



WORLD SKULL BASE E-LEARNING MATERIAL

Active Middle Ear Implants



Middle Ear Implants

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Products

Implantable middle ear devices were developed to treat conductive and sensorineural hearing loss.

Category

Implantable hearing device, middle ear

Device details

Middle ear implants include the following:

- Envoy - Esteem Implantable Hearing System
- Med-EI - Vibrant Soundbridge Middle Ear Implant System
- Otologics - Carina Fully Implantable Hearing System (Europe only)
- Soundtec - Soundtec Direct Drive Hearing System (withdrawn from the market)

Design Features

Implantable middle ear devices were developed to treat conductive and sensorineural hearing loss. The rationale for these devices is multifaceted. They improve fidelity by directly stimulating the ossicles, and they improve comfort by allowing the ear canal to remain open rather than occluded. In addition, by uncoupling the sensor and driver, most implantable middle ear devices almost completely eliminate feedback, one of the most significant adverse effects of [conventional hearing aids](#).

Another benefit of middle ear implants is the improved cosmesis that can be achieved with the miniaturization and concealment of the components. Finally, totally implanted devices allow the patient to continue receiving amplification while swimming or bathing.

Many believe that middle ear implants may represent a new era in hearing rehabilitation, much as the largely successful (but more narrowly indicated) [cochlear implants](#) did. Although hurdles still remain, the significant advantages these devices possess, as well as the increasing number of people who may benefit from them, support their use and development.

Implantable middle ear devices are generally available in 2 types: piezoelectric and electromagnetic. They are now further categorized as either partially implanted or totally implanted.

Piezoelectric devices

Piezoelectric devices operate by passing an electric current into a piezoceramic crystal, which changes its volume and thereby produces a vibratory signal. The major disadvantage of such devices is that power output is directly related to the size of the crystal. Studies of early designs indicated that such an approach benefits only people with up to moderate (about 60 dB) hearing loss. This limitation has been challenged by the newer piezoelectric technologies.

Piezoelectric transducers have the advantage of being inert in a magnetic field and therefore compatible with magnetic resonance imaging (MRI). It should be noted that MRI compatibility studies have not been done by the Envoy Medical Corporation for the Esteem II.

Rion Device E-type

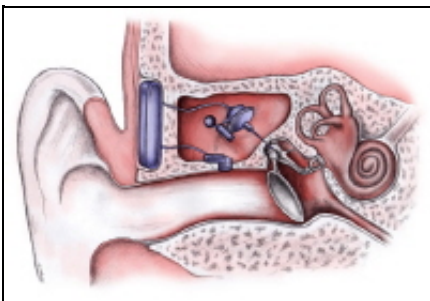
One of the earliest piezoelectric devices, the Rion Device E-type, has been used for both conductive and sensorineural losses. It is a partially implanted device composed of an external ear-level microphone and amplifier and an internal electromagnetic coil and vibrator element. The piezoelectric vibrator element is anchored to the squamous portion of the temporal bone with a titanium screw. It is attached to the stapes with a hydroxyapatite tube, which is interposed between the tip of the vibrator and the head of the stapes.

In 39 patients in Japan, an initial hearing improvement of 36 dB at 3 months after surgery eventually decreased to 21 dB with long-term follow-up.^[1] The reason for the diminished performance was thought to be to a decrease in the sensitivity of the ossicular vibrator, caused by aging and tissue reaction around the vibrator element. The authors reported that sensorineural hearing was not affected and that all patients preferred the device to a conventional aid.

In 2005, manufacturing of the Rion device in Japan was discontinued because of regulatory issues.

Cochlear Totally Integrated Cochlear Amplifier

The Totally Integrated Cochlear Amplifier (TICA; Implex American Hearing Systems, now owned by Cochlear Corporation) is totally implantable (see the image below). The microphone is implanted subcutaneously in the external ear adjacent to the tympanic membrane. A digitally programmable processor located subcutaneously on the mastoid processes the signal. A piezoelectric transducer is coupled to the body of the incus and drives the ossicular chain by vibratory actions. Both European and North American research programs have used this device.



Totally Integrated Cochlear Amplifier (TICA; Cochlear).

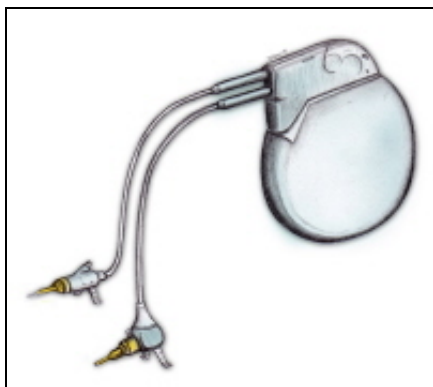
The TICA received the CE mark in Europe in the late 1990s but has not undergone studies in the United States. In 2004, Cochlear acquired Implex; however, no further studies have been published.

Envoy Esteem

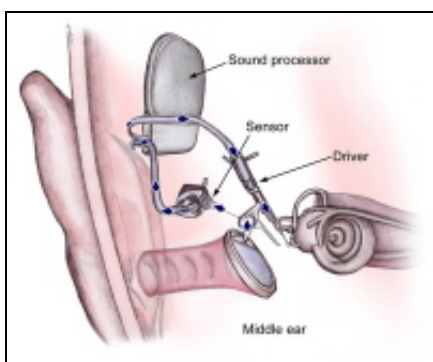
Another totally implantable piezoelectric device is the Esteem by Envoy Medical (originally St. Croix Medical). Formal approval of the system was granted by the US Food and Drug Administration (FDA) in March 2010. Overseas, the Esteem received the CE mark in 2006, and it is currently being implanted in several countries.

The Esteem uses the eardrum as the microphone, taking advantage of the natural acoustics of the ear canal

without obstruction, interference, or any external devices. Therefore, the input is identical to that received by a person with normal hearing. This mechanical signal is detected from a piezoelectric transducer at the body of the incus (the sensor) and converted to an electrical signal by using existing transducer technology (see the images below).



Processor and transducers of Esteem (Envoy).



Esteem (Envoy), implanted.

The electrical signal is then amplified, filtered, and converted back to a vibratory signal. The processed vibratory signal is delivered by means of a piezoelectric transducer (the driver) attached to the capitulum of the stapes. The lenticular process of the incus is removed to prevent feedback to the sensor. The second-generation piezoelectric transducer can produce a sound pressure level (SPL) output close to 110 dB.

An audiologist programs the Esteem using a device called the commander. After the device is programmed, patients are given a personal programmer that allows them to turn the device on or off, to adjust the volume, and to remotely modify background noise filters.

The Esteem faces some hurdles as it is developed further. Whereas the first-generation battery was expected to last, the current battery has a predicted lifetime of 5-7 years, depending on use; it can be replaced with the patient under local anesthesia. In addition, removal of a portion of the incus permanently alters the ossicular mechanism and makes full recovery of hearing to preimplantation baseline levels difficult if the device fails or is in the off position.

A newer prosthesis, the Kraus K-Helix System (marketed by Grace Medical), was developed to reconstruct the defect in the incus created by placing the Esteem.

Electromagnetic hearing devices

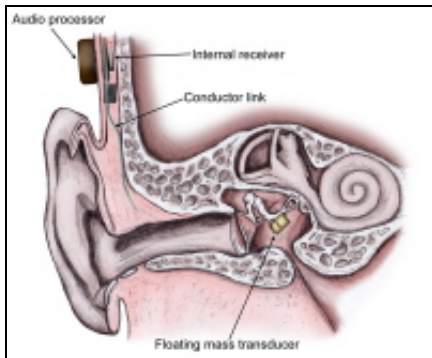
Electromagnetic hearing devices function by passing an electric current into a coil, thereby creating a magnetic flux that drives an adjacent magnet; the coil may be either separate from the magnet or integrated with the magnet. The small magnet, or a magnetic piston, is attached to one of the vibratory structures of the middle ear (eg, tympanic membrane, ossicles, or round window). In some cases, the external coil can be housed in a completely-in-the-canal (CIC) type of hearing-aid shell.

The major disadvantage of this arrangement is that power is decreased by the square of the distance between the coil and the magnet; therefore, the coil and magnet must be close. A slight shift of coil position in the external ear

results in unpredictable or insufficient power output. Furthermore, the anatomy of the middle ear space restricts the size of the magnet or coil.

Med-EI Vibrant Soundbridge

One example of an electromagnetic device is the Vibrant Soundbridge (see the image below). Originally developed by Symphonix Devices, the Soundbridge was the first FDA-approved implantable middle ear hearing device to treat sensorineural hearing loss. It was marketed and implanted in the United States for a few years, until the technology was purchased by Med-EI of Austria. It is now marketed by Med-EI and implanted worldwide.



Vibrant Soundbridge (Med-EI).

The Vibrant Soundbridge is a semi-implantable device composed of an external sound processor and amplifier, an audio processor, and an internal vibrating ossicular prosthesis (VORP). Sound passes into a microphone on the postauricular audio processor and is transmitted through the skin to an implanted receiver on the VORP.

The VORP, which is implanted postauricularly (in much the same way as a cochlear implant), conducts the sound to a magnet surrounded by a coil called the floating mass transducer (FMT). This transducer is attached to the long process of the incus, and the magnet hugs the long axis of the stapes, which causes it to vibrate.

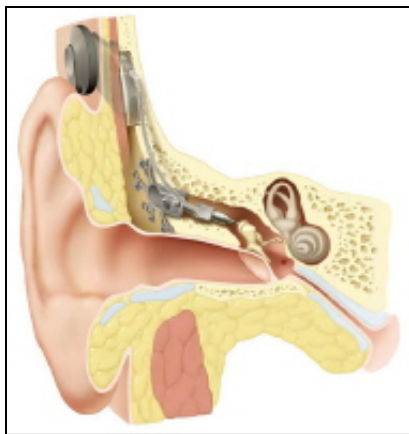
In 2007, the use of the Vibrant Soundbridge began to be expanded. The device was implanted successfully on the round window membrane in patients with aural atresia and mixed hearing losses.^[2, 3, 4] It was also applied to the incus in a more traditional sense in patients with otosclerosis.^[5, 6]

In 2008, the Vibrant Soundbridge received the CE mark for conductive and mixed hearing loss in adults. In 2009, it received the CE mark for the same indication in children. A phase II (pivotal) trial is ongoing in the United States for conductive and mixed hearing loss indications.

Since its original development, the audio processor has evolved from the original analog Vibrant P unit to the digital 3-channel Vibrant D unit to the current digital 8-channel Vibrant Signia unit. Compared with the Vibrant D device, the Signia device achieves modest increases in functional gain and speech-in-noise understanding results.

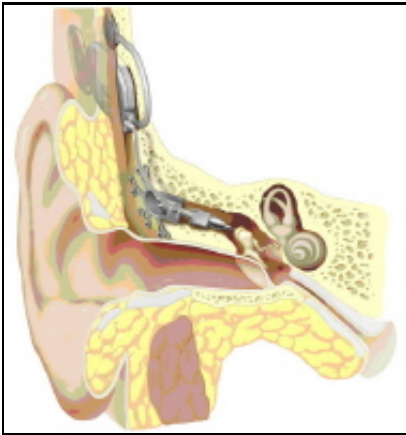
Otologics Middle Ear Transducer and Carina

The Middle Ear Transducer (MET) was first introduced by Otologics LLC as a semi-implantable device (see the image below). The MET has a CE mark representing pan-European approval for marketing.



Semi-implantable Middle Ear Transducer (MET; Otologics).

A totally implantable version was subsequently developed and named the Carina (see the image below). The Carina received European approval in October 2006. In 2006, the device received the CE mark for moderate-to-severe sensorineural hearing loss; in 2007, it received the CE mark for conductive and mixed hearing loss. Phase II of the FDA clinical trial is currently ongoing in the United States.



Carina (Otologics), a fully implantable ossicular stimulator.

The original MET device was composed of an implanted transducer mounted in a laser-drilled hole in the body of the incus. The transducer translates the electrical signals into a mechanical motion that directly stimulates the ossicles and enables the wearer to perceive sound. The transducer is coupled with an externally worn audio processor (the button audio processor), which contains the microphone, battery, and signal processor. To date, more than 300 patients have received the implant in Europe and in the United States.

The Carina consists of 4 primary components: the implant, the programming system, the charger, and the remote control. The implant component consists of 2 main parts: the electronics capsule and the MET. The electronics capsule contains the microphone, battery, magnet, digital signal processor, and connector.

A sensitive microphone located under the skin picks up sounds, which are amplified according to the wearer's needs and converted into an electrical signal. The signal is sent down the lead and into the transducer, which is the same as that used in the semi-implantable version. The semi-implanted version can be upgraded to the fully implanted version in a single surgical procedure done with local anesthesia.

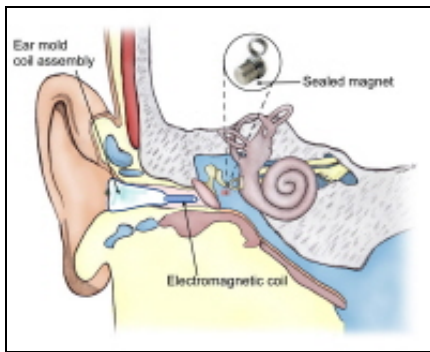
The programming system coil is placed over the implant site and held in place magnetically. The coil couples with the implant by means of a radiofrequency signal that is used to program the device in the same manner as with a traditional digital hearing aid. The programming system also allows extensive testing and diagnostics of the stimulator.

The charger system consists of the base station, the charging coil, and the charger body. To charge the implant, the wearer removes the charger body from the base station and places the coil on the skin, over the implant site. The charger body contains a clip that allows the charger to be attached to the belt of the wearer during charging. Typically, charging takes about 1 hour if performed daily. While recharging the implant, the wearer can perform normal daily activities, turn the implant on and off, and adjust the volume.

A remote is used to control the stimulator when the device is not being charged. This remote allows the wearer to turn the implant on and off and to adjust the volume. To use the remote control, the wearer holds the remote against the skin over the implant.

Soundtec Direct Drive Hearing System

The Soundtec Direct Drive (see the image below) was introduced to the US market in 2001 and voluntarily withdrawn in 2004. This semi-implantable device converts sound energy to electromagnetic energy to stimulate the ossicles directly.



Soundtec Direct Drive (Soundtec).

A surgically implanted neodymium-iron-boron (NdFeB) magnet is attached to the ossicular chain by positioning a collar around the neck of the stapes. An earmold coil assembly consisting of an acrylic skeleton mold with an embedded electromagnetic coil stimulates the magnet. The earmold coil assembly is inserted deeply into the ear canal, ideally approximately 2 mm away from the tympanic membrane. It is attached to a sound processor that is fitted either in the canal or behind the ear, much like a hearing aid.

Such a design offers several possible advantages. Because it works by electromagnetic energy through the ear canal, the Soundtec device does not require an acoustic seal, which may lead to the occlusion effect or alter the resonance qualities of the ear canal (which causes distortion). Also, functional gain can be improved without necessarily precipitating feedback, a common problem with traditional aids that occurs when sound pressure escapes the ear canal and cycles back through the microphone.

A relative disadvantage is that the procedure requires separation and then reconstitution of the incudostapedial joint. In one study, residual hearing was not affected in most subjects. Average bone-conduction thresholds decreased by 1.1 dB over the 250-4000 Hz range, possibly from movement of the stapes into the vestibule during disarticulation of the incudostapedial joint, which may cause sensorineural hearing loss. Average air-conduction thresholds decreased by 4.2 dB over the 250-8000 Hz range, primarily from the loading effect of the implant on the ossicles.

A long-term follow-up retrospective review of 64 patients receiving the Soundtec device revealed a significant average functional gain of 26 dB.^[7] About 55% of patients complained of hearing the magnet move or rattle when the processor was not being worn. This effect was reduced, but not completely eliminated, by further stabilizing the implant with the placement of adipose tissue between the implant collar and the neck of the stapes.

A patient questionnaire aimed at assessing sound quality, speech in noise, and satisfaction with the Soundtec as compared with conventional hearing aids failed to show a significant difference.^[7] The authors concluded that the ideal patient is one younger than 70 years who has moderate sensorineural hearing loss, speech discrimination scores equal to or better than 60%, appropriately sized ear canals, and sufficient manual dexterity to insert the processor.

To date, around 600 Soundtec devices have been implanted, most of them in the United States. The device was voluntarily withdrawn from the market in 2004 when the company identified ways to improve it and to eliminate the magnet rattling some patients experienced. The rattling sound, which occurred primarily when the external processor was not used, occurred in as many as 7% of patients. It was thought to result from movement of the magnet around its single point of fixation with the ossicular chain.

Additional studies of the Soundtec in a magnetic field indicate that it should be mechanically stable and nondestructive during 0.3T open MRI with a modified MRI protocol.^[8, 9]

Ototronix Maxum

The Ototronix Maxum system is based on the Soundtec Direct Drive technology, which Ototronix acquired from Soundtec in 2009. The general concept of stimulation is the same. The Maxum is a partially implantable device that converts sound energy to electromagnetic energy in order to stimulate the ossicles directly.

The Maxum comprises 2 main components: the implant and the external processor. The implant consists of a surgically implanted NdFeB magnet encased in a titanium canister that is attached to the ossicular chain by

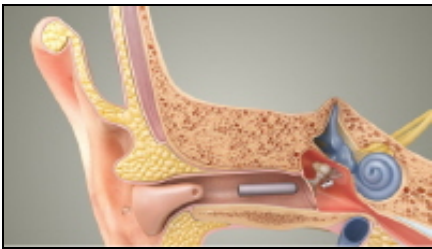
positioning a collar around the neck of the stapes.

The external processor consists of a digital sound processor and electromagnetic coil. The sound processor gathers and processes speech and sounds. The processor sends signals to an electromagnetic coil located in the ear canal near the tympanic membrane, thereby directly stimulating the magnetic implant and thus the ossicles.

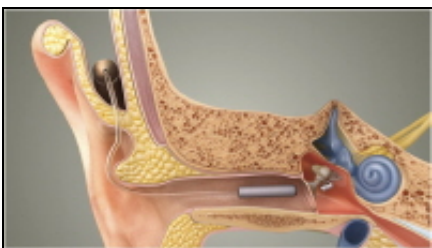
Because of the direct stimulation of the ossicles by the magnetic implant, no acoustic speaker or receiver is used. This arrangement eliminates the use of sound energy in the canal and thus offers several possible advantages over hearing aids, as follows:

- Because it works by electromagnetic energy through the ear canal, the Maxum does not require an acoustic seal, which may lead to the occlusion effect
- Because there is no increase in sound energy in the canal, which can alter the resonance qualities of the ear canal and cause distortion, distortion may be reduced
- Functional gain can be improved without necessarily precipitating feedback, which occurs when sound pressure escapes the ear canal and cycles back through the microphone

The processor is available in either an in-the-canal or a behind-the-ear configuration. The former (see the first image below) consists of an integrated processor and electromagnetic coil that fits in the canal, similar to an in-the-canal or CIC hearing aid. The latter (see the second image below) has an earmold coil assembly consisting of an acrylic skeleton mold with an embedded electromagnetic coil inserted deeply into the ear canal, ideally about 2 mm away from the tympanic membrane.



Maxum (Ototronix), in-the-canal configuration.



Maxum (Ototronix), behind-the-ear configuration.

Ototronix has redesigned the processor to include digital circuitry. This offers several possible advantages. The digital design is easier to program and incorporates directional microphones, noise cancellation, and wide dynamic range compression. It is also compatible with the original Soundtec device, and patients can be upgraded simply by changing to the Maxum digital processor.

In a clinical study in which patients who were all originally Soundtec patients were fitted with newer digital processors for comparison with the performance of their original processors, the results indicated that the digital processor could be expected to provide performance similar to that originally reported for the Soundtec device, which included the following:

- A statistically significant average increase of 7.0-7.9 dB in functional gain in the pure-tone average (PTA) and an increase of 9.2-10.8 dB in the high frequencies (2000 Hz, 3000 Hz, 4000 Hz)
- A statistically significant increase of 5.3% in speech discrimination
- Superiority in subjective measures of feedback, occlusive effect, perceived aided benefit, patient satisfaction, and device preference over the patient's optimally fitted hearing aid

As in the original study, the Maxum implant has an average decrease of 4.2 dB in air-conduction thresholds across the 250-8000 Hz range, primarily because of the loading effect of the magnet implant on the ossicles.

Average bone-conduction thresholds decrease by 1.1 dB over the 250-4000 Hz range.

With the original Soundtec device, patients complained of hearing the magnet move or rattle when the processor was not being worn (see above). This effect can be alleviated, though not completely eliminated, by placing adipose tissue between the implant collar and the neck of the stapes. It has also been found that the use of a very small amount of glass ionomeric cement (as is typically used with a prosthesis) can fixate the implant and prevent it from moving.

Unlike the original Soundtec device, the insertion of which required separation and then reconstitution of the incudostapedial joint, the Maxum will be available with a connection design that does not necessitate separation of the incudostapedial joint. Like the original Soundtec device, the Maxum should be mechanically stable and nondestructive during 0.3T open MRI with a modified MRI protocol.^[8, 9]

Indications

Hearing loss affects up to 10% of the population in the United States. Its prevalence increases with age, and more than one third of people older than 65 years have significant hearing loss. Only about 20% of people with hearing loss seek assistance from hearing aids. Of these, as many as 20% do not wear their hearing aids, and another 17% are dissatisfied with them.

Although technical improvements and modifications have improved the fidelity of conventional hearing aids, these devices still have many limitations, including the following:

- Hearing aids may be difficult to maintain, requiring frequent cleaning, dehumidification, and battery changes
- Some patients may perceive hearing aids as being uncomfortable because they simply cannot tolerate an object in the ear canal; patients often report the occlusion effect of an object blocking the entire ear canal
- Chronic otitis externa, canal exostoses, or frequent cerumen impactions make it difficult for some patients to wear hearing aids
- Poorly fitting ear molds, faulty circuitry, or canal issues can lead to annoying feedback; feedback also limits the amount of functional gain that may be delivered to the patient
- Poor sound quality and problems hearing background noise are frequent complaints of those who wear hearing aids
- Some patients may perceive a social stigma associated with hearing-aid use

In general, candidates for implantable middle ear devices should have tried conventional aids with limited success. Most current devices are designed for patients with mild-to-severe sensorineural hearing loss. This degree of loss can often be adequately improved with conventional hearing aids. Patients with severe sensorineural hearing loss, however, often have difficulty with feedback because of the amount of gain required. Furthermore, a tight-fitting ear mold, as is necessitated by severe hearing loss, leads to discomfort and hygiene issues.

Implantable middle ear devices, which do not necessitate occlusion of the ear canal and which uncouple the receiver from the microphone, are particularly well suited for more severe hearing losses. Current high-output middle ear drivers may allow patients in the so-called gray area between hearing aids and [cochlear implants](#) to be rehabilitated effectively.

Candidates for middle ear implants should be free of significant middle ear disease or infection. Hearing loss should be stable, and word recognition scores (WRS) should be sufficient to allow adequate discrimination of sounds. Additionally, the patient's expectations of benefit should be reasonable.

Totally implantable middle ear devices may be particularly attractive to athletes and swimmers, whose ability to hear may be limited by water or sweat when they are active. Actors, performers, and any other persons who desire a completely concealed hearing aid will find totally implantable middle ear devices an appealing option.

Successful applications of these devices to the round window have placed rehabilitation of conductive hearing losses within the realm of possibility for middle ear implants. With appropriate modifications, existing implantable middle ear devices may be further adapted for conductive hearing loss use.

Currently, implantable middle ear devices are indicated for patients aged 18 years or older in the United States.

As of early 2011, the semi-implantable Med-EI Vibrant Soundbridge and the totally implantable Envoy Esteem have been approved by the US Food and Drug Administration (FDA) for implantation in the United States. The Vibrant Soundbridge, the Esteem, and the Otologics Carina are available outside the United States. The Carina is undergoing FDA investigation in the United States.

Clinical Trial Evidence

Envoy Esteem

The phase I clinical trial of the Esteem system included 7 patients, 5 of whom had working implants in the 2-month postactivation period. The remaining 2 derived no benefit from the device, because of a breach in the hermetic sealing that allowed moisture to pass into the circuitry; this breach was corrected in the current version of the device.

Overall, the 5 patients with functioning devices perceived a benefit with the Envoy device as compared with their hearing aid in terms of ease of communication in favorable conditions, background-noise reverberation, and aversiveness of sound. There was a marked (17%) improvement in speech discrimination over that achieved with hearing-aids. Functional gain and speech reception thresholds were similar for the Esteem device and for the hearing aids.

Phase II of the US Food and Drug Administration (FDA) clinical trial was composed of 2 parts. In the first part, which included more than 70 patients, pure-tone average (PTA) and word-recognition score (WRS) improved significantly. However, a significant number of revision procedures were required; this prompted a second part of the FDA clinical trial, a "pivotal clinical study" involving 54 patients undergoing implantation at 3 sites in the United States.

Results of the second part of the trial, presented at the FDA panel meeting in December 2009, indicated an improvement of 11.4 ± 1.8 dB over the preimplant aided condition at 10-month follow-up. WRS at 50 dB was improved in 56% of the subjects in comparison with the preimplant aided condition; WRS was reported unchanged in 37% and decreased in 7% at 4 months in comparison with the preimplant aided condition. There was no postoperative decline in bone thresholds in comparison with the preimplant condition.

In the phase I study of the Esteem device, functional gain was similar to that of conventional hearing aids but was limited above 3000 Hz. Substantially better results were obtained in the phase II studies.

Med-EI Vibrant Soundbridge

The phase III FDA trial of the Vibrant Soundbridge found the device to be safe, with no notable change in preoperative and postoperative bone thresholds; furthermore, functional gain and WRS were higher with the Vibrant Soundbridge than with conventional hearing aids.^[10] In self-assessment inventories, 94% of the patients preferred the overall sound quality of the Vibrant Soundbridge device to that of their conventional hearing aid.

Otologics Carina

The US phase I trial results for the Carina system yielded a 15-20 dB functional gain across audiometric frequencies in 20 patients; PTA and monaural WRS were better with the hearing aid in the same ear preoperatively, whereas patients generally perceived more benefit in the postoperatively implant-aided conditions.^[11]

Soundtec Direct Drive

The phase II FDA clinical trial of the Soundtec Direct Drive, which included 103 patients with moderate to moderately severe sensorineural hearing loss who had previously worn hearing aids for at least 45 days, found that this system yielded a statistically significant improvement over hearing aids in average soundfield threshold and functional gain over the 500-4000 Hz range.^[12] The improvement in average functional gain consisted of a 7.0-7.9 dB increase in PTA and a 9.2 dB increase in the high-frequency average (2000, 3000, and 4000 Hz).

In addition, there was a statistically significant increase of 5.3% in speech discrimination.^[12] Furthermore, subjective measures of feedback, occlusive effect, perceived aided benefit, patient satisfaction, and device preference over the patient's optimally fitted hearing aid showed that 89% of the patients preferred the Direct Drive in terms of overall satisfaction, 99% preferred it as having the least amount of feedback, and 89% preferred it as providing better sound quality.

Clinical Implementation

A few major biomechanical issues must be addressed in the development of implantable middle ear devices. The first is that the device should not affect the normal functioning of the middle ear. Optimally, it should not alter air-conduction thresholds. If the device is unsuccessful, the added mass of the unit attached to the vibratory structure of the middle ear should not impair that structure's ability to vibrate.

Another important issue is the anchoring of the device to the ossicular chain. Even a little laxity at the interface between the prosthesis and bone could diminish the transmitted power enough to render the device ineffective. The long-term stability of the fixation must also be considered. The mechanical forces acting at the interface could affect the life expectancy of the device.

The direction of the transducer's vibration must be coincident with the axis of normal sound transmission through the ossicular chain. In effect, the device must be attached to the tympanic membrane, the long process of the incus, or the head of the stapes. Otherwise, the transmitted force is reduced. However, cases involving implantation in the round window membrane have begun to challenge this more traditional approach.

Finally, with totally implantable devices, battery life must be long enough to avoid frequent replacement (and consequent reoperation). A rechargeable battery offers a potential solution to the battery-replacement problem, provided that the battery is able to maintain a charge over a long period.

Contributor Information and Disclosures

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Additional Contributors

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