between the convexity of the tubal cartilage and the overlying skull base. This tissue may be continuous with the medial fat pad. It is bounded laterally by the fiber tract extending to the lateral lamina.

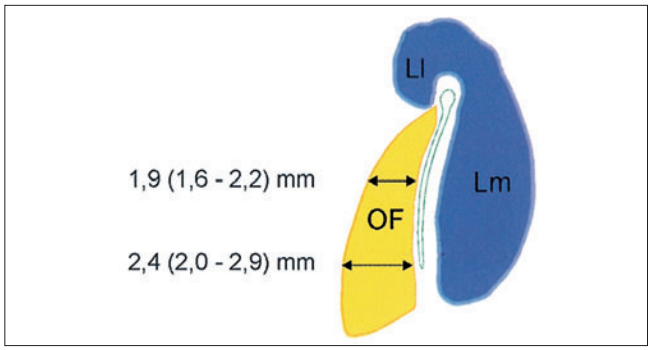

Fig. 1.**5** Typical shape of the Ostmann fat pad (OF) and the tubal cartilage with its medial lamina (Lm) and lateral lamina (Ll). The numbers indicate the maximum thickness of the fat pad in its central and lower portions measured in series of anatomical sections.

3. Lateral to the band to the lateral lamina, where it permeates the fibers of the tensor veli palatini muscle in the pharyngeal third of the cartilaginous part.
4. In some cases below the lateral lamina between the superficial and deep parts of the tensor veli palatini muscle, appearing as a division of the Ostmann fat pad.

In the Würzburg material, the Ostmann fat pad has an average maximum thickness of 2.4 mm measured in transverse sections (Fig. 1.**5**). This value is reached 20 mm posterolateral to the pharyngeal orifice. The fat pad becomes thinner toward the pharyngeal end of the tube, and more glandular packets are found in the lateral tubal wall.

Rüdinger [22] stated a value of 2 mm for the mucosal thickness of the lateral wall, including the lateral fat pad. He noted that this fatty tissue was present even in thin individuals. Ostmann [41], however, claimed that the fat pad showed varying degrees of attenuation in thinner subjects. He also noted that the fat pad normally performs a protective function by keeping the lateral mucosa apposed to the medial mucosa in the resting state. According to Schuknecht and Gulya [42], obesity can lead to tubal obstruction while weight loss can lead to a patulous tube. The fat pads in children and adolescents are already almost as thick as in adults [43]. The height of the fat pads is believed to increase substantially during postnatal development.

Given the very consistent posterolateral morphology of the fat pad, it is reasonable to assume that it has an important function in tubal closure. Besides keeping microorganisms and potentially harmful sound and pressure waves [21] from entering the middle ear from the nasopharynx, an important function of the fat pad may be to prevent evacuation of the middle ear spaces due to negative pressure in the nasopharynx (the "sniff theory") [44, 45]. Of course, this also prevents air from entering the nasopharynx in the resting state when there is positive pressure in the tympanic cavity. Even at rest, the fat pad is believed to exert a certain amount of closing pressure on the tubal lumen. Reportedly, a thick fat pad is a predisposing factor for otitis media [43].

Pharyngeal Recess

The eustachian tube is accompanied for a variable distance by the pharyngeal recess on its medial side (Fig. 1.**4**). Adenoidal tissue that backs the mucosa of the pharyngeal recess (Rosenmüller's recess) can also be traced far posterolaterally behind the tubal cartilage. The roof of the pharyngeal recess is closely related to the basilar fibrocartilage. When the depth of the recess is greater than average, it also relates closely to the petrous segment of the internal carotid artery. Fiber systems that help strengthen the superior portion of the pharyngeal recess distribute numerous fiber bundles to the medial lamina of the tubal cartilage and stabilize the tube from the medial side.

According to Bryant [30], the pharyngeal recess provides space for movement of the medial tubal cartilage, which forms much of the anterior wall of the recess. Its depth, measured at the anterior wall, is approximately 18 mm [30].

Isthmus

The isthmus is the term commonly applied to the junction of the bony and cartilaginous parts of the eustachian tube. It is difficult to define its precise extent, because the temporal end of the cartilage may be so heavily encased by bone that significant expansion of the tube in this area cannot occur. In terms of wall structure, there is no sharp dividing line between the bony and cartilaginous parts of the tube. When the lumen at the pharyngeal end of the bony part is surrounded by bone on all sides, it is still common to find a small cartilaginous extension several millimeters long in the roof of the tube. The isthmus shows marked variations in its luminal diameter. The "isthmus" is described as such mainly because both the medial lamina and the lateral wall of the tube are surrounded by bone that "narrows" the tube by restricting transverse expansion of its lumen (Fig. 1.**6**). As a general rule, bone tissue closely invests the tube, including its caudal aspect, just posterolateral to the plane of the foramen spinosum. At the same time, the medial and lateral laminae of the tubal cartilage are not fully developed in this region.

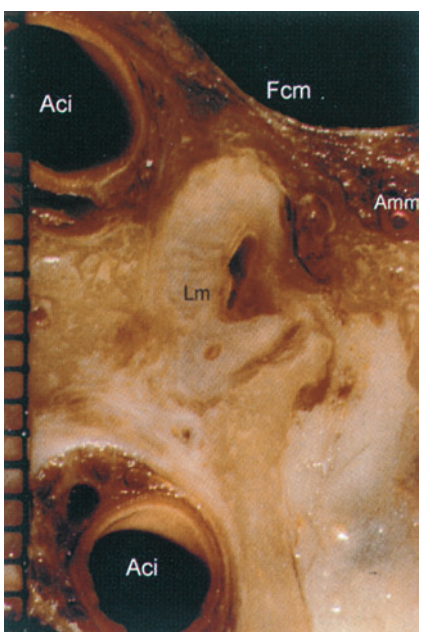

Fig. 1.**6** Isthmus region. The tube is almost completely surrounded by cartilage, which in turn is completely surrounded by bone. Aci = internal carotid artery, Fcm = middle cranial fossa, Amm = middle meningeal artery, Lm = medial lamina of tubal cartilage, with a cartilage hook around the lower part of the lumen. Female age 77 years.

The cartilage extends an average of 4.9 mm into the bony portion of the tube. The bony roof area is completely free of cartilage over its entire length in just 5% of cases. Schwalbe [14] localizes the isthmus to the site where the most anterior end of the osseous wall of the bony part terminates. He emphasizes that cartilage is still present in the tubal wall at this location, and that the medial and lateral cartilage plates are of equal size. Bezold [20] also mentions that the isthmus may have a certain longitudinal extent. According to his measurements in corrosion specimens, the lower end of the isthmus is located 13.4 (8.5–17.5) mm from the tympanic orifice and 24.6 (21.5–27) mm from the pharyngeal end of the tube. Its average height is 3 (2–4.5) mm, its average width 0.25–1.5 mm [20, 23]. Graves and Edwards state that the isthmus is located at the level of the medial surface of the sphenoid spine [6]. When the tube is examined in longitudinal transverse section, an abrupt change in transverse diameter is noted that clearly marks the junction of the bony and cartilaginous parts (Fig. 1.**14**). Luminal dimensions in the isthmic region are of practical interest for the introduction of surgical instruments. For example, fine endoscopes are now being passed through the eustachian tube into the middle ear for diagnostic purposes.

Sadé et al. [46] tested the "tight eustachian tube" hypothesis in petrous bone specimens from children. They found that luminal size in the isthmic region did not correlate with a predisposition to inflammatory diseases of the middle ear. When the eustachian tube is subdivided into anatomical segments as described by Sadé et al. [46, 47], the isthmus represents the fourth segment starting from the pharyngeal orifice and is approximately 4 mm in extent.

Bony Part of the Eustachian Tube

On its medial aspect, the bony part of the eustachian tube is separated from the carotid canal by a thin bony layer that may be only a few tenths of a millimeter thick (Fig. 1.**7**). The distance between the tube and internal carotid artery is increased when the intervening bony layer contains air cells. The medial wall of the tube is also very thin in these cases (Fig. 1.**8**).

In the roof of the bony part, the bone may be dehiscent or cartilaginous. Gaps in the roof may allow direct access to the middle meningeal vein. When the bone is dehiscent, only a fibrous layer of connective tissue separates that vessel from the tubal mucosa. The bony boundary with the middle cranial fossa may be absent over the vein. When the semicanal of the tensor tympani muscle is converted

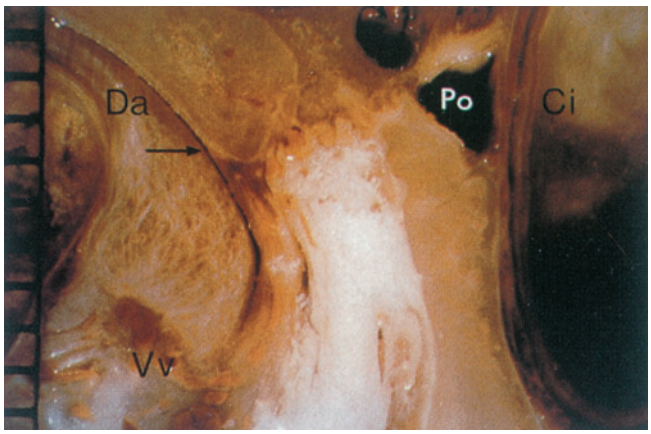

Fig. 1.**7** Typical shape and topography of the bony part of the eustachian tube (Po). The wall between the tube and internal carotid artery (Ci) is extremely thin. Several millimeters lateral is the temporomandibular joint: Da = articular disk, Vv = veins of retroarticular pad (of Zenker), arrow = superior joint space. The plane of the section is perpendicular to the long axis of the tube. Male age 68 years.

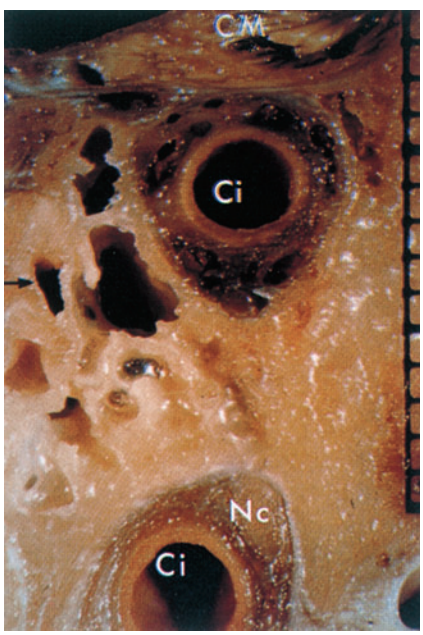

Fig. 1.**8** Prominent air cells around the bony tube (arrow). Some of the peritubal cells are considerably larger than the tubal lumen. Ci = internal carotid artery, cut twice by the section; Nc = carotid nerve, CM = trigeminal cavity. Male age 35 years.

to a tubal lumen by inserting a steel stent as described by Heermann [50], an absent or dehiscent bony boundary can pose a risk of injury to the dura mater and to the middle meningeal artery or veins.

Typically the lumen has a triangular shape with the apex pointing downward (Fig. 1.**7**). In the roof area, the semicanal of the tensor tympani muscle bulges slightly toward the lumen. The smallest height averages 2.9 (1.3–4.4) mm and is located 7.6 (4.2–11.2) mm from the tympanic orifice. Below the tympanic orifice, it is common to find openings of cells that pneumatize the bone under the tube (Fig. 1.**9**). The ostia of air cells are also commonly found just in

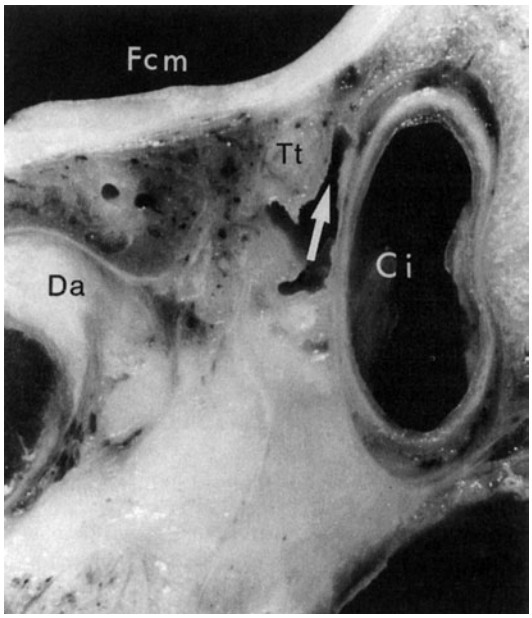

Fig. 1.**9** Bony part of the eustachian tube. Note the high, narrow recess (arrow) between the tensor tympani muscle (Tt) and the internal carotid artery (Ci). Fcm = middle cranial fossa, Da = articular disk of temporomandibular joint. Male age 76 years.

front of the tympanic end of the tube. The roof is located an average of 3 mm below the dura of the middle cranial fossa. The chorda tympani runs in close proximity to the lateral wall (Fig. 1.**9**).

While Proctor [4] defines the bony tube as the protympanon, Schuknecht and Gulya [42] regard the protympanon as the anterior part of the tympanic cavity, separate from the tube. Schwarzbart [48] argues that the term eustachian tube should be limited to the cartilaginous part because the bony part is more closely related to the tympanic cavity from a phylogenetic, anatomical, and pathological standpoint. This would conform more closely to the original concept of Eustachio. He therefore suggests that the bony part be called the protympanon. One argument against this concept is that the walls of the tympanic cavity, being pneumatized, have a much more irregular surface than the bony part of the tube, which is surrounded by a much smaller degree of pneumatization.

The cartilaginous part of the tube is angled about 7° outward from its bony part. Membranous or fibrous occlusions and new bone formation can occur as a result of severe chronic inflammation [49].

In a postmortem study, Luntz and Sadé [51] compared the tubal lumina in patients with secretory and acute otitis media with those in patients without petrous bone disease. The lumina were patent in both groups, but the specimens with otitis media were found to have a significantly smaller lumen in the bony part. The cartilaginous part showed no differences between the two groups. At the same time, there are many skeletal diseases such as Paget disease, otosclerosis, and renal osteodystrophy that do not involve the bony portion of the tube [49].

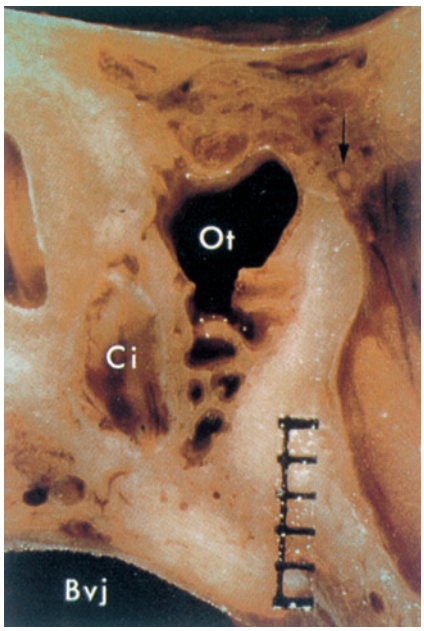

Fig. 1.**10** Tympanic orifice (Ot) of the eustachian tube. The openings below the tube arise partly from the tube and partly from the tympanic cavity. About 1.2 mm lateral to the tube is the chorda tympani (arrow). The opening on the left edge of the photo is the sectioned cochlea, and next to it is a tangential section of the internal carotid artery (Ci). Bvj = superior bulb of the jugular vein. Female age 59 years. The plane of the section is perpendicular to the long axis of the eustachian tube.

The close but variable relationship of the bony eustachian tube to the carotid artery is an important consideration in petrous bone surgery. In rare cases, aneurysms of that vessel may protrude through defects in the bony wall [11]. When a probe is passed through the tube, generally it will push aside the artery rather than perforate it [50]. More than a century ago, Siebenmann [23] noted the clinical significance of the thin wall and stated that ulcerative processes like those occurring in tuberculosis could lead to fatal hemorrhage. Bony prominences or bone spurs can block the passage of instruments and endoscopes, and instruments may become snagged or misdirected in the ostia of air cells.

A recess is consistently found between the tensor tympani muscle and the medial tubal wall [52]. A pronounced variant is illustrated in Figure 1.**10**.

The lateral, medial, and superior walls of the bony tube merge with the corresponding walls of the tympanic cavity with no discernible boundary line. The inferior boundary can be discerned because the floor of the tube turns downward at a rounded obtuse or right angle at its junction with the tympanic cavity [23]. The tympanic orifice is approximately 4.5 (3–6) mm in height and 3.3 (2.75–4) mm in width [20]. It is located 4–6 mm from the floor of the hypotympanum. The middle ear space directly bordering the orifice is the protympanon, located anterior to a frontal plane passing through the anterior rim of the tympanic ring [42]. The difference between the levels of the tympanic orifice and pharyngeal orifice is 1–2.5 cm [53].

Peritubal air cells may arise from the tympanic cavity and from the tube itself [54]. When pneumatization is pronounced, it can be difficult and hazardous to pass a dilator through the tube. Instruments can become snagged or stray from the intended path due to air cell ostia and thin, dehiscent bony walls [55]. Because the air cells communicate with the aerated space of the middle ear, they effectively increase the air reservoir, like the mastoid cells, and contribute to a more gradual pressure drop in the middle ear when the tube is closed. They can also provide a route for surgical access to the petrous apex [42]. Air cells were present in 75 % of the Würzburg specimens.

Levator Veli Palatini

Viewed in cross section, the levator veli palatini muscle may appear round, elliptical, or teardrop-shaped with a sharp inferior taper. In its pharyngeal portion, the superior and medial aspects of the muscle are directly apposed to the inferior edge of the medial lamina of the tubal cartilage. Often it is slightly indented by the cartilage at that location (Fig. 1.**3**). The internal carotid artery may relate very closely to the inferior and medial aspects of the muscle and may deform it. In one case, the tendon of origin below the tube in the isthmus area could be traced into its own, short bony canal. It may also be embedded in a bony groove formed by the petrous part of the temporal bone. The inferior tubal artery, which arises from the ascending pharyngeal, is consistently located in the fatty tissue below the muscle (Fig. 1.**3**). It distributes muscular branches to the levator veli palatini.

Luschka [3] viewed that muscle as an antagonist of the tensor veli palatini. Because it thickened on contraction, he called it the compressor tubae. Other authors consider the levator veli palatini to be a dilator because it can pull the medial lamina posteriorly [24, 30]. Although some authors have described the muscle as arising from the inferior edge of the medial lamina, we could not identify that attachment in the Würzburg specimens. There is, however, a fascial attachment to the inferior border of the tubal cartilage that keeps the muscle from slipping off the medial lamina [30]. In its course, the muscle crosses the longitudinal axis of the tube at the tubal incisure [24]. After passing through the interval between the superior border of the constrictor pharyngis muscle and the skull base, the muscle becomes intrapharyngeal [4], its fibrous sheath gaining attachment to the pharyngeal fascia. This creates an anatomical pathway between the lateral pharyngeal space and the nasopharynx.

In experiments on anesthetized dogs, Rich [56] showed that the levator veli palatini contracts on deep, reflexly triggered inspiration while the pharyngeal orifice remains closed. This means that the levator veli palatini could be placed in the category of an accessory respiratory muscle. Finkelstein et al. [57] investigated functional disturbances of the levator veli palatini in patients with submucous and occult palatal clefts and velopharyngeal incompetence. Finding these patients to have healthy middle ears, the authors conclude that the levator veli palatini is strictly a pal-

atal muscle and that only the tensor veli palatini functions as a tubal dilator.

Motor innervation is supplied by the glossopharyngeal nerve.

A long, loop-shaped pharyngeal branch of the vagus nerve has also been described as supplying the levator veli palatini muscle [6]. The motoneurons in various species have been localized to the nucleus ambiguus and the axons to the glossopharyngeal nucleus [58, 59].

Tensor Veli Palatini

A lateral or superficial layer of muscle fibers runs lateral to the lateral lamina, extending as far as the skull base. Fatty tissue is generally interposed between the fiber bundles above the tubal cartilage. At the level of the lateral lamina, the medial surface of the superficial layer is directly applied to the lateral lamina. At that site the fiber bundles show a marked change of direction, running medially around the lateral cartilage layer. Slightly below the level of the lateral lamina, the deep medial part of the muscle may be separated from the superficial part by fatty tissue.

In the pharyngeal half of the cartilaginous part of the tube, the muscle forms almost a flat plate. It may also be convex medially. Closer to the tympanic cavity, however, the muscle consistently shows a lateral convexity. The corresponding medial concavity encompasses the Ostmann fat pad. Posterolaterally, the deep part of the muscle receives increasing numbers of fibers from the medial border of the lateral lamina and from the membranous wall. The muscle is interrupted mainly in its lower, tendinous portion by veins that communicate with the pterygoid venous plexus.

Valsalva (quoted in [22]) observed centuries ago that traction on the muscle causes the eustachian tube to dilate. The muscle has been given various names based on its course and the functions that have been ascribed to it, including dilator tubae [22], abductor tubae [3], and musculus sphenosalpingostaphylinus [2]. The muscle arises from the sphenoid spine, the scaphoid fossa, the lateral lamina of the tubal cartilage, the posterior half of the membranous tubal wall, and the salpingopharyngeal fascia. The lateral part of the muscle arises from the skull base between the sphenoid spine and pterygoid process and reportedly does not exert a significant action on the eustachian tube [24]. The fact that it runs parallel to the lumen in adults also suggests that the muscle cannot compress the lateral tubal wall. With its attachment to the lateral membranous tubal wall, the deep (medial) part of the muscle may open up the tube by drawing the lateral wall away from the medial wall [35]. The anterolateral aspect of the muscle is covered by the Weber–Liel fascia, which is an extension of the buccopharyngeal fascia [4].

Because the lateral lamina of the tube acts like a fulcrum for the superficial part of tensor veli palatini, redirecting its line of pull, at least that portion of the muscle can displace the lateral lamina medially when it contracts, compressing the upper portions of the lumen. The superficial part of the muscle is thickest in the area of the scaphoid fossa. It becomes increasingly thinner posterolaterally. The deep part, by contrast, receives increasing numbers of fibers from the lateral lamina of the tubal cartilage in the posterolateral direction [13]. The forces that the muscle exerts on its surroundings when it contracts appear to be modified by the Ostmann fat pad in two ways. First, the concavity of the tensor veli palatini must flatten when the muscle contracts, causing the fatty tissue within it to push medially the lateral mucosal surface that is below the lateral lamina. Second, the muscle fibers arising from the lateral plate are directed slightly laterally, causing them to pull the cartilage hook downward and also to the side. The Ostmann fat pad, tubal suspensory ligament, and lateral cartilage layer form a functional unit that tends to open the upper portion of the lumen while compressing the lower portion in response to muscular contraction. The fat pad acts as a fulcrum for the tensor veli palatini by redirecting its fibers of origin toward the cartilage in a way that creates a net opening force that is laterally directed (Fig. 1.**11**).

Because fatty tissue is clearly defined by MRI, visualization of the Ostmann fat pad and its shape changes during swallowing could be used to analyze the function of the tensor veli palatini muscle. This requires high-resolution imaging with scan times measured in tenths of a second. With the development of snapshot and turboflash techniques, it is now possible to acquire images in the subsecond range [60, 61].

A relative predominance of the superficial part of the tensor veli palatini over its deep part could lead to functional obstruction of the eustachian tube, resulting in serous otitis media. This can explain the findings of Takahashi [62], who localized the site of the obstruction with a polyethylene catheter in 10 patients with serous otitis media. Seven of the subjects could correct for the reduced middle ear

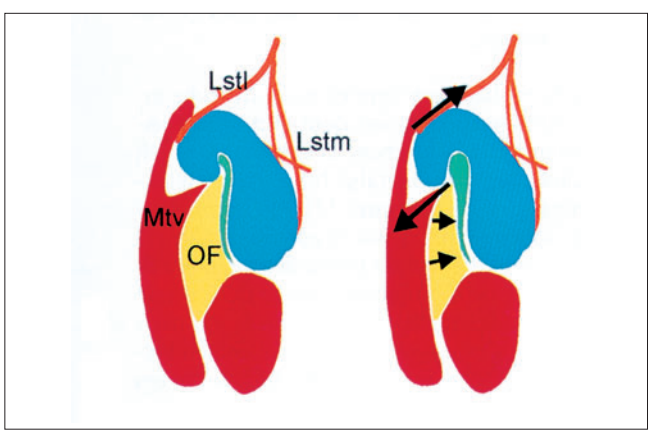

Fig. 1.**11** Schematic cross sections through the tubal region demonstrating tubal biomechanics. Left: at rest. Right: on tubal opening. The tensor veli palatini muscle (Mtv) and lateral tubal suspensory ligament (Lstl) rotate the lateral lamina outward, expanding the upper portion of the lumen (long arrows). For the opening component of the Mtv, the Ostmann fat pad (OF) acts as a fulcrum. The muscle and fat pad compress the lower portions of the lumen (short arrows). Lstm = medial tubal suspensory ligament.

pressure when the catheter had been inserted 10 mm into the eustachian tube. In one patient, the tube had to be inserted 15 mm past the pharyngeal orifice to reach the site of the obstruction.

The primate experiments described by Doyle [63] suggest that the tensor veli palatini muscle is also important for normal closure of the eustachian tube. Doyle found that the closing pressure of the tube decreased when the muscle was sectioned or removed. With a normal anatomical arrangement, the tensor veli palatini can transmit a certain degree of pressure to the lateral tubal wall via the Ostmann fat pad in the resting state.

From a surgical standpoint, the tensor veli palatini muscle forms an important boundary with the extensive blood-filled spaces of the pterygoid venous plexus. It does not form a complete boundary, however, as it may be permeated by the veins of the pterygoid plexus. It receives its motor innervation from the trigeminal nerve [4]. When horseradish peroxidase was injected into the tensor veli palatini of monkeys and guinea pigs, labeling occurred in the ventral region of the ipsilateral trigeminal motor nucleus [59].

Various authors have identified tensor veli palatini muscle fibers blending with the fibers of the tensor tympani tendon [64, 65]. This does not necessarily indicate a common phylogenetic origin for both muscles, however, because the associated motoneurons are at separate locations [59]. A symptomatic or essential tremor of the muscle can lead to a persistent clicking or ticking form of tinnitus. Spontaneous muscle activity is effectively suppressed with botulinum toxin. Because the narrow muscular plate is difficult to reach in a blind transpalatine approach, Leuwer recommends the EMG-guided application of botulinum toxin with a disposable hollow needle electrode [66].

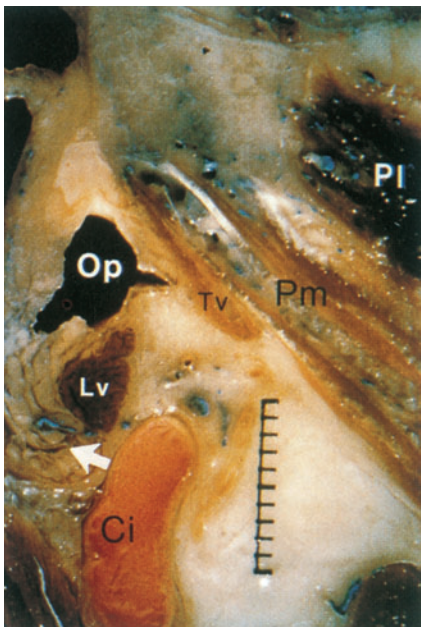

Fig. 1.**12** Internal carotid artery (Ci) located close to the levator veli palatini muscle (Lv) and the pharyngeal orifice of the tube (Op). Its distance from the floor of the pharyngeal recess is 3 mm (arrow). Pm = medial pterygoid muscle, Pl = lateral pterygoid muscle. The plane of the section is perpendicular to the tubal long axis. Female age 92 years.

Topographic Anatomy

Internal Carotid Artery

This large artery can come very close to the eustachian tube at a variety of sites. Very small distances may separate the cervical part of the internal carotid artery from the cartilaginous part of the eustachian tube.

Especially when the artery is elongated, it may relate very closely to the pharyngeal end of the tube. It may also closely approach the posterolateral part of the tube and the levator veli palatini (Figs. 1.**12**, 1.**13**). In these cases only a few millimeters separate the artery wall from the muscle. The artery may also be very close to the pharyngeal recess [13] (Fig. 1.**12**). In the plane of the sphenoid spine and foramen spinosum, we found that the distance of the internal carotid artery (transverse petrous part) from the upper part of the tubal lumen averaged only 4.4 (1.4–8.3) mm (Figs. 1.**13**, 1.**14**).

The petrous segment of the internal carotid artery runs just posteromedial to the bony part of the eustachian tube. Only a thin, occasionally dehiscent bony layer and the carotid venous plexus separate the artery from the tubal mucosa.

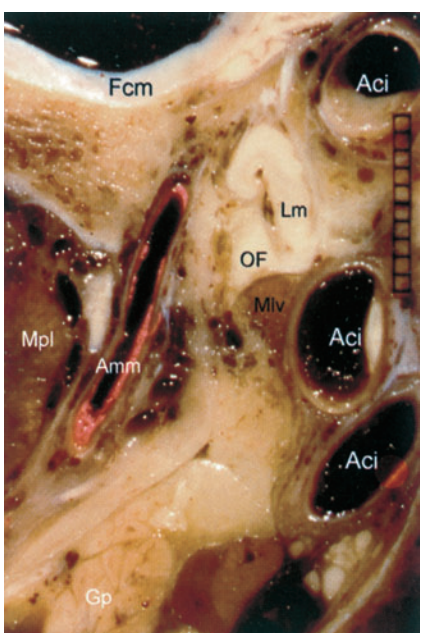

Fig. 1.**13** Anatomical relationships in the posterolateral one-fourth of the cartilaginous part of the tube (sphenoid spine region). The plane of the section is perpendicular to the tubal long axis. Aci = internal carotid artery, Fcm = middle cranial fossa, Lm = medial lamina, OF = Ostmann fat pad, Amm = middle meningeal artery, Mpl = lateral pterygoid muscle, Mlv = levator veli palatini muscle, Gp = parotid gland. Male age 76 years. The caliber difference between the cervical part of the internal carotid artery and its petrous segment is due to atherosclerotic changes.

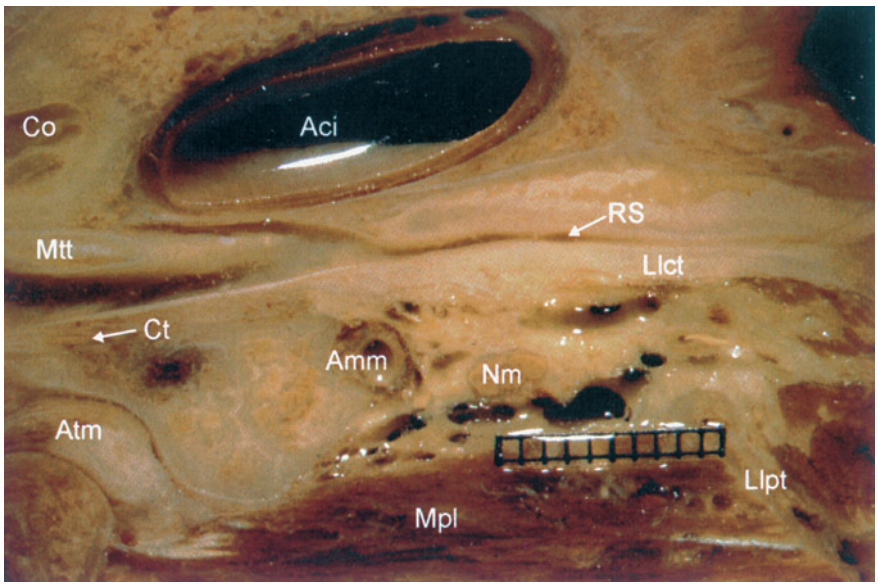

Fig. 1.**14** Transverse longitudinal section through the eustachian tube. The plane of the section is angled 30(forward and downward relative to the orbitomeatal plane. Co = cochlea, Aci = internal carotid artery, Mtt = tensor tympani muscle, Ct = chorda tympani, RS = Rüdinger's safety tube, Llct = lateral lamina of tubal cartilage, Amm = middle meningeal artery, Atm = temporomandibular joint, Nm = mandibular nerve, Mpl = lateral pterygoid muscle, Llpt = lateral plate of pterygoid process.

Very few detailed descriptions have been published on the close relationship of the internal carotid artery to the cartilaginous part of the eustachian tube. This applies both to the cervical part of the artery and to the ascending and transverse petrous parts of the vessel in the carotid canal as far as the anterior genu. The cervical part is particularly apt to show positional variants due to elongation, kinking, or coiling. Because the levator veli palatini muscle may be deformed by the internal carotid artery, it does not provide a reliable guide for avoiding the large vessel. Positional variants near the pharyngeal orifice can be especially hazardous. Surgeons are much more familiar with the occasional proximity of the artery to the lateral pharyngeal wall in the area of the palatine tonsil. A displaced or looped segment of the internal carotid artery that encroaches medially on the pharynx will produce palpable and occasionally visible pulsations in the pharyngeal wall. This has led several authors to stress the importance of palpating the operative area prior to surgical procedures on the pharynx [67, 68]. Demme found pharyngeal wall pulsations in 2 % of a large population. The surgical implications of positional variants of the internal carotid artery are self-evident and merit particular consideration when injections are administered for tissue augmentation along a patent eustachian tube.

Middle Meningeal Artery

The average distance of the middle meningeal artery from the lateral lamina of the tubal cartilage is 1.5 (0.8–2.7) mm. Its distance from the pharyngeal orifice of the tube is 23.5 (20.4–28.6) mm, which is close to the isthmus. Depending on the prominence of the sphenoid spine, either bone or connective tissue separates the terminal ascending segment of the middle meningeal artery from the lateral lamina and from the tensor veli palatini muscle. The foramen spinosum is actually a 7–8-mm canal in the sphenoid spine [70].

Before entering the foramen spinosum, the artery comes very close to the lateral surface of the tensor veli palatini. Many authors believe that an interruption of flow in this artery can lead to cranial neuropathy affecting nerves V and VII [71]. Immediately after entering the skull through the foramen spinosum, the middle meningeal artery gives off the petrous branch, which supplies the geniculate ganglion and other portions of the facial nerve; it also sends a branch to the trigeminal ganglion [72]. Inside the skull, the middle meningeal artery provides a landmark for gaining surgical access to the bony part of the eustachian tube via the middle cranial fossa [73].

Maxillary Artery

The maxillary artery may be relatively far from the eustachian tube or close to it, depending on whether the vessel runs superficial or deep to the lateral pterygoid muscle. When it runs deep in the masticatory space, the vessel lies very close to the tensor veli palatini muscle. This particularly applies to the origin of the middle meningeal artery.

Mandibular Nerve

Over a century ago, Siebenmann [23] noted the proximity of the eustachian tube to the third division of the trigeminal nerve in the area of the foramen ovale. The tight space between the mandibular nerve and the lateral lamina of the tube is occupied mostly by the medial portions of the venous plexus of the foramen ovale and by fatty tissue. The medial veins of this plexus in particular establish a connection between the cavernous sinus and the pterygoid venous plexus [15]. Below the foramen ovale, the mandibular nerve has a consistently close relationship to the eustachian tube. The nerve limits the space that is available for approaching the tubal area from the lateral side. Injury to its motor portion would result in paralysis of the masticatory muscles and of the tensor tympani and tensor veli palatini.

Above the convexity of the tubal cartilage, a thin bony plate provides the only separation from the foramen ovale and middle cranial fossa. Generally this plate is only 0.5 mm thick.

Medial Pterygoid Muscle

Near the pharynx, the medial pterygoid muscle lies very close to the tensor veli palatini, although both are separated by their own fasciae and by the Weber–Liel fascia. About 5–10 mm behind the pharyngeal orifice, fatty tissue and veins are increasingly interposed between the medial pterygoid and tensor veli palatini muscles. The medial pterygoid muscle is apposed to the outer surface of tensor veli palatini in the area of the pterygoid fossa [26]. In patients with malocclusion or an edentulous jaw, the short, thickened muscle can reportedly cause clinical symptoms relating to the eustachian tube [74]. According to Pulec, the medial pterygoid muscle functions with the Ostmann fat pad to assist closure of the tube from the lateral side [73]. This is confirmed by the observations of Georgopoulos, which indicate that protrusion (forward movement) of the mandible promotes opening of the eustachian tube [75].

Lateral Pterygoid Muscle

Numerous veins of the pterygoid venous plexus are located between this muscle and the tubal region. Because the muscle forms approximately the same angle with the midsagittal plane as the eustachian tube, its distance from the tube shows little variation. The uniform distance between the eustachian tube and the lateral pterygoid makes it easier to locate the tube in sections that are coronal or perpendicular to the tubal axis (Figs. 1.**16**–1.**18**).

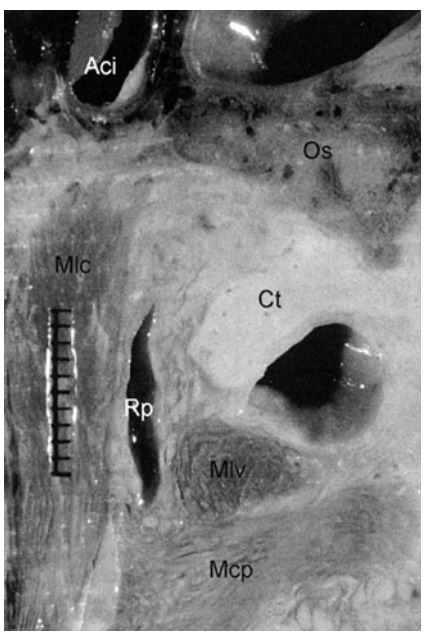

Fig. 1.**15** Parasagittal section near the pharyngeal orifice. As is typically the case, the tubal cartilage (Ct) is apposed to the sphenoid bone (Os). Mlc = longus capitis muscle, Rp = pharyngeal recess, Mlv = levator veli palatini muscle, Mcp = constrictor pharyngis muscle, Aci = internal carotid artery. Male age 71 years.

Based on a functional 3D model, Leuwer and coworkers could demonstrate that the medial pterygoid muscle can act as a fulcrum, influencing the shape of the distal part of the tensor veli palatini muscle. This interaction may be of clinical significance in patients with disturbances of the eustachian tube, for instance in cases of patulous tube or cleft palate.

Temporomandibular Joint

The temporomandibular joint is located close to the bony part of the eustachian tube and its tympanic orifice. The upper temporomandibular joint space is particularly close to the bony part of the tube. Its distance from the lateral wall of the tympanic orifice is approximately 3–6 mm. When maxillofacial surgery is performed in this region, care is taken to preserve the medially situated tube. Faas described a case in which a gouty tophus of the temporomandibular joint was compressing the cartilaginous part of the tube from the lateral side. Conductive hearing loss developed as a result of the ventilation disturbance [76].

Association of temporomandibular joint dysfunction and aural symptoms are often described. A spasm of masticatory muscles in patients with temporomandibular joint disorders does not effect significant alterations of the function of the tensor veli palatini muscle [141].

Constrictor Pharyngis Muscle

The levator veli palatini muscle and pharyngeal recess are located just above the superior border of the constrictor pharyngis muscle (Fig. 1.**15**). Reportedly, this muscle aids in elevating the medial lamina of the eustachian tube [4].

Middle Cranial Fossa

The distance of the eustachian tube from the middle cranial fossa declines fairly steadily from the pharynx to the tympanic cavity. In the area of the tympanic orifice, the distance between the dura mater and the roof of the tubal lumen is only 2.9 (1.5–5.6) mm. In sections through the foramen ovale, the distance ranges from 5 to 13 mm.

The consistently small distances make it easier to locate the eustachian tube in imaging procedures. Lesions of the middle cranial fossa, such as meningiomas, can exert pressure on the eustachian tube, leading to secretory otitis media with conductive hearing loss at an early stage before neurological symptoms appear [77].

Parotid Gland

The deep portion of the parotid gland consistently extends far into the parapharyngeal space and may closely ap-

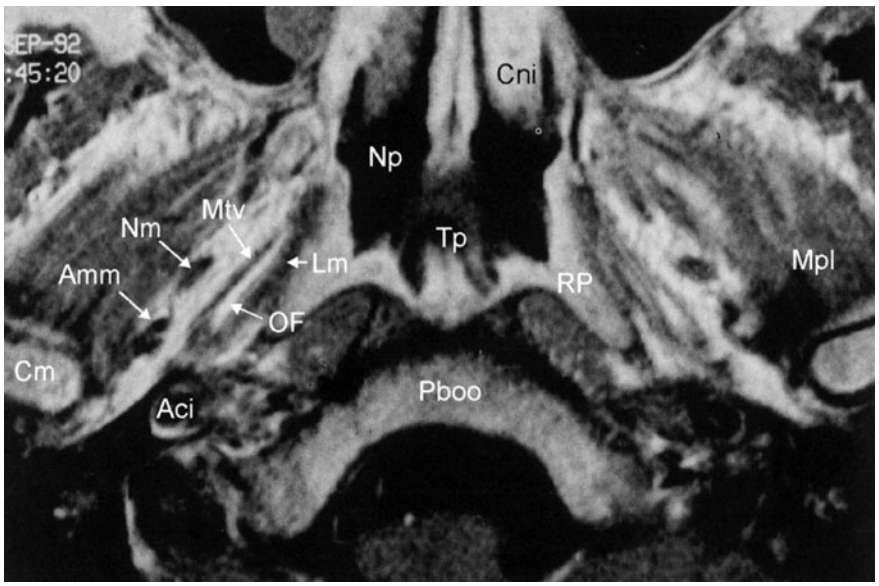

Fig. 1.**16** T1-weighted MR image through the nasopharynx. Np = nasopharynx, Tp = pharyngeal tonsil, Cni = inferior turbinate, Mtv = tensor veli palatini muscle, Nm = mandibular nerve, Amm = middle meningeal artery, Cm = mandibular condyle, Aci = internal carotid artery, OF = Ostmann fat pad, Lm = medial lamina of tubal cartilage, RP = pharyngeal recess, Mpl = lateral pterygoid muscle. Male 35 years of age with no otologic disease.

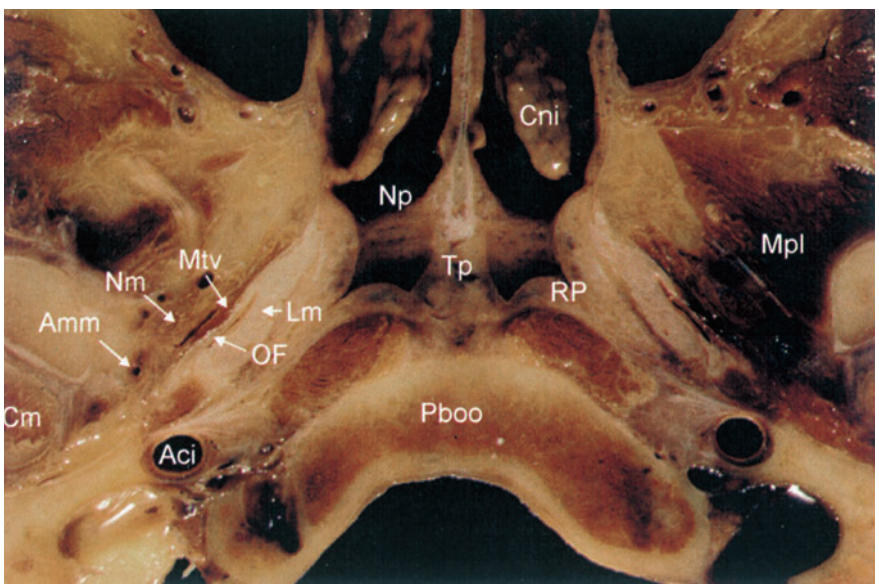

Fig. 1.**17** Transverse section through the nasopharynx in an anatomical specimen corresponding to Figure 1.**16**. Np = nasopharynx, Tp = pharyngeal tonsil, Cni = inferior turbinate, Mtv = tensor veli palatini muscle, Nm = mandibular nerve, Amm = middle meningeal artery, Cm = mandibular condyle, Aci = internal carotid artery, OF = Ostmann fat pad, Lm = medial lamina of tubal cartilage, RP = pharyngeal recess, Mpl = lateral pterygoid muscle.

proach the eustachian tube. Salivary-gland and neurogenic tumors are the most common neoplasms in the parapharyngeal space [78]. Due to the limited capacity for expansion in other directions, these tumors exert mass effects on the pharynx and eustachian tube. The thin connective tissue that invests the deep portion of the gland tends to promote the parapharyngeal spread of parotid tumors [78]. One symptom of these tumors is conductive hearing loss caused by extrinsic pressure effects on the eustachian tube.

Imaging Studies

High-resolution CT provides well-defined images of the bony eustachian tube in both axial and coronal sections. The proximity of the bony tube to the transverse part of the carotid canal makes it easier to identify the tube in doubtful cases.

MRI is the modality of choice for defining the cartilaginous part of the tube [80]. T1-weighted spin-echo sequences are particularly effective for defining the anatomy of the tubal region (TR 450 ms, TE 15 ms, slice thickness 2–3 mm, 3–4 acquisitions, 512 × 512 matrix). Transverse and coronal slices can provide systematic coverage of the nasopharynx and parapharyngeal tissue (Figs. 1.**16**, 1.**17**). The relationship of the tube to major neurovascular structures (internal carotid artery, mandibular nerve, middle meningeal artery) can also be accurately evaluated. The palatal muscles near the pharynx are also visualized, which is helpful in determining tumor extent.

Additional details of the cartilaginous tube can be visualized by angling the image plane to match the plane of the tube [8]. The image can be angled 30° forward and downward relative to the orbitomeatal plane to obtain longitudinal scans that depict the full length of the Ostmann fat pad and the tensor veli palatini (Fig. 1.**19**). The scan can additionally

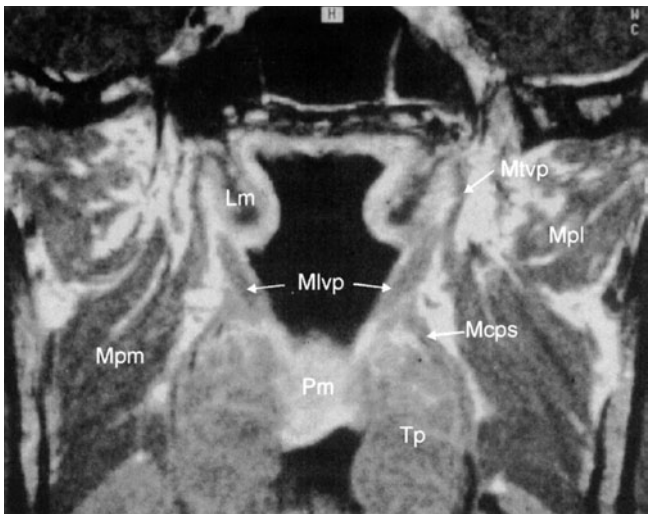

Fig. 1.**18** T1-weighted coronal MR image through the nasopharynx. Lm = medial lamina of tubal cartilage, Mtvp = tensor veli palatini muscle, Mlvp = levator veli palatini muscle, Mcps = superior constrictor pharyngis muscle, Mpm = medial pterygoid muscle, Mpl = lateral pterygoid muscle. Male 44 years of age with no otologic disease.

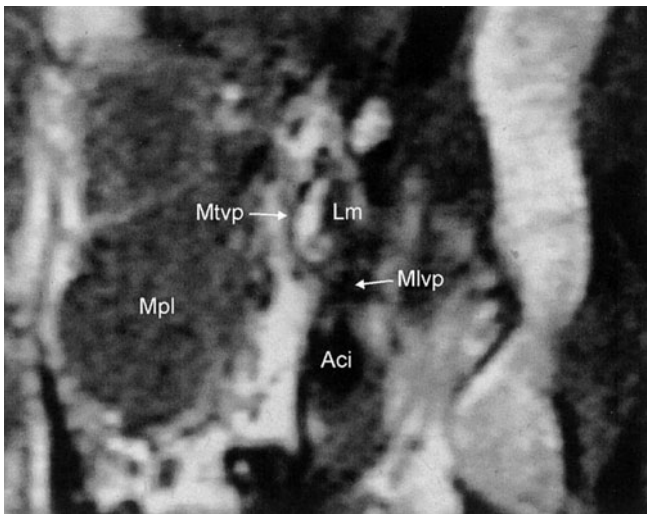

Fig. 1.**20** T1-weighted MR image angled 45° from the sagittal plane and 30° from the horizontal plane. Mtvp = tensor veli palatini muscle, Lm = medial lamina of tubal cartilage, Mlvp = levator veli palatini muscle, Mpl = lateral pterygoid muscle, Aci = internal carotid artery. Note the typical shape of the Ostmann fat pad between the Mtvp and Lm.

be tilted 45° relative to the sagittal plane to obtain transverse images of the eustachian tube displaying the configuration of the tubal cartilage, the tensor veli palatini, and the Ostmann fat pad (Fig. 1.**20**). Normal anatomical values are helpful in detecting the atrophy or deformation of individual structures. Larger notches in the medial lamina and processes of the tubal cartilage can be clearly identified, whereas the lumen is only occasionally defined. The origin of the superficial part of the tensor veli palatini muscle can be traced as far as the skull base. In an ongoing study, we have been compiling the anatomical data from series of T1-weighted spin-echo images obtained in 29 adult subjects to provide a data base for scan interpretation.

The data obtained from 3D sequences can be used to reconstruct secondary images that conform to the oblique course of the eustachian tube. This can be done with the FLASH (fast low-angle shot) modes described by Frahm et al. using 40° and 70° of angulation, repetition times of 60–24 ms, and echo times of 22–10 ms [81]. Besides providing high geometric resolution and the ability to accurately portray the anatomically complex temporal bone region by reconstructing arbitrary planes, these pulse sequences offer a very high signal-to-noise ratio compared with 2D sequences and excellent contrast (contrast-to-noise ratio and tissue contrast) of critical structures. The high signal intensity of cartilaginous tissue clearly distinguishes it from the low signal of vessels and muscles. Fatty tissue has an intermediate (FISP 70) to high signal intensity (FLASH 70), while air-filled spaces appear as signal voids in all MR sequences. Mucosa has an intermediate signal intensity on T1-weighted and proton-density images. Cortical bone tissue is devoid of signal, while the bone marrow shows definite contrast, depending on the sequence, and can define the location of the skull base. In this way the skull base is clearly differentiated from the cartilaginous part of the eustachian tube and its neighboring structures.

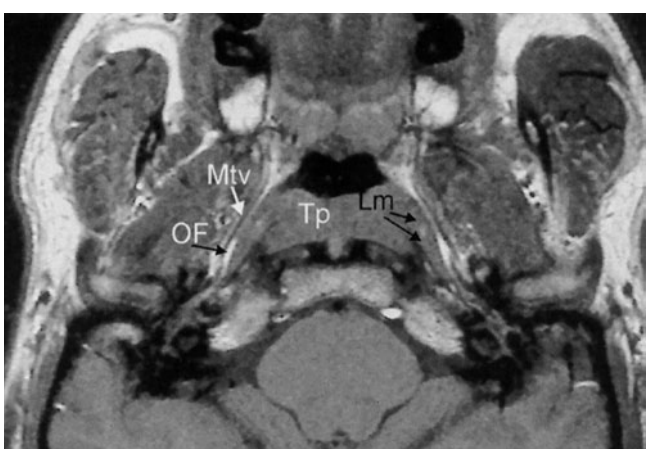

Fig. 1.**19** T1-weighted MR image with the scan plane angled 30° forward and downward relative to the horizontal plane. Mtv = tensor veli palatini muscle, OF = Ostmann fat pad (note the typical posterolateral broadening), Tp = pharyngeal tonsil, Lm = medial lamina of tubal cartilage. Male 25 years of age.

Since several muscles in the vicinity of the eustachian tube are easy to identify based on their location, the musculature can provide a useful reference structure for comparing signal intensities in MR images.

The discrimination of specific structures is aided by the fact that the cartilage and muscles are often separated by zones of lower signal intensity containing glandular and connective tissue.

Normal Tubal Function

Bluestone ascribes at least three physiological functions to the eustachian tube: (1) equalizing the pressure between the atmosphere and middle ear; (2) protecting the middle

ear from nasopharyngeal sound pressures and secretions; and (3) draining secretions from the middle ear into the nasopharynx. More than a century ago, Hyrtl stated that the eustachian tube functioned as a drainage route for mucus secreted in the tympanic cavity while keeping the middle ear aerated [83]. Even earlier, Rebsamen stated that tubal opening was accomplished by the interaction of several muscles [64]. This view is still reflected in current textbooks of anatomy. In 1920, stimulation experiments on the tubal muscles of anesthetized dogs led Rich to conclude that the tensor veli palatini was the only muscle that could effectively dilate the tube [1]. This view was later confirmed by experiments in monkeys [84] in which stimulation of the levator veli palatini did not produce tubal opening. Studies using contrast medium in patients with perforated eardrums have also confirmed the dilating action of the tensor veli palatini, showing that the levator veli palatini only causes dilation of the pharyngeal orifice [85].

The tensor tympani muscle is believed to assist in tubal opening. By drawing the tympanic membrane inward, this muscle creates a positive pressure in the middle ear that helps to disrupt the mucous film within the tube [86]. This is supported by the fact that the middle ear muscles contract during swallowing and yawning [87]. It has also been suggested that the fibers of the tensor tympani muscle arising from the tubal cartilage can assist in tubal opening [88]. However, the direction of fiber pull and the small muscle mass create a mechanism that is too weak to exert significant force on the lateral lamina or on the tubal cartilage as a whole, and presumably it could not contribute to tubal opening. Studies in patients with varying degrees of cleft palate have shown that the levator veli palatini does not significantly affect tubal function and that only the tensor veli palatini can function as a tubal dilator [57]. This is supported by hamulotomy studies in experimental animals [89], which showed that eliminating the pterygoid hamulus as a fixed point or fulcrum for the tensor tendon leads to ventilation problems. Another theory on tubal opening states that the angle at the junction of the bony and cartilaginous parts of the tube increases from 160° at rest to 180° on tubal opening [90]. However, this is unlikely on the basis of anatomical findings, since the pharyngeal end of the tubal cartilage is firmly connected to the skull base.

Recoil forces in the elastic, cap-shaped junctional zone between the medial and lateral laminae, along with adjacent elastic fiber systems, are thought to play a significant role in tubal closure [22, 35]. If this view is accurate, a deep notch in the cartilage disrupting the convexity of the junctional zone could compromise this function.

The blood vessels of the tubal mucosa also have an effect on tubal closure. Rundcrantz showed that occluding the blood flow through the neck veins and assuming a horizontal body posture decreased the passage of air through the eustachian tube [91]. Vasoactive drugs also affect tubal patency [92].

From our review of anatomical and clinical findings, it may be concluded that the functional unit composed of the tensor veli palatini muscle, the lateral lamina of the tubal cartilage, the Ostmann fat pad, and the lateral suspensory ligament has the effect of dilating the upper portion of the tubal lumen while compressing the lower portions of the lumen. This creates a bidirectional mechanism that transports air toward the tympanic end of the tube and mucus toward the pharyngeal end. This mechanism is particularly active in the tubal segment where the Ostmann fat pad is most prominent, i.e., the posterolateral portion of the cartilaginous tube just before the isthmus. This concept is supported by the absence of cilia in the roof area of the tube and the abundance of goblet cells in the lower portions [6, 100].

In vivo observation and analysis of tubal function show four sequential movements: (1) palatal elevation causing passive, then active rotation of the medial cartilaginous lamina; (2) lateral excursion of the lateral pharyngeal wall; (3) dilation of the lumen caused primarily by the tensor veli palatini muscle movement; (4) opening of the tubal valve at the isthmus [142]. These observations are consistent with recent understanding of the functional morphology of passive and active tubal and peritubal structures.

Tubal Dysfunction

Browning et al. report that the prevalence of eustachian tube dysfunction in adults is 0.9% and increases with age [93].

More than 50% of patients with cleft palate have conductive hearing loss secondary to tubal dysfunction. Tensor veli palatini dysfunction is considered to be the cause [94, 95]. Improved middle ear aeration following surgical repair of the cleft is attributed to a change in muscular traction [96]. Tubal opening and closing are also affected by substances that lower surface tension [97, 98]. Since the presence of bacteria reduces the efficacy of the surfactant, the impaired ventilation in otitis media is believed to result from an absence of these substances. The presence of air bubbles in serous otitis media is considered an indicator that sufficient surfactant is present. On the other hand, Malm claims that high surface tension is necessary to ensure effective tubal closure [99]. He supports this view by noting that patulous tubes are more prevalent in pregnant women; secretions may show increased surface tension during pregnancy.

Compere describes several cases in which middle ear clearance was impaired in chronic otitis media, although air could easily be insufflated through the eustachian tube [101]. He claims that the cause of the functional obstruction is located in the hypotympanon. Sadé maintains that clearance problems are not necessarily the result of eustachian tube obstruction, and that true obstructions are relatively rare. Other authors believe that chronic otitis media is always associated with eustachian tube dysfunction [103]. Ligation leads to serous otitis media with mucosal hyperplasia, but this does not occur in animal experiments when a concomitant myringotomy is performed [104]. Obliteration of the lymphatic vessels that run posterior to the tube could also induce serous otitis in experimental animals, but obliterating the lymphatics anterior to the tube did not produce this effect [105].

In patients with chronic otitis media, contrast radiographs of the eustachian tube demonstrated pathological changes such as polyps or strictures in only 9 of 30 cases [106]. In another radiographic contrast study in patients with chronic otitis media, the blockage of contrast flow was associated with impaired pressure equalization through the eustachian tube in a high percentage of cases [107]. According to Tos, occlusion of the eustachian tube plays an important role in the early pathogenesis of chronic secretory otitis. This may be an external occlusion due to adenoid vegetations or an internal occlusion due to mucosal edema. The transport function of the eustachian tube (mucociliary clearance) is important with regard to the further clinical course of the disease in the secretory and degenerative stages, particularly the relationship between mucus production by the middle ear mucosa and the transport capacity of the tubal mucosa [108].

Mason and coworkers [143] measured ciliary activity in adenoidal explants. Ciliary activity of adenoidal epithelium is not reduced by the constituents of middle ear fluid in chronic otitis media with effusion. Hemophilus influenzae endotoxin was not able to reduce ciliary mobility.

Zechner [109] summarizes the effects of eustachian tube dysfunction or functional obstruction as follows: (1) secretory otitis media leading to adhesive processes; (2) an atelectatic tympanum with retraction pockets and subsequent atypical cholesteatoma; and (3) chronic proliferative mastoiditis with bone destruction and apposition [109]. The "sniff theory" relates the pathogenesis of cholesteatoma to incompetent tubal closure. If tubal closure is weak or impaired, inhaling air forcibly through the nose can cause air to be aspirated through the tube from the middle ear, creating a negative pressure that causes retraction of the tympanic membrane [45]. In patients with retraction-type cholesteatomas, Falk and Magnuson found a sniff-induced negative middle ear pressure in 52 % of the cases examined. They considered this to be an important factor in the pathogenesis of retraction-type middle ear diseases, which range from simple reversible changes in the tympanic membrane to frank cholesteatoma.

To improve sound conduction in patients with a fully developed adhesive process, Palva feels that it is essential to restore middle ear ventilation either by inserting a myringotomy tube or by restoring eustachian tube function [111].

Holmquist investigated the importance of eustachian tube function in the success of myringoplasty: 90 % of his patients with tubal dysfunction did not show satisfactory healing, versus 16 % with normal tubal function [112]. Besides the biomechanical and mucosa-related factors that can compromise tubal function, a recent study points to a lack of coordination between the action of the tensor veli palatini muscle and the act of swallowing as a potential cause of tubal dysfunction [113]. When the lumen is obstructed due to inflammatory mucosal changes, the fluid-filled lumen can be directly visualized on T2-weighted MR images (Fig. 1.**21**). Suitable implants can be inserted to surmount obstructions [114] (Fig. 1.**22**). Clinical data show that displacement of the orifice or lumen by space-occupying lesions of the pharyngeal and parapharyngeal compartment alone will not necessarily lead to ventilation problems, and that infiltration of the tubal muscles or involvement of the tubal mucosa itself is necessary to induce serous forms of otitis [115] (Fig. 1.**23**). We can explain this from a physiologic and anatomic standpoint by noting that the functionally critical tubal segment near the isthmus is located in the posterolateral one-fourth of the cartilaginous tube, placing it a "safe" distance from the pharynx.

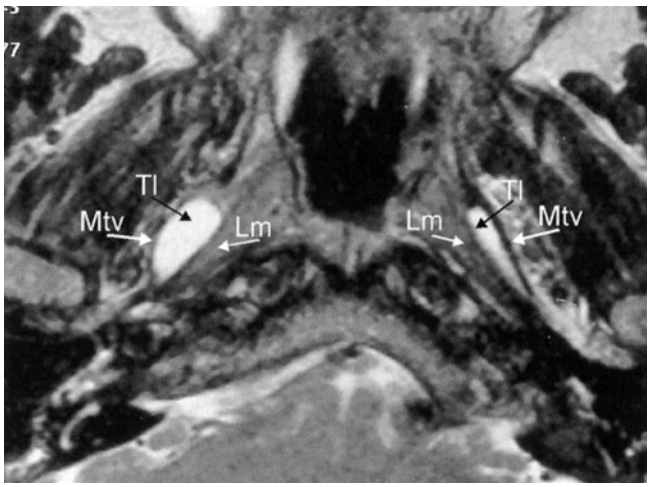

Fig 1.**21** Transverse MR image at the level of the nasopharynx, turbo spin-echo sequence. The tubal lumen (Tl) is fluid-filled due to a chronic inflammatory mucosal reaction with adhesion of the mucosal layers. Mtv = tensor veli palatini muscle, Lm = medial lamina of tubal cartilage. Female 52 years of age.

Stammberger performed endoscopic studies [116] to investigate the relationship between chronic sinusitis and eustachian tube dysfunction that has often been cited in the literature. He found that ciliary drainage from the eth-

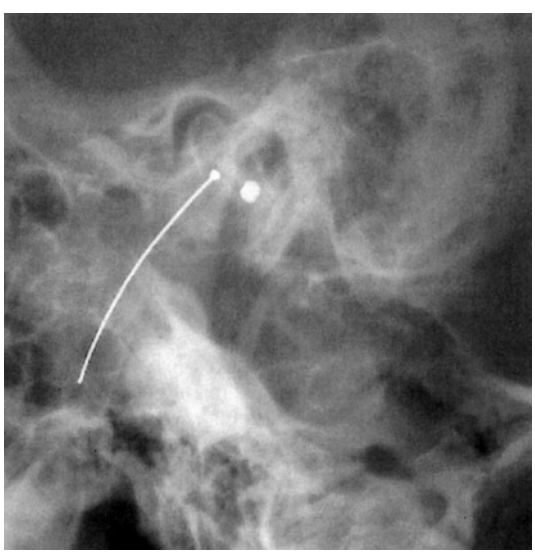

Fig. 1.**22** Schüller radiograph of the patient in Figure 1.**21**, following treatment by middle ear drainage and tube implantation.

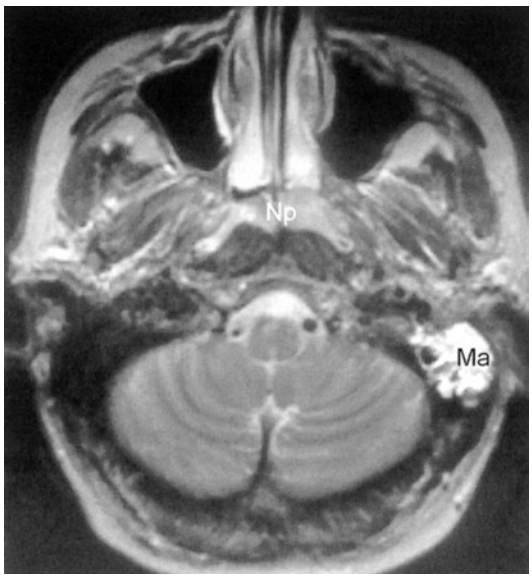

Fig. 1.**23** Nasopharyngeal involvement by non-Hodgkin lymphoma with paraepipharyngeal infiltration and serous otomastoiditis. Np = nasopharynx, Ma = mastoid. Turbo spin-echo sequence, transverse image.

moid leads directly past the pharyngeal orifice of the eustachian tube and that this can lead to ascending infections of the tubal mucosa. The beneficial effect of intranasal operations on eustachian tube dysfunction has been documented by tubal manometry [117].

Adenoids and Tubal Function

Good long-term hearing after a tympanoplasty is dependent on adequate tubal function [111, 129]. Holmquist noted healing problems due to deficient tubal function in a high percentage of his patients who underwent myringoplasty [112]. The Valsalva maneuver is not a useful test for evaluating the functional result of a tympanoplasty [121]. In an ongoing study of our patients at the Würzburg clinic, we found that a negative Valsalva maneuver following tympanoplasty for cholesteatoma was not associated with an increased incidence of recurrent perforations or retractions. In patients with chronic suppurative disease of the mucosa, however, the incidence of recurrent perforations and retractions was increased. The difference may relate to the different operative techniques, but it may also indicate that tubal function does not affect the disease process in cholesteatoma. Tubal manometry can provide a good preoperative evaluation of active and passive tubal function [122]. These tests show that every adhesive process starts with a disturbance of tubal function. A recurrence after tympanoplasty can occur even in cases with normal tubal function, however. This is attributed to decreased elasticity of the tympanic membrane, a reduction of middle ear volume, and the associated disturbance of pressure regulation [112].

In cases with preexisting eustachian tube dysfunction, tympanoplasty has no significant effect on the recovery of tubal function [124]. Even the treatment of middle ear effusion in adults with myringotomy tubes will not improve the function of the eustachian tube itself [125].

The Valsalva and Politzer maneuvers are not always sufficient to surmount adhesions of the tubal mucosa following surgery. For a time, intratubal irradiation was given to improve tubal function [128], but this method has been abandoned due to potential long-term risks. While obstructions in the bony tube can be forced open using special steel dilators described by Heermann et al. [50], the cartilaginous tube requires the use of more permanent tubal implants to keep the normally apposed mucosal layers from sticking together. The gold wire developed by Steinbach has become an established implant for this application [114]. Lieberum and Jahnke have shown in a large series of patients with impaired tubal patency that gold wire insertion can significantly improve middle ear ventilation after tympanoplasty as well as postoperative hearing results [129]. Several years of follow-up have demonstrated good tissue tolerance and a high degree of patient acceptance.

Patulous Tube Syndrome

There is no apparent age or gender predilection for abnormal patency of the eustachian tube [130]. Frequently there is a prior history of weight loss. Tonsillectomy and radiotherapy are also thought to promote the syndrome. Ostmann suggested in 1893 that a reduction in the size of the fat pad on the lateral tubal wall was a major factor in the pathogenesis of a patulous tube [41]. When MRI was performed in 10 of our patients with autophony, the Ostmann fat pad was found to be small or nonvisualized in 7 cases (Fig. 1.**24**) [126]. All the patients had a history of substantial weight loss. Following gains in body weight, the autophony persisted. One explanation for this phenomenon could be that connective-tissue fibers in the Ostmann fat pad spontaneously shorten when its volume is reduced

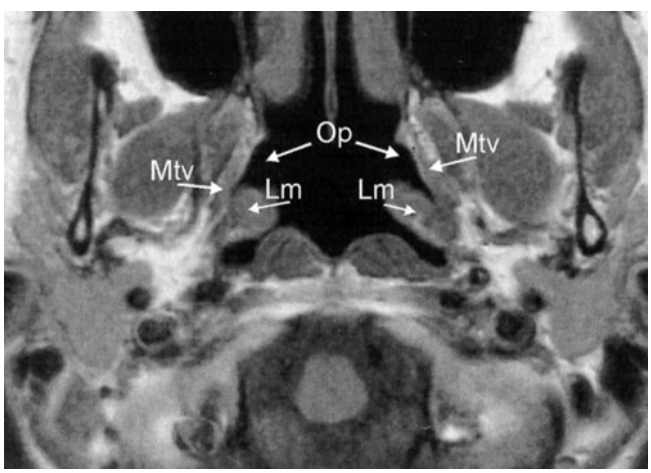

Fig. 1.**24** Woman 54 years of age with bilateral patulous eustachian tube syndrome. The pharyngeal orifice (Op) on each side is very broad and deep, and the Ostmann fat pads are not visualized. Mtv = tensor veli palatini muscle, Lm = medial lamina.

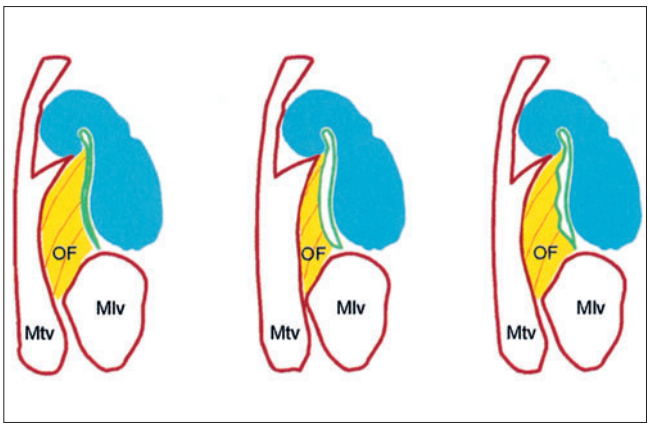

Fig. 1.**25** Schematic cross sections of the eustachian tube. Left: normal configuration. Center: narrow fat pad with a patent tube. Right: persistent tubal patency due to shrunken connective tissue septa and tendon fibers. OF = Ostmann fat pad, Mtv = tensor veli palatini muscle, Mlv = levator veli palatini muscle.

and remain in a contracted state even when the fatty-tissue volume later increases (Fig. 1.**25**).

The insufflation of boric acid and salicylic acid powder has been recommended for the local treatment of abnormal tubal patency [130], but this is of only transient benefit and can cause severe mucosal irritation [131]. Stroud et al. were able to improve complaints in 8 of 9 patients by transposing the tensor veli palatini tendon to the medial side of the pterygoid hamulus [132]. Other authors could temporarily relieve patulous tube symptoms by introducing gelatin sponge into the tubal lumen [113]. Robinson and Hazell achieved partial or complete relief of autophony in 9 of 13 patients by inserting a urologic diathermy probe [134]. Peritubal tissue augmentation was first performed by Zöllner, who injected paraffin along the tube [135]. The use of Teflon paste led to serious complications caused by accidental injection of the paste into the internal carotid artery [136].

Endoscopy of the Eustachian Tube

A rigid, oblique endoscope introduced transnasally will generally provide an excellent view of the nasopharynx. The inlet funnel and the area around the tubal orifice can be closely examined [116]. With this technique, Takahashi et al. examined 155 patients (77 children and 78 adults) with chronic middle ear effusion [137]. The most frequent finding in the children was blockage of the pharyngeal tubal orifice by nasal secretions (72.7 % of cases), followed by compression of the orifice by adenoid tissue (52 %), hypertrophy of the peritubal lymphatic tissue (16.9 %), and edema of the torus tubarius (10.4 %). The most frequent abnormal finding in adults was edema about the tubal orifice (26.9 %). For examining deeper tubal segments and for transtubal inspection of the middle ear, special microfibroendoscopes have been available since 1987. When Chays et al. [138] used this instrument to examine 125 patients undergoing tympanoplasty, they found that tubal obstruction in chronic otitis media was rare (2 % of cases). Su used transtympanic microendoscopy under local anesthesia to examine the eustachian tube in 16 patients with chronic otitis media [139]. This author found that the cartilaginous tubal segment near the isthmus was closed at rest, while the lumen closer to the pharynx was patent. The bony part of the tube was patent in all cases. This method can be used to diagnose circumscribed mucosal changes and lesions that impair tubal opening.

Linstrom et al [144] performed transtympanic endoscopy of eustachian tube during major surgical procedures. The risk for abnormal tubal mucosa was four times greater for persons with long-standing disease than for persons without. Stenotic blockage occurred mainly in isthmus region and at the infundibulum.

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2 Biomechanical Aspects of Middle Ear Reconstruction

K.-B. Hüttenbrink

Abstract

Biomechanics of Middle Ear Reconstruction. Restoration of sound conduction towards the inner ear is a major goal of middle ear surgery in addition to the eradication of destructive processes. As the tympanic membrane is responsible for the transformation of the air-borne sound into vibration of solid bodies, its acoustic quality is of paramount importance. From an acoustical point of view, this membrane should be thin and soft, similar to the natural tympanic membrane with a thickness of 100 μm. However, in chronic tubal dysfunction such a delicate membrane will not provide sufficient resistance against the constant negative pressure. To prevent retraction in these cases, cartilage with its higher degree of stability is often used for replacement of the tympanic membrane. The thickness and composition of a cartilaginous tympanic membrane should represent a compromise between sufficient stability and adequate acoustic sensitivity. Effective sound transport to the inner ear requires a reconstructed ossicular chain, which can vibrate without restraint. A loose contact will result in decreased efficiency. The solid anchoring of a prosthesis to the ossicular remnants also prevents postoperative slipping off its contacts, which could lead to a drastic loss in energy transport.

Introduction

In cases where the sound conduction apparatus of the middle ear has been destroyed due to inflammatory disease, techniques are now available for eradicating the disease to a reasonably satisfactory degree. Many ears become dry, and chronic inflammation can be cured with modern surgical techniques that are tailored to the individual case and avoid reliance on otosurgical dogma (e.g., a two-way approach instead of a radical mastoid cavity) [1–3]. Unfortunately, the prognosis for the restoration of hearing in such cases is less favorable. It is true that more than 70 different prosthetic materials [4–6] have been used in animal studies and clinical trials since the introduction of tympanoplasty almost 50 years ago, and more materials are in the developmental stage. But even prostheses that incorporate the most up-to-date biotechnology cannot guarantee good acoustic function of the middle ear. Too many non-implant–related factors affect the postoperative hearing results—although covering the surface of the prosthesis with cartilage appears to reduce the risk of perforation through the tympanic membrane, especially with bioinactive implants [1]. Mucosal pathology with effusion or fibrosis and scarring in the tympanic cavity can significantly reduce the ability of the tympanic membrane to vibrate, resulting in unsatisfactory hearing despite a technically flawless acoustic reconstruction. Due to the very low energy content of the sound waves reaching the tympanic membrane—the sound pressure at the audible threshold is less than 1 billionth of a bar (see Fig. 2.**1**)—the slightest constraint of the vibratory structures is enough to cause significant compromise of sound conduction.

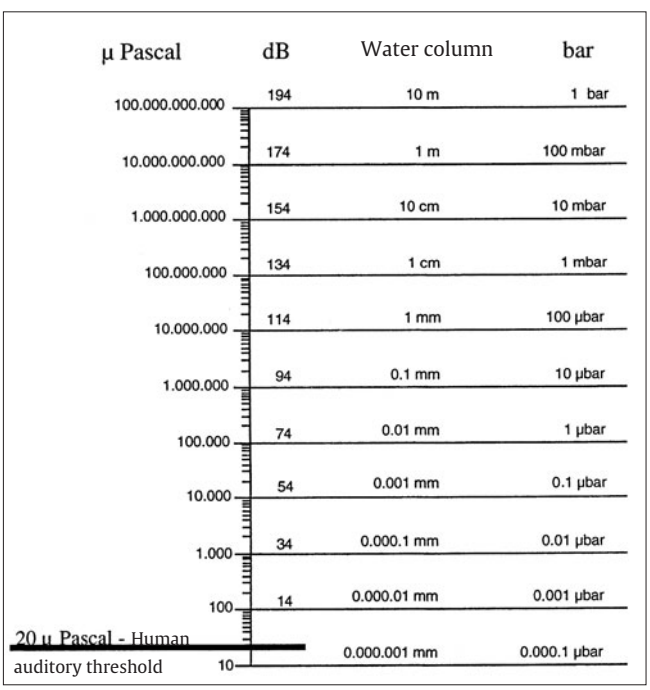

Fig. 2.**1** Dimensions of the acoustic and atmospheric pressures that act on the ear.

But even in cases where the middle ear has healed without irritation and the reconstructed tympanic membrane is thin, surrounded by air, and apparently allows unimpeded sound transmission, the postoperative hearing result is too often unsatisfactory. Although the inflammation has been eradicated in these cases, the surgeon has probably failed to reconstruct the acoustic function of the tympano-ossicular system.

In recent years, these functional failures have engendered a new desire among ear surgeons to better understand the mechanical acoustic principles of their otosurgical procedures. To perform a successful middle ear reconstruction, it is necessary to understand the acoustic function not just of the reconstructed middle ear but also of the normal middle ear. Given the extremely small amplitudes of the vibrations that are involved in sound conduction (vibrations at the audible threshold are smaller than the diameter of a hydrogen molecule [7]), the otosurgeon requires the help of an acoustic engineer in understanding the function of the middle ear. International symposia on middle ear mechanics, first held in Dresden in 1996 [8] and continued in Boston in 1999 [9] and Ehime, Japan in 2003 have brought together otosurgeons and engineers to elucidate the complex properties of the middle ear and establish a basis for developing acoustically optimized techniques of middle ear reconstruction. It is hoped that this exchange of ideas will advance the development of reconstructive otosurgery in the same way that international cholesteatoma conferences over the years have advanced the treatment of chronic otitis media. The published proceedings of the Dresden and Boston symposia may be consulted for a detailed review of current knowledge on the mechanics of the normal, diseased, and reconstructed middle ear [8, 9].

In recent years, moreover, technical progress in diagnostic modalities has contributed greatly to disclosing the secrets of middle ear function. Modern laser-assisted measuring techniques, with their high sensitivity, make it possible to analyze vibrational characteristics over the physiological range of the middle ear [10–14]. Laser Doppler vibrometry (LDV) has freed middle ear researchers from the burdens of older, more complicated techniques (Squid, Mössbauer, etc.) that were necessary for measuring the almost inconceivably small amplitudes that are involved in hearing. A strict separation of the acoustic functions of the middle ear from its response to atmospheric pressure changes [15] has also improved our understanding of middle ear functions. Today we should no longer interpret the microscopically or endoscopically visible vibrations of the tympano-ossicular system induced by extremely loud sounds as the normal movements that occur during hearing. It should be noted that the vibrational amplitudes in the normal, linear working range of the middle ear below approximately 100 dB [16] are in the order of a few nanometers. Since they are smaller than the wavelengths of visible light, they cannot be visually perceived even under the highest optical magnification. If movements of the tympanic membrane or ossicles can be seen in an acoustic experiment, this means that unphysiologically large movements (or high sound volumes) are present. These high pressures and motion amplitudes are sufficient to cause slippage and uncoupling to occur in the structures that normally are func-

tionally fixed when conducting sounds of physiological intensity [17]. The relationship between the two different functional systems of the middle ear—sound conduction and responses to atmospheric pressure changes—is discussed in our 1995 publication [15].

Another advance has been the use of modern computer technology for investigating middle ear function and developing more advanced reconstructive techniques. It has been the goal of many generations of middle ear researchers to use model calculations to better understand the functions of the middle ear. With the use of programs for mechanical vibrational analysis that generate a finite-element computer model of the vibrating structures of the middle ear, this goal has become attainable. Given the great importance of these computer models for future middle ear research, we shall describe them in a separate section at the end of this paper (written with the help of Mr. M. Bornitz, Middle Ear Laboratory, Department of Otolaryngology, Dresden University).

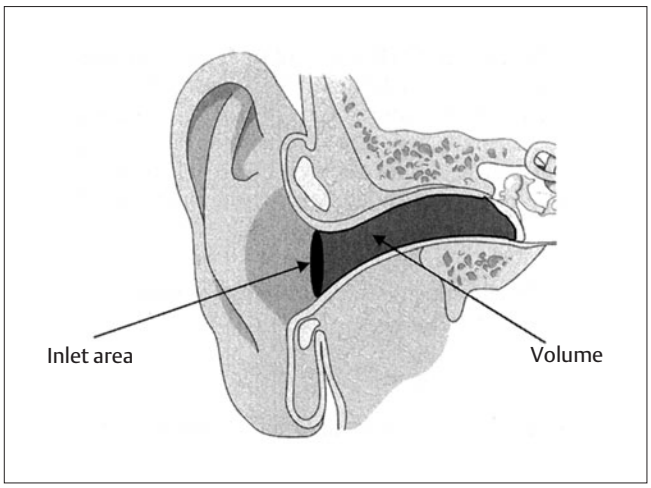

Fig. 2.**2** In ear operations, the inlet area and volume of the ear canal are variables that can change the amplification of sound pressure at the tympanic membrane due to physiologic resonance within the canal.

Sound Conduction through the Reconstructed External Ear

In principle, any surgical procedure on the ear can affect its acoustic function, including surgery of the external ear. It appears that this is also true to a very limited degree for auricular surgery. While the auricle is important for hearing in the wind, especially in animals [18], there is no clinical or published evidence that plastic surgery of the anthelix, for example, has any impact on hearing. At most, a complete absence of the auricle could alter the perception and forward/backward localization of acoustic information due to loss of the acoustic shadowing effect. These patients also complain of unpleasant resonance effects that are perceived out of doors on a windy day [18].

By contrast, the ear canal plays a major role in modulating the sound that is incident upon the tympanic membrane. The sharp anterior tympanomeatal angle, where the oblique ear canal meets the tympanic membrane, can significantly alter the sound pressure levels and impedances at various sites in front of the drum, especially at high frequencies. For this reason, the technique of multifrequency tympanometry, which provides some information on middle ear pathology, at least in experimental animals [19], is not useful at frequencies above 2 kHz [20], since any change in the geometry of the measured ear canal volume due to a change of probe position will alter the result in unpredictable ways.

More important factors in sound conduction are the volume of the ear canal and the width of the canal inlet (see Fig. 2.**2**), which affect the resonance of the canal. A resonance-induced amplification of sound pressure of up to 20 dB occurs in the normal ear canal at frequencies of 2800–3000 Hz, depending on the length and diameter of the canal. The wavelengths of these frequencies are equal to four times the canal length [22]. A perforation of the tympanic membrane has practically no effect on this resonance [24].

Increasing the canal volume, as by the surgical creation of a radical mastoid cavity, shifts the resonance to significantly lower frequencies [25]. In experiments on the petrous bone, this lowered the sound pressure level by 22 dB at 4.3 kHz while increasing it by 14 dB at 2 kHz. In clinical studies, however, the patients perceived only slight shifts in the resonance frequency that were due to the smaller volume change associated with a sclerotic mastoid [22]. The nature of the cavity surface (smooth or angular) led to a relatively small change in the resonance amplitude (about 6 dB) but did not alter the resonance frequency [26].

The width of the canal inlet is also a major acoustic factor in a radical cavity, which functions as a Helmholtz resonator. Increasing the surface area of the inlet increases the resonance frequency, as was demonstrated in a petrous model [26]. In a study where both factors, width and volume, were considered together, in-situ computer measurements in 18 patients with a radical cavity (2.5-fold volume increase, 20% increase in inlet surface area) showed a decrease in resonance frequency by approximately 1000 Hz. In the speech range of 3–4 kHz, which is important for consonant comprehension, the level decreased by approximately 10 dB [21]. Owing to the redundancy of speech comprehension, this frequency shift is more important in listening to music, where the ear is subjected to the entire frequency spectrum. Certain surgical measures that are desirable to ensure optimum aeration (cavity reduction, enlarging the inlet) [1, 3] can also help match the acoustics of sound reception in a radical cavity to that of the normal ear canal [26].

Postoperative hearing results depend far more on the quality of sound conduction through the middle ear, however. In the sections below, we shall review the acoustic mechanical aspects of middle ear reconstructions. To aid understanding, it is helpful to subdivide the acoustic function of the middle ear into two elements: (1) sound reception by the tympanic membrane and (2) sound conduction by the normal or reconstructed ossicular chain.

Biomechanics of the Reconstructed Tympanic Membrane

Basic Considerations

The tympanic membrane has special anatomical and physical features that are designed to receive acoustic pressures with high sensitivity over a large dynamic range and transform them into effective movements of the malleus. The tympanic membrane is the connecting element between sound waves in the air and the anatomical structures of sound perception. Its acoustic quality critically determines the quality of postoperative middle ear function. Additionally, it has the important ability to resist large pressure fluctuations (such as atmospheric pressure changes), compensate for them, and protect the ear from pressure injury. These performance features are closely related to the macro- and microanatomy of the tympanic membrane. Its structure is so complex that researchers have been unable to develop an artificial membrane that can replicate all the functions of the tympanic membrane.

Acute and chronic inflammations of the middle ear can lead to the partial or complete destruction of the tympanic membrane. The treatment of choice is surgery, the goal being to eliminate the cause of the inflammation and provide effective closure of the tympanic membrane. This will prevent new infections from invading the tympanic cavity from the outside. Clinical studies show that permanent closure of the defect is achieved in 85–90% of cases [1, 3]. Reports on the hearing results after myringoplasty are generally good, regardless of the surgical technique used. But a careful review of the literature shows that normal hearing (air–bone gap < 10 dB) is achieved in only 43–80% of cases [27–29]. Given the current demand for function-conserving surgery, these results leave considerable room for the future improvement of otosurgical techniques. From a functional standpoint, then, the goal of surgery is not just effective closure of the tympanic membrane but also the optimum restoration of its acoustic properties. Although some air–bone gaps that persist after myringoplasty are due to causes behind the tympanic membrane (chronic inflammatory changes in the middle ear mucosa or ossicular chain, aeration problems), in some cases the reconstruction technique itself can adversely affect the transmission properties of the tympanic membrane. For example, a cartilage graft placed in the tympanic membrane can increase the impedance of the membrane to a degree that restricts its ability to vibrate and causes part of the incoming sound to be reflected [30–32].

Available surgical techniques have evolved from decades of clinical experience. Modern anatomical examination techniques, acoustic test procedures, and computer models of the tympanic membrane can help to determine why sound components are lost after myringoplasty and to improve operative techniques in terms of restoring the acoustic mechanics of the tympanic membrane. To achieve this, it is necessary to know the function of the normal tympanic membrane in its capacity as a sound collector. Since few recent survey works have been published on this topic (as opposed to the extensive literature on ossicular chain function), below we shall briefly review the acoustic mechanics of the normal tympanic membrane.

Acoustic Mechanical Properties of the Normal Tympanic Membrane

The macro- and microanatomical structure of the tympanic membrane largely determines the function of this extremely thin membrane, which is only 30–90 μm thick [33]. The tympanic membrane is covered externally by the stratified squamous epithelium of the meatal skin and internally by the mucosa of the tympanic cavity.

The membrane has a conical shape (120° angle) with the umbo at its deepest point (see Fig. 2.**3**). The radially directed collagen fibers of the lamina propria of the pars tensa

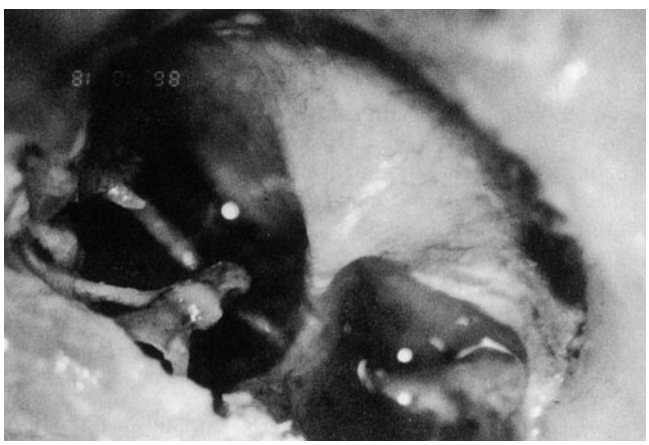

Fig. 2.**3** Tympanic membrane geometry. A view from the medial aspect (middle ear) demonstrates the conical shape of the tympanic membrane, with the umbo as its deepest point, and the convex bulge of the outer membrane surfaces.

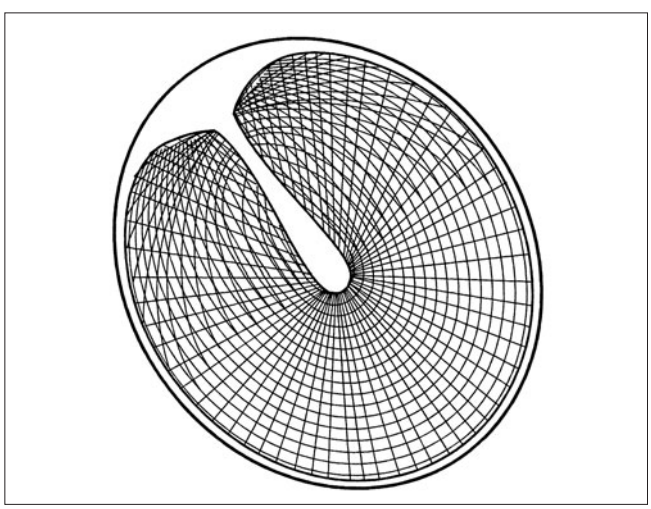

Fig. 2.**4** Diagram showing the radial, circular, and parabolic arrangement of the collagen fibers in the lamina propria of the tympanic membrane.

converge at the umbo. The lamina propria is the most important element for the mechanics of the tympanic membrane. In addition to an outer layer of radial fibers, it contains an inner layer of circularly oriented fibers. These fiber structures are interconnected by a parabolic arrangement of collagen fibers (see Fig. 2.**4**).

The fibers in the pars flaccida of the membrane are randomly oriented and are predominantly elastic [34]. Apparently these elastic fibers have a pressure-regulating and protective function with regard to low-frequency sound waves [35–38]. The size of this area of the tympanic membrane is remarkably variable in different animal species [33, 38].

Histologically, the lamina propria contains Schwann cells and axons that are described as tension receptors [39]. Clinical studies in healthy subjects have confirmed the theory that they function as mechanoreceptors for eustachian tube function. After the tympanic membrane was anesthetized, a pressure drop was measured in the middle ear on the anesthetized side. This was assumed to be caused by functional closure of the eustachian tube in response to the loss of tension-receptor function [40]. Presumably, reconstruction of the entire tympanic membrane could lead to the loss of these receptors and thus to eustachian tube dysfunction. These mechanoreceptors have been found to be particularly numerous in the pars flaccida, which consequently has special importance in the regulation of tubal function [38].

In 1868, Helmholtz [31] published his classic study on middle ear function in which he interpreted the outward convexity of the tympanic membrane surface as a special mechanism for amplifying sound pressures (see Fig. 2.**5**). This mechanism is necessary to compensate for the different acoustic impedances of the fluid-filled inner ear and the air. Even a small change in air pressure at the tympanic membrane, producing a slight change in membrane curvature, leads to a relatively large change of tension in the radial fibers of the tympanic membrane and thus generates a relatively large force at the umbo. In response to a large increase in external air pressure, the malleus handle can move inward until the radial fibers of the tympanic membrane are pulled taut and straightened [36]. In theory, a further rise in pressure would cause the radial fibers to curve inward (assuming the membrane is intact). This would shorten their tendon, and the malleus handle would again be pulled outward.

Recent velocity measurements of tympanic membrane movements in response to rapid changes in static air pressure, like those induced by a Valsalva maneuver [42, 43], have shown that even high pressure levels do not cause the tympanic membrane to flatten completely. Thus, the geometry of the tympanic membrane, together with its fiber architecture, serves to protect the ear from extreme static pressure effects while also making it more sensitive to very small pressure changes—a unique property that does not exist in synthetic membranes. As a result, the complete replacement of the tympanic membrane with an artificial membrane, like the copolymer membrane used in a total middle ear prosthesis [44], cannot equal the acoustic quality of the natural tympanic membrane, especially under everyday conditions.

Measurements with a capacitive probe led Bekesy to conclude that the entire tympanic membrane vibrates in concert with the malleus handle like a rigid, hinged plate up to a frequency of 2400 Hz, causing him to reject the Helmholtz theory [7]. Tonndorf and Khanna were unable to reproduce Bekesy's concepts and measurements, however [35]. They were the first to use holographic methods to analyze the vibrational characteristics of the tympanic membrane. As this method was much more sensitive than a capacitive probe, they were able to perform measurements within the physiological range of sound pressures. They confirmed the Helmholtz theory of an amplification factor intrinsic to the tympanic membrane. They and many subsequent researchers found that the entire tympanic membrane and malleus vibrate as a unit at low frequencies. Two peaks occur in front of and behind the manubrium, the am-

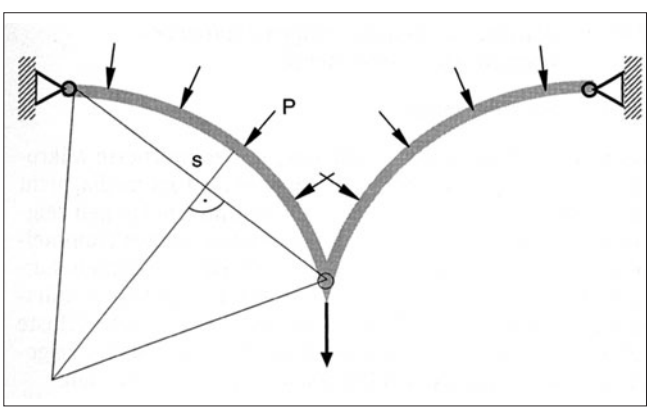

Fig. 2.**5** Mechanism of sound amplification by the tympanic membrane, as described by Helmholtz. Owing to the curvature of the radial fibers, even slight changes in air pressure (sound waves) cause a large force to be generated at the umbo.

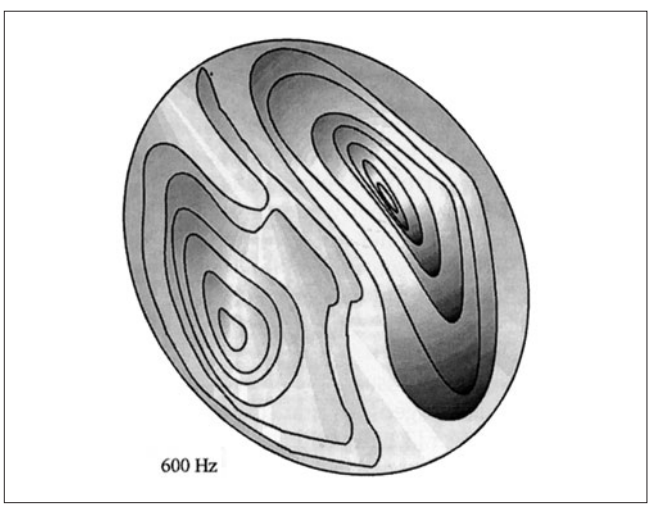

Fig. 2.**6** Pattern of tympanic membrane vibration below 2–3 kHz. The malleus handle and the entire tympanic membrane vibrate as a unit. The anterior and especially the posterior quadrants show up to a three times greater amplitude than other areas (after [45]).

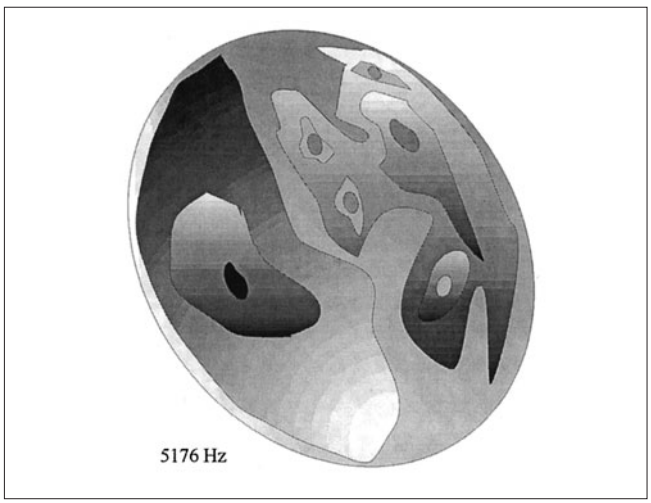

Fig. 2.**7** Pattern of tympanic membrane vibration above 3 kHz. At higher frequencies, vibration peaks occur at multiple sites in the tympanic membrane (after [45]).

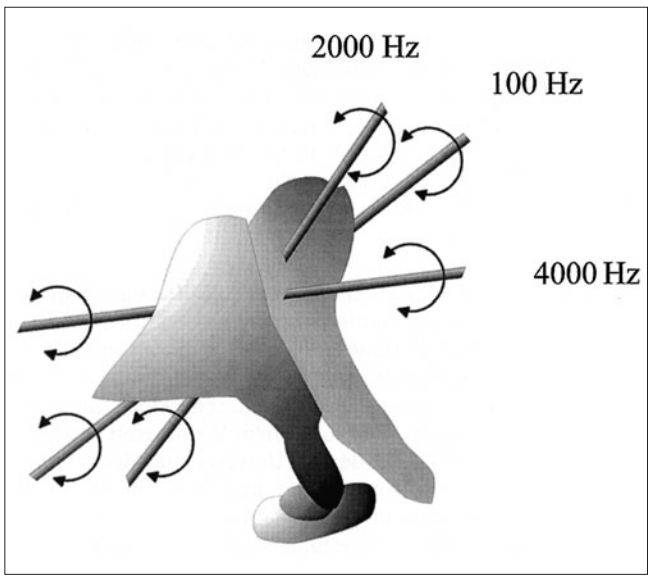

Fig. 2.**8** Vibration pattern of the malleus and the position of its rotational axis at various frequencies. Translational and rotational movements yield a complex vibration pattern that changes at different frequencies (after [47, 48]).

plitude of the posterior part of the tympanic membrane measuring about three times greater than that of the malleus handle (see Fig. 2.**6**). At frequencies above 2–3 kHz, this vibrational pattern dissociates into multiple separate peaks (see Fig. 2.**7**). Now the malleus handle and a narrow surrounding rim of tympanic membrane vibrate more than the rest of the membrane. It has also been shown that the movement pattern of the tympanic membrane is radically altered by removal of the lamina propria. This means that the lamina propria, with its complex fiber architecture, is the layer that is essentially responsible for the micromechanics of the tympanic membrane [45].

Recent studies using advanced laser measuring techniques have documented 3D movements of the malleus [46–48]. The malleus does not vibrate about a fixed rotational axis, as was once believed, but undergoes a complex vibration in all spatial directions, involving a combination of rotational and translational movements. The translational movement and rotation about the long axis of the malleus handle are attributed to the different areas of the tympanic membrane in its anterior and posterior quadrants, which at times vibrate out of phase with each other. The location of the rotational axis is frequency-dependent and may even be located outside the ossicles [46, 47] (see Fig. 2.**8**). Because of these new discoveries, we must discard the older concept of sound pressure amplification by a lever action of the ossicular chain based on an anatomically defined rotational axis in the axial ligament as described by Helmholtz.

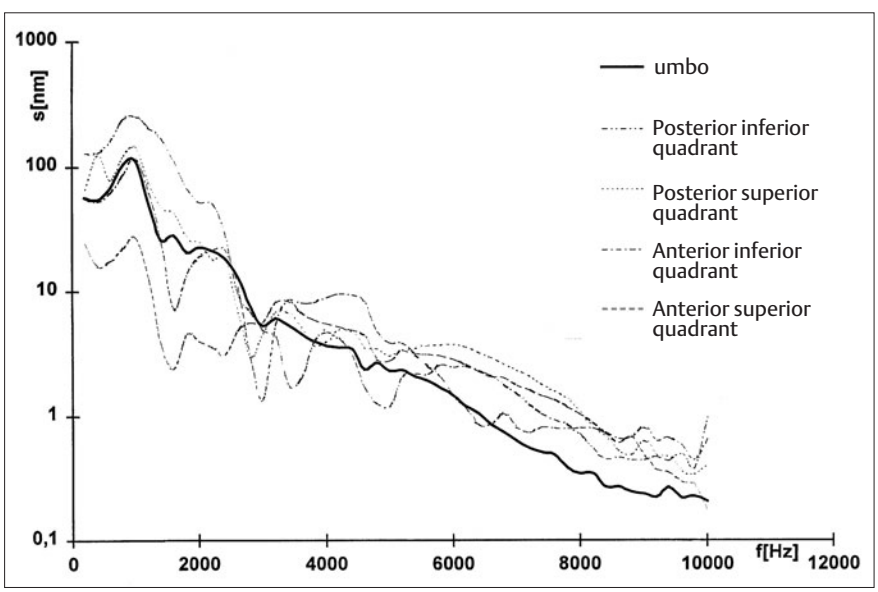

Fig. 2.**9** Amplitude-frequency curves for various quadrants of the tympanic membrane compared with the umbo. Resonances in the tympanic membrane are smoothed by its attachment to the malleus handle.

All studies to date indicate that the vibrational pattern of the tympanic membrane is directly determined by the geometry and material properties of the membrane. The relatively low stiffness of the tympanic membrane, as compared with a steel microphone membrane for example, is responsible for its high sensitivity to very low sound pressures. (By contrast, the output of a metallic membrane microphone must be amplified several times to achieve a similar sensitivity.) One disadvantage of this low stiffness and high sensitivity is the occurrence of resonance even in the low frequency range. This gives rise to vibration peaks (e.g., in the anterior and posterior quadrants of the tympanic membrane) that are unfavorable for hearing.

Measurements in the cochlea have shown, however, that the intracochlear sound pressure levels exhibit a relatively smooth frequency response. The marked frequency-dependent shift in the rotational axis of the malleus may smooth out the frequencies that are received by the tympanic membrane and transmitted to the inner ear [48]. At different frequencies, each vibrational peak of the tympanic membrane corresponds to a particular rotational axis of the malleus, and the resultant "lever arm" creates a more uniform vibration pattern over all frequencies [47, 48] (see Fig. 2.**9**).

A key factor in this frequency-smoothing effect is the attachment of the tympanic membrane along the full length of the malleus handle, not just at the umbo. To maintain this acoustic function, therefore, the ear surgeon should treat this area with respect and avoid detaching it without good reason.

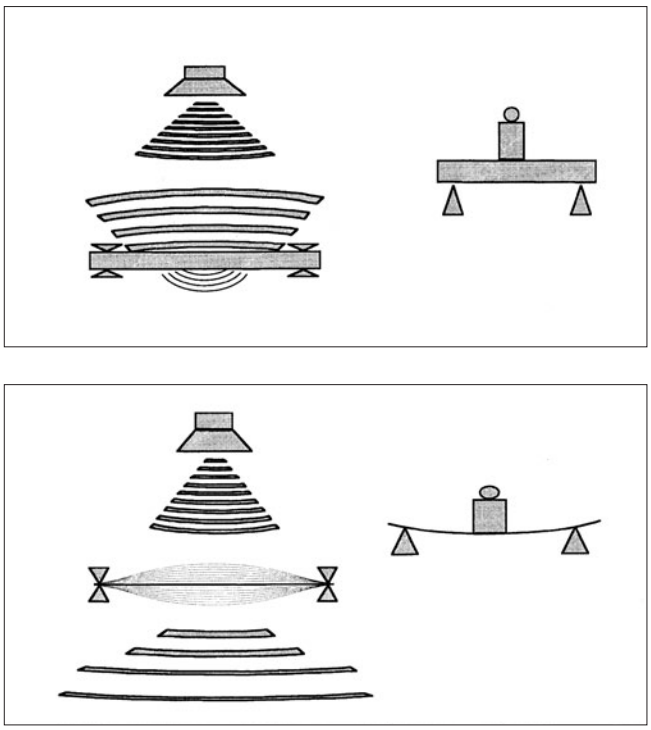

Fig. 2.**10** Schematic comparison of a thin membrane and a thick cartilage plate. The more stable the plate, the greater its ability to withstand static pressures, but the lower its acoustic sensitivity due to the greater reflection of vibrational energy.

Acoustic Mechanical Properties of the Reconstructed Tympanic Membrane

Healed Perforations

It should be emphasized that the complicated microstructure of the tympanic membrane, especially its intermediate layer, is not entirely reparable. Histological studies have shown that even when a tympanic membrane perforation heals spontaneously, its organized fibrous structure is not restored [49]. Once the structural and elasticity features of the normal lamina propria have been lost, losses also occur in the acoustic transfer properties of the tympanic membrane and its stability in response to atmospheric pressure changes.

In rats with experimentally perforated tympanic membranes that were allowed to heal, the low-tone air-bone gap returned to normal in the healed membranes [40, 41]. But the high-tone losses that occurred with very large perforations were still present after membrane healing, with persistent losses of up to 12 dB. These results cannot be applied to humans, however, because the high-tone loss in rats is caused by the formation of a thick, plaquelike scar that increases the mass of the tympanic membrane. In humans, by contrast, eardrum perforations almost always heal with a thin, membranous scar.

Using a finite-element model (FEM) of the human tympanic membrane, the acoustic effects of a healed tympanic membrane perforation were realistically simulated by varying the elastic modulus of the radial fibers. Significant changes were found in the vibration patterns of the second and third natural frequencies [52, 53]. It is assumed that these altered tympanic membrane vibration patterns have consequences in terms of the movements that are conveyed to the footplate [48].

It is doubtful that the experimental "tightening" of a tympanic membrane by laser treatment that shortens its collagen fibers will produce the same clinical improvement in low-frequency sound transmission that has been measured in a nonliving tympanic membrane in a petrous bone model [54, 55]. Actually, one would expect to see an improved vibrational response at higher frequencies if the collagen fibers in the living tympanic membrane were permanently shortened by the thermal laser energy.

The properties of a reconstructed tympanic membrane are determined chiefly by the material properties of the graft (size, mass, stiffness) and the reconstruction technique (graft position, graft attachment to the bony frame and malleus handle).

Material Properties of Grafts

Grafts whose material properties (mass, stiffness, damping) differ significantly from the properties of the tympanic

membrane can alter the impedance of the tympanic membrane and contribute to acoustic transmission losses. At present, the graft materials that are most widely used for tympanic membrane reconstruction are fascia and perichondrium. Based on their material characteristics, one would expect them to have acoustic properties similar to those of the tympanic membrane. Cartilage may be used as a full-thickness graft or may be split into thinner plates or palisades for the treatment of tubal ventilation problems, adhesive processes, tympanic fibrosis, or total defects of the tympanic membrane [1, 2, 56—59]. By increasing the mass and particularly the stiffness of the tympanic membrane, this material can alter the acoustic transfer properties of the tympanic membrane that are influenced by these parameters (see Fig. 2.**10**). A soft membrane that vibrates easily in response to acoustic energy will offer very little resistance to static pressures. Conversely, a thick cartilage disk has excellent stability but will reflect most of the incoming sound.

The elastic modulus (E modulus) for various graft materials has been determined in mechanical traction experiments [7, 33, 60, 61] (see Table 2.**1**). The higher the E modulus, the stiffer the material. The values for conchal and tragal cartilage were tested by the author in a small series of eight ear specimens. The tragal cartilage was stiffer in some cases and the conchal cartilage in others, so there was no statistically significant difference in stiffness between the two materials.

Table 2.**1** Elastic moduli of the tympanic membrane and various graft materials

Tympanic membrane	
Pars tensa	3.3×10^7 N/m^2
Pars flaccida	1.1×10^7 N/m^2
Temporal fascia	1.5×10^7 N/m^2
Perichondrium	2.0×10^7 N/m^2
Conchal cartilage	0.6×10^7 N/m^2
Tragal cartilage	0.3×10^7 N/m^2

A comparison of the E moduli yields information on the stiffness of different materials having the same thickness. Fascia and perichondrium are considerably softer than the tympanic membrane. So when these materials are used to graft a large area of the tympanic membrane, the reconstructed membrane is likely to become unstable in response to a static pressure load. This can lead to membrane retraction if eustachian tube function is impaired. While cartilage has a smaller E modulus than the tympanic membrane, this softness is apparent only when the thickness of the graft is comparable to that of the tympanic membrane, e.g., approximately 100 μm. In practice the cartilage is always thicker, giving it a greater overall stiffness than the thin tympanic membrane. Its compliance to atmospheric pressures is then dependent on its thickness.

An experimental model of the auditory canal and tympanic membrane has been used to measure these properties for various graft materials [31, 32, 61] (see Fig. 2.**11**). For testing, cartilage taken from the tragus and concha was cut into approximately 1-cm disks of varying, defined thickness using a cartilage cutter (Kurz Medical, Dusslingen). The deflection of the grafts in response to static pressure loads was determined by laser Doppler vibrometry. By comparing the slopes of the strain curves, it was possible to compare cartilage disks of varying thickness with the tympanic membrane and also with perichondrium and fascia (see Fig. 2.**12**). Cartilage disks with a thickness of 500–600 μm had a slope similar to that of the tympanic membrane in the range of atmospheric air-pressure variations, i.e., the stiffness of the disk was comparable to that of the tympanic membrane. Thicker disks have a higher stiffness than the tympanic membrane. The thinner cartilage disks (420 μm) show a steeper upslope than the tympanic membrane, indicating lower stiffness. In the normally or partially aerated middle ear, these thinner cartilage disks should provide adequate stability. But in cases of impending chronic eustachian tube dysfunction with a fall of middle ear pressure, thicker cartilage disks (> 500 μm) should provide a more stable reconstruction.

The graph (see Fig. 2.**12**) also illustrates the complex mechanical properties of the tympanic membrane. At very low pressure loads that are still within the range of acous-

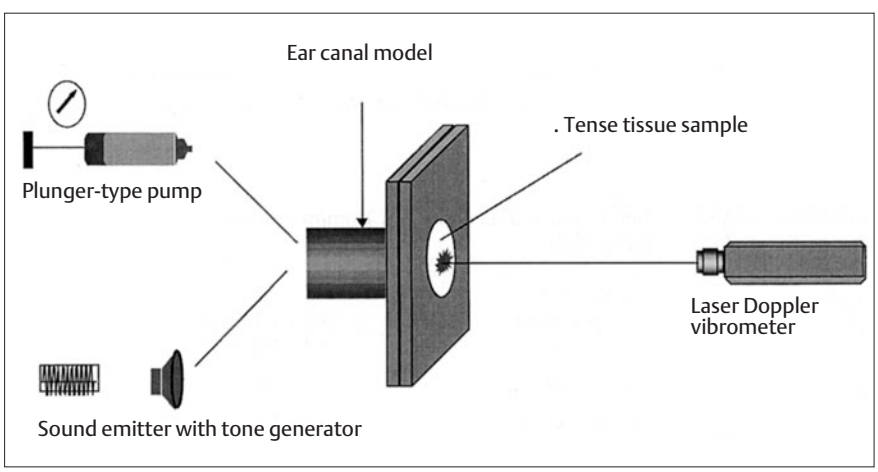

Fig. 2.**11** Diagram of an experimental setup for determining the mechanical stability to static pressures and acoustic sensitivity of the tympanic membrane and various graft materials in a model of the ear canal and tympanic membrane.

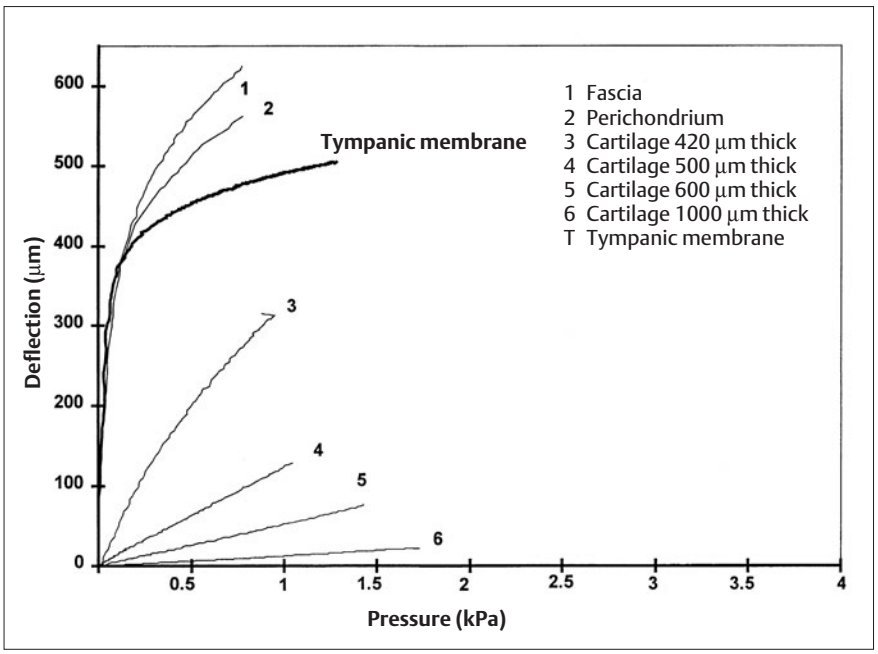

Fig. 2.**12** Deflection of cartilage disks of varying thickness compared with tympanic membrane, fascia, and perichondrium exposed to a static pressure load in the ear canal-tympanic membrane model. The thicker the cartilage disk, the lower its deflection and the greater its stability in response to pressure loads.

tic pressures, the curve for the tympanic membrane rises sharply, following the pressure with greater motion in a pattern similar to that of thin perichondrium and fascia grafts. This reflects its high acoustic sensitivity to sound pressures. But as the pressure load increases, entering the range of atmospheric pressures, the tympanic membrane does not undergo further stretching like the fascia and perichondrium but becomes stiffer and behaves much like a rigid wall, so that its curve flattens out. Thus, atmospheric pressure changes do not lead to unlimited displacement of the tympanic membrane; they are suppressed. This property is based on the directional arrangement of the collagen fibers in the lamina propria (see Fig. 2.**4**), which tighten in response to even slight elongation and oppose further stretching. This is quite different from the randomly directed fibers in fascia and perichondrium, which can offer no resistance to rising pressures. This property and its relevance to the mechanics of the normal ear were discussed in our 1995 publication [15].

The ear canal-tympanic membrane model has also been used to investigate the acoustic transfer properties of var-

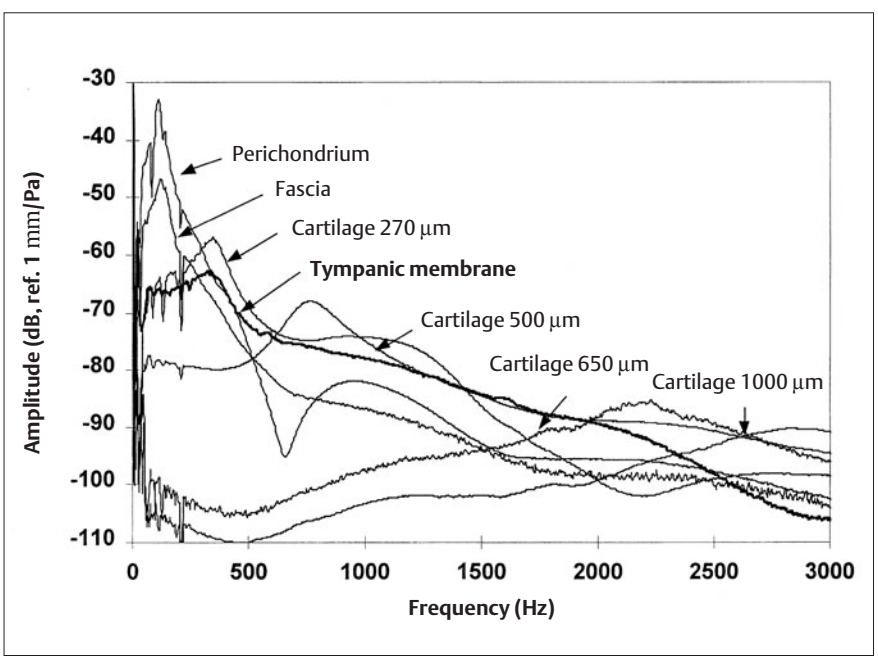

Fig. 2.**13** Amplitude-frequency curves for tympanic membrane, perichondrium, fascia, and cartilage disks of varying thickness stimulated by exposure to white noise at 70 dB in the ear canal-tympanic membrane model. The fascia and perichondrium show the anticipated low-frequency resonance peak of soft membranes. The tympanic membrane has a much smoother frequency curve with a resonance peak at 400 Hz. As the cartilage disks become thicker, their vibrational amplitudes decline. Cartilage 270 μm thick resembles the tympanic membrane. At 500 μm, the loss is 5 dB. At the original thickness of 1 mm, there is a loss of 25 dB in the first resonance frequency.

ious materials for tympanic membrane reconstruction (see Fig. 2.**13**). The amplitude-frequency curve for perichondrium and fascia shows the low-frequency resonance peak that would be expected for the thin, soft membranes. The curve for the tympanic membrane is much smoother, indicating its good transmission properties over a broad band of frequencies. A thin cartilage graft less than 500 μm thick has a frequency response comparable to that of the tympanic membrane and shows no significant decrease in vibration amplitude between 500 and 1500 Hz. Thicker cartilage vibrates at a lower amplitude. For a cartilage thickness of approximately 500 μm, the amplitude at the first resonance frequency is about 5 dB lower and is shifted toward higher frequencies. Cartilage in its original thickness of about 1 mm shows a loss of approximately 25–30 dB at 1 kHz.

Thus, to achieve optimum acoustic transmission in the well-aerated middle ear, the cartilage graft should be cut as thin as possible. If aeration is impaired, the cartilage should be no thinner than 500 μm. This should provide an acceptable tradeoff between acoustic sensitivity and stability.

Effect of Reconstruction Technique on Sound Transmission

When membranous materials such as fascia or perichondrium are used for tympanic membrane reconstruction, the geometric and material properties of the tympanic membrane can be essentially preserved. If cartilage is used in patients with chronic tubal ventilation problems, however, its greater stiffness will affect the vibration properties of the new membrane depending on the size and location of the graft and especially on its area of contact with the bony annulus (see Fig. 2.**14**).

A smaller cartilage graft placed within an otherwise normally vibrating tympanic membrane will mainly affect the vibration of the membrane at the frequency at which the cartilage graft is located within an amplitude peak ("belly") of the vibrating membrane. The stiffening of the tympanic membrane that occurs over a cartilage-capped prosthesis has been demonstrated experimentally with a laser Doppler scanning vibrometer [32, 62]. The increased mass load and damping are critical: the smaller and thinner the cartilage, the smaller this limited effect becomes.

Larger cartilage disks, on the other hand, affect transmission properties over the entire frequency range, because the bending stiffness of the tympanic membrane as a whole increases with the size of the implanted cartilage grafts. When the entire tympanic membrane is reconstructed with a cartilage disk placed in the bony annulus, the stiffness of the cartilage determines the acoustic transfer properties of the new tympanic membrane. The thickness of the cartilage is the dominant factor in this regard, as illustrated in Figure 2.**13**.

The experimental measurement of the vibrational mode shape of this kind of membrane, composed of several individual components, is very difficult and time-consuming

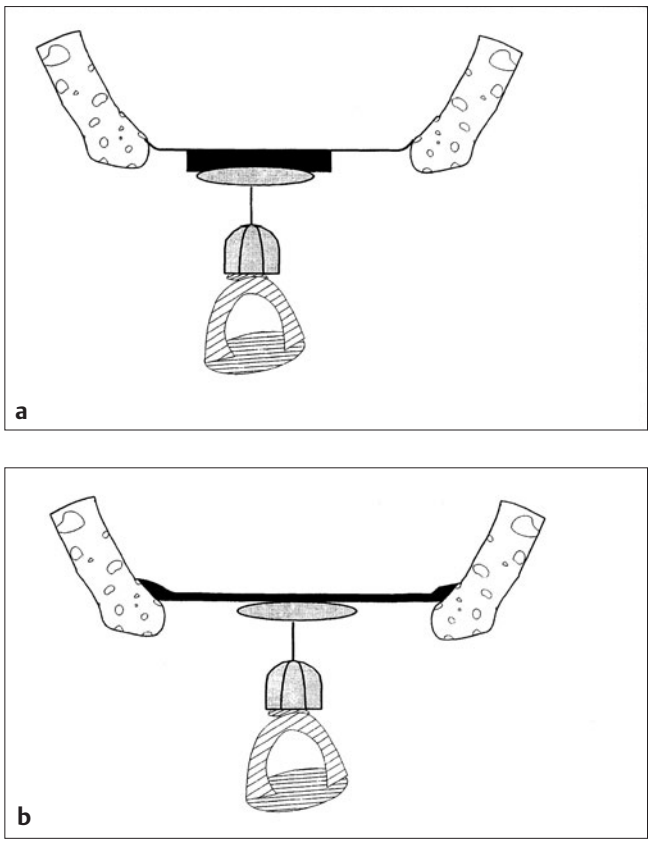

Fig. 2.**14 a** When cartilage is used for tympanic membrane reconstruction, its size and contact area play a critical role. For example, with a small cartilage graft that covers a prosthesis and is surrounded by normally vibrating tympanic membrane, the mass of the cartilage chiefly determines the vibration properties of the grafted membrane. **b** When the cartilage graft consists of a large plate or long palisade that is placed into the bony annulus of the tympanic membrane and heals in a taut condition, the principal effects are from the greater mass of the cartilage and also its inherent stiffness. This stiffness chiefly determines the vibration properties of the new membrane (see also Fig. 2.**13**).

with conventional laser Doppler vibrometry, which is a single-point measuring technique. With a homogeneous membrane, the center of the membrane vibrates at the greatest amplitude, and a laser vibrometer can take measurements at that location. But with more complex mode shapes, several vibration peaks would have to be measured successively in a number of separate measurements in order to map the vibrational pattern of the membrane. With laser Doppler scanning vibrometry, the mode shape of a vibrating surface is determined more efficiently by mechanically scanning a laser beam over the test surface and taking almost simultaneous readings at numerous sites (see Fig. 2.**15**).

This technique maps the sites with the highest and lowest vibrational amplitudes, which may go undetected with single-point measurements. Especially with a nonhomogeneous membrane in which the thickness, stiffness, and stresses vary considerably over its surface (as in a reconstructed tympanic membrane), laser Doppler scanning vibrometry can give an accurate picture of its acoustic prop-

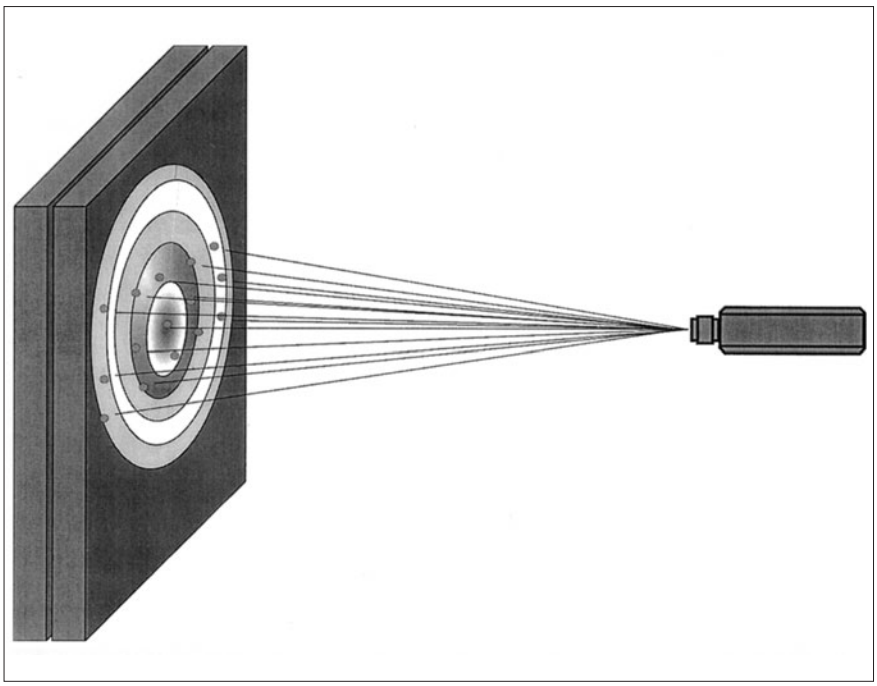

Fig. 2.**15** Principle of laser Doppler scanning vibrometry. A point laser beam is scanned mechanically at high speed over the surface of the object being tested. The scanned vibrational pattern is composed of many single-point measurements. The resolution of the system depends on the total number of individual readings.

erties. However, these instruments have an extremely complex design compared with single-point LDV and are costly to acquire. They are frequently installed at institutes of applied research (mechanics, acoustics, industrial research, etc.) and have rarely been used for otological investigations.

We used a model of the ear canal and tympanic membrane to measure the transmission properties of cartilage grafts of varying thickness and design (island grafts and palisades) [32]. It should be noted that the specimens in this model are vibrating "idly," i.e., they are not connected to an ossicular chain or prosthesis that is coupled to the inner ear, as would be the case in actual ear surgery. The resulting impedance would cause significant damping of the vibrations. Despite this drawback, the tests provide much information that is helpful in understanding the vibrational characteristics of reconstructed tympanic membranes. It is a basic principle that a middle ear prosthesis will pick up the vibrational energy of the tympanic membrane most effectively at the point where the membrane is vibrating at its greatest amplitude. This site is easily identified in a laser-scanned map of the vibrating membrane. The vibrational amplitude of that area can then be selectively determined.

A large, homogeneous cartilage plate whose margin is in contact with the bony annulus has its peak amplitude at the center of the plate, as would be expected (see Fig. 2.**16**). But when we simulate a cartilage island graft placed in a soft membrane (see Fig. 2.**17**), we find that the whole area

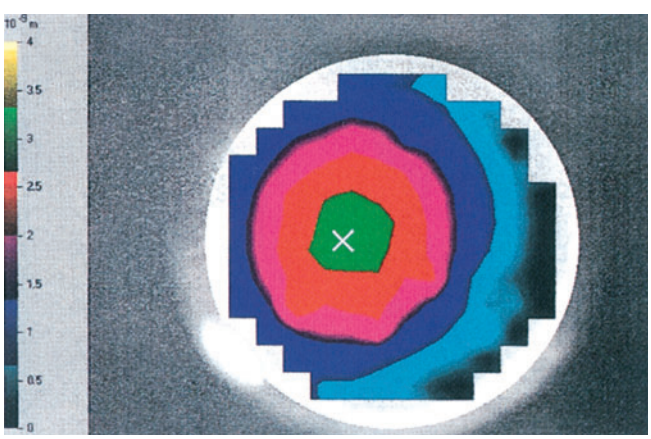

Fig. 2.**16** Laser Doppler scanning vibrometry of a cartilage-perichondrial plate. The amplitude peak of the homogeneous plate is located at the center (green area). The frequency curve is plotted at the position of the white cursor (see Fig. 2.**18**).

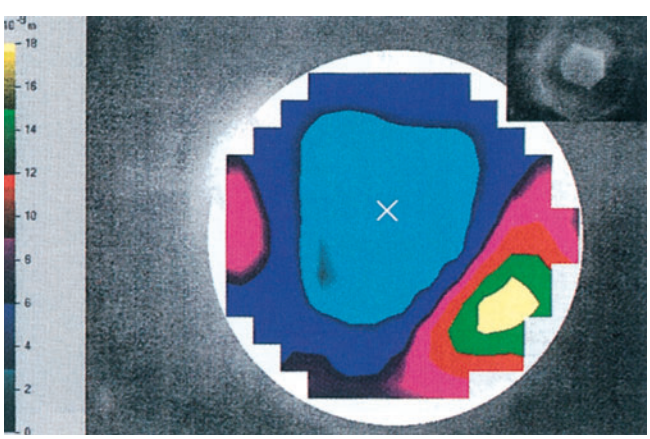

Fig. 2.**17** Laser Doppler scanning vibrometry of a cartilage island graft. The cartilage graft vibrates as a unit (light blue). The position of the graft is shown in the black-and-white inset. The adjacent membrane vibrates at a considerably greater amplitude (yellow). The white cursor marks the site for plotting the frequency curve (see Fig. 2.**18**).

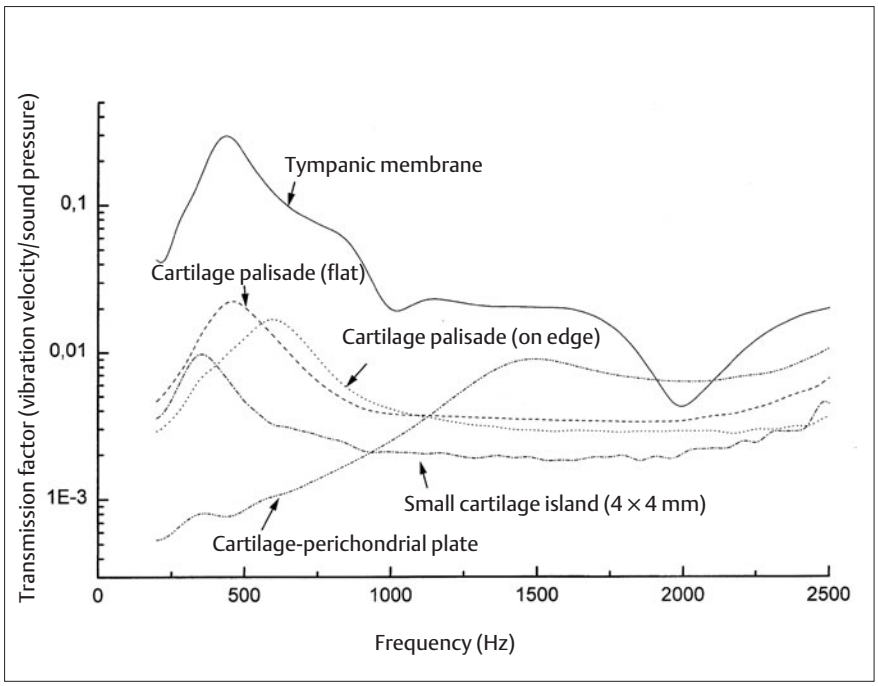

Fig. 2.**18** Transmission-frequency curves for cartilage island grafts and plates compared with the tympanic membrane. The cartilage island (4 × 4 mm) shows a frequency response similar to that of the tympanic membrane, but with smaller amplitudes. The large plate shows poor vibration at the lower frequencies due to its greater stiffness. The transmission-frequency curves for cartilage palisades positioned flat and on edge are very similar to the curve for the cartilage island, due to the comparable degrees of graft stiffness.

of the cartilage graft vibrates as a unit while the adjacent free membrane vibrates at a considerably greater amplitude. When the transmission-frequency curve is plotted for this type of construct, the cartilage island vibrates with an amplitude-frequency response that is much more like that of the tympanic membrane than of the full-size plate. The cartilage plate has large transfer losses due to its stiffness, particularly at lower frequencies (speech range) (see Fig. 2.**18**).

The same method can be used to map the vibration patterns of cartilage palisades, although this application is less precise because it does not take into account graft healing. With a full-size cartilage plate, the circumference of the specimen in the test model can be clamped in place to simulate the natural fixation of the graft edges to the bony annulus by scar tissue. The cartilage palisades, however, are placed side-by-side on the membrane and are fixed only at their ends. The bonding that normally occurs between the palisades and contributes substantially to the overall stiffness of the new tympanic membrane cannot be simulated in the test model.

It is not surprising, then, that the vibration properties measured in the model were unaffected by whether the cartilage strips were placed flat, i.e., side-by-side in their natural orientation, or on edge, i.e., rotated 90° so that their perichondrial surfaces were touching.

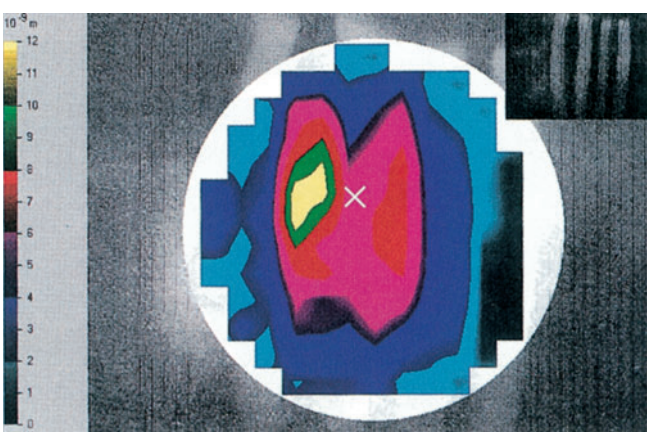

Fig. 2.**19** Laser Doppler scanning vibrometry of cartilage palisades in the on-edge position. The arrangement of the cartilage is shown in the black-and-white inset. Where the cartilage strips are slightly apart, the intervening membrane can vibrate at a considerably greater amplitude (yellow). The frequency curve was plotted at the white cursor (see Fig. 2.**18**).

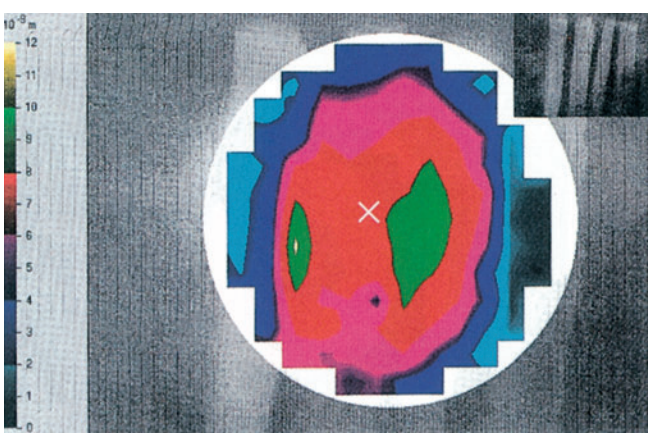

Fig. 2.**20** Laser Doppler scanning vibrometry of cartilage palisades in the flat position. The arrangement of the cartilage is shown in the black-and-white inset. The peak amplitude of membrane vibration (yellow-green) between two cartilage strips slightly farther apart is greater than that of the cartilage. The frequency curve was plotted at the white cursor (see Fig. 2.**18**).

Vibrometry clearly shows, however, that at sites where the cartilage strips are spaced slightly apart, the intervening membrane vibrates at a considerably greater amplitude (see Figs. 2.**19** and 2.**20**). The vibration pattern at the center of a single palisade resembles that of a cartilage island (see Fig. 2.**18**) and is more favorable than that of a full-size cartilage plate of equal thickness. This is attributable to the lower stiffness of the narrow cartilage strip, which, as mentioned, was not connected to the adjacent cartilage strips in the experimental model.

Cartilage appears to be well suited for tympanic membrane reconstruction from the standpoint of its acoustic and mechanical properties, as years of clinical experience have shown. When circumstances allow, the cartilage should be as thin as possible or used in the form of an island graft to make the reconstruction only as stable as necessary while recreating as closely as possible the acoustic transfer properties of the natural tympanic membrane. If the stability of the reconstructed membrane is a higher priority, thicker cartilage plates or a palisade technique can be used, although this entails some sacrifice of acoustic quality. Further experimental studies that take into account postoperative healing processes and realistic middle ear conditions (coupling to a prosthesis) are necessary in order to obtain reliable information.

Biomechanics of the Reconstructed Ossicular Chain

Basic Considerations

The function of the ossicular chain is to transmit acoustic energy received by the tympanic membrane into the inner ear without losses or distortion and under variable environmental conditions. With the three auditory ossicles—the malleus, incus, and stapes—nature has developed a tiny but ingenious mechanism that conforms ideally to these requirements. The middle ear can transmit sounds without distortion up to very high sound pressure levels of 100–120 dB, which border on the pain threshold [16]. Numerous elastic fibers in the joint capsules of the ossicles maintain a fixed functional position of the ossicular joints by pressing the articular cartilage surfaces together. This enables the ossicular chain to vibrate as a unit, in almost a piston-like motion, when transmitting sound (see Fig. 2.**21**). Rotatory components occurring at the stapes footplate, for example [63], are of very small magnitude and occur only at high sound pressures and at higher frequencies. Very high pressures, which are considered physiological only as a change in ambient air pressure (sound pressures > 120 dB were unknown during evolution), can disrupt the articulating surfaces in the ossicular chain, causing a slippage of the joints. When this occurs, the motion pattern within the chain becomes entirely different from that caused by acoustic vibrations owing to the special anatomy of the joints and the geometry of the ossicular suspension [15]. This micromechanics of the ossicular chain has a twofold effect: (1) the sensitive pressure receiver of the inner ear is uncoupled from the relatively huge environmental pressure changes, and (2) the stapes is held in its resting position, regardless of ambient air-pressure fluctuations. Displacement of the stapes from this neutral position would cause the annular ligament fibers to tighten, with a corresponding loss of sensitivity (see Fig. 2.**22**) [17]. Further details on the micromechanics of the normal ossicular chain can be found in our previous paper [15].

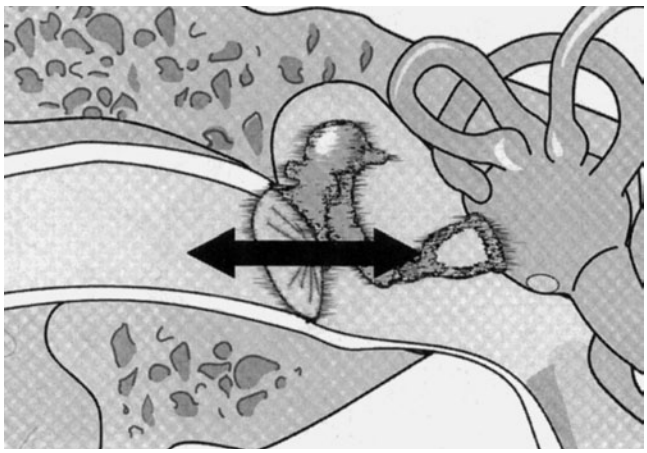

Fig. 2.**21** Pattern of ossicular chain movement in sound transmission. The ossicular chain basically vibrates inward and outward as a unit, in a piston-like motion, with its joints in a fixed position.

The ossicular chain, by connecting the large tympanic membrane to the inner-ear fluid via the much smaller stapes footplate, also creates the hydraulic gain in the middle ear that is necessary for impedance matching. Model calculations have shown that this middle-ear gain is frequency-dependent, increasing from 20 dB at 500 Hz to 25 dB at 1 kHz, and then falling by 6 dB per octave at higher frequencies [64]. Due to the shadowing effect of the intact tympanic membrane (approximately 10–20 dB) and the phase difference between the round and oval windows, a loss of up to 60 dB occurs when the ossicular chain is absent and the tympanic membrane is intact. This presents

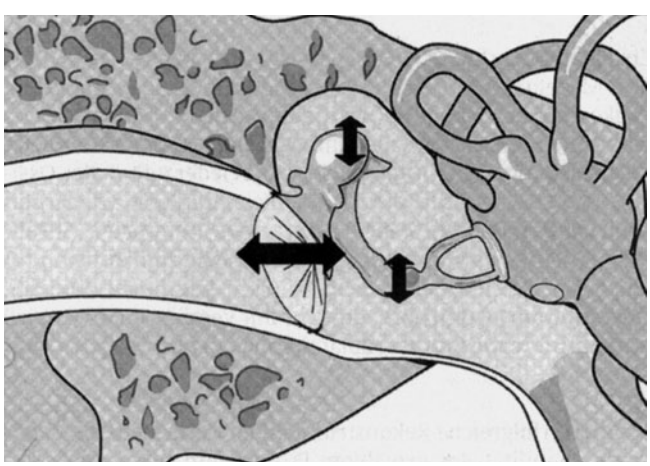

Fig. 2.**22** In response to atmospheric pressure changes, the ossicular joint surfaces move in relation to one another. The gliding movements and the special suspension of the ossicles redirect ossicular motion in a way that functionally uncouples the stapes from the very large excursions of the tympanic membrane-malleus complex.

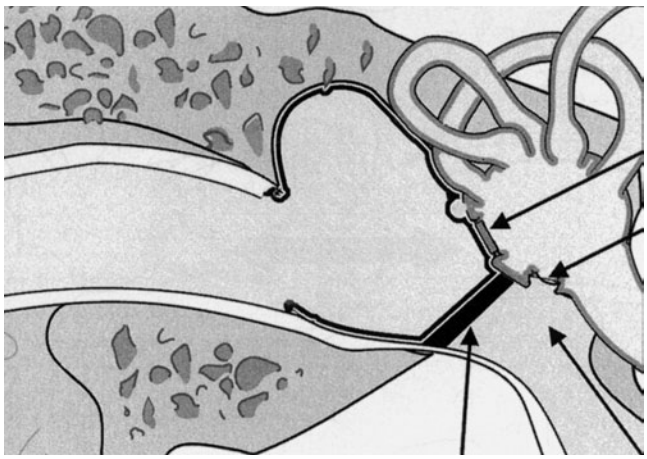

Fig. 2.**23** Cavum minor in a Wullstein type IV tympanoplasty. The footplate is directly exposed to incoming sound. To exploit the phase difference between the two windows, the round window is isolated from direct sound by placing an acoustic shield of hard material over the cavum minor chamber. The cavum minor air space in front of the round window should be larger than 20 μL so that inner ear impedance is not increased.

as a "sound conduction block" in clinical audiometry. If the tympanic membrane is opened in this situation, its shadowing effect is eliminated while the air–bone gap is reduced to 40–50 dB when the ossicular chain is deficient [64]. In a Wullstein type IV tympanoplasty, the tympanic membrane is absent along with the ossicular elements as far as the stapes footplate (see Fig. 2.**23**). Since this eliminates any hydraulic gain, the importance of the phase and sound pressure difference between the round and oval windows, which is relatively minor in the intact middle ear (less than 2 dB), becomes substantial. This sound pressure difference between the two windows can be optimized by maximum acoustic shielding of the round window niche (e.g., with a thick cartilage plate), so that the resulting conduction loss is limited purely to the loss of hydraulic gain. A residual hearing loss of only 25 dB is possible in theory, explaining the favorable attitude of some otosurgeons toward the type IV tympanoplasty [64–66]. But this result requires ideal healing processes in the operated middle ear, as in all reconstructive procedures, because even a small mucosal pad on the footplate or poor sonic shielding of the round window will quickly compromise the acoustic result. Additionally, a small but definite air space (larger than 20 μL) should be present in front of the round window membrane to reduce the impedance of this "cavum minor" chamber. Otherwise the round window could not vibrate freely, resulting in higher inner ear impedance and a poorer hearing result [67, 68].

Thus, an acoustically successful type IV depends upon healing of the middle ear mucosa and an aerated residual middle ear space. So if the eustachian tube is functioning normally, even a complete reconstruction of the tympanic membrane and ossicular chain will have a good chance of success, provided the ossicular reconstruction restores the hydraulic gain so that there is a chance of achieving less than 10 dB conduction loss. Patient selection for a type IV reconstruction is usually based on clinical criteria, therefore, such as operating on a last-hearing ear while avoiding a potentially traumatizing implant placement on a fragile footplate, etc.

The biological stability of the selected prosthetic material is the prime factor in a successful reconstruction of the ossicular chain and is more important than any biomechanical considerations. Even an acoustically perfect implant will be useless if it undergoes disintegration or extrusion in the body.

In the still-brief history of tympanoplasty, a vast number of materials have been employed [1, 4–6]. Synthetic implants have been the dominant materials in recent years for various reasons and are expected to function for many decades when used in children, but their long-term biological stability is still uncertain. Poor late results such as foreign-body reactions to materials formerly considered biocompatible [1, 2, 69] or the softening of cartilage used for ossicular replacement [70] suggest that caution is warranted in predicting outcomes. This also applies to the increasing use of metals (gold, titanium), for which only a few years' clinical experience is available. Nevertheless, the theoretical advantages of metals, especially from an acoustic standpoint, appear to justify their current use, especially when we consider the lack of biologically superior alternatives.

Clinical–Biological Parameters of Ossicular Chain Reconstruction

In many clinical studies, the postoperative hearing result serves as the criterion for determining whether a certain material or implant shape is favorable for tympanoplasty. However, the postoperative pure-tone audiogram is influenced by such a larger number of extraneous factors not directly related to the reconstruction technique that this clinical assessment is not suitable for evaluating acoustic quality (see Table 2.**2**). To a degree, the biological acceptance of a material can be assessed by the occurrence of extrusion, although other factors such as persistent eustachian tube dysfunction with tympanic membrane retraction could disqualify an inherently good material that undergoes pseudoextraction.

Table 2.**2** Clinical-biological parameters that can affect postoperative hearing after a tympanoplasty

- Postoperative condition of the middle ear
  - Acoustic quality of the reconstructed tympanic membrane
  - Condition of the middle ear mucosa (granulation, effusion)
  - Operative technique: ear canal resonance, volume of tympanic cavity
  - Scar formation
  - Stiffness of the annular ligament (e.g., inflammatory sclerosis)
- Operator experience
- Patient variables: coexisting disease (diabetes, cleft lip and palate, etc.)
- Length of follow-up
- Change in cochlear function (bone conduction threshold)
- Healing of the prosthesis in the conduction chain
- Conduction properties of the prosthesis (design, material parameters, etc.)

Sound transmission through the reconstructed middle ear depends critically on the acoustic quality of the tympanic membrane, which is also reconstructed in most cases (see pp. 53). An acoustically perfect prosthesis will do less well in a cholesteatomatous ear with a deficient or retracted tympanic membrane than will an acoustically inferior implant in an ear with an essentially normal drum. Examples of this may be seen clinically in cases of traumatic incus dislocation where the stout, transparent body of the incus is visible behind the delicate, intact tympanic membrane, but still the patient's hearing is almost normal.

Moreover, changes in the tympanic cavity such as massive scarring, mucosal granulations, or even a middle ear effusion can seriously compromise the acoustic properties of a prosthetic implant.

The volume of the ear canal and the width of the inlet also influence the postoperative air conduction threshold by creating resonance effects, particularly in the range of 1–2 kHz, which is important for understanding speech. The depth of the reconstructed tympanic cavity, and thus the air cushion behind the tympanic membrane, has little direct bearing on sound conduction through the middle ear, contributing only about 10% to the total impedance of the ear in humans. Most of the impedance comes from the stiffness of the annular ligament. In many mammals, however, the total stiffness of the middle ear is determined largely by the impedance of the air filling the bulla. Opening the bulla immediately alters the transmission through the middle ear [16, 71, 72]. In humans, on the other hand, the varying degrees of mastoid pneumatization have no impact on hearing. Only at very small volumes less than 0.5 mL is the stiffness of the air cushion measurably increased, so that an air–bone gap of up to 10 dB can develop mainly at low frequencies [64, 68]. The acoustic effects are greater in a "shallow middle ear" (e.g., in a radical cavity) when the plate of a columella prosthesis slips and comes into contact with the promontory or facial canal. This effectively damps vibrations across the prosthesis, leading to a significant transmission loss in the audiogram. Also, proximity of the tympanic membrane to the medial wall of the tympanic cavity can predispose to scarring and adhesions that damp vibrations across the tympanic membrane and prosthesis.

Some of these factors have been singled out for analysis by creating subgroups in comparative clinical studies. But given the many variables that are involved, huge amounts of data based on many thousands of operations have to be compiled in order to prove statistical significance [73].

On the other hand, conditions such as unrecognized sclerosis of the annular ligament, as a variant of tympanosclerosis, can lead otosurgeons to misinterpret the cause of unsatisfactory hearing results. Intraoperative needle palpation can detect stapes fixation only in extreme cases. Lesser degrees of fixation, like that caused by incipient stiffening of the annular ligament, are not detectable by palpation but still lead to significant impedance increases and thus to conductive loss. Attempts to detect these vibration-inhibiting conditions experimentally [74] or intraoperatively, as by the use of sonic probes [75–77], have been unsatisfactory due to methodological problems and subjective ratings (the patient had to describe his auditory impressions while under local anesthesia). The intraoperative recording of auditory brainstem responses has not found routine clinical application because of its high expenditure [78].

A newly developed hand-held intraoperative probe that can objectively measure the vibration capacity of the stapes in its annular ligament has been successfully tested in the petrous bone. Initial clinical results suggest that the probe may be able to detect this factor as the cause of a persistent postoperative conductive component [79].

Besides these direct causes located in the middle ear itself, there are indirect factors that can affect the postoperative hearing result. First and foremost, the experience of the surgeon will determine whether the selected prosthesis is optimally fitted and positioned. It is often difficult to factor "experience" into the clinical results of cholesteatoma surgery. This has to do with patient selection: more experienced surgeons are more likely to perform more difficult operations with a poor prognosis (e.g., recurrent disease, eustachian tube dysfunction), and this tends to worsen their statistical results [1]. But at the same time, this "handicap" for experienced surgeons is offset in ossicular reconstructions by their greater expertise in manipulating the prosthesis, whose optimum selection and placement are essential for a good hearing result. Other benefits of experience are less hand tremor and greater manual precision. In an experimental study of tremor in microsurgical manipulations (see Fig. 2.**24**), it was found that, besides prior physical exercise, the experience of the surgeon was a critical factor in determining the magnitude and force of tremor in microsurgical operations [80]. The measurements showed that prior physical exercise, such as knee bends, significantly increased tremor. Although hunger or excessive coffee drinking are often implicated in busy surgical units, they were found to have no effect on tremor or manual precision in a simulated middle ear manipulation. The test also confirmed the clinical experience that grasping an instrument with both hands can significantly reduce tremor and improve precision for both experienced and inexperienced surgeons.

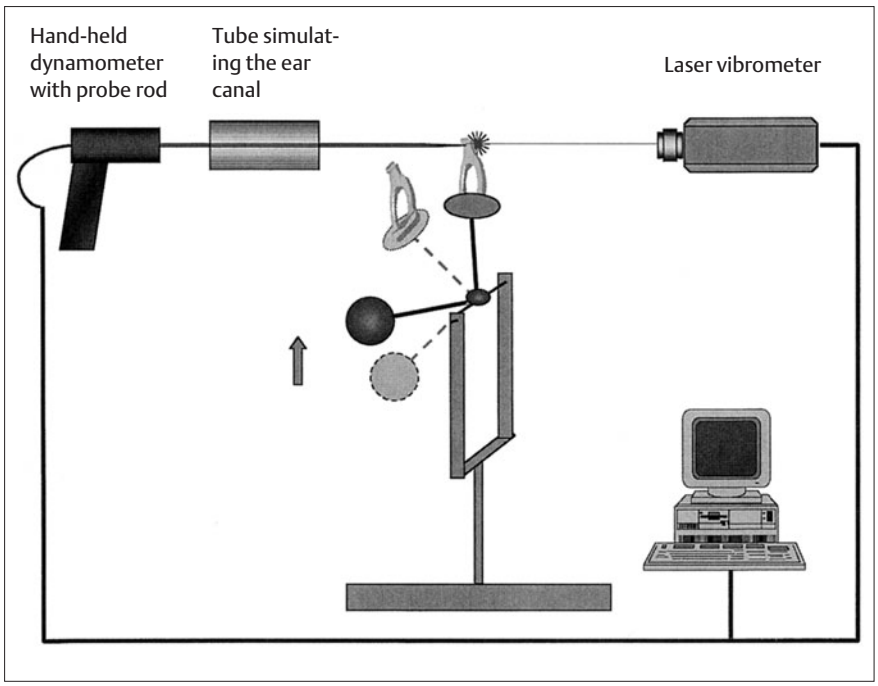

Fig. 2.**24** Setup for testing tremor and manual precision in simulated microsurgical manipulations. When the stapes is displaced, the weight is raised, creating a constant counterpressure.

In the patient, concomitant diseases can affect the surgical outcome. Diabetes impairs the healing ability of the reconstructed middle ear [1]. Chronic eustachian tube dysfunction, like that associated with cleft lip and palate [1, 3], is particularly damaging because the aeration problems lead to tympanic membrane retraction, middle ear effusion, and adhesive processes that can spoil even a perfect ossicular reconstruction.

The follow-up period after the reconstruction apparently plays a less important role. While the number of recurrences (and thus the number of acoustic failures) increase with time after cholesteatoma surgery, transmission through the healed middle ear remains relatively constant during the years after the reconstruction, provided the prosthetic material has been accepted by the body [1].

One should always be careful in interpreting audiogram data. The change measured in the bone conduction threshold after middle ear surgery does not necessarily reflect true cochlear function. For example, a Carhart effect can lead to misinterpretation of the change in the air–bone gap. It is better in these cases to compare the pre- and postoperative air conduction thresholds [81].

Mechanical Parameters of Ossicular Chain Reconstruction

Healing of the prosthesis between the ossicular chain remnants, while of major acoustic importance, is very difficult to assess clinically. The eye cannot evaluate biomechanical factors such as the position of the prosthesis, its contact with the tympanic membrane, malleus handle, and stapes, the axial alignment of the prosthesis, and the tension of the suspensory ligaments. Usually these factors can be evaluated only when revision surgery is carried out.

If we wish to rule out the many clinical factors when evaluating the acoustic quality of a certain prosthesis or reconstructive technique, one option is the petrous bone experiment. Even this cannot eliminate biomechanical variables, however (see Table 2.**3**). Errors in methodology can also occur [82]. Before the results are applied to clinical reality, moreover, it should be considered that all other acoustically important structures in the petrous bone, especially the tympanic membrane, are of normal consistency and function in the model, whereas in reconstructive surgery there is usually some involvement of the tympanic membrane in the disease process. Given the parametric insensitivity of the ear, this aspect cannot be ignored. A single factor in the petrous bone experiment can be radically altered without causing a significant deterioration in global transmission. For example, when the incus of a normal ear is removed in the petrous bone experiment and replaced with a prosthesis, it is enough for the prosthesis simply to touch the normal tympanic membrane or malleus handle in order to restore essentially normal sound conduction [83]. But in a clinically diseased ear with destruction of the tympanic membrane, chronic negative pressure, scar tethering, etc., this weak water-adhesion force cannot provide adequate sound transmission when there is concomitant impairment of other parameters.

Table 2.**3** Mechanical parameters that can affect the transmission of an ossicular reconstruction in the petrous bone experiment

– Axial alignment of the prosthesis to create a piston-like action in the middle ear
– Coupling of the prosthesis to the malleus handle or tympanic membrane
– Size of the contact area (flange size of the prosthesis)
– Material properties of the prosthesis (weight, elasticity coefficient)
– Quality of the prosthesis attachment
– Tension on the ossicular suspension

Even reducing the parameters further to a mechanical model of the middle ear [84, 85] cannot eliminate the methodological sources of error that are inherent in a comparative experiment. Whenever a prosthesis is implanted, whether intraoperatively or in an experimental model, several parameters are always changed: the axial alignment of the prosthesis relative to the direction of vibration of the tympanic membrane and footplate; the position, size, and quality of the contact area between the prosthesis and the tympanic membrane–malleus handle; the initial tension of the ossicular ligaments, etc. All of these variables must be redefined each time, and each of them influences transmission.

Due to the pistonlike mode of ossicular vibration, sound transmission becomes less efficient when the axis of the prosthesis is tilted away from the direction of the vibration. This decrease is proportional to the square of the cosine of the angle of the connection that is placed between the tympanic membrane and footplate. For example, a 45° angle can lead to a loss of 6 dB [86] (Fig. 2.**25**). This effect has been demonstrated in the petrous bone experiment using various techniques such as LDV [86–89] and hydrophone measurements [83]. Thus, a prosthesis mounted between the footplate and malleus handle, whose long axis is approximately in line with the vibrational axis, will transmit sound better than a prosthesis placed obliquely between the stapes capitulum and the umbo. If the malleus handle is located far in front of the stapes and is also retracted, the result will be a very oblique connection leading to ineffectual tilting movements of the prosthesis. This situation is exacerbated by the fixation of the footplate in the annular ligament. The suspension is tightest along the tall axis of the stapes, but the side-to-side mobility of the ossicle is six times greater [90]. Thus, if the prosthesis is not exactly perpendicular to the stapes capitulum, it will tend to tilt the stapes laterally, causing ineffectual wobbling movements at the footplate. The desired piston-like stimulation is best obtained with a prosthesis that is placed at right angles between the tympanic membrane and the footplate or stapes capitulum (Fig. 2.**25**).

One problem with this arrangement is that acoustic vibrations are no longer picked up by the malleus handle, which receives practically all of the energy from the vibrating tympanic membrane. The prosthesis, by contrast, is in contact with only the posterior superior quadrant of the tympanic membrane. So far, no precise data or computations have been published on this problem. Petrous bone experiments designed to study the effectiveness of coupling a prosthesis to either the malleus handle or the tympanic membrane [86] should be interpreted with caution, as they have been based on the change in total transmission through the middle ear. When the contact site is changed, many other parameters are altered as well, such as tilt angles, tension, or the size of the contact area. Also, the total transmission through the middle ear as determined by measurements at the middle ear outlet (e.g., vibration of the stapes or round window or inner-ear sound pressure [83, 86, 91]) is again made up of many individual components. This makes it practically impossible to isolate a single factor. The problem could be solved only if, in addition to global transmission, the vibrations of the prosthesis itself were measured in three dimensions using a technique such as LDV. In practical terms, however, it is difficult or impossible to apply this complex test setup to the tiny, hidden structures of the middle ear.

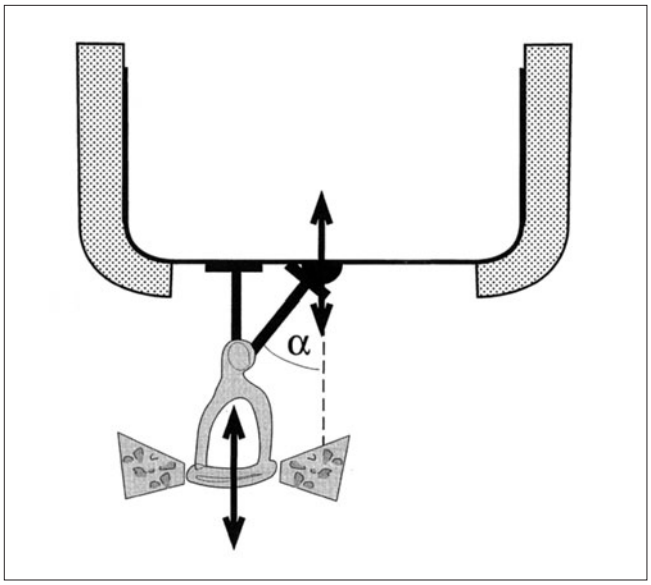

Fig. 2.**25** Since the tympanic membrane, malleus, and stapes have an essentially piston-like mode of vibration, an interposed prosthesis transmits vibrations more effectively when it is placed parallel to that axis, rather than at an angle. The loss calculation is based on the cosine of the angle α.

As a result, no reliable data have yet been published on the optimum size for the plate of an interposition prosthesis or its coupling area to the tympanic membrane. A larger plate would be advantageous in principle, as it has a larger area for receiving vibrations from the tympanic membrane. Experiments have shown that a plate with a contact area of 3–4 mm gives better transmission, especially at moderate frequencies. This effect has not been reproduced in all experiments, however, probably due to the methodological pitfalls noted above [86]. With a large plate, there is a danger that slight postoperative tilting of the prosthesis (e.g., due to scar traction or after consolidation of the tympanic membrane plane) could cause the edge of the plate to impinge on the bony annulus and become adherent to it. This would immediately produce a very strong vibration-damping effect [92], and any acoustic advantage of the larger plate (several dB) would be nullified by a much greater hearing loss (see Fig. 2.**26**).

The weight of a prosthesis, which theoretically is a factor in its transmission properties, plays a minor role in clinical and surgical reality. It has long been known that heavier prostheses do not transmit as well as light materials in experimental models, particularly at higher frequencies [85, 86, 93]. This effect is surprisingly small, however [94–97]. Recent measurements show that increasing the weight of a prosthesis by a factor of 8 decreases sound conduction by only 4 dB [68]. When the weight is increased 16 times, the consequent hearing loss is still less than 10 dB [64]. It should also be considered that in an ossicular chain recon-

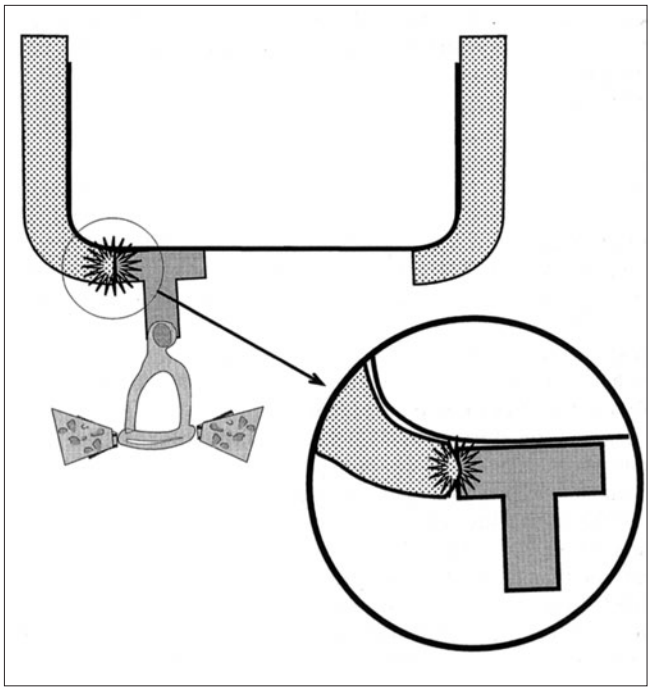

Fig. 2.**26** While a large plate on a prosthesis offers a slight acoustic advantage owing to its larger sound-collecting area, any tilting of the plate could cause it to impinge on the bony wall of the middle ear. This would lead to increased impedance and the massive damping of vibrations, resulting in significant transmission loss.

struction, the weight of the ossicle that has been destroyed by inflammation or surgically removed (about 25 mg for the malleus, 27 mg for the incus, 3 mg for the stapes) is subtracted when it is replaced by the prosthesis. Most modern prostheses are considerably lighter than the ossicles (see Table 2.**4**): the titanium columella manufactured by Kurz Medical (Dusslingen) weighs approximately 4 mg [98], and even the thick gold columella from the same manufacturer weighs 42 mg, which is less than the weight of the biological chain (56 mg).

Table 2.**4** Weights of serval columella-type prostheses (total implant)

Titanium (Kurz Medical)	4 mg
Plastipore (Richards)	5 mg
Dentin (own manufacture)	9 mg
Gold (thin, Dresden type; Kurz Medical)	16 mg
Glass ceramic (Covoc)	36 mg
Hydroxyapatite (Xomed)	40 mg
Gold (solid; Kurz Medical)	42 mg

But if additional parameters of middle ear function are altered, as may occur with extensive middle ear destruction, the weight factor can become significant. At present, however, this speculation has not been experimentally proven or clinically demonstrated. It is equally conceivable that this slight weight effect is of no real consequence next to a dominant transmission loss due to other causes, such as a stiff reconstructed tympanic membrane. For this reason, the weight decrease in the vibrating system caused by intraoperative removal of the malleus handle [59] is without definite experimental or clinical effects [99, 100].

Other material parameters, most notably the elastic modulus and its effect on vibration properties, also play a minor role in total sound transmission through the middle ear. The essential point in this regard is that the stiffness of the prosthesis should be greater than the impedance of the stapes, annular ligament, and inner ear [64]. This relationship is clinically apparent in the deteriorating transmission properties of the cartilage columella, which gradually softens after implantation [70]. Rigid materials, such as the methylmethacrylate cement formerly used in petrous bone experiments, transmit sound vibrations with essentially no losses [101]. Calculations in the finite-element model show that the more rigid titanium has a slightly higher natural vibration than the softer, widely used gold and also provides somewhat better pressure transfer along the principal vibration axis than gold (author's measurements).

However, this theoretical advantage of a stiffer material ranks behind the acoustic importance of a secure, reliable attachment of the prosthesis to the ossicular chain. A secure, wobble-free attachment of the prosthesis to the stapes superstructure, like that achieved with the soft bell of the Dresden gold prosthesis (Kurz Medical, Dusslingen) [102], consistently provides loss-free transmission in the petrous bone experiment [87, 103]. We did further tests at our middle ear laboratory to investigate the acoustic importance of this connection using a titanium prosthesis that had an identical design but could not be locked securely in place because of its rigid bell shape. We found that loss-free transmission was not consistently achieved in this situation. The "wobbly contact" between the titanium bell and stapes superstructure that caused the transmission loss could be eliminated by stabilizing the contact. The bell element was removed, and the tip of the titanium shaft was inserted directly into the center of the articular surface of the stapes capitulum and securely anchored there. The gold and titanium specimens now showed equally good transmission, which, incidentally, reflects the minor importance of the theoretically more favorable weight and stiffness of the titanium. When the original titanium prosthesis was secured by placing a drop of acrylate glue between the loosely mounted bell and the stapes superstructure, the initially poorer transmission increased, matching the values for the clamped gold prosthesis. It should be added, however, that the slight transmission change demonstrated in the petrous bone experiment is of less importance in the surgically treated ear. In many cases, postoperative scar formation will bind the titanium bell securely to the stapes capitulum. This is evidenced by the remarkably good clinical hearing results that are achieved with these prostheses [98]. The results also confirm that a theoretical or experimentally demonstrated acoustic advantage may be insignificant in clinical practice and may be entirely negated by serious flaws such as slippage of the prosthesis. Building on this experimental and clinical experience, we worked with Kurz Medical (Dusslingen) to develop a self-retaining clip prosthesis made of spring titanium that locks in place when slipped over the stapes capitulum [104].

At present, the secure, wobble-free attachment of a prosthesis in the ossicular chain can be achieved only when a suitable prosthetic design, such as a solid implant with a deep drill hole (incus, dentin, ceramics, etc.), is connected to the stapes superstructure [15]. If the crura of the stapes are absent, the prosthesis must be placed on the footplate, where it is retained only by water-adhesion forces. There have been isolated reports of attempts to stabilize this attachment by making a central perforation in the footplate [105]. But as this involves opening the inner ear, it is a potentially hazardous step in patients with pre-existing chronic otitis media, and the concept has not gained wide acceptance.

Secure contact with the tympanic membrane or malleus handle can be achieved only by using a prosthesis of adequate length. The prosthesis should push the reconstructed tympanic membrane slightly outward, much like the center pole of a tent. This ensures that any lateralization of the tympanic membrane plane, which sometimes occurs due to scar contraction of the healing membrane, will not break contact between the tympanic membrane and prosthesis. This "overcorrection" of the tympanic membrane–footplate distance with a long prosthesis shaft also allows for postoperative displacement of the tympanic membrane due to atmospheric pressure changes (see Fig. 2.**27**). Blowing the nose a single time after the operation can cause more than 1 mm lateral displacement of the tympanic membrane, which is no longer held in place by the attached ossicular elements. A prosthesis that "just fits" at operation or is slightly too short is apt to lose contact with the tympanic membrane. Or if it has already bonded to the membrane, it will be pulled off the stapes capitulum or footplate (see Fig. 2.**28**). If the prosthesis has been positioned at an angle for connection to the malleus handle, it may even be completely dislodged. These displacements are a common finding in revisions of acoustically failed tympanoplasties [1].

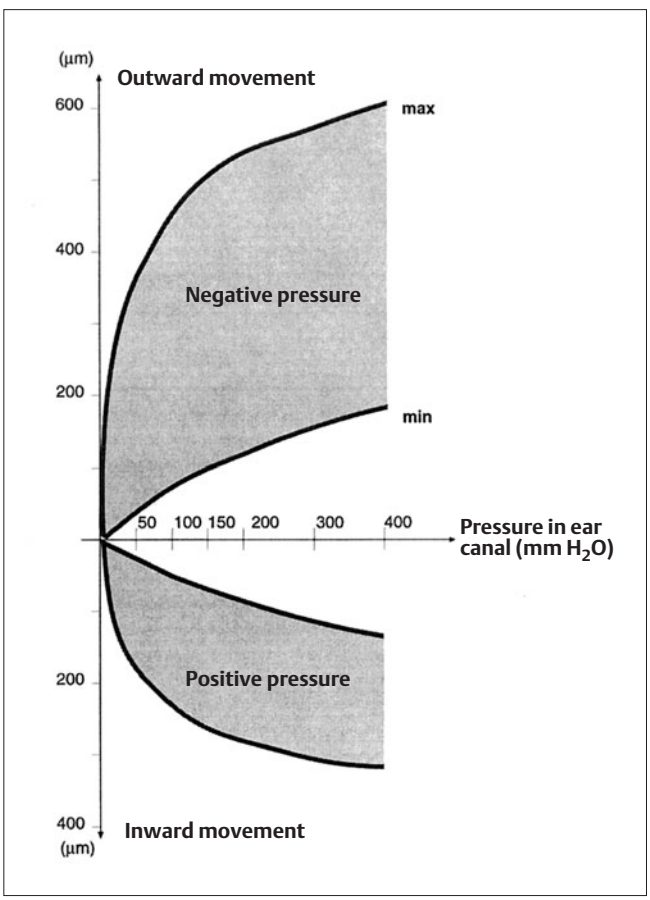

Fig. 2.**27** Displacement of the umbo with an intact ossicular chain due to atmospheric pressure changes in the ear canal. The shaded area covers the intraindividual differences from 25 ears.

This loss of contact with interruption of the chain not only abolishes ossicular transmission and middle ear gain but also leads to shielding of the inner ear windows due to the acoustic shadowing effect of the tympanic membrane, resulting in a complete sound conduction block with a 50 to 60 dB hearing loss. This risk of "middle ear meltdown" in otosurgery shows that, from a clinical standpoint, it is sometimes more prudent to use a secure, stable prosthesis that may not be acoustically perfect and to accept several decibels of hearing loss rather than use a laboratory-bred, frequency-optimized prosthesis that does not function reliably enough in routine surgical practice.

Even if a loosely placed prosthesis does not slip or dislodge in response to inevitable postoperative atmospheric pressure changes, connective tissue can still grow into the resulting gap and damp vibration transmission like a rubber buffer. This effect can also be demonstrated in the petrous bone experiment [83] and in animal models [106]. Deliberately underlaying a small flap of connective tissue between the prosthesis shaft and footplate [59] would presumably cause a similar deterioration of transmission.

The bony bonding of a prosthesis to the footplate, even one made of bioactive hydroxyapatite, would be desirable from an acoustic standpoint but apparently does not occur, at

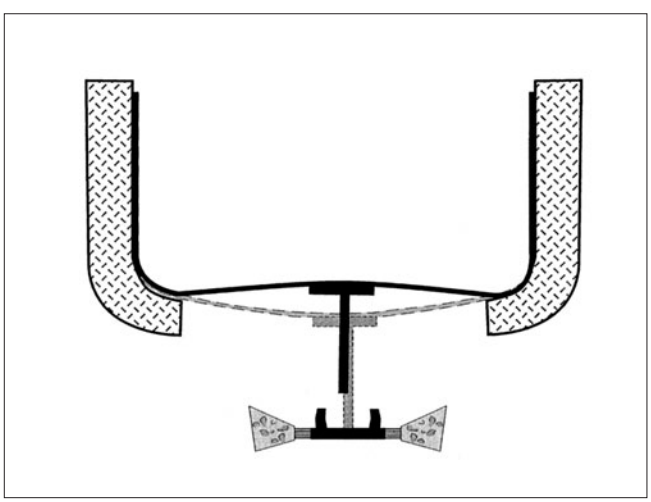

Fig. 2.**28** With a prosthesis that has been "fitted" at operation, lateral displacement of the tympanic membrane due to scar contraction or air pressure changes can pull the implant outward, breaking contact with the footplate.

least in animal experiments [107]. If a solid bond were to form, it would pose a high risk of stapes dislocation during revision surgery, since the annular ligament can only withstand forces up to about 35 g [108]. There would be an even greater danger of fracturing the footplate, which requires much less force but would have the same effect in terms of inner ear survival. At present, using a prosthesis of sufficient length appears to be the only way to attach a columella firmly to the center of the footplate [91, 109, 110] to produce the physiological pistonlike mode of vibration.

But the use of a prosthesis long enough to tent the tympanic membrane compromises an important factor in the transmission properties of the middle ear: the tension of the ossicular suspension. The extra-long prosthesis pushes the footplate inward from its resting position, causing the fibers of the annular ligament to tighten (see Fig. 2.**29**). For maximum sensitivity, however, the suspensory ligaments should be tension-free so that minimal acoustic energy is needed to incite a vibration. Any increase in the tension of the suspensory ligaments leads to stiffening, thus causing a resonance shift toward higher frequencies [83, 90, 111–114]. The resulting transmission loss can reach values as high as 40 dB [110].

So far, it has not been possible to analyze the transmission change caused by the tension from a "tight" prosthesis in the petrous bone experiment, because the causative tension could not be measured, only characterized subjectively as "loose" or "tight" [83, 86]. However, an accurate analysis of the influence of this factor is important not only for classic ossicular reconstructions but also for the future design of implantable hearing aids. This is because the mechanical transducers that transfer vibrational energy to the ossicular chain, either directly or via a coupling rod, must exert some pressure on the ossicle in order to maintain optimum contact [115]. But this deflects the chain from its resting position, and the vibrations are damped by the tension on the ligaments. This not only reduces energy transmission but also compromises the function of the ossicular chain due to a nonfunctioning vibrator. It would be difficult in this case to treat the patient with a conventional air-conduction hearing aid because of the iatrogenic air–bone gap. A deflection of the stapes of only 10 μm, which is roughly the diameter of an erythrocyte and almost impossible to detect visually, is sufficient to damp vibrations by more than 10 dB due to tightening of the annular ligament (see Fig. 2.**29**).

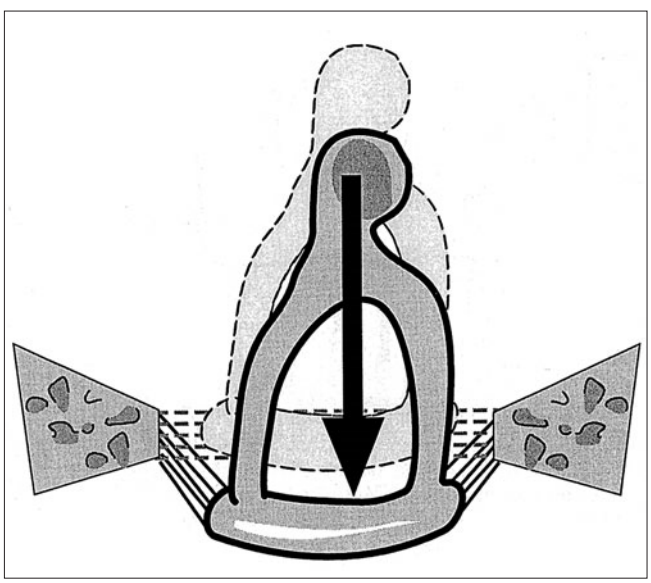

Fig. 2.**29** Displacement of the stapes by just 10 μm from its resting position, as by a long prosthesis, tightens the fibers of the annular ligament and causes approximately 10 dB of vibration damping.

Stapesplasty

In a stapesplasty, tension changes in the suspensory ligaments are of minor importance because the annular ligament is functionally neutral and the most commonly used piston is immersed without tension in the inner ear fluid. Only a small number of petrous bone experiments have dealt with stapes replacement [116], and the acoustic effect has not been measured. This is because there is still no way to accurately simulate the physiological sealing of the inner ear opening that results from its postoperative overgrowth by middle ear mucosa, which prevents the leakage of inner ear fluid. Any experimental sealing of the inner ear would produce an artificial fixation, resulting in impedance changes.

In recent years, however, several theoretical speculations and computations have been published on this subject using finite-element models [68, 117, 118]. A key focus of these studies has been on the acoustic effects of different piston diameters. The data seem to show that a piston of larger diameter (0.6 mm) has slightly better transmission properties (approximately 5 dB) than a thinner piston (0.4 mm) [64]. The sound pressure at the cochlear inlet depends critically on the volume velocity of the piston, i.e., the volume of cochlear fluid that is "displaced" by the vibration of the piston. It is easy to see that a thicker piston displaces more volume than a thin one. However, these considerations ignore the fact that the displaced volume is determined not only by the diameter of the piston but also by its "stroke," i.e., the amplitude of its vibration. Given the large area of the footplate in the normal middle ear, a relatively small stroke is sufficient for the desired sound transmission. The limit of this stroke is defined by the tight annular ligament, which in humans accounts for some 90% of the stiffness of the middle ear [71, 72]. Eliminating the annular ligament by the piston replacement also eliminates this key determinant of middle ear impedance. Now the chain can vibrate without constraint, the amplitudes are increased, and the smaller volume of the piston is offset by its greater stroke. As the piston diameter becomes smaller, the product of piston stroke and volume, and thus the critical volume velocity, remains constant until the maximum amplitude of the vibrating system is reached. After that point, transmission decreases as the piston becomes thinner. Conversely, greatly increasing the size of the piston will not further increase the volume velocity and improve transmission over normal middle ear conduction, because the input impedance of the cochlea remains unchanged. In theory, the volume velocity shows an appreci-

able decline only when the piston diameter is less than 0.4 mm [71].

These considerations are confirmed by clinical experience showing that a 0.3-mm piston has poorer transmission properties than a 0.4-mm piston [119]. Audiometry showed no differences between piston diameters of 0.4 and 0.6 mm, even in large case numbers [120]. The 0.6-mm piston was slightly superior at 4 kHz, but the difference, at 3 dB, was below the detection limit of an ordinary tone audiometer with its 5-dB increments. Another study of 0.4- to 0.8-mm piston diameters showed better clinical transmission for the thicker piston [121].

The apparent contradiction between calculations and clinical results is resolved by noting that the vibrating, sound-transmitting surface is not just the piston itself but also the connective tissue sheath surrounding it in the stapedotomy hole. For example, when a 0.4-mm piston is placed in a 0.6-mm perforation, the effective vibrating surface will have a diameter greater than 0.4 mm. This mechanism of sound transmission in stapesplasty also explains why different techniques of stapesplasty (wire-connective tissue prosthesis of Schuknecht, cup prostheses, etc.) all provide comparably good postoperative hearing results.

The hearing result is also influenced by stable attachment of the piston clip to the long process of the incus. According to model calculations, too much play at this connection can lead to an undesired increase in ineffectual side-to-side vibrations [117]. Based on the elasticity of the metal clip, the loop always remains slightly loose even when fully tightened. The holding force of this attachment must be greater than the impedance of the inner ear, however, and therefore the loop should be placed as securely as possible. If the loop is still found to be slightly mobile when probed with a needle, it can often be seated more securely by pushing it somewhat further onto the widening, conical incus process. A somewhat more complicated but very stable option is to insert a bone wedge between the loop and incus process. This same technique can be used to secure the titanium clip of a Symphonix FMT (implantable hearing aid) to the long process of the incus in cases where bone cement is unavailable.

The extreme case of a loose wire loop occurs when the long process of the incus undergoes circumferential erosion at its interface with the wire loop. Although this complication has often been attributed to mechanical pressure erosion secondary to decreased blood flow to the bone [122, 123], this is probably not the true cause. The inherent elasticity of the metal (usually gold, platinum, titanium, or steel) always leads to a slight spring-back of the clip when the loop is tightened. This is easily demonstrated by needle manipulation, which will always show some lateral mobility of the tightened wire loop. Also, the usual technique of crimping the wire loop to the incus process with a small forceps always deforms the loop into an oval shape, creating just two opposing points of contact with the incus process, which has a circular cross section. The "tunnel" formed at the upper edge may be filled by inserting the bone wedge mentioned above. Other arguments against a mechanical disruption of blood flow as the cause of the bone erosion are the continued interior blood supply to the incus via the marrow spaces and the marked depth of the constriction that is found when stapesplasties are revised due to audiological problems. Some cases even show a complete separation of the articular process from the base of the long crus of the incus. But if pressure were the cause of the bone destruction, it would be relieved after eroding just a few microns into the cortex. The granulation tissue that occupies the erosion is more consistent with local bone resorption caused by a foreign body reaction. This is also the presumed cause of the rare footplate perforations caused by a TORP columella made of nonbiological material [15]. Enzymatic osteoclastic resorption at the bone-metal interface also explains why the incus process is affected all around its circumference and not just at mechanical pressure points.

Placing an interposition connective-tissue or vein graft below the piston in the stapedotomy, as suggested by some surgeons, cannot improve the transmission of the piston due to the functional principle described above. The added impedance is more likely to reduce sound transfer across a piston of small diameter. At the same time, restricting piston motion in the vestibule would make the system less sensitive to atmospheric pressure changes.

The reconstructed ossicular chain is permanently exposed to these forces. In a stapesplasty, even relatively small, physiologic air pressure changes of ± 400 mm H_2O, as in tympanometry, can displace the piston by up to 0.5 mm in the vestibule [116]. Given the proximity of the piston to the underlying structures of the saccule and utricle [124] (see Fig. 2.**30**), there is a risk of impingement that could jeopardize the inner ear. But if this problem is avoided by making the piston too short, the first nose blow or Valsalva maneuver after the operation could pull the piston out of

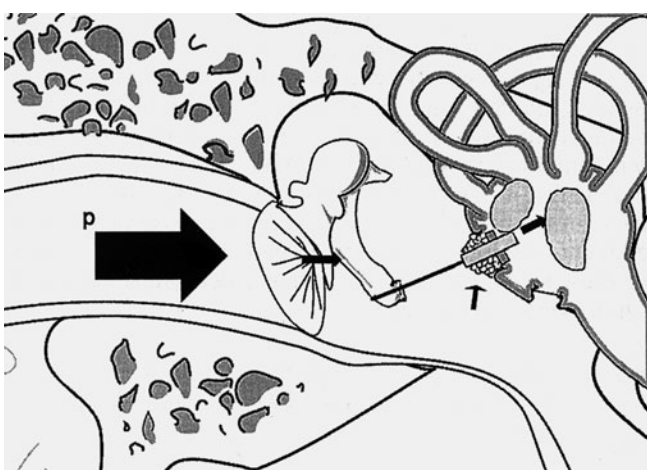

Fig. 2.**30** A rise of pressure in the external ear canal (p), like that caused by diving or flying, produces a tympanic membrane displacement that drives the piston into the vestibule. If the piston were too long, it could perforate the saccule or utricle. With a negative ambient air pressure (or a positive pressure in the tympanic cavity, like that caused by a Valsalva maneuver), a short piston could be pulled out of the stapedotomy. Connective tissue placed to seal off the oval niche (arrow) encircles the piston and suppresses air-pressure-induced displacements.

the stapedotomy, as has been known to occur in an ossicular reconstruction with a columella prosthesis (see also Fig. 2.**28**).

Given the narrow limits for an optimum immersion depth of the piston, it is a good idea to check the depth intraoperatively. After choosing a sufficiently long piston (usually 4.5-mm) and hooking it in place, the surgeon takes a needle and presses gently on the long process of the incus to simulate the inward movement of the piston in response to atmospheric pressure changes. If the patient, who is awake and under local anesthesia, reports that this maneuver does not cause dizziness, this means that the piston is not immersed too deeply. If dizziness is reported, the piston should be shortened slightly. Even if the patient gives no subjective complaints, interaction between the shortened piston and the membranous inner ear can be detected postoperatively by sensitive recording. One-third of 53 patients had ENG signs of nystagmus after piston stapedotomy when the tympanic membrane was abruptly displaced by pressure changes produced in the ear canal with a tympanometer bulb [125, 126]. Ordinarily these movements are checked by friction of the piston surface with connective tissue placed over the oval window niche (see Fig. 2.**30**), and diving or flying is not allowed postoperatively until that tissue has formed a stable scar. This abstinence should be maintained in any case until the tympanomeatal flap has healed.

Fitness for Diving and Flying Sports after Ear Surgery: Biomechanical Issues

Sports that involve potentially severe pressure changes such as diving, flying, and parachute jumping are not necessarily prohibited after otologic surgery. The presumed threat to the inner ear from a prosthesis becomes less of a concern when we take a closer look at the underlying mechanics. Passive opening of the eustachian tube, which may be assisted by a Valsalva maneuver, usually does not allow the pressure differential between the tympanic cavity and the environment, causing displacement of the tympanic membrane-ossicular system, to exceed 400 mm H_2O, although large individual differences can occur [15]. With normal pressure equilibration, the force of the ambient air or water pressure on the tympanic membrane will not exceed the stability of the footplate, and the perforation of a columella into the vestibule is unlikely to occur at these "physiologic" pressures [127]. It is more likely that the tympanic membrane, perhaps weakened by the surgery, will rupture. For this reason, the otologic examination that is routinely done to assess fitness for these sports should first assess the condition and pressure tolerance of the tympanic membrane. For example, the bulb of a Siegle pneumatic otoscope can easily generate pressures in excess of 1000 mm H_2O [128, 129]. If this instrument or a tympanometer elicits no vestibular symptoms (this can be objectively documented with concurrent ENG readings), it may be assumed that there is no threat to the inner ear following a tympanoplasty or stapesplasty. This is because even higher pressures—if they can be tolerated due to pain—will not be transmitted to the inner ear. As the collagen fibers in the tympanic membrane become more tense, the drum increasingly hardens and, at pressures above 400 mm H_2O, behaves like a rigid wall [128]. So even if the pressure rises above 400 mm H_2O, a prosthesis coupled to the tympanic membrane will not undergo significant additional displacement (see Fig. 2.**27**).

The experience of military pilots who continued to fly after stapes surgery and were still exposed to substantial decompression forces confirm these experimental measurements [126]. There appears to be no justification, then, for pilots or divers to give up their occupation or hobby merely because they have an ossicular prosthesis. The clinical examination described above can identify the actual threat that is posed to the inner ear. The greatest danger, however, stems from the limited mechanical stability of the tympanic membrane. For when a scarred, atrophic eardrum ruptures under water, the thermal stimulus from the inrushing cold water can provoke life-threatening disorientation and vomiting.

Models for Simulating the Middle Ear (in Collaboration with M. Bornitz)

Groups of Models

Various groups of middle ear models have been developed over the years. The oldest group consists of electroacoustic circuit models, which were first used by Zwislocki [130]. These models were developed jointly by experts in acoustics and electrical engineering and incorporate the traditional elements of those fields. The middle ear is modeled as an electrical circuit composed of resistors, coils, and capacitors. The models are easy to construct and allow for computational (analytical or numerical) analysis as well as simple experiments. Only modest computer facilities are required [16, 131–136]. A major drawback of circuit models is that complicated analogies are needed to describe the mechanical and acoustic properties of the middle ear in terms of electrical quantities. This makes it more difficult to model structural and material changes in the middle ear. It is also extremely difficult to model the middle ear in three dimensions, and so far this has not been satisfactorily accomplished [137].

The second large group consists of structural mechanical models. They include dynamic continuum (DC) models [138], multibody systems (MBS) [139, 140], and finite-element models (FEM) [52, 140–145]. These models are all virtual mathematical models that are usually created and investigated with the aid of computers. The dynamic behavior of the middle ear is described in terms of mathematical equations. All the models are based on "motion differential equations" (MDE) that may be derived from equilibrium considerations (force and moment equilibrium) or energy considerations that include an elasticity law and kinematic relationships. The methodology is described fully in textbooks on structural dynamics (e.g., [146]).

Certain limitations apply to some models in this group. In the MBS models, it is assumed that the individual bodies

are rigid over the range of frequencies investigated. For the ossicles of the middle ear, this assumption is valid up to approximately 3500 Hz [147]. The models are made up of separate rigid bodies. The bodies have inertial properties and are interconnected by springs and dampers. Wittenburg [148] and others may be consulted for theoretical explanations on rigid multibody systems. In DC models, the entire structure is treated as an elastic, deformable body comprising a closed system. This approach becomes very difficult as the geometry of the system becomes more complex. Rabbitt and Holmes [138] designed a DC model for the tympanic membrane that allows a closed analytical solution only for a simplified membrane geometry and otherwise must be treated numerically. DC models are particularly difficult to handle with regard to model variations.

One way out of this dilemma is to use the finite element method (FEM), which has become increasingly important with advances in computer technology and has now become the most widely used technique for model simulations. Even complex models like the middle ear can be handled with the computing capacity of an ordinary PC. The FEM involves a process of "spatial discretization," in which the complex structure to be modeled is broken down into a finite number of small elements having a simple structure. These may consist of point elements (measuring point, spring), 1-dimensional elements (bar, rod, cord), 2-dimensional elements (plate, shell, membrane, disk), or 3-dimensional elements (block, tetrahedron, pyramid). Appropriate material properties are assigned to each of the elements. With finite-element discretization, the approach to solving the system is greatly simplified. It should be added that it is not important to reproduce fine structural details in this method (e.g., every dimple in the surface of the ossicles) but to describe the physical properties that are to be investigated. In the case of the middle ear, this would be the dynamic behavior of the middle ear over the audible range of frequencies. This means that certain abstractions are involved in the modeling process, and all geometric information is not accurately reproduced. Certain geometric information is pivotal, however, and should be specified as accurately as possible, such as the points of attachment of the ligaments to the ossicles and the position of the ligaments and ossicles in relation to one another.

The advantage of FE models is that structures of arbitrary complexity can be modeled as systems of simple MDEs. The model parameters represent definite physical quantities, and all important geometric information goes directly into the model, so that variations in the object (shape, material properties, distance between individual parts) can be reproduced relatively easily and directly (i.e., without mathematical conversion) in the model. No analogies are necessary, as in electroacoustic circuit models, in order to compare measurable quantities in the object with calculated quantities in the model. Owing to their structure, FE models can be broken down into virtually any number of sub-models, which is particularly useful for making fine adjustments in the model as a whole.

Besides the groups of models described above, there has been renewed interest lately in functional mechanical models, which are used chiefly for demonstration purposes [112, 149–152]. The model of Taschek et al. [152] is also used as a prelude to taking complex three-dimensional measurements and in the prospective analysis of middle ear implants. The model designed by Meister et al. is already being used to measure the transmission characteristics of middle ear prostheses [84, 85]. The advantage of these models is the good reproducibility of the measurements compared with experiments in petrous bone specimens. However, they are less flexible than electroacoustic and structural mechanical models regarding the variation of geometric and material parameters and the simulation of different types of middle ear reconstruction.

Creating Finite Element Models (FEMs) for the Middle Ear

In simplified terms, the creation of a FE model consists of three steps. First, the mechanical structure of the model is defined. This determines the degree of abstraction of the model. The mechanical structure is defined based on the practical purpose of the model (its dynamic behavior), the range of application (100–1000 Hz), and accuracy requirements (limits of error). This step defines how the individual structural components are to be described mechanically, i.e., as a simple beam, plate, or shell or more generally as an elastic 3-D body. It is not feasible to select elastic 3-D volume elements for all the components, as this would lead to a large, numerically unmanageable system of equations or to erroneous results due to the omission of certain physical effects. For example, if it is assumed that the ossicles undergo non-negligible elastic deformations in the investigated range of frequencies (e.g., due to natural frequencies in that range), then the ossicles will be broken down into elastic 3-D elements. A simpler approach is to characterize the ossicles by the inertial properties that can be described with a single point element (at the center of gravity) for each ossicle. Between the center of gravity and the points of connection to other structures (ossicles, ligaments), rigid connections are defined in the form of a simple scaffold. In the case of the tympanic membrane, it should be noted that its thickness is very small in relation to its other dimensions, and therefore the membrane is described as a shell structure.

In the second step, a geometric vector model is created containing all the information that is necessary according to the way the structure has been defined. The initial data for the geometric model can be obtained by measuring the individual components of the middle ear, including microscopic measurements [147, 153], or by using modern imaging techniques such as microcomputed tomography [145, 154]. The latter technique can supply very useful information on the relative positions of the individual ligament components. Only geometric information that is essential for the model is used. For this reason and because of the abstraction, the resulting FE models are often difficult to appreciate visually, and so the underlying geometric models are often presented for comparison (Fig. 2.**31**) [155].

In the third and final step, the geometric model is subdivided into small areas, and the elements defined in step 1

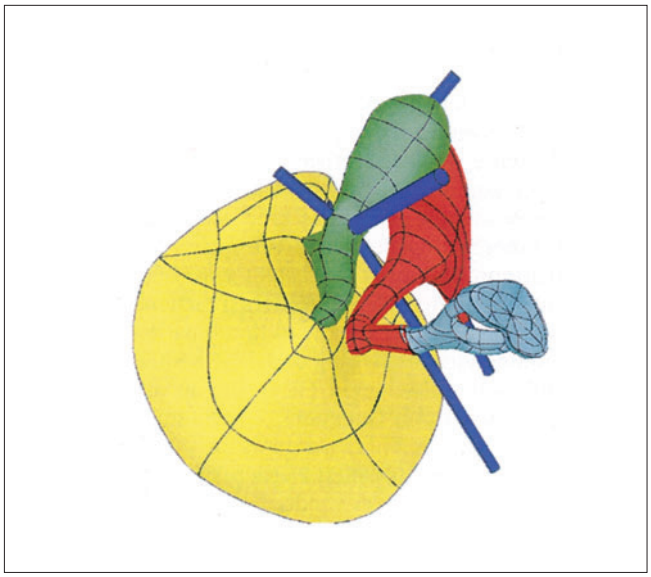

Fig. 2.**31** Geometric vector model of the middle ear with the tympanic membrane (yellow), malleus (green), incus (red), stapes (light blue), muscles and ligaments (blue).

are assigned to these areas (Fig. 2.**32**). This step also defines the material parameters of the model (inertial, elastic, and damping parameters) and also the boundary conditions such as the mode of attachment of the tympanic membrane, ligaments, etc. The result is the "finite element model." Defining the material parameters is the key point in the modeling process, as the behavior of the model is essentially determined by these parameters. Correct material parameters provide the foundation for mathematical simulations with the model if the results are to reflect actual, measurable phenomena.

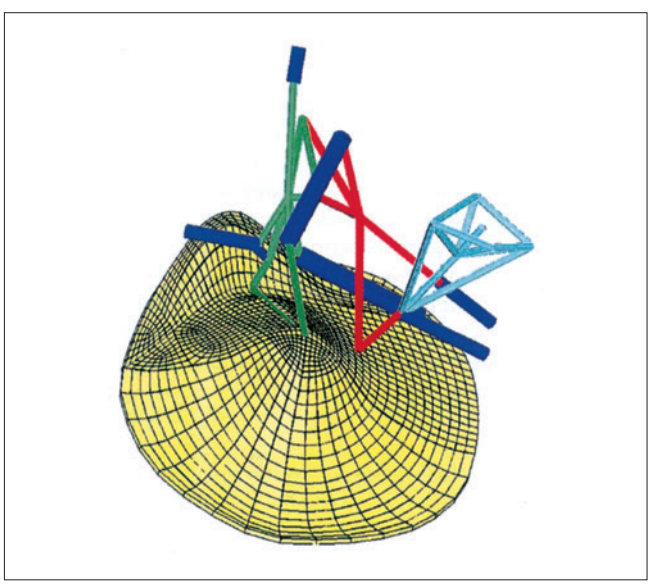

Fig. 2.**32** Finite element model of the middle ear. The individual components are represented according to their mechanical description. Tympanic membrane = elastic shell elements, ossicles = rigid scaffold, ligaments and muscles = elastic beams.

All FE models in current use have a similar mechanical structure, but all are not represented in the same way. The tympanic membrane is represented as a shell structure in which the fiber architecture is approximated by variations of stiffness in the radial and tangential directions. The ossicles are usually represented as rigid bodies, and so they are satisfactorily described by a point element with its inertial properties at the center of gravity. Connections with other elements (ligaments, ossicles, tympanic membrane) are rigid and without mass and are represented differently in different models. In some models the ossicles are crudely represented by discrete elastic volume elements [52, 156]. The ligaments and muscles are usually approximated as simple elastic beams. An exception is the annular ligament. This structure may be represented in the form of a stiffness matrix (with six degrees of freedom) at the center of the footplate, it may be discretized as elastic elements surrounding the footplate and conforming to the geometry of the annular ligament [144], or it may be represented as a combination of both, i.e., its volume is discretized and also reduced to a matrix at the center of the footplate [147]. The structures bordering the middle ear (inner ear, air volume in the ear canal and tympanic cavity) are handled in a variety of ways. In some models they are ignored [141, 147]. Other models employ a single-mass-vibrator to approximate the air in the ear canal and the inner ear fluid [87, 157]. In the models of Prendergast et al. [144] and Wada et al. [156], fluid elements are used to represent the air volume in the ear canal. In the latter model, the air volume in the tympanic cavity is represented by discretized fluid elements.

Important comparative quantities for the models are the eigen values and eigen vectors. As characteristic quantities, they depend only on the model itself. The eigen values of the model correspond to natural frequencies (when damping is ignored) and the eigen vectors to the vibration patterns at the natural frequencies, which can be determined experimentally in petrous bone specimens. Figures 2.**33** and 2.**34** show the vibration patterns calculated for the tympanic membrane at 1550 and 4200 Hz. At 1550 Hz, the membrane displays two areas of peak vibrational amplitude, with both areas moving exactly opposite to each other. This pattern agrees well with the actual vibration of the tympanic membrane (cf. Figs. 2.**6** and 2.**7**).

Other quantities that can be calculated in the model are displacements in response to static loads, e.g., pressure on the tympanic membrane or static forces at other points in the middle ear. Figure 2.**35** shows the displacement of the tympanic membrane in response to a static pressure from the meatal side [142]. Eiber and Kauf [140] compared these quantities with the results of petrous bone experiments [158], using them to verify the model in the static range.

To characterize dynamic behavior, the transfer functions of the system must be used in addition to natural vibration quantities. They are used to calculate the dynamic response of the structure (vibrations of various structural points, dynamic reaction forces) to certain dynamic excitations (force, pressure, distance; pulsed, sinus, multisinus, noise). The transfer functions can be theoretically derived

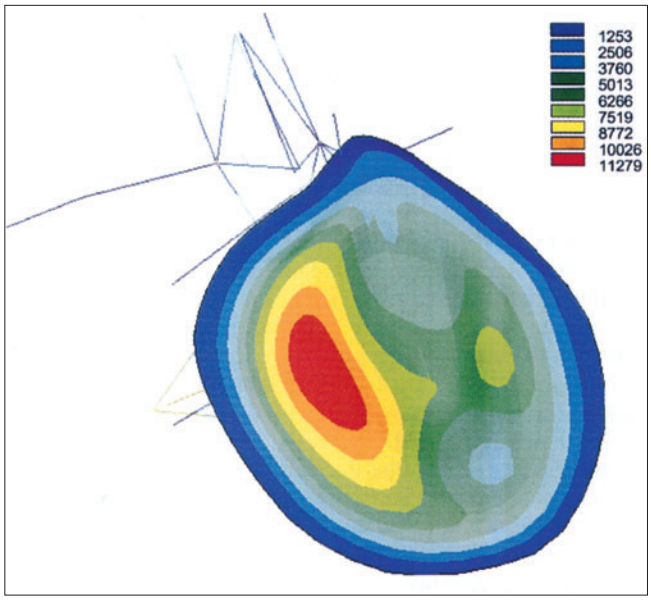

Fig. 2.**33** Result of a calculation in the FE model: vibration of the tympanic membrane at 1550 Hz. The tympanic membrane is viewed from the ear canal. Areas of peak vibrational amplitudes are shown in red.

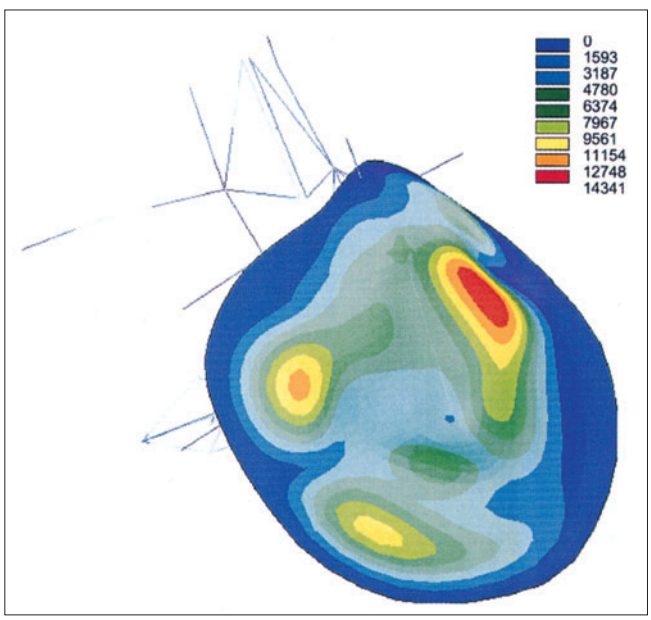

Fig. 2.**34** Result of a calculation in the FE model: vibration of the tympanic membrane at 4200 Hz. The tympanic membrane is viewed from the ear canal. Areas of peak vibrational amplitudes are shown in red.

for harmonic excitation, since the response is also harmonic. Theoretical studies have shown that for undamped systems, the measured resonance frequencies are equal to the natural frequencies. In damped systems, slight deviations arise that become significant only when damping is very strong.

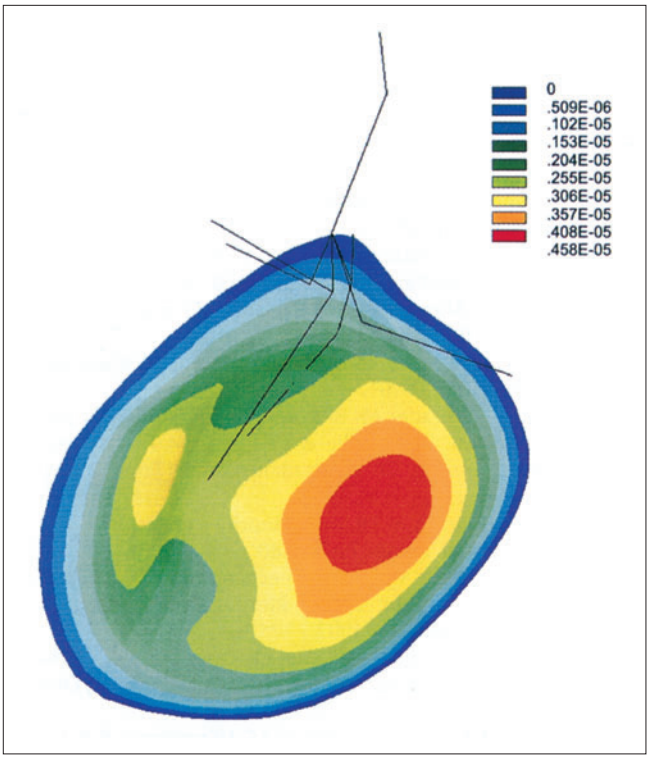

Fig. 2.**35** Result of a calculation in the FE model: deformation of the tympanic membrane (in mm) in response to a static pressure of 0.02 Pa. The tympanic membrane is viewed from the middle ear cavity. The area of maximum deformation is shown in red.

Application of Finite Element Models

The quality of these models depends critically on the structure by which the principal properties of the model are defined and on the values for the system parameters. In this way the model can be fitted to a concrete object, and realistic computer simulations can be obtained. The quality of FE models is determined by geometric parameters and boundary conditions and particularly by the material parameters. For years, FEM studies were done mainly to refine and perfect the models by comparing the calculated quantities described above with corresponding measured quantities [159]. Since then, many models have reached a quality that allows various simulations to be performed. They can supply at least qualitative information. Quantitative results are extremely difficult to obtain, because the substantial interindividual differences in middle ear structures [15] cannot be simulated.

In one study, model simulations were done to analyze the response of the middle ear to various acoustic events [157]. The study focused on the transient response of the middle ear (i.e., vibration buildup and decay in the ossicular chain) to sinus excitation and various impulses (pistol and canon shots). Footplate vibrations were analyzed as a criterion for assessing the injurious effect of the noise on the inner ear, although the precise effects on the inner ear are unknown. The sound impulses ranged as high as 170 dB, with the assumption of a linear middle ear response. This type of study can provide only qualitative information, however,

and no quantitative data. The model simulation showed that besides the amplitude and duration of a sound impulse, the waveform of the sound pressure has an important bearing on the response of the ossicular chain and thus on potential injury to the inner ear.

The great majority of model simulations deal with the use of prostheses in the middle ear [87, 103, 117, 139, 144, 160, 161]. In some models, prostheses were placed between the stapes capitulum and the tympanic membrane [87, 103, 144] (see Fig. 2.**36**). The simulations showed how the transmission properties of the reconstructed middle ear change when different parts of the ossicular chain are removed (long process of the incus, entire incus, malleus handle with ligament). Some of these studies vary considerably in their qualitative results. In one study the vibrational amplitude of the stapes footplate decreases when a prosthesis is inserted [87]. In another simulation [144] the vibrational amplitude of the stapes footplate remains almost constant while that of the umbo is decreased, so that the amplitudes of both points are almost equal after the insertion of a prosthesis. The transmission frequency responses also show marked qualitative differences, even though equal excitations were used. One result of the model calculations is consistent with practical experience: there is little if any difference between gold and titanium prostheses that have the same mode of attachment to middle ear structures [162].

Other model simulations deal with variations in the attachment of a stapes piston to the incus [117] and with the behavior an active piezoelectric prosthesis placed on the stapes capitulum [139]. The latter studies are qualitative studies of prosthesis parameters that do not supply information on practical use.

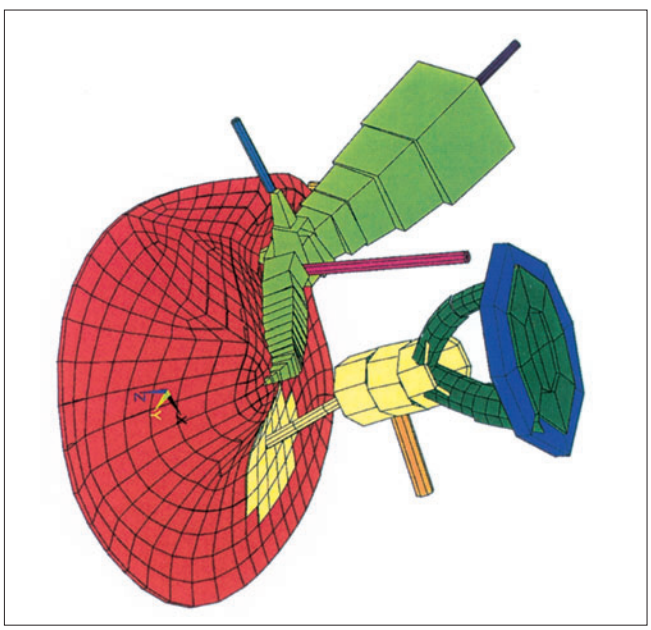

Fig. 2.**36** Finite element model consisting of the tympanic membrane, malleus, stapes and ligaments, with a prosthesis interposed between the stapes capitulum and tympanic membrane.

Besides studies on the transmission properties of the middle ear after reconstruction with various prostheses, there are also FE simulations for assessing the long-term stability of implanted prostheses. Prendergast et al. [163] ran computer simulations of tympanic membranes with myringotomy tubes to investigate their effect on extrusion rates and the development of tympanosclerosis. From the different vibrational amplitudes associated with different myringotomy tubes, the authors found that the extrusion rate with light tubes (HDPE) was higher than that with heavy tubes (titanium). The calculated mechanical tensions in the tympanic membrane due to the presence of the tubes were very small, indicating no significant effect on the development of tympanosclerosis.

In summary, it may be said that model simulations are constantly evolving from the verification stage to application-specific computations. Models are becoming increasingly important for middle ear surgery. It is still difficult, however, to compare the simulation results in different models with one another and with experimental results. This is due partly to differences in model structures (e. g., with or without allowance for air volume) and partly to differences between calculated quantities and measured quantities (e. g., different modes of excitation in calculations and measurements). As the models continue to be refined and more accurate parametric data are obtained, it should be possible to solve these problems in the near future. Another problem is the influence of interindividual differences and how they can be represented in the models. This point will be critical if the models are to be used in analyzing and optimizing specific middle ear reconstructions. Microcomputed tomography provides an initial step toward solving this problem, with its ability to furnish complete and highly detailed geometric data for a single, individual petrous bone [154].

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3 Biomaterials in Reconstructive Middle Ear Surgery

P. Dost and K. Jahnke

Abstract

Biomaterials in Reconstructive Middle Ear Surgery. Biomaterials are a necessity in modern otosurgery, but none is usefull for all applications. Surface properties, particularly structural characteristics, critically influence the quality of the implant-biological interface. Micropores promote fixation whereas polished surfaces tend to resist it. Prior to the introduction of any new biomaterials, safety precautions must be adhered to rigorously. We showed that osteoblast-like cells grew from human stapedes. This model detected cytotoxicity but it did not show difference in growth when several biomaterials were compared. Hence, animal studies are necessary to evaluate the complicated interactions of mucosa, bone, ventilation and possibly infection with respect to the placement of middle ear prostheses. Nevertheless, animal study results must be interpreted cautiously. In the future therefore, it is clear that rigorously controlled pilot introduction in humans will be required after the biomaterial has passed detailed in-vitro and in-vivo experimental test examinations. The use of plastics often leads to foreign body reaction in the middle ear. Teflon used in stapes prostheses as the only exception, has proved valuable as a result of its low surface energy, and consequently, the avoidance of prosthetic epithelialization. Most ceramics are biocompatible, but glasses are degradable and therefore of no use in potentially infected ears. Titanium and gold are playing an increasingly important role. However, it should be noted that gold may cause damage to the inner ear, when used as stapes prosthesis. The use of ionomeric cement resulted in fatal complications, when it came in contact with cerebrospinal fluid and consequently, the use of this material has been completely abandoned.

Introduction

Since Wullstein [1, 2] and Zöllner [3, 4] laid the foundation for reconstructive middle ear surgery in 1952, there has been a desire for safe and effective biomaterials and implants. It is not unusual for inflammatory ear diseases to destroy the patient's own ossicles or make them appear unsuitable for reconstruction due to adherent cholesteatoma matrix. In 1953, Wullstein was the first surgeon to use plastic for ossicular reconstruction [1]. Interposition grafts of autologous cortical bone [5] seldom remained viable and tended to fuse with surrounding middle ear structures [6, 7]. For decades, banked homograft ossicles were the gold standard for ossicular chain reconstruction. They have been used less frequently in recent years, however, due to the uncertain potential for infectious disease transmission. One reason is that the human immunodeficiency virus (HIV), even when stored in sterilizing solutions, has been detected by the polymerase chain reaction in a variety of human tissues [8]. The mode of transmission of Creutzfeldt-Jacob disease is not yet fully understood. Formalin and alcohol do not kill the transmitting agent. Infections from homografts harvested near the brain (dura, cornea, etc.) have been documented [9] but to our knowledge never for the ossicles. Experience with HIV and Creutzfeldt-Jacob disease has also taught us that the new occurrence of previously unknown, transmissible diseases is an ever-present possibility. As a result, the use of homografts is always associated with an extremely small but finite risk of disease transmission. We continue to use autogenous ossicles, e.g., the head of malleus or the incus in proper cases, as well as homograft ossicles gained from the organ donor program of our university hospital for very selected cases.

Requirements of Biomaterials for the Middle Ear

For a variety of reasons, there has been growing interest in synthetic materials for reconstructive middle ear surgery. These materials are free of infection risks, and many are available in assorted prefabricated shapes and sizes that can be quickly tailored to individual requirements during the operation. Synthetic materials that are proven to be tissue-compatible may be classified as biomaterials. It should be noted, however, that a material that has proven safe in a soft-tissue bed (e.g., muscle, subcutaneous tissue) or hard-tissue bed (e.g., tubular bone) is not necessarily suitable for use in the middle ear. The aerated tympanic cavity, with its bony wall, delicate epithelial lining, and its vulnerability to ventilation problems that can affect its communication with a potentially infected environment, is a particularly challenging region for implant use. The implants used in middle ear surgery must meet a variety of requirements within a very confined space. For example, while good surface wettability (high surface energy) promotes the desired epithelialization of an ossicular prosthesis, low wettability is desirable for a ventilation tube in order to maintain patency and prevent crusting. Materials for reconstructing the ossicular chain must have good sound transmission properties, should have the lightest possible weight, should be able to withstand infection without damage, and should not induce new bone formation. By contrast, new bone formation is desirable in a material that is used to obliterate a mastoidectomy cavity, and there is no problem if the material is broken down and replaced by endogenous bone. Also, the implant material should not interfere with subsequent imaging procedures.

Table 3.**1** Requirements of biomaterials used for middle ear reconstruction (according to Jahnke et al. [10])

Biocompatibility
High surface energy (exceptions: stapes pistons and ventilation tubes)
High resistance to degradation and infection
High mechanical stiffness
Low weight
No bone deposition (exceptions: mastoid obliteration, canal wall reconstruction, implant fixation to the stapes footplate)
Function-appropriate design
Easy to tailor and position different implant shapes and sizes intraoperatively
No imaging artifacts

Many different biomaterials have been used in middle ear surgery during the past decades. Many of these materials are of only historical interest today, while others have been well tested and established. No material is suitable for all indications in middle ear surgery. Some implants have been used clinically without adequate prior testing. For example, prostheses were marketed before the materials had been tested in laboratory animals, or in some cases animal studies were done only years after the prostheses had been introduced clinically. For new implants, we must require that clinical trials be preceded by animal experiments in an analogous implant bed [11], and cell culture studies should be performed using cells from the proposed implant bed [12, 13]. Below we shall briefly describe the properties of different biomaterials introduced into middle ear surgery, relate experience with the in vivo and in vitro testing of the materials, and review their clinical applications.

Metals

A number of metals have been successfully used in middle ear surgery. Gold and titanium have found wide application in recent years. All metallic prostheses undergo measurable deflection when placed in the strong magnetic field of a modern MR imager [14], but this appears to pose no danger to the inner ear [15].

Steel

Schuknecht and Oleksiuk [16] used stainless steel wire implants for stapedioplasty in 136 patients. In 86% of the patients, an air-bone gap of less than 30 dB was achieved at speech frequencies an average of 3 months postoperatively.

Hayden [17] abandoned the use of polyethylene implants due to their high rate of early extrusion. Instead, he used a steel-wire-reinforced polyethylene implant that was separated from the oval niche by a vein graft. This implant did not extrude in a comparably short period of time. Plester [18] advocated the use of steel wire for middle ear reconstruction and also suggested the use of cartilage or bone in the plane of the tympanic membrane for cases with an absent malleus. Jansen [19] armed banked homograft septal cartilage with steel wire to fabricate a T-shaped prosthesis. He reported no immune-related problems with this device in 219 patients who were followed for 3 years. Palva et al. [20] introduced a 2- or 3-legged stainless steel implant. They reported an 8% extrusion rate in 155 surgical patients who were followed for at least 3 months. In patients found to have an approximately normal middle ear mucosa (n = 44), useful hearing could be achieved in 75%. In patients with a poor mucosal status (n = 111), this level of hearing was achieved in only 45%. Later, the same group of authors [21] reported on long-term results at 1 to 7 years postoperatively and compared the results with ossicular autografts and homografts. The ossicles fared significantly better than the partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) in terms of hearing results. Also, extrusion did not occur with the ossicles, which remained covered by tympanic membrane epithelium even when adhesive processes were present. Robinson [22] used his stainless steel stapes prosthesis in 46 patients with otosclerosis. Postoperatively, he achieved an air-bone gap of less than 10 dB in 97% of the patients, and in 80% the air-bone gap was completely closed. These results were slightly better than those in opposite ears subsequently treated with a Teflon implant of the same design. The way the study was set up, however, the predetermined sequence of materials created a selection effect. Later the same author [23] described the long-term results in 3277 patients who were treated with the steel prosthesis for otosclerosis over a 15-year period. In 95.5% of the patients, the postoperative air-bone gap was less than 10 dB, and in 74.0% the air-bone gap was closed. Over the entire follow-up period, 93.0% of the patients had an air-bone gap less than 10 dB. Only 1.6% later developed new conductive hearing loss, and incus necrosis was the cause in only 5 cases. More than 10 dB of additional sensorineural hearing loss subsequently developed in 1.2% of the patients. Reichel [24] introduced a self-retaining steel wire prosthesis for ossicular chain defects. A tympanic membrane defect was found in only 1 of 8 patients 18 months after implantation. Himi et al. [25] examined 23 human petrous bones histologically an average of 19 years after middle ear surgery had been performed. Wire implants had been used in 8 patients, and the authors saw no signs of incus erosion or foreign body reactions.

Tantalum

Between 1956 and 1959, Schuknecht and Oleksiuk [16] also used tantalum wire implants in 30 otosclerosis patients. From 3 to 6 months after implantation, the wires in the tympanic cavity were covered by a thin layer of mucosa. Harrison et al. [26] used a tantalum wire to bridge a defect in the long process of the incus.

Stainless steel and tantalum wire implants are economical, e.g., the famous Schuknecht steel connective tissue implant for stapes surgery. They must be individually tailored during the operation, but this is advantageous for individual solutions in uncommon situations (malformations, malleo-platinopexy, malleo-vestibulopexy).

Gold

Gold is an "oligodynamic" material, meaning that it inhibits bacterial growth. Heumann et al. [27] described in vitro experiments with various implant materials in media incubated with Pneumococcus mucosae and Haemophilus influenzae. They found that bacterial counts around gold and gold-plated materials were significantly reduced compared with Teflon and plain controls. Our own in vitro experiments with human osteoblast-like cells from the stapes also confirmed the good biocompatibility of this metal, which was comparable to that of aluminum oxide ceramic [13] (Fig. 3. **1**).

As early as 1963, Schubert introduced a gold stapes prosthesis and described the theoretical advantages of gold over other materials [28]. He stated that the material was 99.999% pure, and he improved the design of the implants over the course of many experiments [29]. It is unknown

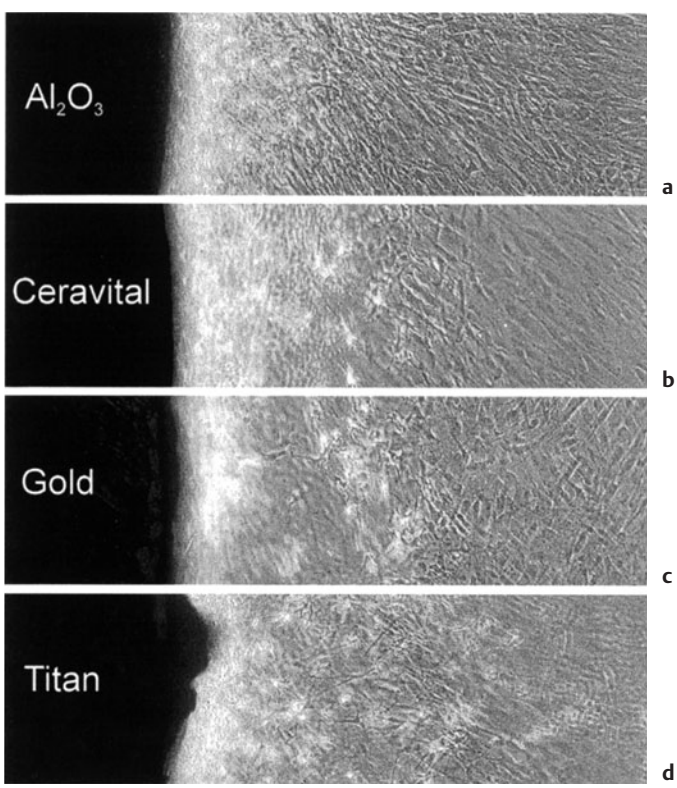

Fig. 3.**1** Human osteoblast-like stapes cells in proximity to aluminum oxide ceramic, Ceravital, gold and titanium 33 days after implantation. There is no evidence of premature cell death.

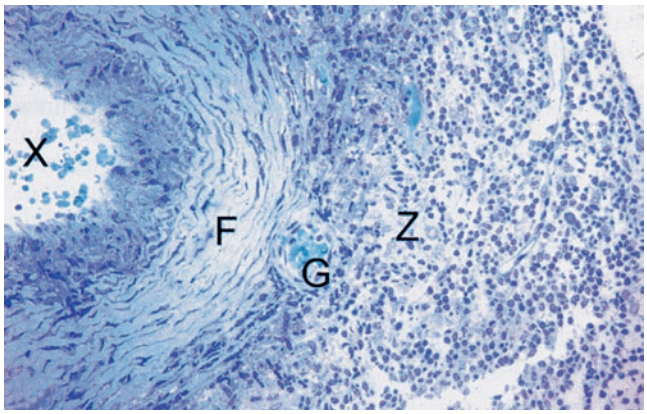

Fig. 3.**2** Light microscopic appearance of a tissue mantle on a gold stapes prosthesis that had to be removed due to progressive sensorineural hearing loss. X = site of removed gold prosthesis, F = fibrous tissue layer, G = blood vessel, Z = very cellular granulation tissue.

why these implants were no longer used in later years. Gold pistons have been again available since the late 1980s, introduced by Steinbach and Pusalkar, and they have been used at many German centers owing to their favorable shape and ease of handling. Tange et al. [30] used a pure gold piston in 62 patients and saw no instances of sensorineural hearing loss or vertigo. The average preoperative air-bone gap of 25 dB was reduced to 9 (3–25) dB postoperatively. In contrast to wire-connective tissue prostheses and platinum band-Teflon prostheses, Schimanski [31] found no signs of incus erosion with 121 gold stapes prostheses. Jahnke et al. [32] managed four cases of progressive sensorineural hearing loss after gold piston implantation in stapedioplasties by revising and removing the material (Fig. 3.**2**).

Steinbach et al. [33] introduced gold implants into ossicular chain reconstruction. Pusalkar and Steinbach [34] reported on 102 patients who had been treated with gold PORPs or TORPs and were followed for at least 3 years. The implants were either placed in contact with the malleus handle or covered by a thin cartilage plate if the handle was absent. Two extrusions were reported in this series. Gjuric and Schagerl [35] reexamined 59 patients at least 1 year after they had undergone tympanoplasty and reconstruction with a gold PORP or TORP. Hearing in these patients improved from an average conductive hearing loss of 30 dB at 500–3000 Hz to a loss of 21 dB. However, 19% of the implants had extruded after a period of 7–21 months. Maassen and Zenner [36] used a Plester-type gold-titanium prosthesis (Fig. 3.**8**) to reconstruct an incus defect as part of a type II tympanoplasty. At 3–6 months postoperatively, they found that the air-bone gap had been reduced to less than 10 dB in 7 of 11 patients (64%).

Starting in the mid-1980s, Steinbach [37] inserted fine, solid gold wires 3.5 or 4 cm long (tube conductor) into the eustachian tube to improve the aeration of the middle ear. Of 117 patients who received this implant, 30 were available for follow-up and showed no clinical evidence of foreign body reactions. Middle ear aeration was satisfactory in more than two-thirds of the patients, and an average

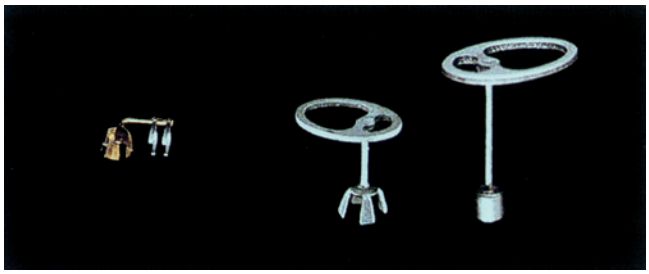

Fig. 3.**3** Plester-type gold-titanium angle prosthesis for bridging a short defect in the long process of the incus. PORP and TORP of titanium (Heinz Kurz Ltd., Tübinger Strasse 3, 72144 Dusslingen).

hearing gain of 10 dB could be achieved. To improve middle ear aeration via the eustachian tube, Jahnke and Lieberum [38] used the same type of gold wire in 31 patients with absent or impaired middle ear ventilation. Before the surgery, 72% of patients could not successfully perform a Valsalva maneuver. After the surgery (1–50 months, median of 13.9 months), 64% of patients could ventilate the middle ear via the eustachian tube. Gold ventilation tubes, which were introduced by Plester in 1978, appear to be less frequently involved in otorrhea due to pseudomonas infection than silicone tubes [39]. They are still the favourite type of ventilation tube in many European centers for ear surgery.

Gold has gained an established place in otosurgery as a material for ventilation tubes and tube conductors. Meanwhile, many results have been recorded on the improvement of middle ear aeration in patients with eustachian tube dysfunction after the implantation of gold tube conductors. Gold should be viewed with caution as an implant for stapes surgery. The cases of progressive sensorineural hearing loss documented at our center appear to have been caused by material intolerance.

Platinum

Platinum has been widely used as the bandlike part of a platinum-Teflon stapes prosthesis that fits around the incus. It is easy to shape and causes minimal damage to the incus mucosa. Plester et al. [57] started to use this type of prosthesis routinely in 1980. Platinum is classified as a biocompatible material. Schimanski [31] used 541 platinum-Teflon prostheses for the treatment of otosclerosis. Four of the cases (0.7%) required revision due to erosion or necrosis of the incus crus. When the same author used the Schuknecht-type wire-connective tissue prosthesis in 201 patients, another 4 cases (2%) required treatment for the same complication. Incus destruction was not observed with gold stapes prostheses (n = 121).

Titanium

Based on the pioneering work of Brånemark et al. [40] and Tjellström et al. [41, 42], titanium implants have gained an established place in reconstructive surgery of the head and neck. Inflammatory reactions generally did not occur, even

when the titanium screw heads were not covered by skin or mucosa. Fixation to the surrounding bone was usually more solid than the surrounding bone itself, with extraction tests culminating in bone fracture away from the implant-bone interface [40]. The addition of titanium to glass ceramic appeared to slow its rate of degradation in an animal model [43]. According to McComb [44], an adherent oxide layer forms on the surface of pure titanium and functions like a ceramic. In the body it is coated by glycoproteins, which are receptive to the ingrowth of collagen fibers, cellular processes from connective tissue cells, and osteogenic cells at sites of bony contact. When titanium implants were protected from loads for 4 months, they bonded to the surrounding bone with no intervening layer of connective tissue. Kasano and Morimitsu [45] implanted a titanium-nickel implant in 24 middle ears of 12 cats. In each case the implant was looped around the long process of the incus. One year later, significant implant displacement was noted in only one ear. Bone resorption was observed around the implant. Similar bone resorption was noted in three sham-operated animals in which some mucosa had been removed from the incus process without inserting an implant. No histologic evidence of a foreign body reaction was found. The authors concluded that neither the metals nor the strength of the loop around the incus process was responsible for the bone resorption, which was actually caused by accidental mucosal injury during the implantation. Schwager and Geyer [46] investigated titanium pins used as TORPs in the rabbit middle ear. The implants were examined histologically after periods of 28 to 504 days. Dilated vessels and granulation tissue were still present after 28 days, but the implants were already covered by mucosa. No signs of inflammation or foreign body reactions were evident after 84 days. New bone had formed along the implants by 168 days, and by 336 days a bony attachment had formed between the implant and the middle ear wall. Several culture studies of human stapes cells showed that osteoblast-like cells proliferated near titanium (Fig. 3.**11d**) as well as near other biomaterials, though not at a measurably faster rate [13].

Tjellström et al. introduced titanium implants for the fixation of bone-anchored hearing aids and documented excellent acoustic transmission properties [41] and good long-term success [42]. McComb [44] implanted 80 titanium screws in 22 patients for the attachment of facial prostheses and hearing aids. Only two of the screws were not fully integrated into the bone.

Plester was the first to introduce titanium implants—combined with gold—for ossicular chain reconstruction (Fig. 3.**3**). Stupp et al. [47] were the first to use titanium PORP and TORP implants in humans. They first reported on 33 patients, who showed no signs of extrusion or tympanic membrane defects. A planned second operation was performed in three of these patients, and in all cases the titanium implant was firmly adherent to the plane of the tympanic membrane. No mucosa was found on the pin of the implant. The same group [48] later reported the results of 661 tympanoplasties (average 11.6 months), 45.2% of which were done as a two-stage procedure to optimize conditions for hearing gain. One case of extrusion was observed in this group. Seventy-two percent of the patients had a persistent air-bone gap of 20 dB or less. No difference was noted between the TORP and PORP groups with this procedure. Shortly thereafter, Linder and Fisch [49] reported on their initial experience with titanium implants in seven patients, although they had no audiologic findings to report. Maasen and Zenner [36] used a titanium implant-gold prosthesis for type II tympanoplasties in 11 patients and had good results (see above). Schwager et al. [50] reported on titanium implants used in 264 patients. Revision was necessary in 12 of the patients due to recurrent perforation (4), recurrent cholesteatoma (4), implant

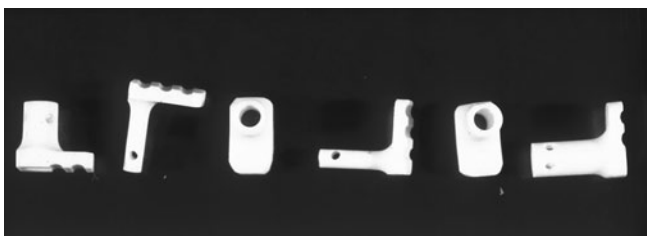

Fig. 3.**4** Aluminum oxide ceramic implants:
columella, lengths of 5.0 mm and 6.5 mm; hollow shaft implant, lengths of 3.5 mm and 5.0 mm. All implants are perforated at the distal end for connective tissue grafts to improve the medial anchorage.

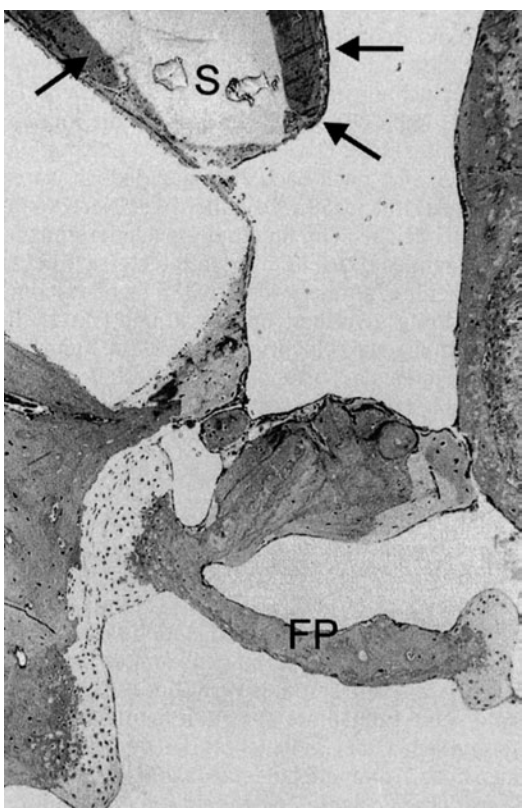

Fig. 3.**5** New bone formation (arrows) along a silicone film (S) implanted in the guinea pig middle ear after removal of the stapes superstructure, 25 weeks postoperatively (FP = footplate).

protrusion (3), or insufficient length of the prosthesis (1). No bone fixation or foreign body reactions were detected. Böhm et al. [51] implanted 84 patients with titanium prostheses (Fig. 3.**8**) and saw no instances of extrusion. The average hearing gain was 25 dB with the PORPs and 15 dB with the TORPs. There were also 12 instances of recurrent perforation and 8 recurrent cholesteatomas. Dalchow and Stupp [52] related their experience with titanium middle ear implants in children. They were able to reduce the air-bone gap in 42 patients from an average of 32 dB before the surgery to 20 dB at 13 months postoperatively. In 200 patients with titanium TORPs, Elies et al. [53] saw no extrusion for up to 2 years postoperatively, and the average residual air-bone gap was 10–20 dB. Acar et al. [54] first reported on the use of 9 titanium stapes prostheses in 1999. A new titanium stapes implant was developed independently at our center and has yielded very good results in an initial short-term observation [55]. Titanium prostheses have become widely used in middle ear reconstructions.

Important advantages of titanium implants are their low weight (approximately 4 mg), ease of handling, and minimal tissue reactions, leading to a good audiologic result. The histologic results with titanium implants have been contradictory with regard to new bone formation in animals and humans.

Comments

Ventilation tubes made of gold and titanium have been successfully used for more than two decades. In recent years, titanium prostheses have become particularly well established for reconstructions of the ossicular chain. They are available in various sizes, are easy to handle intraoperatively, and yield good results when the tympanic membrane is protected with cartilage. Steel and tantalum implants are economical and they are especially justified for rare indications such as the surgical treatment of malformations. Platinum has proven effective in stapes surgery when used in conjunction with Teflon, but there are increasing numbers of incus necrosis in our stapes revision cases.

Plastics

Wullstein [58] first used Paladon implants in otologic surgery, using them as stents in fenestration operations for the treatment of otosclerosis. Later (1952) he became the first surgeon to use a plastic material, Palavit (a vinyl resin), for ossicular reconstruction [59]. Armstrong [60] used a vinyl tube about 1.5 mm in diameter for transmembranous middle ear drainage with good results. Shea [7] first implanted a Teflon "stapes replica" into the oval window in May, 1956, for the treatment of otosclerosis. The patient's hearing was immediately improved, and this gain lasted for at least 3 years until she was lost to follow-up. Austin and Sanabria [61] and Austin [62] used polyethylene and Teflon to reconstruct the sound conduction apparatus. The air-bone gap was reduced to 20 dB in 54 % of the patients (n = 45), but revision was necessary in 34 % of the patients.

Vinyl Acrylate

No long-term results on Palavit have been published since Wullstein first reported on the use of that material. Other authors have reported, however, that Wullstein did not continue to use that material [63–65].

Silicone

Reddy and Igarashi [66] used small silicone tubes for stapes replacement in cats following stapedectomy. The tubes were encased by a fibrous capsule, and some of the animals developed a severe exudative otitis media. Merwin et al. [67] used silicone as a middle ear implant in mice. Light microscopy at 1 and 2 months postimplantation showed fibrous scar tissue causing adhesions as well as giant cells and macrophages consistent with a foreign body reaction. Kuipers [68] implanted silicone into the middle ear of 16 rats and observed fibrous encapsulation of the implant with a small number of giant cells at 1 to 8 months postoperatively. Liening et al. [69] compared silicone film with polydioxanone film for the prevention of tympanic membrane adhesions in mongolian gerbils. They found no foreign body reactions around the silicone, but inflammatory infiltrates were present in 13 % of the animals even at 15 weeks. We did studies in which silicone films were placed in the guinea pig oval window niche along with various ceramics to prevent undesired bony fixation of the ceramic to the middle ear wall. Conspicuous new bone formation was evident along the silicone film in this species [13] (Fig. 3.**5**).

Silicone is used for reconstructive surgery in various disciplines [70–72]. Armstrong recommended inserting silicone film after sectioning the calcified tendon of the stapedius muscle to prevent new adhesions [73]. In revision operations, Palva et al. [20] examined the middle ear tissue after the deepithelialized middle ear bone had been splinted with silicone. In all cases they found fibrous material but no epithelium. This led them to recommend that the silicone film not be removed from the middle ear. Sheehy et al. [74] saw the extrusion of Silastic film in less than 1 % of cases. They attributed the extrusion to deformation of the film due to tympanic scarring and subsequent perforation of the tympanic membrane by the displaced film edges. Shea [75] reported on his long-term experience with silicone film in the middle ear. Extrusion occurred about 10 years after insertion, preceded by a discharge from the middle ear. Shea believed that this occurred because the film lining curled and came into contact with the tympanic membrane. He therefore used silicone film near the tympanic membrane only in staged procedures where the film could be removed at the second operation. Although liquid silicone accidentally introduced into the human middle ear leads to ossicular injury, Schimanski [76] found that this does not cause permanent changes in the mucosa. Ng and Linthicum [70] had the opportunity to examine six human petrous bones by light microscopy in patients who had received middle ear silicone implants during their lifetime. They saw no foreign body reactions but consistently found a fibrous capsule that had formed around the plastic film.

Adhesions could not be reliably prevented, even in one case of otosclerosis. Silicone has also been used for ossicular chain reconstruction. El Seifi and Fouad [77] interposed silicone myringotomy tubes between the eroded long process of the incus and the stapes capitulum. In both patients, the air-bone gap at 3 and 5 years was less than 10 dB over 5 speech frequencies. Silicone myringotomy tubes are commonly used. While Schmäl et al. [39] found no greater incidence of otorrhea after the insertion of a silicone tube compared with a gold tube, the problem organism *Pseudomonas aeruginosa* was found much more frequently in middle ears that were drained with silicone tubes.

Silicone is commonly used in the middle ear. Histologic examinations in animals and humans consistently show that this material undergoes fibrous encapsulation. Findings have been contradictory on the occurrence of foreign body reactions. So far, experiments have not justified the hope that silicone would acquire an epithelial covering that could prevent atresia of the middle ear cavity in the long term. It is possible, however, that the tolerance for this material depends on the size of the implant. Based on the experience at our centers, it appears that films with a larger surface area are not encapsulated in the tympanic cavity in contrast to smaller films.

Polyethylene

Polyethylene has been used in a number of variations as an implant material for reconstructive middle ear surgery. It has been used simply as solid "polyethylene," without further classification, or as Plastipore in a semisoft, white, spongy version with a pore size of 25 μm [63, 78, 79, and 80].

Oppenheimer et al. [81] and Bering et al. [82] had shown that polyethylene implanted in the abdominal wall of rodents induced sarcomas in the fibrous capsule surrounding the implant in 13 % of the animals tested. Control experiments with cotton swabs and glass disks did not induce sarcomas, and additional tumors occurred with a species-typical frequency. Goldman et al. [83] investigated various materials in the feline middle ear. They were placed as loose implants in the middle ear and also as oval window seals after stapedectomy. In contrast to Teflon, palladium, and steel, large numbers of foreign body giant cells were found in the area around polyethylene implants.

An average of 19 years after stapedectomy, Himi et al. [25] conducted histopathologic studies of the middle ear and of various stapes implants in 23 petrous bones. In 3 of 11 middle ears reconstructed with polyethylene implants, bone resorption was found on the incus. Giant cells were found in two middle ears, signifying a foreign body reaction. No such signs were seen in the other materials examined (Teflon, steel wire). Plester [84] felt that polyethylene was acceptable only for stapes surgery.

Plastipore is dense polyethylene with a spongy, porous structure that is receptive to fibrous tissue ingrowth for implant fixation in the tympanic cavity. Shea [79] first used Plastipore for ossicular reconstruction in human patients in 1976, long before animal studies.

Most histologic studies were based on prostheses that had been extruded or removed at revision surgery, and subsequent animal studies merely confirmed those findings [67, 68, 85, 86]. Cousins and Jahnke [87] implanted Polycel (another high-density, porous polyethylene) into the middle ear of gerbils and examined the material by light microscopy (Fig. 3.**7**) and electron microscopy (Fig. 3.**6**) 1 to 5 months postimplantation. A collection of foreign body giant cells and vacuolated cells was found beneath the submucosa and the underlying thin fibrous layer. There was some bony ingrowth into the pores of the implant. Electron microscopy revealed intracellular foreign material in all of the specimens.

When Shea [79] implanted 54 of these so-called biocompatible implants as PORPs, he saw no short-term extrusion but measured significant hearing gains in 43 (80 %) of the patients. Sheehy [88] reported on 106 operations with TORPs or PORPs made of Plastipore, which was first used to protect again extrusion along with a cartilage disk interposed between the plastic implant and the plane of the tympanic membrane. The extrusion rate was not reported. When the patients were reexamined at 6 months, 85 % of the TORP patients and 76 % of the PORP patients were found to have less than 20 dB of conductive loss. The extrusion rates in other clinical reports range from 2 % to 38 % [63, 64, 77, 89–99].

Belal and Odnert [98] reoperated 6 patients 7 to 18 months after the implantation of a Plastipore TORP or

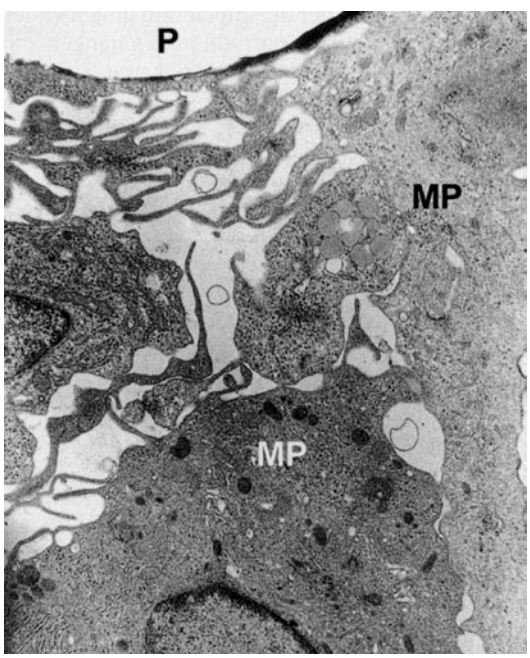

Fig. 3.**6** Transmission electron micrograph of Polycel in the gerbil middle ear 2 months after implantation. P = plastic, MP = macrophages with tentacle-like cellular processes.

PORP because of hearing problems. Light and electron microscopic examination revealed macrophages, giant cells, and cellular inclusions consistent with a foreign body reaction. Jahnke and Galic [100] reported similar findings. When Kerr [101] examined 52 revised Plastipore implants, he found superficial fibrous tissue with many multinucleated foreign body giant cells and plastic particles within granulomas. This was the first documented evidence that plastic degradation takes place in the middle ear. Galic and Jahnke [102] performed light and electron microscopic studies of 10 explanted Plastipore implants (Fig. 3.**8**). They consistently found that the material was encapsulated by four layers: (1) an outer epithelial layer, (2) a subepithelial tissue layer, (3) a fibrous capsule, and (4) a deep tissue layer in direct contact with the plastic and growing into its pores, composed of vacuolated cells and multinucleated foreign body giant cells, some containing lipid droplets. Macrophages were found in the cavity of the implant. Palva and Mäkinen [103] saw foreign body giant cells in three patients with Plastipore implants and intracellular foreign material in two patients. Postma and Shea [104] histologically examined the Plastipore implant and surrounding petrous bone from a patient who had suffered a fatal accident after receiving the middle ear implant 20 months earlier. They found signs of chronic inflammation in the middle ear, but they saw no inflammatory changes around the implant itself and no foreign body reactions.

Brackmann et al. [105] reported on 1042 operations with Plastipore implants that had been followed for up to $4^1/_2$ years postoperatively. Ninety percent of the patients had no further changes in hearing after 6 months. The air-bone gap after 6 months was 20 dB or less in 55 % of the TORP patients and in 73 % of the PORP patients. Without stating the frequency of implantations, Gamoletti et al. [106] removed 43 Plastipore implants from 2 to 32 months postimplantation and reported their histologic findings. Examination of the material in the hollow shafts of the implants revealed fibrous tissue with giant cells and debris but no intracellular particles. Belal et al. [107], from the same group, reported on 24 revised Plastipore implants that were permeated by fibrous tissue with macrophages and foreign body giant cells. On electron microscopy, these cells contained dense particles that were interpreted as a sign of microdisintegration. Schuknecht et al. [108] reported on microscopic studies of Plastipore implants and conventional polyethylene implants examined from 1 to 21 years after implantation. Foreign body giant cells were found in the heavily vascularized fibrous tissue on the implant surface. Chüden [97] reported on the 4-year results with Polycel implants: 76 % of the patients (n = 46) had an air-bone gap of less than 20 dB. In 1991, El Seifi and Fouad [77] reported that 2 of 5 patients had marked deterioration of hearing 3 years after receiving a Plastipore PORP. Similar deterioration occurred during just the first year in 7 of 15 patients who had been implanted with a TORP. Later the same authors [99] reported on long-term results. The extrusion rate was 18 %. Histologic examination of four implants showed fibrous encapsulation, signs of implant absorption, and occasional foreign body giant cells.

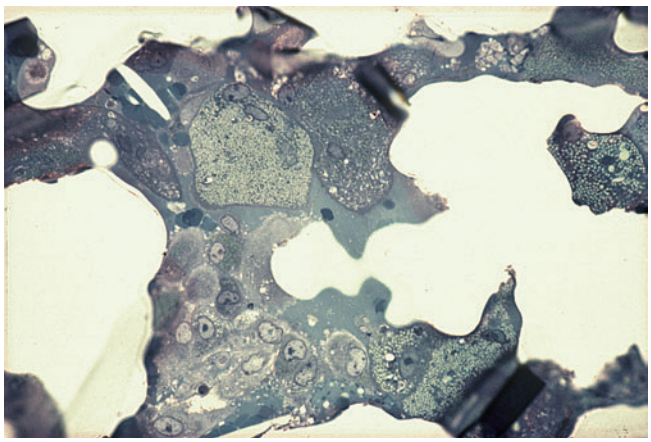

Fig. 3.**8** Light microscopic appearance of a Plastipore prosthesis that was removed from the human middle ear at revision 4.5 years after the original operation. White area = plastic. The pores are filled with foreign body giant cells and macrophages.

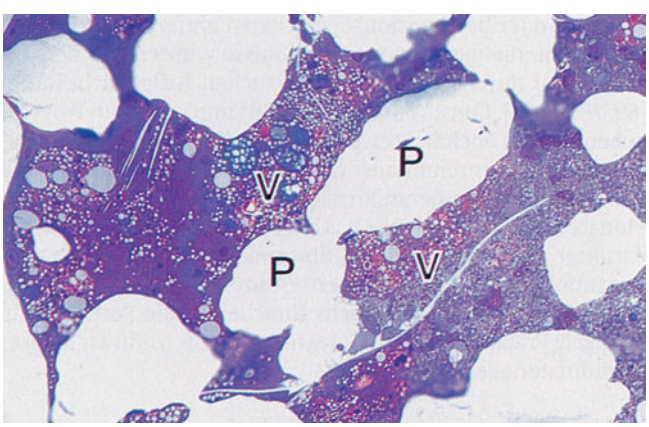

Fig. 3.**7** Light microscopic appearance of Polycel from the gerbil middle ear 3 months after implantation. The pores between the plastic constituents (P) are filled with vacuolated cells (V).

Teflon (Polytetrafluoroethylene)

Teflon

Polytetrafluoroethylene (Teflon) is a plastic that was developed by William Gore in the 1940s and was first used as the membrane in an oxygenator. Teflon is a hydrophobic material with low surface energy [109].

Goldman et al. [83] investigated various implant materials in cats (Teflon, palladium, steel, polyethylene) that were implanted as chips in the hypotympanum and compared them with autologous grafts used to seal the oval niche after stapedectomy. When implanted loosely in the hypotympanum, Teflon showed the least amount of reaction with its surroundings compared with the other foreign materials. Within two weeks it was encapsulated by a thin fibrous layer. When very thin Teflon film was placed by itself in the oval niche, it did not provide an effective inner

ear seal. But when the Teflon was covered by autologous tissue (fat, vein wall), an effective oval window seal was obtained. Kuijpers [68] analyzed Teflon that had been experimentally implanted in 16 rats. Examination at 1–8 months showed fibrous encapsulation of the implants with small numbers of giant cells present only on the sharp edges of the material.

Teflon is the oldest and most widely used biomaterial in stapes surgery [110, 111]. Shea et al. [112] inserted a Teflon piston into the vestibule through an opening in the footplate and were able to improve otosclerosis-related conductive hearing loss in 250 patients without injury to the inner ear. At 3 months' follow-up, the air-bone gap was closed in more than 90 % of the first operations and in more than 80 % of the revisions. Later Shea [113] introduced the use of fine polyethylene tubes. Heermann and Heermann [114] saw only one case of incus erosion causing significant hearing loss in approximately 600 stapes operations with the Teflon implant. In 46 patients whom Robinson [22] implanted with his Teflon stapes prosthesis for otosclerosis, the postoperative air-bone gap was less than 10 dB in 96 % of the cases. In 52 %, the air-bone gap was completely closed. In 126 malleovestibulopexies with a wire Teflon implant, Scheer and Amjad [115] saw one case of inner ear damage and no problems with the materials in the middle ear (Teflon) or on the malleus handle (wire). Krumpholz and Jakse [95] used a wire Teflon implant in 650 patients with otosclerosis. They rated the results as "good." Shea [116] performed a malleovestibulopexy with a Teflon implant in 35 middle ears. He reported no problems with the material in the middle or inner ear at 10-year follow-up, and a hearing loss of less than 20 dB was achieved in 27 of the 35 cases. Plester and Cousins [57] reported on 17 000 partial stapedectomies including 1040 revisions and mentioned also their experience with the platinum band-Teflon prosthesis. Himi et al. [25] performed histopathologic studies of 23 petrous bones and examined stapes implants that had been inserted an average of 19 years earlier. Teflon implants had been used in six ears. The Teflon was covered by a thin fibrous layer. No foreign body reactions were seen.

Austin and Sanabria [61] achieved better results with Teflon implants for tympanoplasty than with traditional polyethylene implants. They developed a columella with an umbrella-shaped plate that was positioned below the tympanic membrane graft. Feldman and Schuknecht [117] reported on the use of Teflon disks to prevent adhesions in the tympanic cavity. Tabor [118] implanted a Teflon piston in 23 patients who had lost the entire ossicular chain as far as the footplate. He saw no tympanic membrane perforations during the first 2–12 months after the operation, and half of the patients had a residual air-bone gap less than 15 dB. He reported no instances of sensorineural hearing loss in the first 100 operations. Sadé et al. [119] treated 14 patients with a composite implant consisting of a Teflon stapes superstructure and an ossicle that established contact with the tympanic membrane. None of the patients had any problems in the tympanic membrane area over at least a 6-month follow-up period.

Teflon with Carbon (Proplast)

Proplast is a Teflon-and-carbon composite that Shea and Homsy [120] and Janeke and Shea [121] introduced into otologic surgery. To circumvent the low surface energy and consequent lack of epithelialization of the Teflon surface, carbon is applied to the implant to make the surface hydrophilic. The intent is to promote the deposition of endogenous proteins, masking the implant to the body's immune system. Proplast is 70–90 % porous, with pore diameters of 200–500 μm.

Janeke et al. [122] implanted Proplast to obliterate the mastoid cavity in monkeys. After 1 to 9 months, the air-exposed material was covered by a thin layer of mucosa. Below that was loose connective tissue in which the number of multinucleated giant cells dwindled with the duration of implant placement. Bone ingrowth into the implant commenced after 7 months. Additional animal studies were done only after the use of these implants was discontinued due to their high clinical failure rate. The new studies revealed giant cells [85, 123, 124], some of which appear to have phagocytized plastic particles [68] and ingrown bone [67]. According to our personal experimental experience, particles of such small size will incite a marked foreign body reaction even if the material is otherwise biocompatible.

Shea and Homsy [120] and Janeke and Shea [121] reported on 23 patients in whom a Proplast implant had been inserted as a columella. No instances of extrusion occurred during the first 12 months and the hearing results were good, with an average gain of 20 dB and an average residual hearing loss of 17 dB. When Smyth et al. [90] examined Proplast implants removed at revision, they saw marked inflammatory reactions with many multinucleated giant cells but no intracellular foreign bodies under polarizing light. Kerr [101] performed histologic examinations of 16 revised Proplast implants and found numerous multinucleated giant cells, in which he could see foreign material under polarizing light. He interpreted this as evidence of material degradation. Palva and Mäkinen [103] used Proplast to reconstruct the posterior wall of the ear canal in three patients. After initial uneventful healing, extrusion occurred after periods of up to 4 years. Histologic examination in all cases showed innumerable foreign body cells in which foreign material could be identified. Coletti et al. [125] implanted 79 Proplast and Plastipore prostheses and observed 14 extrusions (18 %) within 1 to 5 years. Babighian [126] compared the results of tympanoplasties using Proplast with those using Ceravital. The author noted a 13 % extrusion rate with Proplast over a follow-up period of up to 2 years and 9 months, compared with an 8 % extrusion rate with Ceravital followed for an equal period. The audiologic results were also better with the ceramic than with the plastic.

Comments

Plastics were almost never tested in animal models before being used in clinical trials. Revised porous implants have consistently evoked sustained foreign body reactions. For

this reason, many otologic centers have stopped using plastic implants for middle ear reconstructions [20, 84, 127, 128]. In approximately 50% of larger studies (n > 50) with at least a 6-month follow-up, porous polyethylene implants were extruded in more than 10% of the cases. This is a failure rate that can no longer be considered acceptable, given the large number of more reliable alternatives.

One exception is Teflon, which yields dependable results when used as the piston of a stapes prosthesis or for malleo-vestibulo pexis. Furthermore, we continue to use large pieces of silastic to prevent adhesions, especially in staged procedures.

Ceramics

Aluminum Oxide Ceramic

Aluminum oxide (Al_2O_3) ceramic is composed of corundum crystals 3–5 μm in size that are sintered at 1500–1800 °C to produce an essentially nonporous, polycrystalline material. Chemically, the ceramic resembles a sapphire or ruby without the iron or cobalt ions. Aluminum oxide ceramic has a hardness of 9 on the Mohs scale, placing it second only to the diamond, which has a hardness of 10. As a result, this ceramic can be shaped only with diamond drills. All other instruments are abraded by it, creating surface impurities on the material [129].

Immediately after implantation, the surface of the ceramic binds proteins that supposedly protect the material from the immune system. Aluminum oxide ceramic is the prototype of a bioinert implant material [130]. Here the term "bioinert" means that when the material has been implanted in the body, none of its constituents can be detected in the tissues by any available analytic methods, or at least its constituents enter the tissues in such minute amounts that they produce no local or systemic effects [130]. In culture studies of human stapes cells that were formerly identified as "osteoblast-like cells," the authors saw no impediment to the proliferation of these cells in direct proximity to the aluminum oxide ceramic [13] (Fig. 3.**1a**).

Jahnke and Galic [100] and Jahnke and Plester [132] performed animal studies to investigate aluminum oxide ceramic in the rabbit middle ear and found that the material was covered by a thin mucosal layer within 3 weeks postimplantation. Fibroblasts were found at the submucous level, but there was no fibrous capsule and, more importantly, no cellular evidence of a foreign body reaction. When Friedberg and Reck [133] implanted this material in the same animal model, they likewise found a thin mucosal layer on the implant after 8 days to 18 weeks, although they also saw small numbers of foreign body giant cells.

Jahnke et al. [131] introduced this material into otology in 1978, after it had already been used for reconstructive surgery in neighboring disciplines [120]. They described one year's experience with industrially prefabricated implants of their own design that were used in a PORP or TORP configuration. Yamamoto and Iwanaga [134] also introduced their own series of aluminum oxide ceramic implants. Jahnke and Galic [100] observed 2 cases of extrusion in 150 patients treated with their implant. Even at 3- to 24-month follow-up, the number of extrusions did not increase [135]. The extrusion rate at up to 4 years' follow-up was 3%. A good audiologic result (air-bone gap < 30 dB) was achieved in 90% of the patients [136]. Yamamoto [137] saw no extrusions in more than 100 patients followed for up to 3 years. He consistently placed a cartilage disk medial to the fascial graft and medial to the head of the prosthesis, so that the cartilage served to prevent tympanic membrane retraction but could not protect the reconstructed tympanic membrane plane from the ceramic implant. Later, Jahnke [138] introduced a second generation of aluminum oxide ceramic implants that had small perforations in the medial part of the shaft, designed to secure the implant to the stapes capitulum (PORP) or footplate (TORP) through fibrous tissue ingrowth.

Glass Ceramics

Glass ceramics are produced by the fusion of bioactive glasses. The oldest of these products for biomedical use is Bioglass [139]. Bioactive glass, like the glass ceramics (see below), interact with body fluids to form a calcium phosphate surface layer that subsequently bonds to the adjacent bone. The activity of these materials, their ability to bond to bone, and their degradation rate in the body can be modified by varying the proportion of oxides in the ceramics [130, 139]. The principal component is always SiO_2.

Bioglass

Bioglass, a bioactive ceramic, was first tested in laboratory animals in the reconstruction of long tubular bones [140] before it was introduced to otology in 1982 [67]. It showed good biocompatibility in short-term studies, but its rapid degradation in the middle ear made it unsuitable for long-term use. It has been known since the early 1970s that bioglass may be completely broken down in liquid media. This material has, however, provided a basis for the further development of other bioactive ceramics.

Ceravital

According to Beleites and Rechenbach [141], Brömer et al. in 1971 were able to reduce the solubility of the glass ceramic developed by Hench et al. by lowering its total potassium content. This produced a surface-active, less biodegradable glass ceramic that was introduced to reconstructive surgery under the brand name Ceravital.

Reck [142, 143] implanted Ceravital in the rabbit middle ear and found that it healed well without irritation (Fig. 3.**9**). When the material was placed in contact with bone, a mucosa-covered bony layer up to about 40 μm thick formed on the surface of the implant. This bone deposition continued until about 4 months postimplantation. When the implant was placed in an inflamed middle ear, combining the glass ceramic with titanium appeared to make it more resistant

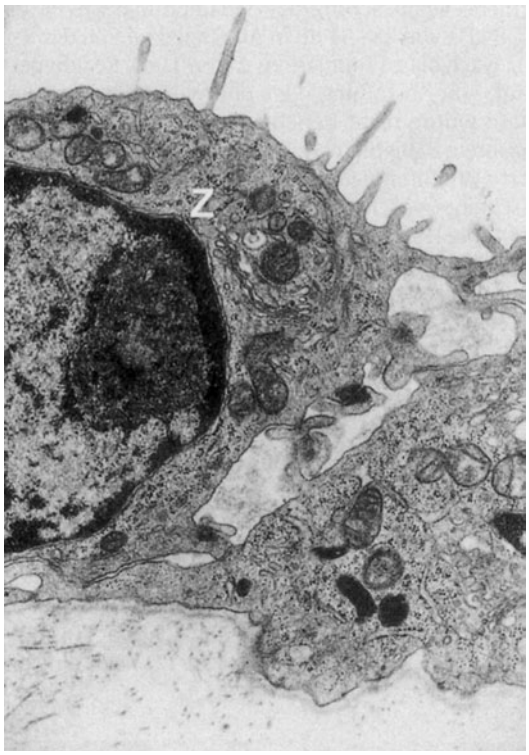

Fig. 3.**9** Normal mucosa on a Ceravital implant. Epithelial cell (Z) with a few microvilli.

to degradation [43]. In our own studies in the guinea pig middle ear in which the stapes superstructure had been removed and a Ceravital implant placed on the bare footplate, avoiding contact with the tympanic membrane, the implant formed a bony attachment to the remnants of the stapes crura. This process began 6 weeks postoperatively [144] and was more pronounced by 3 and 6 months [145]. The implant also gained attachment to the walls of the middle ear. No evidence of foreign body reactions was seen. In vitro experiments [13] showed that human stapes osteoblasts proliferate normally when in proximity to Ceravital, just as

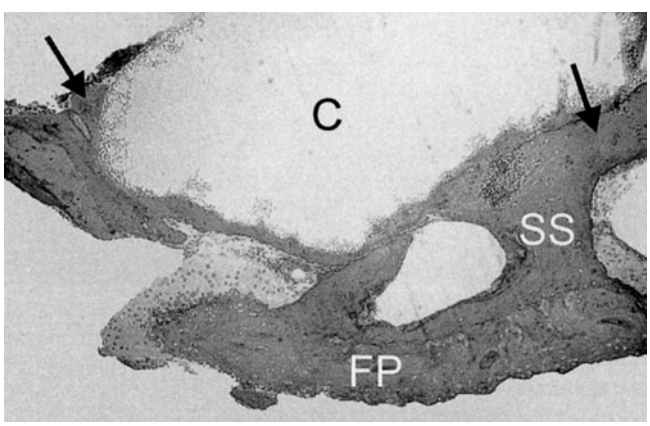

Fig. 3.**10** Ceravital implant (C) 3 months after insertion into the guinea pig oval niche following removal of the stapes superstructure. Note the bone deposition on the material (arrows) arising from the remnants of the stapes crura (SS) (FP = footplate).

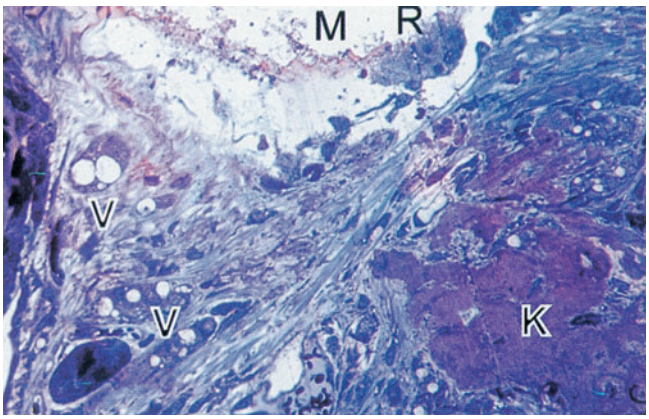

Fig. 3.**11** Light microscopic appearance of Macor from the rabbit middle ear 3 months after implantation. Near the ceramic (M) are vacuolated cells (V), newly formed bone (K), and a giant cell (R).

they do with other established inert and bioactive materials (Fig. 3.**1**). These experiments also showed no increase in the formation of bone cells, however.

Reck was the first, in 1978, to use Ceravital implants for ossicular chain reconstruction in human patients [142]. In 85 patients followed for up to 14 months, he saw 9 recurrent perforations and an average improvement in conductive hearing loss of 22–31 dB at 1–3 kHz, depending on the reconstruction. There was an 11.4% rate of recurrent perforations at up to 5 years, and no instances of extrusion or undesired implant fixation were reported [146]. Babighian [126] followed 70 patients with Ceravital implants for up to almost 3 years. He reported an 8% extrusion rate, despite having placed a cartilage disk between the ceramic and the tympanic membrane. The hearing results were better with Ceravital than with plastic implants, and extrusions were less common. Some degradation of Ceravital implants has occurred in patients with otitis media [146]. While better than bioglass, these implants have not shown acceptable biostability.

Macor

Macor is a bioactive ceramic introduced in 1980. In standardized animal experiments to test biomaterials used in bone reconstruction, Pauler and Plenck [147] tested this material in the femoral condyles of rats and always found a thin soft-tissue layer between the bone and implant containing macrophages and foreign body giant cells. Jahnke and Schmidt [148] found that material implanted in the rabbit middle ear (Figs. 3.**11**, 3.**12**) was covered by a thin layer of mucosa after 9 months' implantation. Bony fixation of the material to the wall of the bulla was consistently observed, however. This did not support the manufacturer-recommended use of the material as a stapes prosthesis. Examination of the submucous layer revealed fibroblasts, macrophages, and foreign body giant cells. Intracellular and extracellular electron-dense foreign material was also observed.

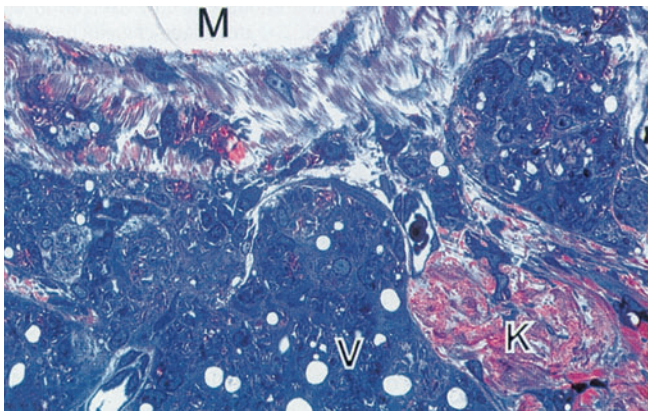

Fig. 3.**12** Same specimen as in Fig. 3.**11**. M = Macor, V = vacuolated cell, K = newly formed bone.

Bioverit

Bioverit is a glass ceramic developed in Jena, Germany, and consisting of a glass phase and a mica phase. Its proportions of CaO and P_2O_5 have been modified in an effort to control its bioactivity [149, 150]. However, cell culture tests with embryonic rat fibroblasts and epitheloid cells from neonatal rat livers have shown no difference in the proliferative behavior of the cell lines in the presence of the different ceramics [149].

Experimental studies in the rabbit middle ear [149] have shown overgrowth of the material by multi- and single-layer epithelium but no attachment to bone. Our own experiments in the guinea pig middle ear have shown no differences among Bioverit implants with different theoretical bioactivities [13]. They form a bony attachment with the remnants of the stapes crura and also with surrounding middle ear structures (Fig. 3.**13**).

Beleites et al. [151] introduced Bioverit implants to middle ear surgery. These authors particularly note the ease of shaping the material intraoperatively with a burr and even fashioning it into filigrain structures.

Tricalcium Phosphate (TCP) Ceramic

Tricalcium phosphate, like hydroxyapatite, is a natural constituent of bone tissue [152]. For equal pore sizes, TCP ceramic was broken down several times faster in solution than hydroxyapatite [152]. Its microporosity (powder grain size 1–20 μm) was responsible for this breakdown, while its macropores (200–500 μm) were responsible for the ingrowth of bone tissue [153].

Zöllner et al. [154–156] performed comprehensive animal studies in which TCP ceramic was used to reconstruct the ear canal wall and was also implanted in the infected mastoid. They found that by 3 months postimplantation, the material was completely covered with epithelium from the middle ear. By 6 months the implants were completely covered by newly formed bone. After a total follow-up period of 18 months, ceramics with 35% porosity showed considerably more osseointegration than ceramics with 20% porosity. Jahnke [127] implanted TCP ceramic under the middle ear mucosa of guinea pigs and found that by 3 to 6 months, the material had been partially replaced by bone with no apparent associated foreign body reactions (Fig. 3.**14**).

Jahnke and Plester [65] have been using TCP ceramic clinically since 1979 for partial obliteration of the deepithelialized mastoid cavity.

Hydroxyapatite Ceramic

Hydroxyapatite is a natural constituent of bone and is used as a biomaterial in the form of a dense or porous ceramic [152]. After implantation, this material was found to be covered by a microscopically thin apatite layer by which it bonded to the bone. The rate of subsequent implant degradation is proportional to its degree of porosity. This pro-

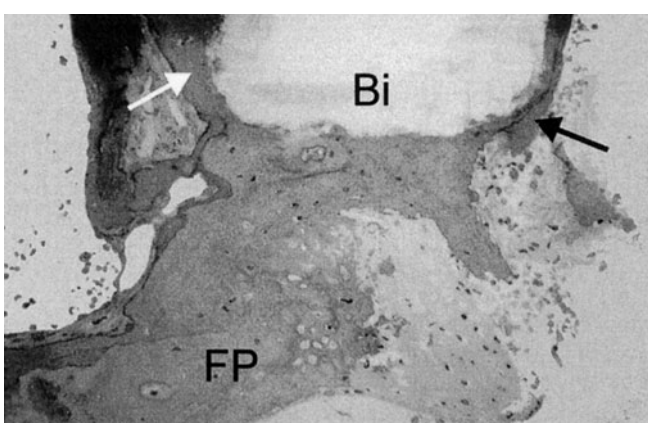

Fig. 3.**13** Bioverit implant (Bi) 25 weeks after insertion into the guinea pig oval niche following removal of the stapes superstructure (FP = footplate), with evidence of new bone formation (arrows) along the ceramic (magnification 90X).

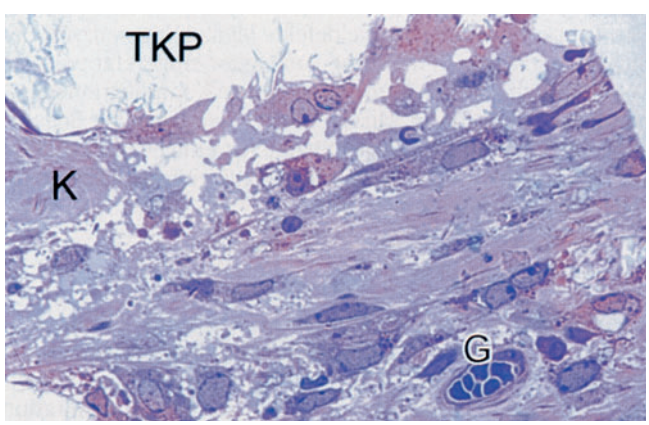

Fig. 3.**14** Light microscopic appearance of tricalcium phosphate from the guinea pig middle ear 3 months after implantation. Newly formed bone (TKP) is visible on the remnants of the TCP ceramic. An adjacent blood vessel (G) can be seen.

cess was not associated with a measurable rise of calcium or phosphate levels in the blood or urine of experimental animals [152]. The degree of porosity can be controlled over a wide range by shaping and sintering [157].

Grote et al. [157] tested dense hydroxyapatite in the canal wall of rats. At up to 22 months postoperatively, they found noninflammatory new bone formation in the macropores of the sintered, coarse-pored hydroxyapatite implants [157]. Kuijpers [68] investigated porous hydroxyapatite in the rat middle ear and initially saw few inflammatory cells at 1–18 months. Later he observed a thin mucosal layer on the material surface and mature bone in the pores. Scattered giant cells were also found, however. Blitterswijk et al. [158] investigated dense and porous material in the rat middle ear, both in a sterile condition and after infection with *Staphylococcus aureus*. They likewise saw a delicate mucosal layer covering the material, below which a few multinucleated giant cells were found. They could see no difference in the surface characteristics of the implant in the infected ear.

Grote and Blitterswijk [159] followed 30 patients with ear canal implants made of coarse-pored hydroxyapatite for at least 2 years. In these patients the implants were covered with periosteal flaps and residual canal wall epithelium. No extrusions were observed. Grote [160] implanted 60 patients with ossicular prostheses of dense hydroxyapatite and followed them for at least 1 year. He dissected a pocket between the tympanic membrane and malleus handle [161] into which he implanted his PORPs and TORPs of dense hydroxyapatite. The implants were cut to the required length with a drill or chisel. In two-thirds of the patients, the air-bone gap was closed to 10 dB. No prostheses were extruded. Grote [162] reported on 15 patients implanted with a composite prosthesis for severe destructive otitis media. He placed a dense hydroxyapatite TORP on the remaining, mobile footplate and connected it to an artificial tympanic membrane made of a bioactive, absorbable copolymer (polyethylene oxide hydatoin/polytetramethylene terephthate), which in turn was secured in a canal wall prosthesis made of porous hydroxyapatite. The results at 1 year were still acceptable in 12 of the 15 patients. After 3 years, however, the total middle ear prosthesis was removed in 7 cases due to obliteration and infection of the middle ear. All of these failures occurred in patients who had an absence of middle ear ventilation prior to the surgery.

Comments

Ceramic implants with markedly different properties can be created by varying their physicochemical characteristics. Aluminum oxide ceramic is considered the gold standard of a bioinert ceramic. It is particularly useful for reconstructing the interrupted ossicular chain but, like any material, should be protected with the malleus handle or autologous cartilage from extruding through the tympanic membrane. So far, bioactive ceramics have achieved solid, bony fixation to the stapes footplate only in our animal experiments. But there is a risk of implant degradation, especially in the infected middle ear, and of bony fixation to the canal wall, similar to ossicles. Hydroxyapatite seems to exhibit superior properties when compared with other bioactive ceramics. This also applies to some sophisticated implants, e.g. HA/steel, which are available.

Porous hydroxyapatite and tricalcium phosphate appear to be suitable for partially obliterating the mastoid cavity and are gradually replaced by autogenous bone.

Glass Ionomer Cement

This material is synthesized by a neutralization reaction in which basic calcium aluminum fluorosilicate glass is placed in an aqueous solution of polyalkenic acid. This yields glass ionomer cement in a slightly exothermic, strongly acidic reaction. When fluids (e.g., in a surgical field) interfere with this reaction, the hydrophilic material goes into solution [163, 164]. The cement, initially used in dentistry [165], forms such an intimate bond with the surrounding bone that fractures may occur adjacent to the interface [166]. The manufacturer [166] recommended the material in the scientific literature not just for repairing ossicular defects but also for sealing CSF leaks. No animal studies have been published on the latter application. Glass ionomer cement has also been used to make prefabricated middle ear implants that can be shaped intraoperatively [164].

Kupperman and Tange [167] used liquid glass ionomer cement (Ionocem) to obliterate the tympanic cavity and mastoid in rats. Five of 16 animals had to be culled from the experiment due to a suppurative middle ear infection. After 12 months, 9 of the animals showed a marked granulation tissue reaction but no signs of infection. Cochlear destruction was found in two animals. Kobayashi et al. [168] obtained quite different results in 56 guinea pigs implanted with liquid glass ionomer cement on the promontory or in the round or oval window niche. They found neither morphologic (electron microscopy) nor functional (electrocochleography) differences between the operated and nonoperated ears. Geyer et al. [164] implanted glass ionomer cement in solid and liquid form into the middle ear of the baboon. The posterior canal wall was reconstructed with liquid cement. The material showed solid osseointegration, but unlike ossicular implants, did not become fully epithelialized over time. There was no apparent evidence of foreign body reactions.

Thallemer and Draf [169] used Ionocem for skull base reconstructions and observed complications such as wound healing problems, seromas, granulations, fistulas, etc. in half of their 44 cases. In the long-term study of Geyer et al. [170], one-third of 74 patients who underwent posterior canal wall reconstruction developed epithelial defects that necessitated revision. Kupperman and Tange [171] reported an unacceptably high extrusion rate when this material was used to reconstruct the tegmen tympani or obliterate the mastoid.

Müller et al. [172] examined 7 patients 3 months after a glass ionomer cement implant had been used to bridge a

defect in the long process of the incus. The conductive hearing loss in these patients was reduced to an average of 11 dB at 500–2000 Hz. Maasen and Zenner used liquid glass ionomer cement to bride an incus defect. In 13 patients reexamined at 3–6 months, they found a significantly smaller air-bone gap than in patients who had been treated with an autologous incus interposition graft [36]. Thallemer and Draf [169] published their experience on the successful use of ossicular implants in 40 patients.

Hantson et al. [173] reported on two fatal complications associated with the use of glass ionomer cement. Ionos had been used in two patients to repair a bone defect following vestibular neurectomy. The patients subsequently developed a CSF fistula with severe refractory seizures, cerebral failure, and death. As the disease was progressing, aluminum levels of 112 and 63 μg/L were measured in the CSF, 4.4 and 4.3 μg/L in the blood, and 495 and 1440 μg/L in fluid from the fistula. The normal serum and blood levels of aluminum are less than 1 μg/L. At autopsy, an aluminum level of 2.5 μg/L was measured in the brain of the second patient (normal = 0.85 μg/L). In laboratory tests where Ionos was placed into CSF and left for 16 hours at 37 °C, an aluminum concentration of 2570 μg/L was measured in the fluid. Renard et al. [174] reported two cases in which Ionos had been used in the setting of acoustic neuroma surgery. Both patients developed a CSF fistula, followed later by seizures and coma. Stereotactic biopsy in one of the cases documented the presence of aluminum in lysosomes by electron microscopy. Aluminum concentrations of 135–185 μg/L were measured in the CSF (normal = 3.5 μg/L or less) and 56–64 μg/L in the serum (normal = 10 μg/L or less). Presumably an internal CSF leak caused the bone cement, which had not adequately set, to go into solution, thereby gaining access to the CSF and damaging the brain tissue. In total, six patients who died after this application are known. As a result of these complications, both the solid and liquid forms of glass ionomer cement were removed from the market in 1995 [164], and the German firm marketing the cement was dissolved.

Glass ionomer cement could have remained an important tool for bridging small ossicular defects, had it not been carelessly used in proximity to the CSF. The resulting dramatic complications discredited the material and caused it to be banned. A similar cement has been marketed for some time by a British company, but its safety has not been adequately documented by animal studies.

Carbons

Jahnke and Schrader [175] investigated carbon implants (graphite, porous pyrolite carbon, carbon-fiber-reinforced porous carbon, smooth glassy carbon) in the gerbil middle ear by light microscopy at 1–7 months postimplantation. Graphite particles were seen in the reticuloendothelial system. Additionally, particles had been shed from the porous carbon and carbon-fiber-reinforced materials, and foreign body giant cells were found around the implants. The glassy carbon implants were associated with a hypocellular, fiber-rich connective tissue and minimal foreign body reaction. With their poor wettability, the implants showed only partial overgrowth by mucosa. Blayney et al. [176] examined carbon fiber implants by light and electron microscopy that had been implanted from 6 weeks to 6 months in the middle ear of guinea pigs and rats. The material showed fibrous encapsulation and appeared to be well tolerated, with an absence of giant cells. Krummel et al. [177] performed light and fluorescent microscopic studies of glass carbon implants in the rabbit middle ear. Free pus was found in the tympanic cavity of all the animals at 14 days, and later (up to 12 months) it was present in almost all the animals. The implants were encased by a heavy layer of granulation tissue that contained macrophages and foreign body giant cells. Nonreactive bone necrosis was found at some sites of contact between the implant and bone. Beleites et al. [149] performed in vitro studies of cells cultured from rat fibroblasts and exposed to glass carbon. They found that these cells spread out on the surface of the material and remained viable for at least 6 days.

Jahnke and Schrader [175] reported on the first clinical use of ventilation tubes made of glass carbon. They used the material for this application owing to its low weight and low surface energy. Blayney et al. [176] implanted 23 patients with PORPs and TORPs made of carbon fiber material. Approximately 40 % of the implants were extruded. Histologic examination revealed fibroblasts around the implants along with numerous carbon particles in the tissue surrounding the implants, signifying material degradation.

Adhesives

Otosurgeons have long appreciated the need to secure grafts and implants in their new position, at least temporarily, and protect them from displacement [178]. Austin and Sanabria [61] used the patient's own clotted blood as an adhesive to stabilize middle ear implants and vein grafts used to reconstruct the tympanic membrane. Still, the search continued for adhesives that could function for a longer period.

Histoacrylate

Starting in the late 1940s, several cyanoacrylates were developed that varied in their toxicities [179]. Histoacryl blue had to be processed quickly and in small quantities. It polymerized at 40–80 °C in a strongly exothermic reaction that could damage tissues [95].

Tabb [180] saw no evidence of toxicity from isobutyl cyanoacrylate placed in the middle ear of guinea pigs. However, Kerr and Smyth [181] saw poor functional results with small amounts of the same adhesive placed in the cat middle ear, and marked footplate erosion occurred in 12 of 13 animals. The middle ear mucosa showed signs of acute inflammation after 1 week. At 3 weeks, it showed signs of chronic inflammation with giant cells, histiocytes, and foam cells consistent with a foreign body reaction. In one animal, the entire tympanic cavity was filled with the adhesive. Examination revealed severe damage to the inner ear with rupture of the endolymphatic system, curling

of the tectorial membrane, and collapse of large portions of the organ of Corti. Samson and Marshall [182] stated that cyanoacrylates were carcinogenic. In experiments with rabbits, Toriumi et al. [179] compared the histotoxicity of ethyl-2-cyanoacrylate (Krazy Glue®) with butyl-2-cyanoacrylate (Histoacryl) when those materials were used to fix autologous bone to cartilage. The inflammatory changes caused by Histoacryl were comparable to those seen in control operations without adhesive, and there were only minimal signs of a foreign body reaction. The tissue reaction was much more intense, however, when the adhesive came in contact with well-perfused tissue (e.g., muscle).

Maniglia et al. [183] reported on a new adhesive for cementing a titanium-encased magnet to the body of the incus as part of an implantable hearing device. The cement, called 4-META/MMA-TBB, is composed of 4-methacryloyloxyethyl trimellitate anhydride, methylmethacrylate, and tri-n-butyl borane. When the device was implanted into the middle ear of 5 cats and the animals were subsequently killed at an average of 9.6 months, the titanium casing was firmly adherent to all the incudes with no failure of the bone-cement interface. Histologic examination showed no inflammatory or foreign body reactions.

Schnieder [184] reported on his clinical experience with 123 middle ear operations involving the use of minimal amounts of cyanoacrylate (Histoacryl). When the patients were seen again at 2-year follow-up, the majority showed good, stable hearing results. Three of the patients experienced transient facial nerve palsy, and five had sensorineural hearing loss. Jahnke [185] saw definite signs of a foreign body reaction in the human middle ear 12 years after implantation.

Fibrin Glue

Wullstein [178] was the first to describe the use of "human glue" in tympanoplasty. Wigand and Panis [186] used fibrin glue in the middle ear of 102 patients as part of an ossiculoplasty. The air-bone gap was reduced from an average initial value of 18 dB to 12 dB postoperatively. Today, glues that contain human materials are viewed with greater caution. Adequate studies have not yet been done to detect or exclude the transmission of HIV or hepatitis virus infection by fibrin glue.

Comments

Cyanoacrylate adhesives have been discredited for medical use because of their reproducible foreign body reactions. Maniglia et al. [183] attributed the much more favorable results of their three-component adhesive in animal experiments to its low exothermicity and its minimal shrinkage during setting. They also claimed that acidic demineralization did not occur at the bone-cement interface. Adhesives obtained from donors always carry at least a slight risk of transmitting diseases with a substantial psychological impact, and their use should always be considered with caution.

Conclusion and Outlook

Modern otosurgery relies on the use of biomaterials [187, 188]. When new biomaterials are introduced, cell culture studies and animal experiments should be conducted prior to clinical testing. As in other areas of medicine, several generally valid principles should be followed. In the past, the approval process for new biomaterials has included short-term (24-hour) tests on relatively indifferent cell lines (mouse fibroblasts, tumor cell lines) [189]. But a more rational approach would be to expose the material to cells that are as similar as possible to the cells of the proposed implant bed [12, 190, 191]. In our own experiments [192, 193] (Fig. 3.**11**), we have shown that materials can be tested using primary cultures of human osteoblast-like cells from the stapes. In animal studies as well, it should be standard policy to implant the material in an analogous tissue bed [129]. Only animal models allow us to study the complex interaction between an implant and a bed composed of mucosa and bone in an environment that may be normally aerated or may be poorly aerated, moist, or even infected. But even the results of these experiments must be interpreted with caution. Our own control studies with stapes superstructure implants have shown that when the stapes crura in guinea pigs are removed, a new superstructure can form even if no new material has been introduced into the tympanic cavity. Almost all animal studies that have been published on middle ear implants to date have omitted this type of control. These results confirm observations from other disciplines that nearly all laboratory animals have a much greater capacity for repairing bony injuries than our own species. As a result, we must be careful in applying the seemingly good results of new bone formation, fracture healing, and implant integration to humans. For the future, then, the final step in testing must be a controlled trial in human patients, with its attendant risks.

Table 3.**2** Steps involved in the testing of new materials

1.	Cell culture, preferably with human cells from the proposed recipient tissue
2.	Animal studies with implantation in standard tissue (muscle, bone, subcutaneous tissue)
3.	Animal studies with implantation at specific sites and situations (e.g., middle ear, possibly with infection) and sham operation for control
4.	Human trial, preferably with a control group using an established procedure

For various reasons, all defects that occur in and around the middle ear cannot be reconstructed with autologous grafts. Common principles apply to many of the biomaterials in current use. For example, many otosurgeons recommend interposing thin, disk-shaped cartilage grafts between the implant and the tympanic membrane (or autologous reconstructed tympanic membrane). This recommendation applies in cholesteatoma surgery, adhesive processes, and stabilization of the atrophic tympanic membrane, regardless of the type of implant used [194]. The thin tympanic membrane, which is supplied by blood

Table 3.**3** Evaluation of biomaterials for various otosurgical indications (Department of Otolaryngology, University of Essen)

	Stapedioplasty	Ossiculoplasty	Canal wall reconstruction	Cavity obliteration	Drainage of tympanic cavity
Steel/tantalum	+	–	–	–	–
Gold	–	–	–	–	+
Titanium	+	+	–	–	+
Platinum	+	–	–	–	–
Teflon	+	–	–	–	+
Al_2O_3 ceramic	–	+	–	–	–
Glass ceramic*	–	+	–	–	–
TCP ceramic	–	–	–	+	–
Hydroxyapatite	–	+	+	+	–

* Bioverit

vessels at its periphery, appears to be particularly sensitive to contact with foreign materials, and there is a tendency for defects to form in the contact area between the implant and the tympanic membrane. The surface characteristics of an implant, and especially its surface structure, have a major impact on the quality of the interface between the implant and its biological surroundings. Micropores promote the fixation of the material, while polished surfaces inhibit it.

In otosclerosis surgery, Teflon has established its value as a piston material for stapes prostheses. This appears to be due partly to the fact that Teflon, when used as a stapes piston, has a very small area of contact with middle ear structures. A property that is otherwise unfavorable for middle ear implants—low surface energy with a consequent lack of surface epithelialization—is advantageous for an oval window implant, as it tends to prevent implant adhesions and keep the implant mobile. Materials that appear to have excellent properties in the middle ear can be harmful when they come into contact with the inner ear. For example, while pure gold has been established as a safe and effective material for ossicular implants, it is less suitable as a stapes piston based on reports of postoperative sensorineural hearing loss [32].

In our department, bioinert ceramics have become the material of choice for tympanoplasties. They are easily tailored to individual situations, they are rigid, and they are resistant to infection. Titanium prostheses have also found an established place in ossicular reconstruction, and they are a favourable choice under many specific circumstances. The latter have the advantage of lighter weight [195]. It should be noted, however, that the suspension or attachment of the implant is also an important factor [196]. When these materials are covered by thin autologous cartilage, extrusions are rare. Plastics are obsolete for ossicular reconstruction. They consistently incite foreign body reactions and have a high extrusion rate. Prefabricated glass ionomer implants had little opportunity to demonstrate their value for this application. The improper use of liquid glass ionomer cement caused them to be banned along with that material. The more judicious use of glass ionomer cement, scrupulously avoiding contact with the CSF, would probably have given us a very useful bone adhesive for the reconstruction of tiny ossicular defects. The fixation of grafts or implants to the stapes footplate continues to be a problem for which an adequate solution has not yet been found.

Porous hydroxyapatite can be used to reconstruct the canal wall and obliterate the excavated mastoid cavity in cases where sufficient autologous material is not available.

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4 Principles of an Individualized Approach to Cholesteatoma Surgery

H. Hildmann, H. Sudhoff, and K. Jahnke

Abstract

Basic Principles of Cholesteatoma Surgery. The behaviour of middle ear cholesteatoma appears to depend on the pathogenesis and the specific location of its origin. As well as the classical acquired form of cholesteatoma, we discuss subgroups such as the congenital form of the disease, posttraumatic and external meatal cholesteatomas. The impact that basic research has had on cholesteatoma surgery, the scientific knowledge of tissue interactions and controversies on the reuse of ossicles are presented and discussed. Available data on cholesteatoma epidemiology and the possible influence of tubal function will be considered. The basic principles of individualised cholesteatoma surgery are pointed out, specifically the treatment of the posterior canal wall and the surgical options available depending on the site of predilection and the pneumatisation characteristics. In general, the most important surgical principle of following the cholesteatoma epithelium is emphasised. Open-cavity surgery, treatment and replacement of the ossicular chain, the most frequently occurring mistakes and revision surgery are discussed. Complications such as exposed dura, labyrinthine fistula, exposed facial nerve, sinus thrombosis, extradural abscess/subdural abscess, meningitis and brain abscess are presented. Specific problem areas in cholesteatoma surgery such as surgery in the only hearing ear or in the paediatric age group are also discussed.

Introduction

This paper examines the principles of an individualized approach to cholesteatoma surgery from the perspective of two neighboring hospitals who both have their origins in the Plester school. In 1979, Plester gave a lecture in Berlin in which he reviewed the various techniques of cholesteatoma surgery and discussed their relative merits [1]. At that time, the results of long-term studies of cholesteatoma operations at the Tübingen hospital had already led to a more differentiated approach in selecting patients for an open (canal wall-down) or closed (intact canal wall) operative technique [2]. The indications for these techniques have been fairly well appreciated since the 1980s (see below). Other long-term studies have shown that results were significantly better in terms of function and freedom from recurrence, although they are still far from satisfactory. This has confirmed our conviction that, given the varied pathogenesis and extent of cholesteatomatous diseases, there can never be only one approach to cholesteatoma treatment. Below we shall present new discoveries on the pathogenesis of cholesteatoma, which have an important bearing on our clinical management of this disease.

The decision to use a particular surgical technique in any given case will depend on the preoperative and intraoperative findings and also on the personal experience of the surgeon. This includes his or her assessment of the extent to which the pathogenetic factors still exist. An intriguing aspect of this assessment is the fact that the experience and opinions at our centers differ markedly in several respects, and these different viewpoints will be noted where relevant.

Definition

For the surgeon, cholesteatoma is defined as the ingrowth of squamous epithelium into the middle ear compartments and its continued growth that destroys tissues in the middle ear and adjacent structures. The precursors of cholesteatoma may include retraction pockets, adhesive processes and associated crevices, and surgical cavities. **The propensity of cholesteatomas to erode bone and the lack of effective, nonsurgical management add significance to the understanding of this disease.**

Classification

The traditional classifications of cholesteatomas are based essentially on the different theories of their pathogenesis.

Congenital Cholesteatomas

Cholesteatomas that develop behind an intact tympanic membrane are classified as primary or congenital. According to Derlacki and Clemis, criteria for diagnosing a congenital cholesteatoma are an intact tympanic membrane, no previous ear operations or injuries, no irritation of the middle ear mucosa, and a negative history of otitis [3]. Recurrent bouts of otitis do not exclude a congenital cholesteatoma, however, because both diseases may coexist independently of each other. Levenson et al. [4] therefore extended the diagnostic criteria to include patients with prior otitis media. Tympanic membrane perforation, otorrhea, and otosurgical procedures are the criteria that exclude congenital cholesteatoma [4]. Congenital cholesteatomas that occur in the middle ear or in other regions of the petrous bone and are diagnosed early will show no contact with the epidermis of the tympanic membrane.

Pathogenesis of Congenital Cholesteatomas

Various explanations have been advanced on the pathogenesis of congenital cholesteatoma. Besides the migration of epithelial cells through the intact tympanic membrane, the reflux of amniotic cells, the metaplasia theory, and aberrant embryonic cell rests, it has been suggested that congenital cholesteatomas may develop from "epidermoid formations" (EF) that persist from the embryonic period [5–11].

Acquired Cholesteatomas

Secondary cholesteatomas generally result from the ingrowth of squamous epithelium through a primary defect in the tympanic membrane or through retraction pockets that are no longer self-cleaning.

Pathogenesis of Acquired Cholesteatomas

The pathogenic mechanism of acquired cholesteatoma is variable. Despite many new discoveries, a definite pathogenesis cannot be established in all cases. Four classic theories have been advanced on the pathogenesis of acquired cholesteatoma.

1. The migration theory, marked by the ingrowth of squamous epithelium into the middle ear through a peripheral defect in the tympanic membrane [12, 13].
2. The retraction pocket theory, which states that cholesteatomas develop from a retraction pocket forming as a result of chronic eustachian tube dysfunction [14].
3. The basal cell hyperplasia theory, in which the cholesteatoma results from the invasive papillary growth of keratinocytes in the stratum basale [15, 16].
4. The metaplasia theory, which postulates a metaplastic transformation of the epithelium of the middle ear mucosa into the cholesteatoma matrix [7, 17]. While most cholesteatomas are readily assigned to the first three theories based on their clinical presentation [1, 2] and histologic features [3], the metaplasia theory has neither been confirmed nor refuted by the latest molecular biological studies.

Recently, Sudhoff and Tos proposed a combination of the invagination and basal cell theories as an explanation for retraction pocket cholesteatoma formation [30]. Furthermore, breaks in the basement membrane could allow the invasion of epithelial cones into the subepithelial connec-

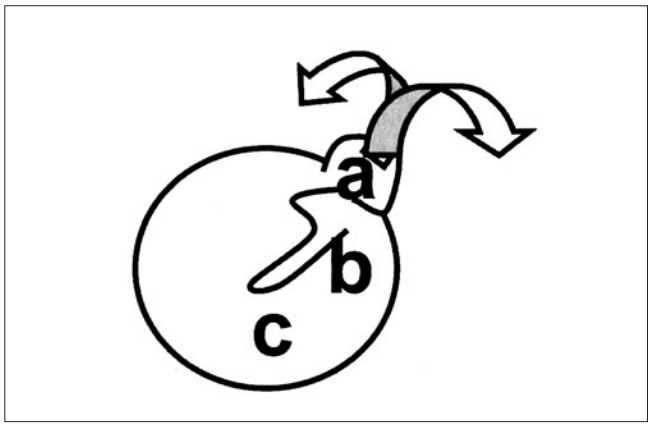


Fig. 4.**1** Tos system for the surgical classification of cholesteatomas.
a Attic cholesteatoma.
b Sinus cholesteatoma.
c Pars tensa cholesteatoma

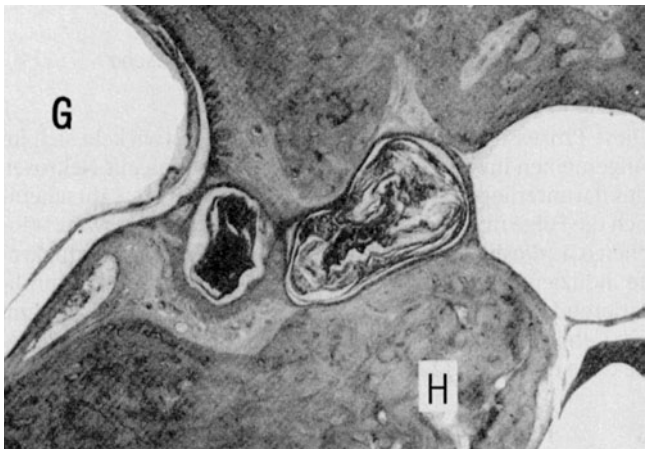


Fig. 4.**2** Histologic specimen of an attic (epitympanic) cholesteatoma. G = ear canal, H = malleus handle (H&E stain, 20×, Lange petrous bone collection, Leipzig).

tive tissue and the formation of microcholesteatomas. This mechanism may explain some types of human cholesteatomas, even those occurring behind an intact tympanic membrane [104].

Surgical Classification

Ernst Müller of Kiel proposed a classification that, while based on the classic pathogenetic theories, was more useful from a surgical standpoint. He distinguished between epitympanic, mesotympanic, and pantympanic lesions. Tos later modified the Müller classification to better suit otosurgical requirements (Fig. 4.**1**) [18].

Attic Cholesteatoma

This is an epitympanic cholesteatoma involving a retraction or perforation of the Shrapnell membrane with extension into the epitympanum (attic) or to the aditus ad antrum. There may be further extension into the mastoid or retrograde growth into the mesotympanum (Fig. 4.**2**).

Sinus Cholesteatoma

Sinus cholesteatoma arises from a retraction or marginal perforation in the posterior superior quadrant of the tympanic membrane, with extension to the region of the stapes, sinus tympani, and mesotympanum. The aeration block is usually located in the area of the malleus handle. Generally the anterior middle ear cavity and mastoid are not involved.

Pars Tensa Retraction Cholesteatoma

This lesion arises as an adhesive process from a large perforation in the pars tensa, with possible extension into the eustachian tube orifice and epitympanum (Fig. 4.**1**).

Plaquelike Cholesteatoma

"Epidermosis" is a special condition in which epithelium spreads onto the inner surface of the tympanic membrane. Tran Ba Huy attributes this to perforations located directly in front of the malleus handle [19]. The epithelium then grows directly onto the bone, as in the case of a peripheral defect. The distinctive feature of this lesion is its plaquelike pattern of growth. It is easier to dissect off the affected surface than cholesteatoma matrix located elsewhere. Even with small perforations, however, large portions of the tympanic membrane should be resected to ensure adequate epithelial removal.

Posttraumatic Cholesteatoma

This type of lesion results from the iatrogenic or traumatic implantation of epithelium into the middle ear cavity.

Postoperative Cholesteatoma

For evaluating surgical results and deciding further management, it is important to distinguish between residual cholesteatoma, which arises from squamous epithelium not removed in the first operation, and recurrent cholesteatoma [1, 2, 18, 20]. The latter develops postoperatively as a new lesion due to persistence of the original pathogenetic factors.

Ear Canal Cholesteatomas and Aseptic Bone Necrosis

External ear canal cholesteatomas are an entity that generally develops in the area of the canal floor, with necrosis of the underlying bone [21]. Many of these lesions probably result from mechanical manipulations (e. g., cotton swabs) that incite a periostitis leading to bone necrosis.

Chronic inflammation, the actively proliferating epithelium, and the accumulation of keratin debris can cause an ear canal cholesteatoma to develop on the basis of osteonecrosis [22].

Histologic Features and Surgical Implications

Cholesteatoma is accompanied by a chronic inflammatory process characterized by a progressive growth and by the subsequent destruction of epithelial and bony structures of the middle ear. The mechanisms and factors that underlie the hyperproliferative behavior of cholesteatoma epithelium are not yet fully understood. Several studies have shown alterations in the proliferation, differentiation, and migration of keratinocytes in the cholesteatoma matrix along with the activation of perimatrix fibroblasts [23–29]. This process is perpetuated by the accumulation and breakdown of cellular debris on the epithelial side of the squamous epithelium that has invaded the middle ear spaces. Removal of the debris is beneficial, as it creates a site where a number of different factors that induce cholesteatoma growth are synthesized and released. From a surgical standpoint, it is important that the squamous epithelium of the cholesteatoma is basically similar to the epithelium of the external ear canal. If free drainage and free aeration can be established by surgical means (and formerly by irrigation treatments), the process will lose its aggressiveness. Hence there is no objection to using the epithelium to line a mastoid cavity, for example, provided it is free of deep papillary extensions (Fig. 4.**3**) [1, 30].

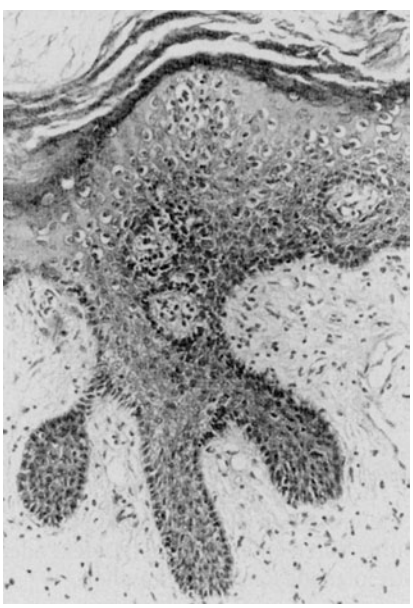


Fig. 4.**3** Hyperkeratotic epithelium (matrix) showing invasive papillary growth (H & E stain, 200×).

Tissue Interactions

Growth factors and cytokines play a major role in cellular interactions, especially in the regulation of cell growth and differentiation. Most cells in the human body seem capable of forming these regulatory peptides, depending on their state of activity [28]. An overexpression of various growth factors and cytokines has been described for benign "hyperproliferative" diseases such as psoriasis and for a variety of malignant tumors [25, 27].

Invasive Cholesteatoma

The "aggressive" behavior of the cholesteatoma matrix appears to be influenced by the release of cytokines and growth factors from cells of the inflammatory infiltrate [23, 25, 28]. The authors, too, have documented an increase in the proliferative behavior of cholesteatomas that show a clinically "aggressive" type of growth [25, 27].

Clinical Conclusions

Treatment of Retraction Pockets

Cholesteatoma may develop clinically from a retraction pocket, later spreading to the epitympanum, sinus tympani, or middle ear cavity as a pars tensa cholesteatoma. Only a small number of retraction pockets develop into a cholesteatoma. Papillary ingrowth through the floor of the retraction pocket may occur in response to internal (e. g., otitis media) or external inflammatory stimuli (e. g., otitis externa, accumulation of debris) [30]. Apparently this process does not occur as long as the retraction pocket retains its self-cleaning ability and the keratin is sloughed off. For this reason, retraction pockets should be regularly cleaned and inspected to assess their integrity [30].

Squamous Epithelium in the Open Mastoid Cavity

Squamous epithelium in the open mastoid cavity generally does not show destructive clinical behavior like cholesteatomatous epithelium. Clearly, this is due in large part to the adequate external drainage of desquamated epithelium and is based on an effective self-cleaning mechanism. This mechanism is less susceptible to potential disturbances when located a greater distance from the external ear canal.

Auditory Ossicles

In a 1972 histologic study by Hildmann and Steinbach, auditory ossicles removed in cholesteatoma patients showed rarefying inflammatory changes in approximately half of cases, precluding their reuse for reconstruction of the sound conduction apparatus [31]. The changes were not due to destruction by invading squamous epithelium but to an inflammatory resorption of the subepithelial bone and the bone around the haversian canals. The auditory ossicle loses its stability in these cases. Of course, the firmly

adherent keratinizing squamous epithelium also prohibits ossicle reuse, as this would reimplant cholesteatoma cells into the middle ear.

An exception is the stapes superstructure, which should be removed with crurotomy scissors only in exceptional cases. If the matrix cannot be removed with absolute certainty, a second look will be necessary at a later date. We feel that the body of the incus and the malleus handle can be reused on condition that their bony elements are not covered by cholesteatoma matrix and the ossicles do not crumble when grasped with a forceps for grinding. Previous follow-ups of our patients support this policy. Frese and Hoppe made similar observations [32]. Like Helms [33], however, they feel that structural changes basically preclude reusing ossicles for chain reconstruction, not just with cholesteatoma but also in cases of chronic mucosal suppuration.

Epidemiology

Although cholesteatoma is a focus of interest in otologic research, only a few studies have been published on its epidemiology. Older studies by Nager in 12 000 patients with chronic otitis media showed that cholesteatomatous disease was present in one-third of all the patients examined [34]. Further studies by Harker documented an annual incidence of 6 cholesteatomas per 100 000 population in Iowa [35]. The prevalence was 0.01 %. The peak incidence of the disease was between the second and third decades. In Denmark, Tos found an annual incidence of 3 cholesteatomas in children and 12.6 in adults per 100 000 population [36]. Studies on the epidemiology of cholesteatoma were also conducted in Greece. These studies showed no impact of socioeconomic factors on the incidence and prevalence of cholesteatoma. A recent study from Finland showed an average annual incidence of 9.2 per 100 000 population, with no apparent increase in low socioeconomic groups [37]; 72.4 % of the patients had a history of recurrent otitis media. In another epidemiologic study from Denmark covering the 5-year period from 1979 to 1983, Jensen et al. [38] found an annual incidence of 10.9 per 100 000 population. The resulting estimated cumulative risk per 1000 was significantly higher for men (1.1 %) than for women (0.7 %). Cholesteatoma is especially prevalent in individuals with chronic eustachian tube dysfunction, and it is 20 times more common in individuals with cleft palate than in the normal population [39]. Kim found that the prevalence in South Korea was relatively high, at 0.5 %, but was extremely low among the Inuit Eskimos of Greenland, at only 0.005 % [40]. This contrasts with the markedly high incidence of 1.1 % in the children of Alaskan Eskimos [41]. The 0.1 % incidence in the offspring of Australian Aborigines is also quite high [42]. In Thailand, cholesteatoma appears to be a rare disease with a declining incidence. This has been attributed to the improved management of acute otitis media in that population [43].

Reportedly, 10–17 % of cholesteatoma patients have involvement of the contralateral ear [44]. This means that the disease risk is increased by a factor of 100–1000 compared with the normal population. Our own studies showed a 14 % incidence of cholesteatoma in the opposite ear [2]. On the other hand, bilateral cholesteatoma appears to be quite rare in the Afro-American population [45]. The National Center for Health Statistics reported a relatively low prevalence of 4.2/100 000 population for the year 1978 [46]. We know of no epidemiology studies from the German-speaking countries, but it is reasonable to assume that population structure, ethnic composition, and the availability of specialized otologic care significantly affect the incidence and prevalence of cholesteatoma.

Diagnosis

History

The prior history is often nonspecific. Patients may complain of periodic or constant aural discharge. Pain is somewhat unusual. The degree of hearing loss is highly variable. A cholesteatoma may develop insidiously for some time without otorrhea and may be detected incidentally in an ear examination. Involvement of the vestibular labyrinth, cochlea, or facial nerve will produce vertigo, sensorineural hearing loss, tinnitus, or facial palsy. Intracranial complications are extremely rare in the absence of premonitory signs and symptoms.

Otoscopy

After secretions have been aspirated and the ear cleansed, the external canal and tympanic membrane should be examined with an otomicroscope. With a typical epitympanic or attic cholesteatoma, a perforation (usually peripheral) can be seen in the tympanic membrane. Polyps, especially when located at the posterior superior margin of the membrane or in the epitympanum, can occasionally provide evidence of disease even when squamous debris is not visible. With a sinus cholesteatoma, an atrophic scar is often seen over the incudostapedial joint, indicating the mechanism by which the lesion developed. The scar is retracted and enlarged from the accumulation of epithelial debris. With the less common pars tensa cholesteatoma, the periphery of the tympanic membrane is intact. Whitish areas may signify a cholesteatoma behind an intact tympanic membrane. Residual cholesteatoma should be excluded in patients who have had previous surgery.

“Genuine” cholesteatomas occur outside the middle ear cavity and are associated with a normal-appearing tympanic membrane. Wullstein pointed out in a commentary that vague dizziness may be the only presenting symptom of a perilabyrinthine lesion. In children, a middle ear effusion can mask a cholesteatoma located behind an intact tympanic membrane. Mastoid cavities that cannot be clearly inspected may contain extensive cholesteatomas. Ear canal cholesteatomas are located on the meatal floor and generally are easy to identify. They can mimic a tumor of the external ear canal. Epithelial cysts are occasionally found postoperatively in the ear canal entrance, having been caused by the iatrogenic implantation of epithelial cells. Usually they are removed with a sickle knife under magnification while the patient is still in the examination chair.

Endoscopy

Endoscopy can supplement the preoperative microscopic diagnosis in selected cases. It can be used, for example, in deciding whether a retraction pocket or a spontaneous cavity requires operative treatment. With a central perforation, it may even be possible to evaluate the auditory ossicles under favorable conditions. Endoscopy with fine scopes passed through the eustachian tube [47] is not widely practiced in current otologic surgery. As resolution improves, it will become an important future tool for detecting or excluding residual cholesteatoma. We also use Hopkins telescopes intraoperatively (see below).

Microbiology

The principal organisms that superinfect cholesteatomas are *Pseudomonas aeruginosa, Staphylococcus aureus, Proteus* species, and anaerobes [48–51]. Tests at the ENT hospital in Bochum have shown that coagulase-negative staphylococci can be identified in many cases. The cholesteatoma sac is colonized by a mixed aerobic-anaerobic flora, usually consisting of two or three different organisms [50]. Contamination by ear canal flora should be avoided when smears are taken for bacteriologic analysis. Prospective studies conducted at the Ruhr University ENT hospital in Bochum involving children and adults with a clinically and otomicroscopically normal ear canal have shown that a variety of organisms including coagulase-negative staphylococci, apathogenic corynebacteria, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* (!) can be identified. This means that the latter, gram-negative organism can occur as a harmless saprophyte [51]. Fungi have also been identified in some cholesteatoma smears [48, 52–54].

Antibiotic Therapy

The treatment of choice in cholesteatoma patients is a microsurgical procedure on the diseased ear. Antibiotics are of no value unless used to treat complications or postoperative inflammation. If the otolaryngologist decides to administer antibiotic therapy as a prelude to cholesteatoma surgery, it should be based on sensitivity results. Anaerobes are found in virtually all otogenic brain abscesses that arise from cholesteatoma, and *Bacteroides fragilis* is consistently identified [54]. These cases should be treated with a combination of three agents such as cefotaxime, flucoxacicillin, and clindamycin (or metronidazole) [54]. Perioperative antibiotic prophylaxis is not routinely used in Bochum, but in Essen it is used regularly in cholesteatoma patients.

Fistula Sign

When a semicircular canal has been eroded by cholesteatoma (the lateral semicircular canal in more than 90 % of cases), dizziness can be evoked by raising or lowering the pressure in the external ear canal. Usually a Politzer bag and Frenzel goggles are used in this examination. A negative fistula sign does not exclude erosion of the semicircular canal, however [55, 56]. In the 56 ears described by Kleinsasser and Jahnke that were found to have a semicircular canal fistula at operation, only 61 % showed a positive fistula sign. Ten of these patients already had sensorineural deafness preoperatively. Other patterns may be seen such as complete destruction of the lateral semicircular canal with no fistula sign and preservation of hearing. These cases probably result from ossification of the semicircular canal, walling off the rest of the intact inner ear [56]. With extensive destruction of the posterior meatal wall or after previous surgery, the fistula sign can be evoked by pressing on the exposed fistula site in the semicircular canal with an instrument.

Audiometry

Pure-tone threshold audiometry should be performed, supplemented by the classic Weber and Rinne tuning-fork tests. If there is an interaural discrepancy of inner ear function, especially when due to severe inner ear damage on the affected side, masking by the audiometer is often not sufficient. Loud speech testing of the affected ear with headphone masking of the opposite ear is the key practical test for evaluating the functional capacity of the ear and thus the potential to improve hearing. Significant hearing improvement cannot be achieved if loud speech is not understood. In preoperative discussion with patients who have a small conductive component, it should be mentioned that the cholesteatoma may be conducting sound ("hearing through the cholesteatoma") and that it may be necessary to interrupt an intact chain due to involvement by the cholesteatoma or its direction of growth. Speech audiometry can improve the yield of scientific information. Objective audiometric tests, especially brainstem audiometry, can furnish additional information in small children and handicapped patients. The measurement of otoacoustic emissions does not add to the study, however.

Evaluation of Eustachian Tube Function

There are no methods in routine otosurgery for detecting an abnormality of eustachian tube function that could provide an indication for operative treatment. Eustachian tube (ET) dysfunction is more commonly observed in patients with craniofacial malformations, especially cleft palate, and with insufficiency of the orofacial muscles due to neurologic disease. An example is Down's syndrome, in which a craniofacial malformation and orofacial dysfunction lead to impairment of tubal function [57]. Even minor anatomic variations in the midfacial region can affect aeration in the nasopharynx, with consequent effects on tubal ventilation. For example, we found that in patients with a narrow midface, the distance between the premolars correlates with eustachian tube width, and that a high palate is associated with a short septum with a decreased nasal cross section [58]. Koch found that tubal patency was reduced in two-thirds of patients with adhesive processes [59]. He also showed that one factor contributing to middle ear aeration was the elastic resiliency of the tympanic membrane. From a present-day perspective, cases of this kind would be an indication for a tympanoplasty with cartilage [59, 60]. The

role of eustachian tube dysfunction in the development of cholesteatoma is still uncertain, especially when we consider the long-term observations by Tos. In 6-month follow-ups of 123 patients at the Bochum hospital, the patients with cholesteatoma had a recurrent perforation rate of 3.1 %. This is lower than the rate reported in the literature and less than the frequency of recurrent perforations that we have seen in chronic suppurative mucosal disease. These perforations were not caused by residual or recurrent cholesteatomas, which generally cause later manifestations. We take this as evidence that eustachian tube function is less impaired by cholesteatoma in patients with chronic middle ear disease. Also, our clinical observations have shown that the aeration block is located between the malleus handle and promontory, especially with sinus cholesteatoma, while the protympanum is well aerated. In the future, greater attention should be given to the diverse pathogenesis of cholesteatomas in the preoperative evaluation of patients. Recently, Hasebe and coworkers carried out a study to establish which type of cholesteatoma is controllable by conservative treatment from the viewpoint of mastoid ventilation. Their clinical observations suggest that progressiveness of cholesteatoma is related to the ventilatory conditions in the mastoid rather than ET function, and that conservative treatment may be effective when ears with cholesteatoma have aeration in the mastoid [103].

Nasal Surgery Preceding Cholesteatoma Surgery

Koch and Opitz [61] and Laszig [62] showed over a decade ago that nasal surgery affects tubal ventilation. Gronemeyer has confirmed this in yet-unpublished studies. Nevertheless, the summary recently published by Mayer and Krebs applies equally well to cholesteatoma surgery [63], i.e., the indication for surgery of the nasal turbinates or septum prior to cholesteatoma surgery should be decided on a case-by-case basis. We feel that this also applies to surgery for paranasal sinus disease. In cases where surgery is elected for significant nasal airway obstruction, conditions for tubal ventilation are more favorable if time is allowed (2–3 months) for the effects of the nasal or paranasal sinus surgery to subside completely. Occasionally, however, we perform the nasal and ear surgery in one stage to avoid a second hospital stay and a second general anesthesia, especially if the patient desires it. Our case numbers are still too small for statistical analysis, but our clinical impression is that one-stage operations are not associated with significant healing problems.

Imaging Procedures

We feel that the Schüller radiograph is still the most valuable tool for the preoperative evaluation of cholesteatoma. It provides information on the position of the middle cranial fossa and sigmoid sinus and the extent of mastoid pneumatization. This aids in planning the surgical approach. With poor mastoid pneumatization, canal-wall-up techniques should not be used. If the floor of the middle fossa is low, the surgeon using a canal-wall-up technique cannot see the interior of the epitympanum. Also, the location of the sigmoid sinus should be noted so that it can be avoided during drilling. The extent of the disease process is difficult to assess on the Schüller radiograph, but generally there is no need for an additional imaging procedure.

The indications for high-resolution CT of the petrous bone are listed in Table 4.**1** [64]. This study can define the extent of large cholesteatomas and of genuine cholesteatomas located outside the middle ear cavity. Semicircular canal fistulas and areas of bone destruction can be clearly identified. Sites of ossicular chain destruction can also be detected when careful technique is used. This is unimportant for routine surgical procedures, however.

Table 4.**1** Indications for preoperative CT in cholesteatoma patients

Landmarks obscured due to previous surgery
Labyrinthine fistula
Facial palsy
Intracranial complications
Congenital cholesteatoma
Coexisting pathology (e. g., following a laterobasal fracture)

Unfortunately, cholesteatomas do not have a very characteristic appearance in MRI. They may show a relatively low or high signal intensity on T1- and T2-weighted images. Peripheral enhancement may be seen on T1-weighted spin-echo images after gadolinium injection, due to granulation tissue surrounding the cholesteatoma [65, 66]. MRI is helpful in patients with intracranial complications or extensive destruction, and it can aid in differentiating cholesteatomas from cholesterol granulomas and tumors [67].

Surgical Techniques

Anesthesia

Cholesteatoma surgery in most adult patients can be performed with sedation and local anesthesia. With good injection technique, the surgery can extend as far as the internal auditory canal. The sedation protocol should be discussed with the anesthesiologist. After general analgesia has been provided and continuous drip infusion has been started with ECG monitoring with pulse oximetry, a standard local anesthetic with epinephrine is injected. Generally, no more than 8 mL of the local anesthetic is necessary. First the aural crease is infiltrated, and then additional retroauricular injections are made toward the external ear canal in a fan-shaped pattern. Finally the canal itself is directly anesthetized, injecting a 0.25-mL depot at the 12, 3, 6 and 9 o'clock positions. Some pressure should be applied when injecting the solution. In revisions, the quality of the anesthesia should be rechecked just before the start of the operation, since additional anesthesia cannot be given once the bone has been exposed. In the middle ear cavity, a 4 % local anesthetic solution that acts on the mucosa can

occasionally be of some help. Children, handicapped patients, anxious patients, and patients with severely scarred or inflamed ears should be operated under general anesthesia. Halothane is no longer used for induction of general anesthesia. Supplementary local anesthetic with epinephrine can be applied as needed [68, 69].

General Surgical Techniques

The basic goal of cholesteatoma surgery is to remove the squamous epithelium as completely as possible to minimize the risk of recurrence. In principle, cholesteatoma is a life-threatening disease because, without surgery, there may be intracranial complications leading to death. This means that when disease is extensive, it may be necessary to sacrifice even functionally important structures like the auditory ossicles and accept the limited risks posed to the inner ear by, say, a labyrinthine fistula or intralabyrinthine cholesteatoma.

Below we shall describe the surgical techniques used by the authors, which are based largely on the techniques developed by Plester [1]. Many other variations are possible and will give consistently good results in the hands of those experienced in the techniques. The excellent books by Tos, Helms, Plester et al., and other surgical textbooks may be consulted for a broad overview of available techniques [18, 33, 69].

Approaches

We generally favor the retroauricular skin incision for cholesteatoma surgery (Figs. 4.**4**, 4.**5b**). It provides sufficient room for working on the bone and especially for extensive debulking measures in the mastoid region. Early provisions can be made for cavity obliteration with a Palva flap. The greater the degree of pneumatization and the greater the extent of cholesteatoma ingrowth into the mastoid, the greater the importance of the retroauricular approach. At the Essen hospital, the endaural approach is preferred in cases where the mastoid is poorly pneumatized. For more extensive measures, the incision may have to be extended superiorly or even carried around the auricle (Figs. 4.**4**, 4.**5a**).

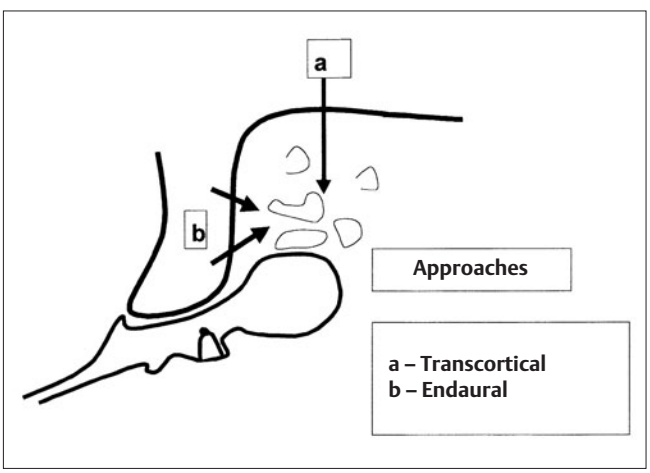
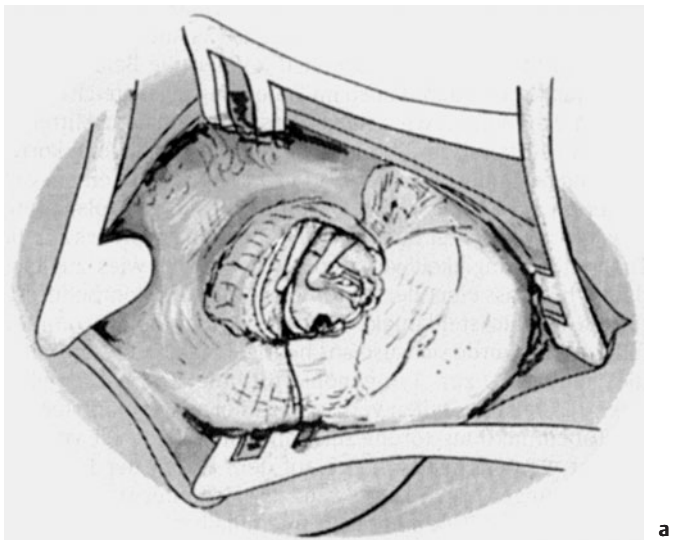


Fig. 4.**4** Routes of approach in cholesteatoma surgery: retroauricular-transcortical and endaural.



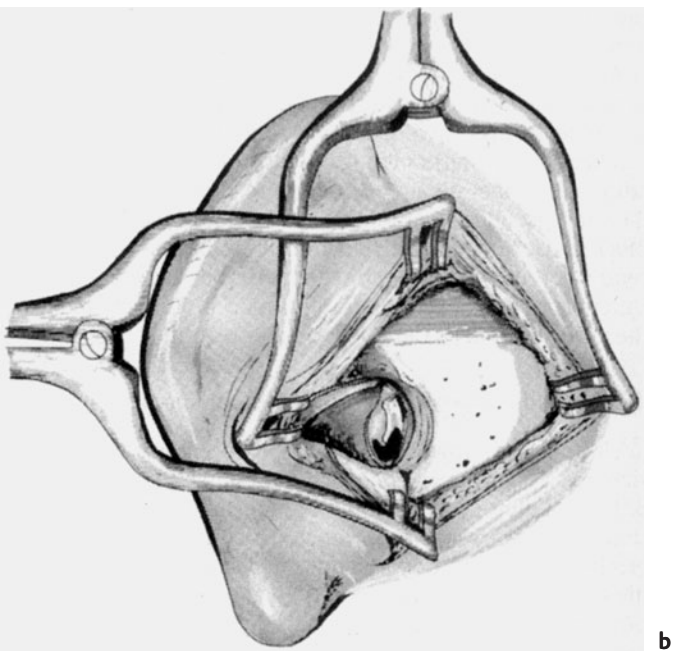


Fig. 4.**5** **a** Operative field in the endaural approach. Two retractors maintain exposure of the field. **b** Retroauricular approach. Two sharp retractors are used.

A broad approach ensures good exposure. Thus, after a broad tympanomeatal flap has been outlined and raised, bony overhangs and prominences that restrict access to the external ear canal should be burred down so that the tympanic membrane and a defect in the lateral attic wall can be clearly visualized (Fig. 4.**5b**).

Open and Closed Operative Techniques

The main goals of surgery are an ear that is easy to care for and is free of recurrent or residual cholesteatoma. Hearing improvement is of secondary importance. The basic question is when to use a closed (intact canal wall) technique and when to use an open (canal wall-down) technique. The principal factors that influence this decision are listed in Fig. 4.**6** [2, 75]. It is important to consider the pathogenic factors that were responsible for development of the cholesteatoma and determine whether these factors are still present. Mastoid pneumatization is very important along with the assessment of eustachian tube function, the age and personality of the patient, and the status of the other ear. The choice of technique depends basically on the location and extent of the disease process. The personal experience of the surgeon will also influence the techniques that are preferred in any given case. The results of long-term studies emphasize, however, that cholesteatoma surgery can achieve satisfactory results in the long term only when a variety of disease configurations are met with a variety of surgical techniques.

Clearly defined principles should be rigorously applied at teaching hospitals. Techniques that have a high recurrence rate in inexperienced hands, such as the posterior tympanotomy described by Jansen [70] (see below), should be taught with restraint and practiced under strict instructor guidance.

Definitions: A closed technique is one in which the posterior wall of the ear canal is preserved or reconstructed (canal wall up), and at least an aerated antrum is present behind the canal wall. This ensures that the middle ear cavity has an approximately normal depth, which allows for good vibration of an intact or reconstructed ossicular chain. By this definition, it is immaterial whether the antrum remains aerated, and this will depend on the pathophysiology of the affected ear.

Consider, for example, a technique in which the posterior bony wall of the ear canal is removed and, following mastoidectomy and partial obliteration, the wall is either reinserted or replaced with a large autologous cartilage graft. We do not consider this a closed technique unless there is an adequate aeration pathway to the antrum.

Atticoantrotomy

Small cholesteatomas of the epitympanum or antrum are an increasingly common finding. In these cases we perform an atticoantrotomy and follow the cholesteatoma (in poorly pneumatized bone) from the external ear canal. In doubtful cases, auditory ossicles involved by cholesteatoma should be removed at an early stage, as in the other operative techniques. Hard-to-see crevices should be inspected, unless the surgeon has been able to remove the squamous epithelium as a complete sac. A good number of these cholesteatomas can be freed up under vision by extensive posterior and superior drilling of the bony ear canal.

With normal to moderate pneumatization, a small bur hole can be placed to inspect the antrum and may be extended if necessary to define the extent of disease (Fig. 4.**7a, b**). Occasionally, however, we pass an endoscope through the ear canal to see whether the cholesteatoma has been completely removed, especially from the antrum and sinus tympani and from other sites poorly accessible to direct vision. This can eliminate the need for extra drilling and simplify the reconstruction. If the cholesteatoma can be removed in toto without having to remove large portions of the lateral attic wall, the scutum is reconstructed with tragal cartilage and overlapping perichondrium.

Regarding the size of the tragal cartilage, we worked with Wolfram Kühn and the Pathology Department of Essen University Hospital to measure 460 specimens from 230 adults (142 male, 88 female). We found that the size of the

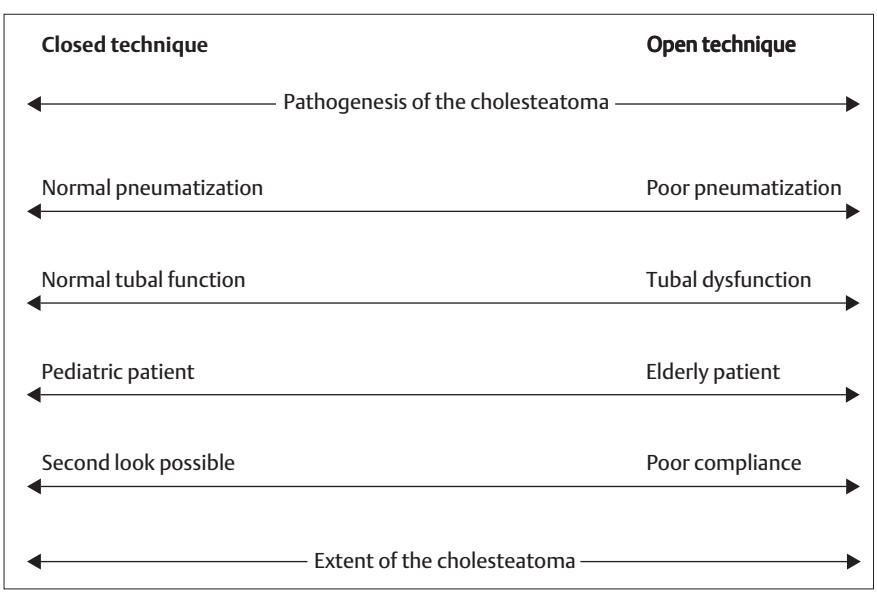
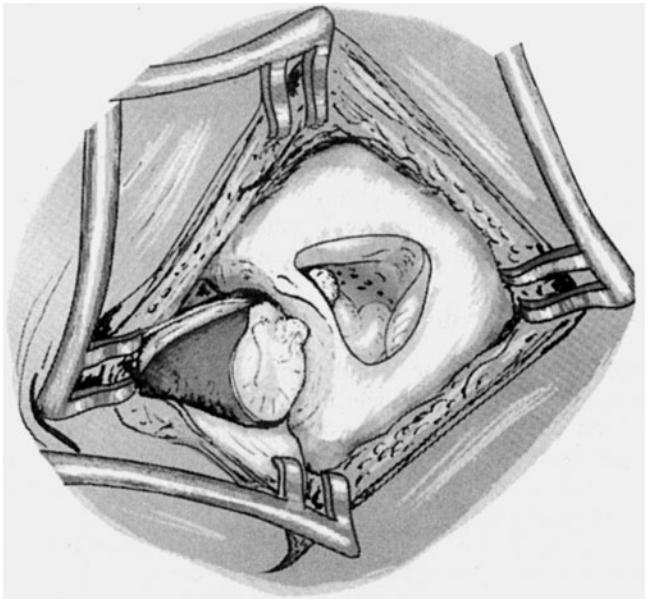
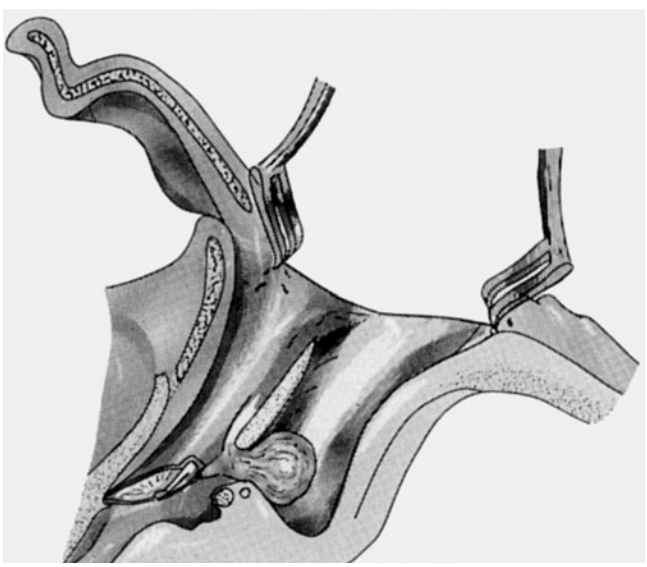


Fig. 4.**6** Criteria for selecting a technique for cholesteatoma surgery [2]. The pathogenesis of the cholesteatoma is an important factor, as is its extent. A large mastoid, normal eustachian tube function, young patients (who often require a staged procedure), and reliable aftercare are criteria for preserving or reconstructing the posterior canal wall. Recurrent cholesteatoma, a small mastoid, a prominent sinus, chronic eustachian tube dysfunction (e. g., in patients with craniofacial anomalies), and uncertain aftercare are indications for creating an open mastoid cavity.



a



b

Fig. 4.7 **a** A spheroidal or bean-shaped cholesteatoma with an intact matrix that has invaded the mastoid can be completely everted into the ear canal and removed from there. **b** For less extensive disease, the procedure of choice is an extended antrotomy in which the incus is exposed and aeration is established from the middle ear cavity to the mastoid process.

tragal cartilage was relatively constant. The smallest tragal cartilage measured 1.5 × 1.4 cm, the largest measured 2.3 × 1.7 cm. The average size was 2.11 × 1.57 cm. That is enough material to cover even relatively extensive defects. For cosmetic reasons, an outer strip of cartilage should always be left in place when the graft is harvested.

The above technique is used in almost 40 % of initial cholesteatoma operations performed at the ENT Hospital at Essen University. For smaller defects, the tragal cartilage used to reconstruct the scutum and the cartilage lamellae or a thinned cartilage island graft are left attached to a large piece of perichondrium, like the cover of a book, to reinforce the posterior superior portion of the tympanic membrane (Fig. 4.**8**). This creates a very stable aeration pathway toward the antrum [64].

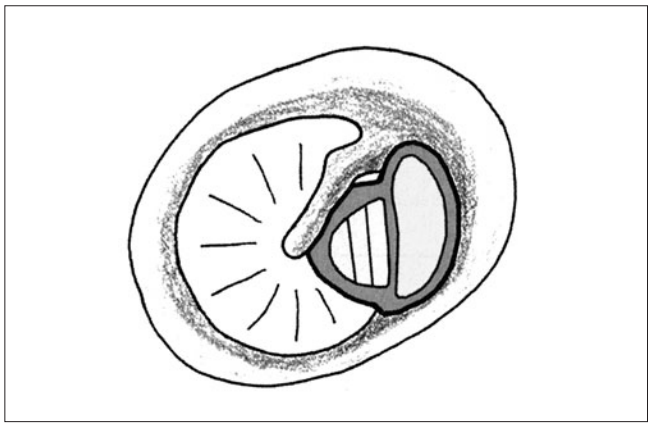


Fig. 4.8 Reconstruction of the scutum after atticoantrotomy. A large piece of tragal cartilage and cartilage lamellae are used to reinforce the posterior superior tympanic membrane plane on a piece of perichondrium, securing the aeration pathway (Jahnke 1987, 1996).

Posterior Tympanotomy

With cholesteatomas that extend far into a well-pneumatized mastoid process, it may be possible to leave the posterior wall of the ear canal intact and to dissect the epithelium forward after gaining access through an extensive mastoidectomy and posterior tympanotomy (Jansen 1962). The goal of this technique is to mobilize the entire cholesteatoma sac forward into the ear canal. In the posterior tympanotomy, the cortex lateral to the sinus plate should also be burred down, as described by Jansen, to improve exposure of the chordofacial angle [70]. We use a posterior tympanotomy in the occasional cases with extensive pneumatization and also for pediatric cholesteatomas. These cases will require a second look 1–2 years later, however (see below).

Closed techniques are almost always preferred for posttraumatic cholesteatoma and congenital cholesteatoma of the mesotympanum. The middle ear spaces are normally aerated in the great majority of these cases. Exceptions include cases in which the fracture line extends into the eustachian tube area.

With the closed techniques, essentially normal conditions are preserved or restored. This requires an anatomy that is amenable to closed techniques, adequate eustachian tube function, and confidence that the cholesteatoma has actually been removed from the mastoid. We almost always use cartilage from the tragus or cavum conchae to reconstruct the posterior canal wall.

Open Mastoid Cavity

An open cavity technique is definitely indicated in patients with a small, poorly pneumatized mastoid or a prominent

sinus location that would preclude a posterior tympanotomy. An intact canal wall technique is also contraindicated if there is evidence that eustachian tube function is impaired, as in patients with craniofacial anomalies or orofacial muscular insufficiency. If there is doubt that all squamous epithelium has been removed from the mastoid, an open cavity should be created. An open technique is also recommended in elderly patients (see below), because an open cavity is safer in cases where aftercare is uncertain. In all of these cases, it is best to create a small, self-cleaning cavity. A "radical cavity" in the traditional sense should be avoided, and the mesotympanum should be protected. An alternative in cases with an intact canal wall is to plan a second look after about one year in children and adolescents, and not before two years in adults. Prior to that time, any residual cholesteatoma is still quite small and may be difficult to identify.

Generally the decision for an open or closed technique is made preoperatively. But with lesions that are inaccessible to vision, it may have to be decided intraoperatively whether to preserve, temporarily remove, or destroy the posterior canal wall and often the superior wall as well. As the disease process is traced from the ear canal, the posterior and/or superior wall of the canal is burred down until the process is adequately exposed. This technique is justified in moderately to poorly pneumatized mastoids. The latter are best for obtaining an easy-to-clean mastoid cavity that is safer from residual and recurrent cholesteatoma. By contrast, a heavily pneumatized mastoid poses a formidable surgical challenge and creates less favorable conditions for obtaining a dry cavity after the surgery.

The most important measures for obtaining *a small, self-cleaning open mastoid cavity* are as follows:

A very *broad ear canal entrance* is of prime importance. We achieve this mainly by resecting a generous amount of cartilage from the cavum conchae. With its adherent posterior layer of perichondrium, this cartilage is an excellent material for partial cavity obliteration or sealing. The resection should be done early in the operation, using a fresh scalpel blade, and the bony canal entrance is widened with a grinder. The remaining steps are carried out at the end of the operation (Fig. 4.**9a–d**).

In all cases the cortex should be drilled back along with the outer portion of the os tympanicum. After the cholesteatoma has been removed, the facial ridge is lowered. This should include the inferior part of the ridge toward the mastoid tip. Next, all bony overhangs and cellular septa are smoothed with a diamond bur. All of these measures are generally sufficient when the mastoid process is poorly pneumatized (Fig. 4.**10**).

With extensive mastoid pneumatization, additional measures are required. Above all, the cortex should be drilled down to the level of the sigmoid sinus. This will significantly reduce the size of the cavity. Bone that is not contaminated by cholesteatoma can be collected for reuse, as it makes an excellent material for subsequent partial oblit-

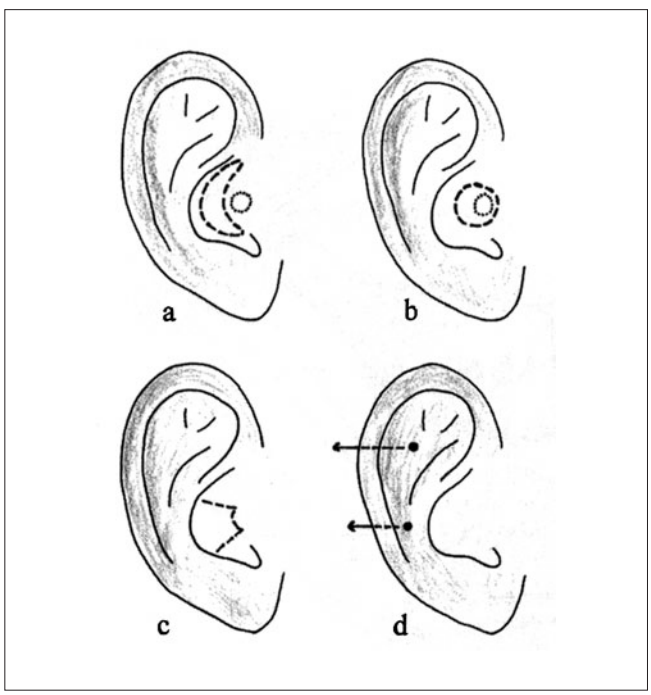


Fig. 4.**9** Techniques for widening the ear canal entrance. **a** Following a retroauricular incision, excess connective tissue and cartilage are removed from the cavum conchae. **b** The canal entrance is burred open, including the bony canal wall, without opening the mastoid air cells. **c** The skin of the canal entrance is incised posteriorly, leaving a posterolateral pedicle. **d** The concha is pulled back with heavy subcutaneous sutures and fixed to the periosteum, and the widened meatal entrance is tightly packed.

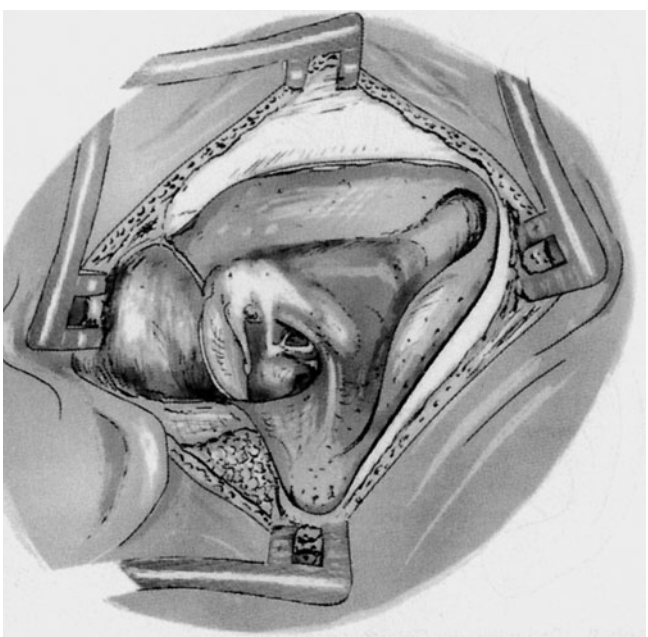


Fig. 4.**10** Open mastoid cavity technique. The cortical bone has been burred down, and the cells of the mastoid process have been largely removed. The facial ridge has been lowered almost to the level of the facial nerve. A smooth transition is created between the ear canal and the mastoid cavity.

eration of the cavity (see below). The mastoid tip is also drilled away, leaving a thin, mobilized bony layer to which the sternocleidomastoid muscle is attached. Usually this layer is swung into the cavity with its attached soft tissues to reduce the cavity size. In this way an open, self-cleaning cavity can be constructed even in patients with an initially very extensive mastoid cell system (Table 4.**2**).

Table 4.**2** Surgical measures for obtaining a small, self-cleaning cavity

1. Lower the facial ridge to the level of the facial nerve.
2. Smooth all bony overhangs and cell septa with a diamond bur.
3. If necessary, drill down the mastoid tip.
4. Reduce the sinodural angle by partial obliteration.
5. Widen the ear canal entrance by cartilage excision, skin incision, and tacking the concha posteriorly.

The cholesteatoma matrix that was mobilized initially can be used for rapid epithelialization of the cavity, but only if the perimatrix is free of irritation and a smooth, stable tissue layer is available. Otherwise the tympanomeatal flap is swung into the cavity near the end of the operation.

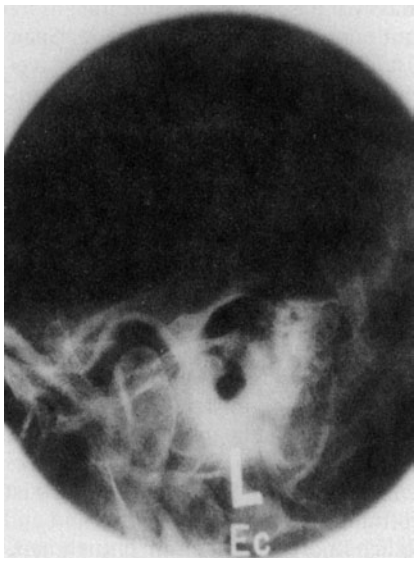


Fig. 4.**11** Schüller radiograph following cavity revision. The high facial ridge has been left alone so that, after the cavity is cleaned, it will provide an optimum bony recipient bed for bioactive ceramic material used for partial cavity obliteration.

Obliteration Techniques

Before turning to the obliteration or partial obliteration of crevices like the sinodural angle, the surgeon must be certain that all disease foci, and particularly the entire cholesteatoma matrix, have been removed. If there is the slightest doubt, the surgeon should do no more than seal off deep cell tracts with cartilage and overlapping perichondrium. We rarely perform cavity obliteration in the first operation and usually do it only in revisions. At that time we can remove all squamous epithelium from the mastoid with maximum certainty. For example, it may be necessary to dissect a thickened, inflamed lining out of the cavity. First, however, the open mastoid cavity should be reduced using the measures described above.

Table 4.**3** lists the autologous or ceramic materials that can be used for partial or complete cavity obliteration. The Palva muscle-periosteal flap (which Leland described in the early 1900s) is often heavily scarred at revision. This is not necessarily a disadvantage, as it keeps the flap at a relatively constant size. A particular advantage of this flap is that its periosteal side is toward the ear canal. It should be slightly oversized when outlined and can be either used alone for large cavity obliteration or as a cover for other materials such as bone dust or ceramic granules.

Table 4.**3** Materials for mastoid cavity obliteration

Palva muscle-periosteal flap
Bone dust
Cartilage
Bone replacement materials (TCP ceramic, hydroxyapatite, BMP)

Bone dust can be collected in a special glass vessel connected to the suction apparatus [71, 72], or it may be harvested with a Freer dissector. We use this material to obliterate hard-to-see crevices located above the lateral semicircular canal, in the epitympanum, and in the area around the labyrinthine capsule. It is sufficient to cover smaller areas with connective tissue. Small cartilage plates with overlapping perichondrium are used mainly to seal off small crevices.

Since 1981, surgeons at the hospital in Tübingen have been using bioactive ceramics such as porous TCP ceramic and hydroxyapatite as bone replacement materials for *partial obliteration*. But even these materials, when used over a relatively large area, should be covered with cartilage and overlapping perichondrium or with muscle-periosteal flaps to separate them from the cavity and ear canal. We frequently use ceramic in revisions, which are often very beneficial for cavity problems even after many years. We have had good results with the technique described in an earlier publication [73], in which the high facial ridge is *not* lowered, or is lowered only partially, and the residual crevice toward the mastoid tip is filled in with ceramic granules (Fig. 4.**11**). Nakano and other Japanese surgeons have started using this technique routinely in cavity surgery. Plester and Heumann used bone morphogenic protein (BMP) in selected cases in the mid-1980s, and Jahnke has successfully used it along with hydroxyapatite granules to cover a large area of exposed dura [64].

Ossicular Chain Reconstruction

The techniques used to reconstruct the ossicular chain in cholesteatoma surgery basically follow the general principles of tympanoplasty. In most cases there are no autologous ossicles available for chain reconstruction. At the Essen University Hospital, limited use is made of homograft ossicles from organ donors. For the most part, however, we use synthetic materials such as metal or ceramic implants.

Discussions on the role of these materials can be found in Jahnke and Plester, Geyer, Hildmann and Borkowski, Helms and Müller, and Jahnke et al. [74–82].

It should be noted that when organic grafts, especially ossicles, are used in cholesteatoma surgery, they may become fixed to the intact stapes by fibrous tissue. This can be difficult to release in operations for recurrent or residual disease. Synthetic materials are easy to remove, however. Most operations can be completed in one stage, removing the cholesteatoma and then reconstructing the ossicular chain in the same sitting. A two-stage procedure is indicated only in special situations. In rare cases it will not be possible to remove all squamous epithelium from the oval window or from between the stapes crura. In these cases the epithelium is initially left in place and then removed in a second-look operation one year (in children) or two years later. By that time the residual epithelium will have formed pearly masses that are much easier to locate and remove. Occasionally the epithelium will disappear in the interval, probably due to a trophic deficit. In noncompliant patients who have good postoperative hearing and most likely will not present for follow-up, it may be wise to postpone hearing improvement until a second stage.

Synthetic implants that are used in cholesteatoma surgery to restore sound conduction in the middle ear should be routinely covered with cartilage to prevent extrusion. This measure does not depend on the type of material used, for otherwise the risk of developing a retraction pocket would be too high. Table 4.**4** lists the reconstructions that were used in 112 consecutive, initial cholesteatoma operations performed at the Tübingen hospital in the early 1980s [83]. We have the same preference for these techniques today. In the classic type III procedure, a small cartilage plate is always placed on the stapes capitulum to reinforce the tympanic membrane and maintain aeration of the oval window niche [84]. This technique (Fig. 4.**12a**) is particularly well suited for an open cavity procedure. With a closed technique, it would obstruct the aeration pathway to the antrum.

Table 4.**4** Tympanoplasties used in 112 cholesteatoma operations [83]

Type I	n = 11
Type III classic	n = 27
Type III interposition	n = 36
Type III columella	n = 16
Type IV	n = 4
No reconstruction	n = 18

For a classic type IV tympanoplasty, we use crescent-shaped pieces of tragal cartilage with overlapping perichondrium (Fig. 4.**12b**) to ensure optimum acoustic shielding of the round window and good aeration of the tubofenestral tract.

The indication depends not only on the condition of the operated ear (eroded footplate) but also on the status of the contralateral ear. In the rare cases where remnants of the stapes crura are still present, excellent hearing results may be achieved.

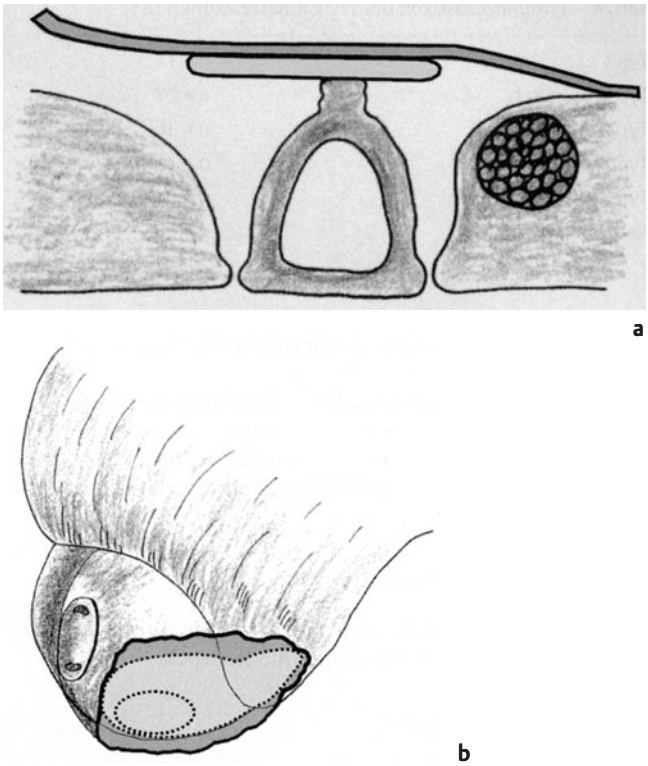


Fig. 4.**12** **a** Classic type III tympanoplasty. The plane of the tympanic membrane is reinforced with a small cartilage plate that secures aeration of the oval window niche. **b** In the classic type IV reconstruction, a crescent-shaped piece of cartilage with overlapping perichondrium is inserted to secure aeration of the tubofenestral tract and shield the round window from sound.

We see from Table 4.**4** that in the great majority of cases, an effort is made to achieve hearing improvement in a one-stage procedure.

There are several situations in which reconstruction of the ossicular chain is omitted:

a Usually with granulations in the oval window niche
b Erosion of the stapes footplate
c In some cases, a last-hearing ear. However, a classic type III tympanoplasty can still be performed in these cases without additional risk.

Closure of the Tympanic Membrane

We use only autologous materials for tympanic membrane closure: fascia, perichondrium, and cartilage.

Temporal Fascia

Fascia is still the most commonly used graft material at the Bochum hospital. Fascial grafts can be harvested over a large area after the skin incision has been made for ap-

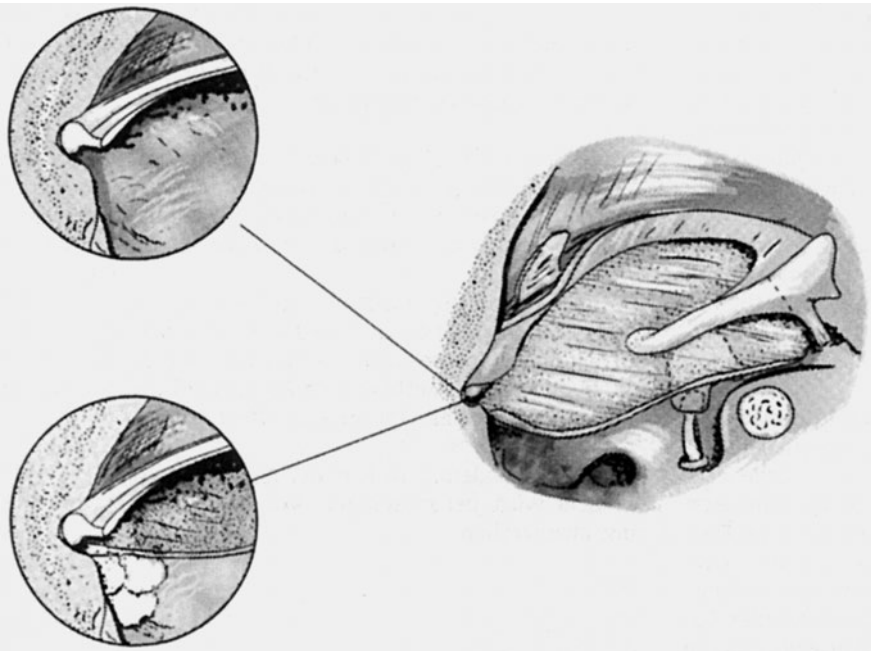


Fig. 4.**13** The underlay technique is even recommended for a subtotal tympanic membrane defect. The back of the tympanic membrane remnant is denuded over a distance of 2–3 mm to promote graft healing. Small pieces of fast-absorbing Curasporn can provide temporary support at critical sites.

proaching the middle ear. These grafts can be used not just for tympanic membrane closure but also for obliterating radical surgical cavities near the tympanic membrane. One disadvantage is that fascia is less dense than perichondrium, and this difference is easily appreciated under the microscope: the fibers are more loosely arranged. Nevertheless, we consider fascia to be a good material for tympanic membrane closure. Its lower fiber density can lead to atrophic scarring in the intermediate term, but we compensate for this by covering the fascial graft with meatal skin or thin retroauricular split-thickness skin. Fascia is easy to place and adheres more reliably to the back of the tympanic membrane. We use underlay techniques exclusively. Fascia has a greater tendency to shrink than perichondrium, however, and so the underlay should be cut slightly larger than the defect (Fig. 4.**13**) [69].

Perichondrium

Perichondrium can be harvested from the posterior side of the auricle during cartilage removal or from the tragus. This material is very strong but does not adhere to the back of the tympanic membrane as well as fascia, so it must be carefully applied. Müller emphasized its favorable healing tendency [85]. Disadvantages are the limited size of the perichondrial graft and the need for an extra incision when tragal perichondrium is used. With a retroauricular approach, perichondrium can be harvested along with additional cartilage, if needed.

Cartilage for Tympanic Membrane Closure

Cartilage can be used in the form of a plate, with or without attached perichondrium (Fig. 4.**14**), or in the form of palisades as described by Heermann [86–90]. The usual practice in cholesteatoma operations at the Essen University Hospital is to use tragal cartilage with overlapping perichondrium. Because the middle-ear side of the cartilage remains free of perichondrium, there is less potential for adhesions with the promontory. One advantage of a cartilage graft is the greater stiffness of the tympanic membrane replacement. This reduces the likelihood of retraction. Also, cartilage has no appreciable tendency to shrink. Cartilage is particularly advantageous for large defects, suspected eustachian tube dysfunction (as in patients with cleft lip and palate), and for covering synthetic ossicular chain implants to prevent extrusion.

To improve its vibrational properties, the cartilage is thinned to form an island graft. This is done by taking the tragal cartilage between the ends of a dissecting forceps and splitting it with a fresh scalpel. This can be done even more accurately with a cartilage cutter (Kurz Medical).

Another technique that is used at the Essen hospital to improve vibrational properties is to construct a layered graft consisting of four or five cartilage strips 1.5–2 mm attached to a piece of perichondrium (Fig. 4.**8**). At the Bochum hospital, smaller tympanic membrane defects are closed with a cartilage plate while larger defects are reconstructed with Heermann-type cartilage palisades. By placing narrow strips side by side, the palisade technique tends to cancel out the gross warping that can occur in larger cartilage grafts. The material does not need to be completely covered with skin or fascia. Larger cartilage grafts are more difficult to handle than fascia and perichondrium and adhere less well to the back of the tympanic membrane. It should also be considered that cartilage is thicker than the other replacement materials, and this can narrow the lumen of the middle ear cavity. In reoperations, the stiff cartilage can make it difficult to swing the tympanomeatal flap into position. It may then be nec-

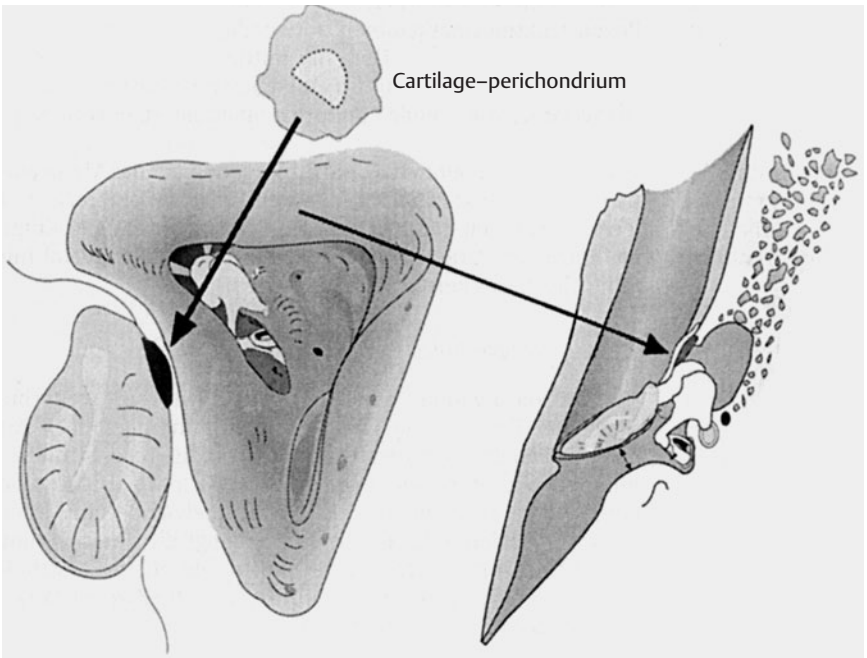


Fig. 4.**14** A cartilage plate with perichondrium is used to reconstruct a scutum defect.

essary to remove portions of the original graft material and revise the reconstruction. Experience with the palisade technique in Bochum has shown that the ingrowth of squamous epithelial can occur between the palisades. Great care should be taken, then, to fit the cartilage strips tightly together with no intervening gaps. Another theoretical disadvantage of using cartilage is that it may delay the detection of residual cholesteatoma. Recently, Velepic and coworkers showed that patients can dive after cartilage palisade tympanoplasty. Approximately 2 years after the surgery patients were able to dive without any difficulties [105].

Reoperations

Revisions are extremely common in cholesteatoma surgery and are performed more frequently than first operations at some centers. Only a small percentage of revisions are planned, such as second-look operations to exclude residual cholesteatoma. The younger the patient, the greater the importance of a second look when an intact canal-wall technique has been used. Another indication may be a planned two-stage procedure to improve hearing, but generally we try to do this during the first operation.

In the great majority of cases, revisions are not planned. The indications are diverse, and multiple indications often coexist in the same patient. The first operation may have been done years or decades earlier, and some patients have already undergone three or more operations. Experience has shown, however, that significant improvement can often still be achieved in these patients. The main presenting problem may be recurrent perforations or significant conductive hearing loss, as in chronic otitis media. But most cases involve true recurrent cholesteatoma or problems with a non-self-cleaning mastoid cavity that is constantly or periodically inflamed. Less common indications are early or late complications.

The basic questions relate to the pathophysiology of the affected ear and the technique that was used in the initial operation. Special attention should be given to possible eustachian tube dysfunction. Suggestive signs include small recurrent perforations and marked adhesive processes that preclude effective mastoid aeration, even in revisions. In these cases the surgeon should opt for an open or obliterative treatment of the mastoid cavity. Some patients are helped by the insertion of a gold tubal wire like that developed by Steinbach [91, 92].

In advanced stages of a new cholesteatoma, it is not always possible to distinguish between residual and recurrent disease.

Residual Cholesteatoma

The cause of residual cholesteatoma is incomplete initial removal of the keratinizing squamous epithelium. Like many others, we state the confidence of total cholesteatoma matrix removal in the surgical report.

Residual cholesteatomas are discovered in planned second-look operations, which should be done at one year in children and at two years in adults. In other cases residual cholesteatoma is detected incidentally in an operation to improve hearing. In exceptional cases, the appearance of new symptoms such as facial weakness or vertigo suggest the presence of residual cholesteatoma, and in these cases the lesion may have reached considerable size by the time it is diagnosed (Fig. 4.**15**). Imaging procedures appear to be of limited value in the early detection of residual disease. Small or plaquelike lesions in particular are difficult to dis-

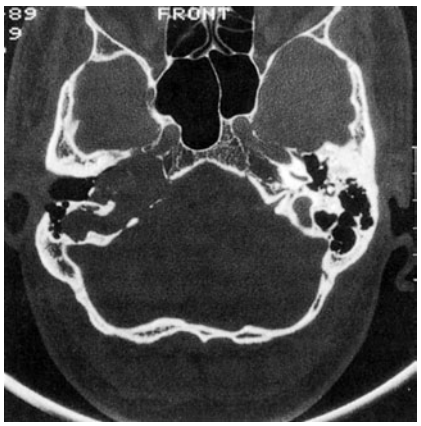


Fig. 4.**15** Extensive residual cholesteatoma 19 years after tympanoplasty. The lesion fills almost the entire petrous bone. The labyrinthine capsule and cochlea are mostly destroyed. The cholesteatoma abuts a long segment of the internal carotid artery and extends to the clivus.

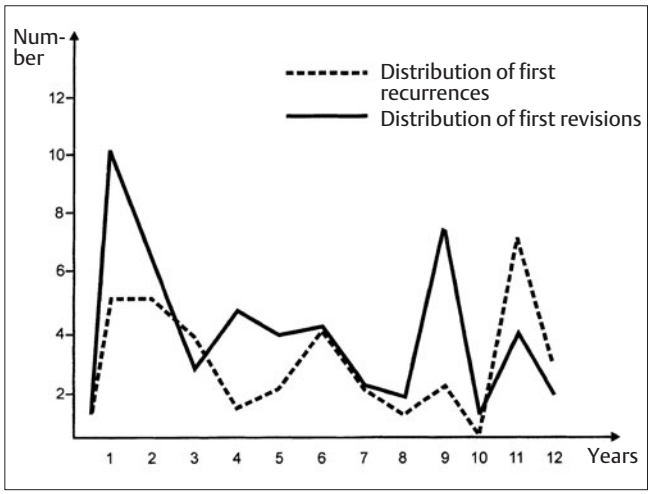


Fig. 4.**16** Recurrent and residual cholesteatomas and time of first revision after cholesteatoma surgery, based on a long-term study [2]. Follow-up accounts for the last peak.

tinguish due to postoperative anatomic changes. It is reasonable to assume that endoscopy will assume greater importance in the future, either in the form of flexible endoscopic via the eustachian tube (assuming adequate resolution) or as part of a minor intervention via the mastoid, for example, or an antrotomy bur hole.

Basically the same surgical technique is used in the treatment of residual cholesteatoma. The entire ear should be scrutinized, however, if it was involved by cholesteatoma in the first operation. With residual cholesteatoma in the mesotympanum, the epitympanum and mastoid should also be checked as it is common to find additional small cholesteatoma pearls in those areas. Critical sites for residual cholesteatoma are, in order of frequency, the epitympanum (especially its anterior portion), the mesotympanum, and occasionally the hypotympanum and mastoid. The most difficult cases are those in which cholesteatoma has grown over, behind, or below the labyrinth. This may necessitate more extensive drilling and correspondingly involved reconstructive measures. In exceptional cases, the dura of the middle or posterior cranial fossa can be exposed to obtain a better view of perilabyrinthine cholesteatoma.

If the cholesteatoma was confined to the mesotympanum in the initial operation and could not be removed, say, from the oval window niche with absolute certainty, the Essen hospital favors a strictly transcanal approach with inspection of this region in selected patients, usually children.

Recurrent Cholesteatoma

Recurrent cholesteatomas occur mainly in patients with continued eustachian tube dysfunction. Like attic cholesteatomas, they can also result from epithelial migration following an incomplete reconstruction of the posterosuperior canal wall or the displacement of implanted cartilage plates. After the epithelial sac has been removed, the decision between reconstructive techniques and an open mastoid cavity depends basically on eustachian tube function. In doubtful cases, we create an open mastoid cavity.

Long-term studies [2] show that recurrent cholesteatomas can develop even after a period of many years (see Fig. 4.**16**). This underscores the need for long-term follow-up of cholesteatoma patients, especially children and adolescents.

If a new cholesteatoma develops from the middle ear cavity, similar to a sinus or pars tensa cholesteatoma, removal of the squamous epithelium should be followed by a cartilage technique for closing the tympanic membrane. Safe clearance from the promontory should be maintained. If a palisade technique was used previously, squamous epithelial ingrowth may be found between the palisades if gaps were left between the implanted cartilage strips.

Draining Mastoid Cavity

An open mastoid cavity that drains constantly or intermittently and is difficult to inspect is a very common indication for revision surgery. The reasons for a draining mastoid cavity include tympanic membrane defects, persistent cells with inflamed mucosa, multiple blind spots in the cavity, and incomplete epithelialization.

Before reoperation, the cavity should be meticulously cleaned and prepared. Several questions should be addressed to analyze the reasons for the failure:

a Adequate width of the ear canal entrance?
b Epithelialization of the tympanic membrane and ear canal?
c Height of the facial ridge?
d Is the mastoid cavity self-cleaning? Does it contain blind spots or a cavity cholesteatoma?

Cavities that are difficult to inspect can be examined endoscopically with Hopkins rods. CT is indicated if portions

of the cavity cannot be examined by other means. A retroauricular approach is generally used for cavity revisions. The surgeon should proceed with great caution to avoid injuring a potentially exposed sigmoid sinus. The air cells are treated as needed, and the facial ridge is burred down to the level of the facial canal to create a smooth transition with the floor of the ear canal. As an alternative, Essen surgeons sometimes leave the facial ridge in place and use it as a bony implant bed for partial cavity obliteration (e. g., with ceramic granules, see above). Obliterative measures should be used only if it is absolutely certain that all epithelium has been removed; otherwise the ossifying bone dust or ceramic might conceal residual cholesteatoma. Cavity cholesteatomas most typically occur behind the facial ridge and grow toward the mastoid tip. All of the above techniques of cavity surgery may be considered in these cases, including the complete removal of the mastoid tip.

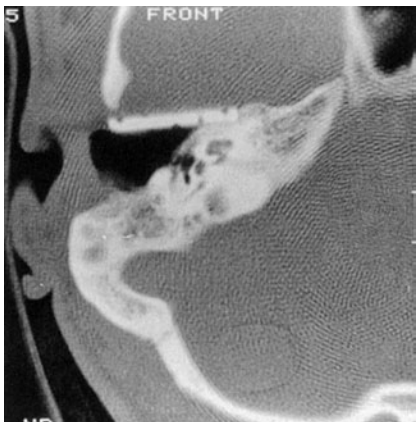


Fig. 4.**17** CT scan in a woman previously operated for a cholesteatoma that had invaded the middle cranial fossa. She had been referred to Essen University Hospital with meningitis. The large defect was covered with an epidural ceramic plate (soft-tissue coverage is not shown here).

Common Errors and Complications

The patient should be informed that cholesteatoma with suppuration is a potentially life-threatening condition and that the primary goal of surgery is to clear the ear of disease. Hearing improvement, though desirable, is less important than disease removal and may have to be deferred. Particularly in children and adolescents, the patient and parents should be counseled about the frequent need for a planned second operation. The more detailed the preoperative counseling, the greater the likelihood that patients will accept the surgical outcome.

The preoperative examination should exclude inner ear damage. Tuning fork tests and earphone testing should be used to eliminate crossover hearing.

Broad exposure makes it easier to operate, and so a narrow ear canal should be widened. Removing the skin from the posterior meatal wall will facilitate drilling. The meatal skin can be replaced as a free graft at the end of the operation without causing healing problems. With extensive cholesteatomas, important landmarks should be identified early in the procedure. For example, the facial nerve should be identified at the oval window and in its mastoid segment. Within the mastoid, the bone should be burred down until the nerve is visible through it. This greatly facilitates the approach and permits a safer, faster operation [69].

Exposed Dura and Prolapsed Brain

If more than a 1-cm area of dura is exposed, we cover it with cartilage or a piece of bone inserted as an epidural graft. Any dural injury is repaired at once, and broad antibiotic coverage is routinely applied. The surgeons in Essen have had very good results with epidural ceramic plates for covering larger defects (Fig. 4.**17**). Any prolapsed brain tissue is resected rather than reduced, and the dural defect is repaired with fascia (e. g., fascia lata). The defect is then covered epidurally with bone replacement material.

Labyrinthine Fistula

Labyrinthine fistulas cannot always be detected preoperatively on the basis of fistula symptoms. The surgeon should be particularly careful, therefore, when dissecting in the region of the lateral semicircular canal. More than 90 % of labyrinthine fistulas involve the lateral semicircular canal. An alternating pressure phenomenon can be elicited at the exposed fistula by tipping the stapes with a probe. A grading system has proven useful for classifying labyrinthine fistulas [55]. The ingrowth of squamous epithelium into the labyrinthine system is rare. Fistulas may occur in other semicircular canals, or in multiple canals, in accordance with the route by which cholesteatomas spread. Fistulas in the anterior side of the superior semicircular canal are particularly difficult to see, as are fistulas in the presence of perilabyrinthine cholesteatoma growth.

Fistulas rarely occur in the cochlea. They may be seen with extensive cholesteatomas, however.

Our standard technique is to remove the epithelium from the fistulas. For more than 10 years, the surgeons in Essen have had good results by dissecting the fistula “under water,” i. e., under a solution of azlocillin. This has made it possible to preserve inner ear function even with relatively large fistulas. Next the endolymphatic tube is covered with bone dust (which takes about 6 months to ossify), followed by coverage with a cartilage disk and overlapping perichondrium. The repair does not necessarily require a canal wall-down technique. Interestingly, hearing can be preserved in a number of patients despite considerable destruction of the semicircular canals. When the inner ear is opened, the practice at the Bochum hospital is to inject 1 g of methylprednisolone intraoperatively to protect the inner ear, as recommended by Milewski (personal communication).

Exposed Facial Nerve

With extensive cholesteatomas, exposure of the facial nerve can occur with or without preoperative paralysis. With a labyrinthine fistula, the facial nerve is exposed in more than 50 % of cases. The nerve is identified at surgery, if necessary by burring down the intact bone over the fallopian canal in the mastoid. If there is uncertainty, the nerve can be located by drilling from healthy bone into the diseased area. Even in very difficult cases, the nerve can almost always be approached from the front via the promontory, identifying the round and oval windows at the level of the nerve. Generally there is no need for nerve monitoring in cholesteatoma surgery, but it may be helpful in selected cases.

Any injuries to the nerve should be repaired right away. With partial injuries, the nerve should not be completely divided and reconstructed with an interposed graft, as was once recommended. The results of older surgical techniques for facial spasm in which portions of the nerve were deliberately sectioned have shown that good recovery of nerve function can occur with partial injuries. If the nerve is completely divided, a tension-free end-to-end anastomosis is better than interposition grafting.

Sinus Thrombosis and Otogenic Sepsis

Exposure of the sigmoid sinus cannot always be avoided. We recommend careful peripheral undermining of the sinus shell, followed by the insertion of a small cartilage plate with overlapping perichondrium. Small injuries to the sigmoid sinus (e. g., scalpel pricks) are repaired with fibrin sponge or small muscle flaps. Packing is necessary only for larger injuries.

Sinus thrombosis refers to intravital blood coagulation usually caused by the spread of inflammation from the perisinus space. The diagnostic method of choice is gadolinium-enhanced MRI, which can also demonstrate intracranial complications such as edema [67]. The first step in all operations is the eradication of middle ear disease. In cases with massive inflammation, needle aspiration of the sinus should be performed. When thrombosis of the sigmoid sinus has been confirmed, it is treated with low-dose heparin therapy. If there is a bacterial infection of the thrombosis, jugular vein ligation is justified to prevent embolization and sepsis from dislodged thrombus particles. The development of otitic hydrocephalus is a potential risk during the postoperative period.

Meningitis and Brain Abscess

Otogenic meningitis can develop by contiguous spread along bone-perforating vessels or nerves or by the translabyrinthine route.

In patients with meningitis or brain abscess, the cause of the disease should first be eliminated by removing all cholesteatoma. After all disease has been removed from the mastoid and epitympanum, the inner table of the middle and posterior cranial fossae is ground smooth, the portal is identified, and the dura is exposed mainly to detect or exclude an epidural abscess. Effective antibiotic coverage is essential. If an encapsulated abscess has formed, it is treated neurosurgically [46, 52, 67]. This treatment is geared toward the patient's general state of health as well as the location, size, and stage of the abscess. The current treatment of choice for brain abscess is stereotactic needle aspiration. In the age of precision imaging techniques, exploratory brain puncture is contraindicated due to the risk of implanting infectious organisms and the additional injury to brain tissue.

Epidural Abscess

Epidural abscesses are exposed into healthy tissue and drained. As with other intracranial complications, removal of the posterior meatal wall tends to be problematic since a covered defect in the inner table would border on an inflammation-prone mastoid cavity.

Last-Hearing Ear

Any otosurgical operation, especially cholesteatoma surgery, carries a risk of deafness in the operated ear. This means that special recommendations apply when surgery is performed on a last-hearing ear. In many cases a "spontaneous radical cavity" should be smoothed laterally and carefully cleaned. With extensive cholesteatomas, the incudostapedial joint should be divided at an early stage. Unnecessary manipulations of the stapes (e. g., in an effort to improve hearing) should be avoided. When reconstructing the ossicular chain, we use only very safe and proven techniques, such as a classic type III operation with a cartilage plate or stably placed implant. As a matter of policy, cholesteatoma surgery in the last-hearing ear should be done only at centers where such operations are performed frequently by experienced surgeons.

Cholesteatoma Surgery in the Elderly

Beyond the usual risks of general anesthesia, there is practically no upper age limit for performing cholesteatoma surgery. Disoriented patients from nursing homes seem to have a higher incidence of complications, because many of these patients are debilitated, have difficulty communicating, and are unable to report the early onset of complaints. Any further hearing loss is more likely to be attributed to general deterioration than to local otologic disease. Moreover, this subset of patients is often difficult to examine, and consequently their diagnosis tends to be delayed.

We are less hesitant in recommending a canal wall-down procedure in older patients, especially since many of these patients have poor mastoid pneumatization. The risk of recurrence is generally low in patients who are over age 60 when they have their first cholesteatoma operation [2]. It is particularly important in older patients to create favorable conditions for fitting the patient with a hearing aid.

Cholesteatoma Surgery in Children

Many authors believe that cholesteatomas in children are more aggressive and destructive than in adults [94, 95]. When Palva et al. [95] compared 65 children and 65 adult cholesteatoma patients, they found that extensive cholesteatoma growth was present in 22 % of the children versus only 6 % of the adults.

Sheehy et al. [96] examined 181 children with cholesteatomas. Eight of the children had a labyrinthine fistula, and one child had facial nerve paralysis. They observed no intracranial complications. A higher incidence of complications was found among the 843 adults in this series. In examinations conducted in Bochum [97], the incidence of ossicular chain destruction in adults (84 %) was similar to that in children (88 %). This agrees with the findings of Sade and Fuchs [98]. In immunohistochemical tests for growth factors EGF, TFG-α, and FGF-2, the results did depend on the extent of inflammatory infiltrate in the perimatrix but did not depend on patient age [97]. In our opinion, the pneumatization of the mastoid process is determined both by genetic factors and by inflammatory conditions leading to mastoid sclerosis [99]. As a result, children are more likely to have air cells that are receptive to epithelial ingrowth. This is an anatomic explanation for the greater frequency of aggressive cholesteatomas in the pediatric group. We conclude that complications such as ossicular chain destruction and the biological behavior of cholesteatomas are similar to those in adults and depend upon mastoid pneumatization, the duration of the disease, and the extent of perimatrix inflammation [100]. The increased pneumatization in children also accounts for the unquestionably greater frequency of residual cholesteatoma. Another important factor may be the higher incidence of persistent eustachian tube dysfunction among children. We also note the greater difficulty of preoperative diagnosis in children and the problems that are encountered in the postoperative care of cases that do not heal well, especially in small children [101]. The choice between an open cavity versus intact canal-wall procedure in children depends on the overall situation. In Essen, almost all children undergo an intact canal-wall procedure and a planned second look at 1–2 years. In this way, approximately normal long-term otologic conditions can be established in the majority of the children. Even with a canal wall-down procedure, a certain (smaller) percentage of the patients would have to be reoperated due to the relative frequency of recurrence in the mesotympanic region. Another problem is that an initially self-cleaning cavity may develop problem crevices due to osteoneogenesis during growth [2].

For true recurrent cholesteatomas that develop toward the antrum, we either construct an open cavity secondarily or use a Palva obliteration flap if we have been able to remove all of the cavity epithelium with absolute confidence.

Primary cholesteatomas are a special case. An example is the pediatric cholesteatoma, described by Michaels, that develops at a typical site in the anterior superior middle ear cavity. Initially this lesion may cause only a middle ear effusion, and later it can be identified as a whitish mass in front of the malleus handle. When discovered in time, these cholesteatomas can be removed without opening the mastoid process. Occasionally with lesions that arise in front of the cochleariform process, it is necessary to remove the malleus handle and reconstruct the ossicular chain. Taken as a whole, congenital cholesteatomas are a definite indication for an intact canal-wall procedure followed by a planned second look.

A canal wall-down procedure would be justified only in patients who additionally have a refractory impairment of eustachian tube ventilation. Andersen and coworkers recently investigated whether reconstruction of the eardrum with palisade cartilage technique could prevent retraction of the new eardrum after surgery for sinus and tensa retraction cholesteatoma in children. They found that the palisade technique effectively prevented postoperative retraction of the eardrum and resulted in postoperative good hearing [102].

Children and adolescents with cholesteatoma require long-term specialist care to permit the early detection of cholesteatoma regrowth. The surgeon should be included in this follow-up process. There should be little hesitation in recommending second-look surgery and procedures to ameliorate hearing in this age group. Some patients will be unable to present for follow-up because their family has moved, for example. But the number of patients who do not present for a scheduled second look is small in cases that receive appropriate preoperative counseling and thorough postoperative care.

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5 Advances in Stapes Surgery

R. Häusler

Abstract

Advances in Stapes Surgery. Since Shea introduced stapedectomy as a surgical treatment of otosclerotic hearing loss in 1956, numerous ENT surgeons worldwide have used this procedure with great success. Over the years, many of them have contributed towards progressively improving and refining the surgical techniques. The retroauricular approach has been changed to the less invasive endaural approach, and today a large number of otologists routinely use the transcanal approach under local anaesthesia. The total removal of the footplate has been changed to the less traumatic small fenestra stapedectomy or stapedotomy, where, in a central footplate perforation, a piston of 0,3–0,8 mm diameter is fitted. Stapes prostheses in biocompatible materials such as titanium, teflon and platinum have become available and are sometimes equipped with ingenious automatic fixation mechanisms. The microsurgical instrumentation has been gradually expanded. New technical tools, such as the minimally traumatic, ultralight, low-speed skeeter microdrill, have been developed. Several lasers allowing a precise intervention on the stapes without mechanical trauma have been tried and applied with success. The optic quality of the operating microscopes has been increased. All of these advances have contributed to making stapes surgery an example for the concept of "minimally invasive high success surgery". The aim of the present study is to analyze the recent progress in stapedectomy. The working basis is the body of literature mainly from the last 10 years as well as personal experience with ca. 700 stapedectomies performed with various surgical techniques (skeeter stapedotomy, argon laser stapedotomy by using a fiberoptic microhandpiece, erbium laser stapedotomy, laser stapedotomy with preservation of the stapes tendon, stapedotomies with piston insertion of various diameters, atypical stapedectomies with piston fixation on the malleus head, stapedectomy in middle ear malformation and abnormal courses of the facial nerve with piston insertion into the promontorium as well as techniques and results in stapes revision surgery).

Introduction

Half a century ago, Shea [1, 2] described the microsurgical technique of stapedectomy with the insertion into the oval window of a stapes replacement prosthesis made of Teflon. Thanks to this operation it became possible in most cases to correct the otosclerotic conductive hearing loss, which represents a serious social and professional disability for the affected patients. Since then, otologists throughout the world have used the stapedectomy technique with decisive success. Over the years, many of these otological microsurgeons have continued to make further improvements to the surgical technique. The retroauricular approach was abandoned in favour of the less-invasive endaural approach; today many otological surgeons make almost exclusive use of the transcanal approach through an aural speculum and the operation is often carried out under local anaesthesia. Total removal of the footplate was abandoned in favour of the small-calibre footplate perforation, a so-called stapedotomy, in which piston prostheses with a diameter of 0.3–0.8 mm are used. Stapes prostheses made of biocompatible materials such as Teflon, platinum, gold and titanium are commercially available, sometimes with ingenious mechanisms for their fixation to the incus. The microsurgical equipment has been expanded and improved. New technical tools, such as particularly fine, low-frequency microdrills that spare the inner ear, have been developed. Various laser systems, which allow precise, atraumatic work on the stapes, have been tested and successfully used. The illuminating power, optical quality and user-friendliness of the operating microscope have been improved. All of these advances have made stapedectomy into a textbook example of minimally invasive high-success surgery today.

The aim of this paper is to describe the basic principles of stapedectomy and also various new technical developments in stapes surgery. The working basis for this is the clinical and medical-scientific literature and also personal experience with about 700 stapedectomies, which were carried out using different techniques and have been evaluated in several prospective and retrospective studies. Certain subjective opinions and technical surgical suggestions in this paper have been significantly influenced by the educational establishments which I personally have attended, thanks to my esteemed otological teachers, P. Montandon from Geneva, and H. Schuknecht from Boston.

Historical Development of Stapedectomy

Early Attempts at the Surgical Treatment of Stapes Ankylosis

The first description of a stapes ankylosis as the cause of hearing loss that has been passed down to us comes from Valsalva [3] from Bologna [4]. It is not known when the first attempts at stapes mobilization to improve hearing were carried out. A reference to this is to be found in Ménière[1], 1842 [5]. This is the description of a patient whose hearing could be temporarily improved by tapping directly on the stapes with a gold rod. Kessel (1876) from Graz, and later Jena [7, 8] is considered to be the actual founder of stapes surgery. On the basis of experimental investigations in the pigeon, he demonstrated that opening of the oval window did not necessarily result in destructive damage to the inner ear as was generally feared. He subsequently published a description of transtympanal stapes mobilization and stapedectomy as a method for the improvement of hearing in stapes ankylosis. The German otologists, Schwartze [9] and Lucae [10], also carried out stapes mobilization and removal of the stapes. In France, Miot [11] reported that he had achieved a hearing gain in 74 cases out of 126 stapes mobilizations. The operation was also performed in France by Boucheron [12] and Pottier [13] and in Italy by Feraci [14]. In the USA, Blake [15] and Jack [16–18] at the Eye and Ear Infirmary in Boston and also Sexton [19] and Alderton [20] in New York practised mobilization and removal of the stapes. Since the postoperative hearing gain often only lasted for a period of days to weeks and cases of fatal labyrinthitis with lethal intracranial complications could occur, this early stapes surgery fell into disrepute. It was vehemently criticized, in particular also by the leading otologists of the time—Politzer, Siebenmann and Moure—who in 1899 at the 6th International Otology Congress in London declared that stapes surgery was useless and dangerous [21]. The early stapes surgery that had started with great enthusiasm therefore came to an abrupt end for the time being.

The Era of Fenestration Operations

Since surgical operations on the fixed stapes were considered too dangerous, the idea of an inner ear opening outside of the oval window was taken up. The suggestion of a promontory fenestration made by Passow in1897 [22] did not become established, but in 1899 Floderus [23] suggested an opening of the vestibular labyrinth, which in 1913 was described by Jenkins in London as a “fenestration of the lateral semicircular canal” [24]. In the 1920s, the electric head light was then introduced by Sexton in New York and in Sweden Nylen [25] developed the first operating microscope. With these tools, Holmgren [26, 27] propagated a closed, microsurgical fenestration operation on the lateral semicircular canal, with which he achieved, admittedly only slight but relatively permanent, improvements of hearing in patients with otosclerosis. The Frenchman Sourdille, a pupil of Holmgren, was the first to develop the fenestration of the lateral semicircular canal towards the out-

[1] Prosper Ménière, the director of the school for deaf and dumb children in Paris, not only described the well-known disease of the inner ear that bears his name but was also an experienced and well-read otologist, who, amongst other things, translated into French from an English translation the fundamental work on otology published in 1836 by the famous Berlin otologist Kramer [6], adding relevant personal comments to this. On the occasion of the EUFOS 2000 in Berlin it is of interest to observe that European multilingualism was not an insuperable barrier in the field of medicine even at that time.

side in a two-stage operation. In 1937 he achieved a lasting hearing improvement in 64% of 109 operated patients with his "tympano-labyrintho-pexie" [28]. In 1938 Lempert in New York [29] finally simplified the semicircular canal fenestration into a one-stage operation. Both he himself and also a number of other otologists achieved considerable and lasting hearing gains in fairly large series with the use of this well-standardized operation [30].

Start of the Era of Modern Stapedectomy

Rosen [31] from New York used a transcanal approach from 1952 in order to test the mobility of the stapes prior to a semicircular canal fenestration, and rediscovered the effect that stapes mobilization had in the improvement of hearing. Meanwhile great advances had been made in otological microsurgery, which was now routinely performed under the binocular operating microscope, chiefly through the work of Wullstein and Zöllner. After a study of the early literature, Shea [32], who as Clinical Fellow learnt the technique of ear surgery in Vienna with Novotny and Burian, came to the conclusion that it must be possible to replace an otosclerotic stapes with a prosthesis. In collaboration with the engineer Treace, he created a stapes prosthesis made of the then newly discovered biocompatible material Teflon (Fig. 5.**1**). In a female patient with otosclerosis, after removal of the stapes and covering of the oval window with a vein he used this Teflon stapes prosthesis for the first time on May 1st 1956, with complete success [1, 2].

From this date onwards, stapedectomy for the treatment of otosclerotic conductive hearing loss started on a triumphal march around the whole world. In the 1960s, thousands of hearing-impaired patients with otosclerosis were treated with great success. After the Teflon stapes, Shea used a hollow polyethylene tube for a certain period of time, but this sometimes caused inner ear fistulae. Later he used a piston made entirely of Teflon, which is still used today by many surgeons. In 1960, Schuknecht developed a steel wire-adipose tissue prosthesis made directly during the operation, which became used worldwide [33]. This prosthesis also had its disadvantages, because lateral displacements of the wire and adhesions in the vestibulum could develop, which represented a certain inner ear risk during revision surgery. The combination of a Teflon shaft in the vestibulum with a metal wire for fixation to the incus led to the metal wire–Teflon piston prosthesis, which is still routinely used in many centres [34, 35].

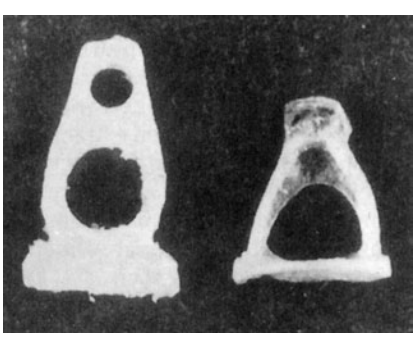

Fig. 5.**1** Photograph of the stapes replacement prosthesis made of Teflon, which was successfully used by Shea in 1956 for the first stapedectomy. A normal human stapes is shown on the right for comparison (Shea, 1998).

At the beginning of the '60s Plester [36] suggested the technique of partial stapedectomy, in which only the posterior third of the footplate was removed. A further development of this principle led Shea et al. [37] and Marquet from 1962 [38] to just make a small opening in the middle of the footplate into which the prosthesis piston fitted exactly, in order to reduce the inner ear risk. This initiated the era of "stapedotomy," which is now used worldwide.

As an alternative, Portmann and Claverie in 1957 [39] and Zangemeister in 1958 [40] suggested that the superstructure of the stapes should be left in situ and one of the stapes crura used as an interposition. The advantage of this is that no foreign material is implanted. For the same reason, Zöllner in 1960 [41] replaced the extracted stapes with an autologous cortical bone chip. After covering the oval window with periosteum, Pfaltz [42] made a graft with a bone chip. Stapedectomy methods without the use of foreign material are still used today in modified form.

Pathogenesis of Stapes Ankylosis

Otosclerosis is by far the commonest cause of stapes fixation. Stapes ankyloses also occur, but more rarely, in malformations of the middle ear. They may also be due to trauma, e. g. through secondary ossification of the footplate after petrous bone fractures, or they may develop in the context of inflammatory infectious processes of the middle ear.

Histology and Pathogenesis of Otosclerosis

Anton von Tröltsch in Würzburg [43] coined the term otosclerosis in 1872, but he did not distinguish between otosclerosis and tympanosclerosis. Politzer [44] then described otosclerosis as an entity and as a primary disease of the bony labyrinth capsule in 1894. On the basis of histological investigations, Siebenmann [45] later introduced the term "otospongiosis," which is still used today as an alternative name for the early stage of otosclerosis. The histopathology of otosclerosis was subsequently characterized in detail by a number of distinguished otologists: Manesse, 1914 [46]; Weber, 1930 [47]; Wittmaack, 1930 [48]; Mayer, 1931 [49]; Greifenstein, 1935 [50]; Nager, 1939 [51]; Rüedi, 1963 [52]; Nager, 1969 [53] and Schuknecht, 1974 [54].

Histology of Otosclerosis

Otosclerosis is characterized by a progressive focal dysplasia with the destruction, remodelling and finally sclerosis of the endochondral bone of the labyrinth capsule. The initial so-called otospongiosis stage is characterized by osteoclastic processes, the presence of lymphocytes, histiocytes, plasma cells and the deposition of antibody com-

plexes [55, 56]. In addition an increased activity of proteolytic enzymes and cathepsin is found [57]. In the late stage (otosclerosis stage), progressive sclerosis takes place through a highly mineralized bone of mosaic-like structure [55]. The disease mostly starts in the anterior part of the oval window, in the so-called fissula ante fenestram. Significant conductive hearing loss mostly first develops through additional fixation of the posterior part of the footplate, either through a further focus of ossification or through ring-shaped growth of the otosclerosis around the oval window [58]. A thick ossification of the entire oval window is described as obliterative otosclerosis, which is accompanied by severe conductive hearing loss. This is also possible when the annular ligament is very constricted and shows fibrous thickening [59]. Clinically this can become manifest as the so-called "biscuit" footplate, with a thick ossified footplate which is only loosely fixed in the oval window at the margin. In such cases, there is the risk that the complication of a floating footplate may occur during the footplate perforation (see p. 144, Stapedectomy technique in special situations).

In the course of their development, otosclerotic lesions can progressively involve the entire labyrinth capsule, in rare cases (0.3 %) with total occlusion of the round window. In these cases a stapedectomy in the oval window does not result in any hearing gain. The inner ear structure remains preserved surprisingly often, despite advanced otosclerosis of the labyrinth block. Sometimes, however, progressive degenerative changes occur in the inner ear, in particular atrophy of the spiral ligament, which takes on a "hyaline" appearance. Such changes within the labyrinth then bring about an additional inner ear hearing loss. In rare cases the otosclerotic adhesions affect not only the oval and round window but also wide areas of the petrous bone and of the inner ear. Patients who have such so-called "malignant" otosclerosis [60] become progressively deaf.

Aetiology and Epidemiology of Otosclerosis

An inflammatory-immunological process is becoming ever more clearly established as the actual cause of the otosclerosis. In several studies, the measles virus genome has been identified in otosclerotic lesions by immunohistochemistry. The otosclerosis might therefore correspond to a chronic inflammatory reaction that is maintained by the measles virus (slow virus infection) [61–66]. It has still not yet been demonstrated that measles virus replication with transmission to another organism (e. g. monkey kidney cultures) can be achieved from otosclerosis lesions, as the final proof of an infectious aetiology.

A familial occurrence of otosclerosis can be demonstrated in 25 to 50 % of cases. In my own patient collective, 30 % of the stapedectomized patients had relatives who also suffered from otosclerosis [67]. On the basis of the increased familial occurrence, a hereditary factor, mostly an autosomal dominant mode of inheritance with variable penetrance, was postulated for otosclerosis [68–70]. In more recent genetic studies, a responsible gene was localized to chromosome 15q25–q26 [71, 72].

Different sex ratios and variations in the incidence of the disease in different population groups have also been observed. Guild [73, 74] found otosclerotic lesions in 6.5 % of 374 investigated petrous bones in men and in 12.3 % in women. The histological incidence of otosclerosis is reported as 8.3 % for the white population and 1 % for the black population. More recent radiological data from petrous bone computed tomography studies confirm that the incidence of otosclerosis in the European and white American population is between 6 to 10 % [75]. In the new studies women are also affected more often than men [68]. This sex specificity of the otosclerosis, together with the observation that otosclerotic hearing loss often first occurs in women during a pregnancy, suggests that hormonal factors have an important influence. In male patients with otosclerosis, Ribari [76] demonstrated adrenocortical hypofunction in several cases.

Clinically manifest otosclerosis with hearing loss develops in only about 10 % of the patients with histological otosclerosis, i. e. in about 0.5 to 1 % of the population. A similar incidence to that of Europeans and Americans of Caucasian origin is also found in India [77] especially southern India, in Abyssinia and North Africa [78]. Otosclerosis occurs more rarely in American Indians, black Africans and Asiatic populations [68, 79].

The assumption has often been expressed recently that the incidence of otosclerosis is decreasing, because the number of stapedectomies performed has fallen in many centres in the last ten years. It is assumed by some that the

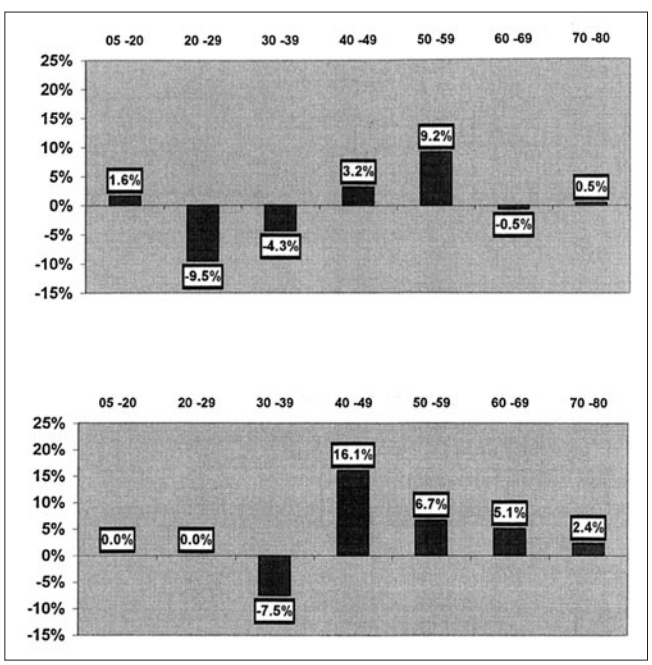

Fig. 5.2 Percentage change in the mean age of men (above) and women (below) in relation to the time at which stapedectomy was performed, this being carried out at the Bern ENT Department during the periods 1978–1987 and 1988–1997. It is evident, especially in women, that over the past two decades there has been a shift in the age at the time of the operation from that of young adults (20–40 years) to that of the middle-aged groups (40–60 years).

decrease in otosclerosis might possibly be a consequence of the protective measles vaccination that commenced at the beginning of the 1980s. Others believe that the fluoridation of drinking water and salt practiced in many places might prevent the development of otosclerotic lesions[2]. The decrease might also be due to the fact that an increasing number of otologists are carrying out stapes surgery, so that the number of operations per surgeon is reduced. Finally it should not be forgotten that the previous enormous reservoir of patients has been progressively operated on over the past 40 years, so that only new cases still present for treatment. Stahle [87] calculated at the beginning of the 1970s that the annual incidence of stapedectomies for otosclerosis was 0.012 % in Sweden. In Bern about 100 stapedectomies are performed annually out of a total population of just over one million in the catchment area. This would result in a similar operation incidence to that calculated by Stahle 20 years ago.

Over the past two decades, the average age of the Bern patients has increased in the middle-aged groups by a full ten years[3] (Fig. 5.**2**). This might indicate either that the otosclerosis becomes manifest at a later age now or it might be a first confirmation of the fact that the number of new otosclerosis cases is actually in the process of falling.

Stapes Ankylosis in Malformations of the Middle Ear and Malformation Syndromes

Unilateral or bilateral conductive hearing losses with stapes ankylosis and malformations of the stapes occur in the context of small middle ear malformations [88]. Inter alia, monopedic stapes, aplasia of the stapes superstructure, footplate ossifications with co-existing aplasia of the annular ligament, absent footplates, footplate dedifferentiation and ossification of the stapedius muscle tendon have been described [89]. In rare cases persistence of the stapedial artery is also present, and the facial nerve often takes an abnormal course above or even below the oval window (see Section 8, Stapedectomy technique in middle ear malformations). All of these disorders may occur together in any combination. Such middle ear malformations may occur in isolation or in the context of malformation syndromes such as the dysostosis craniofacialis of Crouzon [90], Marfan's disease and Klinefelter's syndrome. Both genetic and exogenous disorders, e. g. intrauterine rubella virus infection, are possible causes. Stapes malformations indicate damage between the 19th and 22nd week of gestation [91–93]. A stapes ankylosis is also found in osteogenesis imperfecta [60, 94]. These patients typically have blue sclera and in most cases a history of bone fractures.

The frequency of stapes fixation due to malformation was estimated as being between 0.5 to 1 % [95, 96]. In Bern a congenital middle ear malformation (ear canal atresia type A and B, abnormal course of the facial nerve abnormal stapes) with stapes fixation was recorded in 10 % of all stapedectomies. An important preoperative indication that there is middle ear malformation is that the hearing loss has existed since infancy.

New investigations show that an additional ankylosis of the malleus head may possibly occur to an increased extent in patients with otosclerosis [97, 98]. If both a malleus head ankylosis and an otosclerotic fixation of the stapes are present, only a partial hearing gain occurs after stapedectomy [99]. The problem can be solved through an additional loosening of the malleus head by partial tympanectomy [100], or through the technique of malleus handle stapedectomy.

Post-traumatic and Inflammatory Stapes Fixations

Lesions of the middle ear with stapedial footplate fractures, luxation and subluxation of the stapes in the context of petrous bone fractures or direct middle ear trauma can lead to bony fixation of the footplate through a secondary osteogenic reaction, which becomes manifest as conductive hearing loss. This has also been demonstrated experimentally [101].

In rare cases chronic states of infection and inflammation in the middle ear lead to fixation of the stapes through massive fibrosis and hyalinosis, which can extend up to the ossification. Because of the risk of labyrinthitis, it is recommended that in infectious states only meticulous cleaning of the stapes should be carried out at the initial middle ear revision. If the conductive hearing loss persists after otherwise good recovery from the infection, an improvement in hearing can then be achieved secondarily, e. g. after one year [102], through a stapedectomy with piston fixation at the incus or, if necessary, at the malleus handle.

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[2] It has been known for a fairly long time that an increased fluoride content in drinking water reduces the incidence of osteoporosis [80]. This is explained by the fact that the hydroxyapatite compounds in the bone are partly replaced by fluoroapatite when fluoride intake is increased. This fluoroapatite compound cannot easily be broken down by enzymes. Because of a presumed analogy between osteoporosis and otosclerosis, fluoride was also used for the treatment of otosclerosis from the 1960s [81]. The hope that it might be possible to cure the otosclerosis pharmacologically with fluoride therapy was not fulfilled. On the other hand there are indications in several studies that the fluoride has a beneficial effect on the progression of otosclerotic inner ear hearing loss [82–84]. Some doctors therefore use fluoride therapy for the treatment of patients with otosclerosis plus inner ear hearing loss [85]. It should be noted that long-term treatments with fluoride can result in toxic side effects with changes in the bone structure [86].

[3] Interestingly enough this age increase mostly affects women, which is why a relationship with hormonal factors was investigated. In fact there has been a marked change in the hormone metabolism of women in relation to their age over the past two decades: birth statistics show that the age at first pregnancy has continued to rise in Switzerland. The use of hormone replacement therapy has also become increasingly widespread from middle age in recent years. Finally, hormonal contraceptives, which are especially popular with young women, now have a significantly lower oestrogen- and gestagen- content than 20 years ago. Further epidemiological and statistical investigations are currently being carried out into these factors [67].

Diagnosis and Clinical Features of Otosclerosis

Clinical Diagnosis

The diagnosis of otosclerotic middle ear hearing loss is usually unproblematic. Typically there is a progressive loss of hearing, which occurs in young adults that can be bilateral and symmetrical or also unilateral, with a positive family history in 30 % of cases. About half of the patients complain of tinnitus [103–106] and vertigo. The vestibular symptoms tend to be rather mild, except in co-existing Ménière's disease. In rare cases (in 1.5–3 %) the otosclerotic hearing loss appears before and during adolescence [107–108], although a first slight loss of hearing had already been noted before the age of 20 years in 15 % of patients whose otosclerosis was first diagnosed when they were adults [109]. In the Bern statistics, six (1 %) patients were operated on before the 18th year of life (11–17 years). A marked obliterative otosclerosis was present in three cases. An inner ear component was already present preoperatively in two of them. Stapedectomy was first performed after the age of 60 in about 10 % of the patients, mostly with a good result. Individual studies suggest that elderly patients develop a high tone loss postoperatively more often than younger patients [110–113]. However, in other studies [105, 114–117] and in our own statistics, this greater inner ear sensitivity in elderly patients was not observed.

Elderly patients with advanced otosclerosis not infrequently develop progressive inner ear hearing impairment in addition to the conductive hearing loss. Ramsay and Linthicum [82] state that inner ear hearing loss eventually occurs in almost 10 % of all patients with otosclerosis, and in some cases, in so-called "malignant" otosclerosis [54], complete deafness develops. In recent years bilateral deafness due to malignant otosclerosis has become a typical indication for a cochlear implant in the elderly [118].

In connection with the progression of the inner ear hearing loss in patients with otosclerosis, an interesting finding in several studies was that in patients who had been stapedectomized on only one side, the bone conduction threshold remained significantly better in the operated ear than in the non-operated ear over an observation period of ten years [119–123]. On the basis of this important observation, these authors recommend that in bilateral otosclerosis an early sequential bilateral stapedectomy should be carried out.

Audiological Investigations

A correct preoperative audiological investigation with a classic pure tone audiogram is obligatory [124]. According to the new guidelines of the Committee on Hearing and Equilibrium of the American Academy [125], in addition to the classic octave frequencies 0.25, 0.5, 1, 2, 4 and 8 kHz, the hearing threshold should also be measured at 3 kHz. A conductive hearing loss of about 40 dB in the low frequencies with a reduction of the gap towards 2 kHz is typical, because the ankylosis of the stapes joint in the oval window primarily has functional effects in the low frequencies [126]. Conductive hearing losses of up to 65 dB have been measured in obliterative otosclerosis and also in fibrosis of the annular ligament, but only when this was very severe [59]. Flat conductive hearing losses of between 50 and 70 dB are atypical for otosclerosis and are more indicative of discontinuity in the chain of the auditory ossicles or a middle ear malformation. An interesting finding in otosclerotic conductive hearing loss is the additional deterioration in the bone conduction threshold found in the middle frequencies, the so-called Carhart notch, which can reach up to 25 dB at 2 kHz [127, 128]. In the case of stapes fixation, the absence of middle ear resonance, which in humans is at 2000 Hz, is given as the cause, together with the reduced movement of fluid in the inner ear due to the immobile stapes [129]. The Carhart notch is eliminated through the stapedectomy, but the resulting improvement in the bone conduction threshold does not correspond to an improvement or "reserve" of the inner ear function.

The speech audiogram shows a normal increase in speech discrimination at a raised acoustic pressure. Reduced speech discrimination indicates additional inner ear involvement, which may or may not be otosclerotic in nature and which should be investigated further.

In middle ear impedance measurements, the tympanogram shows a small peak in otosclerosis, and stapedius reflex responses are absent. In the early stage of otosclerosis a biphasic stapedius reflex with a so-called on-off response can be observed [124]. The measurement of otoacoustic emissions plays hardly any role in the diagnosis of otosclerosis at the present time. Scientific investigations for study purposes in patients with otosclerosis have shown that transitory evoked otoacoustic emissions react sensitively to an ankylosis of the oval window and can no longer be measured even in the early stage [130].

It is important that the various test results in the clinical and audiological investigations coincide. The cause of any discrepancy must be elucidated. Not infrequently it is then found that instead of classic otosclerotic conductive hearing loss, a sensorineural hearing loss is present with a small, additional conductive component, for which surgical treatment is not indicated.

Imaging Procedures

Radiographic investigations in patients with otosclerosis were published for the first time in 1928, by Graham Hodgson. From the 1960s onwards, it became possible to visualize foci of otosclerosis of up to 1 mm in diameter with the use of the polytomographic technique [131]. High resolution computed tomography is currently the best method for obtaining precise information about the bone structure of the petrous bone. Constrictions and ossifications of the oval window can be recognized radiologically in 90 % of cases of surgically confirmed otosclerosis [132, 133]. The demineralization in active otospongiosis lesions is seen as a characteristic "double ring structure" or as a "halo effect" [134, 135]. Inactive, highly sclerotic lesions present as a uniform hyperdense mass and are sometimes difficult to

distinguish from the normal compact labyrinth capsule. In cases with a histological-radiological correlation, even massive otosclerosis lesions have remained unrecognised in a preliminary CT-investigation [136]. On magnetic resonance imaging, slight-to-marked contrast agent enhancement can be seen in otosclerotic lesions, which is interpreted as inflammatory hypervascularization or as an increased content of blood or fluid [135, 137]. Discrete contrast agent uptake by the labyrinth fluid has also been described in massive otosclerosis of the otic capsule with inner ear hearing loss [138]. Active otosclerosis lesions of less than 1 mm in diameter could also be detected through tympanocochlear scintigraphy using technetium-labelled phosphate [139].

Most ear surgeons consider that preoperative imaging is unnecessary in an ordinary case of otosclerotic hearing loss [137, 140]. We also follow this practice in Bern for ecological (radiation exposure) and economic reasons. If, however, complications have developed after a stapedectomy, the position of metal prostheses and their displacement can be identified on the high resolution CT, although with a certain degree of volume distortion [141, 142]. In progressive inner ear hearing loss and if a cochlear implant is envisaged in subtotal deafness, otosclerotic changes of the labyrinth capsule including an ossification of the round window can mostly be detected without problems on the high resolution–CT.

Patient Counselling before Stapedectomy

In-depth counselling of the patient and providing preoperative information is of the utmost importance before a stapedectomy. Stapedectomy is an elective, not a vitally essential operation. According to the law currently in force, the burden of proof for correct preoperative information having been given rests with the surgeon.

Since stapedectomy is a relatively standardized, well-codified operation, it is not difficult to produce an information sheet with a diagrammatic sketch of the operation.

In principle, a stapedectomy can be carried out at any age. In children it is possibly prudent to fit hearing aids at first and not to carry out the operation until both the affected adolescent and also his/her parents insist on the operation. A certain degree of caution is also indicated in elderly patients, especially if they have become successfully accustomed to hearing aids over many years. On the other hand it may also be clearly stated that the chances of success for an improvement in hearing are high, over 90 % in most statistics and often over 95 %. This excellent result is achieved through minimally invasive surgery with an operation that almost always lasts for less then one hour and often involves less than 30 minutes of operating time.

The main problem of stapedectomy remains the possible development of postoperative deafness, the incidence of which is put at 1 % (see p. 117, sensorineural hearing loss and deafness). The patients must be very clearly informed about the risk of this serious complication. Slight postoperative symptoms of vertigo occur fairly often in the first days after stapedectomy. Permanent disabling disorders of balance are rare, however, and can almost always be eliminated through a revision operation (piston shortening, rarely removal). Tinnitus that is present preoperatively often becomes less pronounced or even disappears altogether after the stapedectomy, probably because it is also masked by the improved hearing ability [116]. In this sense stapedectomy even represents one of the most successful possibilities of treatment for tinnitus. In individual cases (about 1 %) a marked tinnitus develops postoperatively, but the intensity of this mostly decreases again within one year.

The patient should also be informed of the fact that in rare cases a revision operation may be necessary. A relatively insignificant and transient postoperative phenomenon is the possibility of a temporary dysfunction of the chorda tympani, the incidence of which in the Bern statistics is 15 to 30 % [143]. Only in 0.3 % of cases did a slight dysgeusia persist permanently.

Iatrogenic lesions of the facial nerve after stapedectomy have only been reported occasionally, mostly in cases with an abnormal nerve course. There is also the possibility (incidence 1 : 1000) of secondary, probably inflammatory, facial nerve paralyses, which occur after a latent period of a few days and are always reversible within a few weeks.

In principle the operation should be carried out on the ear with less good hearing, because of the risk of a postoperative hearing loss or even deafness. Stapedectomy must not be carried out in patients with only one functional ear because of the possibility of this complication. On the other hand, the advantages of binaural hearing are so great that if a stapedectomy on the first ear takes a favourable course, the second ear can also be operated on after a waiting period of about one year. After a bilateral improvement in hearing, the patients benefit from a normalisation of the capacity for sound localization [144], from the restoration of binaural acoustic focussing and stereophony and also from an improved understanding of speech in noise [145, 146]. In unilateral otosclerosis, the end-result often does not reach the hearing threshold of the completely healthy ear, so that the subjective hearing gain is less spectacular.

New technical developments in stapes surgery

Technical Tools

Microsurgical Equipment

The basic equipment consists on the one hand of standard instruments such as needles, small hooks, grasping forceps and microscissors, and on the other of specially designed instruments created by the surgeon in question for his own convenience.

The angulated and black-finished otological instruments of Richards (Smith & Nephew) are preferred as a basis for stapes surgery in Bern for transcanal surgery carried out

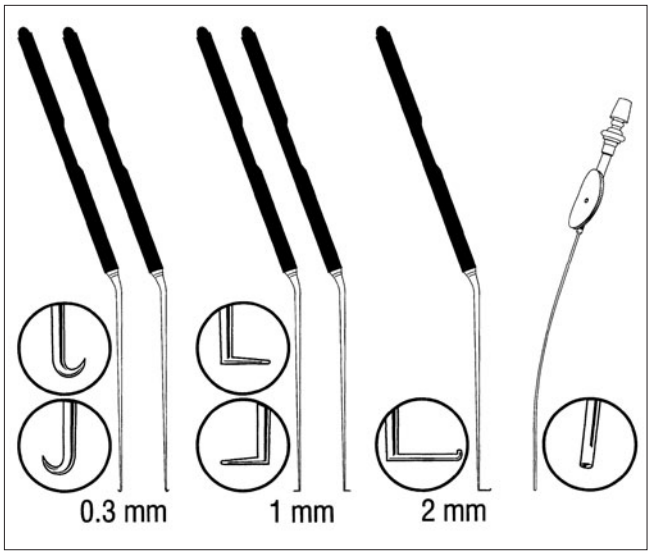


Fig. 5.**3** Different microhooks and otological microsuction devices that are used in transcanal ear surgery. Illustration on the left of the 0.3 mm microhook angled towards the top and bottom, which must have a curve of more than 90 °C. In the centre, the 1 mm hook with a right-angled, not too thin tip. On the right, the right-angled 2-mm hook with a slightly raised end, with which an incus body, for example, can be fished out of the epitympanum. On the far right an otological microsuction device (0.8 to 1.2 mm in diameter), which must be fitted with a bypass.

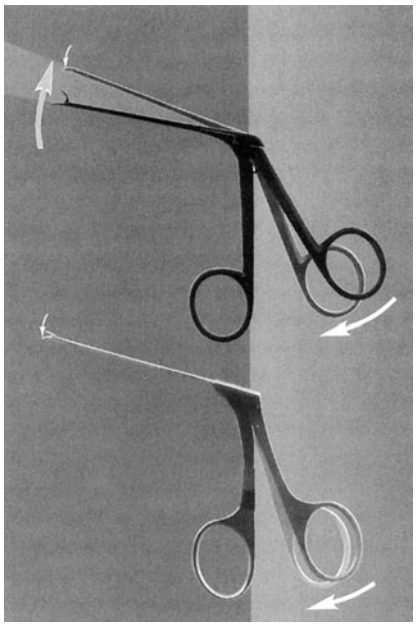


Fig. 5.**4** Illustration of classic closure forceps (top), used for the fixation of the substitute stapes prosthesis round the long incus process, by comparison with the newly developed closure forceps (bottom, with which there is no longer any additional deflection of the lever arm during the closing movement with the thumb.

in accordance with the method of Schuknecht [147, 148]. This equipment incorporates many details that have resulted from the long years of otological experience and the critical intellect of this great ear surgeon. Apparently minimal details can have a significant effect in practical use: a small 0.3 mm hook, for example, should have a curve of more than 90 °C, since otherwise it will be much less effective when dissecting off small pieces of the stapes base or lifting off the mucosa (over the footplate). In the case of the small 1 mm hook, on the other hand, a completely straight, not too thin tip with a 90° angle is best, because this lessens the danger of hooking up soft tissue structures such as nerves or the tympanic membrane (Fig. 5.**3**). Otological microsuction devices are fitted with a bypass. For transcanal stapes surgery, aural specula of 4 to 8 mm in diameter (in radical cavities up to 14 mm in diameter) are used, which are secured with a supporting arm that can be adjusted in all directions, fixed loosely to the operation table.

The closure forceps, with which the metal loop of the piston prosthesis is fixed around the long incus process, is a particularly important instrument in stapes surgery. Fine flat forceps may be adequate for this [102], but it is better to use closing forceps that have a relatively strongly bent clamping tip and which cannot be completely closed so as to protect the long incus process [147, 148]. We have created a specially developed original closure forceps that are stabilized with the middle and index fingers, the closing movement being effected by the movable thumb, to be particularly useful (Fig. 5.**4**).

Use of Microdrills in Stapes Surgery

Even today, well-known ear surgeons still dispense with the routine use of a microdrill to carry out a conventional stapedectomy. Nevertheless, an adequate drill system still forms part of the standard stapedectomy equipment, since it is not possible to do without this mechanical tool in about 10 % of stapes operations, e. g. in obliterative otosclerosis [102, 147]. A conventional otological microdrill system can serve the purpose if fine and long burs 0.5 to 1 mm in diameter are used. The particularly fine and ultralight Skeeter micro-drill (Xomed Treace) has proved extraordinarily useful; this was developed with a long thin guide shaft and very fine diamond and cutting tips for transcanal stapes surgery (Fig. 5.**5**). The number of revolutions can be limited to 500 Hz to protect the inner ear. Many ear surgeons regularly use the 0.5 to 0.8 mm tip of the Skeeter microdrill for the footplate perforation. The Skeeter microdrill is not suitable for the removal of coarser bone, e. g. in the external auditory meatus or in the mastoid.

Novel microdrill systems are currently in development that recognize when the drill tip has reached the inner ear during the footplate perforation, and then automatically terminate the drilling process [149]. Such new technical tools, which are being developed from robotics, will undoubtedly also find their way into stapes surgery in the near future.

In 1992, Novak et al. [150, 151] described a non-conventional stapedotomy technique using ultrasound. A commercially available ultrasound device (Cavimed DN) used in dental medicine was employed, the transducer in the handpiece being connected to a slightly bent otological

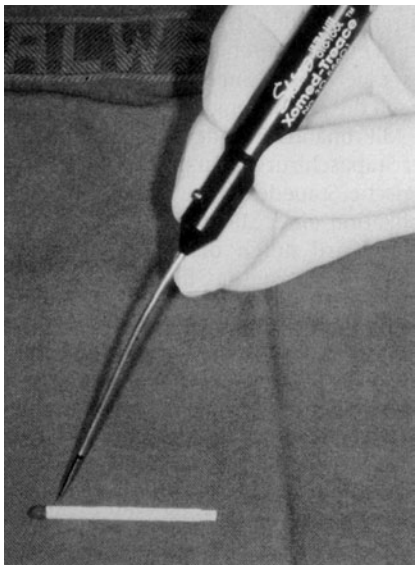


Fig. 5.**5** The ultra-light and precise Skeeter microdrill that is particularly suitable for transcanal stapes surgery.

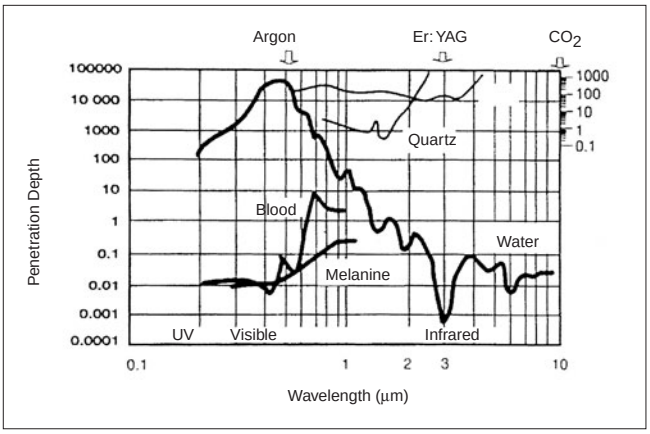


Fig. 5.**6** Depth of penetration in water, blood and melanin of various lasers, in dependence on the wavelength. The argon laser radiating in the visible light has a great depth of penetration in H_2O and at the same time shows strong absorption in melanin and blood. The depth of penetration in H_2O of the erbium laser that radiates in the infrared range at 3 μm is minimal and the CO_2 laser has a moderate depth of penetration in H_2O. There is little absorption in blood and melanin of the erbium and CO_2 lasers that radiate in the infrared range. The loss of energy with fibre optic transmission is also shown on the right of the diagram for different lasers: argon light can be conducted through quartz fibres with relatively little energy loss. Erbium light is absorbed in quartz fibres but can be conducted through zirconium fibres. Conduction through quartz and zirconium fibres is not possible for the CO_2 laser.

needle here. With ultrasound oscillations of 25 kHz, the crura of the stapes could be severed through gentle application of the needle and the otosclerotically fixed footplate could also be perforated.

Use of Lasers in Stapes Surgery

The use of lasers in otology began with Escudero, who in 1979 [152] used the argon laser for the first time to carry out a tympanoplasty. In 1980, Perkins [153] and Di Bartolomeo [154] then successfully used argon laser for the first time in stapedectomy. Following the argon laser, the CO_2 laser was used from 1989 [155] and, from 1996, the erbium laser as well [156, 157]. The advantages of laser use are the contact-free procedure with no mechanical trauma and also a high degree of precision, such as is required in the narrow and deeply localized operation field in the middle ear. Because of the coagulation effect (argon and KTP laser) the operation field remains bloodless. The use of lasers does entail some risks however: lasers produce heat, which can damage the delicate structures of the inner ear. Explosive tissue removal with pulsed lasers generates dangerous pressure waves. In the case of continuously radiating lasers, the laser radiation brings about tissue carbonisation with potentially toxic degradation products, which might result in delayed healing and possibly long-term degeneration.

Principle and Physical Properties of Different Lasers

Laser stands for "Light Amplification by Stimulated Emission of Radiation". The principle of stimulated emission is that a laser medium is caused to emit monochromatic and coherent light in an amplified way through the input of energy. Coherent electromagnetic radiation, ranging from the infrared to the ultraviolet range, can be generated in this way. Some lasers can be used continuously (cw = continuous wave) and also pulsed (argon, KTP, holmium, CO_2), others only in pulsed form, the excimer and the erbium laser for example [158–162]. A continuously radiating system is currently in trials for the erbium laser.

Lasers have differing properties depending on the wavelength. Fig. 5.**6** shows the optical depth of penetration in H_2O, which is biologically particularly important since tissue largely consists of water and bones also have a water content of about 15 %. The argon lasers radiating in the visible range (488 and 514 μm) and KTP lasers (532 μm), have a great depth of penetration in water, but are very strongly absorbed in blood and melanin. The erbium laser, which radiates with a wavelength of 2.94 μm in the infrared range, has a minimal depth of penetration in H_2O (in the range of a few μm). There is correspondingly strong absorption of this laser wavelength in the tissue and bones. The CO_2 and holmium lasers, which similarly radiate in the infrared range, have moderate values in respect of the depth of penetration in water.

An important advantage of the argon, KTP and also of the holmium-laser is that they can be conducted through quartz fibres. Zirconium fluoride or sapphire fibres must be used for the transmission of erbium laser radiation, because even quartz fibres with their low water content still show an attenuation of 1 dB/m at 3 μm. Conduction of the CO_2 laser through optical fibres has so far only been possible with poor results and with silver halide fibres that are very expensive and not very suitable for hospital use [164]. The flexible hollow delivery systems that have been proposed are technically demanding, imprecise and show

transmission behaviour that is dependent on the radius of curvature [164].

Experimental Investigations

The main risk factor associated with the use of lasers on the ear was originally considered to be the temperature effect. The greatest temperature increases were measured with the argon and KTP lasers and the lowest with the erbium laser. Medium values were obtained for the CO_2 and the holmium lasers. The temperature effect is less with short laser pulses than with continuous radiation [158–160, 165–167]. The safety of the argon laser was criticized in respect of possible inner ear damage due to the temperature effect [168, 169]. An elegant solution to this temperature problem was subsequently achieved through fiberoptic application using a micro-hand piece [170]. The advantage of the fiberoptic application over the use of the micromanipulator-controlled, focused laser beam from the microscope is that because of the marked beam divergence at the exit point of the optical fibre, a very rapid fall in the energy density occurs as the distance increases [171, 172]. In the inner ear model, a temperature rise of only 1 °C was measured in the perilymph during stapes footplate perforation using a fiberoptic argon laser [143].

The question of temperature damage is less problematic with the CO_2 laser. In the cochlea model and in the petrous bone [159, 160], temperature rises of a few degrees were measured and in animal studies in cats a temperature increase in the perilymph of 1–2 °C was found [173]. An even lower rise in inner ear temperature of only 0.5 °C was recorded with the use of pulsed CO_2 laser [169]. The erbium laser is by far the best in respect of the temperature effect however. Absolutely no temperature rise in the perilymph of the inner ear is measured during the erbium laser–induced explosive bone removal at the footplate [162]. On histology, only a minimal marginal zone of thermal damage of the stapes footplate perforation of 5 to 10 μm is seen here by comparison with 100 μm with the use of the argon laser [161, 165]. However, the erbium laser generates vapour bubbles during the perforation of the stapes footplate, which generate dangerous shock waves during the subsequent collapse. These shock waves during footplate perforation with the erbium laser automatically reach 140–180 dBA in the inner ear [161]. The pressure wave formation is weaker with the pulsed CO_2 laser at values of up to 135 dBA. The pressure wave formation becomes negligible at values of less than 100 dB with continuous CO_2 laser radiation and with the use of the argon laser [166, 167].

Clinical Experience

Several authors have in recent years published good and very good stapedotomy results after laser use [143, 171, 174–179]. Argon laser stapedotomy with the fiberoptic micro-hand piece has proved to be particularly practical. Both the posterior and the anterior crura of the stapes can be cut through without any problems. A rosette-shaped perforation of the required diameter is made in the footplate with several laser shots. In 1998, Shea [32] wrote that, in his opinion, the introduction of the argon laser with a fiberoptic micro-handpiece represented the greatest technical advance in stapes surgery since he himself introduced microsurgical stapedectomy in 1956. The dreaded complication of a floating footplate or a footplate luxation is virtually eliminated through the use of the laser. With the use of the fiberoptic micro-handpiece it is also possible to carry out a stapedotomy with preservation of the stapedius tendon, which helps the patient to achieve a stapedius reflex and reduces the postoperative hyperacousia. Another advantage of the fiberoptic argon laser is that the equipment required is technically less demanding and is financially several times more economic than other laser systems. For stapes surgery, it is sufficient to have a small air-cooled argon laser unit with a maximum power of 3 watts, such as forms part of the routine equipment of every ophthalmology department. In Bern, we have been using an argon laser (Argus Aeskulap Meditec) with a micro-handpiece made in the hospital's electronic laboratory (Fig. 5.**7**) for coming on eight years without any problems.

Good stapedotomy results with precise footplate perforation have also been reported with the CO_2 laser [174, 180–183]. An important detail with the use of the CO_2 laser is that the target beam and the invisible laser beam must strictly coincide. The author knows of cases of facial nerve paralysis after CO_2 laser stapedotomy, in which the facial nerve was hit because of an axis-shift of the laser beam.

Great hopes were initially placed in the erbium laser for carrying out stapedotomy [184]. It has since been found that the pressure waves generated during the use of the erbium laser for stapes surgery are not harmless and that the pressure waves can bring about transient or even permanent acoustic trauma with high tone losses. Such acoustic trauma has been observed both in stapedotomies carried out with the micromanipulator-controlled erbium laser [157, 185] and with the erbium laser applied through

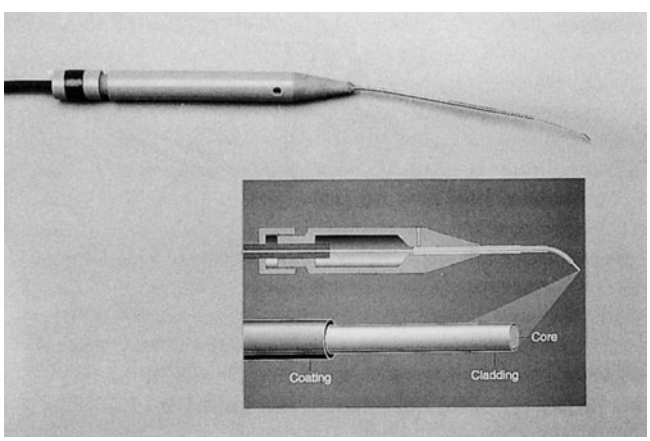


Fig. 5.**7** Illustration and structure of the fiberoptic micro-handpiece developed in Bern for argon laser stapedotomy. The micro-handpiece contains a quartz fibre of 200 μm in diameter and can be sterilized in gas for repeated use. The tip is slightly bent so that the laser beam can be applied at different angles. In the event of damage the glass fibre can be guided to the tip and recut.

a fiberoptic micro-handpiece [157]. In view of the exceptionally favourable properties of the erbium laser in other indications, with the possibility of very precise and efficient bone removal, it is to be hoped that in the future this problem can be overcome through new application parameters. The erbium laser cannot be recommended for stapes surgery at the present time.

Comments on the Operating Microscope

Classically a lens for a working distance of 250 mm is used for stapes surgery with magnifications of 6, 10, 16, 25 and 40 or with continuous magnification. The narrowness and depth of the otological operating area explains the desire for strong light. Modern otological microscopes are therefore increasingly fitted with the particularly efficient xenon light sources. However, xenon light is not without danger, because of its intensity and its UV component, and it is not used, for example, in eye surgery because of the possible risk to the patient's retina [186–188]. Obviously, the xenon light is filtered in ear surgery and the light reflected out of the operating field via the microscope oculars into the eye of the surgeon is attenuated. No relevant studies are available on the long-term risk to the eyes of a surgeon who operates through the microscope with xenon light for several hours every day. In several studies defective colour vision was demonstrated in the operating surgeons after argon laser use [189, 190]. It may be good advice to only ever use just the light strength that is specifically required for a certain operating field.

The spatial positioning is of great importance. In otological surgery, the viewing angle is constantly changing, especially with the transcanal approach, which causes relatively wide microscope movements. Motorized systems are generally too slow and the positioning of the oculars is mostly carried out with one hand by the ear surgeon. Modern microscopes have sophisticated magnetic and electronic devices (e. g. Contraves), which reduce the amount of force required for the movement (Fig. 5.**8**), but the microscope oculars are increasingly becoming heavier due to supplementary accessories (camera, video camera, laser inserts, filters, etc.). Achieving an optimal balance is therefore of the greatest importance. In discussions several older ear surgeons have complained of troublesome pain in the basal joint of the right thumb, which they attribute to arthrotic changes after manipulating the operating microscope daily over many years.

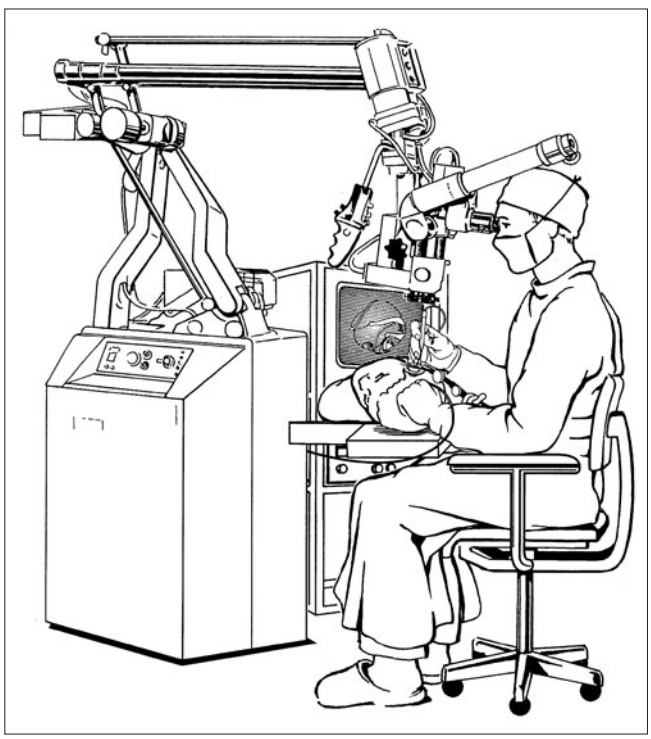


Fig. 5.**8** Positioning of the patient and of the surgeon in transcanal middle ear surgery through the fixed aural speculum. The patient lies on his back and his head is turned away by the surgeon and lowered slightly using the headpiece so that the external auditory canal assumes a vertical position. The surgeon sits straight upright on a five-wheeled (note the safety factor must be considered) movable surgeon's chair which is fitted with armrests, and looks straight ahead through the angled microscope oculars and through the aural speculum into the tympanic cavity. The aural speculum is fixed to the operating table with an articulated metal holder that can be adjusted in all directions (see Figs. 5.**9** and 5.**10**). Since the viewing angle is constantly changing during transcanal ear surgery, an operating miscroscope that is easily moved, equipped with an electronic suspension device, makes things much easier. A sketch of the Zeiss operating microscope used in Bern (Opmi-1) is shown in the Figure with additional oculars on the left and a video-camera on the right.

Surgical Technique of Stapedectomy

Choice of Anaesthesia

In Bern, stapedectomy is performed under local anaesthesia in over 90 % of cases, after intramuscular premedication with morphine (number of mg corresponding to one tenth of the body weight in kg) and scopolamine (0.25–0.5 mg). Additional intravenous analgesic sedation (e. g. propofol combined with opioids) under supervision by an anaesthetist is recommended for the painful injection of the anaesthetic substance into the ear. A stapedectomy can of course also be carried out under general anaesthesia, and this is unavoidable in adolescents, handicapped patients and over-anxious patients. The surgeon loses important intraoperative information because of the anaesthesia, however, such as any symptoms of vertigo, and it is not possible to confirm the hearing gain at the end of the operation.

The local anaesthesia is carried out by injecting 2–4 ml xylocaine/adrenaline 2 % into the four quadrants of the cartilaginous auditory canal. A long fine needle (0.4 mm in diameter) is screwed on and injections are then made at two sites in the posterior bony canal wall. With correct subperiosteal injection, blanching of the skin in the external auditory canal is seen due to the vasoconstriction, but no tissue oedema develops. As soon as the tympanic membrane has been completely anaesthetized elevation of the posterior tympanomeatal flap can be carried out. It is very difficult to supplement inadequate anaesthesia after elevation of the tympanomeatal flap.

Technique of Transcanal Ear Surgery

In Europe, the most widely used method is an endaural incision with the insertion of a small automatic retractor followed by the elevation of a tympanomeatal flap. The transcanal approach, with no external skin incision, through the fixed aural speculum (Fig. 5.**9**) is more elegant, quicker and even more atraumatic for the patient. The use of this approach is very widespread in the USA and is increasingly being preferred by otologists in Europe as well. Further advantages of the transcanal approach are minimal intraoperative bleeding and healing without pain or scars. The fixation of the speculum makes it possible to operate comfortably with two hands (Figs 5.**9** and 5.**10**). Transcanal surgery can only be carried out with angled micro-instruments (Fig. 5.**3**), which are held in a special way with the fingertips so that the surgeon's visual field is not obstructed (Fig. 5.**10**). The surgical technique of transcanal middle ear surgery is somewhat more difficult than the endaural technique, and the manual dexterity required for this has to be acquired. The transcanal approach is routinely used for stapedectomy in Bern. An endaural approach because of severe stenosis of the auditory canal was only necessary in 3 % of stapes operations.

Stapedotomy Versus Stapedectomy

The main advantages of stapedotomy are considered to be a reduction in the surgical inner ear trauma, a reduced risk of infections and perilymph fistulae and also a reduced risk of lateral prosthesis displacement [147, 191–197]. The disadvantages on the other hand are that footplate fractures, piston extrusions and tilting of the piston with reduced hearing gain and subsequent incus necrosis occur more frequently after stapedotomy [198–200]. Glasscock et al. [201] initially reported poor experiences with stapedotomy: eight out of 22 stapedotomized patients had to have revision surgery because of necrosis of the incus process or an extruded piston.

The technique of stapedotomy set in motion the development of piston prostheses made of various plastics and metals. Since these piston prostheses fitted the small footplate perforation exactly, some surgeons soon also dispensed with the use of a vein, fascia or adipose tissue graft to cover the fenestra and contented themselves with covering the gap around the prosthesis with a few blood clots, Gelfoam, connective or adipose tissue. Initially pistons with a diameter of 0.8 and 0.6 mm were used as stapes replacement prostheses. In order to reduce the inner ear trauma still further, from the 1970s onwards, pistons with an even smaller diameter were placed in increasingly smaller fenestrae in the oval window. The stapedotomy technique of Fisch [102], in which a fine 0.4 mm metal wire-Teflon piston and later a platinum band-Teflon piston was used, was particularly popular. Thanks to the small diameter of the piston, it became possible to reverse the classic stapedectomy procedure, in that the footplate was perforated first and the fine piston was inserted while the stapes structure was still present and was fixed to the incus process. Since, before the start of the laser era, the stapes crura still had to be broken mechanically, either with a spatula, a small hook or crura-scissors, this reversal of the surgical procedure reduced the risk of a floating footplate.

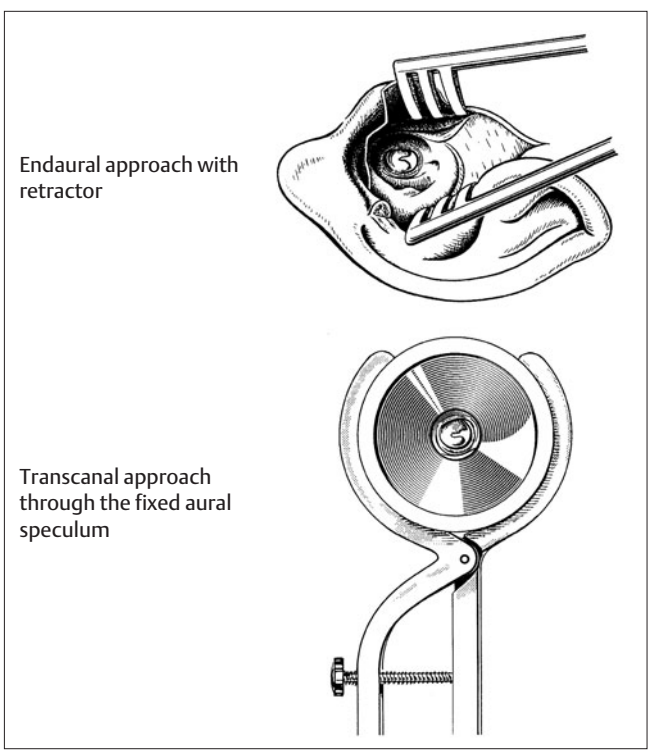


Fig. 5.**9** Surgical approaches commonly used to carry out a stapedectomy. The principle of the approach with an endaural skin incision and the insertion of an automatic retractor is shown above; and, below, the transcanal approach through the fixed aural speculum with no external skin incision.

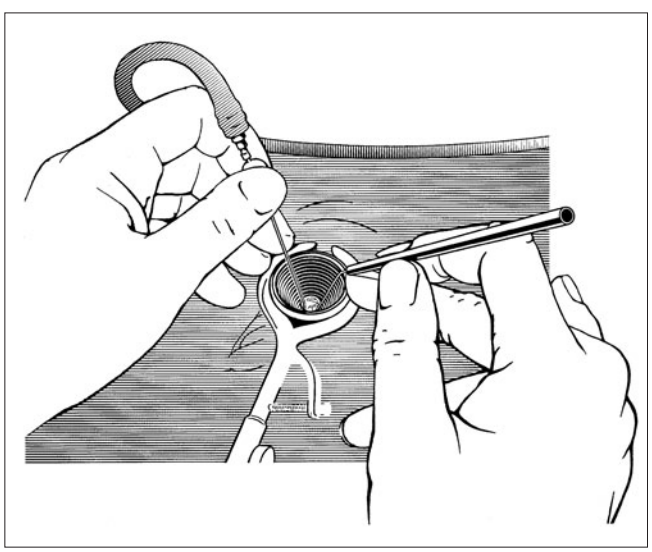


Fig. 5.**10** Manipulation of the instruments in transcanal ear surgery through the fixed aural speculum. The angled instruments are held in a special way using only the fingertips so that the visual field is not obstructed. One or two fingers always rest on the edge of the speculum to additionally stabilize the hand and as a safeguard against involuntary head movements of the patient.

Trials were subsequently carried out with even smaller piston diameters of 0.3 and 0.2 mm, but only a modest hearing gain was obtained with these minimal piston diameters [202]. The differences in respect of the postoperative hearing gain were not very great between the 0.4 mm, 0.6 mm and 0.8 mm piston, i. e. between stapedotomy and partial and total stapedectomy, respectively. A controversy arose that has not yet been conclusively resolved, as to which technique and which piston diameters would lead to the best hearing results (see p. 108). Influence of the piston diameter on the hearing gain). On the basis of their results, many ear surgeons have come to the conclusion that the hearing gain is greater, especially in the high frequency range, with stapedotomy than after stapedectomy [191, 192, 195–197, 200, 203]. Other surgeons dispute this, because they have found that total stapedectomy is superior to stapedotomy in respect of the postoperative hearing gain, especially in the low and middle frequencies [105, 193, 205–207]. It is of interest that this could be demonstrated less in the measurement of the air-bone gap closure than in the fact that there was a better hearing gain after stapedectomy in the comparison of the pre- and post-operative air conduction threshold, chiefly because an overclosure (improved postoperative bone conduction threshold compared with preoperative bone conduction threshold) occurred more frequently. This primarily applies to the low and middle frequency ranges [193, 207].

On the basis of their statistics, the advocates of stapedotomy on the other hand maintain that the air-bone gap closure with the small fenestra is at least equally as good, even in the middle frequencies, within four to six months after the operation as that with a large fenestra, and that significantly better results are achieved in the high frequency range as well [192, 195].

As regards the risk to the inner ear, most studies have unanimously confirmed that total stapedectomy is inferior to a small fenestra stapedotomy [201, 208].

Sedwick et al. [209] found an inner ear hearing loss of >10 dB in 6.3 % after total stapedectomy, in 1.1 % after partial stapedectomy and in 3.2 % after stapedotomy. Fisch and Dillier [210] recorded a postoperative inner ear hearing loss in 2.5 % after stapedectomy compared with 0.4 % after stapedotomy. In a long-term study, Kürsten et al. [191] found an inner ear hearing loss of only 0.7 dB per year after stapedotomy compared with 1.1 dB per year after stapedectomy and therefore recommend stapedotomy as the technique of choice. A difference in favour of stapedotomy is also found in an analysis of the incidence of postoperative deafness quoted in the various statistics. These differences are mostly not statistically significant, however, because of the rarity of inner ear problems after stapes surgery.

Stapes Replacement Prostheses

Intraoperatively Prepared Stapes Replacement Prostheses

Initially the stapes replacement prostheses were made directly at the operating table by the surgeon himself. After removal of the stapes, the oval window was covered with a graft of vein, ear lobe adipose tissue or perichondrium. Plastic, metal wire, a displaced stapes crus or an autologous bone or cartilage chip was used as stapes replacement. Almost all surgeons subsequently abandoned these last-mentioned methods because of renewed bony fixation, resorptions or displacements. The polyethylene tubes which were used as stapes replacement prostheses in the 1970s [211] are also no longer used, because they could lead to perilymph fistulae and cases of purulent labyrinthitis [60, 212, 213]. The tried and tested steel wire–adipose tissue prosthesis of Schuknecht [33], which was made to the required length on a special prosthesis block, remained in very widespread use for a long time (Fig. 5.**11a**). This individually constructed prosthesis is still successfully used today by quite a lot of surgeons.

Commercially Available Piston Prostheses

The individually constructed prostheses were then increasingly replaced by prefabricated prostheses in order to simplify the operation, save time and ensure a standard quality. A whole series of piston ranges of different lengths (3.75–6.5 mm) and different diameters (0.3–0.8 mm) are now available. The combined fluoroplastic-piston prostheses, which are fixed to the incus with a metal wire loop (Fig. 5.**11b**) are probably most widely used at the present time. Initially a thin wire made of stainless steel, tantalum or molybdenum was used for the wire loop [214], and later a fine platinum band. The platinum band has the advantage of being softer so that it can be more easily closed around the incus process.

Many ear surgeons also used prostheses made entirely of plastic (Fig. 5.**11c**). Mostly they are placed in the opened oval window over a vein and are clamped around the incus process with an open loop. Teflon–metal wire prostheses, on the other hand, are often immersed directly into the

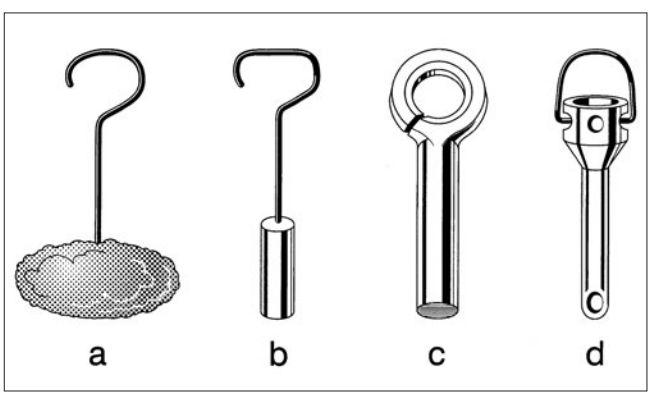


Fig. 5.**11** Different stapes replacement prostheses. From left to right the figure shows the steel wire–adipose tissue prosthesis of Schuknecht, prepared directly at the operating table, the combined metal wire–Teflon piston prosthesis of Guilford, Shea's prosthesis made entirely of Teflon, and Robinson's prosthesis made entirely of metal. There are numerous modified prostheses at the present time derived from these basic types, which differ in respect of their form, metal, and loop (wire or band) and which mostly bear the name of the initiator. Further types of prosthesis are shown in Fig. 5.**19**.

perilymph without a vein graft. In addition, there are the prostheses made entirely of metal, such as the Robinson prosthesis used since the 1960s [215], which is made of stainless steel and is fastened to the incus process at the top with a handle (Fig. 5.**11d**). In recent years, piston prostheses made of pure gold, designed at the beginning of the 1990s by Steinbach, have also become widely used in Europe. These pistons have a broad soft band that can be easily and evenly pressed on to the incus process. According to Schimanski [216, 217], gold pistons also have the advantage of a particularly smooth surface that ensures optimal mobility of the prosthesis in the footplate opening. Moreover, necroses of the incus process hardly ever occur with gold prostheses. Since, then however there have been several reports of granulomatous reactions with inner ear damage after stapedectomies using gold pistons [218].

Titanium prostheses represent the latest development in the field of all-metal prostheses. Titanium is known for its particularly good biocompatibility, but it is slightly more brittle than platinum and gold. Since it is not a noble metal, it should not come into contact with steel and other metals, otherwise the titanium can absorb toxic substances (e. g. the vanadium bound in steel). Clinical studies are currently in progress with all-titanium prostheses. The future will show whether these implants represent an additional advantage.

Influence of the Structure and Weight of the Prostheses on the Hearing Gain

The physical parameters that influence sound transmission in the middle ear include mass, elasticity and rigidity. As regards the rigidity of stapes prostheses, calculations on the theoretical inner ear model have shown that this factor should not be very problematic as long as the rigidity of the materials used is considerably greater than the impedance of the inner ear structures [219]. For clinical purposes this is the case for virtually all materials (plastic and metal) that are used for stapes replacement prostheses.

Changes in the mass also lead to very little change within relatively wide limits in sound transmission [220]. Calculations on the model of the inner ear showed that an increase in the mass of a stapes prosthesis by about 16 times the weight of the natural stapes, which is 3 mg, should only result in a decrease in hearing of 10 dB maximum and only in the high frequencies [221]. In direct investigations on petrous bone specimens, however, measurements showed that the addition of an extra weight of only 5 mg, to the stapes brought about a hearing loss of 15 dB [222]. Contradictory results are also found in clinical studies with stapes prostheses made of materials with different weights. Comparative retrospective measurements of the postoperative hearing gain with the use of a Teflon prosthesis (3 mg in weight) and a gold prosthesis (10 mg in weight) with the same footplate diameter, which were inserted by the same surgical team using the same surgical technique [223], showed that the heavier gold prosthesis resulted in a hearing gain which was better by 4.5 dB than that with the lighter Teflon prosthesis. The difference was especially marked in the low frequencies; the Teflon prosthesis did rather better at 4 kHz than the gold piston, however. Using the Robinson all-metal prosthesis (12.5 mg), Robinson [215] achieved a hearing gain that was significantly better by a few decibels in both the low- and the high-frequency range than with the use of the Robinson all-Teflon prosthesis (3.3 mg).

Influence of the Piston Diameter on the Hearing Gain

The transmission of sound from the middle ear to the fluid of the inner ear is a function of the volume movement per unit of time, which is exerted by the stapes footplate movements on the inner ear fluid. Theoretical calculations on the model of the inner ear have shown that, with a vibration area of a little more than 2 mm^2, which corresponds to the dimension of the natural stapes footplate, optimal sound transmission occurs with the greatest deflection of the basilar membrane [224]. Since stapes replacement prostheses have a smaller terminal area than the stapes footplate, the sound transmission is only suboptimal. To a certain extent the reduction in size of the surfaces is compensated for by greater movement amplitude of the piston. This is one reason why stapedectomies carried out with piston prostheses of different diameters lead to virtually identical hearing results [225]. If the piston diameter is minimal, e. g. if a wire is placed in a minimal opening in the footplate, the sound transmission is greatly reduced. Measurements show that the critical value at which there is a relevant decrease in the sound transmission seems to lie between a piston diameter of 0.4 mm (surface: 0.13 mm^2) and 0.3 mm (surface: 0.07 mm^2). On the basis of the inner ear model, a hearing loss in the low frequency range of 5 dB is already to be expected with a piston of 0.8 mm in diameter (surface: 0.5 mm^2) by comparison with the natural stapes footplate. The loss is 10 dB for a piston of 0.6 mm diameter (surface 0.28 mm^2), and even 15 dB for a piston of 0.4 mm diameter [221]. These calculation only apply, however, if the footplate perforation is not significantly greater than the piston itself.

On the basis of these calculations, in the clinical analyses slightly better hearing gains should be found with total stapedectomy than with small fenestra stapedotomies and the insertion of pistons with a small diameter. Clinical studies in respect of the hearing gain have led to contradictory results, however, as has already been shown on page 107, Stapedotomy versus stapedectomy. The theoretical estimates are confirmed by a number of older and more recent comparative studies, however: in a retrospective study, Grolman et al. [226] found a hearing gain that on average was 5 dB greater with a Teflon prosthesis of 0.4 mm in diameter than with a 0.3 mm diameter prosthesis. Shea [227] and Conrad [123] made the same observation and stopped using the piston of 0.3 mm in diameter because it did not result in an adequate hearing gain, especially in the low-frequency range. Böheim [228] achieved a hearing gain with a gold piston of 0.6 mm in diameter that was significantly greater by 5 dB than that with a 0.4 mm gold piston. The difference was levelled out in the high frequencies. Shabana et al. [229] come to the same conclusion. In his stapedectomy series, Teig [230] found that the hearing gain with the insertion of a 0.8 mm

piston was about 5 dB better than after the use of a 0.6 mm piston and 10 dB better even than after the insertion of a 0.4 mm piston. This difference was apparent less from the residual air-bone gap than in the measurement of the hearing gain, which was measured from a comparison between the postoperative and the preoperative air conduction threshold (i. e. with the inclusion of the postoperative improvement in the bone conduction threshold caused by the Carhart notch). In long-term studies in larger collectives also, better hearing gains were measured after stapedectomy with the insertion of a large-diameter piston (0.8 mm) than after stapedotomy with the use of a small-diameter piston (0.6 mm) [105, 206]. Mangham [193], Möller [198] and Rizer and Lippy [207] also found slightly better hearing gains after stapedectomy than after partial stapedectomy or with the insertion of a 0.6 mm rather than with a 0.4 mm piston.

Exactly the opposite results were published in other studies: Sedwick et al. [209], Kürsten et al. [191], Naramura et al. [192], Plath et al. [196], Herzog [200], Cremers et al. [232], Baily et al. [231], Fisch [195], Smyth [194] and McGee [204] have all found a slightly greater hearing gain after stapedotomy than after stapedectomy and after the insertion of pistons with a diameter of 0.4 mm than after the use of larger pistons. In most of these studies the hearing gain proved to be in the favour of stapedotomy, especially in the high-frequency range.

The fact that all of the clinical studies to date have been carried out retrospectively, and mostly on a selected group of patients with various forms of additional bias, is a problem. Moreover, in studies comparing stapedotomies using pistons of different diameters the size of the footplate perforation was not taken into consideration. In a study carried out by Fucci et al. [233], the same hearing gains were measured with a 0.6 mm and a 0.8 mm Robinson metal piston, which were placed on a vein graft and footplate perforation of similar size.

A prospective, pseudo-randomized study is currently in progress in Bern, in which the postoperative hearing gain and the residual air-bone gap are being compared in groups of 20 patients each after stapedotomy with a 0.4 mm, 0.5 mm and 0.6 mm piston and a group of 20 stapedectomies with the insertion of a 0.8 mm piston [234]. The conscientious conduct of this study has proved to be difficult, e. g. in the case of wide footplate dimensions when the study plan requires the use of a 0.4 mm piston, or if a 0.6 mm or 0.8 mm piston should be used when the dimensions are narrow. Since the interest of the patient comes first, study dropouts occurred in such situations. The interim results after 20 stapes operations show that virtually identical hearing gains and identical air-bone gap closures (± 1 dB) are measured for the 0.4 mm, 0.6 mm and 0.8 mm pistons. Only with the 0.5 mm piston was the hearing gain increased by 7 dB and the residual conductive hearing loss reduced by 5 dB. The better results with the 0.5 mm piston might be due to chance, but they might also indicate that the prosthesis which has been used as standard for many years and with which there has been the greatest surgical experience, also leads to the best results. Such an influence of surgical experience might be a possible explanation for the contradictory results of different surgeons with different types of prostheses.

Prosthesis Fixation to the Incus Process

The fixation of the prosthesis to the incus process is a particularly critical point in stapedectomy. Most otologists accept that an imperfect transmission of movement between the incus process and the prosthesis leads to an incus arrosion with loosening of the prosthesis[4], which is one of the commonest causes of new conductive hearing losses that occur after stapedotomy and one of the most frequent indications for revision surgery on the stapes [102, 147, 236]. The problem of optimal piston fixation is the main reason why many ear surgeons have given up the rigid steel wire prostheses in favour of prostheses with soft band loops made of platinum and gold. These small bands can be fitted snugly with gentle pressure around the long incus process without the spring tension inherent in the steel. Optimal piston fixation is obviously also not unproblematic with the all-Teflon prostheses. The open loop of the plastic prostheses is widened a little before insertion, and, after being slipped on over the long incus process, the plastic ring tightens around the incus virtually by itself thanks to its "memory effect." On the basis of observations made in revision operations, several surgeons have voiced the suspicion that the constant pressure can eventually lead to a pressure necrosis of the long incus process, which is why they did not use this type of prosthesis [102, 147].

In order to get an even better grip on the problem of piston fixation around the long incus process, self-fixing prostheses are currently being tested, such as the new gold titanium or pure titanium prosthesis with which there is automatic fixation to the incus through spring tension [237].

In cases where perfect fixation of the wire loop cannot be achieved with the closure forceps due to an anatomically atypical incus process, I have for several years used a drop of glass ionomer cement for additional consolidation of the piston. Initially I used the hydroxyapatite cement of Ionos for this [238, 239]. Since this can no longer be obtained, we use the English Seronocem that has been specially designed for use in otology (Corinthian Medical Ltd., Nottingham, England; representation in Germany: Bess Company, Berlin). The two-component glassionomer cement, which undergoes cold polymerisation, is supplied in a capsule sterilized with gamma rays; this must be broken open before use to mix the two components and is placed in a special shaking machine for 10 seconds [240]. A drop of the freshly stirred, viscous cement is then taken up on the point of a pick and applied to the incus process and the

[4] The South American stapes surgeon Rivas [235] does not take this view. In his opinion, the incus process arrosion can in fact actually be avoided through the fact that the stapes replacement prosthesis is fastened only very loosely around the incus process, because this would prevent a pressure necrosis of the incus process. He says that in several thousand stapes operations that he personally carried out, thanks to this technique he has virtually never had a case of incus process necrosis.

metal loop. The cement hardens in a few minutes and ensures a solid bond between the incus and the prosthesis over a broad area. Any contact of the cement with the oval window is carefully avoided, and the pick that came into contact with the cement is also no longer used for further manipulations until it has been cleaned and sterilized again. This additional piston consolidation through cement has proved of value in more than 50 stapes operations, which I personally have carried out. No negative effects have been observed. The additional cement consolidation is particularly useful in stapes revision operations carried out when the prosthesis has to be fixed to the stump of the incus process again when this has broken off. Use of the cement has also proved of value for the malleus handle stapedectomy (malleus grip, Hammergriff), in which the additional consolidation of the metal loop around the conical malleus handle facilitates optimal positioning of a prosthesis that is too long (see Fig. 5.**20**, 5.**21** and Fig. 5.**23**).

Sealing of the Oval Window

For the first stapedectomy, Shea [1] used a piece of vein wall to seal the oval window below the stapes replacement prosthesis. This technique has since continued to be routinely used with great conviction by many stapes surgeons [105]. Causse et al. [241] argued that veins from the back of the hand would have similar elastic properties to those of the annular ligament of the stapes footplate and that therefore almost natural sound transmission conditions would be achieved with a vein graft. Moreover, the inner ear would be particularly well protected against barotrauma through an implanted vein. The long-term histological investigation of veins that were removed during revision operations confirmed the persistence of elastic fibres [242]. In other histological studies, however, massive fibrosis and even ossification of previously inserted veins was observed [243]. Tension deformations of veins which led to piston displacements, massive fibrosis of the oval window with piston immobilization or even renewed ossification of the window were also observed several times in the Bern stapedectomy revision series. Other surgeons use thin fascia or perichondrium to cover the oval window. Adipose tissue has continued to be widely used because of its good plasticity and durability [147, 206], but other surgeons consider this to be relatively unfavourable [243].

It was fashionable for a certain period of time to seal the oval window with Gelfoam [148, 243, 244]. This was abandoned because internal ear fistulae were observed fairly often after sealing with Gelfoam. Several surgeons also had the impression that Gelfoam caused inflammatory reactions in the inner ear [213, 245]. This problem is present resolved since the company has changed the sterilization procedure by no longer using to formaldehyde.

Since the use of the stapedotomy technique with the insertion of the piston into a small fenestra of the oval window became widespread, many otologists have dispensed with tissue grafts altogether: Teflon and metal pistons are immersed directly into the inner ear fluid. Only the free gap around the prosthesis is still covered with some blood, or adipose or connective tissue or is even left open. These graft-free stapedotomies are also successful. The problem of tension deformations of veins no longer occurred, and inner ear fistulae or barotrauma were not seen more frequently than after a vein graft. Following Schuknecht [148], the Teflon piston is also immersed directly in the perilymph in Bern. The oval window around the piston is sealed with ear lobe adipose tissue or gel foam. Perilymph fistulae have never been observed to date with this technique in Bern. Additional sealing of the inner ear with autologous tissue is undoubtedly indicated in the case of large footplate openings.

Stapedectomy without Replacement Prosthesis Made of Foreign Material

As a continuation of the principle of stapes mobilization, already practised during the 19th century, attempts have constantly been made to leave part of the stapes superstructure in situ in stapes operations, so as to avoid the implantation of prosthetic foreign material in this way [39, 40]. For a certain period of time, Palva et al. [246] and others used one of the crura of the stapes as graft. The disadvantages of this method are that it is technically relatively difficult and that when displaced to the middle of the oval window, the crus of the stapes—especially if it is not long enough—has a tendency to migrate to the margin of the window or to be progressively resorbed [214, 247]. Laitakari and Laitakari [248] had to carry out a revision in 27 % of cases after posterior crus partial stapedectomy because of renewed footplate ossification. This only occurred in 1 % of their cases after stapedotomy however. Pfaltz [42] replaced the extracted stapes with a perichondrium covering of the oval window and the insertion of an autologous cartilage chip. A disadvantage of this otherwise sparing method is that the cartilage chip softens over the years, which leads to a diminution of the initial hearing gain. In a recent long-term study carried out over 5 to 10 years, Somlo [249] did not observe any cartilage resorptions in his own stapedectomy series carried out using this technique.

Silverstein [250] has recently described a laser stapedectomy technique without prosthesis (Laser STAMP = Laser Stapedotomy Minus Prosthesis), which he uses in the initial stage of otosclerosis when only the anterior margin of the footplate is fixed. Using the fiberoptic laser, the anterior crus of the stapes is cut through at the base and the anterior part of the footplate. The resulting gap in the footplate is sealed with adipose tissue. Silverstein has achieved equivalent results to those of classic stapedectomy in 38 primary stapes operations using this minimally invasive technique. The stapedius reflex is preserved with the Laser STAMP. No long-term results are available yet.

Technique of Transcanal Argon Laser Stapedotomy Using a Fiberoptic Micro-handpiece

Standard Technique

The stapedotomy technique used in Bern and which is presented here has evolved out of the transcanal method of

operation taught in Geneva and Boston and described by Schuknecht [147, 148].

After local anaesthesia has been carried out, the largest possible aural speculum is placed in the external auditory canal with cautious screwing movements. Using a roller knife, the external auditory canal is then incised starting at the 6 o'clock position from the tympanic ring backwards and outwards in a curved incision which then connects up with a second incision from the tympanic ring starting at the 12 o'clock position (Fig. 5.**12a**). Only now is the aural speculum fixed in the optimal position with the articulated speculum holder. The skin of the external auditory canal is progressively elevated using a small sickle knife and held up with the aspirator. Fibrous adhesions are cut with the Bellucci microscissors (Fig. 5.**12c** and **d**). As soon as the auditory canal flap has been elevated up to the tympanic ring, the tympanic cavity is carefully opened using a pick, avoiding the chorda tympani. Using a small raspatory, the tympanomeatal flap is brought forwards and upwards as far as the handle of the malleus. In order to obtain a good view of the stapes, it is usually necessary to remove the scutum. This is done with a bone curette through movements directed from top to bottom towards the outside (not towards the 12 o'clock position because of the risk of incus luxation).

For an accurate inspection of the stapes, of the oval window and of the tympanic section of the facial nerve, the chorda tympani is gently pushed away upwards or downwards. The mobility of all the auditory ossicles is tested by being carefully touched with the pick. As soon as the presence of a stapes ankylosis has been confirmed, the argon laser (Argus Aesculap Meditec) is activated. The correct energy transmission via the fiberoptic quartz fibre from the end of the micro-handpiece is tested in a measuring device (Powermeter 2010, Lasertherapeutics).

The angled fiberoptic micro-handpiece is held like a conventional otological micro-instrument. The following surgical steps of the argon laser stapedotomy are illustrated in Fig. 5.**13**. The tendon of the stapedius muscle and then the posterior crus of the stapes are cut through with 3 to 6 laser pulses (2 watts; 0.1 s) and here there is either delicate contact with the structure to be cut through or it is not touched at all. The anterior crus of the stapes is lasered through with the angled tip of the micro-handpiece, mostly not under direct vision after direct contact has been made. The fine vapour generated is continuously suctioned off with the aspirator. The small 1 mm right-angled hook is used to cut through the incudostapedial joint. The superstructure of the stapes is removed with small flat alligator forceps. Small sources of bleeding are arrested with additional laser pulses from a distance of 0.5 to 1 mm. Fibrous adhesions in the oval window are vaporized off with the laser.

The footplate perforation is achieved with 6 to 12 rosette-shaped laser pulses (1.5 watts; 0.1 s), where a round area of white necrosis about 0.6 mm in diameter is generated between the middle and the posterior third until perilymph begins to trickle through. The footplate area treated with the laser is touched with the measuring instrument and disintegrates into ash, which is now progressively

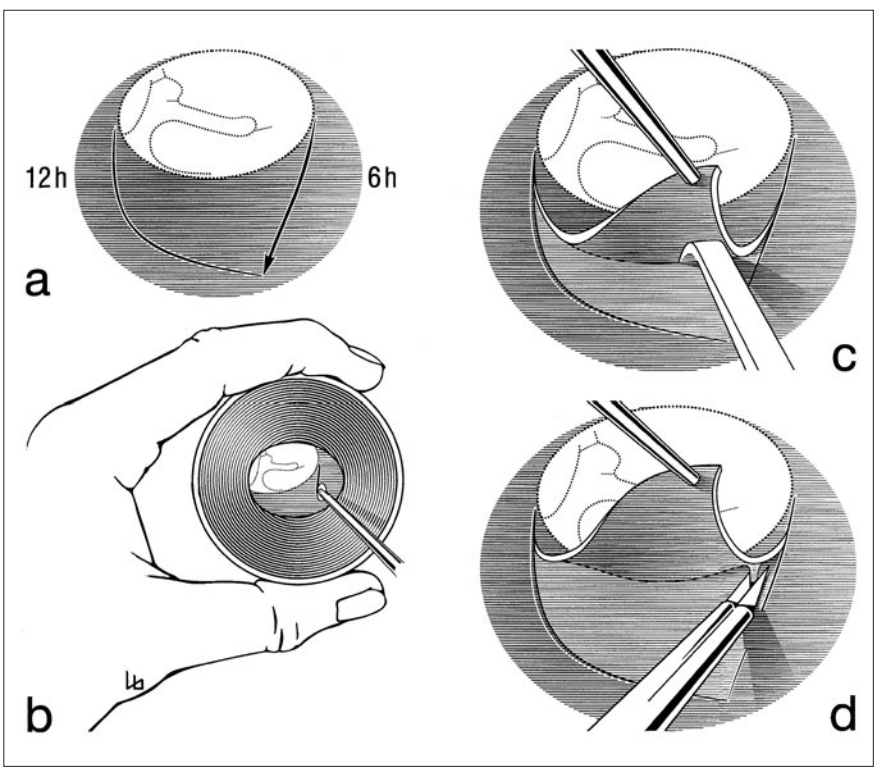


Fig. 5.**12** Transcanal incision of the skin in the external auditory canal using a roller knife (**a**). Progressive elevation of a posterior tympanomeatal flap using the sickle knife and the Bellucci micro-scissors (**b**, **c**).

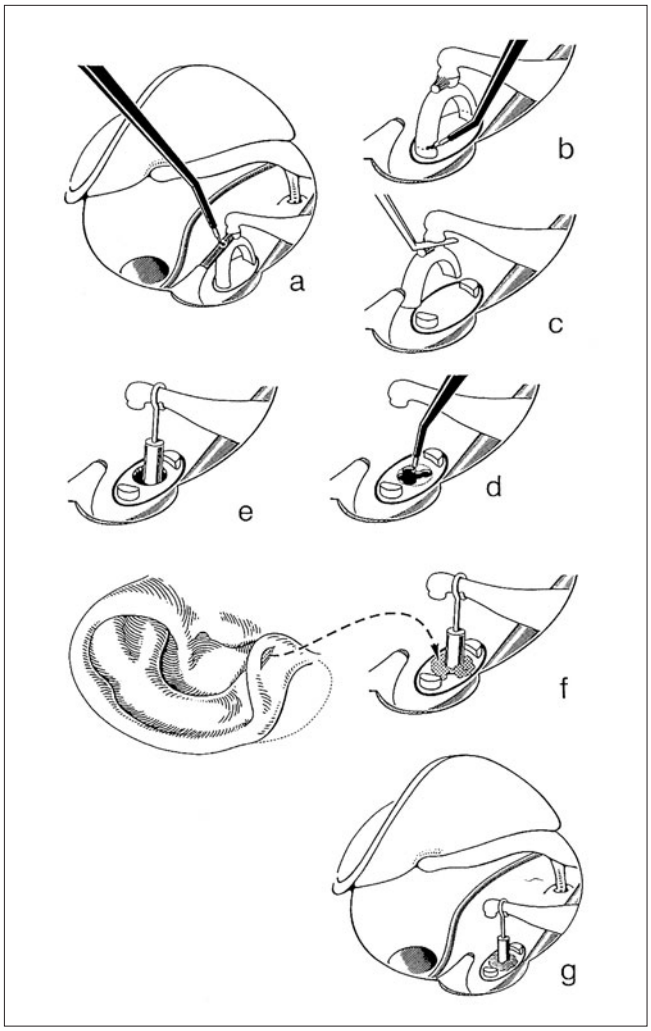


Fig. 5.**13** Technique of fiberoptic argon laser stapedotomy. **a** After elevation of the tympanomeatal flap the stapedius tendon is cut through with 3–6 laser pulses (2 watts; 0.1 s). **b** Laser removal of the posterior crus of the stapes. **c** After laser removal of the anterior crus of the stapes, the incudo-stapedial joint is cut through with the small right-angled 1 mm hook. The stapes superstructure is then removed with fixation forceps. **d** Contact-free rosette-shaped perforation of the stapes footplate between the middle and the posterior third with 6–12 argon laser pulses (1.5 watts; 0.1 s). In principle the aim is to achieve a white carbonized necrosis of the footplate over an area of about 0.6 mm in diameter, avoiding direct laser radiation into the vestibule. The carbonized area disintegrates into ash on contact with the measuring instrument and is progressively washed out of the perforation through the escaping perilymph. **e** Insertion of a piston prosthesis (standard: platinum band–fluoroplastic piston 0.5 × 4.25–4.5 mm) and fixation of the platinum band loop around the long incus process with the closure forceps. **f** Sealing of the oval window with pieces of adipose tissue taken from the reverse side of the ear lobe. **g** Middle ear status after stapedotomy has been carried out.

washed out of the perforation by the escaping perilymph. In the case of thicker footplates, the Skeeter microdrill with a 0.6 mm tip is additionally used for the opening of the vestibule after the laser application. Direct laser pulses into the open vestibule are avoided as far as possible. When they have occurred, however, they have not had any negative consequences.

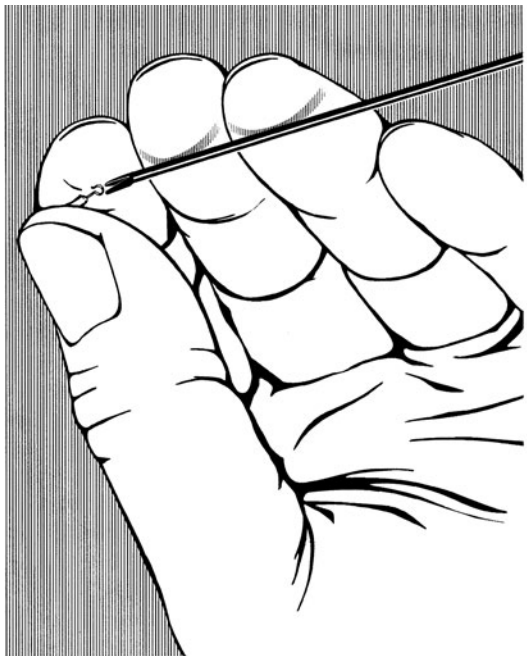


Fig. 5.**14** Grasping the stapes replacement prosthesis with the flat alligator forceps. The prosthesis piston is held between the thumb and the index finger (using powder-free gloves). With the 5.3 mm flat alligator forceps supported on the middle and ring fingers, the platinum band is grasped tightly and carefully at the posterior upper part of the loop and in an angle corresponding to the individual middle ear status, so that the prosthesis can be pushed over the long process of the incus in one single movement, with the simultaneous introduction of the piston end into the footplate perforation.

After measurement of the perforation diameter and of the distance from the incus process a suitable piston prosthesis is chosen (standard: Richards platinum band-fluoroplastic piston [Smith and Nephew] 0.5 mm × 4.25–4.5 mm). The prosthesis is grasped tightly with the small, flat alligator forceps (5.3 mm in length) at the posterior upper part of the metal loop in an angle estimated according to the given anatomical situation (Fig. 5.**14**) and is placed over the incus process in one movement as far as possible and is introduced directly into the perforation (depth of penetration 0.25 to 0.5 mm) simultaneously with the piston. The fixation of the piston is carried out using specially developed, particularly thin and precise closure forceps (Fig. 5.**4**); after stabilization by resting the four fingers on the edge of the speculum a progressive thumb movement is used to close the forceps and achieve fixation of the wire loop around the incus process. Achieving a completely solid transmission of movement from the handle of the malleus to the inner ear with frictionless mobility of the piston in the footplate perforation is regarded as the essential aim. The oval window is sealed with small pieces of gel foam or adipose tissue from the ear lobe, and the tympanomeatal flap is replaced. The hearing gain is confirmed using the tuning fork test of Rinne and whispered speech. The tympanic membrane is then splinted with moist strips of natural silk and the external auditory canal is packed with cotton wool soaked in otosporin and a gauze wick.

Stapes operations are either carried out on an outpatient basis or during a short stay in hospital of one to four days,

depending on the wishes of the patient. The auditory canal dressing is removed after 10 days.

Argon Laser Stapedotomy with Preservation of the Stapedius Tendon

Following a classic stapedectomy with division of the stapedius muscle tendon, after removal of the auditory canal dressing the patient has a marked hyperacousia, which as a rule regresses within a few weeks. In over a third of stapedectomy patients, noise intolerance and also other subjective audiological phenomena, such as slightly reduced speech discrimination in noise, still persist after a period of years [251]. These phenomena are attributed to the loss of the stapedius reflex after the stapedius tendon has been cut through. The stapedius reflex brings about a high-pass filtering of the acoustic stimulus, which results on the one hand in an improved understanding of speech in noise, and on the other in a certain protection against the effects of acoustic trauma [252, 253]. Individual ear surgeons [38, 39, 254, 255] had therefore already attempted to preserve the stapedius muscle tendon shortly after the introduction of stapedectomy. The preservation of the stapedius muscle tendon was technically relatively difficult with the mechanical instruments available, and the method was mostly abandoned because it did not improve the hearing gain and in certain situations was considered to have an adverse effect on the prognosis. It should be noted that Marquet managed to preserve the stapedius tendon using mechanical instruments in over 50% of his 1681 primary stapedotomies [208].

The targeted removal of the stapes crura has become considerably easier with the introduction of the fiberoptic laser. Individual ear surgeons have reported series of laser stapedotomies with preservation of the stapedius muscle tendon in recent years [256, 257]. Causse [258] carried out a reconstruction of the stapedius muscle tendon with a droplet of fibrin adhesive in more than 3500 patients. The postoperative hearing gains published in these studies are quoted as being similar to those after classic stapedectomy. The stapedius reflex can be demonstrated objectively by tympanometry after the stapedectomy [255, 259]. Subjectively patients who had undergone a classic stapes operation on one ear and a stapedectomy with preservation of the stapedius tendon on the other ear, reported that they suffered less from acute postoperative hyperacousia and were less disturbed by noise [257, 259]. It was also postulated that the danger of barotrauma would be decreased through preservation of the stapedius tendon and the risk of necrosis of the incus process reduced [257].

My personal stapedotomy technique for the preservation of the stapedius muscle tendon using the fiberoptic argon laser micro-handpiece is illustrated in Fig. 5.**15**. Laser pulses of 2 to 2.5 watts and 0.1 s in duration are used to remove the stapes crura. It is easy to divide the posterior crus of the stapes at the base and below the attachment of the stapedius tendon. Division of the anterior crus of the stapes at the top and bottom is somewhat more difficult, because it must often be carried out blind through direct contact of the crus with the fibre tip. The piston is inserted in the usual way and is even made easier through the stabilizing effect of the preserved stapedius tendon. The stapedius reflex can be tested intraoperatively using the Bárány noise apparatus or simply with the suction murmur of the aspirator[5]. Care is taken to see that the footplate perforation is large enough for the prosthesis to move freely when the reflex is elicited. The opening of the oval window is covered with some adipose tissue from the ear lobe. No differences were demonstrated in the postoperative hearing gain two months after the operation in 50 patients with or without preservation of the stapedius tendon. When the stapedius tendon is preserved in the stapedectomized ear, the stapedius reflex can be measured postoperatively by tympanometry as a change in impedance (Fig. 5.**16**). Since the phenomenon of postoperative hyperacousia is greatly reduced and the patients seem to be disturbed less by noise

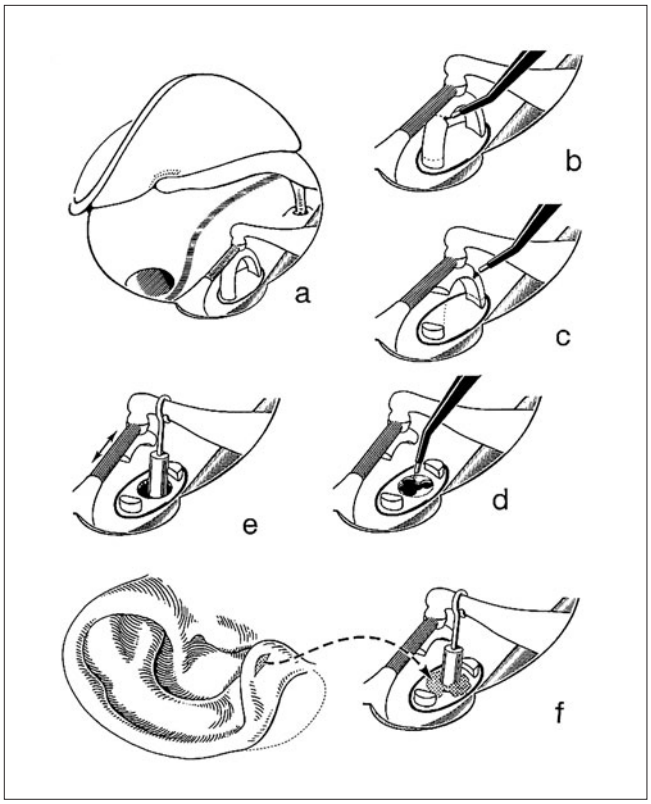


Fig. 5.**15** Surgical technique of fiberoptic argon laser stapedotomy with preservation of the stapedius tendon. **a** Middle ear status after elevation of the posterior tympanomeatal lobe. **b** Division of the posterior crus of the stapes at the base and below the attachment of the tendon of the stapedius muscle using the fiberoptic micro-handpiece and with laser pulses of 2 watts and 0.1 s in duration. **c** Laser removal of the anterior crus of the stapes; this is often carried out blind through direct contact between the crus and the angled tip of the fiberoptic micro-handpiece. **d** Rosette-shaped perforation of the footplate. **e** Insertion of a piston and fixation of the loop around the long process of the incus. The free mobility of the prosthesis in the footplate perforation when the stapedius reflex is elicited is tested intraoperatively using a Bárány noise apparatus. **f** Sealing of the oval window with adipose tissue from the ear lobe.

[5] Silverstein [257], who carries out the operation under anaesthesia, uses the electrical facial nerve stimulator to elicit the stapedius reflex intraoperatively when the stapedius tendon has been preserved.

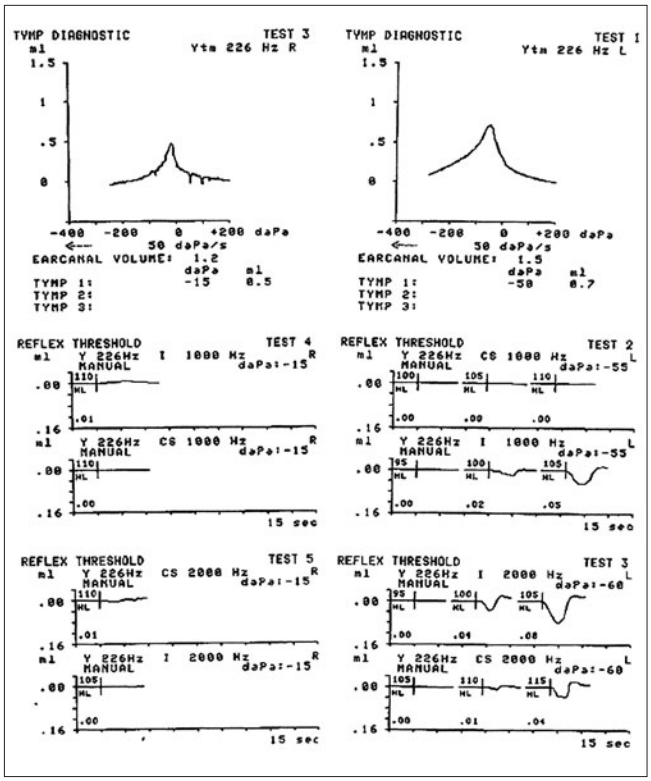


Fig. 5.**16** Tympanometry and stapedius reflex measurements in a patient with bilateral otosclerosis four months after argon laser stapedotomy on the left with preservation of the stapedius tendon. In the operated left ear, a definite stapedius reflex could be documented, especially ipsilaterally; no stapedius reflex could be elicited in the non-operated right ear. The patient had virtually no postoperative hyperacousia despite a hearing gain of 30 dB.

after the operation, preservation of the stapes tendon has now become the norm for me whenever it is technically possible. A controlled long-term study is currently underway in Bern.

Perioperative Medication (Antibiotics and Anti-vertigo Preparations)

Although according to infection specialists there is little point in antibiotic prophylaxis for stapes operations carried out under the strictest aseptic conditions, in Bern every stapedectomy patient receives a broad spectrum antibiotic on the day of the operation (e. g. 3 × 1.2 g Augmentan i.v.) or, in cases of penicillin hypersensitivity, another broad spectrum antibiotic. The reason for this is that an infection, even with commonplace organisms, could have fatal consequences, as is known from individual case reports. In Bern, not a single purulent superinfection has occurred after almost 600 stapes operations over the past eight years.

Stapes operations are only carried out using powder-free, fine ophthalmological surgical gloves.

Since transcanal fiberoptic argon laser stapedotomy is very atraumatic, intraoperative and postoperative symptoms of vertigo are not present in the majority of cases and in the others are mostly not very pronounced. If significant vertigo should occur, the modern anti-vertigo preparation ondansetron (Zofran) 4 mg has proved useful.

Stapedectomy Technique in Special Situations

Floating Footplate

The occurrence of a footplate that is free floating in the oval window or is tilted or depressed into the vestibule is a rare, but dreaded intraoperative complication of stapes surgery. Typically it occurs after perforation with the hand drill or Skeeter drill of only slightly fixated footplates, especially if they show a “biscuit-like” thickening in the middle [59]. This problem is virtually eliminated through the use of lasers. In Bern, ever since stapes surgery has been carried out with the laser a floating footplate has never occurred again, although it was the reason for several revision referrals. In the relevant literature [102, 147], it is recommended that after additional drilling at the lower margin of the oval window a superficial floating footplate should be cautiously lifted out with a small 0.2 mm or 0.3 mm hook. In the case of a depressed footplate, it may be advisable in some circumstances to just cover the oval window and to dispense with the insertion of a piston.

With the use of the fiberoptic argon laser, the problem of the floating footplate can be solved in a simple way through a new, original surgical technique: the floating footplate is left in situ and is perforated in the middle with the fiberoptic argon laser. This makes possible the insertion of a piston prosthesis using the conventional technique (Fig. 5.**17**). The floating footplate is covered with adipose tissue from the ear lobe. This technique has so far been used in two patients. Good hearing gain was achieved in one patient whilst the second patient, who had suffered from a severe mixed hearing loss before the revision, initially experienced an improvement in hearing because of the closure of the air-bone gap. However, the hearing threshold then showed a progressive fall within a period of two years.

Obliterative and Far-Advanced Otosclerosis

Massive ossification of the entire oval window, which is found in 2 to 10 % of stapes operations, is described as obliterative otosclerosis [102, 148, 260, 261]. With the use of the Skeeter microdrill the inner ear can nowadays be successfully opened in such cases without difficulty. I personally first make a cautious progressive opening using the 0.6 mm tip of the Skeeter microdrill. As soon as perilymph escapes, and if the patient remains free of vertigo, the narrow drill canal is widened using the 1 mm diamond drilling attachment on the Skeeter drill, so that correct piston insertion without wobbling in the long canal becomes possible. Schuknecht [148] pointed out that in cases where the otosclerosis extends deep into the vestibule there is an increased risk to the inner ear, and he recommended that the operation should be discontinued in such cases.

If a maximal hearing loss is demonstrated in a not previously operated ear with otosclerosis, which is due to com-

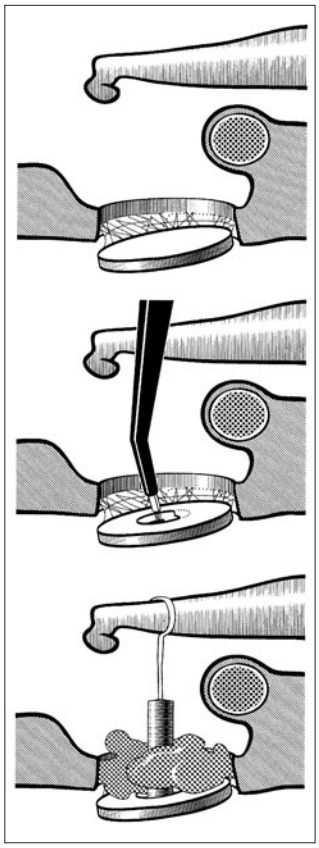


Fig. 5.**17** New technique for eliminating the problem of a floating footplate with the fiberoptic argon laser. The fiberoptic argon laser is used to make a contact-free rosette-shaped perforation in the footplate that is floating in the oval window. This makes it possible to insert a thin 0.4 mm piston prosthesis without touching the floating footplate. The mobile footplate is left in situ and the oval window is sealed with adipose tissue taken from the ear lobe.

bined conductive and inner ear hearing loss, one speaks of so-called "far-advanced" otosclerosis. When the bone conduction threshold is higher than 60 dB and in addition a conductive block is present, with a total hearing loss of 120 to 150 dB, a hearing threshold can no longer be measured on audiometry. In such situations, the conduction component can be eliminated through a stapedectomy and air conduction thresholds of between 70 to 100 dB can be achieved. This makes it possible for the patient to understand speech correctly again with an additional mechanical aid [262–267].

In the Bern series, a stapedotomy was also carried out in six patients with far-advanced otosclerosis, resulting in a certain degree of postoperative hearing improvement, which was between 10–25 dB in the pure tone audiogram. However, understanding of speech remained relatively unsatisfactory, despite additional mechanical aids. The speech discrimination was less good than that achieved through a cochlear implant in four other sub-totally deaf patients with far-advanced otosclerosis.

Stapedectomy in Children

In rare cases (incidence 1.5 to 3 %) children aged less than 14 years are also affected by a marked otosclerotic hearing loss [107–109, 261, 268]. Marked footplate obliteration is often found intraoperatively in patients with juvenile otosclerosis. Unilateral and bilateral conductive hearing losses that have been present since birth or infancy point more to a malformation of the middle ear.

Opinions differ as to when and whether a stapes operation should be carried out in children. Stapedectomies have been successfully performed in children aged from 5–7 years [107, 108, 168]. Other otologists consider that it is more appropriate for a hearing aid to be fitted first in children. It is also thought that in children with bilateral otosclerosis a stapedectomy should only be carried out on one ear [102].

In recent studies, the postoperative results are reported as being just as good as in adults [109, 268, 269]. Earlier studies, however, reported less good hearing gains. In juvenile otosclerosis, in addition to the conductive hearing loss, inner ear involvement is not infrequently found as a sign of cochlear otosclerosis. In these cases, fluoride therapy is sometimes recommended, although at the same time warnings are given against toxic effects on the growing body [270].

In Bern, a stapedotomy was carried out on six (1 %) patients under the age of 18 years (age 11–17 years) at the express request of the adolescents and their parents. Four had one parent and other family members with a known history of otosclerosis. Obliterative otosclerosis was found in three children. Two had a slight to moderate preoperative inner ear component. Correct and even spectacular hearing improvements occurred in all six children. There were no cases with postoperative inner ear hearing losses.

Stapedectomy in Patients with Otosclerosis and Coexisting Ménière's Disease

These two relatively common ear diseases can occur together in patients and such cases are repeatedly cited in the older and also in the recent literature [271–276]. Moreover, on the basis of new histological studies, a direct causal relationship between the two diseases is also assumed: it was repeatedly demonstrated on histology that advanced otosclerotic lesions had completely obliterated the endolymphatic duct [277–279]. It is known that after experimental occlusion of the endolymphatic duct, a hydrops of the inner ear develops [280]. A mechanical effect such as this, but also toxic and biochemical mechanisms, might explain why patients with otosclerosis not infrequently have a fluctuating inner ear hearing loss component, tinnitus and attacks of vertigo as the manifestation of co-existing Ménière's disease.

It was observed that stapedectomies entail an increased risk to the inner ear in cases with co-existing Ménière's disease [82, 85, 281]. In Bern therefore patients with otosclerosis and co-existing Ménière's disease tend to be advised against stapes surgery. Despite being fully aware of the increased risk of deafness, seven patients still wanted to have an operation to improve the hearing in ears with severe hearing loss ≥ 70 dB air conduction threshold). In these patients, the footplate perforation was carried out particularly carefully between the middle and the posterior third of the footplate. In three patients, a slightly reflecting mem-

Table 5.1 Literature comparison of the results after stapedectomy. The table lists a number of chronologically published statistics in which percentage data were given for the residual postoperative conduction component of ≤ 10 dB and ≤ 20 dB. A direct comparison is not possible for all series because these consist of more or less selected collectives. In older studies, the air-bone gap was often only determined for the frequencies 0.5, 1 and 2 kHz; in the recent studies the frequency 3 or 4 kHz is also included in the calculation. Percentage data on the incidence of postoperative sensorineural hearing loss (SNHL) are also listed. The results of my own primary stapedotomies are also given as a comparison.

Author		Year	n	Air-bone gap ≤ 10 dB	≤ 20 dB	SNHL	Deafness
Smyth et al. [194]	Belfast	1978	800				3,5 %
Moon et al. [199]	Virginia	1984	264	85 %		0.0 %	0.0 %
Del Bo et al. [106]	Milan	1987	200				3.5 %
Palva [179]	Helsinki	1987	323				0.3 %
Levi et al. [127]	Petha Tiqva	1990	100	80 %	88 %		
Conrad [123]	Cornwall	1990	50	68 %			
Herzog [200]	St. Louis	1991	49	87 %	96 %	0.0 %	0.0 %
Hodgson et al. [177]	Portland	1991	75	87 %	95 %		1.3 %
Leighton et al. [290]	Oxford	1991	170	73 %	86 %	5.0 %	3.0 %
Moller [198]	Bergen	1992	250	91 %	99 %	0.0 %	0.0 %
Rauch et al. [176]	Boston	1992	100	72 %	93 %	5.0 %	
Backous et al. [288]	Houston	1993	49	68 %	86 %	2.0 %	0.0 %
Mangham [193]	Washington	1993	151	89 %	97 %	0.0 %	0.0 %
Rizer et al. [207]	Ohio	1993	225	93 %		0.0 %	0.0 %
Strunk et al. [289]	Texas	1993	50	96 %			2.0 %
Vartiainen [247]	Kuopio	1993	344	75 %	91 %	5.8 %	0.3 %
Besbes et al. [78]	Tunis	1994	655	40 %		3.0 %	3.0 %
Dubreuil et al. [105]	Lyon	1994	1279	87 %		0.9 %	0.4 %
Fisch [102]	Zürich	1994	340	55 %	83 %	5.9 %	0.4 %
Kürsten et al.	Vienna	1994	117		93 %		1.7 %
Richter et al. [286]	Linz	1994	78	83 %			
Somers (Marquet) [208]	Antwerp	1994	1681	81 %	94 %	0.9 %	0.5 %
Glasscock et al. [201]	Nashville	1995	600	91 %	94 %	0.3 %	0.6 %
Mann [284]	Mainz	1996	1229			1.6 %	1.1 %
Persson et al. [205]	Linköping	1997	162	83 %		0.0 %	0.0%
Ramsay et al. [251]	Helsinki	1997	270	79 %		3.0 %	0.0 %
Sedwick et al. [209]	Utah	1997	550	78 %		3.5 %	
Kós [206]	Geneva	1998	544	77 %	88 %	4.5 %	1.1 %
Shea [283]	Memphis	1998	10900	80 %		1.8 %	0.6 %
Tange et al. [282]	Amsterdam	1998	62	71 %	95 %	0.0 %	0.0 %
Primary Stapedotomies [291]	Bern	2000	293	79 %	97 %	2.0 %	0.7 %
Mean Values				**79 %**	**92 %**	**2.1 %**	**0.9 %**

brane of balloon-like convexity was visible intraoperatively through the perforation in the vestibule, this being interpreted as a dilated saccule membrane. When this membrane was gently touched, the patients had symptoms of vertigo. Short piston prostheses of 0.4 mm in diameter and which did not project more than 0.2 mm into the vestibule were used. In all seven patients with Ménière's disease correct hearing gain occurred postoperatively without any sensorineural hearing loss. Interestingly enough, the patients reported that the stapedectomy had also caused the symptoms of vertigo to disappear.

Results after Primary Stapedectomy

Advances in stapes surgery should logically result in a postoperative improvement of hearing and a reduction in complications. In this section therefore the results of more

recent stapedectomy series will be presented, discussed and compared with my own results.

Literature Data

The mean postoperative, residual conductive hearing loss of ≤ 10 dB and ≤ 20 dB as a percentage of the operations performed is shown in Tab. 5.**1** for a number of stapedectomy series listed chronologically. Several other patient statistics were not included in the table because they did not have these percentage data. The mean hearing gain was often quoted, but this cannot be used for the purposes of comparison, or else the mean residual air-bone gap was specified for the whole series, this fluctuating between 7 to 12 dB in the different studies. A mean residual air-bone gap of ≤ 10 dB is achieved in between 40 %–96 % (mean value 80 %), and of ≤ 20 dB in between 86 % and 99 % (mean value 93 %). Causse and Causse [285] have reported by far the best results. Sequential investigations demonstrate that the hearing gain measured in the first weeks after the operation shows a further slight improvement over the next few months in most patients and then remains relatively stable for a period of years [102, 206, 286]. If one analyses the results of Tab. 5.**1** according to chronological criteria, then in fact no progressive improvement in the operative hearing gain can be demonstrated in the course of the past few years. On the other hand a tendency towards a decrease in inner ear complications and postoperative deafness is found, which becomes even more marked if older statistics are also taken into account [287].

Personal Results

All 536 stapes operations carried out between 1992 and 1998 in Bern have been evaluated in detail in dissertation studies [291, 292]. With the help of a computer database, the preoperative pure tone audiogram was compared with a first postoperative control audiogram 2 to 3 months after the operation and with a later control 1 to 5 years after the operation. Tab. 5.**2** shows detailed results for 346 primary stapedotomies and also for all 536 stapes operations carried out between 1992 and 1998. To date it has only been possible to carry out late audiometric controls in two thirds of the patients. My own results show that a mean air-bone gap closure of 8 dB was achieved 2 to 3 months after primary stapedotomy. This corresponds to a residual air-bone gap closure of ≤ 10 dB in 79 % and an air-bone gap closure of ≤ 20 dB in 97 % of the operations. At the late controls an optimal air-bone gap closure of ≤ 10 dB was only achieved still in 69 % of the patients. An air-bone gap closure of 20 dB was still found in 96 % of the patients, who also reported that they were relatively satisfied with their postoperative hearing. Less good results were found on analysis of the total 536 stapes operations, including the 114 revision stapedectomies, 43 stapes operations in malformations and stapes operations in complex situations, e. g. "far advanced" otosclerosis (Tab. 5.**2a**). It should be noted that in the Bern statistics only 65 % of the stapes operations were primary stapedotomies and that the proportion of revision operations was 20 %.

With respect to the incidence of postoperative inner ear damage, which is 2 % in my own statistics, and of postoperative deafness, which is 0.7 %, the Bern statistics correspond fairly well to the internationally published average.

Complications after Stapedectomies

Sensorineural Hearing Loss and Deafness

Although severe inner ear hearing losses and deafness are rare after stapes operations, they are recorded in virtually all fairly large stapedectomy statistics. The analysis of the primary stapedectomy statistics shows that the mean incidence of postoperative deafness is 0.9 %, and that of a significant sensorineural hearing loss is 2.2 % (Tab. 5.**1**). The incidences published by individual authors show marked variations. Causse and Causse [285] had only two cases of deafness in 6724 stapes operations (incidence 0.029). Persson [205] did not have a single case of deafness in a series of 407, but these were admittedly selected cases. This was also the case as regards the 270 stapes operations carried out by Ramsay et al. [251]. In a series of 250 stapes operations, Möller [198] also had no cases of deafness. On the other hand 7 % severe inner ear hearing losses are reported in the series of Del Bo et al. [106]. Leighton et al. [290] report 3.5 % and Besbes et al. [78] 3 % cases of postoperative deafness. It is difficult to assess the relevance of these considerable differences. For statistical reasons it is entirely possible that not a single case of severe postoperative inner ear hearing loss should occur in limited series of up to 300 operations with an average incidence of deafness of 1 %. Results well above average are also not beyond belief, because patients who develop postoperative deafness do not always return to the original surgeon and are thus not included in the statistics. The author of this paper knows of precisely two such patients who developed deafness after a stapedotomy that had been performed by distinguished otologists with a particularly low incidence of deafness in their published statistics. It becomes more problematic when the deafness rate becomes distinctly greater for an individual surgeon than that found in the large statistical series. In this situation, an investigation must be carried out to discover material and technical errors.

In connection with the statistical incidence of deafness, it should be noted that in my own series not a single case of deafness occurred in 207 consecutive primary stapedotomies. However, two cases of deafness subsequently presented within four months. Depending on the series, the incidence of deafness in Bern is therefore 0 % to 3 %, which corresponds exactly to the deafness rates found in the international publications (Tab. 5.**1**).

The reason for the development of deafness after stapedectomy is still unknown in most cases [284].* The use of var-

* A new possibly important observation might be that the local anaesthetic used for the harvesting of adipose tissue in the ear lobe may have a lasting toxic effect on the inner ear. Since this suspicion has arisen, adipose tissue for sealing the round window was carefully washed out with saline solution or replaced by gelfoam. It is interesting to note that since then in over 250 consecutive stapes operations, no new case of deafness occurred! (May 10, 2003)

Tab. 5.2 Detailed breakdown of the hearing results for my own 346 primary stapedotomies (**a**) and all 536 stapes operations (**b**) including 114 revision operations, 44 malleus handle (malleus grip) stapedectomies, 43 stapedectomies in malformations and stapedectomies in complex situations, e. g. "far advanced otosclerosis" (R. Häusler, Bern, 1992–1998). Mean values were calculated from four frequencies, i. e. 0.5, 1 , 2, 3 or 4 kHz.

a

	500 Hz	1 kHz	2 kHz	3 kHz	4 kHz	Average
Air-bone gap (ABG)						
Preop. (dB)	39	34	16	16	23	27
2–3 mon postop. (dB)	10	10	3	5	10	8
1–5 yr postop. (dB)	11	12	4	7	15	9
Improvement 2–3 mon postop. (dB)	28	24	12	11	13	19
Improvement 1–5 yr postop. (dB)	27	22	11	11	8	18
Residual ABG						
10 dB 2–3 mon postop.	66 %	67 %	95 %	85 %	69 %	79 %
15 dB 2–3 mon postop.	79 %	84 %	98 %	92 %	82 %	92 %
20 dB 2–3 mon postop.	91 %	94 %	98 %	97 %	89 %	97 %
25 dB 2–3 mon postop.	95 %	98 %	99 %	98 %	94 %	97 %
10 dB 1–5 yr postop.	66 %	60 %	91 %	88 %	48 %	69 %
15 dB 1–5 yr postop.	81 %	79 %	96 %	94 %	64 %	90 %
20 dB 1–5 yr postop.	88 %	92 %	98 %	94 %	82 %	96 %
25 dB 1–5 yr postop.	92 %	97 %	99 %	96 %	89 %	97 %
Hearing gain						
Preop 2–3 mon postop. (dB)	29	27	19	14	13	22
Preop 1–5 yr postop. (dB)	27	24	16	18	9	20
Over-closure						
2–3 mon postop. %	41 %	50 %	69 %	70 %	41 %	63 %
2–3 mon postop. (dB)	11	10	12	11	11	8
1–5 yr postop. %	41 %	49 %	69 %	73%	53 %	66 %
1–5 yr postop. (dB)	11	10	12	13	12	8

b

Air-bone gap (ABG)						
Preop. (dB)	38	34	17	18	25	28
2–3 mon. postop. (dB)	14	13	6	7	14	11
1–5 yr postop. (dB)	13	14	6	10	17	11
Improvement 2–3 mon postop. (dB)	24	21	11	11	11	17
Improvement 1–5 yr postop. (dB)	24	20	10	10	7	16
Residual ABG						
10 dB 2–3 mon postop.	55 %	55 %	85 %	78 %	53 %	63 %
15 dB 2–3 mon postop.	68 %	75 %	92 %	89%	69 %	80 %
20 dB 2–3 mon postop.	81 %	86 %	94 %	94%	80 %	89 %
25 dB 2–3 mon postop.	87 %	93 %	97 %	95%	89 %	93 %
10 dB 1–5 yr postop.	58 %	49 %	85 %	74%	39 %	61 %
15 dB 1–5 yr postop.	73 %	72 %	89 %	82%	58 %	81 %
20 dB 1–5 yr postop.	82 %	84 %	95 %	87%	75 %	88 %
25 dB 1–5 yr postop.	88 %	92 %	97 %	93 %	84 %	93 %
Hearing gain						
Preop 2–3 mon postop. (dB)	26	24	17	13	10	20
Preop 1–5 yr postop. (dB)	23	21	14	15	7	17
Over-closure						
2–3 mon postop. %	43 %	49 %	67 %	61 %	41 %	63 %
2–3 mon postop. (dB)	11	10	12	11	12	8
1–5 yr postop. %	38 %	48 %	62 %	65 %	48 %	61 %
1–5 yr postop. (dB)	10	10	12	13	13	8

ious surgical techniques with which the risk of deafness was higher than the average was discontinued, such as, for example, the covering of the oval window with Gelfoam, which was associated with a higher incidence of postoperative inner ear fistulae with the early and late development of deafness [99, 213]. This problem has in the mean time been resolved by eliminating the use of formaldehyde for sterilization. An increased risk of developing postoperative deafness was also found in patients with marked obliterative otosclerosis [148] and in patients who in addition to the otosclerosis had co-existing Ménière's disease [82, 85, 281]. Contradictory statements have been made as regards a pre-existing sensorineural hearing loss. According to some authors, a pre-existing sensorineural hearing loss points to greater inner ear sensitivity [287], whereas in other statistics no increased postoperative risk was found in this situation [284, 293]. It was also observed that stapedectomies in cases of unilateral stapes fixation were associated with inner ear complications more often than stapedectomies in classic bilateral otosclerosis: after stapedectomy, Del Bo et al. [106] found an inner ear complication in 23 % of patients with unilateral conductive hearing loss compared with only 6.5 % in patients with bilateral otosclerosis. Several ear surgeons advise their patients not to wear any hearing aid in the ear intended for a stapes operation for at least two weeks before the operation, because patients who wore hearing aids were said to have an increased risk of labyrinthitis. It was often assumed that the development of deafness after ear operations might be related to pre- and peri-operative herpes infections. A viral herpes–induced cause was also postulated for cases of secondary facial nerve paralysis after ear operations [294]. If florid Herpes labialis or genitalis is present in patients, it is probably advisable to postpone a planned stapedotomy.

Granuloma of the inner/middle ear is a singular finding that has repeatedly been described during revision operations carried out for deafness after stapedectomy [295]. The cause of this granulomatous tissue that envelops the stapedectomy prosthesis and extends into the inner ear and can sometimes fill the entire middle ear is unknown. This seems to be an inflammatory-toxic reaction, possibly due to intolerance of the stapedectomy prosthesis or as a reaction to an inner ear fistula. Early removal of the granuloma from the middle ear and the vestibule can lead to a recovery of inner ear function [147, 295]. Del Bo et al. [106] have also described partial recoveries of hearing with the use of aggressive pharmacological therapy using anti-inflammatory drugs (high-dose corticoids) and antibiotics.

Postoperative Vertigo

With the new atraumatic stapedotomy techniques it is often possible to carry out stapes operations without the intra- and postoperative occurrence of vertigo symptoms. Severe vertigo at the start of the operation can be due to an excessive local anaesthetic injection into the bony auditory canal with absorption through the round window. Anaesthetic fluid in the niche of the round window should therefore be rapidly aspirated. Symptoms of vertigo during the stapedectomy are serious warning signals and point to potentially dangerous irritation of the inner ear. They develop after manipulations carried out too deep in the vestibule, which must be avoided at all costs, or after accidental aspiration of perilymph. Aspirated perilymph must be replaced immediately with physiological NaCl solution, which is administered cautiously into the vestibule in a syringe with a long fine cannula that must lie already prepared on the operating table. If a pneumolabyrinth develops, symptoms of vertigo occur for a fairly long time after the operation [142].

Finally, one has to admit that slight postoperative symptoms of vertigo can always occur in the first few days after a stapedotomy. The occurrence of benign paroxysmal postural vertigo was observed several times after stapes operations, but this could be rapidly cured through suitable physiotherapy manoeuvres [296]. Persistent vertigo and balance disorders are rare. Vertigo on swallowing, blowing the nose and sneezing and on sudden increases in pressure indicate a piston that is too long. If these symptoms do not disappear spontaneously within a few months, a revision operation to exchange or to shorten the prosthesis is often unavoidable. In the literature, atypical symptoms of vertigo after stapes operations are often attributed to perilymph fistulae. The radiological demonstration of a pneumolabyrinth on CT is evidence for the diagnosis of a perilymph fistula [142].

Piston prostheses should not project more than 0.2 to 0.5 mm into the vestibule. On the basis of an anatomical study Pauw et al. [297] calculated that the distance between the underside of the footplate and the saccule is greatest in the middle of the footplate and is more than 0.76 mm at this point. The distance from the membranous inner ear structures may be smaller if an endolymphatic hydrops is present. If an inserted piston seems to "bounce" on inner ear membranes, it should be exchanged immediately for a shorter one.

Facial Nerve Paralysis

Cases of intraoperative facial nerve paralysis sometimes occur after too deep a local anaesthetic injection; recovery occurs within a few hours. In about one case per 1000 stapes operations [147], a transient secondary facial nerve paralysis occurs, which starts to develop several days after the stapedectomy and regresses again spontaneously within a few days to weeks. The cause is unknown and it is probably of inflammatory immunological or viral origin [294, 298, 299].

A surgical lesion of the facial nerve is extremely rare in stapes operations. It has mostly been described in cases where the facial nerve takes an unrecognised aberrant course [300]. In the recent past, cases of facial nerve paralysis were reported several times after the use of the CO_2 laser due to defective installations, in which the laser beam did not coincide with the target beam. From his medicolegal work the author knows of a case of a facial nerve lesion in which "inflammatory" tissue over the oval window was evaporated with the CO_2 laser.

Stapes Revision Surgery

In principle, stapedectomy is a once-only operation with a definitive hearing gain, which should last for a lifetime. This is indeed often the case. Regardless of the surgical technique used, however, the expected hearing gain sometimes does not occur in individual cases, or after an initially favourable result hearing loss recurs for various reasons. In these cases, secondary hearing improvement can be brought about through a stapes revision operation. More rarely, revision operations are performed because of persisting vertigo, intolerable tinnitus, facial nerve problems or postoperative inner ear hearing loss.

Since 1980, about 30 papers with series of 35 to 258 patients have been published in the literature that deal with the subject of stapedectomy revision [94, 155, 236, 260, 301–324]. The proportion of personal revision operations carried out by the different surgeons is 5 to 10% in fairly large series that were performed over periods of between five to twenty years [109, 205, 206, 209, 283, 308, 317]. In various recent studies, it is assumed that the frequency of revision operations has increased in recent years because increasing numbers of otologists are carrying out increasingly fewer stapedectomies and therefore have less surgical "know-how" [176, 212, 236].

Analysis of Causes

In the various stapes revision series, the causes most often given were prosthesis problems (14–58%) with piston displacements with or without concomitant incus necrosis (15–44%) and renewed bony obliteration of the oval window (0–24%). Another cause cited in many statistics (1.5–12%) is persisting perilymph fistulae, which were not found at all in other studies, however, e. g. in Bhardwaj and Kacker [316], Prasad and Kamerer [313], McGee et al. [312], Cokkeser et al. [307] and Peter and Grossenbacher [305]. Perilymph fistulae were observed more frequently after earlier stapedectomies in which a hollow polyethylene tube had been used as interposition. There was also an increased incidence of inner ear fistulae after stapedectomies in which the oval window had been sealed with Gelfoam [213, 245, 308].

Fibrous fixation of the piston is mainly seen after the previous insertion of vein and perichondrium grafts, which were inserted to seal the oval window. Additional fixation of the incus and malleus was found in 0 to 45%. Direct surgical complications that led to revision operations were the dreaded floating footplate or intraoperative incus luxation in individual cases. A cause for revision operations that used to be common but is now becoming rarer is the absence of any hearing gain after a previous fenestration operation of the lateral semicircular canal. This problem still accounted for 25% of the revision stapedectomies in the series of Schuknecht and Bhardwaj, published in 1986, whilst it was only 5% in my own revision series between 1992 and 1998.

Personal Stapes Revision Series

In Bern, the 536 stapes operations (1992–1998) included 114 revisions that were carried out in 100 patients (age: 18–74 years) [292]. These consisted of 102 first revisions, eleven second revisions, four third revisions and three fourth revisions. (One third revision and three fourth revisions finally led to hearing gain!). In 16 cases (4%) these were revisions of my own 346 primary stapedectomies. Half of these personal revisions concerned malformation states (additional malleus head fixations, additional obliteration of the round window, etc.). Three revision operations were carried out because of the development of postoperative deafness (0.7%) after my own primary operations. The other 84 stapes revision operations were refer-

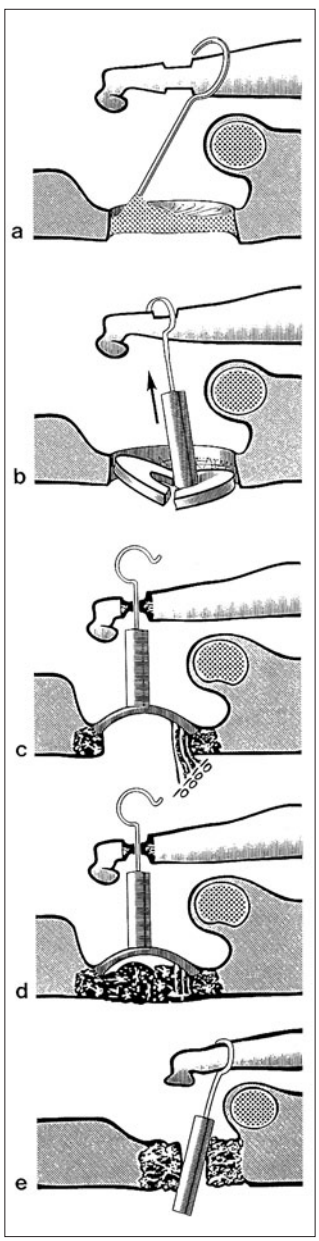


Fig. 5.**18** Diagrammatic illustration of changes found fairly often at stapes revision operations.
a Arrosion of incus process with lateral displacement of Schuknecht wire prosthesis or of a House wire-loop. **b** Incus arrosion due to a piston prosthesis lifted up by a collapsed section of footplate. **c** Incus arrosion due to prosthesis being lifted off by a tense and fibrosed vein graft. Since such veins are most often connected through strands of scar tissue to the underlying inner ear structures, a repeat perforation with mechanical tools is dangerous. On the other hand there are no problems with the contact-free perforation of the vein using the fiberoptic laser. **d** Renewed forward growth of an otosclerotic ossification under a vein graft implanted at the primary operation. **e** Tilting of piston because footplate perforation too narrow. This complication was mainly seen with very thickened footplates.

rals. The primary operations had been carried out in these patients using various surgical techniques.

The reasons that explain the failure of the previous operation are given in Tab. 5.**3** and Fig. 5.**18**. Piston problems were most frequently present. In some cases lateral displacement of a prosthesis wire (Schuknecht prosthesis or House wire loop) was found with or without concomitant arrosion or necrosis of the incus process. After stapedotomies with the insertion of piston prostheses, loosening of the wire loop and prosthesis extrusions out of the oval window occurred, again either with or without additional necrosis of the incus process. In some cases, the wire loop was even found to be in an anterior position in front of the long incus process, which must correspond to a previous progressive migration of the incus process through the bone, as has also been described by other surgeons, especially with platinum band prostheses [217].

Table 5.**3** Analysis of causes of 114 stapes revision operations (R. Häusler, Bern, 1992–1998)

1	**No hearing gain or a loss of hearing**	**101**
1.1	*Stapedectomy with Schuknecht wire adipose tissue prosthesis or House wire-loop with vein/perichondrium graft*	*29*
1.1.1	Tension distortion of vein with necrosis of incus process	14
1.1.2	Tension distortion of vein without necrosis of incus process	4
1.1.3	External migration of wire in the oval window	3
1.1.4	Re-ossification of window with necrosis of incus process	3
1.2	*Stapedotomy with piston insertion with or without vein graft*	*36*
1.2.1	Re-ossification of window with necrosis of incus process	8
1.2.2	Fibrosed window with necrosis of incus process	6
1.2.3	Fibrosed window without necrosis of incus process	8
1.2.4	Extrusion of piston after malleus handle (malleus grip) stapedotomy	4
1.2.5	Only necrosis of incus process	2
1.2.6	Only loosening of piston at the incus process	2
1.2.7	Piston pushed up by broken footplate with/without necrosis of incus process	4
1.2.8	Fixation through incudotympanopexy	2
1.3	*Cartilage graft*	*2*
1.3.1	Lysis of the cartilage	1
1.3.2	Lysis of the cartilage with necrosis of incus process	1
1.4	*Co-existing malformations*	*16*
1.4.1	Ankylosis of incus/malleus	7
1.4.2	Abnormal course of facial nerve with ossification of the oval window	4
1.4.3	Obliteration of the round window	2
1.4.4	Middle ear malformation, not defined more precisely	1
1.4.5	Middle ear malformation with Atresia plate of the tympanic membrane	1
1.4.6	Gusher ear	1
1.5	*Renewed stapes fixation after stapes mobilization*	*4*
1.6	*Previous fenestration of the lateral semicircular canal*	*5*
1.7	*Other previous middle ear operations and demonstration of a fixed stapes footplate in the present operation*	*9*
1.7.1	After TORP ossiculoplasty	5
1.7.2	After incus implant	3
1.7.3	After tympanoplasty	1
2	**Isolated states of vertigo**	**6**
2.1	When piston too long	4
2.2	When piston too mobile due to incus luxation	1
2.3	When piston lying too deep because fallen from incus process	1
3	**Stapedectomy complication with conductive hearing loss and/or vertigo (referred patients)**	**4**
3.1	Floating footplate	3
3.2	Incus luxation	1
4	**Stapedectomy complications with severe inner ear hearing loss (own patients)**	**3**
4.1	Middle/inner ear granuloma	1
4.2	Inner ear hearing loss of unclear cause	2

In cases where the footplate perforation was too narrow, tilting of the piston with subsequent incus arrosion was demonstrated. Tilting of the piston was observed several times after the stapedotomy technique [102], in which the footplate is perforated first, the piston is inserted and the stapes superstructure broken away only afterwards. A fracture of the footplate, weakened by the previous perforation, apparently occurs fairly often during the subsequent removal of the stapes superstructure. The collapsed footplate led to a restriction on the mobility of the piston prosthesis and finally to its extrusion.

A complication repeatedly found (18 %) was fibrous tensions in the oval window, which pushed the piston upwards and which typically occurred after the previous implantation of a vein or fascia to seal the oval window. This was not infrequently also accompanied by renewed ossification of the footplate that had grown forward under it, as has also been described previously by other ear surgeons [322]. This latter complication hardly ever occurred in stapedotomies in which the piston was immersed directly in the perilymph.

In several cases, persisting conductive hearing losses were due to an additional fixation of the incus and malleus that had not received attention in the first operation. Four revision operations were carried out for middle ear malformation and an abnormal facial nerve course, which were not accessible to the classic stapedectomy techniques. In two patients, the failure of an otherwise correctly performed primary stapedotomy was explained by an obliteration of the round window.

A number of revisions (16 %) had to be carried out because of persisting vertigo despite a good postoperative hearing gain. These were mostly cases in which the piston was too long, in one case the piston was too mobile because of postoperative incus luxation and in one case the piston, which had penetrated too deeply into the inner ear, had fallen from the incus.

The referred revisions carried out for direct surgical complications after the primary operation, e. g. for a floating footplate, an incus luxation or a bone splinter in the vestibule, were rare isolated cases (3 %). These patients not only had hearing problems but also vertigo as well in each case.

In three of my own patients (0.70 %), who after an uncomplicated primary stapedotomy developed subtotal deafness within days to weeks after the primary operation, revision was carried out and a middle/inner ear granuloma was found in one case. The other two patients showed a normal stapedotomy status with a correctly positioned prosthesis, with no perilymph fistula and with no signs of infection of any kind.

It is worth noting that perilymph fistulae were never found in the Bern series, despite a meticulous search for these. Even in cases with an extruded piston, the oval window was always either covered with a connective tissue membrane or was sealed through renewed ossification.

Surgical Technique in Revision Operations

Revision operations are often technically more demanding than primary operations. It is of the greatest advantage to carry out revision operations under local anaesthetic, because the patient can give immediate information about symptoms of vertigo and changes in hearing throughout the entire operation. The great usefulness of the new technical tools is seen to the full in revision operations: even footplates with massive ossification can be drilled through without problems using the Skeeter microdrill, narrow oval windows can be widened towards the promontory. The microdrill is unsuitable in the case of a mobile footplate, a floating footplate, a depressed footplate and also fibrosis in the oval window because of possible strands of scar tissue connecting to the sensory inner ear structures. In these cases it is possible to operate using a fine 0.3 mm hook in some circumstances, although several surgeons [317, 320] have advised against removing the membrane over the oval window during revisions. The use of the argon laser with the fiberoptic micro-handpiece is ideal in this situation; with this, not only membranes but also footplates floating freely in the oval window can be perforated without contact and without mechanical trauma. Fibrous adhesions can be lasered away without the bleeding that obstructs the operator's vision and without traction on inner ear structures. The favourable experience of others with the fiberoptic argon laser in revision operations [236, 315] can be completely confirmed in the Bern series.

It is useful to have a wide range of pistons available for revision operations (Fig. 5.**19**). The model used as standard in Bern is the Richards platinum band-Teflon piston of 0.5 mm diameter. If the window is very narrow, a solution is often provided by the thin wire-loop of House with some

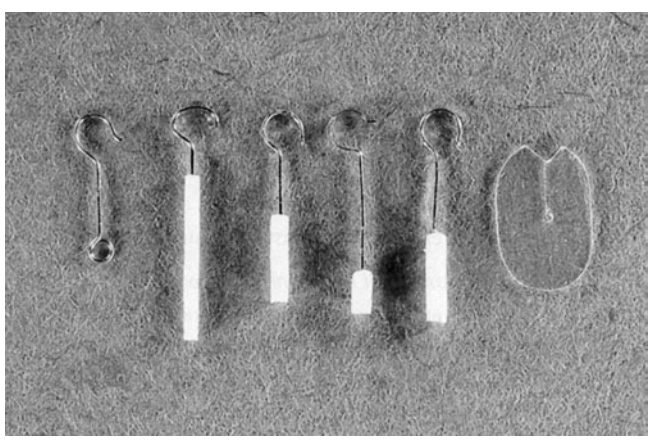


Fig. 5.**19** Piston prostheses and silicone disc used in revision stapedectomies. From left to right: House wire loop, the Fisch prosthesis which can be cut in length (diameter 0.4 mm), the Richards platinum band–fluoroplastic piston prosthesis (0.5 mm), the de la Cruz prosthesis with a short fluoroplastic piston (0.6 mm) and the extra long malleus handle–metal wire piston prosthesis of Schuknecht (0.6 mm). On the far right is the silicone disc that is inserted around the wire of the piston prosthesis between the incus process and the promontory in order to prevent the increased formation of adhesions between the promontory and the incus process that occurs in revision operations.

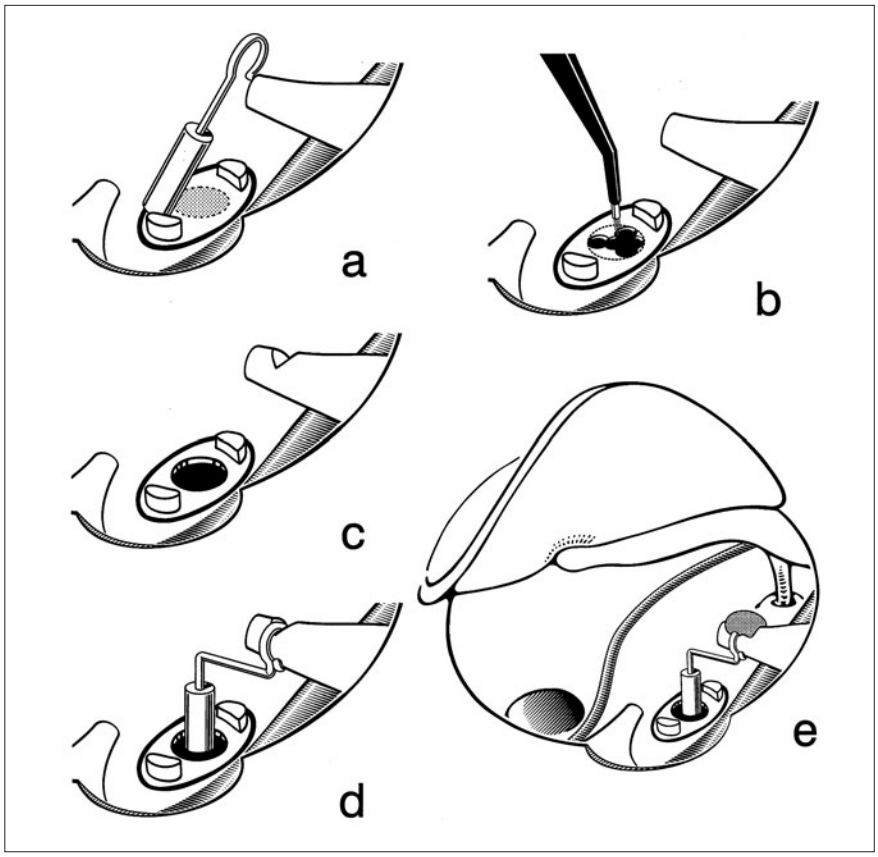
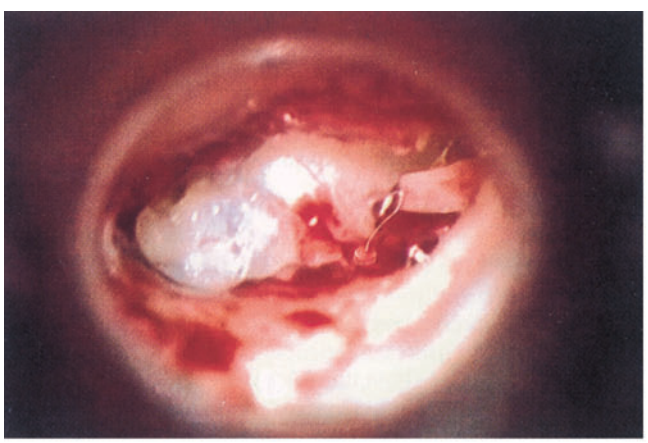


Fig. 5.**20** Surgical technique of piston fixation at the incus stump in necrosis of the incus process. **a** Tympanic cavity status after elevation of a posterior tympanomeatal flap with visualization of an incus process necrosis and displaced piston prosthesis. **b** Status after insertion of a piston prosthesis bent into shape in two places and fixation of the loop to the conical stump of the incus process after this has been previously notched with a Skeeter microdrill. **c** Additional consolidation of the loop with a drop of glass ionomer cement.



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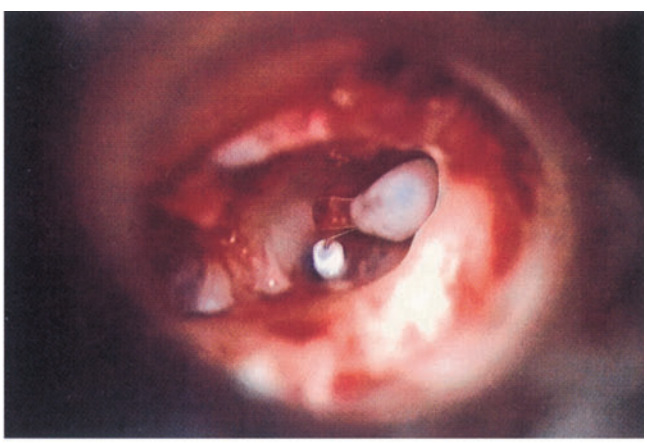

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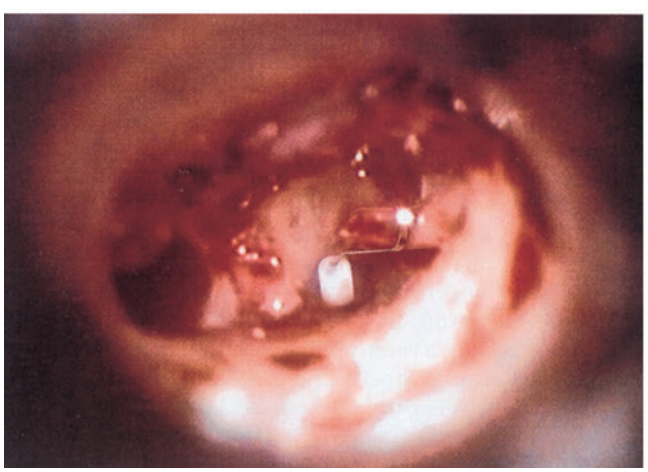

b

Fig. 5.**21** Photographic documentation of a revision stapedectomy in necrosis of the incus process. **a** Intraoperative finding of an incus process necrosis with displaced piston prosthesis. **b** Status after insertion of a piston prosthesis bent into shape in two places with fixation of the loop at the incus stump in accordance with the technique shown in Fig. 5.**20. c** Additional consolidation of the piston with a drop of glass ionomer cement. Postoperatively the patient had an air-bone gap closure to < 10 dB.

adipose tissue, or the thin 0.4 mm piston of Fisch that can be cut to the required length. In individual cases it is possible to bypass a facial nerve prolapse by using the de la Cruz prosthesis that has a short piston section. A tried and tested surgical trick is to place a thin silicone disc (Silicondisk) around the piston in order to prevent the formation of strands of scar tissue between the incus and promontory often seen after repeated operations [147].

The problem of necrosis of the incus process is tackled using various surgical methods: if the proximal part of the incus is still accessible to some extent and transmits malleus movements, a piston bent into shape in two places can be fixed to the proximal part of the incus (Figs. 5.**20** and 5.**21**). To prevent the metal loop from sliding down from the very conical proximal part of the incus, this is notched slightly with the Skeeter micro-drill or the laser and in addition the metal loop can be consolidated with a drop of cement. In cases where the proximal stump of the incus is too short, the incus is luxated or the head of the malleus is fixed, the problem can be solved by carrying out a malleus handle (malleus grip) stapedectomy.

Unconventional surgical measures must be invented ad hoc fairly often in revision operations. Fig. 5.**22** shows an example in which, due to the absence of an incus and of a malleus handle, a piston was suspended from an incus interposition hanging loosely at the tympanic membrane, with secondary stabilization of the tympanic membrane through a hydroxyapatite column that was placed in an indentation of the promontory [325].

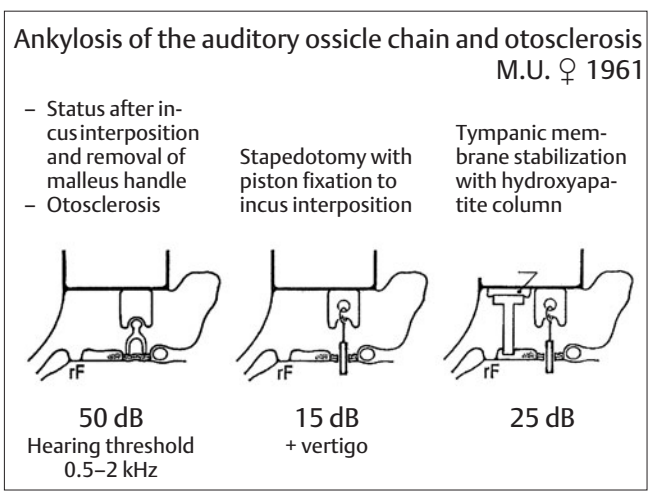

Fig. 5.**22** Unconventional stapedectomy revision technique in status after removal of the malleus handle and incus interposition between the tympanic membrane and an otosclerotically fixed stapes, with persisting conductive hearing loss of 50 dB. The incus interposition hanging freely at the tympanic membrane is left in situ and perforated with the Skeeter microdrill. After the stapedotomy has been carried out a platinum band prosthesis is inserted (middle diagram). This led to an improvement in the hearing threshold to 10 dB. Because of persisting symptoms of vertigo during pressure fluctuations, a third revision had to be performed with consolidation of the tympanic membrane through a hydroxyapatite column anchored in the promontory (diagram on the right). This definitively eliminated the symptoms of vertigo. Two months after the operation, an air conduction threshold of 25 dB was measured. At the final control examination five years after the last operation the patient was still free of vertigo. The air conduction threshold improved to < 10 dB.

Results after Revision Operations

It is generally reported that the results after stapes revision operations are less good than after primary stapedotomies. An optimal postoperative hearing gain with closure of the air-bone gap of ≤ 10 dB was reported in 18 to 80%, as a mean value in 45%, in the articles on stapes revision operations cited in Tab. 5.**4** (including my own series). A hearing improvement with residual conduction of ≤ 20 dB was achieved in 64–92%, as a mean value in 80%. In my own stapes revision series an air-bone gap closure of ≤ 10 dB was achieved in 59% and of ≤ 20 dB in 86%. Differences in the results of the various studies are not necessarily attributable to greater surgical competence, because they depend to a large extent upon the predominant type of causal pathology: vein tension distortions or the softening of cartilage grafts as the reasons for revisions are easy to correct and have good prospects of an improvement in hearing. Revisions carried out for middle ear malformations on the other hand are often complex and therefore have a less good prognosis [102].

An aspect that is often discussed is the risk of an additional deterioration in hearing or of postoperative deafness after stapes revision operations. It is often noted that the risk to the inner ear is significantly greater after revisions than after primary operations. Shea [283] even stated that one would have to reckon with a postoperative hearing loss in about 10% after revision operations. Several authors [307, 320] have observed that the inner ear risk is particularly great when the previous primary operation was already complicated by inner ear symptoms (tinnitus, vertigo, perceptive hearing loss). However, an examination of the results after stapes revision operations in the recent literature shows that the incidence of inner ear damage, at 2.2% on average, seems to be only twice as great as that after primary operations. Not a single case of deafness occurred in several studies with more than 100 stapes revisions. This also applies to our series of 114 revisions. I personally have the impression that inexplicable cases of labyrinthisation, which occur in about 0.5% of the primary stapedotomies, hardly ever occur in stapes revision operations. Improvements in hearing are still possible even after repeated revisions. Since revision operations can be technically difficult, they should be reserved for experienced stapes surgeons.

A particularly useful aspect of the processing of revision stapedectomy series is that it makes possible a precise analysis of the failures and allows one to identify the particular problems and risks of stapes surgery. If the correct conclusions are drawn from this, it should lead to a progressive improvement in the surgical technique and in the results.

■ Malleus Handle (Malleus Grip) Stapedectomy

If fixation of the piston to the incus process is not possible in a stapes ankylosis because the incus is missing, luxated

Tab. 5.**4** Literature comparison of the residual conductive hearing loss and also percentage data on sensorineural hearing losses (SNHL) and postoperative deafness after stapes revision operations. The results of the Bern series (R. Häusler, 1992–1998) are also given as a comparison.

	Number of Patients	Air-Bone Gap ≤ 10 dB	Air-Bone Gap ≤ 20 dB	SNHL	Deafness
		(%)	(%)	(%)	(%)
Feldmann 1970 [321]	142	49	71	0.4	0
Crabtree 1980 [323]	35	46		20	14
Lippy 1980 [320]	63	49	54	11	–
Sheehy 1981 [1981]	258	44	71	7	3,3
Pearman 1982 [319]	74	52	66	3	–
Lippy 1983 [320]	100	71	84.5	0	0
Derlacki 1985 [318]	217	60	72	4	1.4
Glasscock 1987 [317]	79	39	64	3	1.2
Bhardwaj 1988 [316]	100	44		12	2
Lesinski 1989 [155]	59	66	87	0	0
Silverstein 1989 [178]	18	66	89	–	–
Fisch 1994 [102]	81	9	41	–	0
Farrior 1991 [212]	102	57	84	–	–
Vartiainen 1993 [314]	45	45.5	71	4.4	2.2
Prasad 1993 [313]	41	46	88	12.1	–
McGee 1993 [312]	77	80.5	92	2.3	0
Langman 1993 [311]	66	61	84	3	0
Pederesen 1994 [308]	163	51	75	1.2	1.6
Cokkeser 1994 [307]	49	17	60	14	4
Silverstein 1994 [309]	61	47	62	10	4
Glasscock 1995 [201]	166	68		–	2.7
Han 1997 [236]	60	52	82	4.1	1.3
Grossenbacher 1995 [305]	39	44	79	0	0
Bern series [292]	93	59	86	4.3	0
Mean values	91	51	74	5.79	1.98

c

Tab. 5.**5** Literature comparison of the results after malleus handle stapedectomy

Author	Sheehy	Shea	Schuknecht	Eberle (results of Fisch)	Tange	Oestreicher and Häusler
Year	1982 [245]	1983 [326]	1986 [327]	1992 [328]	1996 [329]	1998 [330]
Number of patients	146	35	187	123	41	40
Residual air-bone gap						
≤ 10 dB	51 %		36 %		70 %	40 %
≤ 20 dB	81 %	84%	69.1 %		88 %	85 %
Postoperative hearing gain	84 %			90 % > 20 dB hearing gain in 56 % patients	92.7 %	92.2 % (15–50 dB hearing gain)
Perceptive hearing loss ≥ 30 dB	4 % (≥ 30 dB)		8 % (≥ 15 dB)		0	2.5 % (n = 1)
Deafness	2 %		2 %	1.1 %	0	0

or has become necrotic, a direct connection to the inner ear can be made with an extra long prosthesis fixed to the handle of the malleus. This so-called malleus handle (malleus grip) stapedectomy, also called incus replacement stapedectomy or vestibulomalleopexy, has been carried out since the 1960s. Quite a lot of ear surgeons report that they occasionally carry out malleus handle stapedectomies, especially in revision stapes operations, but with no separate analysis of the results with this special operating technique [212, 236, 309, 320]. Only a few papers deal directly with the subject of malleus handle (malleus grip) stapedectomy giving a description of the technique and an analysis of the results [245, 326–330]. The acoustic transmission with a direct connection between the malleus handle and the inner ear is somewhat less favourable than with an intact malleus/incus chain. For this reason, it is understandable that the results prove to be less good after malleus handle stapedectomy than after primary incus stapedotomy (Tab. 5.**5**). It is seen that a closure of the air-bone gap of ≤ 10 dB is achieved in 40 to 70 % and of ≤ 20 dB in 69 to 88 % of the operations. The figures cited for additional perceptive hearing losses are 0 to 8 % and for postoperative deafness 0 to 2 %. In the more recent studies, a trend towards somewhat better hearing results and fewer complications is becoming apparent. This might be attributable to improved technical tools.

Personal Malleus Handle (Malleus Grip) Stapedectomy Series and Surgical Technique

The indications for 44 of my own malleus handle (malleus grip) stapedectomies are given in Tab. 5.**6**. A transcanal operation is carried out through the fixed aural speculum and as far as possible under local anaesthesia. A posterior tympanomeatal flap is elevated. Once it has been decided that the malleus handle (malleus grip) stapedectomy is indicated, the meatal flap is widened in an epitympanal direction over the handle of the malleus and the latter is carefully detached from the tympanic membrane as far as to the neck using a micro-pick. A connection with the tympanic membrane is usually left at the umbo. If the head of the malleus is fixed, a malleus head punch is used to detach it at the neck of the manubrium mallei proximal to the tendon of the tensor tympani muscle, in order to preserve the stabilizing function of the latter on the handle of the malleus. Then the posterior part of the stapes footplate is opened wide or the entire footplate is removed, either using the Skeeter microdrill or, in revision operations with scar formation in the oval window, using the fiberoptic laser. After estimating the distance a long Teflon piston–metal wire prosthesis 5.0 to 6.5 mm in length and 0.6 or 0.8 mm in diameter is bent to conform to the anatomical situation, and is inserted in one movement as far as possible in such a way that the loop encloses the handle of the malleus and the piston comes to lie either directly in the oval window or at the margin of the window. Using the closure forceps, the loop is clamped on at the very top of the handle of the malleus, because the deflections of the malleus handle caused by tympanic membrane movement are considerably smaller there than in the region of the umbo. In a relatively tricky manoeuvre, the wire is then wrapped completely around the handle of the malleus with a small 0.3 mm hook in the right hand whilst at the same time securing the prosthesis with small forceps or a pick in the left hand. The wire loop is additionally fixed at the handle of the malleus with a drop of cement. The piston is then positioned optimally in the oval window through careful bending of the wire until movements of the handle of the malleus without play and without generating sensations of vertigo are transmitted to the inner ear fluid. The oval window is sealed with pieces of adipose tissue taken from the ear lobe. The wire loop at the handle of the malleus is also covered with adipose tissue from the ear lobe and the tympanic membrane is replaced. The main steps of the malleus handle (malleus grip) stapedectomy technique are shown diagrammatically in Fig. 5.**23**.

Tab. 5.**6** Indications for carrying out the 44 malleus handle stapedectomies (R. Häusler, Bern 1992–1998)

A. Primary malleus handle (malleus grip) stapedectomies	*n = 13 (29 %)*
Stapes fixation additionally with:	
– Fixation of the incus and/or head of the malleus	9
– Luxation of the incus (including one case with mobile footplate and in addition broken crura of the stapes)	3
– Missing incus	1
B. Malleus handle (malleus grip) stapedectomies as revision operations	*n = 31 (71 %)*
– After previous stapedectomy	17
– Ankylosis of the incus and/or head of the malleus	8
– Necrosis of the incus process	6
– Luxation of the incus	3
– After previous fenestration	4
– After other ear operations	6
– After previous incus interposition (in fixed stapes)	5
– In mobile footplate with no stapes superstructure and missing incus	1
– Revision of a malleus handle (malleus grip) stapedectomy	4

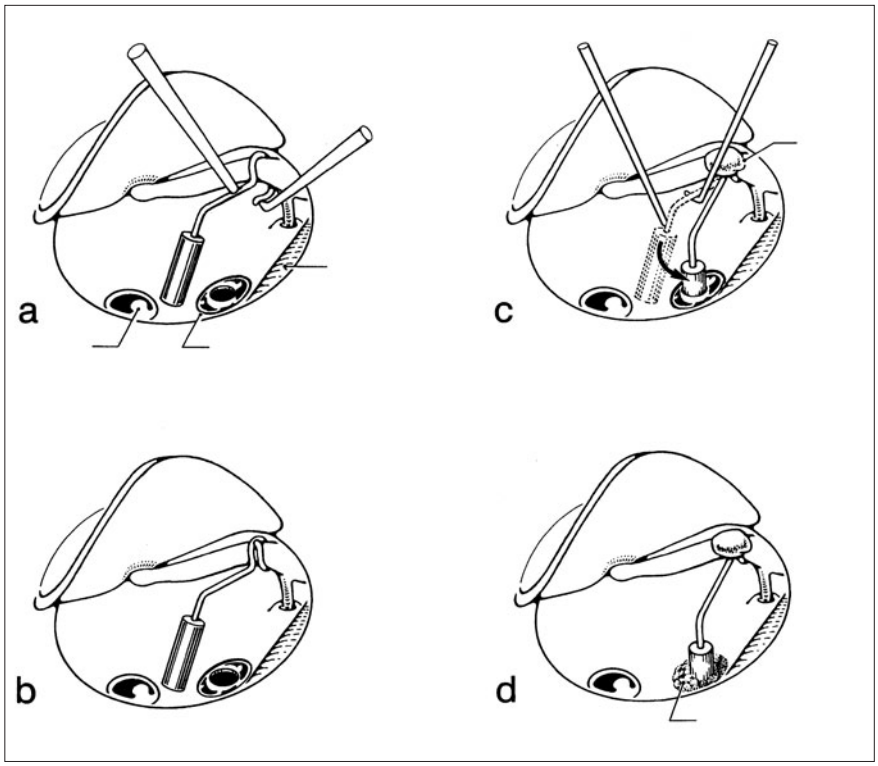

Fig. 5.**23** Technique of malleus handle (malleus grip) stapedectomy. **a** After careful detachment of the tympanic membrane from the proximal handle of the malleus and perforation of the stapes footplate, an extra long, appropriately bent malleus handle (grip) –platinum wire band-piston prosthesis (6–6.5 mm × 6 mm) is inserted with the platinum band being wrapped completely around the proximal handle of the malleus (**b**). The metal loop at the handle of the malleus is additionally consolidated with glass ionomer cement. This makes it considerably easier to achieve optimal positioning of the piston in the oval window (**c**). Sealing of the oval window with adipose tissue from the ear lobe (**d**).

The classic malleus handle steel-wire fluoroplastic piston of Schuknecht was used for the first 34 malleus handle stapedectomies. This long prosthesis has a wide wire loop enabling it to be wrapped completely around the handle of the malleus. The steel wire is somewhat rigid, however, and optimal positioning of the piston is made difficult through the spring tension of the wire. For this reason in a modified piston we have replaced the steel wire with a thin platinum wire, which is flattened into a band at the top of the loop (Fig. 5.**24**). We have been successfully using this modified malleus handle (malleus grip) prosthesis (Häusler modification of the Schuknecht prosthesis; Smith & Nephew) since 1997 [331]: the fixation of the soft platinum wire band around the neck of the malleus and optimal positioning of the piston through bending of the platinum wire is made considerably easier than with the earlier steel wire prosthesis.

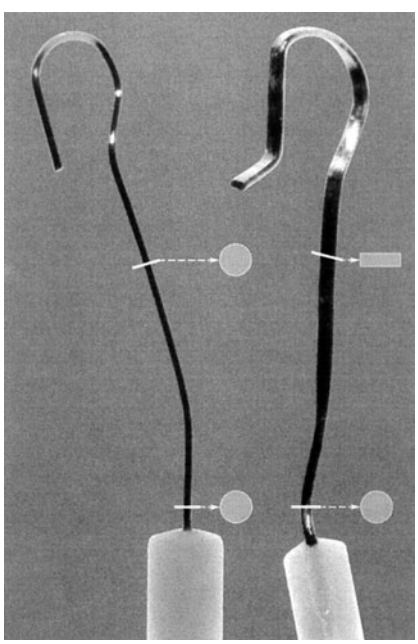

Fig. 5.**24** Classic malleus handle stapedectomy prosthesis of Schuknecht (left). On the right, the modified malleus handle (malleus grip) stapedectomy prosthesis (Häusler modification of the Schuknecht malleus handle prosthesis; Smith & Nephew), in which the steel wire has been replaced by a platinum wire which is flattened into a band at the loop.

Results

Thirty-nine out of 40 patients operated on in Bern could be followed up. One to six years after the operation a postoperative hearing improvement of 15 to 50 dB with a positive Rinne tuning fork test was found in 36 (92 %) cases. A mean residual air-bone gap of ≤ 20 dB was measured in 85 % of the patients. An optimal residual air-bone gap of ≤ 10 dB was achieved in 40 % of the patients. As regards the postoperative bone conduction threshold, it should be noted that an over-closure occurred in 60 %. One patient developed a postoperative sensorineural hearing loss of 40 dB, two other patients had slight high tone hearing losses of 15 and 20 dB respectively. No cases of deafness occurred in this malleus handle (malleus grip) stapedectomy series consisting of a limited number of patients.

In three patients, a lasting improvement in hearing was only achieved after a revision malleus handle stapedecto-

my, carried out because the piston had been extruded out of the oval window (in one patient only after a second revision). Since the middle ear situation was known, the piston could be inserted without problems by selecting a somewhat deeper position in the posterior part of the oval window for the placement of the prosthesis. Most of the patients denied any symptoms of vertigo, even with fairly large pressure fluctuations, after malleus handle (malleus grip) stapedectomy. Only three patients reported that in certain situations, such as going into a tunnel, on slamming a car door shut or vigorously blowing their nose, they sometimes experienced slight sensations of vertigo. This did not adversely affect their daily lives.

Both the data in the literature and also the evaluation of my personal results show that the malleus handle (malleus grip) stapedectomy is a surgical technique that can bring about an improvement in the ability to hear in cases of conductive hearing loss with stapes fixation and additional fixation or loss of the incus. If the piston is positioned correctly, persisting postoperative symptoms of vertigo are rare and inner ear hearing losses also seem to occur with hardly any greater frequency than after a primary stapedectomy. The most frequent complication in my own series was the possibility of a piston extrusion out of the oval window. This problem was brought under better control through the insertion of a newly developed, extra long platinum wire band–Teflon piston prosthesis and also the use of cement for the additional consolidation of the wire loop at the neck of the malleus. These new technical tools have proved very useful in these surgically often demanding operations.

Stapedectomy Technique in Middle Ear Malformations

In this section, the stapedectomy techniques that should be used in cases with an abnormal course of the facial nerve, in gusher ear and in persistent stapedial artery will be described on the basis of the literature and my own personal experience.

Stapedectomy in Cases with Abnormal Course of the Facial Nerve

An abnormal course of the facial nerve in the region of the oval window represents a particularly delicate problem in stapes surgery [89]. Localized nerve canal dehiscences in the tympanal segment are commonplace and are seen in almost 50 % of all people in anatomical studies [332]. More pronounced facial nerve protrusions and prolapses are seen in about 5 % of stapedectomy cases. Highly aberrant antero-inferior courses of the facial nerve over the oval window and the promontory, duplication of the nerve around the oval window or facial nerve courses that fan out over the oval window and the promontory represent rare individual cases [333–335]. Aberrant courses of the facial nerve are typically associated with stapes anomalies, as already described in Section 3.2, Stapes ankylosis in malformations of the middle ear. These stapes rudiments are explained by the fact that the stapes bud cannot come into contact with the lamina stapedialis, from which most of the stapedial footplate develops, in the course of middle ear development [336, 337]. In the majority of cases, the demonstration of an abnormal course of the facial nerve is an unexpected finding during the operation, which one must always be prepared for. Preoperative clues to the possible presence of a facial nerve anomaly are conductive hearing losses that have been present since early childhood and also additional ear malformations, such as an auditory canal stenosis, pre-auricular fistulae and various other cranio-maxillo-facial malformation syndromes.

A facial nerve prolapse often presents intraoperatively as whitish soft tissue. Sometimes the prolapsed nerve has a globular tumoral appearance. Several cases are described in the literature in which a facial nerve coursing over the oval window was mistakenly thought to be an inflammatory "fibrosis" and was curetted off during the stapedectomy, leading to postoperative facial nerve paralysis [60, 300]. I also know of such a case from my own work as a medicolegal expert. Well-known ear surgeons recommend that if an abnormal course of the facial nerve is found, the operation should be discontinued and no stapedectomy should be carried out [300, 340]. Other otologists recommend that in cases of partial facial nerve prolapse the inner ear should be opened at the lower margin of the oval window with additional drilling of the promontory. Some otologists have reported good hearing gains with the insertion of a piston into an opening drilled in the promontory [36, 102, 326, 327]. Schuknecht [148] states that in cases of facial nerve prolapse all-Teflon pistons are less suitable than Teflon-wire pistons, because with the latter the wire can be better bent into shape around the facial nerve prolapse.

In my own stapedectomies, a fairly major abnormal course of the facial nerve was found 40 times (6.7 %) [339, 340]. In 31 cases this consisted of a partial prolapse of the nerve over the oval window, 23 times with an intact bony Fallopian canal and eight times with a totally or partially denuded nerve. In six cases the oval window was covered completely by an aberrant facial nerve. In one patient with a rudimentary stapes, a duplication of the nerve around the oval window was found and in another patient the nerve took a markedly antero-inferior course over the promontory, covering the lower part of the oval window. In one other case the facial nerve fanned out widely over the oval window and the promontory (Fig. 5.**25**).

In seven cases of total prolapse, the stapes prosthesis was inserted through an opening drilled directly below the lower margin of the oval window into the promontory (Figs. 5.**25**, 5.**26a–c**). In these cases, the opening was drilled particularly carefully through the relatively thick promontory bone and, on opening the inner ear, a pick was used to test whether symptoms of vertigo developed. This was never the case. In patients with a duplication of the nerve around the oval window the stapes prosthesis was inserted into the middle of the footplate between the two nerve branches. In the case where the nerve took a course over the promontory and partly over the oval window, the prosthesis was inserted through an unconventional opening

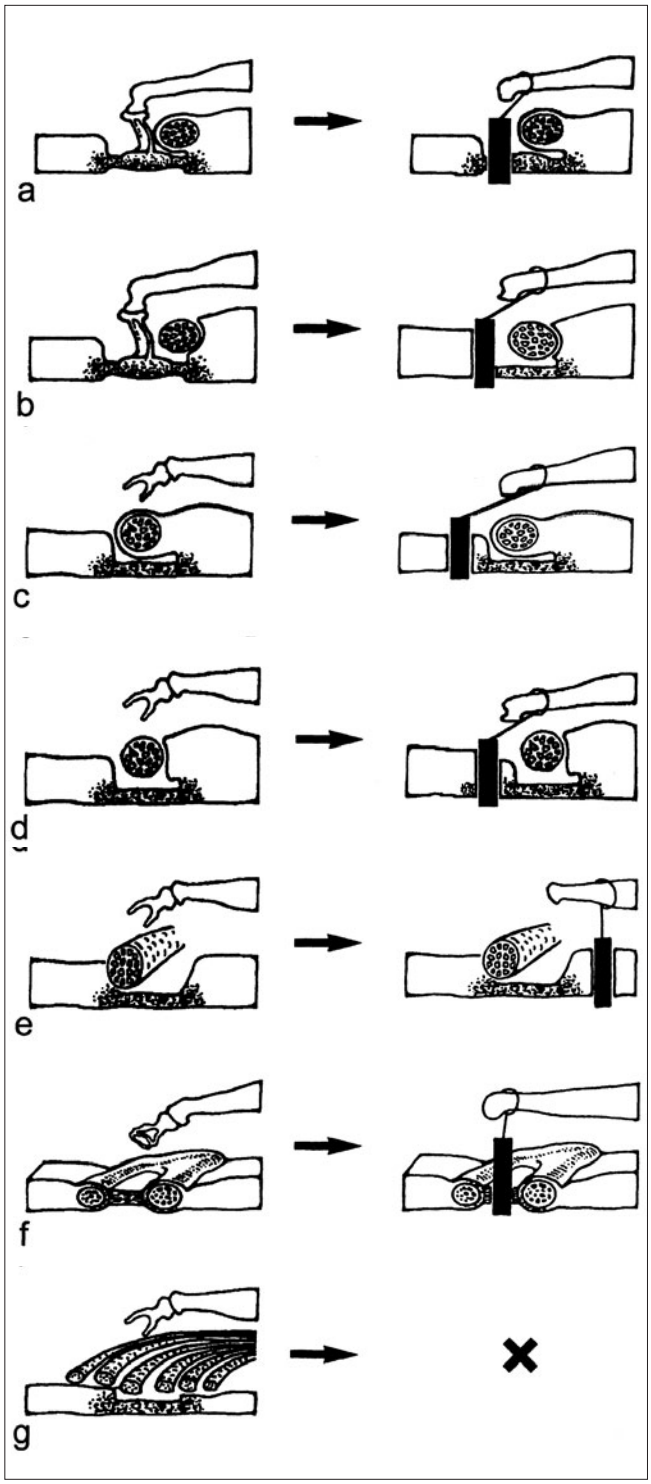

Fig. 5.25 Diagrammatic illustration of abnormal facial nerve courses found intraoperatively with or without additional malformation of the stapes and the stapedectomy techniques used in the different states of malformation.

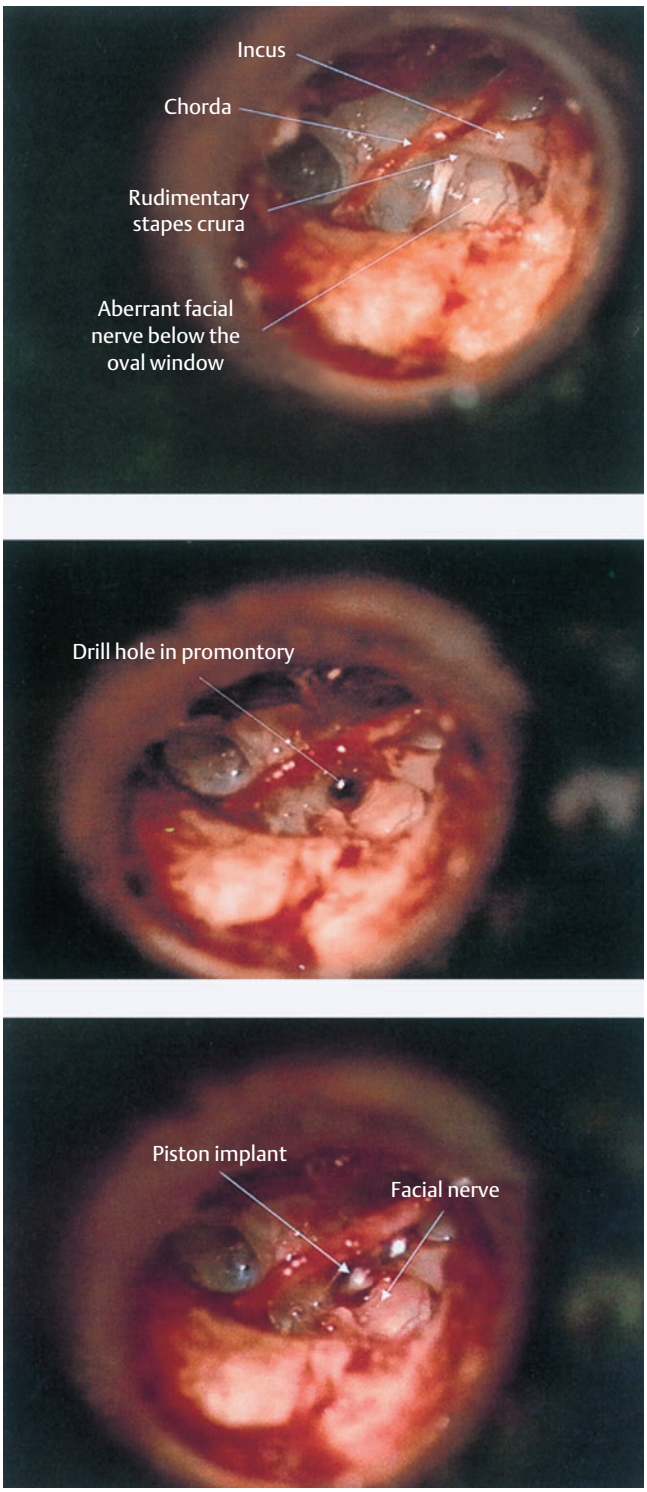

Fig. 5.26 Photographic documentation of an unconventional stapedectomy technique through drilling of the promontory in total prolapse of the facial nerve over the oval window. Status of tympanic cavity with aberrant course of the facial nerve over the oval window. There is only rudimentary development of the stapes. Opening of the inner ear by drilling the promontory just below the oval window and the aberrant facial nerve. Status after insertion of an appropriately bent piston into the opening drilled in the promontory. The patient whose pictures are shown here had an unproblematic postoperative course and has been in a stable state for five years now. The postoperative hearing gain was 40 dB with closure of the air-bone gap to 15 dB.

drilled carefully above the oval window, precisely at the point where the facial nerve would normally run. No prosthesis was inserted in the case where the nerve fanned out widely over the oval window and the promontory.

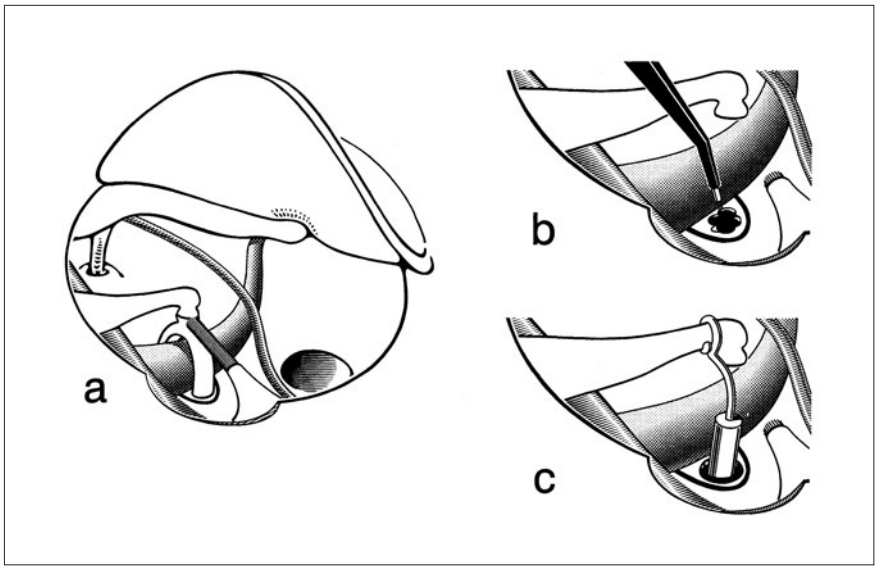

Fig. 5.**27** Stapedectomy technique in persistent stapedial artery. **a** Middle ear status in persistent stapedial artery. **b** Rosette-shaped perforation of the most posterior part of the stapes footplate using the fiberoptic argon laser. The tendon of the stapedius muscle and the posterior crus of the stapes had been lasered away first. After mechanical fracture of the anterior crus of the stapes the superstructure of the stapes was removed. **c** Status after insertion of an appropriately bent platinum band–Teflon piston prosthesis (0.4 mm in diameter). See also photograph of Fig. 5.**28**.

Postoperative hearing improvement of 5 to 60 dB occurred in 38 of the 39 (97 %) stapedectomized patients with an abnormal facial nerve course. A residual air-bone gap closure of ≤ 10 dB was achieved in 49 % and of ≤ 20 dB in 82 %. No cases of postoperative deafness, facial paralysis or vertigo with nystagmus occurred.

As my own results show, a useful improvement in hearing can be achieved for the patient despite an aberrant facial nerve using unconventional surgical stapedectomy techniques. In uncertain situations or if the ear surgeon is not very experienced, it may be more prudent not to carry out a stapedotomy.

Stapedectomy in Cases of "Gusher Ear"

If there is an open connection between the perilymphatic space of the labyrinth and the intracranial subarachnoid space in the internal auditory canal, after perforation of the stapes footplate during a stapedectomy a flow of cerebrospinal fluid [CSF] gushes out of the oval window like a spring; this is described as gusher ear [60, 341, 342]. In particular, after a wide opening had been made in the footplate as used to be the practice, there was the danger in this situation that the heavy flow of CSF would result in a perceptive hearing loss due to trauma to the membranous labyrinth. With the now customary very small-calibre footplate opening of initially 0.2 mm made with the argon laser or with the tip of the microdrill, the CSF flow is less dramatic and the gusher can be efficiently arrested through the rapid insertion of a stapes prosthesis. The gap around the prosthesis must also be carefully sealed with adipose tissue from the ear lobe. If necessary, the middle ear is additionally packed with Gelfoam, before the tympanomeatal flap is replaced. It is often recommended that lumbar drainage should also be carried out for a few days.

I personally have operated on two patients with gusher ear. In one case, this was an unexpected finding during the operation, in the second a referred revision operation. In this case, the previous tamponade of the middle ear had led to an incus luxation, and a malleus handle (malleus grip) stapedectomy had to be carried out at the revision. The flow of CSF could be arrested in both cases. The postoperative course was unproblematic and a partial hearing gain (15–20 dB mean value) was obtained in both patients without any additional inner ear hearing loss.

Stapedectomy in Cases of Persistent Stapedial Artery

The stapedial artery, which emerges directly out of the internal carotid artery and runs through the window of the stapes, normally atrophies in the course of the third month of foetal development in humans [60]. A persistent stapedial artery, which can function as a meningeal artery, is

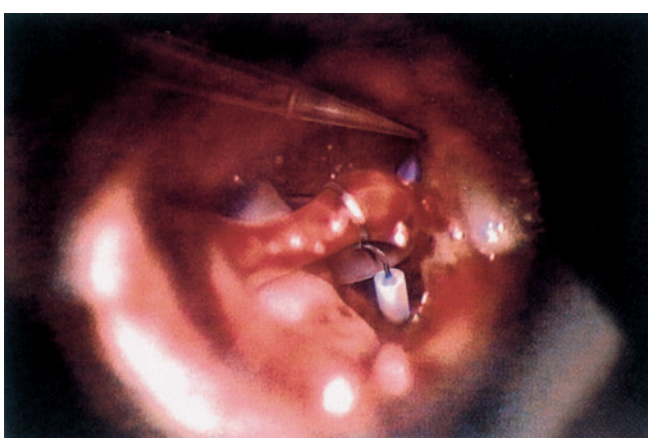

Fig. 5.**28** Photograph of a stapedectomy in persistent stapedial artery. After removal of the superstructure, an appropriately bent piston is inserted into a perforation in the most posterior part of the stapes footplate and fixed to the long incus process. The patient achieved a partial hearing gain postoperatively.

found in 1 : 500–1 : 1000 ear operations [343]. Not infrequently patients with a persistent stapedial artery also have signs of other malformations. Schuknecht [148] states that after careful removal of the stapes superstructure, a persistent stapedial artery can be pushed forwards so that the footplate can then be perforated with the insertion of a stapedectomy prosthesis. If the stapedial artery is injured, massive haemorrhage occurs which must be arrested through a middle ear tamponade. In this case, the stapedectomy cannot be carried out. Ligature of a stapedial artery is rather inadvisable, because it has been demonstrated in anatomical studies that in some cases a persistent stapedial artery provides the blood supply to intracerebral structures [344]. One personal case and the surgical technique used are shown in Figs. 5.**27**, 5.**28**. The postoperative course was unproblematic and a partial hearing gain of a mean of 15 dB was achieved.

Thoughts on the Validity of the Evaluation Methods in Stapes Surgery

In addition to the subjective information given by the patient, objective and quantitative measurement methods should also be used as far as possible for the evaluation of the success of advances in surgical operations. This is often difficult in surgery, e.g. when it is a question of eliminating pain. The situation is favourable for stapes surgery however, in that the success can be simply measured at a primary stage through the number of decibels of hearing gain. The fact that this is not unproblematic—quite apart from the fact that clinical psycho-acoustic audiometry represents a subjective measurement method—will be briefly discussed here.

Limits of Audiometry

The success of a stapedectomy is measured by comparing the postoperative with the preoperative audiogram at the octave frequencies 0.25 to 8 kHz. The low frequencies of below 500 kHz that are less important for the understanding of speech and high frequencies over 4 kHz are not included for the measurement of the mean hearing gain. Their relevance is comparatively slight in any case because of the intra-individual scatter values, which in clinical measurements can automatically amount to up to 20 dB. The mean of the octave frequencies 0.5, 1 and 2 kHz with or without the inclusion of 4 kHz used to be measured previously. According to the guidelines of the Committee on Hearing and Equilibrium Guidelines for the Evaluation of Results of the Treatment of Conductive Hearing Loss of the American Academy of Otolaryngology Head and Neck Surgery [125], the value of 3 kHz should also be included in addition to the octave frequencies[6]. It is also recommended in these guidelines that only data measured at least one year after the operation should be included for the measurement of the success of the operation.

The residual conductive hearing loss, which is measured from the difference between the postoperative air conduction threshold and the postoperative bone conduction threshold, is often used for the evaluation of the surgical success. This is not unproblematic, because cases with a severe inner ear hearing loss may nevertheless have a closure of the air-bone gap and may be assessed, absurdly, as a surgical success. On the other hand, due to the Carhardt notch there may be a postoperative improvement in the bone conduction compared with the preoperative bone conduction threshold, which represents an additional hearing gain that does not become apparent in the measurement of the residual postoperative air-bone gap. In this sense, the earlier practice of comparing the postoperative air conduction threshold with the preoperative bone conduction threshold to determine the postoperative hearing gain is almost more meaningful, because here the bone conduction hearing gain became apparent as so-called “over-closure.” The postoperative change in the bone conduction threshold compared with the preoperative bone conduction threshold should therefore be given for the estimation of inner ear function and of the Carhardt effect.

It may be important to give the audiometric values separately for each octave frequency when comparing different operation methods, because the same results are not obtained in the low and high frequencies. Since, moreover, the high frequencies are particularly important for the understanding of speech, it is an advantage if the results at 4 kHz are also listed.

Numerical tables of figures with averaged results are often confusing and make direct comprehension difficult. Some groups have therefore started to present their stapedectomy results in the form of cartograms, as is the case with the Glasgow Benefit Plot [345] or the Amsterdam Plot [223]. The advantage of this method is that the measurements of the individual patients can be recognized as points. This makes possible the immediate recognition of poor individual results. Differences between groups of patients catch the eye like clouds with different outlines. In cases of bilateral otosclerosis, for example, the benefits of a stapedectomy in both ears could be made clearly apparent through the use of such plots [146].

Finally, it is clear that the pure tone audiogram should only be used as a partial criterion of success: it is not the hearing threshold that is decisive for the patient, but rather his understanding of speech and his hearing in his natural surroundst. A simple method for the comprehensive evaluation of the functional integrity in general and in respect of the monaural and binaural hearing loss, is proposed in the Guides to the Evaluation of Permanent Impairment of the American Medical Association [346], which was produced in collaboration with the American Academy of Otolaryngology, Head and Neck Surgery. This general method of evaluation has also been successfully used for stapes surgery [145].

[6] The aim of this measure was to give more weight to the high frequencies that are important for the understanding of speech. To what extent this additional effort is appropriate is questionable. The results of studies carried out with and without the inclusion of the 3 kHz value, did not find any additional information gain with the inclusion of the 3 kHz value [236].

Conceptual Difficulties in the Calculation of Success: The So-Called Paradox of the High Surgical Success Rate

With the microsurgical techniques used today, many statistics show that postoperative hearing improvement is achieved in over 95 % of cases after primary stapedectomy. If, in addition, complex stapes operations and revision stapedectomies are also included, a total success rate of about 90 % is still obtained. Because of this high standard, stapedectomy is quite rightly classified in the category of minimally invasive high-success surgery procedures. New and often useful suggestions for improvement are constantly being made to optimise the prospects of still further success. This results in a very particular problem. The intellectual, material and technical outlay needed to achieve an additional improvement in the success rate is enormous, given the current high baseline values, but the limit is that such improvements can no longer be demonstrated at all. Eisner described this problem as the so-called "paradox of high-success surgery" in Ophthalmology 1990 and 1994 [347, 348]. Success rates are traditionally expressed as percentages in medicine, even though the significance of the percentage improvement largely depends to a great extent upon whether it concerns the middle or the extremes of the percentage scale. Thus, an improvement in the success rate of 10 % from 45 % to 55 % means little in reality. Despite the 10 % improvement, the prospect of success is about 1 : 2 for both percentage values. By contrast with this, an improvement of 10 % from 80 % to 90 % means that instead of roughly one failure to five successes, now there is only one failure to ten successes, i. e. the 10 % improvement corresponds to a doubling of the success rate here. With an improvement in the success rate from 98 % (one failure to 50 successes) to 99 % (one failure to 100 successes) even the mere one percent improvement also signifies a doubling of the success rate. On the other hand it becomes increasingly difficult to demonstrate the success as the success rate increases. In order to demonstrate with statistical significance ($P < 0.01$) that the success rate has risen from 80 % to 90 % due to an improvement in the surgical technique, a database of 250 cases is required. To demonstrate an improvement in success of 1 % from 98 % to 99 %, 2900 cases have to be evaluated, and to demonstrate an improvement from 99 % to 99.5 % as many as 5800 cases would be needed [349]. It is evident from this that with a success rate of over 95 %, such as is reported fairly often for stapedectomy, it is not possible to demonstrate additional improvements or deteriorations at all. This would in fact require comparable collectives of over 1000 patients, who would have to be operated on by the same surgeon using standardized techniques and under the same conditions.

This also gives rise to the question of whether a surgeon who has achieved a success rate of 95 % with the current stapedectomy operation technique, should alter his surgical technique at all, since in all probability it would not be possible to demonstrate either an additional improvement or a further slight deterioration in the results[7]. If one pursues this line of thought still further, one realizes that an otologist who has achieved a success rate of 98 %, is two and a half times better than a surgeon who records good results in "only" 95 %. The better surgeon will never be able to prove his superiority, however, and the less good surgeon will never become aware of his inadequacy, because his experience is that for one failure he still has the considerable number of 20 successes.

If one understands these statistical problems, it becomes clear that the results of most analyses with respect to stapes surgery are not very meaningful.

Evaluation Proposals

The following conclusions can be drawn from the points touched upon in this section: the postoperative hearing gain should be measured as a comparison between the pre-operative and the post-operative air conduction threshold after the stapedectomy. The results are not clinically meaningful until after one year. For the measurement of the surgical success, the postoperative residual conductive component is determined from the postoperative audiogram one year after the operation. For the measurement of the inner ear function, a comparison should be made between the postoperative and the preoperative bone conduction up to six weeks after the operation. If different techniques are to be compared with each other, it is useful to break down the results according to octave frequencies. The statement of the results should include not only the mean value but also the standard deviation. In future it would be useful if, in addition to the mean values, as many raw data as possible, e. g. in the form of small-print tables (see Tab. 5.**2**) or in an electronic appendix, were to be provided as well. Only in this way will more precise statistical analyses or subsequent meta-analyses be made possible.

Conclusions and Outlook

Stapes surgery has undoubtedly become simpler, less traumatic and very probably also more successful and safer through the many technical advances that have taken place in the past few decades. Thanks to more precise and honest clinical observations, various less successful techniques, such as the use of polyethylene tubes as stapes replacement prostheses, have been abandoned over the years. Other questions concerning the optimal surgical technique, type of prosthesis and material still remain unresolved. Clinical studies are often difficult to interpret, because the differences in the results achieved are small. Contradictory results with "significant" differences may be due to investigation bias or case numbers that are too small. Hardly any correct prospective and randomized studies are available. From personal experience I know that it is also a difficult and ethically delicate matter to carry out such studies in stapes surgery. Despite all the technical advances and scientific studies, stapes surgery is ultimate-

[7] Other evaluation criteria would probably have to be applied, e. g. that certain rare complications are eliminated through a new method, for example that the occurrence of a floating footplate is avoided through the use of the fiberoptic argon laser stapedotomy.

ly not only a high-precision job, but also represents the practice of an art.

Stapes surgeons have received valuable information from calculations on the theoretical model of the ear and measurements on specimens of petrous bone in recent years. It is to be expected that this quantitative research will lead to a better understanding of many aspects of middle ear surgery that are still controversial at present.

The technical advances in stapes surgery also have a certain significance, not least, for teaching practice: thanks to modern technical aids (video, laser, etc.) a budding otologist can be instructed in the stapedectomy technique with relatively little additional risk for the patient, as has been confirmed in several, sometimes controlled, studies [286, 290, 350, 351]. Stapes surgery should probably only be practised by a limited number of suitable microsurgeons, because in this way they can acquire greater surgical skill and experience. This selective practice, which is customary already in many places, will probably be promoted yet further in the future by the decrease in the absolute number of stapedectomies observed worldwide.

Despite all the technical advances, there is still the risk of irreversible postoperative deafness. This risk is admittedly not great, with an incidence of about 1 %, but it is very real and also continues to be reported in virtually all of the larger recent patient series. It would be an enormous advance if the cause of the unexplained postoperative deafness could be recognised and eliminated or if the at-risk patients could be identified preoperatively at least. Stapedectomy occupies a special position here in relation to other kinds otological microsurgery, where the risk of postoperative deafness is much smaller. Since the otosclerotic hearing loss can be largely corrected not only by surgery but also in a risk-free way through the fitting of a hearing aid [352], this results in some degree of reservation when deciding on the indication for stapedectomy. This has recently been discussed in detail by two well-known otologists, Howard [353] and Shea [354], at a high ethical and intellectual level in editorials; here the stapes surgeon Shea, who has come to rely on a hearing aid in old age, argued vehemently in favour of surgery on the basis of personal experience. In fact, it is accepted that the vast majority of patients who suffer from an otosclerotic conductive hearing loss prefer the once-only surgical operation of a minimal invasive stapedectomy, even in full awareness of the surgical risk, to life-long dependency on a hearing aid. If, for example, the minor otological operation is successful, as is fortunately almost always the case, the patients are satisfied with the hearing gain achieved through the surgery.

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6 Implantable Hearing Devices: an Introduction

H. P. Zenner

Abstract

Implantable Hearing Devices – State of the Art. Hearing aids may have fundamental disadvantages: (1) stigmatization of the patient; (2) the sound may be found unsatisfactory due to the limited frequency range and undesired distortion; (3) in some patients, the ear canal fitting device generally necessary leads to an occlusion effect; (4) acoustic feedback may occur when amplification is high. Conventional hearing aids transmit sound into the ear canal via a small microphone. Sound has the disadvantage of requiring high output sound pressure levels for its transmission. This along with the necessary miniaturization of the loudspeaker as well as the resonances and reflections in the closed ear canal contribute to the possible disadvantages mentioned. In contrast, implantable hearing aids do not make sound signals but micromechanical vibrations. An implantable hearing aid has an electromechanical transducer instead of the loudspeaker of a conventional hearing aid. The hearing signal does not leave the transducer as sound but as a mechanical vibration which is directly coupled to the auditory system bypassing the air. This implantable hearing aid is either coupled to the tympanic membrane, the ossicular chain, the perilymph of the inner ear, or the skull. Requirements on electronic hearing implants designed for patients with conductive hearing loss differ from those on implants for sensorineural hearing loss. Conductive hearing loss requires the implant to replace the impedance transformation, thus being an impedance transformation implant (ITI). In various respects, the demands on an ITI are lower than the demands on an electronic hearing aid for patients with sensorineural hearing loss. The latter are mostly patients with a failure of the cochlea amplifier (CA). A damage to the CA is clinically discernible by a positive recruitment and loss of oto-acoustic emissions (OAE). Since these patients form the majority of cases with sensorineural hearing loss, an active hearing implant for such patients should partially replace the function of the CA. Therefore, the suggestion is to refer to an AI (amplifier implant). The implant expressions ITI (for patients with conductive hearing loss) and AI (for patients with sensorineural hearing loss) used in this context allow nomenclatural association with the CI (cochlear implant) for complete inner ear failure as well as with the BSI (brainstem implant) in the case of acoustic nerve failure.

Introduction

In a 1997 review on active electronic hearing implants, the surgical treatment of sensorineural hearing loss with implantable hearing devices was still described as a vision for the future [85–87]. In just the past few years this vision has become a reality, and operations to improve sensorineural hearing loss have become feasible [34, 82, 83]. The present work continues where the earlier one left off, examining the swift progression of technological advances that has engendered a new era in otosurgery. Implantable hearing devices fall into two broad categories: those designed for patients with conductive hearing loss and those designed for patients with sensorineural hearing loss [87]. Cochlear implants for the deaf are not covered in the present review.

Auditory Physiology

The hearing process starts when sound strikes the auricle and ear canal as a wave of compressed air. Different resonances are created within the outer ear, depending on whether the sound is coming from above/below, right/left, or front/back in relation to the outer ear.

- These resonances, also called location-specific frequency bands [2 a], are the basis for one of the two main mechanisms of sound localization.
- The other mechanism is stereophony.

When the incoming sound strikes the tympanic membrane, the air compression wave causes a deflection of the membrane, converting the sound wave into a mechanical vibration [80].

The normal tympanic membrane vibrates easily—quite unlike the fluid-filled inner ear, which offers extremely high resistance (impedance) to an acoustic signal. The function of the middle ear, then, is to force the inner ear to vibrate in response to incident sound. It does this *not* by amplifying the sound but by a process called impedance matching [80]. Through impedance matching, even small sound pressure levels can induce a traveling wave within the inner ear. This traveling wave is too weak to stimulate the inner hair cells, which cannot "hear" sounds lower than 50–60 dB. This is the task of the outer hair cells, which amplify the tiny traveling wave 100–1000 times, enabling them to stimulate the inner hair cells so that an acoustic signal is perceived [80]. This mechanism is called the cochlear amplifier (CA).

Pathophysiologic Aspects of Implantable Hearing Devices

As a result of international research efforts, the surgical options for patients with *conductive hearing loss* go beyond tympanoplasties and stapes surgery to include a bone-anchored external hearing aid (BAHA, Fig. 6.**2**) designed by Tjellström and Branemark [3, 68–71] and a partially implantable middle ear implant (MEI) designed by Suzuki and

Yanagihara and their group [60–67, 78, 79] (Fig. 6.**3**). The Audiant (Fig. 6.**2c**), a subcutaneous, bone-anchored, partially implantable hearing aid, was also available for a time [20, 21]. The function of these conductive-loss hearing aids is simply to replace the impedance matching function of the middle ear [80, 87], which involves straightforward amplification and electronic processing of the acoustic signal. As a result, partial implants (BAHA, MEI, and Audiant) with simple signal processing have been available clinically for many years.

The situation is different in patients with *sensorineural hearing loss*. This requires a much more sophisticated device with capabilities ranging from individual, frequency-specific amplification and the improvement of speech intelligibility to sound discrimination in background noise and entirely different therapeutic actions depending on whether:

- the outer hair cells are damaged while the inner hair cells are essentially intact, or
- the inner hair cells are also damaged.

The first situation, which is much more common, can be treated with the partially implantable, electromagnetic systems. For the second situation, cochlear implants are increasingly used [29]. We shall consider this distinction below in greater detail.

Pathophysiologically, the great majority of patients with sensorineural hearing loss have an underlying insufficiency of the cochlear amplifier, whose function is based on the motility of the outer hair cells [80]. Because the cochlear amplifier is responsible for (1) hearing sensitivity, (2) frequency selectivity, and (3) the production of otoacoustic emissions [80], failure of the cochlear amplifier is manifested clinically by positive recruitment, a partial or complete loss of otoacoustic emissions, a raised threshold (hearing loss), and loss of speech discrimination. In patients with cochlear deafness or very profound hearing loss, the damage goes considerably beyond failure of the cochlear amplifier and includes a complete functional loss of the inner hair cells [80].

Consistent with this pathophysiologic concept, the amplifier in an implantable hearing aid for patients with moderate to severe sensorineural hearing loss partially replaces (for hearing sensitivity) the physiologic cochlear amplifier. Rather than being amplified in the inner ear, the acoustic signal is amplified in the implant. The amplified micromechanical signal that is generated by the implant bypasses nonfunctioning outer hair cells and directly stimulates the inner hair cells of the inner ear. This type of implantable hearing device, designed to function as a micromechanical replacement for the cochlear amplifier, is called an amplifier implant (AI).

In patients with profound hearing loss bordering on deafness, it is no longer helpful to replace the cochlear amplifier with an AI, because there is a concomitant failure of the inner hair cells. These cases must be managed with a cochlear implant (CI), which bypasses the entire inner ear and electrically stimulates the acoustic nerve. The CI, then, can be described as an electrical prosthesis that replaces the inner ear. To summarize: the great majority of patients with sensorineural hearing loss require a cochlear amplifier, while patients with inner ear deafness or profound sensorineural hearing loss require "replacement" of the entire inner ear.

Similarities between Implantable and Conventional Hearing Aids

If we evaluate hearing aids and CIs based on pure-tone audiometry, we can identify three levels of frequency and hearing loss: (I) the level treated by conventional hearing aids, (III) the level treated by CIs, and (II) the treatment gap between I and III. Conventional hearing aids and implantable hearing devices both function as level-I devices based on current technology. This is the major similarity between both types of hearing aid. The differences between conventional hearing aids and implantable hearing devices are *not* in their loudness, as explained in the paragraph below.

Differences between Conventional and Implantable Hearing Devices

Conventional Hearing Aids

Today, very high-performance hearing aids are available for patients with moderate to severe sensorineural hearing loss and for patients with conductive hearing loss that is not responsive to surgical treatment. They can benefit many but not all patients who require a level-I device. Conventional hearing aids operate with acoustic transducers. They transform sound into electrical signals, process and amplify the signals, and convert them back into sound. It is this dual conversion process (acoustoelectrical and electroacoustical), plus the inherent technical limitations of conventional hearing aids based on their small dimensions (e. g., tiny speaker), that limit the hearing aid-amplified acoustic signal compared with the original acoustic signal, although the processed signal is louder. Also, the characteristic occlusion of the external ear canal can so alter its acoustic properties that, even if the device generates an excellent output signal, that signal will undergo considerable distortion in the occluded ear canal. This distortion effect cannot always be corrected by adjusting the fit. The result for the patient may be an unintelligible speech signal at the tympanic membrane. Thus, the use of conventional hearing aids can have fundamental disadvantages in a number of hearing-impaired patients:

- A certain percentage of hearing aid wearers perceive the sound fidelity and speech intelligibility of their devices as unsatisfactory.
- The earmold can create an unpleasant occluding sensation in the ear canal, and some patients have recurrent bouts of otitis externa.
- Acoustic feedback can occur between the speaker and microphone at high gain. In some hearing aids, feedback can be eliminated by turning down the gain.
- Wearers are vulnerable to stigmatization, ridicule, and discrimination. Some patients stop wearing their hear-

ing aid because they feel stigmatized. Others experience social and/or professional ridicule and discrimination.
- Difficulties can occur with everyday activities and situations (swimming, showering, wind, rain).
- Some patients cannot be rehabilitated to their jobs (e. g., athletic instructors, swimming instructors, cooks, secretaries, receptionists, schoolteachers, doctors, workers exposed occupationally to heat, moisture, dust, etc.).
- Despite good audiologic results, psychosocial rehabilitation may be unsatisfactory, resulting in social withdrawal and low self-esteem.

Implantable Hearing Devices

An electronic hearing implant can also function as a level-I device, but it offers several advantages over a conventional hearing aid:

- Better sound fidelity over the entire audible range of frequencies
- Ear canal is left open (no earmold)
- No feedback

Also, the implant should have one or more of the following additional properties:
- It should contribute to directional hearing and the suppression of unwanted ambient noise.
- It should not interfere with bathing, showering, hair drying, diving, etc. The implant should be operational during sports activities and, if desired, during sleep (e. g., hotel wakeup call, mother wants to hear baby).
- Vocational rehabilitation, even in difficult cases.
- The implantable components should have other characteristics whenever possible:
  - Outwardly invisible
  - Not irritating to tissues
  - Good longevity
  - No predisposition to infection [84]

A modern electronic hearing implant is **not** expected to be louder than a conventional hearing aid to fill the pure-tone audiometric gap between hearing aids and CIs.

Definition of Terms

Active Implants

Implantable hearing devices are classified as active implants because they have an electric power source that is independent of the body. CIs are also active implants. Since active hearing implants are controlled electronically, they are also known as electronic hearing implants. By contrast, stapes prostheses, TORPs, and PORPs do not require a battery. They are classified as passive implants.

Nonacoustic Transducers

Implantable hearing devices convert sound into electrical signals and amplify them. Unlike conventional hearing aids, however, these signals are not converted back into sound but into micromechanical vibrations. Instead of the speaker in a conventional hearing aid, an implantable hearing device is equipped with an electromechanical transducer. The audio signal does not exit the transducer as sound (i. e., not as an air compression wave) but as a mechanical vibration that is micromechanically coupled to the auditory system, bypassing the air. The transducer is a vibrator, not a speaker. The advantages of this arrangement are listed in Tables 6.**1** and 6.**2**.

Table 6.**1** Benefits of partially implantable hearing systems

Sound quality
Ear canal remains open
Low distortion
Improved speech comprehension in noise
Less feedback

Table 6.**2** Benefits of modern fully implantable hearing systems

Sound quality
Ear canal remains open
Low distortion (< 0.5 %, hearing aids up to 5 %)
Improved speech comprehension in noise
Large transmission bandwith of approximately 100 Hz to 10 kHz for better speech comprehension, listening to music, etc.
Can prevent feedback
Utilize directional characteristics and noise suppression of ear canal
Compatible with everyday activities (job, telephone use, showering, sleeping, swimming, sports, etc.)
No wind noise, no hair noise
Aural rehabilitation does not rely on patient dexterity, which may be impaired due to disease (proper hearing aid use requires good manual dexterity).
No stigmatization from visible components

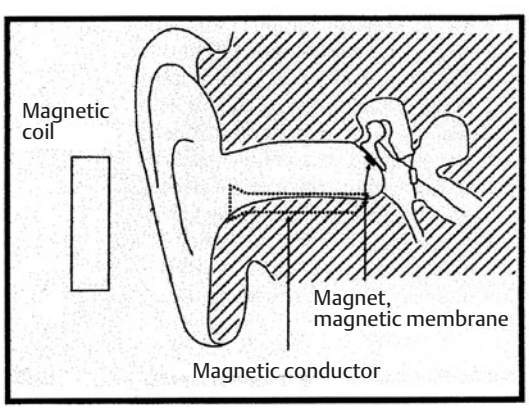

Fig. 6.**1** Electromagnetic system designed by Plester et al.

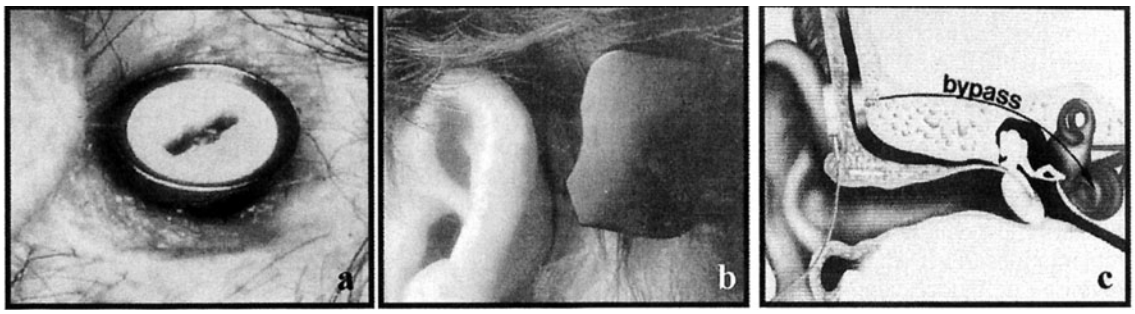

Fig. 6.2 Clinical bone-anchored hearing devices for conductive hearing loss. **a** BAHA Classic designed by Tjellström, with percutaneous attachment system. **b** External vibrator. **c** Subcutaneous Audiant designed by Hough (reprinted with kind permission).

Electromagnetic Transducers

Since Wilska [75, 76] proposed the electromagnetic transducer principle, most authors have utilized it. The system designed by Plester [55] is shown in Fig. 6.**1**. An electrically powered coil generates a magnetic field, which drives a permanent magnet to vibrate. The force of the permanent magnet may be coupled to the ossicular chain (Figs. 6.**5** and 6.**8**) or to the cranium (see Figs. 6.**2** and 6.**7**).

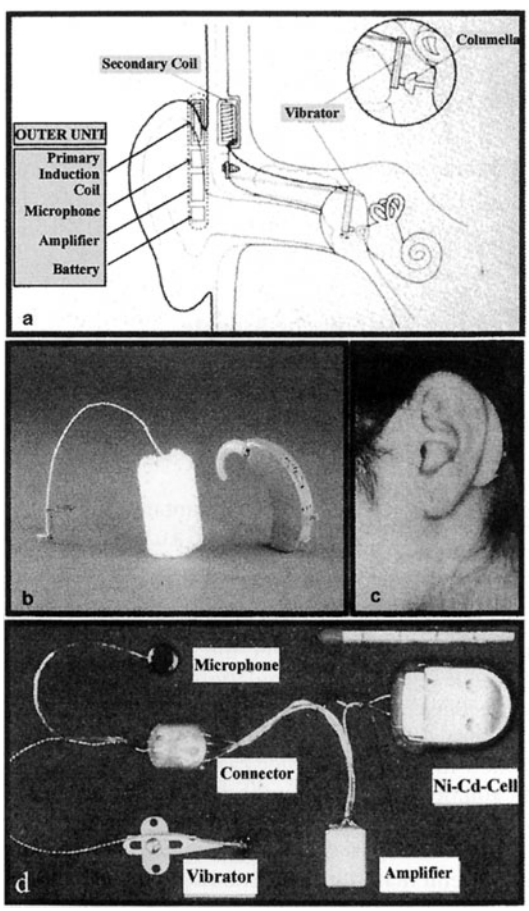

Fig. 6.3 Clinical Rion MEI designed by Suzuki and Yanagihara. **a** Diagram of the piezoelectric vibrator on the stapes capitulum. **b** Individual components. **c** HdO unit. **d** T-MEI (with kind permission).

Piezoelectric Transducers

These are composed of piezoelectric crystals, which alter their shape (vibrate) in response to an electric current. In theory, piezoelectric crystals can be coupled to the ossicular chain (Figs. 6.**3**, 6.**4**, 6.**6**, 6.**10**) or to the cranium. So far they have been coupled only to the ossicular chain in clinical practice [32].

Although both types of transducer can take an acoustic signal that has been transformed into an electric signal and convert it into a vibrational signal, there are major fundamental differences between the two principles that are relevant to their clinical application.

Components of Implantable Hearing Devices

An active hearing implant consists of four functional components:

1. Sensor for receiving sound
2. Electronic processor and amplifier
3. Electromechanical transducer (vibrator, actuator), which converts the audio signal into a vibratory stimulus. The transducer may have an electromagnetic or piezoelectric operating principle. If the actuator is not coupled directly, a separate coupling element is used.
4. An energy source

Fully Implantable Devices

If all four of the above components are implantable, with no visible components in the external ear canal, the device is described as fully implantable or a total implant (Figs. 6.**3d**, 6.**10**). The TICA LZ was a fully implantable device that was available for clinical use.

Partially Implantable Devices

With a partially implantable device, one or more of the components are visible externally on the head or body (see Figs. 6.**3**, 6.**5**, 6.**8**) or are placed within the external ear canal (Fig. 6.**5a**). Several partially implantable active hearing implants are available clinically. The Rion MEI, BAHA Clas-

sic, and Audiant are used to treat conductive hearing loss, while the Vibrant Soundbridge, the Otologics MEI, and BAHA Cordelle are used for sensorineural hearing loss. All have a nonimplantable sensor and energy source. The transducer or at least a coupling element is implanted, while the rest of the components are externally visible (by this definition, modern CIs are classified as partially implantable active hearing prostheses).

Suggested Nomenclature for Active Hearing Implants

The nomenclature that has previously been used for most active hearing implants (e. g., CI, MEI, BAHA) is anatomically derived, i. e., implants are named for their implantation site. The result is a variety of device names that give little information on their functions or indications. It is better to designate a device according to its function. This allows a systematic, indication-based nomenclature that facilitates clinical understanding. The implantation site alone does not necessarily reflect the function and indication of the implant and can therefore be misleading. This is illustrated by active hearing implants for sensorineural hearing loss. An anatomic nomenclature for these implants would be misleading because (except for CIs) these devices are implanted outside the inner ear. But if we designate the implants by their *function* (indication), and thus by the hearing problem that they are designed to correct, we find that the all implants can be assigned to one of the four main categories described below [87].

As noted earlier, the basic function of the middle ear is impedance matching [80]. The fluid-filled inner ear offers such high resistance (impedance) to a direct, air-borne acoustic signal that, without the middle ear, 98 % of the sound would be reflected. The middle ear overcomes this resistance by impedance transformation (IT) *without* amplification; this allows 60 % of the acoustic energy to enter the inner ear [80]. If the function of the middle ear is lost, an implant must replace the missing IT.

Recruitment-positive sensorineural hearing loss is generally the result of a partial or complete loss of the cochlear amplifier in the inner ear [80, 87]. Thus, the primary goal in recruitment-positive sensorineural hearing loss is to replace the function of the cochlear amplifier (A). This line of reasoning can be carried further: profound sensorineural hearing loss and deafness are most likely based on a functional disturbance or loss of the inner hair cells [80, 87]. The only way to correct the resulting subtotal or complete inner ear failure is to replace the function of the entire cochlea. Thus, the functional demands placed on an active implant will vary greatly depending on whether it must replace:

- impedance transformation (IT) in conductive hearing loss,
- cochlear amplification (A) in sensorineural hearing loss, or
- the entire cochlea (C) in complete or profound sensorineural hearing loss. The nomenclature proposed below is based on these functional criteria [87].

I. ITI (impedance transformation implant) for conductive hearing loss. The only function of an ITI is to transform impedance. This device does *not* replace the physiologic amplifier, so it can produce a relatively low output. It compensates only for the middle ear. Once the relatively weak signal has reached the inner ear, it can be amplified by the outer hair cells until the inner hair cells can perceive it. The electronic processor is also relatively simple. Partially implantable devices of this type are available clinically (BAHA, Rion MEI).

II. AI (amplifier implant) for recruitment-positive sensorineural hearing loss. The function of an AI is to replace the function of the cochlear amplifier and deliver a signal to the inner hair cells. Unlike an ITI, an AI must be able to amplify the traveling wave well into the nanometer range (it is not expected to reproduce the physiologic sharpness of the traveling wave peak in the healthy inner ear). An AI must meet considerably higher requirements than an ITI with regard to fidelity, output, and especially its electronic processor. Whereas ITIs are largely standardized, the audiologic parameters of an AI must be individually programmable for a specific hearing disorder. Only partially implantable devices (P-AI: Vibrant Soundbridge, Otologics MEI, BAHA Cordelle) are available for routine clinical use. However, a first group of study patients has been implanted with a total implant (TICA).

III. CI (cochlear implant). The CI completely replaces the inner ear, including the inner hair cells (whereas an AI basically replaces the outer hair cells). Only partially implantable CIs (P-CIs) are available clinically.

IV. ABI (auditory brainstem implant). An ABI replaces the inner ear and the acoustic nerve by directly stimulating the auditory nucleus in the brainstem. Partially implantable ABIs (P-ABIs) are already in clinical use [28].

Aspects of Surgical Anatomy

Transducer

Three anatomic sites are available for implanting the transducer of a partially or fully implantable hearing device:

1. Calvarium for bone-conduction implants (Fig. 6.**2**)
2. Tympanic membrane and middle ear cavity (Figs. 6.**1**, 6.**3**, 6.**5a**,**b**, 6.**6**, 6.**7**, 6.**8**)
3. Mastoid (Figs. 6.**5 c–e**, 6.**10**)

The transducer should be placed as close as possible to the calvarium, ossicles, or labyrinthine window in order to minimize the physical movement of any connecting elements, which will alter the desired stimulation frequency curve [36]. A space of approximately 2 × 3 mm is available in the middle ear cavity for a transducer, which is the approximate size of the Vibrant Soundbridge. The excavated mastoid provides a *useable* space of 1 cm^3, with a maximum diameter of 1 cm, in at least 80 % of patients [44, 45]. The advantage of greater space must be weighed against the possible disadvantage of having to use a connecting element.

Sensor

A sound receiver (e. g., a microphone, Fig. 6.**3**) can be implanted at various sites, depending on the system design:

1. In the middle ear
2. On the tympanic membrane and/or auditory ossicles (Fig. 6.**6b**)
3. In the wall of the external ear canal (Fig. 6.**10**)
4. In the mastoid
5. Below the scalp

The *useable* space that is available in the middle ear and even in the mastoid should not be overestimated. Maassen et al. [44, 45] described a case illustrating how difficult it can be to implant a membrane sensor (TICA, Fig. 6.**10**) in the posterior meatal wall so that the sensor conforms to the anatomy of the ear. Weber et al. [74] illustrated the problem of useable space for an ossicle-coupled piezoelectric sensor (Envoy, St. Croix Medical, Fig. 6.**6b**) that was implanted in the middle ear. Since piezoelectric systems are also available in sheet form, this may offer a solution to the space problem for future sensors implanted in the middle ear.

Preserve or Interrupt the Ossicular Chain?

The ossicular chain may be preserved [24] or interrupted [89] for the implantation of ossicle-coupled devices. In principle, the Vibrant Soundbridge [1, 34] (Fig. 6.**8**), the TICA [41, 82, 83] (Fig. 6.**10**), and the Otologics AI [8, 9] (Fig. 6.**5e**) can be implanted while leaving the ossicular chain intact. On the other hand, the RION MEI (Figs. 6.**3**, 6.**6a**), the Envoy system (Fig. 6.**6b**), and the systems designed by Hough et al. [19, 22] (Fig. 6.**5b**), Goode et al. [12–16], and Heide et al. [18] may require disruption of the ossicular chain. When the chain is preserved or its continuity restored, sound is emitted outward via the tympanic membrane. These acoustic emissions can have two important disadvantages:

1. Energy is lost that would otherwise stimulate the inner ear. In a recent implantation study with and without ossicular chain interruption, a loudness gain of up to 27 dB was achieved when the chain was minimally disrupted (e. g., with a RMND, see below) [89].
2. The acoustic energy lost through the tympanic membrane can cause undesired feedback in full and partial implants with a sensor placed on the head or in the ear. The above study on ossicular chain interruption also showed that a RMND (see below) can effectively suppress feedback.

Various surgical techniques are used for ossicular chain interruption. Of particular interest is a technique that is reversible and shows high reproducibility for restoration of the chain. One such technique is the recently reported reversible malleus neck dissection (RMND) [89], in which a segment approximately 1–1.5 mm long is resected from the malleus neck. Studies using laser Doppler vibrometry have shown that the defect may be reconstructed with a drop of cement, restoring ossicular chain function to the pre-dissection level [89].

Because ossicular chain interruption can benefit the patient, it can be recommended in cases where a reliable reconstruction method is available. The gain for the patient can be considerably greater than the drawback of a middle ear component when the implant is turned off. When the implant is turned on, the middle ear component becomes insignificant because AIs completely replace the function of the middle ear [90, 91]. Patients with implantable hearing devices generally use their implant throughout the day, and the times when the implant is switched off (usually during sleep) are of negligible importance. This refutes the traditional, general recommendation that the ossicular chain be preserved, replacing it with the requirement for dependable restoration in case the implant is later removed.

Acoustic Aspects

Acoustic Bandwidth

Electromagnetic transducers in conventional hearing aids are, for physical reasons, optimized to the range of up to about 6 kHz. The bandwidth at low frequencies depends on the tightness of the earmold. To function as a hearing aid, an implant should have a range from about 50 Hz to 10 kHz so that it can better transmit unvoiced sounds such as fricatives and plosives as well as music.

Deflection, Sound Pressure Level

Vibrational transducers do not produce sound, and so their deflections are not based on sound pressure levels but on the physiologic deflections of the middle and inner ear. In cases of conductive hearing loss with intact outer hair cells, low-amplitude stimulation is sufficient for ITIs since the signal, on entering the cochlea, can be amplified 100–1000 times by the outer hair cells [80, 87]. The situation is different in patients with sensorineural hearing loss and nonfunctioning outer hair cells. In this case the AI must amplify the traveling wave to substantially higher levels that can stimulate the inner hair cells. According to physiologic data, ossicle-coupled AIs can produce deflections between 100 nm and 1000 nm up to 1 kHz, which correspond to subjective audible impressions ranging from 100 dB SPL to 125 dB SPL in the healthy subject. Above 1 kHz, a deflection of 5–50 nm is sufficient to produce the same audible impression (e. g., in the octave from 5 to 10 kHz). At 10 kHz, a deflection of 50 nm corresponds to a sound pressure level of approximately 140 dB [40].

Dynamic Response

For an implant to accurately portray a complex acoustic signal, it must be fast and not lag behind in its response, or else a “sound stew” could result. The response speed of a hearing device is measured in terms of its rise time and decay time. Under physiologic conditions the rise and decay times in response to a 1 kHz acoustic signal of less than 0.1 ms duration should not exceed 1–3 ms in order to min-

imize distortion of the time envelope curve. As a result of the above specifications on output amplitudes in the high-tone range, the amplitude should not decline as the frequency rises, but rather the response time should become faster. At 10 kHz, for example, the rise time should not exceed 100 µs [40].

Distortion

Distortion degrades the quality and fidelity of sound transmission. A distinction is made between linear and nonlinear distortion. Linear distortion refers to the dependence of the amplitude and phase frequency curve on frequency (frequency response). Because hearing is relatively insensitive to phase changes, they need not be discussed here. But amplitude is a different matter: a change in amplitude is immediately perceived as a change in loudness. Resonance in the audible range leads to loudness distortion. If the amplitude declines too much as the frequency rises, the signals are perceived as too faint. Healthy outer hair cells have the remarkable ability to increase their motion velocity into the high-frequency range, so that the amplitude of the traveling wave remains "even" [80]. In the same way, an ideal transducer should function evenly over the audible frequency range and have the smallest possible "waviness" that does not exceed ± 3 dB. Resonances (natural frequencies) of more than 3 dB in the audible range should be avoided whenever possible [40].

But nonlinear distortion products, consisting of higher level-dependent spectral components in sinusoidal input signals ("clatter"), can also interfere with sound quality and speech discrimination. They play an important role in hearing aids, where they amount to 1–5 % (100–120 dB). Fredrickson [8, 9] calls for "extremely low" distortion products for implants, noting that his implant (Otologics) achieves < 0.5 to 1.1 % (500 Hz–10 kHz). Low distortion products of no more than 0.5 % in the range from 50 Hz to 10 kHz (equivalent output level of 120–140 dB SPL) should be required.

Impedance

With otologic implants, impedance is the resistance that the tissues of the ear offer to the excitation of the implant. Impedance comes not only from the ossicles and inner ear but also from postoperative scar tissue, calcifications, and fluids that can occur in the middle ear. This impedance is different in every patient and is variable, so it cannot be predicted. When the impedance of the ear affects the implant, an accurate fitting cannot be planned. It is desirable, therefore, to have an implant that is not affected by the impedance of the ear. This is achieved by making the output impedance of the implant ten times higher than the impedance of the ear [40]. This ensures that the output signal of the implant is "imposed" upon the ear, even in difficult situations.

When the patient is hearing through the implant, he is also hearing through the tympanic membrane (if the ossicular chain is intact). Phase differences between these sources can lead to extinction or reinforcement ("comb filter effects"). These effects can be avoided by raising the output impedance of the implant, which will then determine the frequency response curve [40].

Technological Aspects

Transducer Principles

Transducers in implantable hearing systems can operate by any of five basic principles. Clinically approved implants operate by either the electromagnetic principle (BAHA, Audiant, Vibrant Soundbridge) or the piezoelectric principle (TICA LZ).

- *Magnetostrictive*. When certain materials are exposed to a strong magnetic field, they undergo geometric changes.
- *Electromagnetic*. A permanent magnet (Fig. 6.**1**) is moved through the field of an electric coil. This principle is used in implant transducers because it makes it possible to miniaturize the permanent magnet.
- *Electrodynamic*. This is the opposite of the electromagnetic principle: a coil is moved through a magnet.
- *Dielectric*. Two capacitor plates are mounted opposite each other and are exposed to an alternating electrostatic field.
- *Piezoelectric*. Certain ceramic materials change their length when they are electrically stimulated. When the ceramic is combined with a second body (Fig. 6.**3a**), the length change can be converted to a bending movement, producing a relatively high amplitude with little energy consumption.

Energy Aspects

Energy consumption is a minor concern in partial implants. Total implants, on the other hand, must derive all their power from the implanted energy source. The potential size and capacity of this source are inherently limited.

The energy requirement of an implant can be estimated by first determining the mechanical power consumption of the inner ear. The input impedance of the inner ear with an effective oval window size of 3.2 mm^2 [80] is 4 nW [2, 40]. Taking into account the efficiency (0.3 %) and biological load of the middle ear, we can use this figure to calculate a necessary power output of approximately 0.7 mW for the transducer. If the device is in use for 16 hours/day, the battery must deliver at least 80 mAh/week. This type of battery, if rechargeable, can be accommodated in a space of 2 cm^3.

Full Implantability

The following problems must be solved for a fully implantable hearing aid designed to treat sensorineural hearing loss (T-AI):

Implantable Sensor

Because the tympanic membrane is permeable to sound, an acoustic sensor implanted in the middle ear can receive sound. But since the tympanic membrane and ossicles convert the sound into vibrations (see above), a vibration sensor can also be used. Schaefer applied the latter principle (Envoy, St. Croix, Fig. 6.**6b**) when he designed a piezoelectric element that couples to the malleus/tympanic membrane. Maniglia proposed an electrodynamic principle with a magnet implanted on the body of the incus [49] (see Fig. 6.**5c**, No. 6). Several problems remain to be solved with vibration sensors placed on the ossicular chain and tympanic membrane: (1) The low output impedance of the tympanic membrane and malleus provides a weak sensor stimulus, resulting in a low signal-to-noise ratio. (2) The complex, frequency-dependent, constantly changing movements of the ossicular chain and tympanic membrane can lead to distortion at the sensor input. (3) The sound emissions from a transducer or driven ossicle can stimulate the sensor, causing feedback [40].

Membranes that cover the end of a tube (stethoscope principle), which then leads to a distant microphone, may offer a technical solution. One author suggested placing the membrane subcutaneously in the external ear canal or behind the ear and implanting the microphone in the mastoid [40].

The sensor can also be implanted directly beneath the meatal skin or retroauricular skin. A system employing a flat microphone implanted subcutaneously on the calvarium is under development (Audiant, Symphonix).

Leysieffer et al. [37], following a suggestion by Kodera et al. [16], already developed a sensor that was implanted subcutaneously on the posterior bony wall of the external ear canal (Implex TICA LZ, Fig. 6.**10**). This placement avoids any uncomfortable occlusion of the ear canal. Also, because the ear canal is left open, better speech discrimination and directional hearing are thought to be achieved in patients with sloping sensorineural hearing loss compared with a canal that is occluded with an earmold (Fig. 6.**10a**).

Implantable Transducer

The results of research and development studies published to date indicate that the transducer should be coupled to an ossicle whenever possible. The principal implantable transducer types are electromagnetic and piezoelectric. An important advantage of electromagnetic transfer systems is the high vibrational amplitude that can be achieved. A basic disadvantage is the high energy consumption, which casts doubt on the feasibility of a fully implantable system, given currently available primary and rechargeable (secondary) battery technologies. A way to drastically reduce transducer energy consumption was first proposed 10 years ago [17, 79]. The piezoelectric transducer principle (Rion MEI, TICA, Envoy), as described by Gyo et al. [17], is a highly efficient design that requires less energy than electromagnetic systems [17, 79]. A comparison of published performance data on electromagnetic and piezoelectric transducers [35, 36, 40] shows that, for an equivalent output sound pressure level of 100 dB, the power requirement of piezoelectric systems at approximately 3 kHz is 20 to 40 times less than that of electromagnetic transducers. One such transducer has been developed for the fully implantable TICA [36, 37].

Implantable Battery and Audio Processor

These components must be accommodated in the space available. In the TICA, their combined size is equal to that of a CI receiver.

Modular Principle

Modularity is achieved by placing a hermetically sealed, implantable, detachable plug connector between the sensor or transducer on the one hand and the battery and audio processor on the other. In this way a single defective or upgradable module can be exchanged without having to remove the entire implant.

Longevity

Biocompatibility

The biocompatibility of an implant is determined chiefly by its surface material and its impermeability to gases and fluids in the biologic milieu. The shape of an implant also affects its biocompatibility to a degree. A detailed overview of implant materials can be found in Lehner [30]. Pure titanium has been superseding other materials in recent decades and is now considered an excellent material for implantable hearing devices. The most commonly used materials at present are titanium (BAHA, Audiant, TICA), solid silicone (Vibrant, TICA), polymers (Vibrant Soundbridge), and ceramic (Rion MEI, TICA). Titanium, ceramic, and silicone have demonstrated excellent biocompatibility, whereas some polymers have been associated with intolerance reactions. Hermetic sealing ensures that any nonbiocompatible contents of the implant do not come into contact with body tissues. The current standard is gas impermeability as defined by Mil-Std 883 D, which is also applied to cardiac pacemakers and CIs [40]. This property can be achieved only with metals (e. g., titanium) and high-density ceramics, not with silicone or polymers.

Biostability

Biostability means resistance to influences in the recipient organism like those caused by tissue, fluids (pus!), enzymes, acids, bases, pressure, tension, and heat. Again, materials and hermetic sealing are important considerations. Titanium and most ceramics are extremely corrosion-resistant and biostable. The same is true for silicone, Teflon, and Plexiglas, while other polymers can be degraded by enzymes [30].

Environmental Influences

Implants and their casings must be able to withstand mechanical effects (barometric pressure, vibration, shock) and electromagnetic effects (EMV) so that they can function during daily work activities, sports (swimming, diving), high altitude exposure (flying), and even head injuries. They should also be resistant to diagnostic and therapeutic procedures such as x-rays, ultrasound, MRI, diathermy, and electrocautery [40].

Conductive Hearing Loss

Clinically Approved, Active Hearing Implants for Inoperable Conductive Hearing Loss (IT Implants)

Coupling by Bone Conduction

In these implants, a vibrating stimulator is implanted into the skull behind the ear. The vibrations are transferred by bone conduction to the inner ear. The device corrects for the impedance difference between the air, cranial bone, and inner ear (impedance transformation). Two electromagnetic vibrators have become available for clinical use.

Transcutaneous BAHA Classic (Fig. 6.2)

This semi-implantable device (Entific, Powell, USA) has a titanium screw coupling element, which is anchored in the retroauricular cranial bone and brought out through the skin so that it is visible externally [68–71]. Branemark and his group [3] spent several years solving the problem of a percutaneous metal conduit (NobelBiocare, Goteborg, Sweden). The skin surrounding the implant site must be completely immobile. This is achieved by applying split-thickness skin directly to the bone at the retroauricular implant site. By minimizing implantation trauma, this technique largely prevents the formation of a fibrous capsule between the screw and bone. After the screw has become integrated into the bone, an electromagnetic transducer, combined with a battery and processor unit, is connected to the metal screw protruding from the skin [68–71]. Vibrations are transmitted from the transducer to the coupling screw (bone-anchored hearing aid, BAHA). A BAHA implantation requires a relatively modest surgical procedure and can even be performed in a large radical cavity.

The direct mechanical connection through the perforated skin, unlike the noncontact coupling of the Audiant described below, provides very efficient impedance transformation, leading to effective cranial stimulation. The battery and transducer provide an output adequate for the treatment of conductive hearing loss up to 60 dB. There may also be a bone conduction threshold of up to 45–60 dB that is not improved by the device. Energy consumption generally requires a battery change once weekly, but the battery may last up to 2–3 weeks [7].

Indications. The BAHA Classic designed by Tjellström and Branemark is the most widely used semi-implantable hearing device [7, 68–71]. It is indicated for cases of inoperable conductive hearing loss that are not helped by an air-conduction hearing aid, such as:

- Bilateral chronic draining aural cavities
- Middle ear malformations or acquired auricular deformities (prior tumor resection, trauma) that are incompatible with an air-conduction hearing aid
- Other chronic inflammations of the ear canal
- Cases that fit the indications for bone-conduction hearing aids but are not adequately helped by them

The bone conduction threshold should be 45 dB or less, and the discrimination loss should not exceed 40 %. The bone threshold may be up to 60 dB with the HC 220 pocket model, and it may exceed 60 dB with the BAHA Cordelle.

Surgical procedure. Basically, a hollow titanium screw is implanted into the cranial bone. Later the actual hearing device will be coupled to the screw. A hole is drilled into the bone, the drill hole is threaded, and the titanium implant is inserted. Then the skin around the screw is thinned so that it will adhere stably to the underlying bone. Three months later the skin over the screw is perforated, and the pin occupying the hollow interior of the screw is replaced with a spacer sleeve. After would healing is complete, the hearing device can be attached.

Results for more than 500 implants have been published since 1977, and considerably more have been implanted. The results show that the middle ear component could be successfully rehabilitated in 90 % of the patients treated. There was only an 8.6 % incidence of adverse skin reactions in cases where the skin around the implant was immobile and hair follicles were avoided (e. g., in split-thickness skin grafts) [68–71]. Federspil [7] implanted screws for 56 BAHA units in a series of 40 patients 6–70 years of age with chronic otitis media and congenital malformations. Some of the patients had binaural implantations. All but three of the fitted patients wear the BAHA for 12–14 hours daily. A telephone coil, audio adapter, and directional microphone are available for optimum hearing.

Subcutaneous Audiant (Fig. 6.2c)

In 1986, Hough et al. [20, 21] described an encapsulated samarium-cobalt magnet that was anchored in the retroauricular bone with a bone screw to function as a subcutaneous actuator. This led to the development of the Audiant transcutaneous device for conductive hearing loss (Xomed, Jacksonville, IL). The subcutaneous actuator screw is anchored in the cranial bone behind the ear. In contrast to the BAHA, the skin over the implant remains intact. The external portion of the device includes a microphone, electronic processor, battery, and an electromagnetic coil that stimulates the implanted magnetic screw through the intact skin, causing the screw to vibrate (thus it is a bone-anchored hearing aid, although this term is not usually applied to the Audiant). Some patients reported that the fidelity of the Audiant was superior to that of previously worn hearing aids. However, only patients with a relatively

small skull found that the device had a sufficiently loud output. Patients with a large skull complained that the sound was too faint. This is due partly to the high energy consumption of the electromagnetic system. But the main problem is that the transcutaneous segment causes considerable damping of signal transmission compared with the BAHA system. The result is that the power output of the partially implantable prosthesis in a normal-size skull is often inadequate to produce bone conduction of acceptable loudness (cranial impedance is too high, with inadequate impedance transformation). For the same reason, the treatment of sensorineural hearing loss is possible in theory but is not technically feasible: neither the battery power nor the transducer output are sufficient to amplify the traveling wave in the inner ear through bone conduction. Also, an electronic processor has not yet been developed for the Audiant that would permit this application. Because of its various shortcomings, this device is no longer used.

Coupling to the Ossicular Chain

Partially Implantable Middle Ear Implant (P-MEI) *(Fig. 6.3)*

The partial middle ear implant (P-MEI) designed by Suzuki and Yanagihara is a piezoelectric, semi-implantable hearing device for impedance matching in the middle ear (P-ITI). It is used to treat conductive hearing loss that is not correctable by tympanoplasty [60–67, 78, 79]. The indications are basically the same as for the partially implantable BAHA. The implant (Rion, Tokyo) has been approved for clinical use in Japan. Suzuki and Yanagihara use a piezoelectric transducer that drives the stapes capitulum. The piezoelectric transducer is fixed to the calvarium with a mounting plate and titanium screw via a longitudinally adjustable, rotatable connecting rod that passes through the mastoid. The rod is adjusted intraoperatively and fixed at the desired site with adhesive. The microphone, amplifier, and battery are packed in an external retroauricular unit.

Since 1984, the P-MEI has been implanted in 46 patients with up to 63 dB of conductive hearing loss, including patients with mixed hearing loss, within the framework of clinical trials. The sensorineural component was up to 40 dB. Hearing gains between 25 and 40 dB were observed. Almost all of these gains involved the conductive component, while the sensorineural component generally was not improved. The P-MEI patients who had previously worn hearing aids reported that the sound transmission quality of the implant was definitely superior to that of a hearing aid, and that sound perception was considerably more pleasant with the new device. The patients claimed that the sound quality of the implant was not artificial like that of a conventional hearing aid. The complications that were documented in 30 patients from 1984 to 1992 consisted of isolated instances of wire breakage (n = 2), cutaneous fistula (n = 2), loss of transducer contact with the stapes (n = 1), and cholesteatoma formation (n = 1). The device was modified in 1993 and was approved for clinical use in Japan in 1994. Since then the results have been published for an additional 16 patients, showing hearing gains comparable to those achieved prior to 1992 [60–67, 78, 79].

Further Developments

Fully Implantable Piezoelectric Implants

Totally Implantable Middle Ear Implant (T-MEI)

Yanagihara et al. [78] reported on the theoretical and technical aspects of developing their piezoelectric P-MEI into a fully implantable device with the trade name Rion T-MEI (Fig. 6.**4**). In addition to a piezoelectric vibrator, the authors planned to develop other implantable components: an amplifier with an automatic level limit, a battery with an emergency shutoff, and a microphone. The authors reported, however, that they did not document the reliability or longevity of the T-MEI and were unable to control the acoustic properties of the implant externally. As a result, developmental work on the implant has been discontinued [78].

Totally Implantable Communication Assistant (TICA) *(Fig. 6.**4**)*

Building on the results of the Japanese authors, Zenner and his group, together with Leysieffer, succeeded in modifying their fully implantable, piezoelectric amplifier implant, the TICA (see below), so that it may be used to treat patients with conductive and mixed hearing loss. This is accomplished by inserting the coupling rod into the oval window

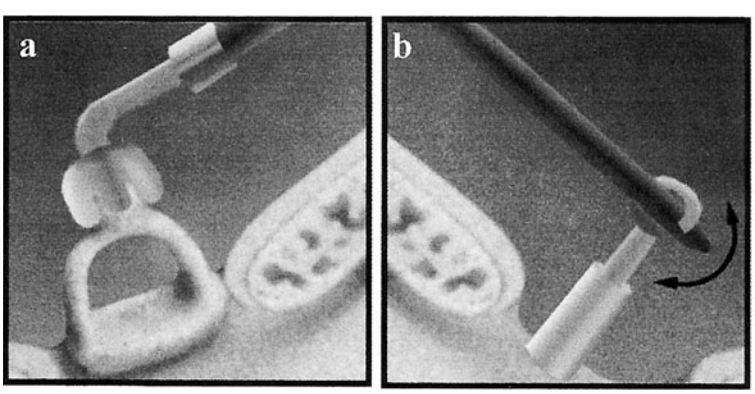

Fig. 6.**4** TICA designed by Zenner and Leysieffer for patients with mixed conductive and sensorineural hearing loss. **a** Coupled to the stapes capitulum. **b** Coupled to the perilymph with absent stapes superstructure [31].

niche through a posterior tympanotomy. In cases where the incus is absent, a coupling element patterned after the Tübingen titanium prosthesis (TTP, Kurz Medical) is connected to the coupling rod of the TICA for transmitting signals directly to the stapes capitulum (Fig. 6.**4a**). If the stapes superstructure is absent, the coupling rod functions as an artificial incus, transferring signals to an oval window piston prosthesis (Fig. 6.**4b**) which stimulates the perilymph through a perforation in the footplate [31, 81]. Because the TICA includes an implantable sensor, the posterior wall of the external ear canal must be present.

Indications. At present, TICA is not FDA or CE approved. Possible future indications for the middle ear TICA include stapes otosclerosis with a significant sensorineural component that cannot be adequately treated with stapes surgery alone, as well as patients with middle ear problems such as tympanosclerosis. Ears in which the posterior meatal wall is absent cannot be treated with this device.

Electromagnetic TORPs and PORPs

Goode et al. [13] and Heide et al. [18] have described magnetic TORPs and PORPs that can, when necessary, be driven electromagnetically with a coil in the external ear canal. If the passive hearing improvement achieved with this type of implant is unsatisfactory, the authors claim that the electromagnetic coil can be used secondarily to drive the magnetic in the prosthesis, compensating for the middle ear component. Preclinical and clinical data are not yet available for these systems, however.

Sensorineural Hearing Loss

History of Amplifier Implants (AIs) for Sensorineural Hearing Loss

The history of implantable hearing devices began with the notion of treating hearing-impaired patients with an intact middle ear, i. e., patients with sensorineural hearing loss [75, 76]. Today, active hearing implants are being used clinically for the treatment of sensorineural hearing loss.

Coupling to the Ossicular Chain

Partial Systems

As early as 1935, Wilska [75, 76] proposed attaching small, 10-mg pieces of magnet to the tympanic membrane as actuators and placing a coil in the external ear canal to generate a magnetic field. Plester et al. [55] also pursued this goal (see Fig. 6.**1**). Wilska's subjects could hear sounds with his device, but the strong magnetic attraction caused pain and discomfort in the ear. Wilska also tried the opposite approach, placing a coil on the tympanic membrane. But the coil temperature led to burns and pain. Today we know that the main advantage of coupling a hearing aid directly to the ossicles, as opposed to a conventional hearing aid, is improved sound fidelity [34, 82, 83]. Mahoney and Vernon [46] recorded microphone potentials in noise-deafened guinea pigs in order to evaluate the relative fidelity of complex acoustic signals, such as speech, transferred by an actuator coupled directly to the ossicular chain in comparison with a conventional hearing aid. Coupling an electromechanical transducer to the incus led to an 18 % improvement in discrimination compared with a conventional hearing aid or headphones. Goode and Glattke confirmed these results in humans [15].

Goode et al. [11–16] have worked on the development of implantable electromagnetic actuators since 1969. They published results on electromagnetically induced hearing in eight human subjects with normal hearing. From 1969 to 1986, they used magnets of 50–85 mg which they attached to the malleus handle for up to 22 months. The magnetic materials included platinum-cobalt and samarium-cobalt. The magnets were stimulated with coils placed either in the ear canal close to the tympanic membrane or on the retroauricular skin. The electric current necessary to produce an equivalent sound pressure level of 80 dB above 100 Hz ranged from 1.5 mA to 28 A, depending on the distance of the coil from the magnet attached to the malleus. The author [13] reported an impressive reduction in distortion levels combined with improved speech discrimination, better sound quality, and reduced feedback. Rutschmann et al. [57, 58] glued 10-mg magnets to the tympanic membrane of normal-hearing subjects. Gloric et al. [11] attached a magnet to the malleus. When a magnetic field was applied via an external coil, the subjects heard music and speech of acceptable quality.

Hough et al. [19, 22] and McGee et al. [50] applied the same method in patients with sensorineural hearing loss. The patients reported the following differences in relation to conventional hearing aids:
1. Absence of feedback squeal
2. Improved hearing in background noise
3. More natural sound perception

Other attachment sites to the ossicular chain have been suggested: the incus [8, 9], the incudostapedial joint, and PORPs [19]. Other authors described the placement of a magnet on the round window [59].

To achieve the closest and most precise placement of the transducer coil in relation to the actuator magnet attached to the ossicle, Heide et al. [18] developed an intrameatal electromagnetic implant (Fig. 6.**5a**). They tried to make the system externally invisible. The implant consists of a battery-powered driver coil in the external ear canal and a small, implantable rare-earth magnet on the tympanic membrane (Sm-Co, samarium-cobalt). This material is a derivative of Sm/CO_5, which has proven to be nontoxic in biocompatibility studies [18]. The magnet consists of a narrow disk 2.5–3 mm in diameter weighing between 25 and 35 mg. The driver unit fits completely into the external ear canal. In vitro tests showed a maximum equivalent output sound pressure level of 100–115 dB between 150 and 1000 Hz and 95–110 dB at higher frequencies, with a total harmonic distortion > 2 %. The 1.3-V battery consumed 0.9 mA of current. Used in patients with sensorineural hearing loss, the implant provided a hearing gain up to

2 kHz better than that of a conventional hearing aid (1 kHz: +16 dB, 2 kHz: +8 dB). At 4 kHz, the conventional hearing aid was superior (4 kHz: -12 dB).

In speech audiometry, the implant provided an average hearing gain of 21 dB, versus 10 dB with conventional hearing aids (n = 6). None of the patients in the small group had poorer comprehension with the implant than with their hearing aid.

Hough et al. [19, 22] also tried to place the electromagnetic coil as close to the ossicle-coupled magnet as possible, aiming for a distance of 15 mm. The actuator magnet was implanted in the incudostapedial joint (Fig. 6.**5b**) in five patients with moderate sensorineural hearing loss. For stimulation, the authors suggested either implanting the coil into the mastoid or placing it into the external ear canal. All five patients achieved significant threshold gains and improved speech discrimination.

In 1988, Maniglia et al. [48, 49] presented an intrameatal unit in which the microphone, processor, battery, and coil were combined in a closed system and drove a magnet attached to the malleus. The 4000-turn coil was located 1–2 mm from the magnet on the tympanic membrane. In 1994 they presented an advanced design [47], which differs in many respects from the 1988 version. Instead of the malleus handle, the magnet is glued to the body of the incus, facing the mastoid. It is driven by an intramastoid coil that is controlled by transcutaneous telemetry from an HF receiver beneath the intact retroauricular skin (Fig. 6.**5c**). An external unit with a microphone, amplifier, battery, and transmitter is placed in a surgically created retroauricular skin pouch.

Hudde et al. [23] designed an elegantly compact, implantable electromagnetic transducer (Fig. 6.**5d**) whose output signal is coupled hydrodynamically to the round window membrane. Perkins and Pluvinage [54] described a modified system for electromagnetic sound transmission to an actuator magnet on the tympanic membrane. The magnet is driven by a coil disguised as a necklace. The advantage of this system is its esthetic concept, which avoids the hearing aid stigma. Disadvantages are the very large distance of the stimulator coil from the receiver magnet, leading to extremely high energy consumption, and the sensitivity of the system to external electromagnetic fields.

Yanagihara and his group [78] have had the most years of experience with piezoelectric implants. After developing a partial implant for conductive hearing loss (T-MEI, Fig. 6.**3**) that was approved for clinical use (see above), they published discussions on how their device might be adapted to create an amplifier implant for sensorineural hearing loss [17, 79]. They reasoned that the output of their implant would have to be increased for the treat-

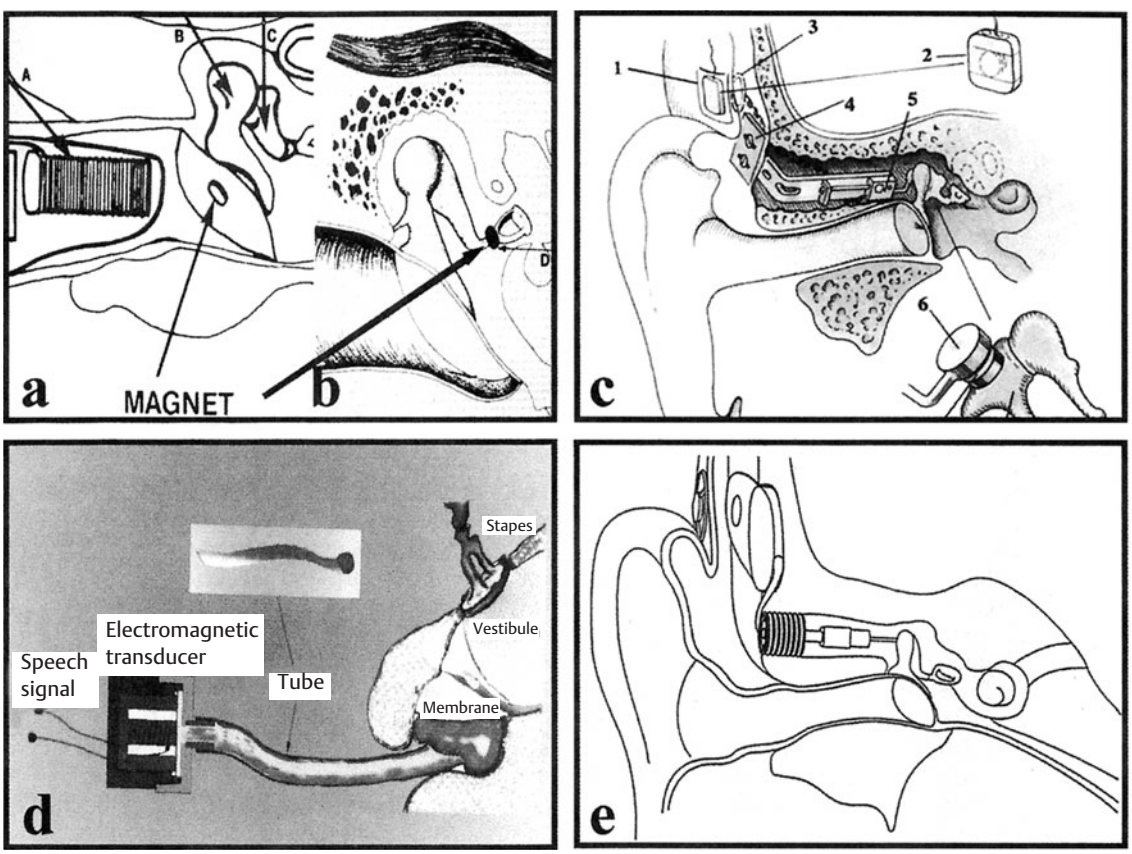

Fig. 6.**5** Electromagnetic designs for the treatment of sensorineural hearing loss. **a** Design proposed by Heide. **b** Design proposed by Hough. **c** Design proposed by Maniglia. **d** Design proposed by Hüttenbrink and Hudde. **e** Otologics system designed by Fredrickson et al. (with kind permission).

ment of sensorineural loss. However, increasing the length of their piezoelectric element from the current 7 mm to more than 9 mm (to increase its deflection) is not compatible with the anatomy of the ear. Making the piezoelectric element narrower, again to increase its deflection, would carry a greater risk of breakage. Simply increasing the electric current is not an option due to current limitations on battery capacities and the thermal problems that would occur in the transcutaneous segment [17]. The authors speculate that using a transcutaneous titanium screw like that described by Branemark for the transcutaneous high-frequency segment could solve the thermal problem and could also provide a 20 dB gain in amplification [68] (Fig. 6.**6a**). With their current implant limited to bone conduction thresholds of 20–40 dB [63], the authors estimate that the Branemark system could expand the application of their implant by another 40 dB in sensorineural hearing loss and to bone conduction losses of 60–80 dB. Assuming that the output can be sufficiently increased, the authors believe that the high fidelity of their piezoelectric implant would provide a significant hearing gain for future patients compared with conventional hearing aids. For now their concepts are still theoretical, and there have been no publications on the actual construction of this type of AI.

Dumon et al. [5] coupled a piezoelectric vibrator to the stapes capitulum without permanently disrupting the ossicular chain. Encouraged by its efficient performance in vitro, the authors have begun a series of animal experiments (guinea pigs) with their implant.

Another interesting approach is the Envoy system (St. Croix, Fig. 6.**6b**), an implantable hearing aid with a piezoelectric actuator and sensor system. Weber et al. [74] reported on initial animal experiments in which the sensor was coupled to the malleus or incus while the actuator drove the stapes. Acute human trials have demonstrated the basic functional soundness of the sensor and actuator. There are plans for a fully implantable system with implantable microelectronics and lithium batteries.

Fully Implantable Devices

Since 1998, in a study group of patients the TICA (Zenner–Leysieffer, Fig. 6.**10**), a fully implantable electronic hearing system [41], has been used in Europe for the operative treatment of sensorineural hearing loss [82, 83]. The implant permits the surgical improvement of sensorineural hearing loss with no external stigmata and, owing to a membrane sensor implanted in the posterior bony meatal wall, can provide some patients with remarkable speech comprehension, even in noise, as well as auditory spatial orientation. The system includes a piezoelectric transducer 8 mm in diameter (weight 0.4 g) that is implanted in the mastoid [35, 36], a subcutaneous sound sensor implanted in the posterior bony canal wall by the transmastoid route (membrane diameter 4.5 mm, weight 0.4 g) [37], an implantable battery, and an implantable, digitally programmable three-channel audio processor [41]. Sound is picked up near the tympanic membrane by the implanted membrane sensor [37]. The signal is transferred to the incus by the piezoelectric transducer, with a frequency response ranging from 50 to 10 000 Hz. Sensorineural losses as high as 30 dB can be compensated up to 500 Hz, and even severe, sharply sloping hearing losses can be compensated at 2000 Hz and higher.

Results. Results have been published on the implant components of the TICA [36, 37, 41], acute and chronic animal experiments [56, 73], and clinical use of the device in 20 patients [82, 83, 90, 91]. Audiologic tests showed improved monosyllable recognition in 89 % of the patients, with the best cases showing a 60-point gain. The dB_{opt} was achieved in 75 % of the patients at ambient speech sound levels of 65–75 dB. In patients who had discrimination loss, the loss was reduced in all cases and was even eliminated in 70 %. In 72 % of the patients, the comprehension threshold in noise was in the range of –2 dB to +1 dB SNR. The maximum amplification gains were frequency-dependent and equaled 40 dB at 2 kHz, 50 dB at 3 kHz, and 55 dB at 4 kHz (an average of 20 dB had been programmed into the units). Spatial orientation was perfect in 89 % of patients. In the standardized Goteburg Profile, all of the patients achieved 80–88 % of the maximum score in comprehension, locali-

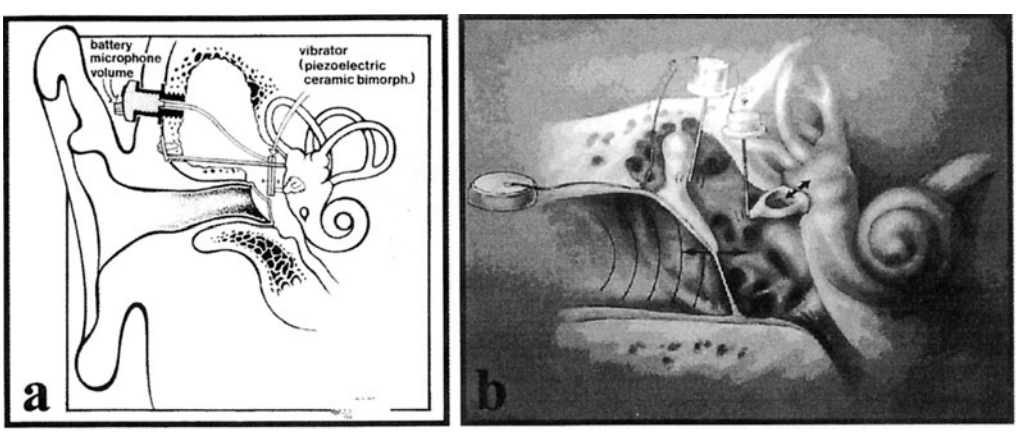

Fig. 6.**6** Piezoelectric systems for the treatment of sensorineural hearing loss. **a** Design proposed by Suzuki and Yanagihara, together with Tjellström and Branemark. **b** Envoy, design proposed by Schaefer (St. Croix) (with kind permission).

zation, social aspects, and subjective well-being. Unlike hearing-aid wearers, the patients fitted with a TICA rated their improvement in social interactions and subjective well-being just as highly as their gains in speech comprehension and directional hearing [91].

Clinically Approved Amplifier Implants (AIs) for Sensorineural Hearing Loss

To date, more than 1000 implantations of AIs have been performed in patients with sensorineural hearing loss. The results for 39 patients have been published [34, 91]. Three very different systems are currently available as clinically approved amplifier implants (AIs) for sensorineural hearing loss:
1. BAHA Cordelle (Tjellström-Branemark, Fig. 6.**7**)
2. Vibrant Soundbridge (Ball-Maxfried, Fig. 6.**8**)
3. Otologics MET (Fredrickson, Fig. 6.**5**).

All systems are partially implantable.

General indications. The general indication is the treatment of sensorineural hearing loss (Table 6.**3**), especially in patients who are not helped by conventional hearing aids. The use of conventional hearing aids to treat sensorineural hearing loss can lead to problems in a certain subset of patients for whom *no adequate treatment* is available other than implants.

1. *Medically*, conventional earmolds can lead to intolerable
   – occlusions and
   – otitis externa.
   – Hand movement disorders can prevent correct earmold insertion.
2. *Audiologically*, several factors can interfere with successful rehabilitation:
   – Nonsuppressible feedback squeals
   – Intolerable distortion
   – Discomfort
   – Poor speech comprehension, especially in work situations
3. *Stigmatization* refers less to cosmetic aspects than to actual handicaps imposed upon the obviously hearing-impaired patient, especially in occupational settings.
   – Ridicule from coworkers
   – Discrimination toward job seekers
   – Social withdrawal
4. *Vocational reasons* are a priority concern. Besides the reasons listed above, which can all adversely affect occupational fitness, there are factors that are specific to certain occupational groups. Physicians and nurses (stethoscopes), workers at call-in centers (ear plugs), workers in humid environments (hearing aid slips out), hot and steamy work environments (hearing aid deterioration), jobs involving heavy perspiration (hearing aid slips out), telephone-dependent jobs, speaking professions (teachers, interpreters), and client- and negotiation-oriented occupations may not be adequately rehabilitated with conventional hearing aids, with all the attendant consequences for the patient and the community at large.

In cases where one or more of the above conditions apply, the treatment options in the past were very limited and unsatisfactory. Today this situation has changed dramatically, and many of the patients in the circumstances described above can be helped with an amplifier implant (AI).

Specific indications. Every implant has its own specific range of audiologic indications (Figs. 6.**9** and 6.**11**). Since partially implantable hearing devices (Vibrant, BAHA Cordelle) can have acoustic advantages over a conventional hearing aid, partially implantable AIs are appropriate for patients who complain of poor sound quality, feedback, or distortion with conventional hearing aids (Table 6.**1**).

Contraindications to an implantable AI. The Vibrant is not indicated for the treatment of pronounced low-frequency hearing loss. It has only limited ability to compensate for hearing losses in the low-tone range. The Vibrant HF are appropriate for a maximum hearing loss of 30 dB at 500 Hz, the Vibrant P for a maximum hearing loss of 65 dB. These devices are also contraindicated in patients who fall into the treatment gap between conventional hearing aids and cochlear implants.

Table 6.**3** Screening criteria for treating sensorineural hearing loss with an implantable hearing device

Three main criteria are applied in selecting adult patients for an implantable hearing device:

1. As with a conventional hearing aid, the pure-tone audiometric hearing loss in the better ear should be 30 dB or more at one or more of the audiologic test frequencies between 500 and 3000 Hz. The hearing loss up to 1 kHz should not exceed 30 dB. The comprehension rate for monosyllabic words in the better ear should not exceed 80 % at a speech sound level of 65 dB.
2. Special audiologic criteria are also applied, depending on the implant. They are shown graphically in Figs. 6.**9** and 6.**11**.
3. The patient cannot be adequately treated with a conventional hearing aid for
   – medical,
   – psychosocial,
   – audiologic, or
   – occupational reasons.

BAHA Cordelle (Fig. 6.7)

In principle, an AI type of device can function by means of bone conduction. Accordingly, the BAHA Cordelle was designed as an AI for use in patients with cochlear hearing loss. The BAHA Classic cannot be used for this purpose, because it is a pure ITI. By contrast, the electronic processor and output of the BAHA Cordelle are designed to compensate for different degrees of sensorineural loss in different individuals. Wearing trials have shown, however, that the high vibratory stimulus levels that are needed to compensate for moderate to severe sensorineural hearing loss can lead to sound emissions from the skull that cause feedback through the BAHA microphone [68–72] when the microphone is worn on the head. Also, the energy and battery consumption of the system are substantially increased because of its high output. For this reason, most of the external components are packed in a pocket unit. As for its advantages, a BAHA can be implanted with little technically

difficulty and low surgical risk. Interestingly, the authors also experimented with a coupling element placed on the wall of the promontory [68]. The tests indicated a 10-times-higher transmission amplitude compared with bone conduction through the cranium.

Table 6.**4** General contraindications to implantable hearing devices for sensorineural hearing loss

Strongly fluctuating or rapidly progressive hearing loss
Deafness in one ear
Diseases of the ear canal, middle ear, petrous bone, or cerebellopontine angle that would interfere with the implantation
Irregular course of the facial nerve
Previous middle ear surgery
Retrochochlear hearing disorder or auditory neuropathy
Organic brain disease
Psychiatric disease
Poor candidate for general anesthesia or surgery
Concomitant use of ototoxic medication
Pregnancy

Surgical procedure. The implantation procedure is the same as for the BAHA Classic (see above).

Indications. Patients with more than 60 dB of sensorineural hearing loss who show a hearing gain when tested with the BAHA Cordelle. The hearing test can be performed with a dental adapter.

Vibrant Soundbridge (Fig. 6.**8**)

Ball and Maxfield [1] developed a device called the floating mass transducer (FMT, Vibrant Soundbridge, Symphonix, USA), consisting of a coil and a magnet (Fig. 6.**8**). Both components are placed very close together in a capsule that is stimulated to vibrate. The capsule is connected to the long process of the incus and drives the ossicular chain. The microphone, battery, and audio processor are packed in another capsule that is worn externally on the head. A receiver coil below the scalp receives the signals and transmits them to the FMT.

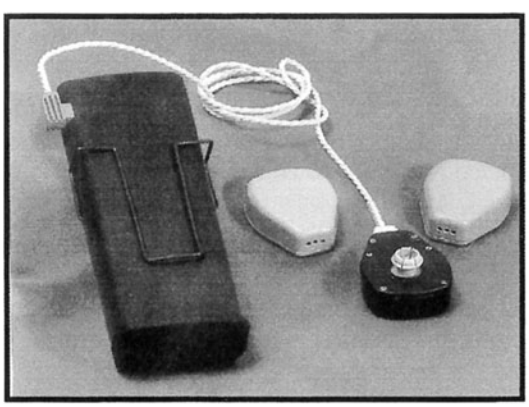

Fig. 6.**7** Clinical BAHA Cordelle system for the treatment of sensorineural hearing loss (with kind permission).

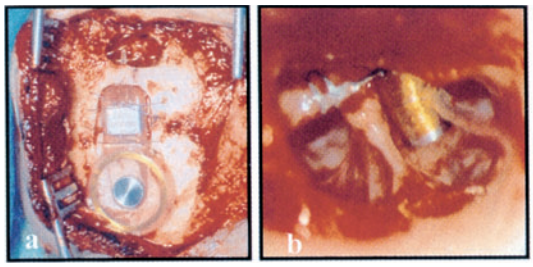

Fig. 6.**8** Clinical Vibrant Soundbridge system. **a** Receiver coil implanted. **b** FMT implanted (with kind permission of Prof. T. Lenarz, Hannover).

Indications. Besides the "general indications" for implantable AIs, the additional selection criteria shown in Fig. 6.**9** are valid for the current versions of the Vibrant Soundbridge.

Surgical procedure. The operation consists of five basic steps:

1. A retroauricular incision is made, and a scalp flap is created like that used in CI operations.
2. A mastoidectomy is performed, if necessary exposing the facial nerve, and an extended posterior tympanotomy is performed, exposing the long process of the incus.
3. A bony depression is created behind the mastoid, and the receiver coil is implanted (Fig. 6.**8a**).
4. The FMT is introduced into the middle ear cavity through the posterior tympanotomy and secured with

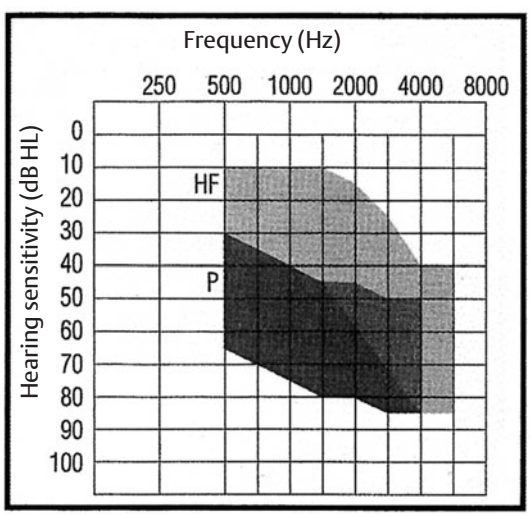

Fig. 6.**9** Indications for the Vibrant P and Vibrant HF devices. 1) Thresholds of sound transmission in air at or below the levels indicated. 2) The side-to-side difference for sound transmission in air should be within 20 dB at the frequencies indicated. 3) The difference between sound transducer in air and bone at 0.5, 1, 2, and 4 kHz should not exceed 10 dB at two or more of these frequencies. 4) Normal tympanometry (with kind permission).

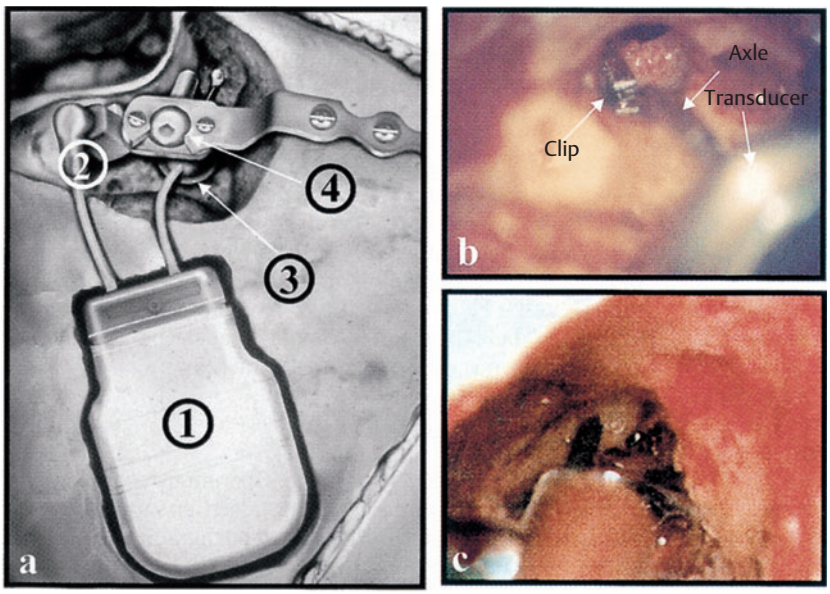

Fig. 6.**10** Clinical TICA LZ. **a** Diagram showing the processor and battery (1), sensor (2), actuator (3), and mounting plate with micromanipulator (4). **b** Coupled with a clip to the long process of the incus. **c** Coupled to the body of the incus, secured with ionomer cement.

two titanium clips (Fig. 6.**8b**). Cement may be used as needed.

5. The wounds are closed.

Results. The performance of the clinically approved Symphonix Vibrant Soundbridge was evaluated in a study by Lenarz et al. [34], who reported on 19 patients treated with the device. They found hearing gains of up to 50 dB, especially in the higher frequency range; remarkably distortion-free hearing; and up to a 40 % improvement in speech comprehension, even in background noise. Dazert et al. [4] and Ernst et al. [6] also reported on patients who experienced more natural tone and speech sounds, better high-tone perception, and improved speech comprehension in noise.

Otologics MET

Fredrickson et al. [8, 9] have developed a partially implantable electromagnetic system that is coupled to the incus body (Otologics). Implanted in the mastoid, it is connected to the ossicular chain via a coupling rod that touches the body of the incus. The coupling element is driven by an implanted electromagnetic actuator, from which the rod arises. The actuator is connected to an HF receiver coil implanted beneath the skin. The receiver coil is stimulated by an external transmitter coil, which is connected to a control unit and transmits energy and sound [8, 9]. The partially implantable system is distinguished by a low-distortion, flat frequency response up to 10 kHz and achieves sound pressure levels up to 140 dB, which are adequate even for severe sensorineural hearing loss. Since 1973, Fredrickson and his colleagues have progressed from in vitro models, acute animal implantations, and chronic primate implantations to short-term implantations in human subjects [8, 9]. They observed the functional performance of the implants, measured by auditory evoked potentials, in primates for one year. Histologic examination of the inner ear of animals explanted after 8 months showed an equal number of hair cells compared with the contralateral control ear. The authors concluded that continuous use of the implant was not associated with any histologic damage to the inner ear. Issing et al. [25] reported recently on the first implantation of the Otologics system in patients. The partial Otologics implant designed by Fredrickson is available for routine use in Europe.

Residual Hearing

Cochlear Implants in Patients with Residual Hearing

In patients with residual hearing, it may be assumed that substantial numbers of hair cells have been destroyed, including numerous inner hair cells. Because an AI requires a large number of undamaged inner hair cells in order to function, this type of device cannot be used in patients with residual hearing. Conventional hearing aids are also of little benefit: while the patients can hear clinically with a hearing aid and can even recognize individual words, they must also lip-read and, in conversational situations, must laboriously infer what is being said from a combination of visual and auditory cues. In almost every case, instructions from the physician must be written down [29].

Since the early 1990s, research has been conducted to determine whether cochlear implants could be beneficial not just in deaf patients but also in patients with residual inner ear function. Laszig and Klenzmer [29] predict that CIs will be used routinely for this indication in the foreseeable future. Starting with a maximum of 30 % monosyllable comprehension in the Freiburg speech test at 70 dB with conventional hearing aids, their patients who had been fitted with a CI showed marked improvement in the Freiburg word test and Göttingen sentence test after just one month. It is important in this regard to develop surgical implantation techniques that conserve the inner ear. An

example is the "soft surgery technique" described by Lehnhardt [33], in which residual hearing is not completely destroyed despite the insertion of a multichannel electrode array into the scala tympani. Also, CIs will soon be available that have telemetry for measuring action potentials at small intervals. This will make it possible to vary the rate at which electrode arrays are stimulated at different sites, improving the treatment not just of deaf patients but also of patients with profound hearing loss [29].

Future Outlook

Clinical results, improved surgical techniques, and technological advances make it reasonable to expect that the indications for CIs will expand toward more severe degrees of sensorineural hearing loss. Meanwhile, AIs may be developed that can benefit patients with residual hearing, even in the low-tone range, and it is conceivable that electronic implants, whether AIs or CIs, can one day cover the full spectrum of patients with sensorineural hearing loss, with no "gaps" in treatment coverage. Fully implantable AIs, like the TICA, supplement these choices with an even broader range of indications (Table 6.**2**). Like partially implantable AIs, they can have audiologic quality advantages over conventional hearing aids. In addition, a total implant has advantages in everyday activities (swimming, showering, wind noise) and in the rehabilitation of certain occupational groups (teachers, athletic instructors, professional cooks, group facilitators, field workers, telemarketers, telephone operators, etc.). Another important benefit of fully implantable devices is the lack of stigmatization of the user, which accounts for the very low social withdrawal of patients who have been fitted with a total implant. Given the degree of social isolation and job discrimination that are suffered by the hearing-impaired, which often goes unnoticed by outsiders, the social reintegration of these patients, whether private or occupational, is the true measure of clinical success (Table 6.**3**). In theory, this would mean that almost all hearing-impaired patients could be candidates for surgical treatment.

The choice between a hearing aid or surgery, like that already being made in patients with otosclerotic stapes fixation or ossicular chain disruption due to prior otitis media, would become an issue in a somewhat greater number of patients.

Concluding Remarks

1. Choosing between surgery and a hearing aid is nothing new for the ENT physician. For 50 years it has been an issue requiring careful deliberation. This particularly applies to cases of stapes fixation and ossicular chain disruption due to (prior) inflammatory disease, which are often amenable to both treatment options. In the future, physicians will find it increasingly necessary to consider both options for patients who present with sensorineural hearing loss.
2. While it may seem surprising to include the microsurgery of sensorineural hearing loss in the treatment arsenal of the ENT physician, it is occasionally assumed that hearing aids can be an acceptable treatment option for *all* patients. This is a prejudiced view! As excellent as modern hearing aids are, they will help *only a certain percentage* of patients. Other patients are not helped by hearing aids, which are inadequate and ineffective for this clinical subset. Ultimately these patients could not be helped at all, were it not for the fact that an implantable hearing device can provide a permanent, effective solution.
3. Even recommending hearing aids to patients who can benefit from them audiologically might not be the best option. The stigma that comes from wearing a hearing aid can have a serious social and professional impact on some patients. Do doctors and the community have a right to ask these patients to bear a stigma that will subject them to wrongful prejudice and discrimination in the world of the hearing?
4. The use of approved electronic hearing implants is a treatment of proven efficacy. These devices are medical products of the highest order and, like any *new* drug, can be legally prescribed only if their safety and efficacy have been established to the satisfaction of the approving agency. Given present-day limitations on funding, health insurers are finding it more difficult to pay for medical progress. Meanwhile, the community of the insured are choosing to pay for old, traditional treatments of unproved efficacy. We must find ethically acceptable ways to limit fund allocation for treatments of unproved efficacy so that more funds will be available for the advancement of "evidence based medicine."

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