Middle Ear Implants: An Alternative to Conventional Amplification

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Introduction

For the past few years, audiologists have heard increasingly more about the topic of implanting hearing aids in the middle ear, devices sometimes simply referred to as middle ear implants (MEIs). Research and development in this field is very active and early clinical trials of MEI devices are underway. This chapter introduces this relatively new area of amplification, and given the rapid pace at which the field is evolving, provides an update to previously published materials on the topic (Chasin, 1998).

When a patient has a conductive or mixed hearing loss that is not correctable by medical or surgical intervention, fitting of a conventional hearing aid typically provides excellent performance. For persons with sensorineural hearing loss ranging from mild to more severe degrees, advances in hearing aid technology and new adaptive signal processing approaches provide a wide selection of devices that are capable of providing significant benefit in most cases. For many patients with moderately severe to severe degrees of sensorineural hearing loss, however, conventional hearing aids can have a number of limitations. These limitations include the occlusion effect (e.g., the patient reports that it sounds like his head is “in a barrel”) and discomfort from wearing occluding earmolds, problems with acoustic feedback, poor perceptual sound quality, and high levels of distortion.

Partly for these reasons, there have been some efforts to reduce the degree of hearing loss at which cochlear implants are considered a viable treatment approach, so that patients with less severe hearing loss may be included in candidacy criteria. The problem is that although cochlear implants have been a major and important breakthrough for patients with severe to profound hearing loss, they do not provide full bandwidth signal cues like conventional amplification, nor is the surgery reversible if performance is poorer than anticipated. For the niche group of patients whose hearing loss is too severe for satisfactory performance with conventional hearing aids, but is not severe enough to justify cochlear implant surgery, MEIs have been proposed as an alternative. Most MEIs under development are intended for this niche group, although it is also notable that some MEI devices have been used on patients with milder hearing loss (Leysieffer et al, 1998), and others have been developed to assist patients who have a conductive component to their hearing loss (Yanagihara et al, 1988; Kartush and Tos, 1995). Patients with recurrent otitis media would not be
good candidates for implantation in the middle ear. The differences among devices and their target populations are discussed later in this chapter. Undoubtedly, the target population for MEIs will expand to those with less severe loss as the technology develops.

MEIs, like conventional hearing aids, have a microphone and circuitry for signal processing. In fact, many of the current semi-implantable MEIs use, as the external portion of the instrument, commercially available hearing aids that have been modified to transmit the signal to the implanted portion of the device. Unlike the output speaker of a conventional hearing aid, which delivers amplified sound through the external auditory canal, however, the MEI delivers sound directly to some structure of the middle ear, usually the ossicles. In the United States and for Europe, three MEIs are on the commercial market at the time of this writing [the Symphonix Vibrant® Soundbridge, the Otologics MET™ ossicular stimulator, and the SoundTec Direct Drive Hearing System (DDHS)].

Why is there such an interest in MEIs? The interest stems from the fact that these devices potentially offer advantages that cannot be found with conventional hearing aids. Theoretically, MEIs should be able to provide higher levels of undistorted amplified sound without feedback, and with better sound quality, than conventional power hearing aids. Further, because there is no need for occluding the ear canal with most types of MEIs, this precludes the occlusion effect and other problems associated with the use of an occluding earmold. Although feedback is possible with an MEI, the potential for a significant feedback problem is greatly reduced with the use of direct ossicular stimulation.

Further, nearly all companies working in the MEI field state that they have in development a fully implantable model, in addition to the semi-implantable versions currently being evaluated in human volunteer subjects. In other words, all components, including the microphone, would be placed under the skin. Although the idea may sound futuristic and even like a “bionic ear” of sorts, fully implantable hearing aids are indeed possible with current technology. In fact, one fully implantable model has already been developed and investigated in Europe (the Impex TICA®; Leysieffer et al, 1998), although much work remains to make such an instrument viable in terms of providing sufficient gain and output without feedback. Consider the potential benefits that a fully implantable hearing aid would provide for persons with moderate to severe hearing loss. Beyond the obvious cosmetic advantage, such devices would provide the patient with the ability to swim, shower, or walk in the rain without fear of damaging the electronics of the hearing aid. MEIs might also be selected for persons who should not have their ear canal occluded with an earmold, for example due to allergies to earmold materials or chronic external otitis.

Beyond this new field of MEIs and the well-known cochlear implant, there are other types of implantable devices currently available or under development. These include the Nobel Biocare bone-anchored hearing aid (BAHA®), a commercially available surgical alternative to conventional bone-conduction hearing aids for patients with conductive hearing loss, which is discussed in Chapter 10 (also see Chasin, 1998, for a review). A brainstem implant has also recently received Food and Drug Administration (FDA) approval and is intended for persons who have had their auditory nerve severed or damaged, usually as a sequela to surgical removal of a vestibular neuroma (Portillo et al, 1993; Shannon et al, 1993; Otto et al, 1998). Although these are also interesting topics, this chapter focuses on the middle ear implantable devices and reviews

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1There are also nonsurgical alternatives that might be appropriate for some patients whose ear canals should not be occluded, including bone-conduction hearing aids and open contralateral routing of sound (CROS)-type earmolds (both are discussed in Chapter 10). Neither option is appropriate, however, for patients who need high levels of high-frequency gain.
their history, development, current status, and future expectations.

**History of Direct Stimulation of the Middle Ear**

Probably the earliest work in the field of middle ear implantable hearing aids was done by Alvar Wilska (1935). Wilska placed iron particles on the tympanic membrane and vibrated these particles with an electromagnetic field to demonstrate that pure tones could be perceived by a subject via mechanical stimulation of the ossicles. In the late 1950s, Rutschmann also successfully stimulated the ossicles, by gluing magnets of 10 mg weight onto the umbo of the tympanic membrane and causing it to vibrate via application of a modulated magnetic field by an electromagnetic coil (Rutschmann, 1959).

The University of Pittsburgh’s Department of Electrical Engineering described the design of an implantable hearing aid in 1967, but a device based on their patent was apparently never fabricated and tested (Goode, 1970). Although the placement of devices into the middle ear was suggested earlier, the concept was not actually developed until the 1970s (Fredrickson et al, 1973; Nunley et al, 1976; Goode et al, 1995). Early bench-top and animal experimentation paved the way for development of MEIs. The first evaluations of such devices in humans occurred in Japan in the 1980s (Yanigahara et al, 1983, 1984, 1987a,b, 1988; Suzuki et al, 1985, 1987). Today, a number of MEI devices are in human trials worldwide, in a variety of types and designs, some of which will be described in this chapter. In the United States, the FDA is in charge of overseeing clinical trials of, and approving the marketing of, medical devices including MEIs. At the time of this writing, one manufacturer’s device in an FDA-approved clinical trial (the Otologics MET™) and two other devices (the Symphonix Vibrant® and the SoundTec DDHS) have recently received U.S. market approval. The Otologics and Symphonix devices also have CE-mark approval for the European market.

**Description of Middle Ear Implants**

**Types of MEIs**

In all MEIs, acoustic energy is transduced to provide vibrational stimulation of some structure of the middle ear, usually the ossicular chain, but sometimes the tympanic membrane or the cochlear fluids themselves. Because the outer ear is bypassed, the impedance mismatch between the air in the outer external auditory canal and the fluid of the cochlea is eliminated, thus resulting in more energy being transferred to the cochlea and less energy reflected back out of the external auditory canal. These devices pick up sound with a microphone like a conventional hearing aid, but then, after processing, deliver it directly as mechanical vibration to the middle ear. That is, there is no electric-to-acoustic transduction as provided by the output speaker (receiver) of conventional hearing aids, but rather a transduction from electric to mechanical energy, as described further below.

In general, MEIs can be divided into three types based on the transduction mode used: piezoelectric, electromagnetic, and electromechanical. Devices of each type have advantages and disadvantages to be considered in terms of such factors as power and efficiency, frequency response, and reliability. Patient candidacy criteria for MEIs vary among the many different devices under investigation, and are dependent on the type of transducer and the method by which it is implemented. At this time, there is a lack of published information describing details of audiometric candidacy criteria for many of the experimental devices. When general aspects of the target population are known, they are described in this chapter. Some of the MEIs within each of the three types are described in the following, with preclinical and early clinical (human trial) results on the devices presented in a later section.

**Piezoelectric**

In this type of MEI, piezoelectric materials are used, which have the property that when
a voltage is applied, there is a resulting deformation of the material. This deformation is used as the mechanical energy to stimulate the middle ear (generally, the ossicles). Piezoelectric devices can be found in two configurations: the monomorph, which utilizes expansion and contraction of the material directly to provide displacement, and the bimorph, which uses two pieces of piezoelectric materials bonded together with opposite polarities to cause bending of the structure, as illustrated in Figure 11–1. There are many piezoelectric materials available, but lead titanate zirconate is the material usually chosen due to its high efficiency (Yanagihara et al, 1983; Dumon et al, 1995).

One of the first piezoelectric MEIs, the Partially Implantable Hearing Aid (PIHA), was developed by Yanagihara and his colleagues (1983, 1984, 1987a) in association with Rion Corporation. In Japan this device has been implanted in patients who have mixed hearing loss of varying degrees caused by chronic otitis media (but who did not have active middle ear infection at the time of implantation). Although description of the patient selection criteria is somewhat limited in published articles on the device, Yanagihara et al (1988) reported that the pure tone average bone-conduction hearing thresholds for these patients did not exceed 40-dB HL, and that they had moderate to severe hearing loss in their non-implant ears. One of the techniques used to evaluate the efficacy of this approach was intraoperative vibratory testing that was done during reconstructive middle ear surgeries (Yanagihara et al, 1988). The Yanagihara device is illustrated in Figure 11–2.

Other piezoelectric-based devices include the Implex Totally Implantable Cochlear Amplifier (TICA) and the St. Croix Envoy. The Implex TICA is a fully implantable device that has been evaluated in Europe (Fig. 11–3) and was developed by researchers at the University of Tübingen in Germany (Leysieffer et al, 1998; Zenner et al, 1998). While some patients continue to use the device, the company is no longer in business. This device incorporates a microphone implanted beneath the skin inside the external auditory canal, which provides the signal to a processor placed subcutaneously over the mastoid bone. The ossicles are then stimulated by a piezoelectric transducer that is controlled by the processor. The processor contains a battery that is recharged via a transcutaneous inductive link. The developers of the device state that it is intended for persons with moderate to more severe sensorineural hearing loss.

Figures 11–1. Piezoelectric transducers work on the principle that when a voltage is applied across the material, it will contract or expand, depending on the direction of current flow (top). If two piezoelectric materials are bonded together with opposing polarities, then as a voltage is applied across this bimorphic material, one will expand while the other will contract. It is this “push-pull” action that causes the bimorph to bend (bottom). (From Yanagihara N, Gyo K, Suzuki K, Araki H. Perception of sound through direct oscillation of the stapes using a piezoelectric ceramic bimorph. Ann Otol Rhinol Laryngol 1983; 92 (3 Pt 1): 223–227. Reprinted with permission from Annals Publishing Company.)
Figure 11–2. This device, developed and studied by Yanagihara and his colleagues in Japan, uses a piezoelectric transducer to provide vibratory stimulus to the ossicles. A subcutaneously placed electronic circuit receives signals from a modified behind-the-ear (BTE) hearing aid, which holds the processor, microphone, and battery. (From Yanagihara N, Aritomo H, Yamanaka E, Gyo K. Implantable hearing aid. Report of the first human applications. *Arch Otolaryng Head Neck Surg* 1987b;113(8): 869–872. Copyright © 1987, American Medical Association. Reprinted with permission from the American Medical Association.)

Figures 11–3. The Implex Totally Implantable Cochlear Amplifier (TICA) uses a microphone placed beneath the skin of the external auditory canal to pick up the sound in the canal (shown here just above the canal). The signal from the microphone is sent to a processor placed subcutaneously behind the ear (not shown). The processed signal is then sent to a piezoelectric transducer (the cylindrical object with the pin attached to the incus). (From Zenner H, Maassen M, Plinkert P, et al. First implantation of a totally implantable electronic hearing aid in patients with inner ear hearing loss. *HNO* 1998;46(10): cover. Reprinted with permission from Springer Journal.)
Like the Implex TICA, the St. Croix Envoy is also intended to be introduced as a fully implantable device and is currently reported to be in an animal trial phase (Adams, 1999), except for two patients reportedly implanted in Europe. It incorporates two piezoelectric transducers. One transducer is used to obtain the acoustic signal from the malleus and, after processing in a replaceable subcutaneous component that contains the circuitry and battery, a second transducer is used to stimulate the stapes. Due to the fact that the signal is obtained from and then resupplied to the ossicles, the ossicular chain must be made discontinuous. This is accomplished by removal of the incus. The subcutaneous component would require replacement periodically when the battery is exhausted (reportedly after several years). The suggested target population for this device is those patients exhibiting a moderate to severe hearing loss. A model of the St. Croix device is shown in Figure 11–4.

The predominant disadvantage with the piezoelectric devices is that there appears to be an inherent limitation in output and frequency response capability. With current piezoelectric materials, gain does not appear to be as high as that achieved with other types of MEIs (especially electromechanical, as described below), and there is controversy about whether adequate high-frequency response energy can be achieved for as broad a bandwidth. This may prevent production of high enough levels of amplification for the moderately severe to severe patient who is currently the primary target for candidacy of most MEIs, because these are the patients believed most likely to receive insufficient benefit from conventional hearing aids. The development of new piezoelectric materials in the future may result in higher power devices of this type.

Another hurdle that must be addressed with these piezoelectric devices is disarticulation of the ossicles. The infliction of intentional damage to the middle ear during surgery is not well received by many surgeons and audiologists, and makes the surgical implantation a nonreversible procedure (i.e., if the device is explanted, presurgical hearing sensitivity and middle ear status are not restored). The Yanagihara and St. Croix devices require removal of the incus during implantation. Surgeons working with the Implex device have also reported the need for ossicular dislocation due to significant acoustic feedback problems. This was due to the fact that, because the microphone is placed in the ear canal, it can pick up energy
transmitted outward by the tympanic membrane. None of these devices are currently in clinical trials in the United States.

**Electromagnetic**

The electromagnetic transducer consists of a magnet and an energizing coil. The magnet, which is usually of the “rare earth” type (either samarium cobalt or neodymium iron boron), is attached to either the ossicular chain or the round window membrane. A fluctuating magnetic field is generated when the coil is energized by a signal corresponding to the acoustic input, and the magnetic field causes the magnet to vibrate. This in turn causes movement of either the ossicular chain or the cochlear fluids directly. The concept is illustrated schematically in Figure 11–5.

Coils in these devices are generally “air-core,” which means that the wire is not wound around a ferrous metal core. Although it is true that a ferrous core coil will increase power output, there are some disadvantages to this configuration. For instance, there is a tendency for the magnet to be attracted to the ferrous core, and this can cause a bias of the magnet toward the core when it is inactive, potentially dislodging the magnet. For the same reason, only a “push force” is generated by the coil, causing the magnet only to be pushed toward the ossicle, not pulled away from it. Also, magnet weight must be kept at 50 mg or less (Goode, 1989), so that a “mass effect” is not produced, altering the frequency response characteristics of the ossicular chain and thus reducing the higher frequency response.

Maniglia and his colleagues (1988, 1995, 1997) at Case Western Reserve University have developed an electromagnetic device that consists of a magnet glued to the ossicles and an electromagnetic coil placed in the attic of the middle ear. A subcutaneous radio-frequency (RF) receiver is placed behind the ear. The target population for this device includes patients with normal inner ear function and a conductive hearing loss.

![Figure 11–5. Illustration of electromagnetic theory. Electromagnetic devices send the processed audio signal through leads to an electromagnetic coil. The magnetic field generated by this coil causes the magnet to vibrate in synchrony with the signal, thus causing the ossicle to also be vibrated.](image)
device is reportedly patients with symmetrical moderate to severe cochlear hearing loss and word recognition scores of 60% or better, but after a preliminary evaluation in one patient, this group has returned to development work on this device and research into fully implantable cochlear implants.

Another variation of an electromagnetic device is that developed by Kartush and Tos (Kartush et al, 1991; Kartush and Tos, 1995), in which the magnet is encapsulated in a Total Ossicular Replacement Prosthesis (TORP) or a Partial Ossicular Replacement prosthesis (PORP) intended for patients with mixed hearing loss (Fig. 11–6). The electromagnetic coil for stimulation of the magnet is placed in a custom earmold in the ear canal. This device is also not being tried in humans at this time.

SoundTec has an electromagnetic device, the DDHS (direct drive hearing system), which has recently received FDA market approval in the United States (Hough, 1999). As shown in Figure 11–7, this device also places the energizing coil in the ear canal, with the magnet placed on the ossicular chain. The proposed advantage of this device is that it can conceivably be done with an in-office procedure using local anesthesia and a transtympanic approach (through the tympanic membrane), rather than requiring surgery under general anesthesia as required by other MEI devices. The disadvantage is the potential for problems caused by having an object in the ear canal, which is also true of the Kartush and Tos device, and takes away the advantage offered by those MEIs that leave the ear canal unoccluded.

In all of the electromagnetic devices, a common problem is that the magnet and coil must be close to one another to provide an efficient transmission system. The force generated is inversely proportional to the square of the distance between the components. For example, a doubling of the distance between the magnet and coil results in an output force of only one-fourth of that produced at the original distance. If the relationship between the components varies due to attachment to different anatomical parts, there may be variations in the frequency response and fluctuations in the output level.

Electromechanical

The electromechanical type of MEI was partly designed as a response to the problem of varying magnet and coil distance, and can be considered as a subtype of the electromagnetic devices (in fact, some authors choose to put both types together under the single category of electromagnetic). With electromechanical MEIs, the energizing coil and magnet are housed together within an assembly, so that optimized spatial and geometric relationships are maintained. The mechanical energy produced is transmitted by a direct connection of the electromechanical

Figure 11–6. Schematic illustration of the Kartush-Tos device. With this device, a PORP or TORP with an embedded magnet replaces part or all of the ossicular chain. The magnet is then caused to vibrate by an electromagnetic coil housed inside an in-the-canal hearing aid shell. (From Tos M, Salomon G, Bonding P. Implantation of electromagnetic ossicular replacement device. ENT J 1994;73(2):92–103. Reprinted with permission from Medquest Communications LLC.)
transducer to the ossicular chain, as illustrated in Figure 11–8.

Both custom-designed and commercially available transducers have been used in electromechanical devices, and a number of electromechanical MEI devices are under development or on the market today. An advantage of this type of device is that it can be designed as a closed magnetic circuit, which is more efficient and can have a more flexible frequency response. A disadvantage of this technique is that it is generally a more complex device and therefore more susceptible to fatigue factors. In simpler terms, the greater the number of components composing the transducer, the greater the possibility of a device failure due to component wear or defect. Thus, the design process is longer and more difficult to produce a reliable device than for the other transduction methods.

Fredrickson and his colleagues at Washington University Medical School in St. Louis have developed an electromechanical device (Fredrickson et al, 1973, 1995, 1996; Esselman et al, 1994; Park et al, 1995a,b). This device, currently called the Middle Ear Transducer (MET™), is in FDA clinical trials in the United States under the auspices of Otologics LLC, the company at which the second author of this chapter is employed. Clinical trials of the Otologics MET are also being conducted in Japan, and the device is now available on the European market. The device is shown schematically in the ear in Figure 11–9. Internal electronics of the device are placed in a recess in the mastoid bone behind the ear, and are shown in Figure 11–10. In its current research configuration, the external component is a behind-the-ear (BTE) unit connected with a cord to an external RF transmission coil, similar to some cochlear implant designs,
Electromagnetic transducers generate vibratory motion in synchrony with the signal, but within an enclosure. This mechanical stimulus is then transmitted to the ossicular chain via an actual physical link to the ossicles (as opposed to a magnetic field link).

Fredrickson/Otologics Middle Ear Transducer (MET™) device in mastoid section. (1) transmitting coil, (2) receiving coil and electronics, (3) anchoring and positioning mechanism, (4) transducer, (5) titanium drive rod and ceramic probe tip coupling the transducer to the incus. (From Miller D, Fredrickson J. Implantable hearing aids. In: Valente M, Roeser R, Hosford-Dunn H, eds. Audiology: Treatment. New York: Thieme, 2000.)
but the commercial version is one piece. This device is intended for patients with bilateral sensorineural hearing loss that is moderately severe to severe in at least the high frequencies. In the Otologics clinical trial, each patient’s performance with his or her own hearing aids, and with newly fitted state-of-the-art digital hearing aids with multichannel compression, is evaluated presurgery to see if there is room for improvement and to serve as a baseline for comparison to performance with the MEI. The digital hearing aids are research versions of a commercial model, and are fitted with an algorithm intended to provide maximal audibility for speech while maintaining listening comfort.

Another device that is electromechanical in nature is the Symphonix Vibrant® (Fig. 11–11), developed by Ball and colleagues (Gan et al, 1997). Clinical trials on this device have been completed and it has recently received approval for marketing in both the United States and Europe. The Vibrant uses a floating mass transducer (FMT) to transmit stimuli to the ossicular chain. The FMT is a small, encapsulated magnet that is free to move longitudinally in its enclosure. A coil wound around the outside of the enclosure energizes the magnet, causing it to vibrate back and forth along its axis. This assembly is clipped to the long process of the incus, thereby transferring the motion of the magnet to the ossicle. The external unit of the Symphonix MEI is a small, disk-shaped unit placed on the surface of the skin over the implanted electronics. Power and signal are transmitted via inductive coupling from the external portion of the device to the implanted electronic receiver and transducer.

**Design and Development Issues**

**Hardware and Software**

Currently, the hardware and software of MEIs are based on conventional air-
conduction hearing aid components and signal processing algorithms because the goal is basically the same; that is, to stimulate the middle ear with a signal modified to best benefit the user. In the future, when more is known about any differences between signal amplification with MEIs and conventional amplifiers, special-purpose hardware and software may be developed. Essentially, MEIs offer conventional amplification that is delivered directly to the ossicles rather than sent as an acoustic signal through the external auditory canal. Therefore, in many MEIs, a conventional air-conduction hearing aid is modified to transcutaneously transmit the signal to the implant via an RF link. The microphone and signal processing of the hearing aid are generally used “as is.” The forms of signal processing used in these devices varies, and is usually indicative of the stage of development of the particular MEI. It may be as simple as analog linear amplification or as advanced as a state-of-the-art, fully digital signal processor incorporating multiband filtering and multichannel compression. As previously described, the output of MEIs is vibrational energy, with the method for delivering that energy depending on both the type of transducer and its location.

After surgical implantation and a healing period, the fitting and adjustment of MEI devices will need to be accomplished by an audiologist/dispenser just like conventional hearing aids and cochlear implants. Fitting algorithms for MEIs at this time are essentially based on current knowledge of fitting conventional air-conduction hearing aids. For example, a threshold-based prescriptive formula such as the National Acoustic Laboratories (NAL; Byrne and Dillon, 1986) or an audibility-based approach such as the Desired Sensation Level (DSL) method (Seewald, 1992) might be used, depending on the signal processing capability of the partic-

Figure 11–11. The Symphonix Vibrant® consists of an external component containing the processor, microphone, and battery, and an implanted component consisting of a subcutaneously placed electronic unit and the floating mass transducer (FMT). The FMT is crimped onto the long process of the incus. (From www.symphonix.com with permission.)
ular device. As more knowledge is gained regarding differences between direct ossicular stimulation and conventional stimulation via air conduction, fitting techniques may be adjusted to take into account differing characteristics of stimulation with an implanted device. If, for example, an MEI is found to provide greater levels of usable high-frequency energy without feedback or discomfort relative to conventional amplification, a fitting approach would need to be developed to account for this difference. Further, because fitting cannot be accomplished with real-ear probe microphone measurements as is commonly done today for conventional hearing aids, new techniques will need to be developed for MEIs to determine the parameters of an MEI fitting and to verify that the fitting is appropriate for the individual patient.

Materials and Biocompatibility

Materials used in the design and construction of any implantable device must take several factors into consideration. The electrical conductors chosen must have good conductivity (i.e., low resistance), be accepted by the body (be biocompatible), and be capable of withstanding the hostile corrosive environment of bodily fluids. Gold is a good choice, because it is nearly as good a conductor as copper and is highly resistant to corrosion. In addition, it has been used for decades in other medical devices and instruments because of its excellent biocompatibility properties. A less conductive but stronger material that can be used is an alloy of 90% platinum and 10% iridium. Pure platinum can be used, but is stronger when alloyed with iridium. Both platinum and iridium are very resistant to corrosion and a platinum-iridium alloy is well accepted by the body.

In some applications, electrical conductors require insulation. If the conductor is to be subjected to bending, the insulator must be flexible. Often, polytetrafluoroethylene, more commonly known as Teflon, is used for this purpose. A ceramic material is chosen instead if the insulator can be rigid or if it is necessary that it be bonded to a metal, such as an electrical feed-through in an enclosure. One such ceramic is aluminum oxide, which has a long history of use in ossicular replacement prostheses. Both Teflon and aluminum oxide ceramics are unreactive and well tolerated when placed in the body (Stensaas and Stensaas, 1978; Jahnke and Plester, 1981).

Nonbiocompatible components frequently also must be used in an MEI device. In this case, such components must be encased in a material that is biocompatible. Titanium and ceramics have both been used for this purpose because they are well tolerated, perform well, and have a long history of success in implantations. Of the two, titanium enclosures are easier to manufacture because they are sealed by welding after the contents are in place. Titanium is also used for structural components of implanted devices, such as mounting platforms and anchors. Further, sometimes components of an implant need to be encapsulated in a flexible shell to maintain their positional relationships and to provide a soft surface for overlying tissue. Silicone elastomers, in a cured, solid form, are typically used in this role and have been shown to be inert and well tolerated by the body (Ng and Linthicum, 1992).

Surgical Issues

A majority of MEIs utilize a surgical approach including a postauricular incision and drilling of the mastoid bone, and thus are done under general anesthesia as a day surgery (no overnight stay is required). The surgery is moderately complex, as the surgeon must identify and preserve important anatomic structures as the middle ear is exposed, but otologists have been entering the middle ear for many decades through the mastoid approach and it is well described. In the SoundTec device, the surgical approach is through the external auditory canal, and such a procedure could be accomplished under local anesthesia. Surgery time varies across devices, but 1 to 2 hours is considered to be typical after the surgeon has sufficient experience with the particular procedure.
Surgical risks vary with the type of implant and its method of implementation. There are the common risks associated with any surgery, including infection or wound complications, and the potential for anesthesia reactions. Some devices offer the risk of disarticulation of the ossicular chain, if indeed that is not done intentionally (e.g., as in the Yanagihara and St. Croix devices). In some procedures, the surgeon is required to work close enough to the facial nerve to pose a risk of facial paralysis, although this risk is extremely small. Another quite remote, but theoretically possible, risk is trauma to the inner ear caused by excessive manipulation of the ossicular chain.

Healing time prior to activation of the implant and programming/fitting of the signal processor also vary by procedure and device. For surgeries in which the middle ear is opened, there must be adequate time for fluid to clear from the middle ear space as well as for wound healing. A typical time period for activation of the processor would be 7 to 9 weeks postsurgery. One of the advantages of at least some models of MEIs (e.g., the Otologics MET™) is that, unlike cochlear implants, the surgery is reversible. That is, the MEI can be explanted and the ear returned to its preimplant state if performance is less than satisfactory.

**Potential Advantages and Disadvantages of MEIs**

The advantages of MEIs, as well as the disadvantages, differ depending on the device type and its implementation. Clinicians should carefully evaluate each device that appears on the market independently in terms of its functioning and risks, and the studies and data supporting its use. As an example, some MEIs have higher gain and output capabilities than do others, and a few are intended only for mixed hearing loss (e.g., Yanagihara’s and Kartush and Tos’s devices). The generalized advantages mentioned here are applicable to the bulk of MEIs that are under development for the moderately severe to severe cochlear-impaired ear. Also, some MEIs have the disadvantage that the ossicular chain is permanently dislocated during the implant surgery. Most MEI surgeries are nondestructive and reversible, however, and the disadvantages listed below are reasonable generalizations for the majority of devices.

**Advantages**

MEIs, in comparison to conventional, acoustic hearing aids, offer better impedance matching with the middle ear and eliminate the acoustic output from a receiver into the ear canal. This results in more efficient energy transmission and is expected to provide lower levels of distortion, higher fidelity sound quality, and a reduced potential for feedback problems. In a normal ear, the ossicular chain acts to improve the impedance mismatch between the air in the external auditory canal and the cochlear perilymph, so that more sound is transmitted through, rather than reflected from, the auditory pathway. Nevertheless, there is still a significant amount of acoustic energy reflected from the tympanic membrane and, in a hearing aid user, it can leak past the earmold, be picked up by the microphone of the hearing aid, and cause loud squealing feedback. With an MEI, the interface at the tympanic membrane is bypassed, so that direct ossicular stimulation is expected to send more energy to the cochlea without reflection.

It would be incorrect to state that MEIs eliminate the possibility for feedback, except possibly for those that permanently disarticulate the ossicles. In fact, it is possible for feedback to occur in an MEI via the following mechanism: the ossicular vibration transmits energy back to the tympanic membrane, causing it to act as a speaker diaphragm, producing sound in the external auditory canal that can be picked up by the microphone. That said, however, feedback is not expected to occur frequently even though the ear canal is left unoccluded in most MEIs, and if it does occur, it is expected to be lower level feedback than with conventional power hearing aids, and relatively easily resolved.
(e.g., by slight reduction in high-frequency gain or a slight increase in the compression ratio). Thus, the potential for significant feedback problems is greatly reduced with middle ear implantation.

Because there is nothing worn in the ear canal with most MEIs (the SoundTec and Kartush-Tos devices are exceptions), the often significant discomfort of wearing an earmold or hearing aid shell is avoided. Also, the occlusion effect (the perception that one’s own voice is louder or that one is “talking in a barrel” when the ear canal is occluded) is nonexistent with these implantable hearing aids. Further, patients who have difficulty wearing an earmold due to allergies to earmold materials, who have persistent problems with cerumen blockage in an in-the-ear (ITE) hearing aid receiver, or who are predisposed to recurrent bouts of externa otitis when moisture accumulates in the occluded canal would benefit from an MEI. Finally, although we believe that cosmesis should not be a primary reason for implant surgery, some of the semi-implantable MEIs can be quite unobtrusive if the patient’s hair covers the external piece (which is usually placed superior and posterior to the pinna), and there is no unattractive earmold and tubing, or ITE casing, as with some conventional hearing aid fittings.

When consideration is made of the fully implantable devices on the horizon, additional advantages are apparent. The cosmetic advantage is obvious with no external components showing. Clearly the fully implantable hearing aid is the culmination of the search for an “invisible” hearing aid, which also resulted in development of the completely-in-the-canal (CIC) models of conventional hearing aids that came onto the market in the past decade. But the potential advantages of a fully implantable device go beyond this consideration. In these devices, all components are placed under the skin and/or in the mastoid bone, including placing the microphone under a thin layer of skin or cartilage. Thus, the patient can walk in the rain, take a shower, and even swim while using his or her amplifying device without fear of moisture causing microphone and electronics breakdown. Further, particularly if the microphone is not placed in the ear canal, cerumen buildup does not become an issue. Finally, the implantation of rugged biocompatible components may actually make the unit more impervious to breakdowns.

With both semi-implantable and fully implantable MEIs, the major goal is improved performance for the patient relative to conventional technology, with an emphasis on improved speech recognition in noise. Depending on the signal processing used and the severity of the patient’s high-frequency hearing loss, some MEIs may theoretically be able to give higher levels of undistorted high-frequency amplification relative to conventional power hearing aids, and this could conceivably result in improved speech recognition and/or enhanced perceptual sound quality. For example, the frequency response of the Otologics MET™ transducer, as shown in Figure 11–12, is broad and flat (although it is important to note that the overall frequency response is modified by amplification parameters and other portions of the MEI device as well). Some preclinical and early clinical research using this ossicular stimulator is described later.

Disadvantages

Despite the potential advantages, one must consider that there are some potential disadvantages of MEIs as well. The obvious disadvantage is that surgery is required for placement of the device, and comes with its attendant potential complications. It is necessary therefore that the advantages outweigh the need for surgery; that is, the level of benefit and satisfaction must exceed that offered by nonimplantable technology. Further, just like cochlear implants, patients must not undergo magnetic resonance imaging (MRI) of the head after implantation without removal of either the magnet or the entire device.

At this point in development, most MEIs are still in semi-implantable form, requiring
an external unit and thus being subject to some of the same maintenance and breakdown issues seen with conventional air-conduction hearing aids. The exception to this is that the lack of a receiver (output speaker) placed in the ear canal precludes some common problems such as cerumen impaction and breakdown due to canal moisture. Although unlikely, the transcutaneous RF transmission used in many semi-implantable devices could have some susceptibility to interference, or possibly to less robust transmission if the internal RF coil is placed at too great a depth. With fully implantable MEIs, this latter problem would be precluded. At the current state of the art, however, implantable microphone technology has not been perfected and there is likely to be at least some loss of sensitivity when the microphone is placed under the skin.

Finally, although the cost of an MEI itself is expected eventually to be equivalent to that of a state-of-the-art digital air-conduction hearing aid, there is also the additional cost of the surgical procedure to be considered. Third-party reimbursement through insurance and Medicare and Medicaid programs continues to be a major issue for all types of implantable hearing devices. The ground was initially broken for third-party reimbursement by cochlear implants, but the percentage of the costs reimbursed still tends to be very limited. At this time, it is not clear if third-party reimbursement will be available for MEIs, although the hope is that, like cochlear implantation, reimbursement will increase as the benefits of the devices become apparent.

**Investigational Studies of MEIs**

**Preclinical Research and Limited Clinical Trials**

Preclinical research in the field of MEIs has been conducted for many years by a number of different groups, using a variety of approaches and techniques. Laboratory experiments using models and temporal bones have helped researchers to better understand how the middle ear reacts to direct vibrational stimulation. In addition, several animal studies have been carried out to study in vivo performance of these devices. Auditory brainstem responses (ABRs) have been the most common tool for acquiring information about the performance of MEIs in animal studies, but laser doppler vibrometry (LDV), otoacoustic emissions (OAEs), and cochlear action potentials (APs) have also been used. Commonly, measurements are compared for acoustic stimulation via insert earphones and vibratory stimulation via an MEI transducer. In general, results of preclinical trials to date have demonstrated that the electrophysiologic responses elicited by mechanical stimulation are similar to those produced by acoustic stimulation and that
signals can be delivered directly to the middle ear effectively. Some of these research groups and their results will be described briefly here.

A piezoelectric device has been under investigation at the University of Bordeaux, in France, by Dumon and his colleagues (1995). Their device was used to stimulate the cochlear fluids in 12 guinea pigs. The device consisted of a small piezoelectric bimorph with a tiny platinum ball extending from the end that was placed in contact with the round window membrane. The other end of the bimorph was anchored in the mastoid bulla. Auditory evoked potentials obtained over a 7-month period illustrated responses that were stable and reproducible, and similar to those obtained with acoustic stimulation. Dumon et al also developed a method for placing a piezoelectric device in contact with the ossicular chain in human temporal bones. It was reported, however, that there was not always sufficient space in the middle ear for this approach.

Welling and Barnes (1995) at Ohio State University in Columbus, Ohio, have evaluated a piezoelectric device not dissimilar to the one used by Yanagihara and his colleagues in Japan. In several cats and one volunteer patient (who was undergoing a posterior semicircular canal occlusion for intractable benign paroxysmal positional vertigo), the ossicular chain and a fenestrated semicircular canal were stimulated intraoperatively for measurement of cochlear microphonics. Results demonstrated a good correlation in frequency response and coherence functions between responses obtained with mechanical stimulation with the piezoelectric MEI and with acoustic stimulation.

Spindel and his colleagues (1995) at the University of Virginia in Charlottesville, Virginia, also are investigating stimulation of the cochlear fluids via a magnet placed on the round window membrane. In one study, 13 guinea pigs were implanted and stimulated by an external electromagnetic coil. ABRs in these animals demonstrated that magnetic stimulation produced results comparable to those obtained acoustically.

In Cleveland, Ohio, at Case Western Reserve University, Maniglia and his colleagues (1988, 1995, 1997) have developed an electromagnetic MEI that is undergoing evaluation. This device was implanted in seven cats and evaluated for approximately 9 months of in vivo operation. The device consists of a titanium-encapsulated magnet attached to the ossicular chain, which is stimulated by a small electromagnetic coil placed in close proximity in the attic of the middle ear (Fig. 11–13). Auditory brainstem responses were obtained to evaluate performance of this device. Results showed comparable thresholds to those obtained with acoustic stimuli, and histologic evaluation demonstrated no adverse effects to the middle ear. The results of this work led to FDA approval for clinical trials with the device, but only one patient was implanted due to a finding of inadequate power output (Maniglia, personal communication, 1998).

Fredrickson and his colleagues at Washington University School of Medicine in St. Louis, Missouri, developed and tested an electromechanical device. This device was the precursor of the Otologics MET™. The device was implanted in 12 rhesus monkeys, and up to 2 years of in vivo evaluation were completed (Fredrickson et al, 1973, 1995, 1996; Park et al, 1995a,b). ABRs and distortion product otoacoustic emissions (DPOAEs) were used to evaluate performance of the device compared to acoustic stimulation. Consistent with other studies, the results showed comparable morphology and thresholds, as illustrated in Figure 11–14 (ABRs) and Figure 11–15 (DPOAEs). In addition, histologic evaluation of the implanted ear indicated no deleterious effect of the implant being in place.

Some limited noninvasive testing in humans was also done with an early design of the Fredrickson/Otologics MET™ device, although these results have not previously been published. This testing was accomplished by placing a long drive rod, attached to the middle ear transducer, in contact with the umbo of the tympanic membrane via insertion through the external auditory canal. Two subjects with moderately severe senso-
rinenaural hearing loss were evaluated with this form of stimulation and with conventional stimulation via insert earphones. Using standard monosyllabic word recognition testing at comparable sensation levels, scores improved from 35% and 37% with insert receivers, to 54% and 48%, respectively, with the MET transducer. The subjects also reported that the perceptual sound quality of the speech delivered directly to the ossicles was superior to that delivered by the audiometric headphone.

An electromagnetic ossicular replacement prosthesis was developed by Kartush and Tos (Kartush et al, 1991; Kartush and Tos, 1995), and evaluated in conjunction with the Smith-Nephew Richards Company. This product was placed in some patients with mixed hearing loss where surgical replacement of all or part of the ossicular chain was indicated. The device reportedly did not, however, provide sufficient benefit, and Smith-Nephew Richards has discontinued their support of the project.

Hough and his colleagues (Baker et al, 1995) at the Hough Ear Institute in Oklahoma City, Oklahoma, examined an electromagnetic device in guinea pigs via measurement of auditory nerve action potentials, and on patients undergoing surgery for otosclerosis and chronic tympanic membrane perforation. During the surgery, magnets were temporarily placed on the ossicular chain and stimulated with an electromagnetic coil placed in the external auditory canal. Positive results from these animal and
Figure 11–14. An example of auditory brainstem responses (ABRs) obtained from a rhesus monkey through acoustical versus mechanical stimulation of the ossicular chain with click stimuli. Note the similarities in amplitude and waveform morphology, as well as response threshold.

Figure 11–15. An example of distortion product otoacoustic emissions (DPOAEs) obtained from a rhesus monkey. A DPOAE “audiogram” was generated using acoustic signals for the first and the second primary tones. This was then compared to the DPOAE audiogram generated using the same signals but with the first tone presented acoustically and the second presented mechanically (MET stimulation of the ossicular chain). As can be seen, the DPOAE level produced by the two primary tones is nearly the same for both modes of stimulation, plotted by frequency of the secondary tone, f2.
intraoperative results led to FDA approval for an early limited clinical trial. In that trial, patients implanted with neodymium iron boron magnets initially showed good results, but the magnets degraded over approximately 3 months’ wearing time and the units stopped functioning. To recover electromagnet function, the magnets were replaced with samarium cobalt magnets. A problem was that because the samarium cobalt magnets had to be larger to provide the same magnetic strength as the neodymium iron boron magnets, mass damping of the ossicular chain occurred and resulted in decreased auditory pathway function. Thus, the magnets were removed and the clinical trial was temporarily halted. Problems were eventually resolved, however, and this work led to development of the SoundTec DDHS.

Clinical Trials Currently Underway

There are a number of devices in clinical trials worldwide (Table 11–1), but only a few devices have been approved by the FDA for U.S. trials in human subjects. The following discussion updates the status of the three device trials under way or completed in the United States at the time of this writing, although this is such a fast-changing area that the field may look different by the time of publication.

First, after some redesign of their device, Hough and colleagues, in conjunction with a company named SoundTec, again moved forward with FDA human clinical trials. These researchers completed Phase I of the trials (the “safety” evaluation portion of an FDA trial), implanting five patients. They completed Phase II (the “efficacy” evaluation portion of an FDA trial), implanting approximately 100 patients. Second, the device developed by Fredrickson’s group, which became the Otologics MET, is also in human clinical trials in the United States. Phase I of the Otologics trial has been completed, with implantation of nine patients in the United States and, additionally, five patients in Europe. Phase II is underway with planned implantation of about 80 patients. This device has received market approval in Europe. Third, the Symphonix Vibrant completed Phase II clinical trials with approximately 80 patients, and recently received U.S. market approval. This device has also received market approval in Europe.

At this time, only limited data have been published from these human trials, although anecdotal and website reports and some conference presentations have suggested promising results, particularly in terms of sound quality perception (e.g., Menapace and Katz, 1999; Chute and Lee, 1999). The audiologist should expect published reports and further

Table 11–1. Middle Ear Implants Currently in or Having Completed Human Clinical Trials

<table>
<thead>
<tr>
<th>Company</th>
<th>Device Name</th>
<th>Type</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implex</td>
<td>TICA</td>
<td>Piezoelectric/fully implantable</td>
<td>European clinical trials discontinued</td>
</tr>
<tr>
<td>Otologics</td>
<td>MET</td>
<td>Electromechanical/semi-implantable</td>
<td>U.S., and Japanese clinical trials, European market</td>
</tr>
<tr>
<td>Rion Corporation</td>
<td>PIHA</td>
<td>Piezoelectric/semi-implantable</td>
<td>Japanese clinical trials</td>
</tr>
<tr>
<td>SoundTec</td>
<td>DDHS</td>
<td>Electromagnetic/semi-implantable</td>
<td>U.S. market</td>
</tr>
<tr>
<td>St. Croix Medical</td>
<td>Envoy</td>
<td>Piezoelectric/fully implantable</td>
<td>Two patients implanted in Europe</td>
</tr>
<tr>
<td>Symphonix</td>
<td>Vibrant</td>
<td>Electromechanical/semi-implantable</td>
<td>U.S. and European markets</td>
</tr>
</tbody>
</table>

DDHS, Direct Drive Hearing System; MET, Middle Ear Transducer; PIHA, Partially Implantable Hearing Aid; TICA, Totally Implantable Cochlear Amplifier.
presentations on these clinical trials in the near future. It will be important to analyze the clinical research designs and reported data from these clinical trials carefully. One factor to consider, for example, is the appropriateness of the comparison condition for the MEI. Typically, for example, a clinical trial will compare the patients’ performance with the MEI to that with a presurgical fitting of a conventional “acoustic” hearing aid (similar to the preimplant trial with amplification done for cochlear implant candidates). An outstanding issue in research of this sort is how to determine that the conventional hearing aid trial (the “baseline” condition) does in fact represent the very best, or optimal, performance that the patient can receive from conventional amplification. Often patients who volunteer for this type of research are doing so because they are very dissatisfied with their current (“walk in”) hearing aids. But obviously it is very important to examine if that dissatisfaction is due to a poorly functioning or poorly fitted hearing aid rather than to poor performance with acoustic amplification per se.

Another important consideration in clinical evaluations of MEIs is characterizing the electrical parameters of the signal processing accurately (gain, frequency response, maximum output, compression parameters, etc.), and matching those to the auditory perception of the patient when the device is stimulated. Unless it is determined that there is a very good predictive relationship between acoustic perception and direct ossicular stimulation, and that variability across individual patients is minimal, the latter measurements will be needed for calculation of prescription amplification parameters from a formula. Efforts are under way to develop methods for these types of measurements, with the goal of eventually establishing techniques that provide the same level of precision in the fitting of MEIs that is now commonplace with conventional hearing aids.

**Conclusion**

The effectiveness of MEIs in human subjects is just now being evaluated. Other than the piezoelectric device developed by Yanagihara and his colleagues in Japan (Suzuki et al, 1985, 1987, 1994; Yanagihara et al, 1987b, 1988, 1995; Saiki and Gyo, 1990), there have not yet been any major long-term clinical studies of an MEI. In the case of Yanagihara’s device, the patients expressed an appreciation for the good perceptual quality of the transduced sound and most have continued to use their device. The degree of hearing loss that can currently be treated with Yanagihara’s ossicular stimulator is relatively mild, however, and the removal of a portion of the ossicular chain makes the procedure undesirable for patients with a normal middle ear.

There is at this time limited evidence of the important potential benefits of the many MEIs that are intended for persons with moderate to severe sensorineural hearing loss; that is, the expectation that direct ossicular stimulation will result in increased levels of high-frequency gain without feedback and with less distortion, thereby producing improved speech recognition in noise. Early reports do appear to be quite promising, as evidenced by the noninvasive stimulation experiment of Fredrickson and colleagues mentioned previously, and reports, albeit largely anecdotal at this time, from clinical trials.

It is important to keep in mind that future developments in conventional air-conduction hearing aids are expected to benefit MEIs as well because the fitting technique and signal processing approaches are expected to be reasonably similar. For example, higher processing speeds and lower power consumption of new digital signal processing (DSP) circuits will provide greater flexibility in frequency shaping and permit a wider frequency response that might prove to be particularly beneficial with some MEIs. Further, the new multimicrophone and “beam forming” technologies now appearing in commercial conventional instruments and being evaluated in research laboratories for improvement of signal-to-noise ratio might be ideally applied with fully implantable MEIs because multiple micro-
phones could theoretically be implanted under the skin without cosmetic concerns.

And clearly this is the most exciting area of MEI work: the imminent introduction of a well-designed, high-fidelity, fully implantable device that could greatly enhance the quality of life for persons with hearing impairment. Development of the battery and microphone technologies that would permit viable fully implantable hearing devices is well under way and may build on work in other medical areas. For example, cardiac pacemaker companies have already produced prototype implantable rechargeable batteries that produce no by-products during charging. They remain functional for over 1000 charging cycles, making them suitable for use in the body. The prototypes now available for MEIs would require recharging every few days, most likely done while the person is sleeping or otherwise inactive. Higher capacity batteries and lower power circuits can be expected to evolve to increase the time between recharging.

Microphones that are constructed of biocompatible materials (or encased in them) are also currently being investigated for use in fully implantable MEIs. Techniques for placing these microphones to avoid a loss of sensitivity due to fibrosis or migration (movement) of the microphone are also under consideration. The major challenge in developing an implantable microphone lies in enclosing a conventional, most likely electret, microphone in a biocompatible case in such a way as to not reduce its sensitivity or significantly affect its frequency response due to the enclosure. Alternatively, a microphone constructed completely of biocompatible materials may eventually be developed. For example, modern microchip technology could be used to construct a microphone from silicon, a ceramic material that has been used successfully in the body for many years. Another important consideration will be to develop an implanted microphone that will not convey biologic noise (i.e., blood flow) to the signal processor.

Although semi-implantable MEI models will undoubtedly first appear on the market and are expected to be quite beneficial, they will likely be replaced over time by fully implantable devices, bringing all the benefits of cosmesis, convenience, comfort, and performance, previously discussed, to persons with hearing impairment. Indeed, when fully implantable hearing devices reach a mature state, and if the surgical risks prove to be relatively minimal, it is possible that they could become a commonplace alternative to conventional hearing aids.

Although at this time MEIs would not generally be considered appropriate for patients with mild to moderate sensorineural hearing loss who perform satisfactorily with conventional hearing aids, they do have the potential to provide significant benefit to patients with moderate to severe hearing loss who are not performing well with conventional hearing aids. There is still much work to be done, however, to ensure that the potential benefits of MEIs are realized because in some ways MEI research and development is still in its infancy. Nevertheless, with the greatly accelerated pace of work over the last few years, there is good reason to believe these devices will become an important addition to the audiologist’s arsenal of tools for treating hearing loss in the not-too-distant future.

References


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