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## Introduction, Historical Remarks

Passive middle ear implants, by definition, reconstruct the disrupted or fixed ossicular chain. A prerequisite for an optimal sound transmission system is an aerated middle ear space and a closed tympanic membrane, both of which are passive conditions, and a normal functioning inner ear as the active part of the system.

Knowledge of the natural environment in the middle ear space and the acoustic and mechanical properties of the sound transmitting apparatus (tympanic membrane, ossicular chain) is a prerequisite to the understanding of ossicular reconstruction. The main focus is on the surface conditions for implantation materials, followed by questions regarding design and mechanics. It is obvious that a strong differentiation of these features is not always possible. Some of the newer implants consist of composites and material mixes, with new surface and acoustic properties. Thus some redundancy and overlap in presentation is unavoidable.

From the beginning, the treatment of middle ear disease had two aims. One was the eradication of chronic middle ear inflammation and the second was the restoration of hearing. Otosclerosis, a noninfectious condition of the middle ear with ankylosis of the stapes as the main symptom, is a separate entity and has to be discussed separately. But in both, otosclerosis and chronic middle ear disease, there is the need for ossicular reconstruction depending on whether the ossicles are fixed by ankylosis or destroyed by the infective process. The needs for new materials increased at the beginning of modern reconstructive middle ear surgery in the early 1950s. The pioneers were Moritz, Wullstein, and Zöllner. In 1952, Wullstein started using Palavit® (vinyl-acrylic resin) [1] as a material for total ossicular replacement prostheses. The clinical results were not encouraging, and the material was

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abandoned after a short period of time because of high extrusion rates. There was a long learning curve to understand the requirements necessary to meet acceptance in the middle ear and to have adequate sound transmission properties. Surgeons usually present audiological results to demonstrate the success or failure of these prostheses. The surface properties therefore have been underestimated in this context for a long time. But they are probably the most important factor in ossiculoplasty [2].

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## Middle Ear Space: A Unique Implantation Site

The requirements for a material in ossicular replacement are multifold. The material should be nontoxic, it should not alter connecting proteins, it should behave like tissue towards tissue, and there are acoustic properties that are necessary for sound conduction [3, 4].

An implantation site may be open, semi-open, or closed [5]. A typical closed situation would be the bone or any other tissue in the body with no connection to the outside environment. An open implantation site is typically an implant that penetrates the skin or mucosa like in a bone-anchored hearing aid or in a dental implant. The situation in the middle ear is unique [6]. In the normal healthy state, the middle ear is a well-defined, good aerated cave, free of any infectious agent. But the connection via the Eustachian tube towards the external environment makes it semi-open. During upper airway infection and especially during acute otitis media, it is potentially colonized by viruses and bacteria. In such an environment and under such conditions, biomaterials require a higher and different quality of surface properties than in closed implantation [3–5, 7, 8]. Audiological and sound transmission properties are fulfilled by many materials, both biological and artificial. But the characteristics of the described surroundings are a crucial factor for the long-term success of a middle ear implant. Most of these questions were poorly understood in earlier times compared to nowadays. More recently, biofilms are considered to play a significant role in foreign material acceptance [9]. Biofilms result when microbes colonize implants. Aqueous and moist surfaces are covered with a thin layer of mucous film, able to host microorganisms. The unique surrounding in the middle ear provides all these requirements. *Pseudomonas aeruginosa* is regularly cultured in chronic suppurative otitis media with and without cholesteatoma. This microorganism is known to form biofilms on implantation materials [10, 11]. Prostheses made of titanium, hydroxyapatite, and Polycel have been studied, cultured with *Pseudomonas aeruginosa*. In the results, titanium prostheses formed less biofilms than plastic and hydroxyapatite. To understand these complex situations of the implantation site, besides in vitro studies, animal experiments are also necessary to be performed [12, 13].

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## Middle Ear Mucosa and Eustachian Tube (ET) Function

Normal middle ear function is based on balanced middle ear aeration. This is a result of a complex system involving at least these two major contributors: the middle ear mucosa and the Eustachian tube [14]. Both aspects seem to be the most important part of the system of a functioning middle ear. Proper diagnoses of severe

aeration problems and tubal dysfunction are difficult because the system, its parts, and their complex interaction are not fully understood. Treatment possibilities of either part of the system are low. The contribution that has been approached in the past by various modalities is the Eustachian tube [15].

More recently, Eustachian tube (ET) dilatation has come into focus in treating middle ear aeration problems. Compared to other therapeutic modalities, the results with dilatation are encouraging to date. “Balloon Eustachian tuboplasty” has been introduced by two different groups: the Bielefeld group [16] and the Boston group [17]. Due to the dilation procedure, micro-fractures of the tubal cartilage with a successive expansion of the Rüdinger’s safety canal could be experimentally observed. But the *in vivo* mechanism of the therapy is still unclear. Sudhoff and colleagues [18] treated 351 patients, of which the short-term results of 167 patients 2 months after the treatment and the long-term results of 53 patients 1 year after the treatment were recently published. According to their results, this procedure was satisfactory for 87 % of their patients. The Eustachian tube function tests were significantly better in more than 90 % of the cases. From this data, it seems that ET dilation may have a positive influence.

Classical tympanoplasty techniques resolve mechanical problems, such as due to the disrupted and fixed ossicular chain and perforated eardrums, but has little effect on tubal dysfunction. There has been a trend toward surgical procedures that preserve the mucosa of the mastoid and antrum, with the concept that disruption of the mucosa is as counterproductive in temporal bone surgery as it is in sinus surgery. Thus, the surgical principle when treating chronic middle ear disease is to support mucosal healing while restoring a closed middle ear space. Real options for the treatment of the mucosal disease are still missing.

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## Basic Considerations in Tympanoplasty and Ossiculoplasty

The first aim of treatment in chronic middle ear disease is still to cure the chronic inflammation. The risk of complications will depend on the entity of the middle ear disease. The most dangerous disease regarding infectious complications is undoubtedly cholesteatoma. Otogenic facial paresis, intracranial complications (sinus thrombosis, meningitis, epidural, subdural and brain abscess), and labyrinthitis are more often associated with cholesteatoma than with other entities of chronic ear disease. In the case of chronic suppurative otitis media, a runny ear may be seen as a less dramatic situation, and the risk of life-threatening complications negligible, but the hearing loss will slowly increase. It starts with a pure conductive loss that can be treated by tympanoplasty and ossiculoplasty techniques, but over time, it will develop a sensorineural component due to toxic inflammatory influences.

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## Materials for Reconstruction of the Tympanic Membrane

Many materials have been suggested for tympanic membrane reconstruction. Three tissues of autogenic origin are used today: temporalis fascia (likely the material most favored by surgeons all over the globe), perichondrium, and cartilage [19].

Temporalis fascia is easy to harvest and elegant to handle. Perichondrium is similar to fascia and can be harvested from either the tragus or the concha. Fascia and perichondrium are of similar resistance although some clinicians see advantages in using perichondrium [20]. Fascia and perichondrium are the materials of choice when the tympanic membrane is still cone shaped because of the flexibility of the material. Fascia and perichondrium should be used in cases of primary surgery. In revision surgery and in atelectasis, a more resistant material is needed, a situation that is often combined with ossicular chain disruption with the need for ossiculoplasty. To avoid protrusion of prostheses in these unfavorable situations of middle ear aeration, cartilage is the material of choice.

Cartilage and perichondrium are harvested from either the tragus or the concha. The ideal region in the concha is the region of the cymba. The cartilage can be used as a composite graft (cartilage/perichondrium island flap), as a cartilage plate, or as shingles or palisades in a palisade technique [21, 22]. Cartilage palisades have been used by Heermann since the late 1950s. The technique consists of placing longitudinal strips of cartilage parallel to the malleus handle while avoiding blockage of the orifice of the Eustachian tube in the middle ear [23].

The acoustic properties of a cartilage have been studied extensively by Zahnert, Hüttenbrink, Mürbe, and coworkers [24]. The results show that there is no obvious acoustical disadvantage using cartilage versus perichondrium or fascia, but the advantages in stability are enormous.

Silastic sheeting of the tympanic membrane helps to avoid major granulation tissue growth in the early postoperative period.

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## **Protrusion or Extrusion**

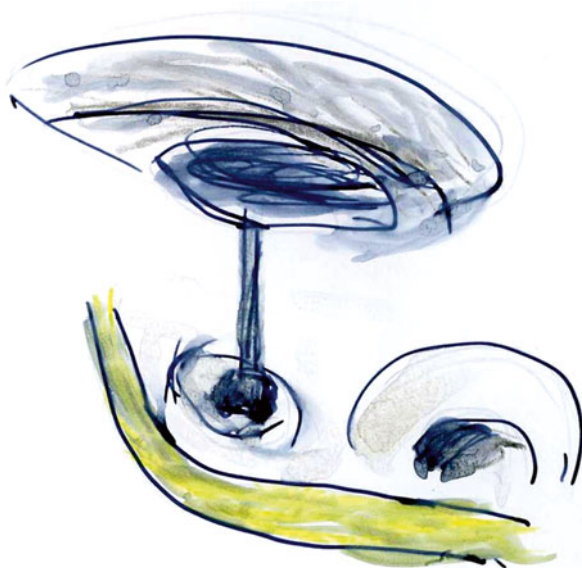
The term commonly used for the loss of an implanted middle ear prosthesis is “extrusion.” It has to be recognized that in the pathologic but otherwise natural situation of an adhesive middle ear cleft, a similar situation happens towards the ossicular chain. The inward movement of the tympanic membrane leads to a protrusion of the ossicles, leading to resorption and extinction. In other words, protrusion is a common development in a poorly aerated pathologic middle ear, resulting from either mucosal disease or Eustachian tube dysfunction. The term extrusion therefore should be restricted for active expulsion. And histological signs like round cells, foreign body giant cells, or massive connective tissue sheets should be present to justify the term extrusion.

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## **Middle Ear Mechanical Aspects for Ossicular Chain Reconstruction**

The sound transmitting system of the middle ear consists of a cone-shaped eardrum integrating the malleus handle, a complex of three ossicles, connected with multi-plane joints, fixated with several ligaments, and with the tensor tympani and the

**Fig. 1.1** Total ossicular replacement prosthesis (TORP)



stapedial muscles as active adjusting power units. Ossicular reconstruction techniques in chronic disease are described as type three according to Wullstein using a partial prosthesis (stapes head toward the tympanic membrane) (Fig. 1.1) or a total prosthesis (stapes footplate toward the tympanic membrane) (Fig. 1.2). This is only a very rough and reduced copy of the difficult and complex natural anatomical situation. At low frequencies a piston stroke-like movement of the stapes is recognized (Fig. 1.3). Above the resonance frequency of the middle ear (800–1,200 Hz), the movement of the ossicular chain turns into a complex three-dimensional action (Fig. 1.4). From these investigations in the normal middle ear [25, 26], several characteristics could be deduced for reconstruction techniques. If possible, the reconstructed tympanic membrane should still be cone shaped. A flattened or convex form should be avoided. If the malleus handle is still present, the prosthesis should be connected towards it.

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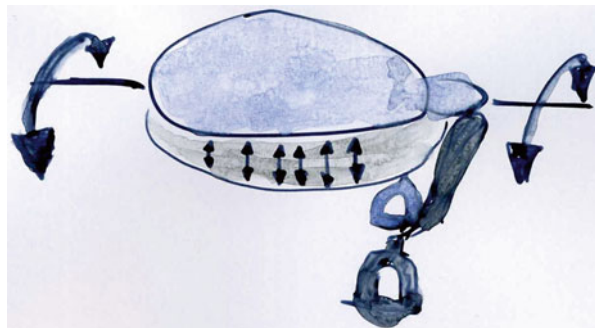
## Requirements for Middle Ear Prostheses, the Surgeons View

The prosthesis should be reliable and versatile. Placement techniques should be easily mastered. Biocompatibility is a major requirement, minimizing problems of extrusion or displacement. The prosthesis should be technically simple; specialized instrumentation and excessive fashioning should be avoided to minimize costly breakages and waste, also the stock of prostheses should be kept to a minimum [27]. Regarding acoustics, the material should have sufficiently high stiffness to enable sound transmission and dampening properties should be minimal. Revision surgery should not be hindered; the implant should be MR compatible and should not alter X-ray studies.

**Fig. 1.2** Partial ossicular replacement prosthesis (PORP)



**Fig. 1.3** Movement of the tympanic membrane and ossicular chain at low frequencies (500 Hz)  
(Adapted from Zahnert, Hüttenbrink 2005 [25])



**Fig. 1.4** Movement of the tympanic membrane and ossicular chain at higher frequencies (1.5 kHz)  
(Adapted from Zahnert and Hüttenbrink [25])



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## Functional Aspect of the Material's Surface for Improved Acceptance

For good acceptance, implant materials must interact like tissue to tissue [28]. The material-tissue interface is linked by proteins (fibronectin and other proteins of the extracellular matrix). Surface conditions therefore should not alter proteins in their confirmation status [29]. The point of zero charge (PZC) should be close to the physiological pH of 7.4. Titanium dioxide, for example, provides this condition at pH 6.8. Biologization of titanium and titanium alloys includes coating with calcium phosphate and integration with collagen [30].

Newest functionalization techniques are presented with nanoparticle surface modifications of prostheses with mesoporous silica films. In experimental studies, these coatings were established on ceramic middle ear prostheses which then served as a base for further functionalization integrating growth factors, antibiotics, etc. [31, 32].

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## Materials for Reconstruction of the Ossicular Chain

In general, there are two material groups available, biological materials (autogenic and allogenic ossicles, cortical bone and cartilage) and alloplastics, that include a broad variety of all different types of artificial materials.

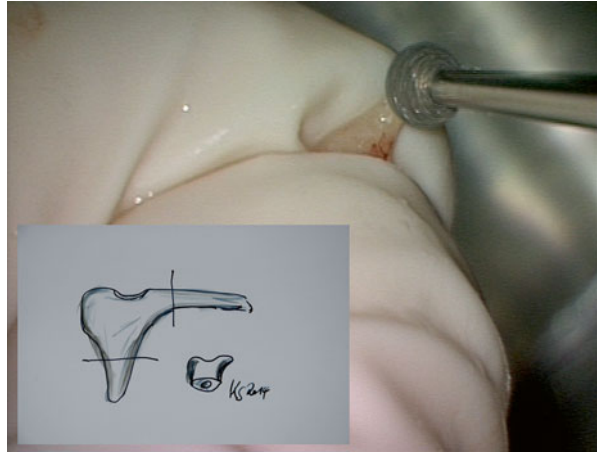
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### Autogenic Tissue

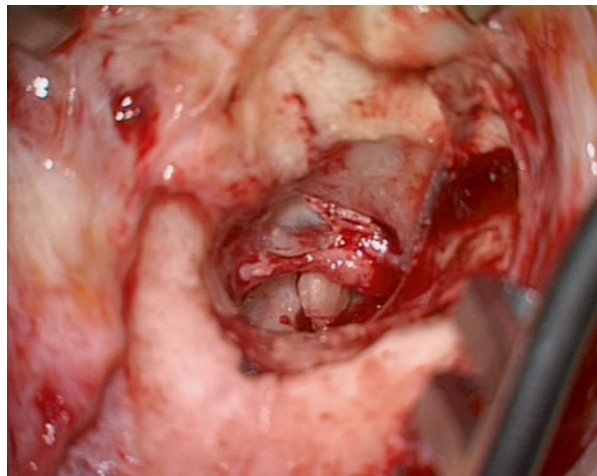
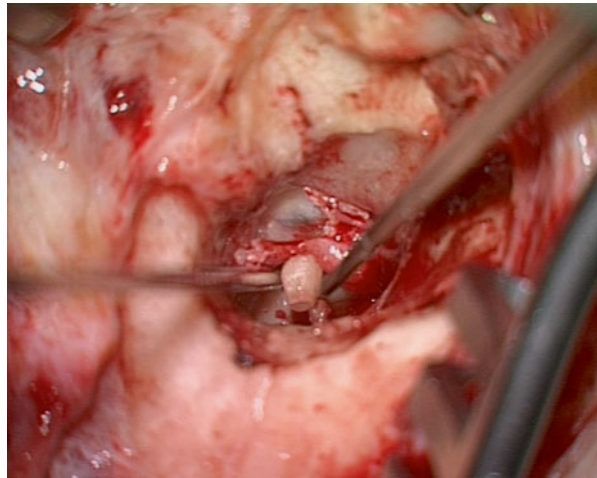
The patient's own ossicle has been used since the beginning of tympanoplasty and is still recognized as the gold standard in ossicular chain reconstruction [33]. Reconstruction in most cases is performed using the transposed incus. Reducing the long process, creating a hole to fit on the stapes head, and connecting the surface of the incudomalleolar joint toward the handle of the malleus are the common technique (Figs. 1.5, 1.6, and 1.7). Another possibility is to use the head of the malleus for reconstruction. Cortical bone has a high tendency for absorption; cartilage can be used as a thin layer between the tympanic membrane and head of the stapes. But for longer distances, cartilage is too soft for major sound absorption [13, 34]. Osseous fixation in autogenic ossicles has been observed. The underlying problem may be inadequate positioning of the ossicles and sequential contact to the bone of the Fallopi canal or promontory. Histological investigations of ossicles in chronic ear disease showed invasion by cholesteatoma and destruction by chronic inflammation. In cholesteatoma cases the use of autogenous ossicles should be avoided and in non-cholesteatoma disease patients' own ossicles should be used with discretion [35, 36].



**Fig. 1.5** Drilling of either short or long process of incus for placement between head of stapes and malleus



**Fig. 1.6** Interposition of prepared incus



**Fig. 1.7** Prepared incus in situ



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## Allogenic and Xenogenic Tissue

The use of allogenic ossicles was widespread until the 1970s [37–39]. With the increasing knowledge about transmissible infectious diseases (Creutzfeldt-Jakob disease, HIV infection, hepatitis, etc.) and the availability of well-accepted alloplastic materials, homogenic ossicles have been abandoned. In addition to allogenic ossicles, dentin and enamel have also been used for middle ear prosthesis. Biocompatibility of these materials was recognized to be good [37, 38, 40].

At present, xenogenic tissue does not play a remarkable role in ossicular reconstruction.

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## Alloplastic Materials

There is a wide range of alloplastic materials that have been and are in use for ossicular replacement prostheses. Although some of these materials have a long history and are well proven, many have been abandoned because of non-acceptance in the special environment of the middle ear space [5, 41–43].

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## Ester-Based Materials

The variability and potential of polyester are enormous. Plastic materials can be created on demand for all types of applications. Plastipore® (HDTS, high-density polyethylene sponge) is a porous material, the pores having a diameter between 30 and 40  $\mu\text{m}$ . It was introduced in the late 1950s and preliminary results were encouraging [44]. The size of the pores was seen as an advantage for fibrous tissue to grow in and to integrate the material. Some studies show extensive connective tissue sheaths, histological signs of biodegradation with macrophages, and foreign body giant cells [45–47]. The extrusion rate was recognized to be up to 80 % [48–50].

Polytetrafluoroethylene (PTFE, Teflon®) is a plastic material which has a low surface energy and thus hydrophobic characteristics. Since the first implantation of Teflon in stapes surgery in 1956, it has been proven to be an excellent material for treating otosclerosis. In the infected middle ear it is less well accepted. Kuijpers [51] studied the material in animal experiments and found fibrous encapsulation of the implants and giant cells but mainly at the edges of the material.

Proplast® (polytetrafluoroethylene combined with carbon fibers) macroscopically appears to be stable [46, 47, 52, 53]. Histologically there is a remarkable activity of macrophages and foreign body giant cells which included carbon fibers and particles of PTFE [51]. Coinciding with these histological findings, high extrusion rates have been reported.

HAPEX™ is a composite of hydroxyapatite and polyethylene. The material is used for the shaft; the prosthesis' plate is made of dense hydroxyapatite. HAPEX™ may be cut with a scalpel and has bending properties, so it can be well adapted and used as a TORP or PORP. The clinical acceptance is reported to be excellent [27].

## The Polymer Paradox

In the noninfected middle ear, as in patients with otosclerosis, polymers are widely used, and the “Richards” Teflon® (polytetrafluoroethylene)-platinum prosthesis is probably the most used stapes piston all over the world. The same acceptance can be seen with the Causse stapes prosthesis, which totally consists of polytetrafluoroethylene. As mentioned earlier, in chronic ear disease, polytetrafluoroethylene and other polymers like Plastipore® (HDTS, high-density polyethylene sponge) behave differently. HAPEX™, the composite of hydroxyapatite and polyethylene is otherwise well accepted. What is the explanation of this apparent paradox?

It is known that intrinsic material properties can be altered by ultrafine structures of the surface. The size of the pores and sharpness of the edges can influence wettability and charge of the implant and this in turn, can influence the interaction between the implant surface and the connecting proteins and tissue cells. Therefore, differences in degradation and stability seem to be dependent on the surface structure, which can be influenced by the manufacturing process. From these facts it can be concluded that new polymers and composites have to be investigated closely for their surface properties, theoretically, and in preclinical and clinical studies [28].

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## Ceramics

Ceramics are an important class of materials with different surface conditions that influence material tissue interaction. There is a differentiation between bio-inert, bioactive, and biodegradable ceramics. Aluminum oxide is a representative of a bio-inert ceramic. There have been numerous reports of good acceptance in the human middle ear [54–60]. Histologically early mucosal coverage [54, 61] and only rarely inflammatory cells and foreign body giant cells have been seen [61].

Tricalcium phosphate, hydroxyapatite calcium silicate ceramic, and the glass ceramic Bioverit® are representatives of bioactive ceramics. Tricalcium phosphate was abandoned early because of its major biodegradation [62–65]. Calcium silicate ceramic (Ceravital®) seemed to be a usable material for reconstruction of the ossicular chain [66]. Stability and low extrusion rates made it a favorite material in the 1970s and 1980s. In long-term studies the resistance of the material against phagocytic cells was recognized to be low. Over time macrophages and giant cells reduced stability [67–70]. In revision surgery the material was found to be pulverized and thus losing sound transmission properties.

The glass ceramic Bioverit® shows an excellent acceptance in the human middle ear, and this is supported by histological studies in animal research. Biodegradation is measured by 5  $\mu\text{m}$  per year [71].

Macor a bioactive ceramic used in the early 1980s appeared to be covered by thin layers of mucosa [72] but showed bony fixation and histologic signs of biodegradation with macrophages and foreign body giant cells.

Hydroxyapatite is the mineral matrix of the bone and was introduced in 1980 to middle ear surgery [73]. The material is covered by mucosa within a short period of

time [74–77]. Apparently there is biodegradation that was measured up to 15  $\mu\text{m}$  per year [76]. Clinical studies showed stable postoperative results [78–84]. The use of hydroxyapatite as part of a polymer composite (HAPEX) has been described in 4.3.1.

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## Carbons

Carbonic materials are again a completely different group. Glasslike materials, materials consisting of carbon fibers, or porous carbons have been used. Histological signs of non-acceptance such as foreign body giant cells and fibrous capsules could be recognized regularly [13]. In carbons the possibility of metabolization by certain bacteria has to be considered [41].

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## Cements

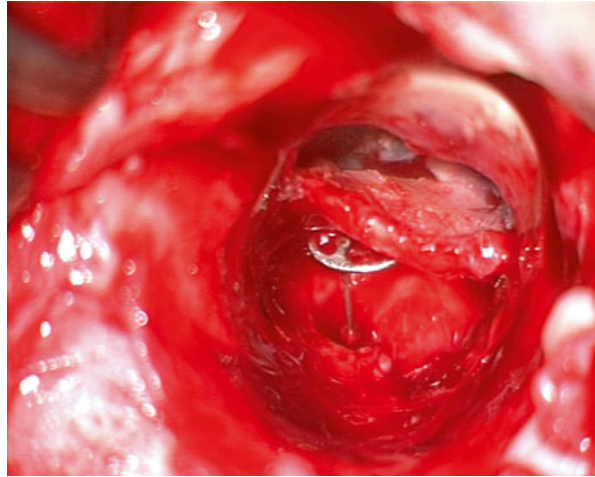
GlasIonomer cement has been proven to be a useful material for ossicular chain reconstruction shown clinically [20, 85–88] and in animal studies [89]. The material is covered by mucosa in a very short period of time [90]. The possibility of milling to individualize prostheses is recognized as an advantage with GlasIonomer. The audiological results are good. The liquid cement has been reported to be useful in reconstructing defects of the ossicular chain like the defects of the long process of the incus [91]. The excellent acceptance by bone was an encouragement to create prostheses combining cement and cortical bone [92]. The cement in its liquid form came to be discredited because of its uncritical application in skull base surgery with direct contact to dura and CSF space. More recently, the material is available again in its solid as well as liquid form for the use in the middle ear but away from the dura. Bone source, synthetic hydroxyapatite cement, was used for incus-stapes bridging in the same manner with encouraging results [93].

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## Metals

Metals have been used since the beginning of middle ear surgery especially in the noninfected environment as stapes prosthesis [94]. As previously mentioned, the biocompatibility property of an implantation material is characterized by its surface. This property has to be differentiated in metals from their metallic and oxidized surfaces. Metals with metallic surfaces include stainless steel, gold, tantalum, and platinum. In chronic ear disease the acceptance of pure metallic surfaces seems to be lower than in noninfected ears [95]. Major tissue encapsulation and giant cells have been reported in gold prostheses [96]. Gold was also been accused of being responsible for sensorineural hearing loss when used as stapes pistons, but this assumption could not be proven with evidence [7, 97]. Adverse reactions in stapes surgery have been observed for other reasons, as contamination with textile fibers was observed to cause an inflammation followed by inner ear depression.

**Fig. 1.8** Typical aspect after positioning of titanium prosthesis (TORP) in the oval niche, tympanic membrane reconstruction with cartilage



Metals with oxidized surfaces appear to be different. Titanium is a material with excellent sound transmission properties, and the prosthesis can be produced with filigree design (Fig. 1.8). Because of its reduction potential, it has a high affinity toward oxygen; thus the blank metal will be oxidized when exposed to air and will build up a passive layer of titanium dioxide. From the standpoint of the connective tissue cells including the proteins of the extracellular matrix, the connection is not toward metal but toward a ceramic-like oxidized surface. The passive layer avoids the contact between the blank metal and the adjacent tissue. This barrier also seems to function in titanium alloys. Nickel in general is not well accepted by tissue and has a high allergic potential. Nickel titanium alloys (Nitinol<sup>®</sup>) seem to be well accepted and can be used in stapes surgery. The advantage of these alloys is the memory effect. Thus fixation of the prosthesis at the long process of the incus is more feasible. Comparing studies of titanium and gold in stapes surgery presented no significant difference in audiological outcome [98].

The evidence of the point of zero charge was mentioned before. For titanium dioxide, it measures 6.8 which is seen as a reason for good acceptance. The passive layer avoids the contact between the blank metal and the adjacent tissue [2]. This barrier is of even more importance in alloys with allergic potential like nickel in nitinol prostheses.

Titanium has been studied extensively in animal experiments and clinical studies [99–102]. The acceptance of titanium in the chronic diseased middle ear is good [103]. Protrusion rates are reported to be 5 % in a retrospective study with a mean follow-up of 5.2 years (62 months) [104]. Air-bone gaps equal or less than 20 dB could be achieved in 74 % of procedures (82 % in PORPs, 63 % in TORPs).

Bridging of the necrosed long process of the incus has been performed with a special titanium angular clip with success [105].

Consequently, pure TiO<sub>2</sub> ceramic was used as basic material for ossicular replacement prostheses. Its biological acceptance was excellent; it was covered with mucosa quickly and uneventfully and inflammatory as well as foreign body giant cells were not noticed. But neither the macroporous nor the microporous oxide could withstand the functional oscillatory stress, so appropriate mechanical stability was missing [106].

The importance of a malleus for good acoustic transformation has been recognized. A special titanium malleus replacement prosthesis (MRP) was designed, and experimental and preliminary clinical studies show better results in an MRP-to-footplate assembly than in a TM-to-footplate situation [107].

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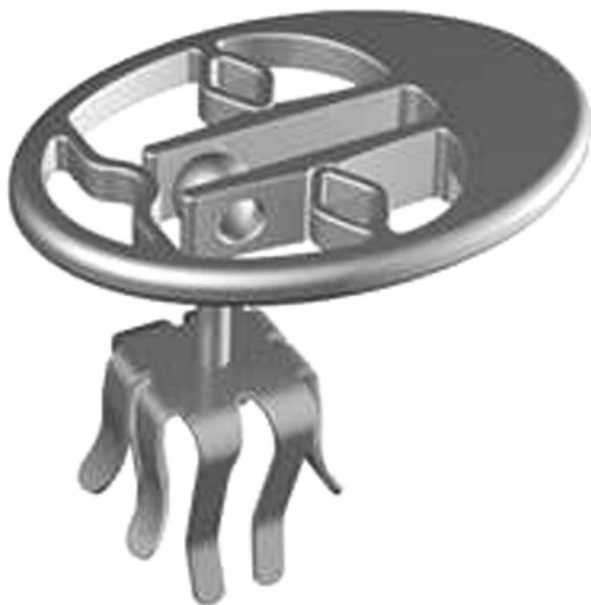
## Mechanical and Acoustic Properties of Passive Middle Ear Implants

It is difficult and impractical to compare clinical trials with different surgeons and individual characteristics of the underlying disease because so many different factors influence the postoperative results. Since the introduction of laser vibrometry, objective data are now available to compare acoustical properties of different materials and designs. These techniques changed the general understanding of the natural movement of the tympanic membrane and the ossicular chain. They help to investigate existing prostheses and develop new tailored prostheses with regard to material and design [108–110]. For good sound transmission, the stiffness of the material is important, and it should be higher than the sum of the impedance of the stapes and inner ear together [111]. A high stiffness is most important for transmission of higher frequencies [25]. Another factor is the mass of the prosthesis. For good acoustical properties, the mass should not exceed 15 mg, again very important for the high frequency range. The contact of the prosthesis toward the handle of the malleus provides better sound transmission [112]. Another important feature is the tension of the annular ligament of the stapes. This was recognized more recently to be of major importance for favorable audiological results [108, 113, 114].

The main impact on tension is the length of the prosthesis. A too short prosthesis means low tension and produces losses at both, low (<1 kHz), and higher (>1 kHz) frequencies. Prostheses that are too long, which means high tension, perform well in high frequencies, but do significantly poorer on low tones.

Defining the optimal length of a prosthesis is a difficult task. The optimal length adjusted during surgery may be too long or short after months and years according to the displacement of the tympanic membrane following adhesion or lateralization [115]. Therefore prostheses are available in different sizes. Some manufacturers provide designs with adjustable lengths (e.g., Grace Medical, Heinz Kurz, Spiggle & Theis), thus avoiding the need of stocking prosthesis of all different lengths.

**Fig. 1.9** Titanium partial clip prosthesis with ball joint to adjust toward the tympanic membrane



To transform the incoming sound into the middle ear, a large enough plate of the prosthesis is necessary [115]. On the other hand, a firm connection toward the stapes in PORPs and the footplate in TORPs is important. The connection toward the stapes can be better provided with special clip prostheses [116]. The more recent version with a ball joint may help to provide a better contact toward the cone-shaped tympanic membrane (Fig. 1.9) [117]. The disadvantage of possible osseous connection of the clip to the head of the stapes is theoretical as in revision surgery the prosthesis could always be easily pulled off the stapes superstructure [116]. TORPs may be used with good audiological results even when the stapes superstructure is still present. The superstructure then supports the prosthesis and helps to center it in position. If only the footplate exists, a special cartilage shoe [109] or a connector (omega connector; Dornhoffer connector) ([118, (Dornhoffer JL, 2014, “personal communication”)]) may help to center the TORP on the footplate. A problem in all types of partial ossicular chain reconstructions is the individual anatomy. The distance between the stapes head and malleus handle may be too long (Fig. 1.10). This problem can be approached with special grooved prostheses that have been developed to connect to the malleus handle [21, 27] (Fig. 1.11). Other possibilities are using a clip prosthesis with a ball joint (Fig. 1.12) or directly connect the prosthesis to the eardrum.

There is always the question whether PORPs perform better, especially audiological than TORPs. Since several factors influence this outcome, it is difficult to answer the question. A study with long-term results of ossiculoplasties with partial and total titanium prostheses did not show significant differences in the audiological outcome [119].

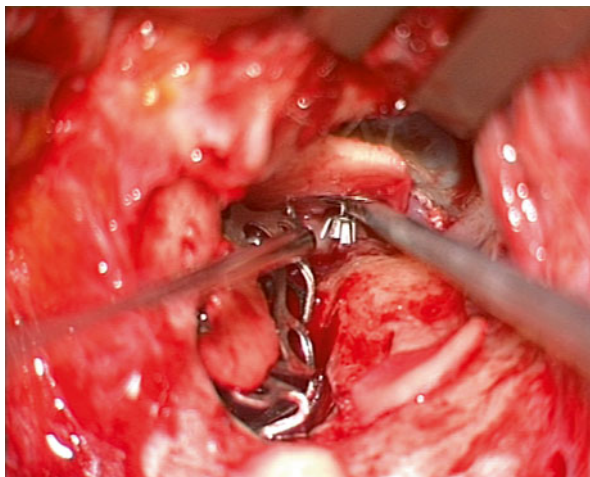


**Fig. 1.10** Unstable bridging between the stapes head and malleus when the distance ( $a$ ) is too wide



**Fig. 1.11** Dornhoffer fixed length partial prosthesis with notch for the malleus handle

**Fig. 1.12** Positioning of titanium prosthesis (PORP) between the stapes and cartilage-reconstructed tympanic membrane. Reconstructed mastoid (titanium cage) partly covered with cartilage



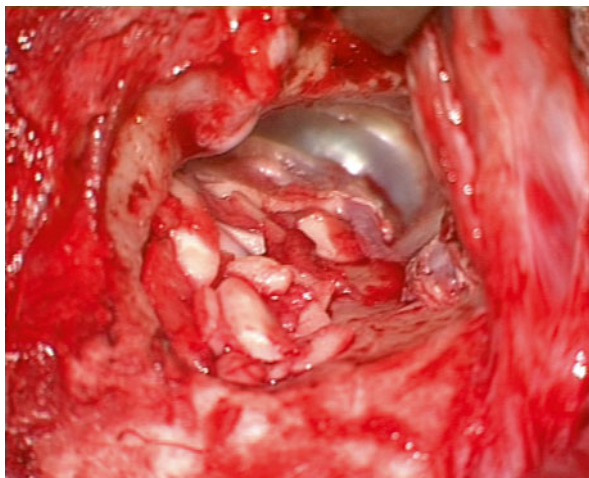
## Differences in Chronic Middle Ear Disease and Stapes Surgery

The normal uninfected middle ear is astonishingly tolerant toward all different types of materials. Polytetrafluoroethylene (Teflon®), which has low acceptance in the middle ear in chronic ear disease, is well accepted in otosclerosis. Platinum wire Teflon prostheses are widely used with good audiological results. Here it is important to mention an interesting fact regarding the Platinum wire Teflon prosthesis - in revision surgery for chronically infected ears, the reason for increasing postoperative conductive hearing loss was often found to be due to the transection of the long process of the incus by the platinum wire. But this transection has not been noted when the prosthesis has been used in otosclerosis. The cause for transection is unknown, but an interesting theory has been proposed by Schimanski [120]. He suggested that the pull of the connective tissue forces toward the oval window is transmitted via the wire loop leading to pressure necrosis of the long process of the incus. But why is there a difference between a chronically infected middle ear space and the noninfected middle ear in otosclerosis? Recalling the principal conditions of the middle ear cleft, the uninfected middle ear is a more or less a closed rather than a semi-open implantation site. In these less aggressive surroundings, materials are accepted and tolerated better than in the infected conditions of the chronic infected middle ear (see also section “[The polymer paradox](#)”).

## Reconstruction of the Posterior Wall

In the inside-out technique of cholesteatoma surgery, there are at least three options for reconstruction. The first would be to leave an open cavity with all its inherent disadvantages like the necessity to see an ENT specialist on a regular basis because of the lack of a self-cleansing cavity and recurrent dizziness when exposed to cold air, water,

**Fig. 1.13** Reconstructed mastoid (titanium cage) completely covered with cartilage chips



etc. The second option would be to obliterate the cavity to some extent and the third option to reconstruct the posterior canal wall. According to the surgical philosophy of avoiding destructive techniques if possible, after safe removal of the cholesteatoma, the first choice should be reconstruction. Cartilage is still the gold standard for attic and posterior wall reconstruction. Epithelialization is a constant problem when using foreign materials for reconstruction. Many efforts have been made to cover reconstructions with cement and other foreign materials including full body titanium molds with local flaps to achieve good skin cover. A recently suggested technique [121] is to reconstruct not only the posterior wall, but also to some extent the mastoid cell system itself using a titanium cage (Fig. 1.12). This cage is covered toward the outer ear canal with cartilage plates and chips (Fig. 1.13). Bradytrophic cartilage has the potential of excellent healing followed by epithelialization.

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## Variety of Ossicular Replacement Prostheses

To give an overview of middle ear prostheses that were and are still on the market is close to impossible. All kinds of materials, material combinations, and different manufacturers are involved in modeling and distribution of ossicular replacement prostheses. Designs then were taken over by other companies with minimal changes, thus multiplying even the variety of prostheses. The situation is more confusing since manufacturers changed names or were taken over by other companies. In addition, every middle ear surgeon with the wealth of his experience has his own self-developed type of prosthesis, adding to the existing several hundred already being marketed! The materials used are different from continent to continent and even from country to country. Titanium is widely used in Europe, increasingly more so since the 1990s. In the USA the majority of prostheses are made of hydroxyapatite, and polyethylene is still used in different varieties.

For stapes replacement, for many years the platinum wire Teflon prosthesis is the gold standard and maybe the most commonly used prosthesis in the USA and worldwide. Europe again leans more toward titanium in stapes replacement. Recently titanium alloys are also becoming popular (Nitinol®).

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## Limitations of Classic Middle Ear Surgery

A poorly aerated middle ear space, unhealthy quality of middle ear mucosa, and poor Eustachian tube function are unfavorable conditions for a reasonable postoperative outcome. In such conditions, the best result may be achieving a dry, stable ear with a 30 dB residual sound conduction hearing loss. Revision surgery for audiological reasons, if indicated at all, should be postponed for a minimum of half a year or better still 1 year. Expectations should be scaled down to a realistic level. In addition, a regular hearing aid may be helpful. Better results may be achieved with bone conduction aids like Baha®, Otomag®, or Bonebridge®. These devices are discussed extensively in the other chapters of this book.

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