Implantable Hearing Devices other than Cochlear Implants

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Foreword

Modern otologic implants are a far cry from the original vinyl acrylic ossicular prostheses first introduced in the early 1950s. The field of otology is rapidly evolving and today more than ever, staying well informed on the breadth of available implantable hearing devices presents a significant challenge for the busy ear surgeon. Dr. Mankekar was able to secure an exceptional cast of world-renowned leaders in the field to provide subspecialty expertise on passive alloplastic ossicular prostheses, implantable bone conduction devices, and active middle ear implants.

Implantable Hearing Devices other than Cochlear Implants was carefully designed to provide a practical, comprehensive reference covering prosthesis development, candidacy evaluation, surgical implantation, adverse events and clinical outcomes. Most otolaryngology texts have limited the discussion of otologic implants to one or two chapters; never before has such a comprehensive book been published on the subject. It is a distinct pleasure and honor to present the first edition of Dr. Mankekar's work. There is no question that this book will prove to be an invaluable resource for otologists and general otolaryngologists alike.

Rochester, MN, USA — Matthew L. Carlson, MD
Nashville, TN, USA — Michael E. Glasscock III, MD

Preface

In his autobiography *No More Laughing at the Deaf Boy*, Geoffrey Ball writes "although my hearing aids made everything louder, they did not make anything clearer" [1].

This has been the experience of millions of hearing aid users around the world. Conventional hearing aids have served to amplify residual hearing and provide hearing rehabilitation. Despite technological advances, conventional hearing aids still have many limitations. They amplify all sounds and not only speech sounds. This makes it difficult for the wearer to understand speech clearly. Hearing aids require frequent battery changes, have to be worn with customized moulds. In tropical countries, digital hearing aids require frequent dehumidification. Some patients are unable to tolerate them either due to blocking of their external ear canal [2] or due to problems with hearing in noise and poor sound quality. The functional gain of the hearing aids can be limited by annoying feedback due to faulty ear moulds or faulty circuitry or external canal issues. Hearing aids cannot be used regularly by those with chronically discharging ears, otitis externa or mastoid cavity issues or exostoses or frequent wax impaction. Also fitting conventional hearing aids does not provide a solution for everyone [3]. In addition to all this, even today, hearing aids are associated with the stigma of "old age" and most patients with hearing impairment try to postpone being fitted with them.

Over the past several decades, researchers, otologists and biomedical engineers have been trying to develop hearing devices to overcome the drawbacks of hearing aids and provide near natural sound quality to hearing impaired patients. These hearing devices can today treat conductive, mixed and sensorineural hearing losses and can be categorized as active (bone conduction devices, implantable middle ear prostheses, cochlear implants and auditory brainstem implants) and passive implants. Some of these devices are partially implantable while some are fully implantable. Each of these devices has specific indications and patients have to undergo several investigations before being confirmed as candidates for these devices.

Implantable hearing devices can be classified as active or passive. Active middle ear implants depend upon an external source of energy for their functioning [4].

Passive middle ear implants include the total and partial ossicular replacement prosthesis and the stapes prosthesis used for ossicular reconstruction in chronic ear disease or otosclerosis. Active middle ear implants are electronic devices which are surgically implanted to correct hearing loss by stimulating the ossicular chain or the middle ear [5]. Since these implants are placed into the middle ear, they do not obstruct the external auditory canal. The implant itself usually consists of a microphone, an audio processor, a battery, a receptor and a vibration transducer which attaches to the ossicular chain [5]. The transducer could be either piezoelectric or electromagnetic and produces vibrational energy that subsequently vibrates the ossicular chain [6]. The attachment of the transducer to the ossicular chain should be secure otherwise the device will separate resulting in device failure [7]. The device is attached either by creating an opening in the incus and using an adhesive or crimping the device to the incus; or disarticulation and placement of the device at the incudostapedial joint [7].

Active middle ear implants may remove many issues relating to hearing aid use such as sound distortion, ear canal occlusion (particularly relevant for patients with chronic otitis externa and media), acoustic feedback, autophony, inadequate amplification, discomfort and social stigma [5, 7, 8]. Some fully implantable devices also allow patients to swim and bathe while wearing the device [9].

On the other hand, there may be potential hazards associated with active middle ear implants: the implants have to be placed surgically usually under general anesthesia. Failure of the device will necessitate another surgery for explantation and re-implantation. There is an intra-operative risk of injury to the chorda tympani nerve leading to dysgeusia or injury to the facial nerve leading to facial palsy [10]. Noise of drilling and suction during surgery can cause decline in cochlear function [11]. Mass loading of the ossicular chain may lead to residual hearing loss, the extent of which is directly related to the weight of the middle ear implant and to the location of its placement in the middle ear [12, 13]. Further, there is a potential risk of damage to the ossicular chain, and the use of magnetic resonance imaging, electroconvulsive therapy and radiotherapy of the head may be restricted with some devices [5].

Much has been written about cochlear implants and auditory brain stem implants. So this book will attempt to dwell on passive implants and the other currently marketed active implants namely Bone Conduction Implants, Vibrant Soundbridge, Esteem and Maxum.

The chapter on passive implants discusses the importance of Eustachian tube function, role of a healthy middle ear mucosa and biofilms in the acceptance of the various middle ear prosthesis. Bone conduction devices, Vibrant Soundbridge, Maxum and Esteem Implants can help those who cannot be provided with hearing rehabilitation with either conventional hearing aids or passive middle ear implants.

Mumbai, India Gauri Mankekar, MS, DNB, PhD (Germany)

Table 1 Types of hearing losses and available options for hearing rehabilitation (Each option has its own specific indication)

Type of hearing loss	Available options
Conductive hearing loss	1. Surgery with or without middle ear prosthesis
	2. Conventional hearing aids
	3. Bone conduction implant devices
Sensorineural hearing loss	1. Conventional hearing aids
	2. Maxum/Esteem
	3. Cochlear implants
	4. Auditory brain stem implants
Mixed hearing loss	1. Conventional hearing aids
	2. Vibrant soundbridge
	3. Bone conduction devices

Passive Middle Ear Implants.-Implantable Hearing Devices Besides Cochlear and Brain Stem Implants.-Bone Conduction Implant Devices.-Middle Ear Implants (*MEI*): Vibrant Soundbridge.-The Envoy Esteem® Hearing Implant.-The Ototronix MAXUM System

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Contents

Passive Middle Ear Implants

1

Konrad Schwager

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].

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].

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.

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.

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.

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.

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 multiplane joints, fixated with several ligaments, and with the tensor tympani and the

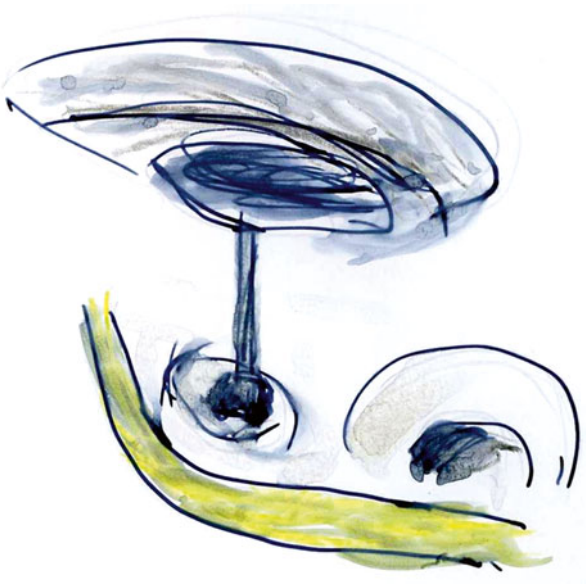

Fig. 1.1 Total ossicular replacement prosthesis (TORP)

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.

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)

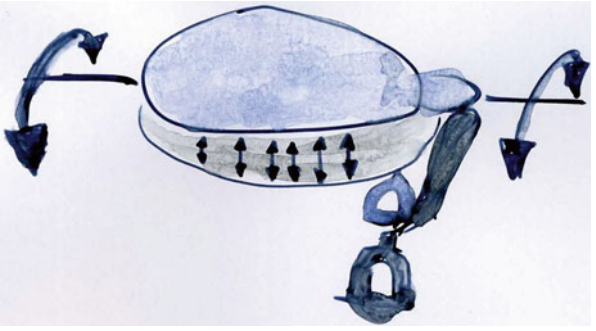

Fig. 1.3 Movement of the tympanic membrane and ossicular chain at low frequencies (500 Hz) (Adapted from Zahnert, Hüttenbrink 2005 [25])

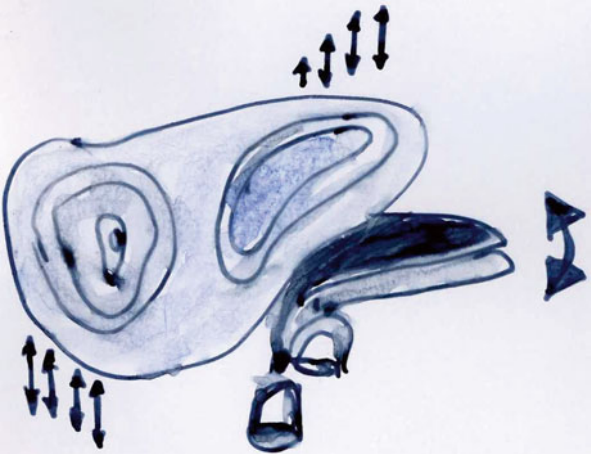

Fig. 1.4 Movement of the tympanic membrane and ossicular chain at higher frequencies (1.5 kHz) (Adapted from Zahnert and Hüttenbrink [25])

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].

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.

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 Fallopian 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].

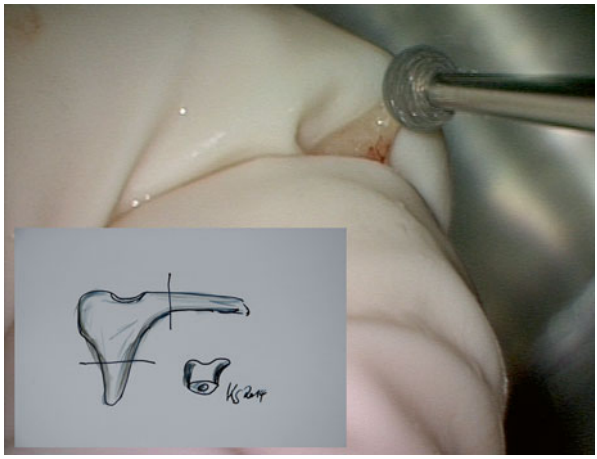

Fig. 1.5 Drilling of either short or long process of incus for placement between head of stapes and malleus

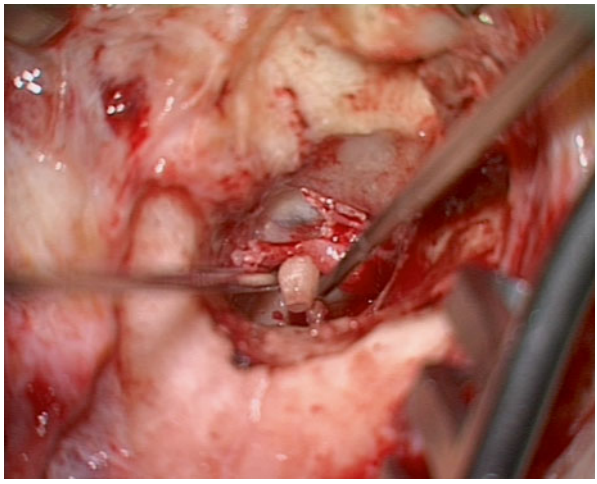

Fig. 1.6 Interposition of prepared incus

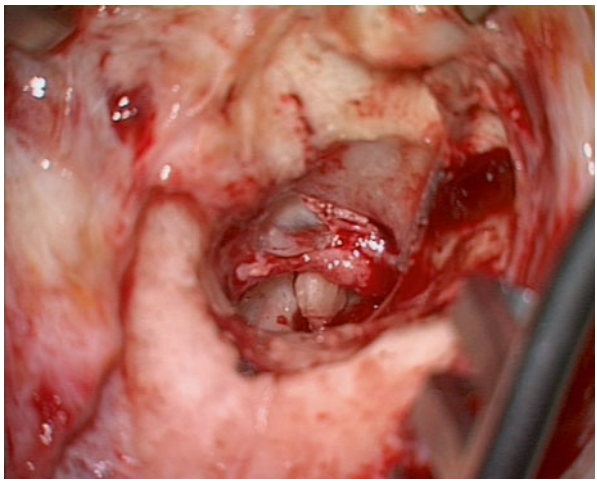

Fig. 1.7 Prepared incus in situ

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.

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].

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 µm. 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].

Polytetrafluorethylene (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].

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 loosing 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 μm 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 µm 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.

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].

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].

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.

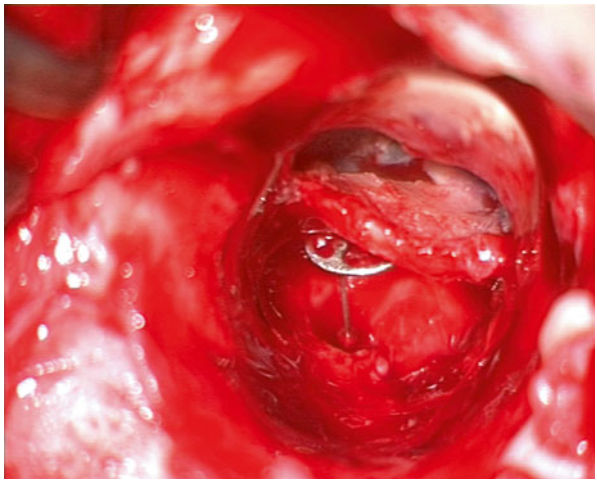

Fig. 1.8 Typical aspect after positioning of titanium prosthesis (TORP) in the oval niche, tympanic membrane reconstruction with cartilage

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®) 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 TiO2 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].

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.

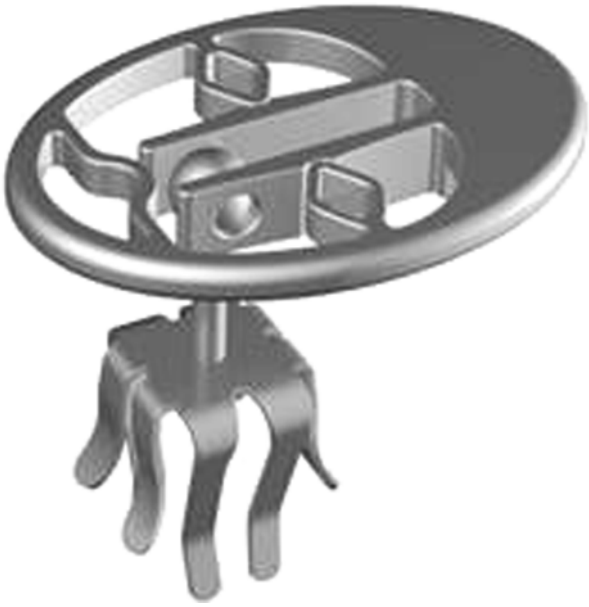

Fig. 1.9 Titanium partial clip prosthesis with ball joint to adjust toward the tympanic membrane

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 audiologically 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

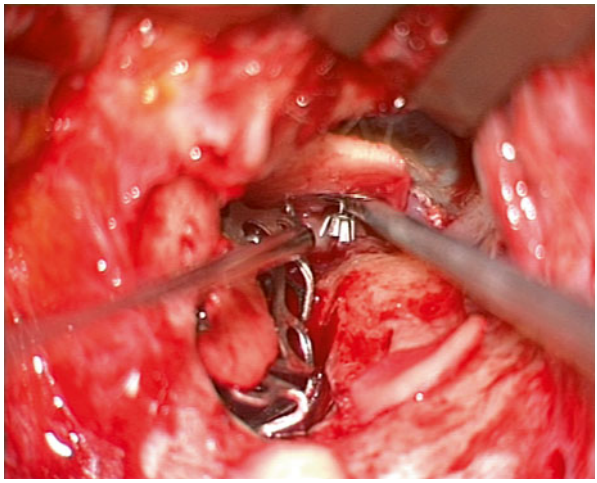

Fig. 1.12 Positioning of titanium prosthesis (PORP) between the stapes and cartilage-reconstructed tympanic membrane. Reconstructed mastoid (titanium cage) partly covered with cartilage

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 transsection of the long process of the incus by the platinum wire. But this transsection has not been noted when the prosthesis has been used in otosclerosis. The cause for transsection 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,

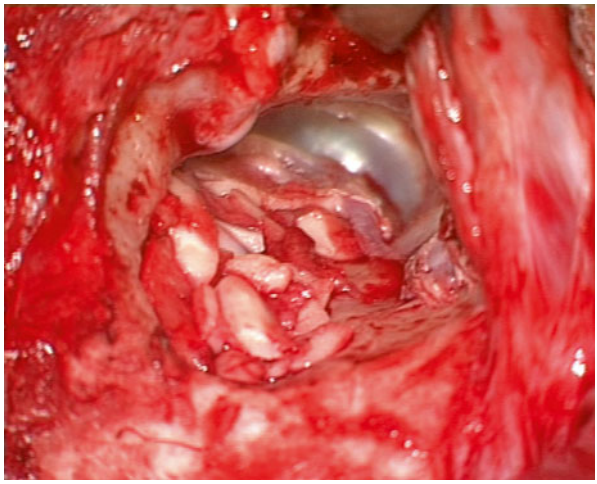

Fig. 1.13 Reconstructed mastoid (titanium cage) completely covered with cartilage chips

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.

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®).

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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Implantable Hearing Devices Besides Cochlear and Brain Stem Implants

2

Gauri Mankekar

Introduction

The prevalence of hearing loss increases with age in the general population. Of the more than 30 million Americans having severe hearing loss, only 20 % with hearing loss significant enough to warrant amplification actually seek assistance for amplification [1]. The severity of hearing loss may range (Table 2.1) from mild, wherein the individual only has difficulty in presence of significant background noise, to profound, wherein the patient is unable to understand and communicate even in the quietest of situations [2]. Patients with a mild loss do not require treatment other than instructions to choose or modify their acoustic environment and to reduce background noise, thereby improving their hearing experience. But patients with moderate to severe and profound hearing loss will require either surgery or some form of amplification to improve their hearing. Amplification with conventional hearing aids is offered when the patient has either a significant sensorineural component of hearing loss or when middle ear reconstruction with passive implants is not beneficial due to middle ear mucosal and tubal dysfunction. Conventional hearing aids are associated with several drawbacks, and so, researchers and otologists have been trying to devise implantable hearing devices for the past several decades.

Middle ear implants (MEI) are surgically implanted electronic devices which attempt to correct hearing loss by stimulating the ossicular chain or middle ear [3]. They are placed in the middle ear and usually do not obstruct the external auditory canal. The basic components of a middle ear implant include a microphone, an audio processor, a battery, a receptor, and a vibration transducer which attaches to the ossicular chain [3]. The transducer could be either piezoelectric or electromagnetic and produces vibrational energy that subsequently vibrates the ossicular chain [4]. Middle ear implants are indicated for patients who have failed to respond to other

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conservative therapies including an optimally fitted digital hearing aid. They are not indicated for patients with profound hearing loss. The types of middle ear implants vary according to the type and severity of hearing loss (Tables 2.1, 2.2, and 2.3).

Table 2.1 Guidelines for interpreting hearing loss [43]

Threshold for hearing (dB)	Interpretation
−10 to 15	Normal
16–25	Slight
26–40	Mild
41–55	Moderate
56–70	Moderately severe
71–90	Severe
91 +	Profound

Table 2.2 Algorithm for management of conductive hearing loss

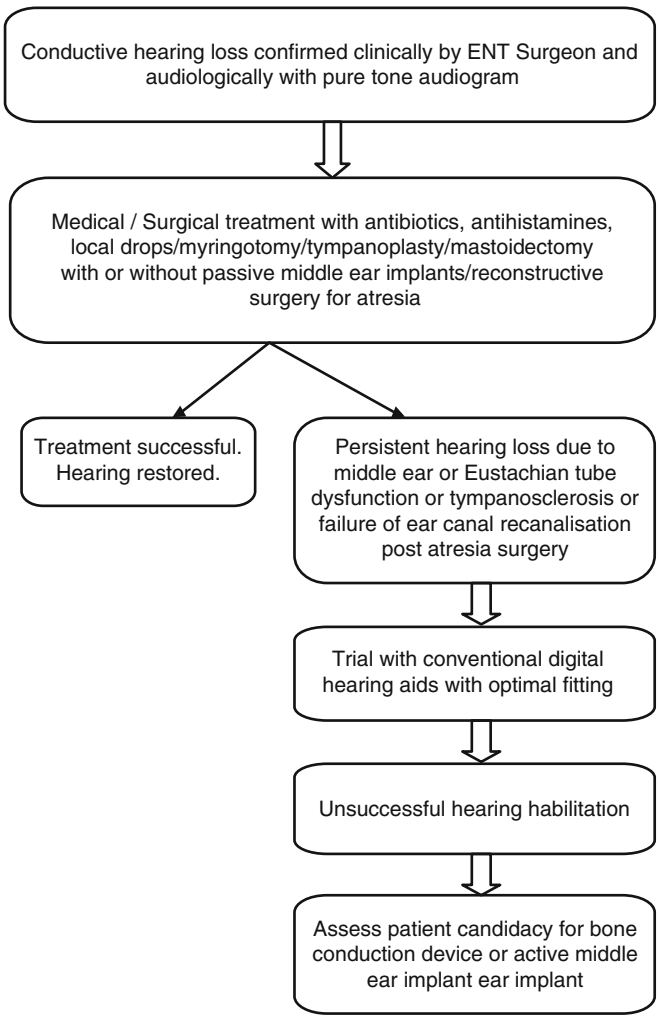
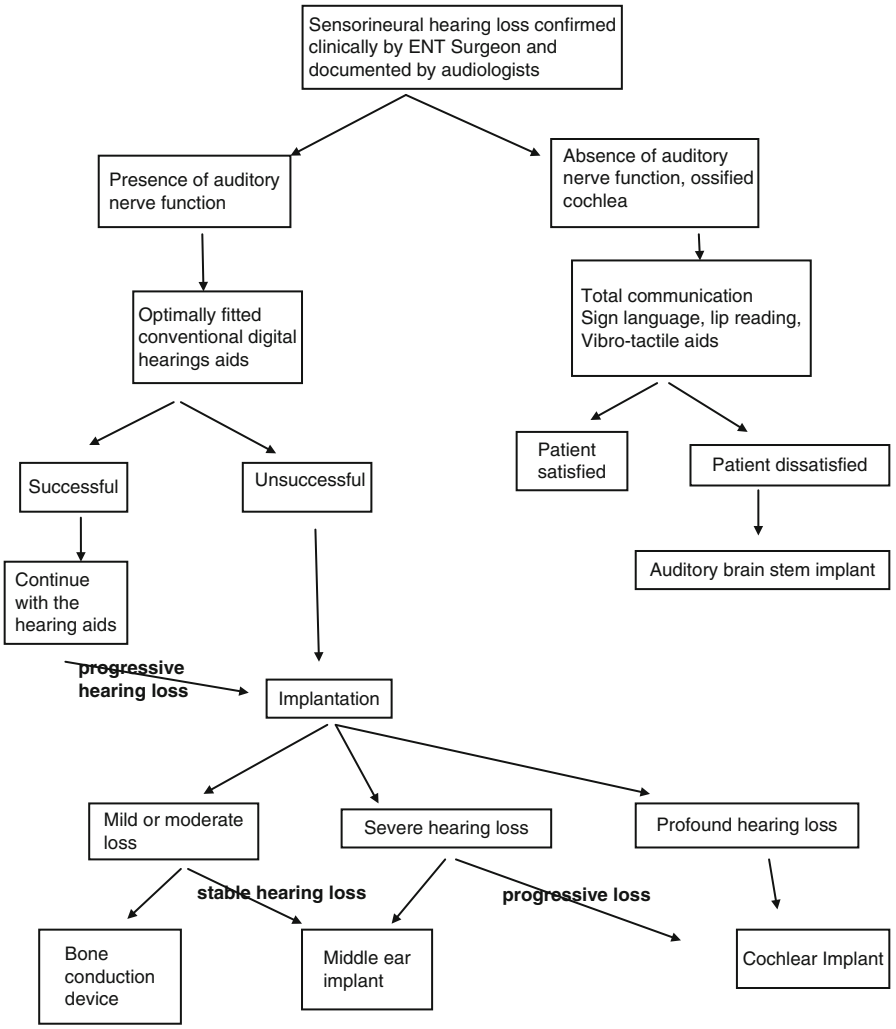


Table 2.3 Algorithm for management of sensorineural or mixed hearing loss



History of Implantable Hearing Devices

Prof. Plester wrote [5] that the history of middle ear implants is as old as the history of tympanoplasty itself. In 1935, Wilska placed iron particles directly on the tympanic membrane creating a magnetic field to stimulate the ossicles. The magnetic field was generated by an electromagnetic coil inside an earphone, which caused the iron fillings to vibrate in synchrony with the magnetic field, producing vibration of the tympanic membrane and simulating hearing [6]. This was the first reported implantable hearing device with the iron fillings taking the place of the receiver. In the 1950s, 28,000 mA was required to produce an 85 dB SPL signal. Today with advances in technology, less than 3 mA can produce this same level of signal [7] (Table 2.4).

Table 2.4 Surgical techniques for various implantable hearing devices [44]

Implantable hearing device	Surgeon/researcher	Hearing loss severity	Attachment	Anesthesia	Surgical technique			
					Incision	Mastoidectomy	Atticotomy	Tympanotomy
Rion	Suzuki, 1989	Moderate mixed HL	–	–	–	–	–	
Heide system	Tos, 1994		Between the stapes and tympanic membrane	–	–	–	–	
Rion	Yanagihara, 1997	Moderate mixed HL	Stapes	LA with mild sedation	–	–	–	–
VSB	Snik, 1999	Moderate to severe SNHL	–	–	–	–	–	
TICA	Zenner, 2003	Moderate to severe SNHL	Incus body	–	–	–		Malleus neck dissection
SOUNDTEC	Hough, 2001		Incudostapedial joint dislocated and attachment ring placed on stapes head	LA	Rosen's trans canal	–	–	
SOUNDTEC	Roland, 2001		Incudostapedial joint	LA	–	–	–	
VSB with D audio processor	Luetje, 2002		FMT attached to incus	–	–	–	–	? Posterior tympanotomy

SOUNDTEC	Matthews, 2002		Incudostapedial joint dislocated, attachment ring placed on stapes head	LA	Transcanal	–		–		
MET	Jenkins, 2004									
Envoy	Chen, 2004		Lateral surface of incus and capitulum of stapes using glass ionomeric cement	GA	Post aural	+		–		–
VSB	Colletti, 2006	Severe mixed HL	Round window	GA	Retroauricular approach	+		–		
Carina device with MET V transducer	Tringali, 2008	Severe conductive hearing loss	Posterior part of the oval window		Facial recess approach				Facial recess approach	
Esteem 2	Barbara, 2009	Moderate SNHL	Sensor attached to body of incus, driver attached to head of stapes with bioglass cement	GA	Post aural		+	–		

In 1959, Rutschmann [8] glued 10 mg magnets to the malleus umbo, causing it to vibrate by applying a modified magnetic field with an electromagnetic coil. The resulting vibration of the ossicles produced hearing sensation. In the 1970s, devices began to be actually placed in the middle ear [9–13]. Frederickson and colleagues [11] developed the first mechanical device at Washington University in St. Louis, in 1973. They showed that an implantable apparatus could provide a safe, efficient transmission of acoustic energy. In their classic work, a magnet was attached to the head of a monkey's stapes; then, an adjacent copper wire created an electromagnetic induction and vibrated the magnet, inducing a signal into the hearing system.

The RION, developed at Ehime University and Tokyo University in Japan in collaboration with the Rion Co. by Yanagihara and colleagues, was first implanted in 1984. The piezoelectric technique was pioneered by Yanagihara (1984) [13]. RION is a partially implantable middle ear device that uses a piezoelectric transducer approach. The device consists of a microphone, speech processor, and battery that are contained in an external behind-the-ear unit. The internal component consists of an ossicular vibrator and internal coil, which are coupled. The essential component is the vibratory element consisting of a bimorph, or two piezoelectric ceramic elements pasted together with opposite polarity, which have been coated with layers of biocompatible material. The free end of the bimorph is attached to the stapes and is attached to a housing unit screwed into the mastoid cortex providing fixation. The bimorph vibrates in response to applied electric current. Yanagihara and his colleagues carried out the earliest human trials using the device in Japanese patients [14–18]. Their device is intended for patients with conductive and sensorineural loss. In collaboration with the Rion Co., Yanagihara performed clinical trials with a semi-implantable piezoelectric device on more than 80 patients with over 10 years of follow-up data [19, 20]. However, the results were mixed, and over time, the piezoelectric elements of the transducer often failed and eventually the project was abandoned [21].

Meanwhile, based on the principle of osseointegration, the bone-anchored hearing aid was first implanted in 1987 [22]. It has evolved from a percutaneous device to a transcutaneous bone conduction device and is being used by several thousand patients. It is discussed in more detail later in the book.

Heide et al. [23] proposed an alternative to the piezoelectric transducer – an electromagnetic system consisting of a small magnet glued on to the eardrum at the level of the malleus. The microphone, battery, electronics, and the driving coil were placed in a special housing and inserted in the ear canal. The driver occluded the ear canal although the coupling between the transducer and middle ear was contactless. Audiometric data of six patients fitted with this device published by Heide et al. [23] suggested a mean functional gain of 10 dB higher than the patient's own conventional hearing aid. But there was no improvement in the speech recognition at 65 dB SPL suggesting that although the device amplified sound effectively, it did not amplify the sounds at normal conversation levels. Another study on the device was conducted by Kartush and Tos in 1995 [24] in patients with conductive or mixed hearing loss.

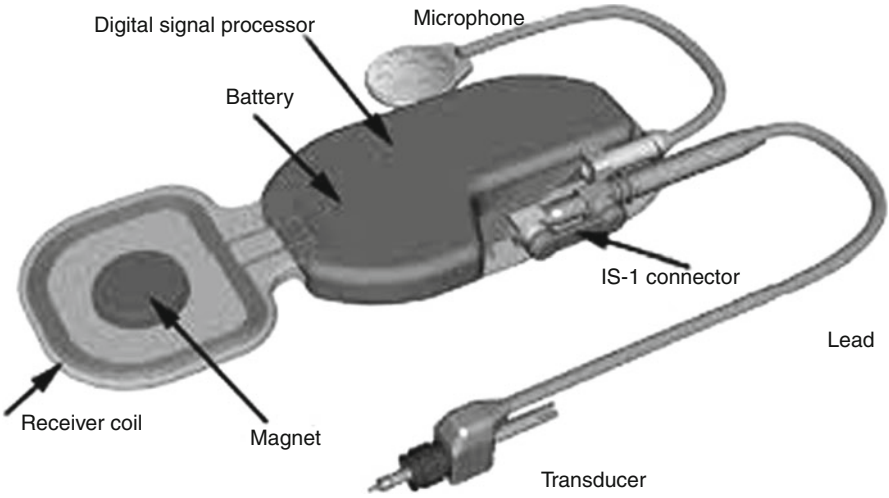


Fig. 2.1 Otologics' MET (Image Courtesy Otologics)

Eventually the device was taken off the market as any slight shift would result in significant changes in power and the magnet had a tendency to dislocate [25].

Another electromagnetic device, Otologics MET (Fig. 2.1), was suggested by Fredrickson et al. [12] in 1995. In this device, there was no air gap between the magnet and the coil and was attached to the incus by means of a connecting rod. The transducer is placed in the mastoid cavity, while the tip of the moving rod was placed in a small hole, made with a laser, in the body of the incus. The transducer was connected electrically to a subcutaneously placed receiving coil. Due to the absence of the air gap, this device was more powerful than the earlier electromagnetic devices with a potential output up to an equivalent of 130 dB SPL [25]. The rest of the device is worn externally. The device has been marketed in Europe for the past 10 years. In 2005, a fully implantable version of the Otologics MET was released for phase I testing.

Prof. Zenner and colleagues, in 1997, published a report [26] on a fully implantable hearing device. They implanted a microphone in the posterior wall of the external auditory canal with a piezoelectric transducer serving as the main component of an implantable hearing aid which was implanted in five patients during middle ear surgery under local anesthesia. The microphone was positioned beneath the skin of the auditory canal such that it completely covered the microphone membrane. The vibratory element of the transducer was coupled to the malleus in four patients with normal ossicular chains and directly to the stapes in one patient with missing incus. The microphone and transducer were electrically connected with an external battery-driven signal amplifier. All patients could hear sounds of 65 dB SPL under free field condition. On the basis of this, they reported that all conditions for a fully implantable hearing device had been fulfilled.

In 2001, Zenner et al. [27] published their studies on the IMPLEX totally implantable communication assistance (TICA) device which was a

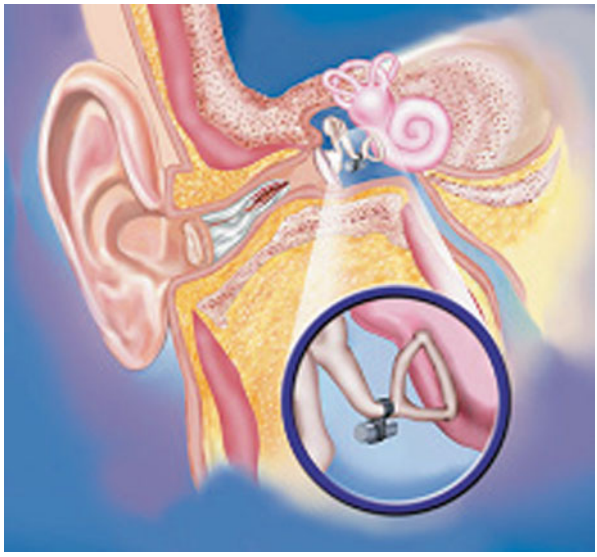


Fig. 2.2 SOUNDTEC device (Image Soundtec)

European-approved totally implantable vibratory amplifier implant. The device could pick up the sound signal transcutaneously from the external auditory canal near the tympanic membrane, amplify the signal, and transduce the signal into micro vibrations that were delivered to the ossicular chain. Phase III trials of the fully implantable device for patients with sensorineural hearing loss were reported in 2004 [28].

In 2001, Hough et al. [29] collaborated with SOUNDTEC and conducted clinical trials on an improved version of Heide's electromagnetic device that incorporated a magnet implanted at the incudostapedial joint (Fig. 2.2). The electromagnetic coil and processor was integrated in a behind-the-ear or in-the-ear canal device which occluded the ear canal. Postoperatively air conduction thresholds were found to have deteriorated by 5 dB. A second FDA study by Matthews [30] of the SOUNDTEC Direct System reported higher functional gain, a significant increase in speech discrimination in quiet, and comparable speech discrimination in background noise. Despite reports that patients preferred the implant (to an acoustic hearing aid), as evidenced by APHAB questionnaire scores, the device had the obvious disadvantage of occluding the ear canal. Subsequent problems with magnets, output, and gain caused this device to be discontinued, and it was eventually withdrawn from the market in 2004.

The Vibrant Soundbridge marketed by Symphonix Devices in San Jose, California, received both FDA approval in the USA in August 2000 and the European CE mark in March 1998 [31–33]. However, the company went out of business in 2002 and was taken over in March 2003 by MED-EL, Austria. The MED-EL Vibrant Soundbridge is a semi-implantable device (Fig. 2.3) that uses an electromagnetic design referred to as the "floating mass transducer" (FMT). It is described in detail later in this book.

Envoy Medical Corporation (formerly St. Croix Medical, Inc.), after extensive research over the past 10 years on a semi-implantable hearing device, has now

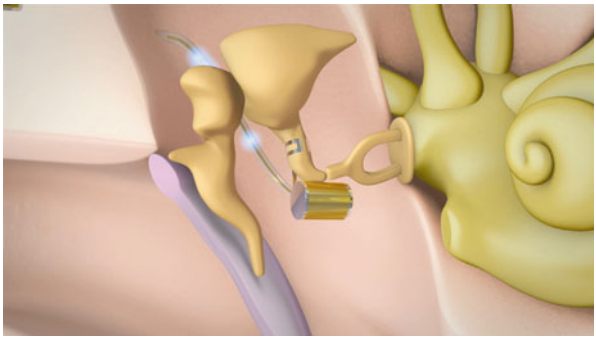


Fig. 2.3 Vibrant Soundbridge (Picture Courtesy MED-EL)

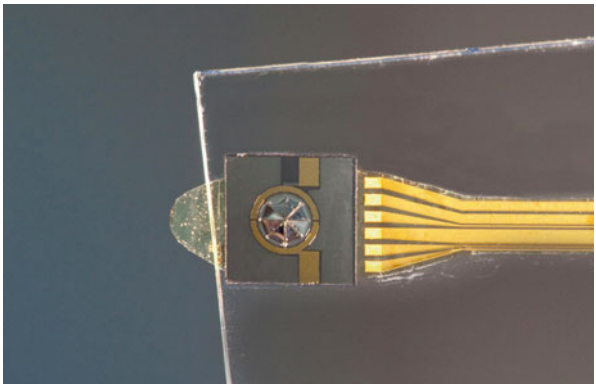


Fig. 2.4 Prototype of the electro-acoustic transducer (Image Fraunhofer IPA)

developed a totally implantable piezoelectric device known as the Envoy System [34] which is also described in detail later.

A new device being developed by researchers [35] from the Fraunhofer Institute for Manufacturing Engineering and Automation IPA in Stuttgart solution is composed of three parts: a case with a microphone and battery; wireless, optical signal and energy transmission between the outer and middle ear; and an electro-acoustic transducer (Fig. 2.4) – the centerpiece and loudspeaker of the implant. The electro-acoustic transducer will be round in shape and measure approximately 1.2 mm. The IPA's partners in the project, which is sponsored by the Federal Ministry of Education and Research, Germany, are the University Department of Otolaryngology, Head and Neck Surgery of Tübingen and the Natural and Medical Sciences Institute (NMI) at the University of Tübingen. According to the researchers, the device can be placed by the surgeons by elevating the tympanomeatal flap and placing the electro-acoustic transducer, which takes the form of a piezoelectric micro-actuator, directly at the round window. From there it transmits acoustic signals to the inner ear in the form of amplified mechanical vibrations, thereby enhancing the hearing capacity of patients. The electro-acoustic transducer works on the same principle as bending actuators. The bending elements, which are arranged in the shape of a pie, consist of a laminated composite made from piezo-ceramics and silicon. If voltage is applied, the

elements bend upward and generate a mechanical vibration. This spreads to the membrane of the round window and the inner ear, stimulating the auditory nerve. The effect: although the round window implant is no larger than a pinhead, it can output volumes of up to 120 dB, which is roughly the noise made by a jackhammer. The first working prototype is being tested in the laboratory and the overall system is planned to be ready in 2014.

Types of Implantable Devices

Implantable hearing devices can be either partially implantable or totally implantable. The microphone and the power supply are also implanted in the fully implantable devices. The implanted microphone can potentially amplify body sounds like swallowing, heartbeats, etc., making the user uncomfortable. Hence several of these devices are partially implantable. Unlike conventional hearing aids, the amplified electrical signals are not converted into airborne sound energy, but rather into mechanical vibrations which are either connected to the anatomical structure of the sound conduction apparatus (tympanic membrane or ossicle) or fed directly into the cochlea without occluding the auditory canal [36].

Implantable devices use three types of transducers:

1. Electromagnetic (Otologics MET, Vibrant Soundbridge)
2. Electromechanical (bone conduction devices) (Fig. 2.5a–c)
3. Piezoelectric (Envoy)

Electromagnetic devices consist of a magnet (made of rare earth element either samarium cobalt or neodymium iron boron) and an energizing coil. The magnet is attached to the ossicular chain, tympanic membrane, or the inner ear (round window or fenestra). A fluctuating magnetic field is generated when the coil is energized by a signal such as an acoustic input. The external microphone of the device sends the signal through an inductive coil that creates a magnetic field. The implanted receiving coil picks up this signal and connects to a transducer attached to one of the three ossicles or the round window membrane and vibrates in synchrony with the magnetic field. Sound is then transduced to the inner ear. The magnetic force generated is inversely proportional to the square of the distance between the coil and magnet; therefore, these two components must be located in close proximity with each other to make the system efficient.

Electromechanical transduction is a variation of electromagnetic transduction. In electromechanical devices, the magnet is attached to one part of the anatomy and the coil is attached to another part. As the relationship between the coil and the magnet changes, it can result in a variance of the frequency response and fluctuation of output levels.

The piezoelectric devices were pioneered by Yanagihara and Suzuki. These devices use a piezoelectric crystal, which has the property to bend and generate an electric charge when an electric charge is applied to it. The crystal can

Fig. 2.5 (**a**) Bone conduction devices – Percutaneous Baha (Courtesy Cochlear Ltd). (**b**) Bonebridge (Picture Courtesy MED-EL). (**c**) Bone conduction device – Baha Attract (Courtesy Cochlear Ltd)

function as a microphone, generating electric charge in response to incoming sound waves which bend the crystal, and as a driver (when attached to the middle ear bones), moving in response to electric charge from the microphone. This causes the middle ear bones to vibrate and transduce sound to the inner ear [7, 37].

Conventional Versus Implantable Hearing Aids

The need for implantable devices has been increasing due to the shortcomings of conventional hearing devices. Whistling or squealing (also called feedback) produced by hearing aids can be discomforting and annoying for users. Feedback is due to the amplified sound traveling back to the input microphone. The problem of

feedback increases with the increase in the degree of amplification and decrease in the size of hearing aid. Due to the possibility of feedback, patients with severe hearing loss cannot be fitted with tiny hearing aids. Secondly, tightly fitting ear molds can cause discomfort for some patients and could also cause irritation, allergies, and infection. Thirdly, occlusion of the ear canal can lead to patient's own voice sounding different or echoing. Fourthly, distortion may be caused by anatomical limitations and placement of the hearing aid. At low amplification levels, the distortion is minimal, but at high amplification levels, the distortion can be significant due to the cavity between the hearing aid and eardrum in which sound resonates. However, many of the constraints related to conventional hearing aids, such as the occlusion effect and the problem of feedback, have been reduced due to recent technological advances [38, 39] such as miniaturization, cosmetically acceptable aids, and the possibility of open or semi-open hearing aids. Along with improved sound quality, this has resulted in improvement in user comfort and higher acceptance. Boeheim et al. [40] found that both open-fit hearing aids (Fig.2.6a, b) and active middle ear implants provided audiological benefit to patients with sloping high-frequency sensorineural hearing loss. However, despite overlapping indication criteria for the two devices, performance with the active middle ear implant was significantly better than for the open-fit hearing aid [40]. For active middle ear implants, the audiological indication spectrum is mostly moderate sensorineural hearing loss, and recently,

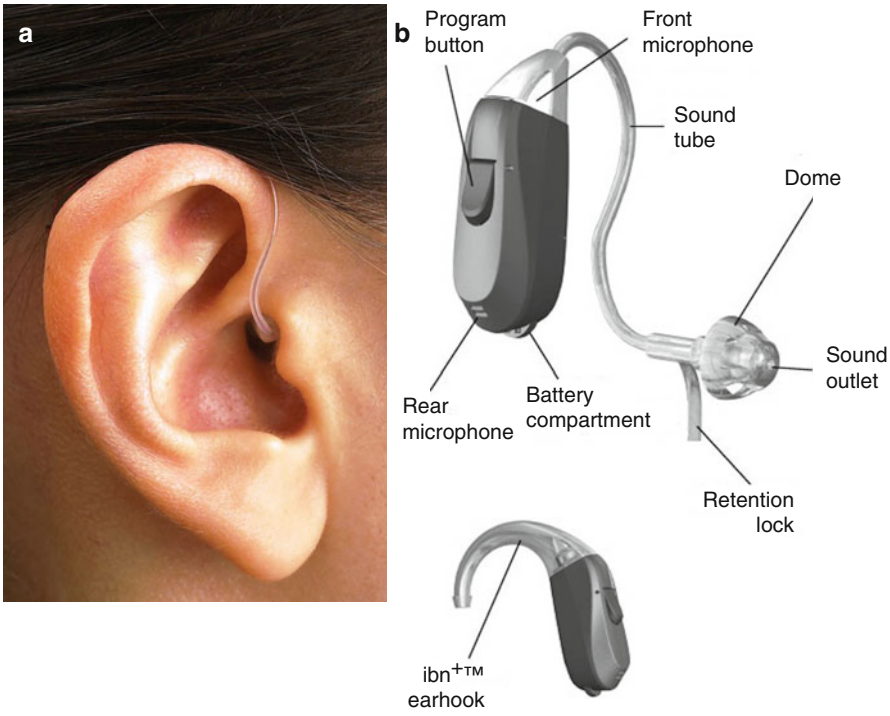


Fig. 2.6 (**a**, **b**) Open-fit hearing aid

temporal bone study experiments [41] indicate that they may be useful for conductive or mixed hearing losses through new operating procedures.

Conclusion

A lot of research, development, expense, and effort have been expended over the past several decades leading to the development of implantable hearing devices. Clinical trials for these devices take a longer time and costs increase more than originally estimated. The cost of the devices, cost of surgery, and rehabilitation are a major issue in marketing these devices especially in countries where insurance does not cover these devices. Government regulations demand strict adherence for patient safety, further increasing cost as well as time taken from the laboratory to the marketplace. In addition, several manufacturers have had difficulty in the mass production of reliable products. Despite several of these devices being currently marketed, there are several more which have been either discontinued or are undergoing modification. Advances in conventional hearing aid technology and cochlear implants are also shrinking the audiological indications for active implantable devices. Although development is rapid and the outcomes from current devices are encouraging, patients' expectations from these devices should be realistic. A totally implantable hearing device [42] (Fig. 2.7) without any external parts, programmed

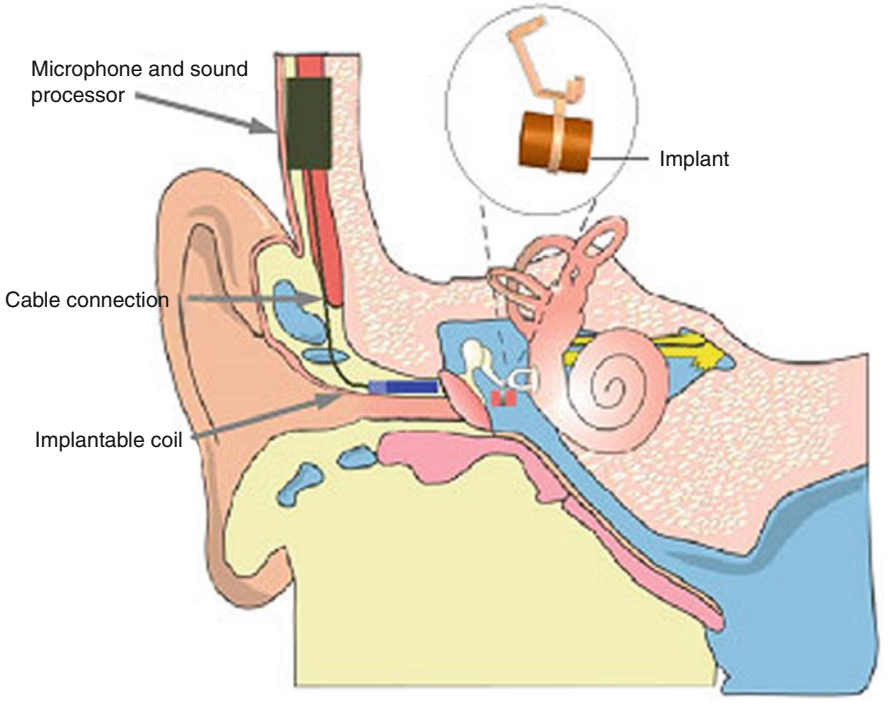


Fig. 2.7 Totally implantable hearing system (Image Prof. Gan and University of Oklohoma)

to individual patient requirements enabling them to hear "near natural sound" without echo, feedback, and occlusion of the ear canal is something to look forward to in the future.

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Bone Conduction Implant Devices

3

Gauri Mankekar

Introduction

Bone conduction implants (BCIs) are semi-implantable devices for the treatment of hearing losses in patients who either cannot wear or underperform with conventional hearing aids. These devices have to be surgically implanted, are based on the principle of osseointegration, and work by enhancing natural bone conduction. Since their first introduction in 1977, they have evolved in their external design and functionality. Even the surgical technique has undergone several modifications. Today, they are available as percutaneous and transcutaneous devices.

History

Bone conduction hearing has been recognized since ancient times. Girolamo Cardano, during the Renaissance period, demonstrated a method of sound transmission to the ear by means of a rod or the shaft of a spear held between one's teeth [1]. According to folklore, Beethoven continued to compose music by using a tuning fork to help him hear tones after he developed hearing loss. He would press the fork against his head and use his bone conduction to hear.

The bone conductor vibrator was developed in early twentieth century following the development of the carbon microphone. In the mid-1960s, Prof. Brånemark of Sweden coined the term "osseointegration" when he observed in animal experiments that a direct contact between living bone and an implant, without intervening tissue, can bear load [2]. This was successfully applied initially in dentistry wherein titanium implants were used for retention of dentures and later in joint reconstruction [3].

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Subsequently it formed the basis for the development of the bone-anchored hearing aid. The first BAHA device was implanted by Anders Tjellstrom and it became commercially available in 1987 [1]. The initial design was improved for marketing by Entific Corp., and when Entific was acquired by Cochlear Ltd., the acronym "BAHA" was converted into a full-fledged trademark. The concept of transcutaneous bone conduction implant was developed by Professor Bo Håkansson at Chalmers University of Technology in Gothenburg, Sweden [2].

Currently, four companies across the world market the bone conduction hearing implants: Cochlear's Baha 3 system, Oticon's Ponto and Ponto Plus, MED-EL GmbH's Bonebridge, and Sophono Inc.–Otomag GmbH's Alpha 1.

Clinical and Audiological Indications for Bone Conduction Implants

Conductive Hearing Losses (Fig. 3.1)

Bone conduction implants could be offered to patients with Jahrsdoerfer atresia scores (Table 3.1) [4] less than 6, chronic ear discharge and otosclerosis.

In congenital aural atresia, surgery is performed to restore the normal sound-conducting mechanism of the ear and normalize the hearing. However, not all

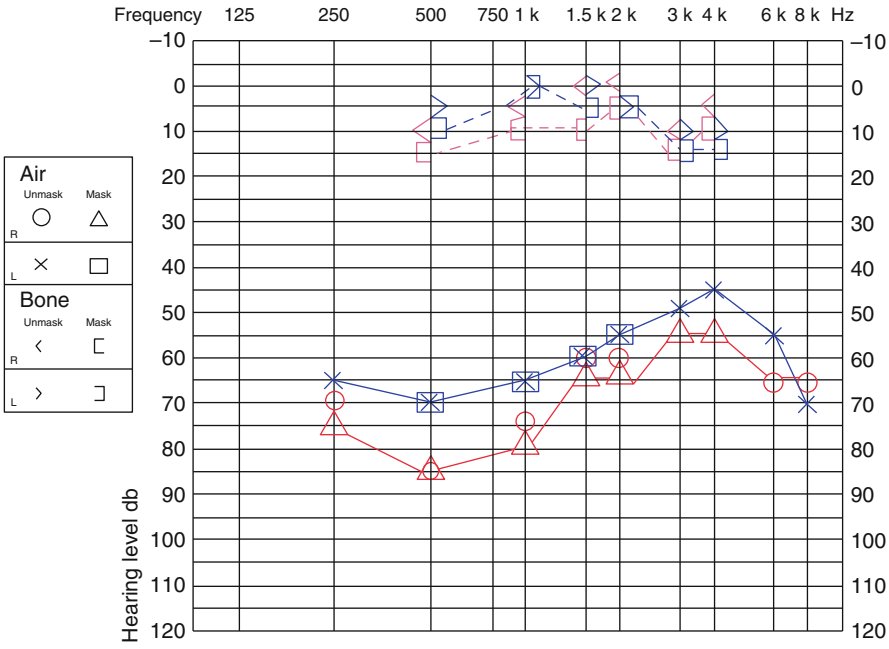

Fig 3.1 Audiogram showing conductive hearing loss

Table 3.1 Jahrsdoerfer atresia score [4]

Anatomical structure	Score
Stapes bone	2
Oval window open	1
Middle ear space	1
Facial nerve	1
Malleus-incus complex	1
Mastoid pneumatization	1
Incus-stapes connection	1
Round window	1
External ear	1
Total possible score	10

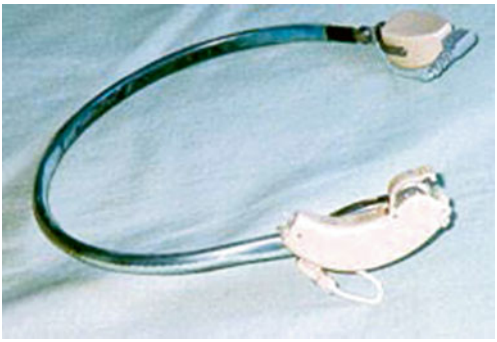

Fig. 3.2 Traditional bone conduction hearing device

patients of aural atresia are candidates for surgery [5]. The Jahrsdoerfer grading scale, proposed in 1992 [4], assigns an anatomical score (1–10 [the higher the score, the better]) for the atretic ear based on the presence or absence of nine structures (Table 3.1). The scale not only evaluates a patient's candidacy for surgery but also, as some have suggested, predicts audiometric outcome. The higher the Jahrsdoerfer grading scale score, the better the chance for normal or near-normal hearing post-surgery for aural atresia [4, 6].

Traditionally, children with a Jahrsdoerfer score of 6 or less have been offered bone conduction hearing aids either held on the head using a steel spring headband or included in the frame of a pair of glasses (Fig. 3.2). These have several disadvantages: the sound quality is poor as the skin acts as a barrier for the sound to travel to the inner ear, they are uncomfortable, and patients often complain of pain and headaches due to the constant pressure of the headband.

The BCI system is a better solution for such patients. The BCI sound processor is directly integrated to the skull bone, and because of this direct interface, it offers significantly better sound quality than that of a traditional bone conductor. It also does not cause any pressure on the skin and therefore does not cause the headaches and soreness associated with conventional bone conductor aids.

BCIs are also suitable for people with a conductive or mixed hearing impairment caused by a chronic infection of the middle or external ear with persistent discharge. The constant discharge precludes their wearing of a conventional hearing aid, and BCIs could be offered as an option for hearing rehabilitation. Conventional hearing aids may potentially aggravate ear discharge by obstructing the external auditory canal and preventing aeration. Subsequently, there is excessive humidity and lack of drainage. The BCI transmits sound through the mastoid bone directly to the auditory nerve, does not occlude the external auditory canal, and therefore does not aggravate ears with chronic discharge.

BCI can offer hearing rehabilitation for patients with conductive and mixed hearing losses when their pure tone audiogram shows a sensorineural component with BC thresholds better than 55 dB and conductive component with air-bone gap >30 dB.

Audiological Indication

An average pure tone bone conduction threshold of the indicated ear better than or equal to 55 dB HL (measured at 0.5, 1, 2, and 3 kHz).

Individuals with an average air-bone gap greater than 30 dB are likely to experience significant benefits using a BCI compared to using an air conduction hearing aid [7].

Individuals should preferably have stable hearing loss, and their word recognition scores should allow adequate sound discrimination. In addition, it is important to ensure that patients have reasonable expectations from their BCIs.

Single-Sided Hearing Loss (Fig. 3.3)

In single-sided hearing loss, the BCI utilizes the body's natural ability to transmit sound through bone to allow sound received on the hearing-impaired side to be heard by the functioning cochlea on the opposite side. The BCI is fitted on the hearing-impaired side and functions as CROS (contralateral routing of signal) by routing the sound signal to the contralateral ear with normal hearing through the bone. The BCI reduces the patient's head shadow effect and improves speech intelligibility in noise [8]. Unlike an air conduction CROS system which requires two units with cables, the BCI is a single device devoid of cables transmitting sound to the hearing cochlea. In addition, the surgical procedure for BCI is simple and reversible and does not expose the patient to any risk of additional hearing impairment.

Single-sided hearing loss may be due to vestibular schwannomas, Meniere's disease, or idiopathic sudden sensorineural hearing loss.

The hearing rehabilitation of patients with single-sided hearing loss is changing with cochlear implants being advocated for them [9].

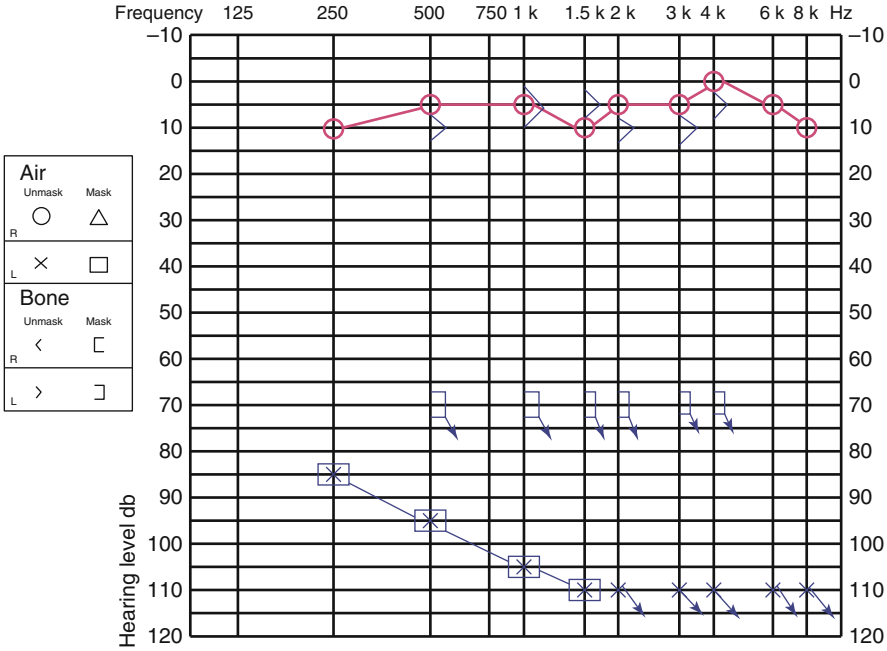

Fig. 3.3 Audiogram showing single-sided hearing loss

Audiological Indication

The hearing in the patient's better ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). Patients are considered to have SSD once it has been determined that their affected ear is unlikely to benefit with amplification provided by a traditional hearing aid.

Audiological Investigations for BCI

Audiological investigations to determine candidacy for BCI are as follows:

- Pure tone audiogram: both unaided and aided
- Impedance audiometry
- Bone conduction auditory steady-state response (ASSR) in children with atresia
- Preoperative trial with a BCI demo processor (Fig. 3.4)

Fig. 3.4 Preoperative trial with demo Baha processor and soft band (Photo courtesy Cochlear Ltd.)

Radiological Investigations

1. HRCT temporal bone (Fig. 3.5) to specifically determine:
   (a) The degree of aural atresia as per Jahrsdoerfer scale in patients with congenital aural atresia. Score of 6 or less is an indication for BCI.
   (b) Bone thickness and quality of cortical bone. If the bone thickness is less than 3 mm or if quality of cortical bone is poor as in irradiated patients, then BCI surgery may have to be performed in two stages.
   (c) Location of the sigmoid sinus and dura
   (d) Location of placement of BCI fixture or FMT preoperatively
2. MRI brain (Fig. 3.6) to rule out retrocochlear lesion in patients with single-sided hearing loss

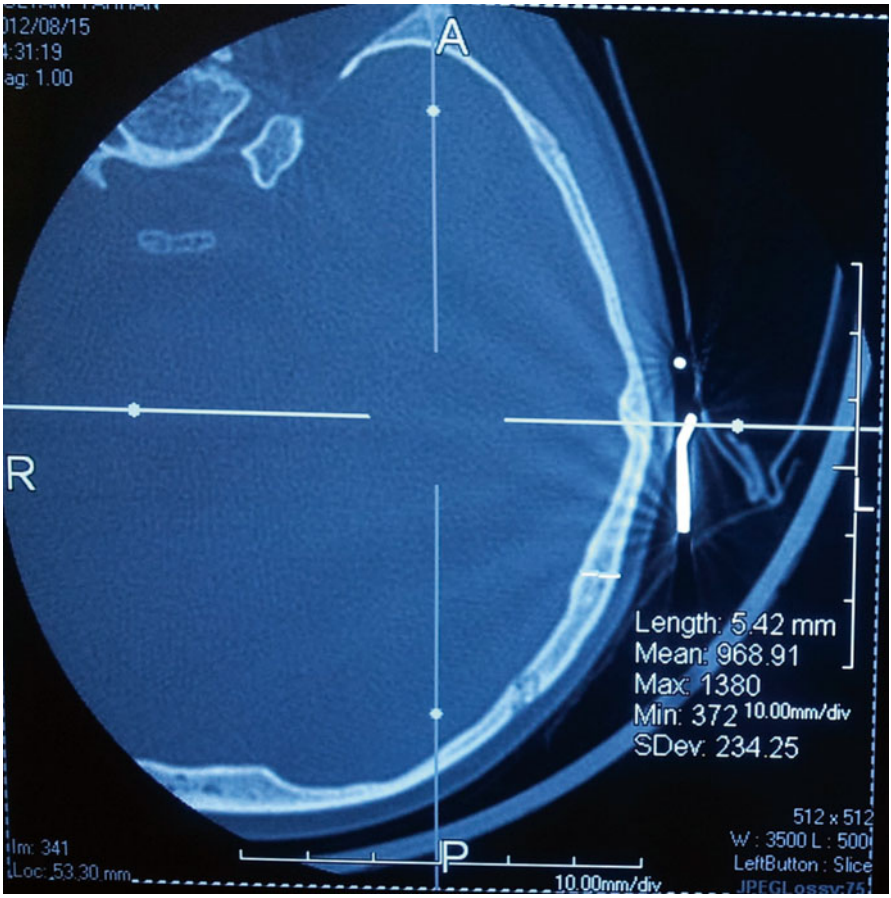

Fig. 3.5 Axial HRCT temporal bone to study cortical skull thickness

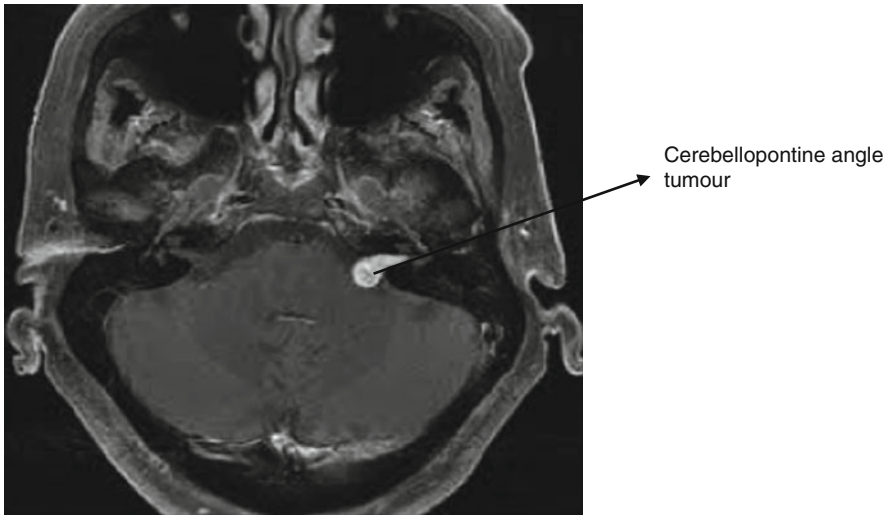

Fig. 3.6 MRI temporal bone and brain

Devices Currently Available

Percutaneous (Fig. 3.7)

This BCI uses a percutaneous and bone-anchored implant. The percutaneous implant protrudes out of the skin and therefore there is a higher risk of granulations and peri-implant infection. Additionally, the processor cannot be loaded until the fixture implant is osseointegrated.

Examples of currently available percutaneous devices: Baha Classic 300, Ponto, Ponto Plus

Transcutaneous (Fig. 3.8)

It is an alternative to the percutaneous system. The device lies completely under the skin, leaving the skin intact. So, the implant site closes and heals completely obviating the need for an abutment [10]. It transmits the signal to a permanently implanted transducer with an induction loop system through the intact skin. Hakansson et al. [2] reported that transcutaneous implants produce approximately 5 dB higher maximum output level and a slightly lower distortion than the percutaneous Baha Classic 300 at the ipsilateral and contralateral promontorium at speech frequencies. They

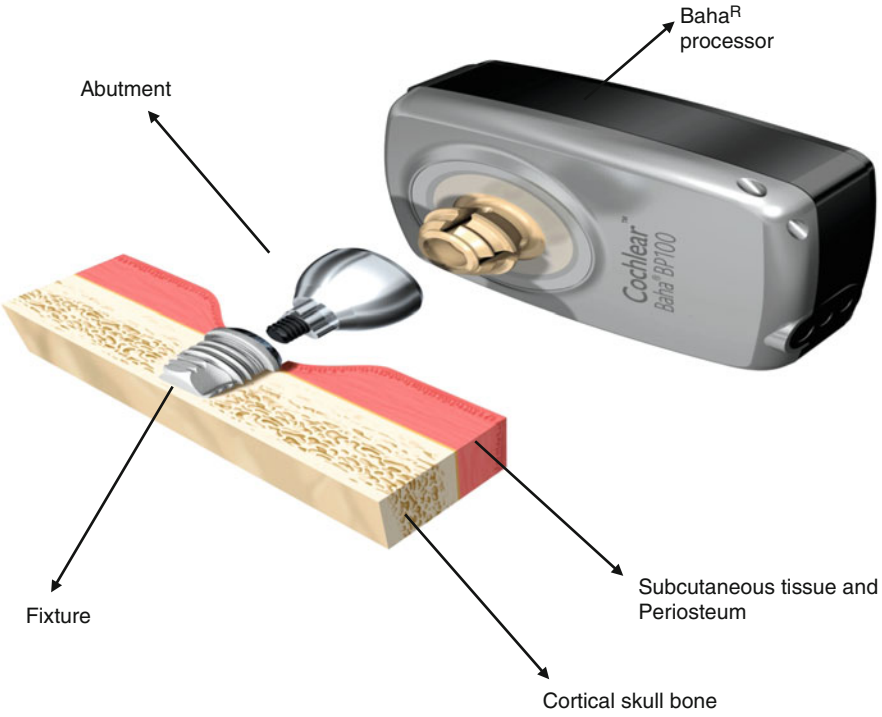

Fig. 3.7 Percutaneous Baha^R and its parts (Photo courtesy Cochlear Ltd.)

Fig. 3.8 Transcutaneous Bonebridge (Picture courtesy MED-EL)

also found that the maximum output level at the contralateral promontorium was considerably lower for the transcutaneous implant than for the Classic 300 except in the 1–2 kHz range, where it was similar. Examples of currently available devices include Bonebridge (MED-EL GmbH), Baha Attract (Cochlear BAS), and Alpha 1 (Sophono Inc.–Otomag GmbH.) The Bonebridge uses a transducer to secure the processor behind the ear while the Alpha System from Sophono–Otomag uses implanted magnets to secure the processor.

Bone Conduction Device Models

Currently, four device brands are marketed: Cochlear Baha 3 system, Bonebridge MED-EL GmbH's Bonebridge, Oticon Medical's Ponto family, and Alpha System from Sophono Inc.–Otomag GmbH. The sound processors are basically similar with variations in design, features, and attachment type.

Fig. 3.9 Baha 3 sound processor (Photo courtesy Cochlear Ltd.)

Cochlear and Oticon units are percutaneous, attach onto a titanium abutment, and act as receivers which send sound through the implant to the skull and then to the inner ear. The external processors of the two brands can be distinguished from each other easily as the Baha 3 BP100 is rectangular while the Ponto is teardrop shaped.

MED-EL launched its transcutaneous implant, the Bonebridge system, in 2012. It differs significantly in appearance from the Alpha System of Sophono Inc.–Otomag GmbH.

Cochlear: Over the past few decades, Cochlear has introduced several models of Baha^{R}:

- HC 100 was introduced in 1985.
- Baha^{R} Classic 300 was launched in 1993 and discontinued in 2007.
- Cordelle II, a second-generation body worn Baha^{R} for people requiring significant amplification for substantial hearing loss, was introduced in 1999. Cordelle II consists of a body worn unit and a transducer which snaps onto the abutment. It is the only Baha^{R} to have a built-in induction telecoil receiver.
- Baha^{R} Compact was launched in 2000. It is smaller than the classic and has added AGCo with improved shielding from mobile telephone signals.
- Baha^{R} Divino was introduced in 2005 and was the first Baha^{R} with digital processing and a built-in directional microphone.

- Baha Intenso. This was launched in 2007. It has more power and clearer sound quality in all kinds of listening environments.
- Cochlear Baha 3 (BP100 Sound Processor) (Fig. 3.9) was introduced in 2009 and has a fully programmable, multichannel digital sound processor
- Cochlear Baha 3 BP110 Power Sound Processor was released in 2011 and is a higher version of the Baha 3 BP 100 Sound processor.
- Cochlear™ Baha® 4 Sound Processor was introduced in 2013 with wireless technology plus a powerful Ardium platform.
- Currently, Cochlear offers two BCI options: (1) percutaneous Baha 4 Connect fixture/abutments which are surgically implanted in the cortical skull bone behind the ear and (2) transcutaneous Baha 4 Attract fixture/magnet implanted subcutaneously in the skull bone behind the ear.

Oticon (Figs 3.10 and 3.11)

Fig. 3.10 Ponto plus power sound processor (Photo courtesy Oticon Medical)

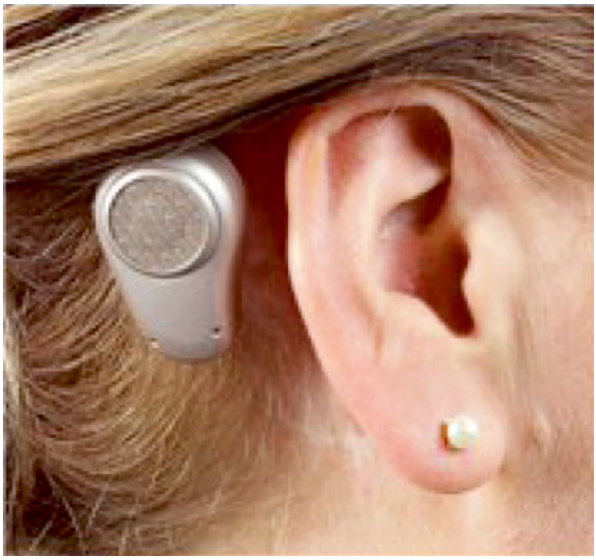

Fig. 3.11 Ponto sound processor on abutment (Photo courtesy Oticon Medical)

- Ponto Pro was introduced in 2009
- Ponto Power was introduced in 2011 and is a high-powered version of Ponto Pro offering more volume with no discernible feedback.
- The latest Ponto Plus has wireless capabilities, a new transducer, and an Inium feedback shield. It is designed to provide better sound quality with reduced feedback and artificial sounds. The Ponto Plus supports tissue-preserving surgical techniques.

Sophono Inc.–Otomag GmbH (Fig. 3.12)

- Sophono Inc.–Otomag GmbH have teamed together to market transcutaneous bone conduction devices.
- Alpha 1 is a transcutaneous BCI and was introduced in 2006 in Europe and 2011 in the USA. The Alpha 1™ (M) bone-anchored hearing system comprises of a behind-the-ear external audio processor containing a traditional bone conduction vibrator. A metal plate held to the head with a spacer shim is attached to the vibrator. The magnetic spacer is in turn held to the head by a magnetic implant which is screwed to the skull with facial plating screws. The implant consists of two magnets hermetically sealed in a titanium case.
- Alpha 2 was introduced in 2012. It can be used on either ear and has dual microphones for directionality plus it is omnidirectional for ambient sounds. The Alpha 2 processor permits a functional gain of more than 30 dB equal to the Baha™ and Ponto™ percutaneous devices.

Fig. 3.12 Sophono processor (Courtesy Sophono Inc.–Otomag GmbH)

MED-EL

Bonebridge (Fig. 3.13) is a transcutaneous BCI and was introduced in 2012. It includes an external part, the audio processor, and an implanted part, the bone conduction implant (BCI). The audio processor is worn on the head and contains two microphones, a digital signal processor, and a battery. The BCI consists of a receiver coil, a demodulator, and a transducer. Information from the audio processor is sent transcutaneously to the BCI so that the transducer (the bone conduction floating mass transducer, BC-FMT) vibrates in a controlled manner, specific to each patient's hearing needs.

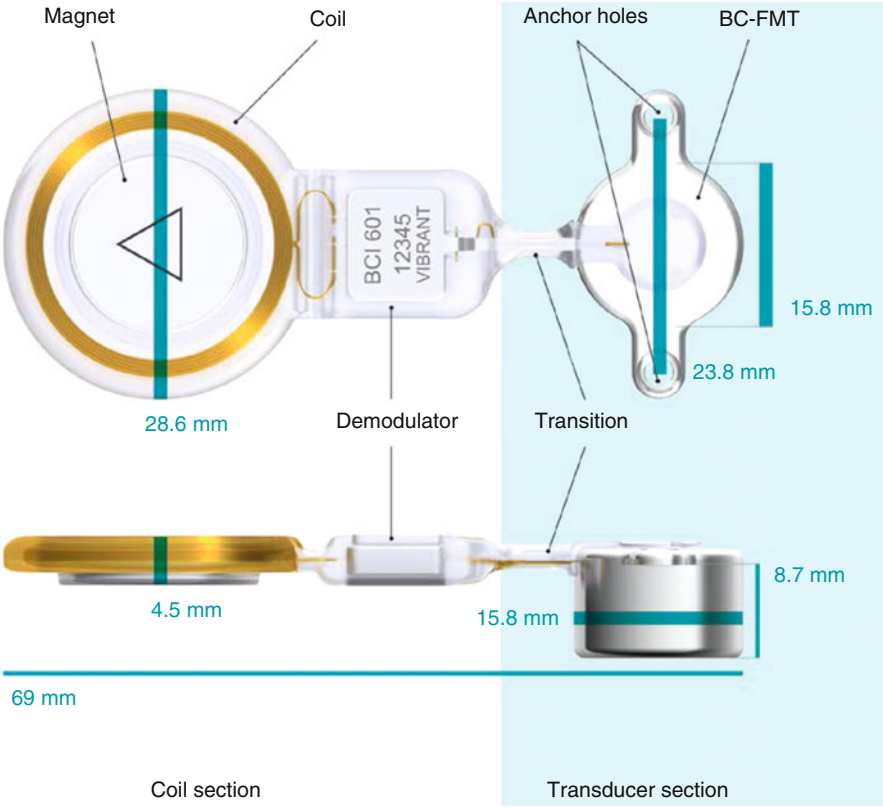

Fig. 3.13 Bonebridge (Photo courtesy MED-EL)

Types of Surgical Procedures

Skin Flap Technique

The different flaps used are (1) a free retroauricular "full-thickness" skin graft, (2) a pedicled parieto-occipital epidermal graft, (3) a dermatome-pedicled parieto-occipital dermal graft, and (4) two broad pedicled local epidermal skin envelopes/skin flaps. According to van de Berg et al. [10], the two broad pedicled local epidermal envelopes/skin flaps are associated with significantly fewer major complications and have one of the shortest times between surgery and loading of the BAHA processor. Linear incision technique has slowly been replacing the skin flap technique and has statistically lower risks of skin problems than the skin flap technique in the first 3 months post-implantation [11].

Dermatome Technique (Fig. 3.14)

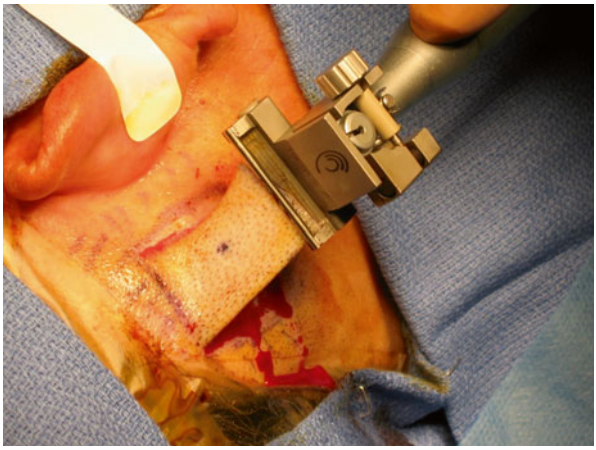

Fig. 3.14 Dermatome technique (Photo courtesy Cochlear Ltd.)

This technique was a standard procedure for raising skin flaps during the early years of BAHA surgery. A dermatome was used to raise a postauricular skin flap through which the abutment could be brought out. According to Conejeros et al. [12], the use of the electric dermatome in BAHA surgery is associated with a higher incidence of skin complications in comparison with the U-graft technique.

Tissue Preservation Technique

BAHA surgery involves reduction of soft tissues around the abutment to minimize the risk of skin-related complications [13]. Wilson et al. [14] have reported that surgery was performed faster with similar postoperative outcomes in individuals undergoing implantation of BCI devices using the minimal soft tissue reduction technique. In animal experiments, Larsson et al. [13] found that there was enhanced dermal adherence and reduced epidermal down growth and pocket formation for hydroxyapatite-coated abutments, with the most significant effect recorded for the hydroxyapatite-coated abutments with a concave shape. According to Gaweki et al. [15], the new Baha (®) BA400 abutment covered with hydroxyapatite can be used without soft tissue reduction. The advantage of the tissue preservation technique is limited bleeding during operation, reduced usage of coagulation, less risk of nerve lesions and numbness or pain after operation [15]. Although this technique requires less time, it is necessary to measure soft tissue thickness with either ultrasound or skin gauge and choose abutments of appropriate length (Table 3.2). This results in longer preoperative time, so the time taken for the entire procedure is only slightly shorter [15].

Table 3.2 Abutment selection guide

Tissue thickness (in mm)	Abutment length (in mm)
4	6
5	8
6	8
7	10
8	10
9	12
10 or more	12 (with soft tissue reduction)

Courtesy Cochlear Ltd.

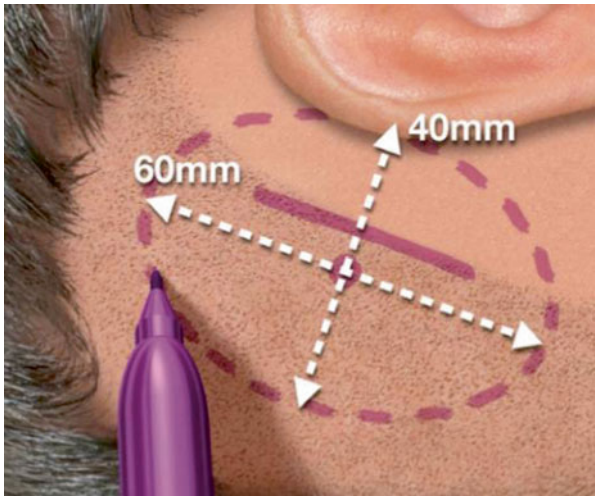

Fig. 3.15 Linear skin incision for Baha^{R} (Photo courtesy Cochlear Ltd.)

According to Gaweki et al. [15] the aesthetic results and healing following the technique without soft tissue reduction have distinct advantages over standard technique. However, in patients with a thick soft tissue, there is a risk of soft tissue overhanging, so in such cases, it is better to make a partial soft tissue reduction [15].

Surgical Technique

The technique depends on the following factors:

1. Whether the device is percutaneous or transcutaneous
2. Whether procedure is to be performed in a single stage (FAST) procedure or two stage
3. Individual implant manufacturer guidelines and specifications

The basic step involves implanting the fixture or BC-FMT in the mastoid cortical bone through the dermatome technique (Fig. 3.14) or linear incision (Figs. 3.15 and 3.16) or flap (Fig. 3.17) technique. The skin thickness is measured using either a thin needle or noninvasive ultrasound or a skin flap gauge for the Bonebridge (Fig. 3.18).

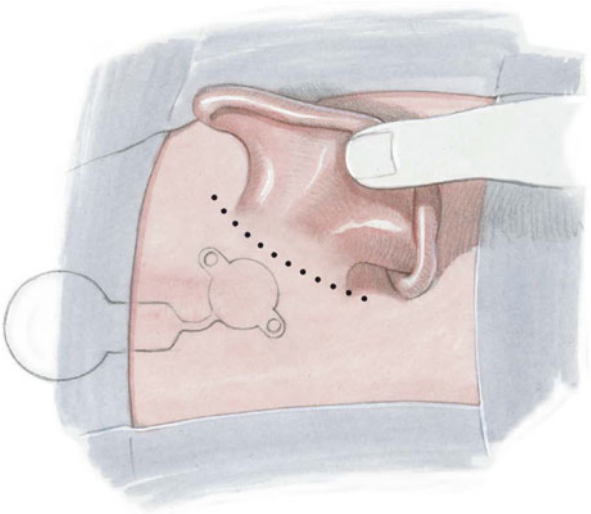

Fig. 3.16 Postaural Skin incision (*dots*) for Bonebridge (Photo courtesy MED-EL)

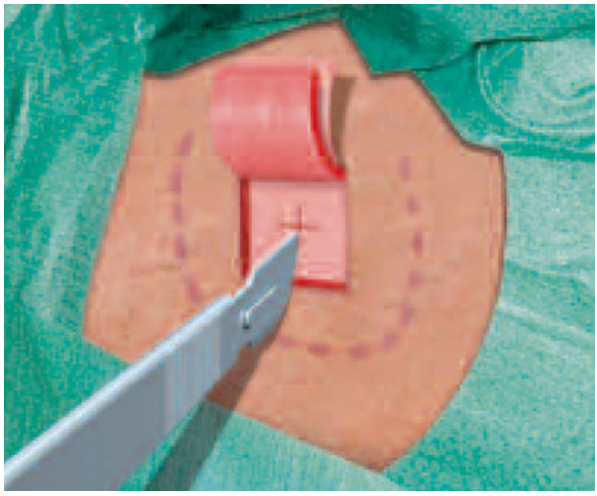

Fig. 3.17 Periosteum incision after raising skin flap technique (Photo courtesy Cochlear Ltd.)

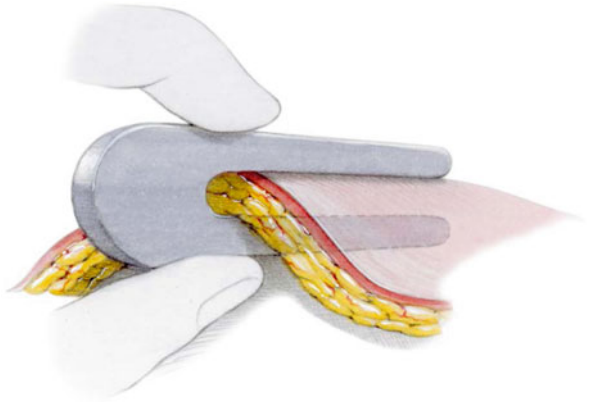

Fig. 3.18 Skin flap gauge (Photo courtesy MED-EL)

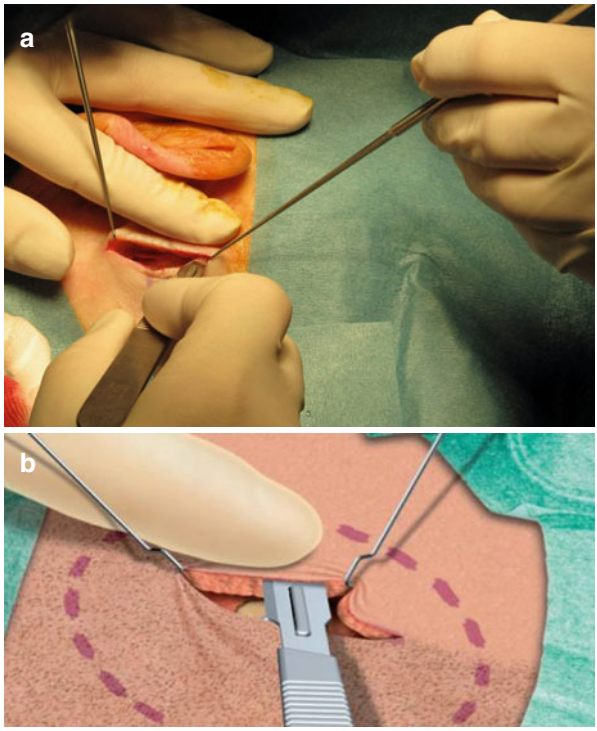

Fig. 3.19 (**a**, **b**) Subcutaneous tissue reduction (Photo courtesy Cochlear Ltd.)

Fig. 3.20 Different lengths of abutments for percutaneous implants (Photo courtesy Cochlear Ltd.)

Depending on the skin thickness, the decision to either preserve tissue or reduce the subcutaneous tissue (Fig. 3.19a, b) has to be taken. Also depending on skin thickness, the length of the abutment (Fig. 3.20 and Table 3.2) is decided for percutaneous BCI. Longer abutments are used for thicker skins. A well is created in the cortical bone to receive the implant (Figs. 3.21, 3.22 and 3.23). Depending on the type of BCI, the implant is placed in a subcutaneous pocket and the implant is fixed with screws to the cortical bone (Figs. 3.24 and 3.25) or the abutment is placed and brought out through the skin (Fig. 3.26a, b). This is followed by wound closure. The processor is loaded 4 weeks to 3 months after surgery, once the fixture has osseointegrated with the mastoid cortical bone or after reduction of the tissue swelling.

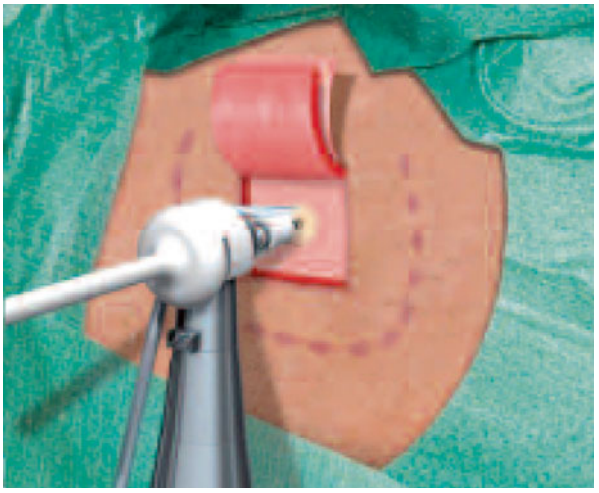

Fig. 3.21 Drilling cortical bone for fixture implant with guide drill and spacer (Photo courtesy Cochlear Ltd.)

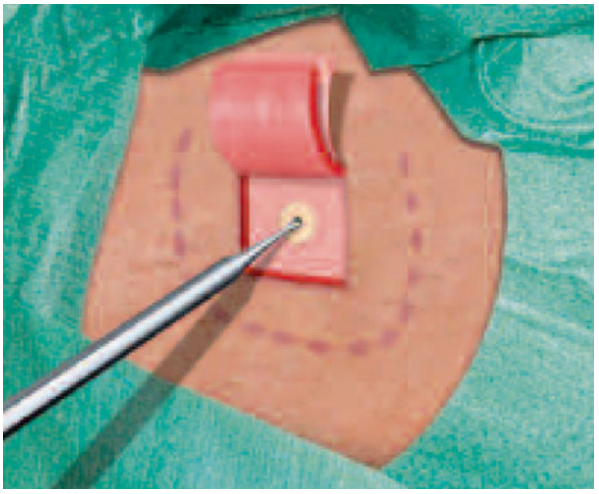

Fig. 3.22 Checking depth of drill hole with seeker to avoid penetration (Photo courtesy Cochlear Ltd.)

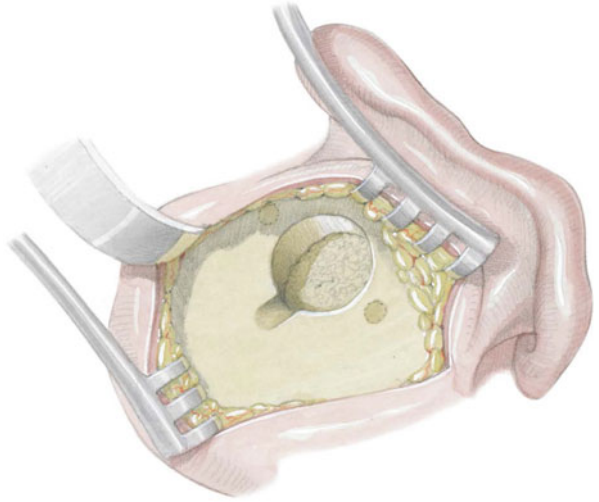

Fig. 3.23 Drilling cortical bone for implant placement (Photo courtesy MED-EL)

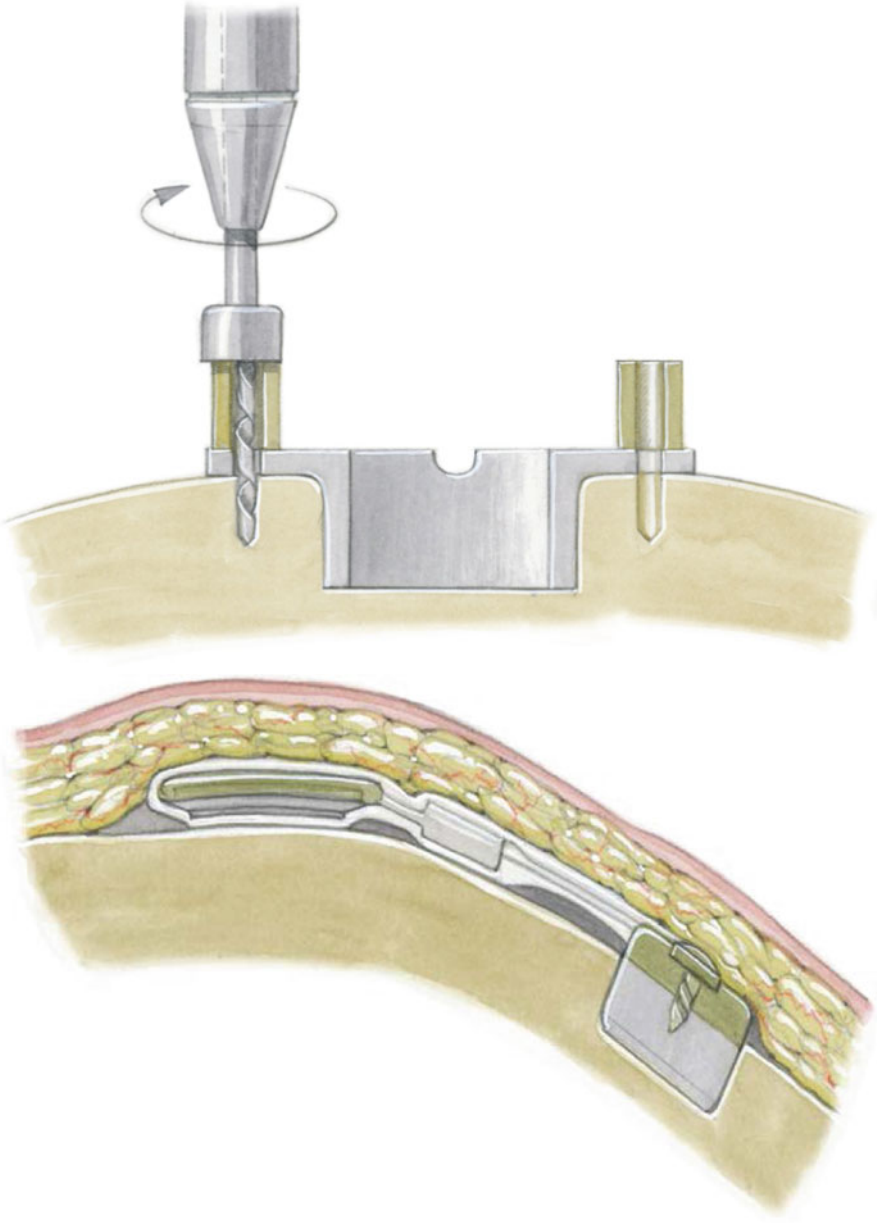

Fig. 3.24 Fixing the Bonebridge implant with screws (Photo courtesy MED-EL)

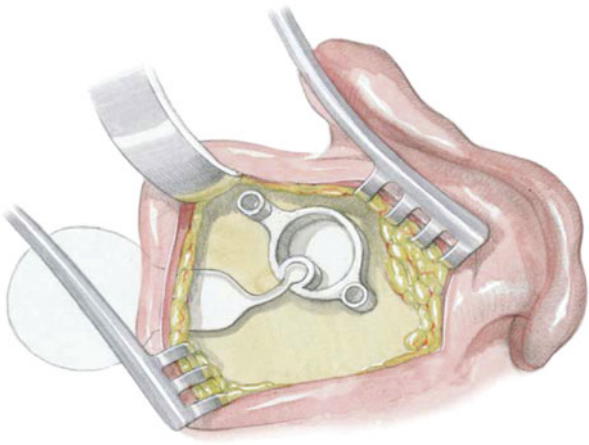

Fig. 3.25 Placement of BCI in subcutaneous tissue pocket (Photo courtesy MED-EL)

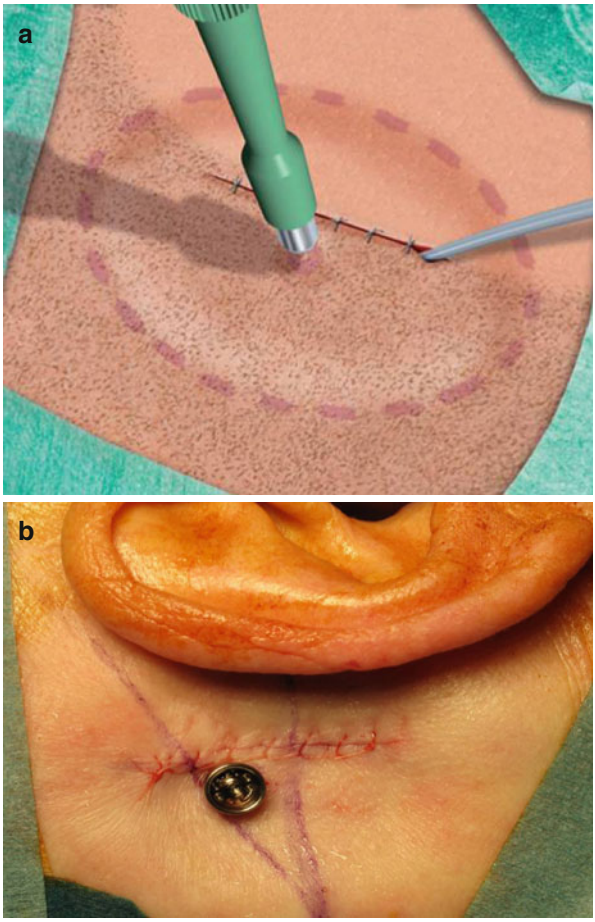

Fig. 3.26 (**a**, **b**) Placement of abutment and brought out through skin (Photo Courtesy Cochlear Ltd.)

Fig. 3.27 Osstell implant stability measurement device for Ponto BCI (Photo courtesy Oticon Medical)

In two stage procedures, the fixture is implanted in the first stage and the abutment is placed after osseointegration has taken place which is usually 3–6 months after the fixture implantation.

For the Ponto implant an implant stability measurement can be performed at implantation followed by measurements at any time after implantation to determine changes in implant stability. The measurement is performed using the Osstell ISQ and Osstell Mentor stability meters (Fig. 3.27). The implant stability quotient (ISQ) values range from 1 to 100. The more stable the implant, the higher the ISQ value.

Surgical Technique Selection (Table 3.3)

Table 3.3 Choosing surgical stages

Bone thickness (mm)	Single-stage or FAST	Two stage	Sleeper fixture	Time before loading fixture (months)
<3		+	+	6
3	±	+	+	4–6
4	+		±	3

Courtesy Cochlear Ltd.

FAST or Single-Stage Surgery

Only performed when there is good bone quality with bone thickness more than 3 mm. In the FAST procedure, all three steps, i.e., fixture implantation, abutment installation, and soft tissue reduction, are performed in a single stage.

Two-Stage Surgery

This technique is indicated when the following conditions are present:

- Compromised, soft, or irradiated bone
- Cortical bone thickness less than 3 mm
- When performed in conjunction with other surgery, e.g., acoustic tumor removal

Complications

Significant complications are uncommon [16] after placement of bone conduction implants. However, patients must be made aware of substantial workload of device maintenance prior to surgery [17]. Complications may require local wound care, antibiotics [16], and frequent visits to the surgeon's office or even revision surgery.

Intraoperative

- Intraoperative bleeding was reported in 3 % of patients by Badran et al. [17]. It is usually encountered during soft tissue reduction.
- Dural injury and CSF leak is potentially possible especially in children with cortical bone thickness around 3 mm or less. A preoperative CT scan can provide guidelines for planning a two-stage procedure in such children and in selecting the exact location for sitting the implant in an area of adequate cortical bone thickness to avoid intraoperative dural injury. Also surgeons have to be extra careful during initial penetration. Ideally one should drill with the guide drill using 3 and 4 mm spacers and intermittently withdraw the drill bit to feel for the dura with a seeker (Fig. 3.22). In case of inadvertent dural injury and CSF leak, the leak may have to be closed. However, the implant fixture itself can act as a seal to stop a small CSF leak.

  Ideally, surgery in children with cortical bone thickness less than 3 mm should be delayed until age of 4 or 5 years. These children can be provided hearing rehabilitation with the processor worn on a soft band around their head (Fig. 3.28) while they await surgery.

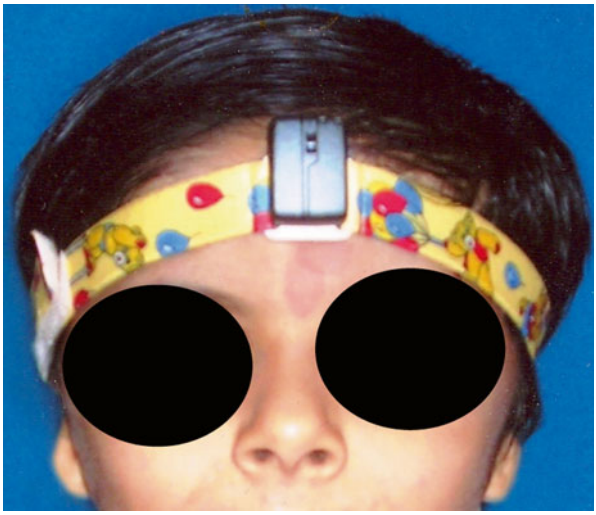

Fig. 3.28 BAHA processor on a soft band

Perioperative

- Epidural hematoma is rare and only one case has been reported by Mesfin et al. [18] post BCI surgery.
- Complete or partial loss of skin graft was reported by Shirazi et al. [19] in 10 % of their patients. They managed the patients successfully with local wound care.
- Infection: Skin and peri-abutment infection in percutaneous implants is the most common complication of BCI surgery. Holgers et al. [20] have classified the skin reactions into the following grades:
  0 = No irritation
  1 = Slight redness
  2 = Red and moist, no granulation tissue
  3 = Red and moist with granulation tissue
  4 = Revision of skin penetration necessary

  Skin infection granulations can usually be managed with antibiotics, local dressing, and ointments and rarely debridement of granulations.
- Skin overgrowth (Fig. 3.29) can occur in 2–5 % [17, 18] of patients. House et al. [16] reported that skin overgrowth tends to occur about 12 months after BCI surgery. Shirazi et al. [18] reported 5 % of their patients had skin growth over the abutment. Two of these cases were managed with office debridement, whereas one patient required revision under general anesthesia.
- Loss of osseointegration at a median interval of 6.3 months was reported by Badran et al. [17] in 17 % of their patients. They observed that loss of osseointegration was more frequent in patients with a 3 mm compared with a 4 mm fixture. Such patients require a new fixture [17].
- Bone overgrowth has been reported by Badran et al. [17] in two of their patients. Wound exploration to remove bone overgrowth was required in these patients.
- Implant extrusion has been reported in about 3 % of patients [16, 18]. These patients then require revision surgery.

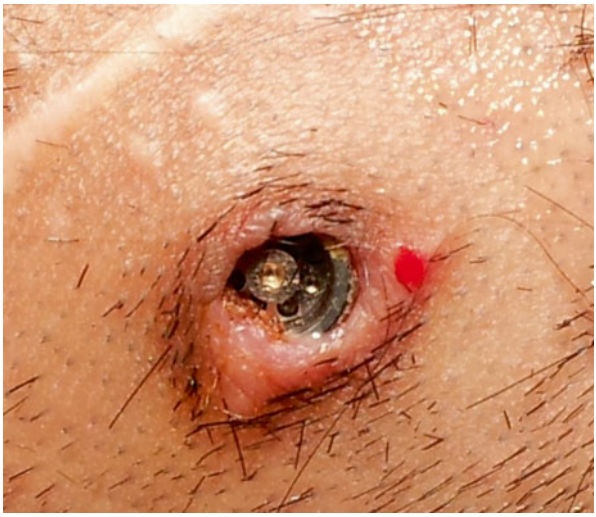

Fig. 3.29 Skin overgrowth over the percutaneous abutment

- Occipital neuropathy: Faber et al. [21] have reported a case of suboccipital neuropathy following BAHA surgery in a 70-year-old patient. Postsurgery, patient developed chronic pain at the implantation site, restriction of neck movements, and complaints of shoulder and arm on the ipsilateral side. Postop scar formation may cause this neuropathy due to occipital nerve entrapment [21]. Badran et al. [17] have also reported implant abandonment in four patients with intolerable pain.

Device Programming and Troubleshooting

- For percutaneous bone conduction implants, patients have to await osseointegration of the fixture implant before the audio processor can be fitted or loaded. Osseointegration can take approximately 3 months after the surgery. Transcutaneous implants do not require osseointegration, and their audio processors can be fitted as soon as the swelling of the wound has reduced.
- The audiologists review parts of the processor with the patient and relatives and also program the audio processor to the patient's hearing requirements. The patient is encouraged to wear the processor for several hours a day or preferably all day.

Recent Advances

Several new advances and additional features are being offered with the new bone conduction implant devices.

Cochlear introduced the DermaLock (Fig. 3.30) abutment in 2012. It allows the skin around the abutment area to be preserved using a hydroxyapatite coating on the implant. The DermaLock surface enhances soft tissue integration by allowing more cell binding proteins to bind to the hydroxyapatite surface. It orients the proteins in a way that makes it easier for the cells to attach to the abutment. The DermaLock procedure is a minimally invasive technique which reduces operative time and the risk of complications such as numbness.

Fig. 3.30 Cochlear Baha^{R} DermaLock™ abutment (Photo courtesy Cochlear Ltd.)

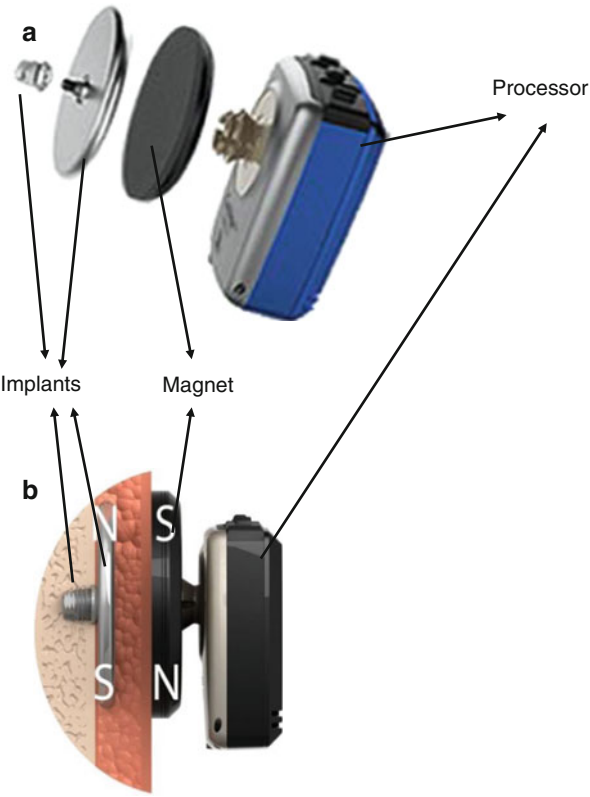

Fig. 3.31 (**a**, **b**) Baha^{R} 4 attract system (Photo courtesy Cochlear Ltd.)

Oticon Medical has introduced a more powerful sound processor which supports hearing losses up to 55 dB. Their devices are also focusing on increasing the output in the mid- and high-frequency range (6–9 k bandwidth) to reproduce louder sounds. This is especially important for kids to understand sounds such as the syllables "s" [22].

In 2013, Cochlear's Baha Attract System (Fig. 3.31) was cleared by the FDA as well as received the CE mark. It is fully magnetic transcutaneous Baha

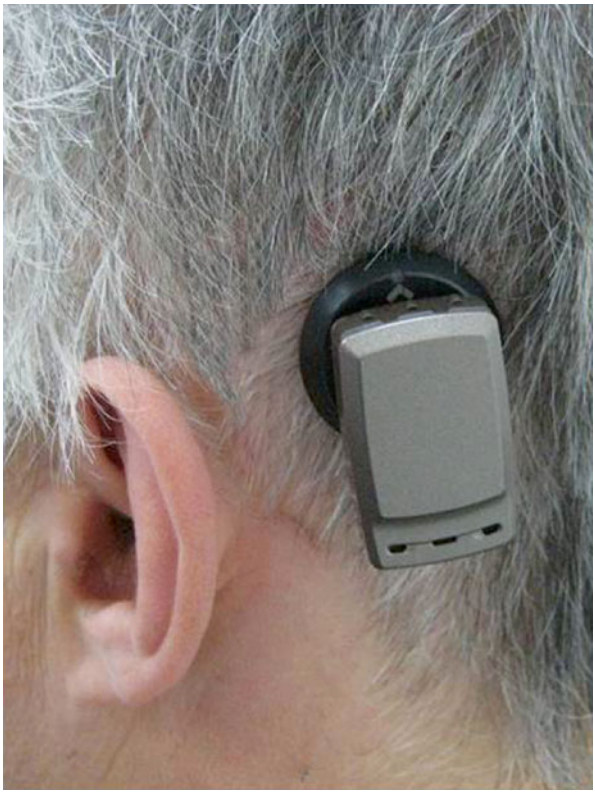

Fig. 3.32 Baha attract real life (Photo courtesy Cochlear Ltd.)

system and uses magnets to connect the sound processor to the implant. It is a more aesthetic option (Fig. 3.32) but has less power (lower volume) as the sound has to move through the skin compared to through the titanium abutment.

Since 2013, Cochlear and Oticon provide a range of wireless products compatible with their sound processors. This enables the user to speak on the phone or listen to a speaker or watch television with the devices streaming directly to the sound processor wirelessly.

Conclusion

Implantable bone conduction devices are gradually becoming more sophisticated as well as aesthetically acceptable. The newer transcutaneous BCIs are a significant improvement on the percutaneous implants which are associated with a higher incidence of skin infections, skin overgrowth, and granulations.

Acknowledgement The author would like to acknowledge Cochlear Ltd., MED-EL GmBH, Oticon Medical, and Sophono Inc. for providing inputs and images.

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Middle Ear Implants (MEI): Vibrant Soundbridge

4

Mario Emilio Zernotti and Peter Grasso

Description of the Vibrant Soundbridge Middle Ear Implant

The Vibrant Soundbridge® (VSB) is a middle ear hearing implant that was first implanted in 1996 as a treatment for moderate to severe sensorineural hearing loss. In February 1998, the device was approved with the CE mark and in August 2000 by the Food and Drug Administration (FDA) as well. Thousands of patients around the world have been implanted with the VSB since 1996. Remarkable patient satisfaction and performance of the device have been reported in scientific publications and presentations. In general, patients who wear the device all day long (up to about 16 h) report a natural sound quality, high device satisfaction, and a better ability to understand speech, especially in noisy environments [1]. Since 2007 the VSB is also approved as a treatment for conductive and mixed hearing loss and in 2009 the VSB got the approval for implantation in children by the EU authorities. The VSB has also proved to be a very reliable device, with a cumulative survival rate of 98.3 % after a period of 105 months.

The system consists of an implanted part, the vibrating ossicular prosthesis (VORP) (Fig. 4.1), and an external part, the audio processor (AP) (Fig. 4.2). The AP is worn behind the ear, held by a magnet, and contains a microphone, a digital signal processor, and a battery. The VORP consists of a receiver coil, a conductor link, and the floating mass transducer (FMT) (Fig. 4.3). The FMT is 2.3 mm long; its diameter is 1.8 mm and weighs about 25 mg. The conductor link has a diameter of 0.6 mm.

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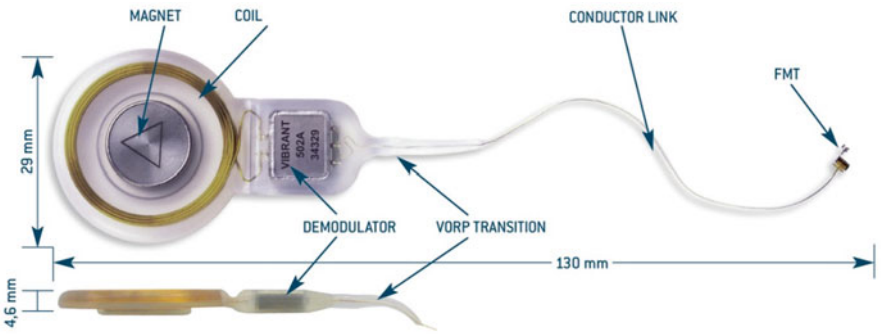

Fig. 4.1 VORP

Fig. 4.2 AP (Amadé)

The sound is picked up by the two microphones of the AP and is processed by state-of-the-art signal processing software. This information is then transmitted via amplitude modulation to the receiver coil of the VORP. Afterwards the information is demodulated into the electrical pulses that drive the vibration of the FMT.

Audiological Indications and Patient Selection

The Vibrant Soundbridge® is indicated for patients who have mild to severe hearing impairment and cannot achieve success or adequate benefit from conventional therapy.

Fig. 4.3 FMT (right)

As with all surgical procedures, the physician must fully assess the potential risks and benefits of the patient prior to the decision to implant the VSB. It is important to take the patient's complete medical history into consideration. For patients suffering from sensorineural hearing loss, the pure tone air conduction threshold levels have to be at or within the levels listed below:

Frequency (kHz)	0.5	1	1.5	2	3	4
Lower limit (dB HL)	10	10	10	15	25	40
Upper limit (dB HL)	65	75	80	80	85	85

For patients affected by conductive or mixed hearing loss, the pure tone bone conduction threshold levels should not be worse than 45 dB in the low frequencies and 65 dB in the high frequencies. See table below. A patient with sensorineural hearing loss shall be a current user of an acoustic hearing aid and should use it for at least 4 h (average) per day for at least 3 months prior to evaluation or shall not be able to wear or benefit from conventional hearing aids for medical reasons.

Frequency (kHz)	0.5	1	1.5	2	3	4
BC upper limit (dB HL)	45	50	55	65	65	–

The potential patient shall present an ear anatomy that can facilitate the positioning of the FMT in contact with a suitable vibratory structure of the ear. Different surgical techniques on how to directly stimulate the residual hearing bypassing the air-bone gap will be described in the following chapters.

Some patients may benefit more than others from a VSB. Certain conditions may preclude the selection of a VSB for a particular patient. These conditions include patients known to be intolerant of the materials used in the implant (medical grade

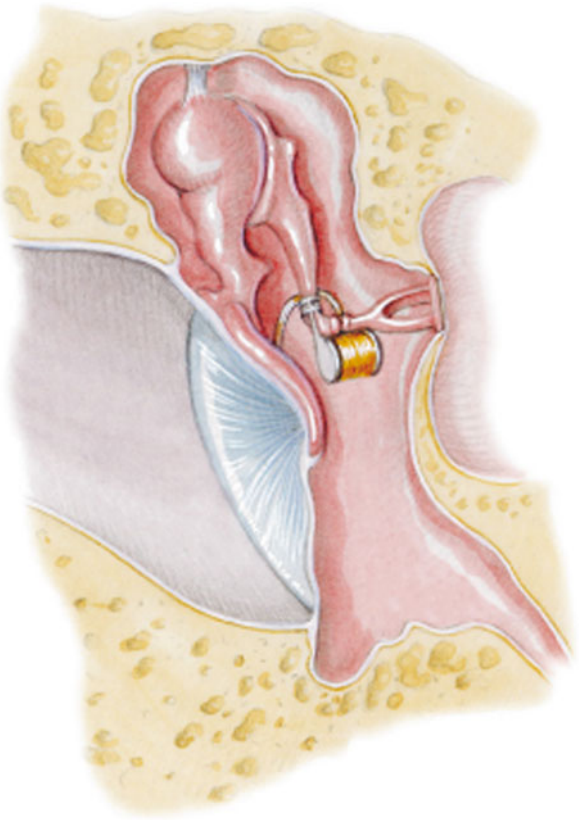

Fig. 4.4 Vibroplasty over the long process of the incus

silicone elastomer, medical grade epoxy, and titanium). It is very important to assess retrocochlear components or central auditory disorders prior to implantation, because such patients are not indicated for a middle ear implant. Special attention should also be given to patients with nonresponsive active ear infection or chronic fluid in the ear as well as to patients whose hearing loss has demonstrated an improving or decreasing fluctuation of 15 dB in either direction over a 2-year period.

Surgery

In 1996, Prof. Ugo Fish implanted the first patient with sensorineural hearing loss. This type of vibroplasty involves partial mastoidectomy with posterior tympanotomy [2]. Through this access, the FMT is introduced into the middle ear space. The FMT is attached by the titanium clip to the long process of the incus, while the VORP is located in a small bed on cortical temporal or parietal bone (Figs. 4.4 and 4.8).

Years later, Vittorio Colletti [3–5], proposed that the VSB could improve profound/severe conductive or mixed hearing via placing the FMT in the round window (Figs. 4.5 and 4.9). This milestone opened up many possibilities to place the FMT

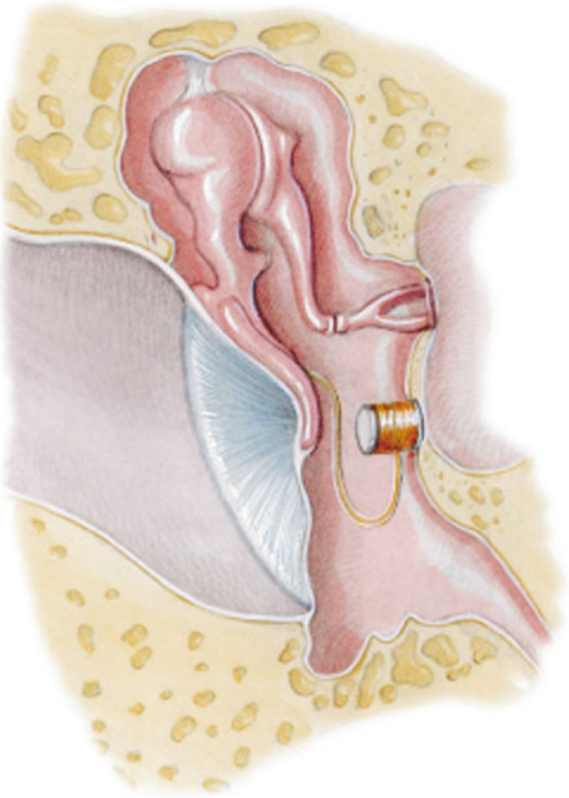

Fig. 4.5 FMT directly on the round window

into the middle ear in various positions and reflects the original idea of Geoffrey Ball – inventor of the Vibrant Soundbridge – which aimed to be able to place the FMT on any mobile structure of the middle ear. Additional accessories, the so-called couplers, also foster the flexibility during surgery, and with their help, the surgeon can place the FMT onto the head of the stapes, into the round window, and the oval window and thus avoids having to reconstruct certain middle ear structures. Thus the prosthesis can be placed on the ossicles (incus or stapes), round window, oval window, or with passive (TORP and PORP) prosthesis (Figs. 4.6 and 4.7).

Later on, Dr. Milo Beltrame from Italy classified the vibroplasty as COR (C is chain, O is oval window, and R is round window).

The original vibroplasty was developed for patients with sensorineural hearing loss who had complete and mobile ossicular chain. However, FMT placement was started in those patients who did not have the full ossicles, could fit on the head of stapes, in one of the crura or directly on the footplate. Some patients need a coupler for the perfect contact with the footplate or a stapes superstructure. These techniques are used with TORP, PORP, or couplers (see Figs. 4.6 and 4.7).

This currently widespread option is the placement directly on the round window which is based on the theory of sonoinversion by Garcia Ibanez. This theory, now proven, explains that the cochlea can be stimulated from the round window in reverse,

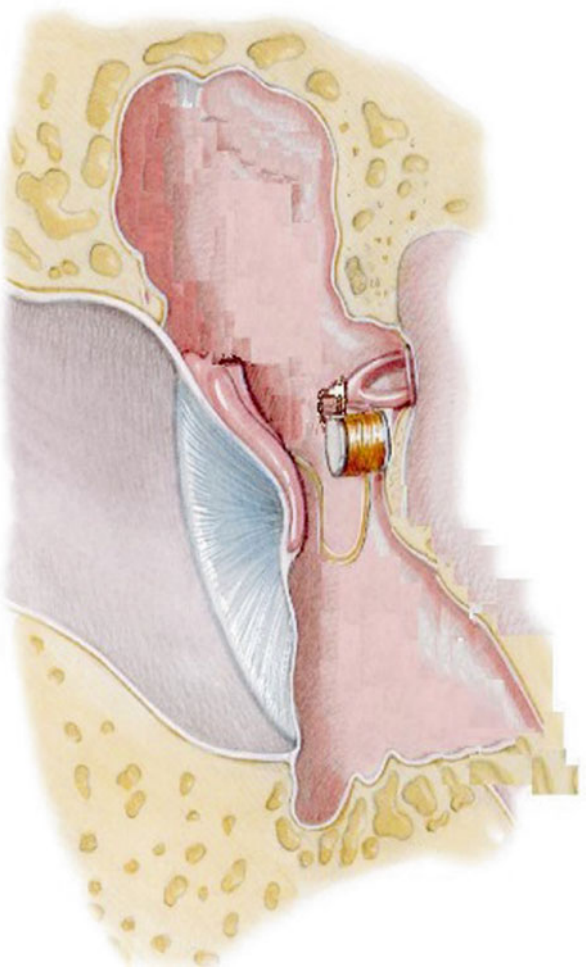

Fig. 4.6 FMT clipped on the head of the stapes

and the patient can hear normally. On this basis Colletti designed the round window technique which requires partial drilling of the overhang covering the round window membrane. The membrane is covered with a small piece of fascia or some synthetic material as pericardium to protect it, and the FMT without its clip is placed directly onto the round window membrane. A better fit is obtained by putting small pieces of cartilage in the hypotympanum to press the FMT over the round window and to prevent it from movement. Furthermore with the use of the round window coupler, a better coupling can be achieved between the surface of the membrane and the FMT [3–6] (Figs. 4.5 and 4.9). It is necessary to mention that the couplers are merely passive prostheses which allow a better coupling of the FMT, are very useful in patients with difficult anatomy, and improve the performance of the vibrating prosthesis.

Another option is the creation of the "3rd window." This is a fenestration or a cochleostomy to expose the membranous labyrinth in the promontory to place the FMT directly over the structures of the inner ear. It is a very difficult and risky technique, and the results are poorer than the results from the other options.

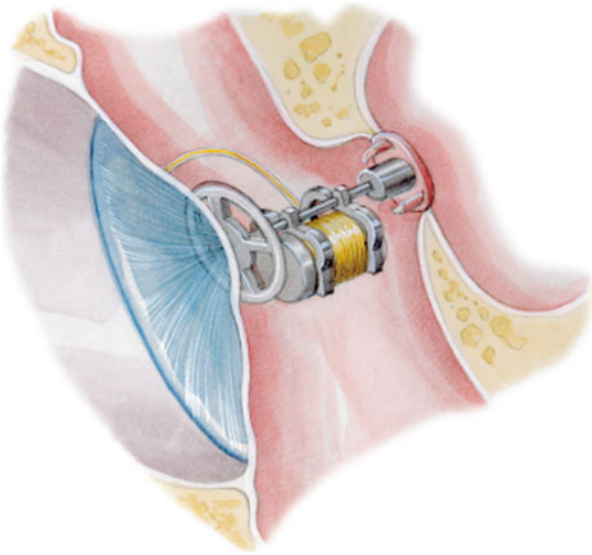

Fig. 4.7 Attached with a TORP

Approaches

As in cochlear implants, there are several approaches to place the FMT in the middle ear structures.

For Non-sensorineural hearing loss (NSHL) the facial recess approach is the most common (the most widely used also in CI). Here it should be noted that the only difference to the classical technique is that we make a generous posterior tympanotomy to allow passage of the FMT (see dimensions) and then to use the forceps when we perform the adjustment.

There are other techniques originally described for cochlear implant surgery and which can also be used for VSB implantation such as the suprameatal approach (SMA) designed by Lela Migirov and Jona Kronenberg or the endomeatal approach (EMA) described by Victor Slavutsky and Nicenboim, where a groove is carved in the bone of the external auditory canal where the cable is placed, without mastoidectomy. The groove is covered with bone pate and the skin of the EAC.

(a) Vibroplasty in sensorineural deafness
This was the original indication and technique. In this case, the FMT directly stimulates the ossicular chain. And the facial recess is used to reach the middle ear space. A wide tympanotomy is required to tighten the clip with a special forceps. The reviewed publications refer to a mean functional gain near to 30 dB [2, 7] (Fig. 4.8).

(b) Vibroplasty in Congenital Aural Atresia (CAA):
In our experience, CAA represents a challenging situation, especially due to abnormalities in the normal anatomy in the external and middle ear. Usually we performed the approach in two ways: directly through the atretic placode or through a mastoidectomy and atticotomy to reach the middle ear space.

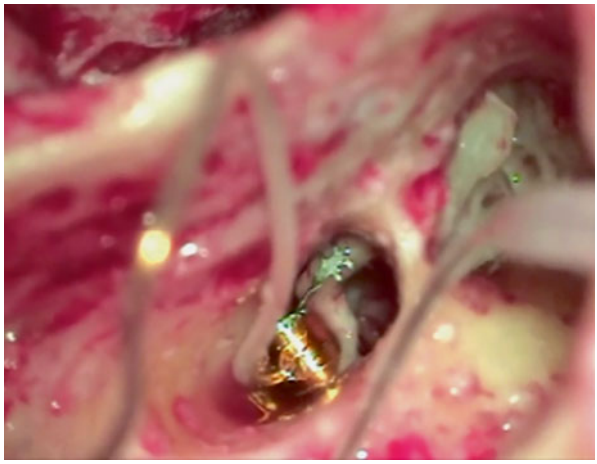

Fig. 4.8 FMT clipped on the long process of the incus

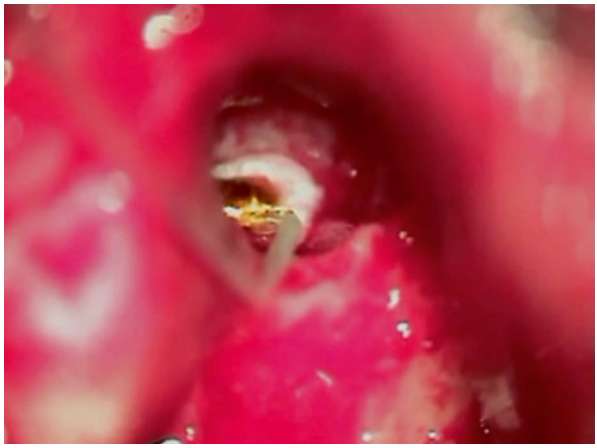

Fig. 4.9 FMT in the round window, previously covered with fascia

The ossicular chain is often malformed, especially the incus-malleus complex. In these cases, there are two possibilities for the FMT placement: into the round window or in the stapes. In the round window technique, a piece of fascia is used to cover and protect the round window membrane, and the clip is cut off. In patients where the FMT was placed on the stapes superstructure, the clip is put on a crura, while in patients with good and mobile stapes, the FMT is placed onto the head. There is a third but less effective alternative as well, when the FMT is directly placed over the footplate or, with a coupler, into the oval window. Finally, only in difficult anatomies, a fenestration is the last option which is called as the third window technique [8] and is only recommended when the anatomy of the middle ear is fully altered (a case with the facial nerve covering both windows) [9–12] (Fig. 4.9).

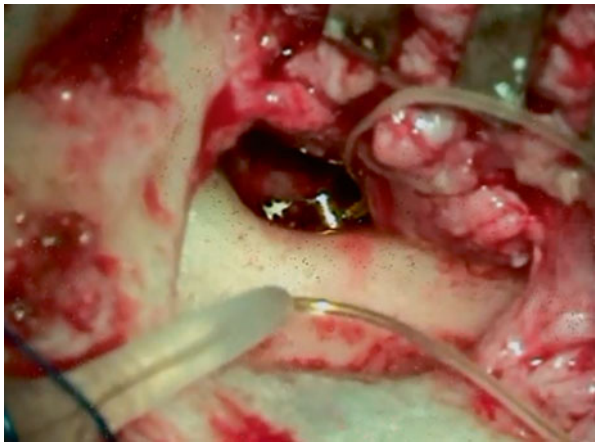

Fig. 4.10 FMT attached to the stapes in a patient with open cavity

(c) Vibroplasty in Chronic Otitis media:
In chronic otitis media, there exist and have been described numerous techniques and prostheses to restore hearing. The ossiculoplasty with many variants of prostheses (TORP, PORP) and different materials (hydroxyapatite, titanium, Teflon, steel, etc.) has only partially solved the problem. While we have established and standardized surgical techniques, functional failure often leads the patient to disappointment because the only alternative remains the conventional hearing aid. Unfortunately, in some cases of otitis media, especially for patients who have sequelae at the tympanic membrane (have perforations or tympanosclerosis) or have large open cavities, the use of conventional hearing aids is difficult and often unsatisfactory. For these patients, vibroplasty represents a good option. Streitberger [13] presented a series of patients, suffering from chronic otitis media with cholesteatoma, who have been implanted with the VSB [14–16]. The preoperative thresholds were 82.38 dB SPL, while thresholds in word recognition were 94.28 dB SPL. Three months later this group obtained audiometric thresholds of 50.63 dB SPL with vocal audio to 61.68 dB. After 6–9 months tonal audiometric thresholds were 47.89 dB SPL and the word recognition test of 53.33 dB SPL [13]. In our study we obtained an average functional gain of 35, 40, 48.7, and 45 dB for the frequencies 500, 1,000, 2,000, and 4,000 Hz, respectively [17].

In many cases, the patients presented open cavities. The implantation of VSB or even cochlear implants in this kind of cavities is really a problem. In these cases, there are two main possibilities: the first one is the obliteration of the mastoid cavity. After the placement of the FMT, in RW, or on the stapes (Fig. 4.10), an obliteration is necessary to avoid extrusion. In this technique, we cover the middle ear space with little pieces of cartilage. After that, we put a rotational muscular flap from the sternocleidomastoid muscle or the digastric muscle into the cavity. The blockage of the Eustachian tube is required. Finally, the use of abdominal fat to cover all the mastoid cavity and closing the external auditory canal is mandatory. In addition, this is an excellent technique to avoid

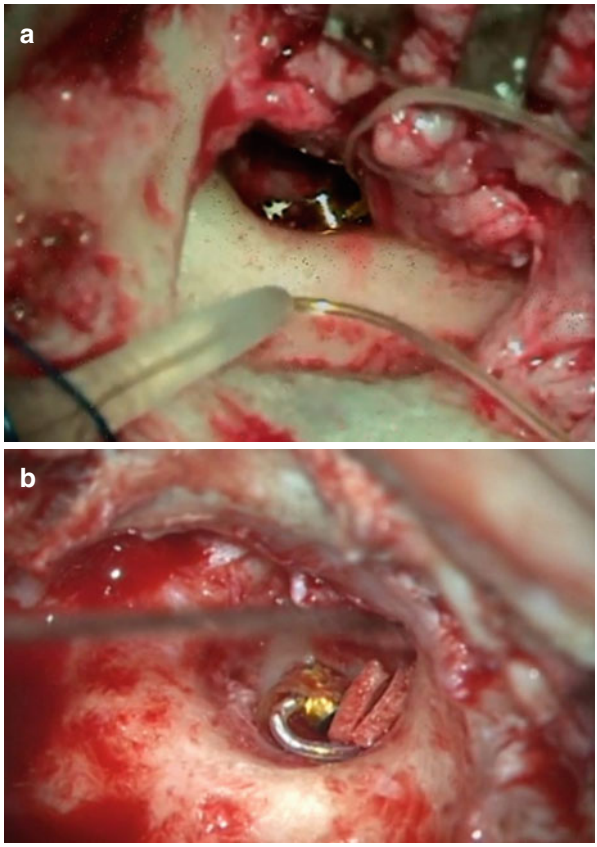

Fig. 4.11 (**a**, **b**) The subfacial approach with the FMT in front of the vertical portion of the facial nerve (Pictures courtesy Prof. Santiago Arauz)

extrusion. In many patients suffering from cholesteatoma, it is very difficult to observe and follow-up the cavity postoperatively. In case of recurrent cholesteatoma, the surgery can be very difficult.

The alternative to this approach is the so-called "subfacial approach" (Fig. 4.11a, b). In this approach, the facial nerve is "used" to anchor the cable of the VSB. A normal anatomy is required to do this technique, specially the jugular bulb should be located in a normal position. The technique consists of making a tunnel behind the third portion of facial nerve to reach the hypotympanum and penetrate the middle ear space. As seen in the figure, the cable goes from the mastoid cavity to the middle ear. The advantage of this technique is the posterior control of the cavity, because the closure of the EAC and the mastoid is not necessary. Only we need to cover the hypotympanum with cartilage to exclude the FMT from the rest of the middle ear. In the mastoid, a groove to put the cable is necessary, and it is covered with bone dust and cartilage. Finally, normal temporalis fascia is used to line the floor of the cavity. In this way one can control the residual or recurrence of cholesteatoma.

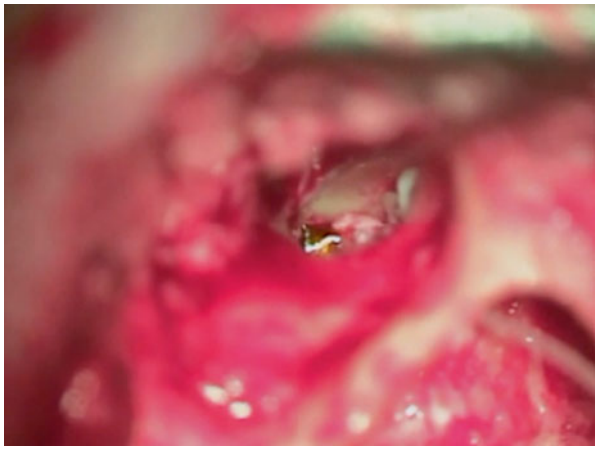

Fig. 4.12 Teflon prosthesis stapedotomy with FMT in the round window

(d) Vibroplasty in otosclerosis
Otosclerosis that produces severe mixed hearing loss means a challenge for treatment. Usually the patients need stapedectomy to improve the conductive component of the hearing loss, but even after a successful surgery, these patients need additional auditory equipment (hearing aid) to improve bone conduction already committed significantly. The VSB can be used in two different surgical techniques.

The first is stapedectomy and the simultaneous placement of the VSB on the incus, while the second alternative is the FMT placed directly into the round window, without stapedial surgery. In the latter case it is necessary to make a stapedotomy and cover it with fascia to recover the membrane's movement (Fig. 4.12).

Complications

Complications during vibroplasty are similar to the ones during cochlear implantation. While minor complications can be solved in outpatient settings, major complications can require the rehospitalization of the patient with revision surgery.

Extrusions, partial or total flap necrosis, and migration of FMT typically count as major complications.

Partial extrusions are more frequent in patients suffering from chronic otitis media with previous radical cavities (canal wall down), where some portion of the cable appears in the open cavity or in the external auditory canal. This is due to the failure to cover the cable of FMT, which in these cavities should be performed with cartilage and bone pate. The solution in these cases can be the drilling of a groove in the floor of the external auditory canal bone covered with cartilage and bone pate

or performing an obliteration surgery with closure of the external auditory canal and permanent blockage of the Eustachian tube.

The subfacial approach offers another alternative. This method anchors the cable below the facial nerve preventing it from extrusion and leaving the open cavity for inspection and cleaning.

Finally, complications can occur due to displacement of the FMT from the round window which results in the sudden loss of hearing gain. In these cases, evaluation with multislice computed tomography is mandatory to see the FMT displacement and to explore the possibilities of surgically reposition the FMT in the same place or even in another position. Temporary facial palsy, seroma, hematoma, and minor skin infections are the main minor complications.

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The Envoy Esteem® Hearing Implant

5

Alex D. Sweeney, Matthew L. Carlson,
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Introduction

Hearing aids have evolved significantly since the use of ear trumpets in the seventeenth century and vacuum tube amplifiers in the early twentieth century. Advances in technology have led to the development of devices that are considerably smaller and more powerful than those that were first marketed to the hearing impaired. However, despite these improvements, a substantial portion of patients with hearing loss are not regular hearing aid users, citing concerns over cost of purchase and device maintenance, cosmetic appearance, discomfort and ear canal irritation, signal distortion, feedback, and insufficient gain [1]. The impetus for the development of active middle ear implants was to overcome many of the drawbacks of conventional air conduction hearing aids [2–4]. Theoretically, a totally implantable system would afford complete concealment and improved freedom, permitting water exposure and use during sleep. Furthermore, by utilizing an implantable microphone and vibromechanical transducer, the ear canal can be effectively bypassed and feedback minimized. The Envoy Esteem® remains the first and only completely implantable hearing aid to have approval by the United States Food and Drug Administration (FDA) for patient use. The Esteem utilizes a unique implanted piezoelectric sensor and driver system that receives, processes, and amplifies sound. This chapter will address the history of the Esteem® Hearing Implant and provide a summary of its surgical implantation and clinical outcomes.

Disclosures Michael E. Glasscock III, MD, is a consultant and stockholder in Envoy Medical. There are no other relevant financial disclosures.

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Device History

Though the Esteem® is a relatively new device, the concept of an implantable hearing aid has existed since the early twentieth century. Alvar Wilska, a Finland-born physiologist, induced middle ear vibration by placing ferromagnetic pellets on the tympanic membrane and subjecting them to an external magnetic field in the 1930s. Rutschmann later expanded on this concept by gluing magnets onto the umbo [5]. The first devices to include actual middle ear implants did not emerge until later in the twentieth century. In the 1970s and 1980s, implants were designed to attach onto the ossicular chain or round window to amplify vibration conducted through the tympanic membrane [6]. Since that time, piezoelectric and electromagnetic forces have been harnessed, and many different devices have emerged.

The Esteem® Hearing Implant was developed by the Envoy Medical Corporation (formerly St. Croix Medical), and in 2010, it was distinguished as the first fully implanted middle ear hearing aid to receive FDA approval. Research and development efforts began in the mid-1990s, and the results of a multicenter, phase one clinical trial were published in 2004 [7]. This trial was conducted in a prospective, nonrandomized fashion with patients acting as their own controls though unaided and aided audiometric testing prior to and following surgery. Study subjects were implanted in their worst hearing ear or, in the case of equivalent bilateral function, in the ear of their choosing. Seven patients received the implant with four reporting hearing benefit immediately after activation and two reporting benefit after replacement of malfunctioning internal components. Compared to best-fit conventional hearing aids in the preoperative period, patients reported improved hearing in noise and word recognition as well as similar functional gain and speech reception thresholds. The results of a multicenter phase two trial were published in 2011 [8]. Fifty-seven patients with mild to severe SNHL and speech discrimination greater than 40 % were implanted. Subjective and objective benefit was noted at 12 months following implantation in the form of improved speech reception thresholds and word recognition score. Following the conclusion of this trial and FDA approval, the device was openly marketed for use in patients.

The function of the Envoy Esteem® relies on principles of piezoelectricity, which coincidentally have been described elsewhere in the natural hearing apparatus as a critical component of cochlear outer hair cell function [9]. Piezoelectric materials are able to generate a mechanical response to an electric current and conversely generate an electric current with mechanical stimulation. The cyclic conversion of mechanical energy into electrical energy allows for energy harvesting, which is partially responsible for the efficiency of a piezoelectric device [10]. In the case of the Esteem®, there are two separate piezoelectric transducers placed at different locations along the ossicular chain (Fig. 5.1). Specifically, one transducer is coupled with the incus and communicates though a processor implanted under the postauricular scalp with a driver implanted coupled to the stapes (Fig. 5.2). The driver applies a mechanical force to amplify the natural, conductive pathway of hearing (Fig. 5.3). With the processor implanted and the native tympanic membrane acting

Fig. 5.1 The Esteem® Implant showing the sound processor and the two piezoelectric transducers (Courtesy of Envoy Medical)

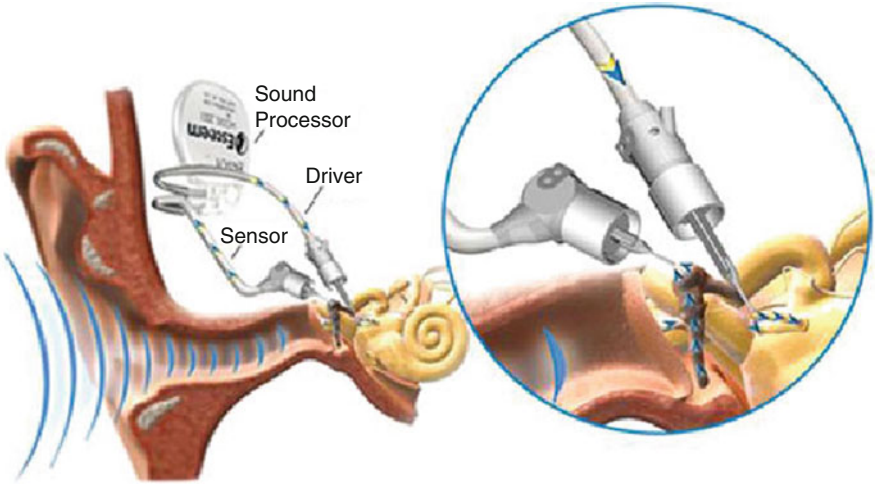

Fig. 5.2 The Esteem® device fully coupled to the ossicles (Courtesy of Envoy Medical)

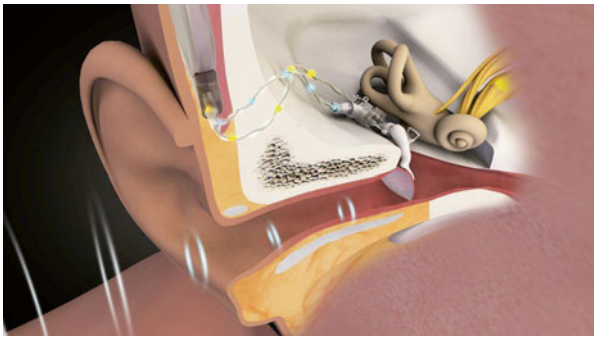

Fig. 5.3 The fully implanted Esteem® device. The tympanic membrane serves as a microphone, and the piezoelectric sensor delivers sound energy to the processor, which then communicates with the piezoelectric driver (Courtesy of Envoy Medical)

as a microphone, there is no external part of the device. This design grants the user improved freedom compared to external hearing aids by allowing use while swimming, bathing, and sleeping.

As with most hearing aids, there are financial considerations associated with the Esteem®. The estimated cost of the device with surgical implantation is $30,000 [11], and insurance coverage is inconsistent. Neither Medicare nor Medicaid currently covers the Esteem®, which is also the case with many private insurers. Therefore, payment for the device often falls on the consumer.

Clinical, Audiological, and Radiological Indications

The indications to use the Esteem® have evolved since the early clinical device trials. During the phase one trial [7], the Esteem® was approved for patients with moderate-to-severe hearing loss and speech discrimination scores greater than 60 %. Currently, the device is indicated for use in patients 18 years of age or older, with stable bilateral moderate-to-severe sensorineural hearing loss, unaided speech discrimination scores greater than or equal to 40 %, normal Eustachian tube function, and normal middle ear and tympanic membrane function and anatomy. Additionally, patients must have trialed an optimally fitted hearing aid for a minimum of 30 days and have radiographic evidence of an adequately sized mastoid to house the implant [12] (Table 5.1). Contraindications to implantation include a postadolescent history of middle ear disease, ongoing otitis externa, Meniere's disease, or retrocochlear pathology; a comprehensive list is outlined in Table 5.2 [12]. Though clinical studies have yet to evaluate the feasibility of cochlear implantation following Esteem® implantation in the setting of progressive sensorineural hearing loss, the Esteem® does not theoretically prohibit cochlear implantation in patients who experience further deterioration of pure tone or speech recognition scores.

Per the manufacturer's recommendations, preoperative imaging should be routinely performed to assess the feasibility of implantation with regard to the bony anatomy of the temporal bone. Non-contrast, high-resolution computed tomography (CT) is the preferred modality for this purpose. Barbara et al. recommended

Table 5.1 Indications for the Esteem®

18 years of age or older
Stable bilateral, moderate-to-severe sensorineural hearing loss defined by pure tone average at 500,1,000, and 2,000 Hz
Unaided speech discrimination score greater than or equal to 40 %
Normal Eustachian tube function
Normal middle ear anatomy
Normal tympanic membrane
Adequate space for the Esteem® implant determined by high-resolution computed tomography scan
Minimum of 30 days of prior experience with appropriately fitted hearing aids

As described by the FDA – Esteem® Implantable Hearing System – P090018 [12]

Table 5.2 Contraindications for the Esteem®

History of postadolescent chronic middle ear infections, inner ear disorders, or recurring vertigo requiring treatment for mastoiditis, hydrops, or Meniere's disease
Fluctuating air conduction and/or bone conduction hearing loss over the past year of 15 dB in either direction at two or more frequencies (from 500 to 4,000 Hz)
Otitis externa or eczema of the outer ear canal
Cholesteatoma or destructive middle ear disease
Retrocochlear or central auditory disorder
Tinnitus that requires treatment
History of keloid formation
Hypersensitivity to silicone rubber, polyurethane, stainless steel, titanium, and/or gold
A preexisting medical condition that may affect the healing process
Pregnancy

As described by the FDA – Esteem® Implantable Hearing System – P090018 [12]

specific evaluation of facial recess size, the proposed location of the implanted sound processor, and the position of the sigmoid sinus and external ear canal wall relative to one another [13].

Surgical Procedure

The Esteem® is implanted under general anesthesia. A lazy "S" incision is performed in which the inferior limb consists of the standard postauricular incision for mastoidectomy. A mastoidectomy is then performed with care to widely expose the body of the incus in the antrum. An enlarged facial recess is then performed to expose the incudostapedial joint and allow for complete insertion of the transducers into the middle ear. Due to the latter step, the chorda tympani is frequently encountered. The consequences of this relationship are discussed later in the chapter. Once ossicular mobility is confirmed, the incudostapedial joint is separated and the distal

portion of the long process of the incus is removed using a cutting laser. The piezoelectric sensor and driver are then cemented to the body of the incus and stapes capitulum, respectively. Prior to the end of the procedure and surgical site closure, the device is tested with a microphone speaker system, a laser Doppler vibrometer, and a system analysis software to ensure proper implantation and device integrity. In most cases, the procedure can be performed on an outpatient basis.

The range of operative times has varied among patients and studies. A general trend toward shorter operating times with increased experience suggests that there is a learning curve for surgeons performing the procedure. Barbara et al. described an average operative time of 5 h and 45 min with a range between 3 h and 50 min and 8 h and 10 min [13]. Kraus et al. reported a range of operative time between 3 and 6 h [8]. In both studies, the last patients implanted generally had shorter operations.

Device Programming and Troubleshooting

Programming of the Esteem® follows a standard protocol. The Esteem® is usually activated no sooner than 2 months following surgical implantation to allow for postoperative healing. An audiologist performs activation through a programming device referred to as the "commander." This device assesses the implant's function and performs programming. In some cases, multiple programming sessions may be needed for functional optimization [14]. After this step, the patient is given a personal remote to adjust volume, to select preset programs depending upon the listening environment, and to turn the device on and off.

The Esteem® implant is powered by a non-rechargeable lithium ion battery. The device generally requires battery exchange every 3–9 years with the manufacturer's disclaimer that certain forms of use may reduce battery life [12]. When the battery has expired, a battery replacement can be performed under local anesthesia in a procedure that takes up to an hour. The piezoelectric transducers do not need to be removed to exchange the battery. Per the manufacturer, the lower end of battery life expectancy occurs with frequent loud noise exposure and/or constant use, 24 h per day [15].

For the protection of the device, there are certain post-implant precautions emphasized by the manufacturer. Due to the location of the processor under postauricular soft tissue, trauma to the surgical site must be avoided. Additionally, the application of external pressure, such as what would be produced by underwater diving to depths beyond to 10 m, is contraindicated. Hat wearing is acceptable as long as the hat does not put pressure directly on the processor. Electric current cannot come in contact with the device, which requires avoidance of electroconvulsive therapy. Monopolar electrocautery use is possible with the device turned off, though there cannot be direct contact with the electrocautery instrument. Magnetic resonance imaging is contraindicated in implanted patients, and metal detectors may be triggered by the Esteem®. The use of cell phones and other household electronics may cause feedback when in close proximity to the implanted ear, but this effect is reported to be temporary [16].

Table 5.3 A summary of current literature on the Esteem® implant

Author, year published	Number of patients	Age range	Patients successfully activated at 2 months following surgery
Chen et al. [7], 2004	7	43–88 years	3
Kraus et al. [8], 2011	57	43–88 years	57
Murali et al. [17], 2009	3	22–38 years	3
Barbara et al. [13], 2009	6	Not reported	3
Barbara et al. [21], 2011	21	Not reported	17
Memari et al. [14], 2011	10	21–56 years	10
Monini et al. [18], 2013	15	18–74 years	15

Outcomes

As the Esteem® is a relatively new device, long-term outcome data is limited. However, the available literature is encouraging with regard to implant-aided functional gain and speech recognition improvement. A summary of several studies can be found in Table 5.3.

Device performance is commonly assessed using both objective and subjective outcome measures and is frequently compared to unaided and optimally aided hearing. Commonly evaluated objective outcomes include functional gain and speech recognition improvement, while subjective measures generally utilize questionnaires evaluating overall satisfaction, presence of feedback or distortion, sound quality, and subjective improvement in speech understanding in noise. A summary of published performance outcomes is outlined in Table 5.4.

The literature demonstrates that the Esteem® can provide statistically significant improvements in functional gain, speech perception, and subjective outcomes compared to the preoperative unaided condition. Murali et al. and Barbara et al. demonstrated more favorable postoperative implant-aided pure tone thresholds, mean SRT, and discrimination scores at the time of implant activation [13, 17]. In a larger study of 57 recipients, Kraus et al. reported a statistically significant improvement in functional gain and word recognition scores between the preoperative unaided condition and the implant-aided condition at 6 and 12 months following surgery [8]. Several subsequent studies have corroborated these findings [18]. In a recently published meta-analysis, Klein et al. reported pooled averages of 18.6 dB in functional gain and 26.5 dB in SRT improvement among previously published studies [19].

Recent studies have reported that the Esteem® generally performs on par with optimally fitted hearing aids. In looking at the outcomes of 57 patients, Kraus et al. demonstrated an 11.8 ± 1.8 dB improvement in SRT compared to that of the preoperative best-fit aided condition. There was also a statistically significant improvement in word recognition thresholds reported. Sixty-two percent of patients were found to have improvement in speech discrimination when compared to the preoperative aided condition, while 27 % had equivalent results and 11 % were reportedly

Table 5.4 A summary of hearing outcomes reported after Esteem® implantation

Author, year published	Time elapsed from surgery to outcome assessment	Speech reception threshold or functional gain	Speech discrimination	Subjective assessment
Chen et al. [7], 2004	10 months	Equivalent compared to baseline aided at 500, 1,000, 2,000 Hz, worse at 3,000 Hz	Improvement compared to baseline aided	Improvement compared to baseline aided
Kraus et al. [8], 2011	12 months	Improvement compared to baseline aided[a]	Improvement compared to baseline aided[a]	Improvement compared to baseline aided[a]
Murali et al. [17], 2009	2 months	Not reported for all patients	Improvement compared to baseline aided	Not reported
Barbara et al. [13], 2009	2 months	Improvement compared to baseline unaided	Not reported	Not reported
Barbara et al. [21], 2011	2 months	Improvement compared to baseline unaided	Improvement compared to baseline unaided	Improvement compared to baseline unaided
Memari et al. [14], 2011	6 months	Improved compared to baseline aided	Improved compared to baseline aided	Improved compared to baseline aided in 4 patients, no change in 5 patients, worse in 1 patient
Monini et al. [18], 2013	5 months	Improvement compared to baseline aided	Improvement compared to baseline aided	Improvement compared to baseline aided[a]

[a]Indicates that the outcome achieved significance as determined by reported *p*-value or confidence interval

worse [8]. Evaluating a subset of the patients with profound high-frequency sensorineural hearing loss from the phase 2 trial, Shohet et al. demonstrated a statistically significant increase in both SRT and word recognition scores when compared to the preoperative aided condition [20]. Additionally, Kraus et al. report that the mean benefit of the Esteem® over the optimally aided condition was statistically significant in all measures of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire at 6 months following implantation [8].

A theoretical concern regarding the Esteem® device relates to cochlear damage after manipulation of the ossicular chain during implantation. In the phase 1 clinical trial, no bone conduction threshold shifts were seen [7]. In the phase 2 trial, one patient had an isolated 4,000 Hz 20 dB threshold shift in bone conduction at 12 months [8]. Barbara et al. demonstrated a slight increase in bone conduction thresholds when measured at device activation, though statistical significance was not determined [21].

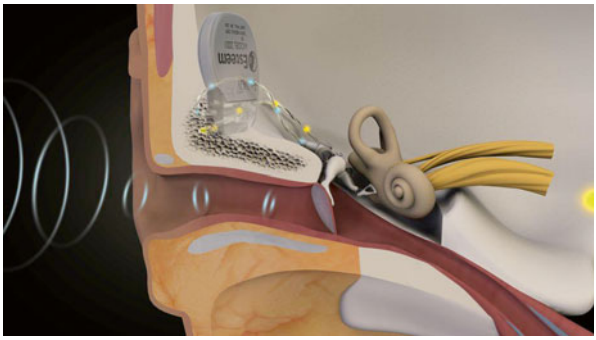

Fig. 5.4 Proper implantation of the Esteem® device requires separation of the incus and stapes. A piezoelectric driver is then attached to the stapes (Courtesy of Envoy Medical)

Complications

Complications arising from implantation and usage of the Envoy Esteem® are generally related to the surgical implantation or malfunction of the device itself. With regard to the former, there are certain aspects of the surgery that are inherently related to potential postoperative issues. Since the sensor and driver are both coupled to the ossicular chain, a portion of the incus must be resected in order to prevent feedback (Fig. 5.4). Such a maneuver is not without functional consequences. Though the gain of the device may overcome the resulting conductive loss, natural acoustic hearing would undoubtedly suffer if the device failed. This is made more relevant in the setting of a meta-analysis that identified 12 reoperations (seven for explantation and five for revision) for device-related performance issues [19]. Should the implant to become nonfunctional or require explantation, an ossicular prosthesis would have to be utilized in order to prevent a maximal conductive hearing loss resulting from an intact tympanic membrane and discontinuous ossicular chain.

The most common complications related to the implantation itself can be attributed to infection and the surgical exposure required for placement of the transducers. As previously described, the need for an enlarged facial recess can lead to chorda tympani damage. The phase 2 trial reported that the chorda tympani was damaged in 60 % of cases [8]. In a meta-analysis performed by Klein et al., chorda tympani injury was noted in 30 % of patients, though symptoms were transient in over half of cases. The facial recess approach can also lead to injury of the main trunk of the facial nerve. Some degree of facial paresis can occur in up to 8 % of cases, with a small fraction developing permanent weakness [19]. The incidence of perioperative infection is of concern in any surgical procedure, particularly one in which a foreign body is implanted and secured with bony cement. Up to a quarter of patients may experience otitis media or effusion following implantation [19]. Additionally, Kraus et al. reported an incidence of post-implant fibrosis of the ossicular chain in five percent of patients. However, it was noted that surgical revision allowed for functional salvage in such instances [8]. A summary of published adverse events is outlined in Table 5.5.

Table 5.5 A summary of adverse events reported after Esteem® implantation

Author, year published	Cases requiring surgical revision	Post-implant bone conduction (BC) thresholds	Procedure related adverse events
Chen et al. [7], 2004	3	No BC threshold shift noted	Wound infection requiring explantation (1 patient)
Kraus et al. [8], 2011	3	1 patient with BC threshold shift of 20 dB at 4,000Hz	Taste disturbance (19 %), imbalance/vertigo/dizziness (8 %), transient facial weakness (5 %), permanent facial weakness (1 %), infection (3 %)
Murali et al. [17], 2009	0	Not reported	Transient facial weakness (1 patient)
Barbara et al. [13], 2009	0	Not reported	Not reported
Barbara et al. [21], 2011	4	Trend toward increase in postoperative BC threshold	Not reported
Memari et al. [14], 2011	1	Not reported	Transient facial weakness (1 patient), permanent facial weakness (1 patient), taste change (1 patient), ossicular fibrosis (1 patient)
Monini et al. [18], 2013	0	Not reported	Not reported

Conclusions

The Envoy Esteem® Hearing Implant represents a promising development in implantable hearing aid technology. As a totally implantable device, it circumvents many of the concerns associated with conventional hearing aids and carries several advantages over other semi-implantable devices including greater freedom of use and improved concealment. In general, functional gain and speech recognition improvements are comparable to optimally fitted hearing aids; however, subjective patient-reported outcome measures frequently favor the Esteem. The fully implantable Esteem device offers an attractive alternative to conventional hearing aids and should be considered in patients with moderate-to-severe hearing loss who have difficulty with hearing aid fitting, feedback, or ear canal irritation.

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The Ototronix MAXUM System

6

Stanley Pelosi, Matthew L. Carlson,
and Michael E. Glasscock III

Introduction

In a considerable percentage of the hearing-impaired population, the benefits of conventional amplification may be limited by acoustic feedback, occlusion effect, and/or ear discomfort. Implantable and semi-implantable hearing devices (IHDs) have been developed as an option for patients who derive limited benefit from traditional HAs, but who are not yet candidates for cochlear implants. The Ototronix MAXUM System (Ototronix LLC, Houston, TX) is a semi-implantable device that amplifies sounds using electromagnetic energy transferred from an external ear canal mold to an internal surgically implanted magnet (Fig. 6.1).

Disclosures Dr. Glasscock III, MD, is the chairman of the Ototronix (Houston, TX) medical advisory board and has a minor equity position in Ototronix.

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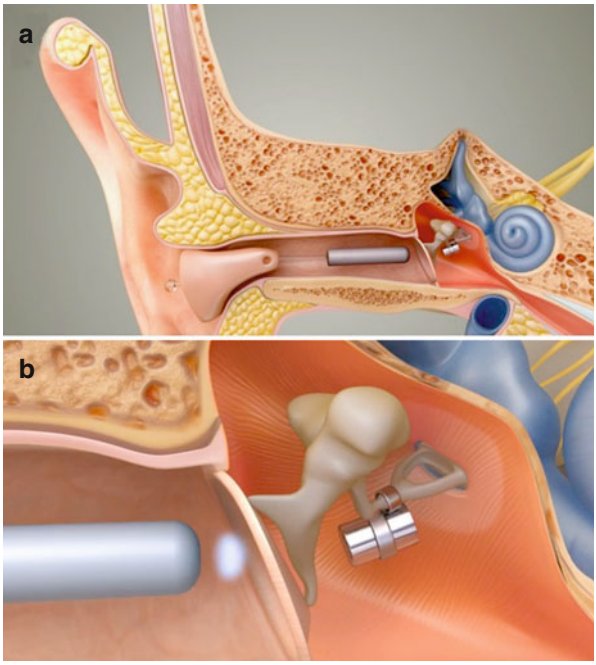

Fig. 6.1 (**a**, **b**) Semi-implantable MAXUM Hearing Implant utilizing an open-fit, completely in-the-canal electromagnetic sound processor

Device History

The MAXUM system is based on technology first developed by Jack Hough and colleagues. The primary issues that were addressed during initial development included device biocompatibility and the mechanism behind ossicular drive. A neodymium iron boron magnet was found to be powerful in its vibratory capabilities but of small size and weight, making it an ideal choice. Early implant designs incorporated a collar prosthesis that was placed around the incudostapedial joint [1]. However, deficiencies in device hermeticity permitted moisture penetration through the magnet housing leading to corrosion and degraded function. Subsequent modifications included use of a stronger magnet and a biocompatible titanium housing cylinder to prevent corrosion. Based on these modifications, in 2000, the SOUNDTEC Direct Drive Hearing System (SOUNDTEC Inc., Oklahoma City, OK) was introduced and preliminary outcomes reported in ten patients [2]. Subsequently, the Food and Drug Administration (FDA) approval was obtained in 2001 from the results of a large phase II clinical trial in 103 patients [3].

In 2009, Ototronix purchased the technology employed by the SOUNDTEC device and subsequently marketed it as the MAXUM system. The internal component is identical for both devices and consists of a permanent magnetic implant attached to the ossicular chain. However, the MAXUM system is unique in that it has a combined digital sound processor and electromagnetic coil worn in the ear

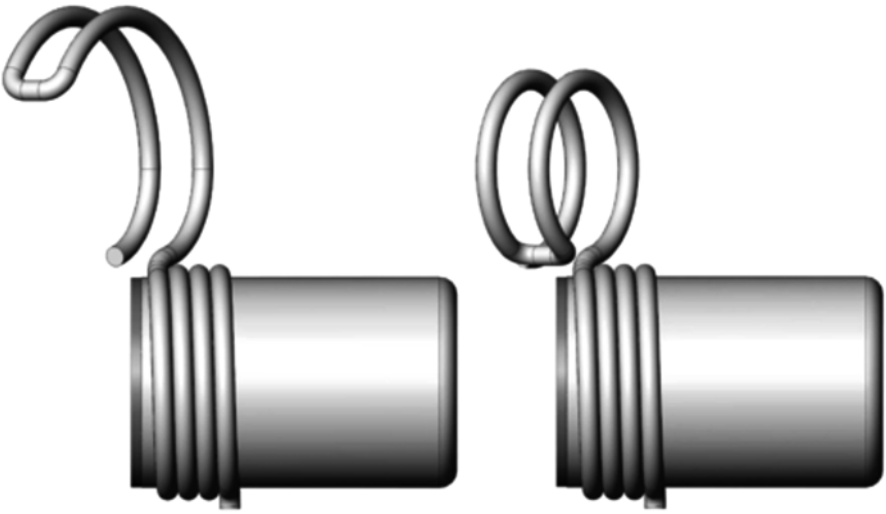

Fig. 6.2 The MAXUM split coil is shown in open and closed configuration. A 30° angle exists between the cylinder and the attachment coil to facilitate optimal implant alignment when attached to the IS joint

canal (known as the integrated processor and coil or IPC), while the SOUNDTEC device employed a behind-the-ear processor.

Device Details

All IHDs have several basic components including a microphone, signal processor, transducer, and ossicular driver that can stimulate the inner ear. The MAXUM system houses its microphone, processor, and transducer in a single external ear canal mold. Sound presented to a patient is received by the microphone, amplified, and processed into an electrical signal, which is then delivered to the electromagnetic coil in the ear canal mold. The charged coil then produces an electromagnetic field, which stimulates the magnet attached to the incudostapedial (IS) joint. Vibrations of the magnet are synchronous to the original sound input, which are then transmitted to the stapes and on to the cochlea. Because the MAXUM system, like all IHDs, does not use a speaker to amplify ambient noise, it eliminates the acoustic feedback seen with conventional hearing aids.

The implant magnet is composed of neodymium iron boron, housed in a titanium cylinder, and attached to an open wireform ring (Fig. 6.2). The cylinder measures 2 mm in length and 1.35 mm in diameter; the implant weighs 27 mg [2]. The open portion of the attachment coil is placed around the incudostapedial (IS) joint (Fig. 6.3). This coil is composed of Nitinol, a memory alloy which when exposed to heat will form a closed coil around the IS joint.

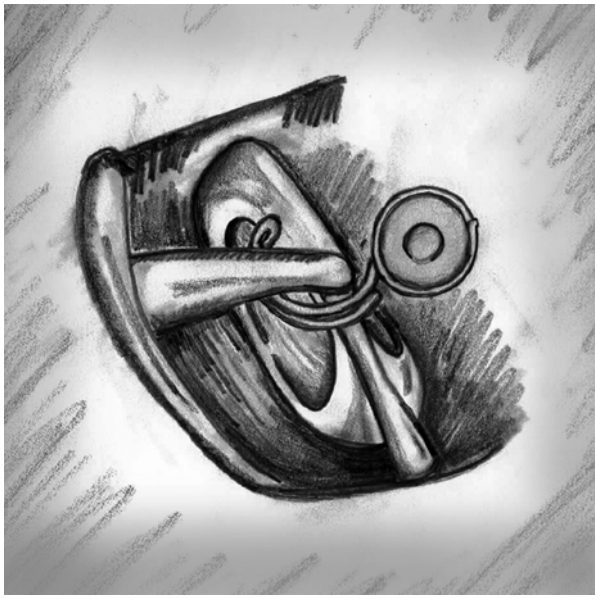

Fig. 6.3 The nonmagnetic MAXUM cylinder-holding forceps may be used to grasp the implant cylinder

Indications

Candidates for the MAXUM system include adults 18 years and older with moderate to moderately severe sensorineural hearing loss (SNHL). All patients should undergo a thorough otologic exam and audiometric evaluation prior to being considered for surgery. The ideal audiometric candidate is a patient with a high-frequency pure tone average (1, 2, and 4 kHz) between 35 and 70 dB, an air-bone gap of less than 10 dB, and a word recognition score of 60 % or better. Patients must have normal middle ear anatomy, no history of middle ear surgery, and no evidence of acute/chronic otitis media, retrocochlear lesions, or central auditory system pathology. Magnetic resonance imaging (MRI) can be helpful to exclude retrocochlear pathology in cases of asymmetric hearing loss, while computerized tomography (CT) can evaluate the extent of middle ear/mastoid pathology when concerns arise based on patient history or otologic examination.

Alternate options for hearing rehabilitation should be presented to patients prior to implantation, including the use of conventional HAs. Validated subjective questionnaires such as the Hough Ear Institute Profile [3, 4] may indicate reveal problems with conventional aids, including acoustic feedback, which can be reduced with an IHD. Patients should have a thorough understanding of surgical risks inherent to middle ear surgery, as well as realistic expectations of device performance.

Choice of ear to implant is based upon several considerations. In patients where there is objective asymmetry in air conduction thresholds, word discrimination scores, or speech reception thresholds, the poorer hearing ear is implanted first. When no objective difference is observed, the ear not used to talk on the telephone

is chosen. If no preference exists, then patient choice alone is used as a deciding factor.

The size and shape of the external ear canal must be assessed before surgery to ensure functionality of the device. Prior to surgical implantation, a deep ear canal impression is taken. In order for the ear canal to be able to accommodate the IPC, the external ear canal must be 20 millimeter (mm) in length, 4 mm in width at the canal aperture, and 3 mm in width at the second bend of the external ear canal to the tympanic membrane [5].

Surgical Procedure

The MAXUM system may be implanted under local anesthesia for most individuals using a transcanal stapedectomy-type approach. Oral and/or intravenous sedation is administered after obtaining intravenous access. The patient is positioned supine with the head resting on a foam cushion and tilted away from the surgeon, facial nerve monitoring electrodes are placed, and the surgical site is prepped and draped in the standard fashion for middle ear surgery. Ear canal injections are performed using a mixture of 1 % lidocaine with 1:30,000 epinephrine.

An incision is made along the posterior canal wall 5–7 mm from the annulus, and a tympanomeatal flap is elevated. The annulus of the tympanic membrane is identified and elevated out of its sulcus to enter the middle ear space. Posterosuperior bone of the medial bony canal is curetted, taking care not to injure the chorda tympani nerve. Bone should be removed until the IS joint, posterior stapes crura, and pyramidal process can be clearly visualized. Next, mobility of the ossicular chain is evaluated along with the position of the facial nerve. Attention is then directed toward the IS joint, the site of attachment of the MAXUM implant.

The surgeon should not directly handle the implant so as to minimize contamination of the implant. Nonmagnetic MAXUM surgical instruments are available for implant handling during package removal and insertion, including a cylinder-holding forceps (Fig. 6.4) and/or a suction insertion tool, controlled by a foot pedal allowing the surgeon to vary suction strength (Fig. 6.5). Once the implant has been introduced into the middle ear, the open portion of the attachment coil is placed around the IS joint (Fig. 6.2). A commercially available low-temperature heating device such as the SMart Piston Heating Device (Gyrus ENT, Stamford, CT) may be used for closure of the coil (Fig. 6.6). Attempts to manually crimp the coil may damage the implant and should be avoided. Older versions of the implant used a full coil (Fig. 6.7) which required separation of the IS joint to secure the implant. Surgical technique with the full coil has been previously summarized [6].

Performance of the MAXUM system will be affected by positioning of the implant. The electromagnetic coil in the ear canal mold and the magnet should be aligned in a parallel manner in order to maximize the magnet's vibratory capabilities and resulting functional gain of the device [2]. To allow for optimal alignment, the implant is designed with a 30° angle between the cylinder and the attachment

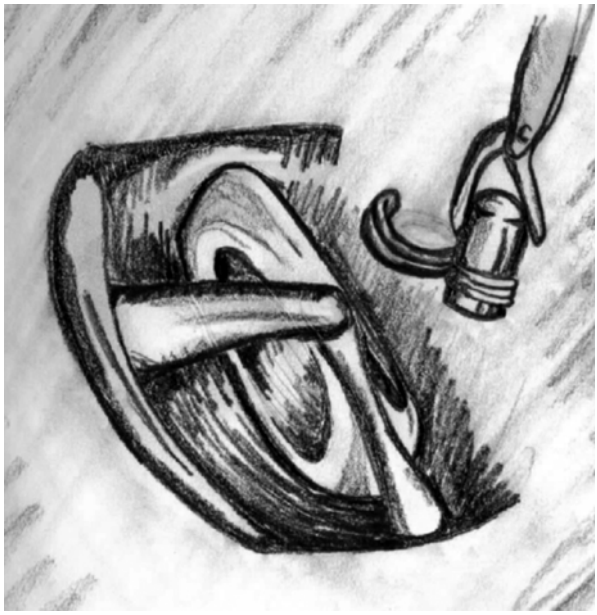

Fig. 6.4 The nonmagnetic MAXUM suction insertion tool may be used to grasp the cylinder. The surgeon can vary suction strength using a foot pedal attached to the insertion tool

Fig. 6.5 The open portion of the attachment coil is placed around the IS joint

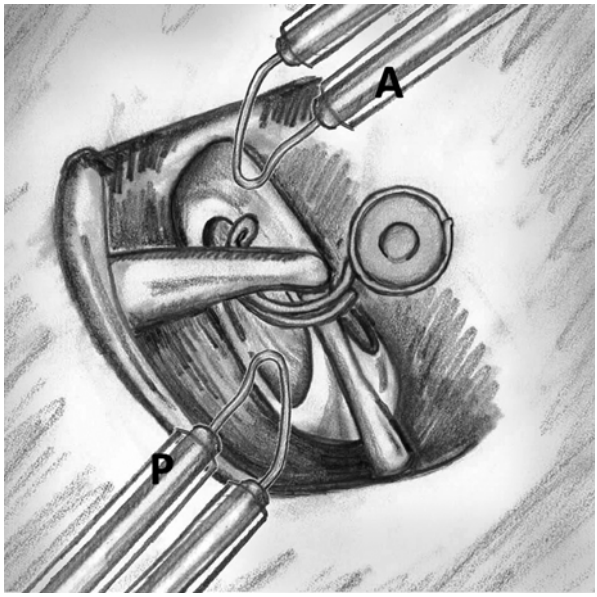

Fig. 6.6 A low-temperature heating device is used for closure of the attachment coil. Shown in the image is a rendering of the SMart Piston Heating Device (Gyrus ENT, Stamford, CT)

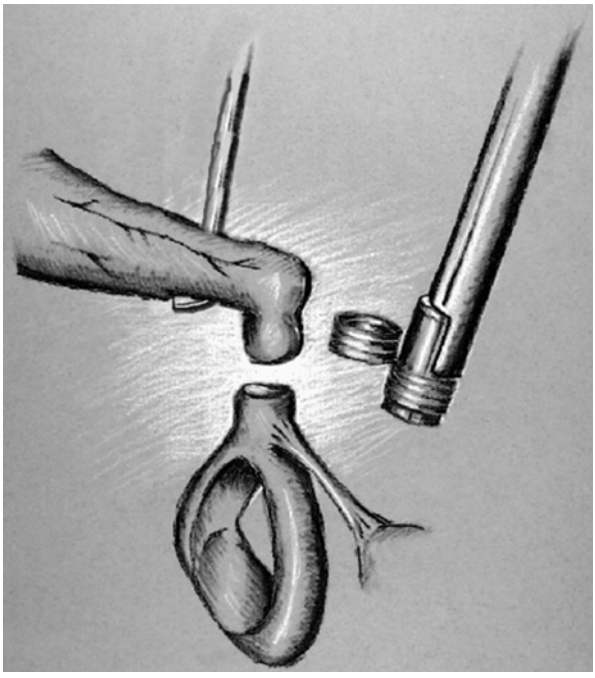

Fig. 6.7 The full-coil version of the wireform attachment ring requires separation of the IS joint

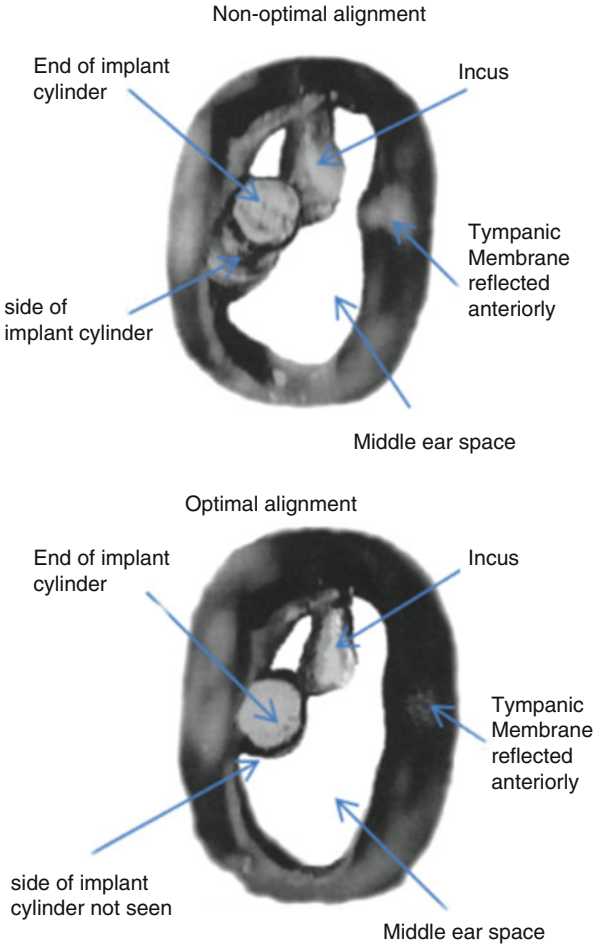

Fig. 6.8 Correct positioning of the implant cylinder parallel to the ear canal will allow the surgeon to see only the end of the cylinder, but not the sides

coil (Fig. 6.2). If the implant is situated correctly, it will be parallel to the ear canal and the surgeon will see only the end of the cylinder, but not the sides (Fig. 6.8).

A shorter distance between the external coil and the internal magnet will create a larger magnetic field and will increase the magnet's vibratory abilities. The attachment ring is designed to be off-center near the base of the magnet cylinder, thus positioning the magnet closer to the tympanic membrane. This design also reduces the likelihood of implant contact with the promontory, which is important for unimpeded magnet vibration. In cases where a high promontory is present, it may also be necessary to rotate the cylinder to avoid contact. The cylinder can be rotated in any one of three positions (Fig. 6.9) to prevent promontory contact.

Once the attachment coil is closed and implant position and alignment have been confirmed, the implant is stabilized with gelfoam. Nonmagnetic instruments are then used to return the tympanomeatal flap to its normal position. If it is found that the implant touches or closely approximates the tympanic membrane, placing a thin tragal cartilage graft just medial to the tympanic membrane may help prevent device extrusion.

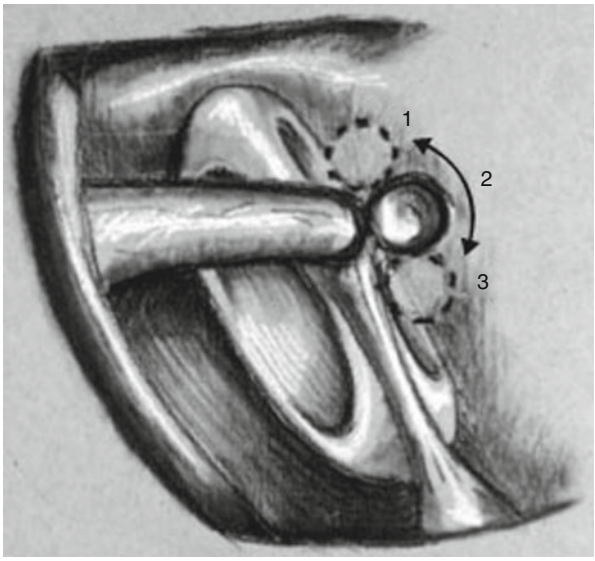

Fig. 6.9 The cylinder can be rotated in any one of the three positions to prevent promontory contact. Usually, position 3 is the most preferable to maximize the implant's distance from the promontory

Medical Follow-Up and Device Programming

The patient is discharged on the day of surgery. The use of postoperative antibiotics is at the discretion of the surgeon, and patients are instructed to follow similar precautions as other individuals undergoing middle ear surgery to reduce the likelihood of postoperative implant displacement. A list of postoperative instructions for MAXUM users is provided by the manufacturer and includes avoidance of nose blowing, exercise, straining, heavy lifting, and contact sports in the weeks after surgery [5]. Water precautions during the healing period are also recommended to reduce the risk of postoperative infection. Once healing is complete, water precautions are not required with the IPC removed. The external device is not waterproof.

Patients are seen for an initial visit 3 weeks postoperatively and are typically fitted with the IPC at that time. Initial device activation is performed with programming adjustments as needed to maximize functional gain and device comfort at various frequencies. Postoperative audiometric evaluation is typically performed about two months after surgery.

Officially, the manufacturer recommends that patients with the MAXUM system should not undergo MRI or be in close proximity to magnetic fields [5]. However, a few reports have examined MRI compatibility in the SOUNDTEC Direct System, which shares the same technology as the MAXUM. One study showed no patient or device-related complications in 11 patients with the SOUNDTEC device who underwent a total of 12 head, 1 shoulder, and 3 lumbar MRIs at a strength of 0.3 T [7]. A significant device-imposed limitation was image degradation in the region of the implant, limiting visualization of the ipsilateral temporal bone.

Other manufacturer precautions have been described for patients with the MAXUM system. The split-coil version of the MAXUM implant contains nickel, which may pose a small risk in patients with nickel hypersensitivity. Electric currents applied to the body in electroconvulsive therapy and diathermy, or during

surgical procedures with the use of monopolar cautery, are all contraindicated in patients with the MAXUM system, since these currents may damage the implant or cause additional patient hearing loss. Finally, the effects of radiation therapies such as cobalt treatment or linear acceleration on the MAXUM system are unknown.

Any device that creates electromagnetic fields, including anti-theft detectors and airport security devices, may cause sound distortion when using the MAXUM system but should not be harmful to the implant or patient. Silverstein et al. reported that patients experienced increased device vibration and noise in areas with surrounding magnetic fields (e.g., near power lines, security systems) [8]. Similarly, radiofrequency identification systems (e.g., keyless entry systems, toll roads) may occasionally cause abnormal sound perception by interfering with the MAXUM system. Finally, while certain conventional hearing aids have been associated with sound distortion when using a cell phone, the MAXUM system is generally considered to be compatible with cell phone technology.

Adverse Events and Complications

All patient candidates should be counseled regarding inherent risks of middle ear surgery including loss of residual hearing, infection, dizziness, taste changes, and facial nerve injury. Other perioperative risks may exist that are specific to the MAXUM system. The largest study reporting on adverse events associated with the technology used in the MAXUM system was a series of 103 patients implanted with the aforementioned SOUNDTEC Direct System device [3]. Perioperative events were relatively limited and most commonly included ear pain ($n=16$), taste changes ($n=2$), and tympanic membrane perforation ($n=2$). One perforation closed spontaneously, and the other required myringoplasty. During creation of the deep ear impression, seven patients developed small canal hematomas, and one patient sustained a tympanic membrane perforation, which healed spontaneously.

External processor failure occurred in 13 patients with the behind-the-ear SOUNDTEC device [5]. A proposed advantage of the MAXUM system over older technology is improved reliability of the digital sound processor found in the IPC. While no patients in the series experienced implant failure or extrusion, patients should be counseled regarding this theoretical risk.

Silverstein found that the most common complaint with the SOUNDTEC device was magnet movement in 55 % of implantees [8]. Three patients complaining of magnet motion underwent revision surgery for magnet stabilization with adipose tissue; they experienced postoperative symptom improvement. Four patients underwent explantation due to dissatisfaction with the device and subsequently were able to successfully use conventional HAs.

Long-Term Benefits and Outcomes

Table 6.1 summarizes outcomes from several reports with the technology used in the MAXUM system. The phase II trial by Hough et al. demonstrated that relative to a conventional HA, the SOUNDTEC device provided an average functional gain

Table 6.1 Clinical outcomes with technology used in the MAXUM system

Study	*n*	Length of follow-up (months)	Control	Residual hearing	Functional gain	Speech perception in quiet	Speech perception in noise
Roland et al. 2001 [4]	23	5	Conventional hearing aid	NS	Mean 9.9 dB > HA at 250–4,000 Hz[a]	NS	NS
Hough et al. 2002 [3]	103	12	Conventional hearing aid	Mean 4 dB AC loss (NS) Mean 1.1 dB BC loss (NS)	Mean 7.9 dB > HA at 500–4,000 Hz[a]	Mean 5.3 % improvement[a]	NS
Silverstein et al. 2005 [8]	64	3	Conventional hearing aid	21 patients with >10 dB mean BC loss	Mean 26 dB > post-op unaided thresholds	Mean 6 % decline (did not assess significance)	DNT

NS no significant difference
[a]Statistically significant difference

of 7.9 dB at 500–4,000 Hz [3]. Roland et al. reported a mean 9.9 dB functional gain relative to conventional aids in a subset of 23 patients enrolled in the phase II trial [4]. Finally, Silverstein et al. corroborated similar results when comparing the amplification provided by the SOUNDTEC device to previously published values of conventional HA gain [8].

Regarding word discrimination scores, Hough et al. demonstrated a statistically significant 5.3 % average improvement in speech discrimination scores with the SOUNDTEC device [3]. Speech-in-noise scores were also higher relative to conventional aids, although this improvement did not reach statistical significance. In comparison, Roland and colleagues found no significant differences in speech perception in quiet or noise [4], while Silverstein et al. reported a mean 6 % decline in word discrimination with the SOUNDTEC device compared with preoperative aided values [8].

Residual hearing after implantation was compared as well. Roland et al. reported no significant change before and after magnet implantation [4]. The phase II trial demonstrated that average air conduction thresholds declined by 4 dB overall and by more than 10 dB in 10.5 % of study participants [3]. Conductive hearing loss may occur after MAXUM implantation for several reasons. One consideration is weighting of the ossicular chain by the implant, with resulting impairment of ossicular vibration. Additionally, since these patients were implanted with the older full coil, temporary separation of the IS joint may have resulted in an additional conductive hearing loss. Increased use of the split coil in future procedures may reduce the degree of conductive loss seen in some patients after surgery.

Variable degrees of SNHL have been reported following implantation. Hough et al. reported an average decline in bone conduction thresholds of 1.1 dB, while Silverstein and colleagues found that 21 patients experienced an average bone conduction threshold shift of 10 dB or greater [3, 8]. One potential cause of sensorineural hearing loss during magnet implantation is ossicular manipulation causing excessive perilymph vibrations and inner ear injury. Such a loss may in part account for the aforementioned decline in postoperative word discrimination scores reported by Silverstein et al. [8].

Several studies have reported subjective patient outcomes for the MAXUM system technology as well. Patient questionnaire results from Hough et al. and Roland et al. showed a statistically significant improvement in patient satisfaction as well as a significant reduction in acoustic feedback and occlusion effect compared to conventional HAs [3, 4]. Silverstein et al. reported that 55 % of patients complained of magnet movement, necessitating device removal in certain instances (see section "Adverse events and complications") [8].

Conclusions

In patients who desire an alternative to conventional hearing aids, the MAXUM system provides a viable option for hearing amplification. Improvements in functional gain together with reduced feedback and occlusion effect have been

demonstrated with the technology in this device relative to HAs. Additional long-term data regarding outcomes, specifically with the newer generation split-coil implant and IPC, will help further define the value of the MAXUM system as an option for aural rehabilitation in the future.

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