

The future of implantable hearing devices: Introduction to a two-part special section

By *Marshall Chasin*
Guest Editor



Marshall Chasin

The last decade has seen astonishing advances in the technology of hearing aids. A comparable degree of technological innovation is now taking place in a related field: implantable devices.

In this context, an implantable hearing device is any instrument that is entirely or partially implanted in the temporal bone or the middle ear. Partially implanted devices include the bone-anchored hearing aid or Baha[®], in which the vibratory “receiver” is implanted in the temporal bone, just behind the pinna. The Baha is

especially useful for conductive and most mixed hearing losses. There is also a range of middle ear implants in which the “receiver” transducer is implanted on the ossicular chain.

The greatest change is taking place among fully implanted devices. Historically, these were restricted to piezo-electric devices that used a very small transducer. However, in the near future we will see electro-magnetic devices that offer the benefits of being completely in the ear.

The benefits of the explosion in hearing aid technology has not passed implantable devices by. We will see many

of the same innovations found in modern hearing aids being used in implantable devices.

The following special section, which begins in this issue and will continue in the September issue, is based on a panel presentation, “New Developments in Implantable Devices,” presented at the American Academy of Audiology’s AudiologyNOW! 2008. I would like to thank the academy for organizing the panel session that brought together many of the leading researchers and audiologists working in this exciting area.

This section primarily focuses on the near future in implantable devices. In doing so, it provides hearing health-care providers with a preview of what’s in the pipeline today that will be able to help their patients tomorrow. However, before looking at the future, we’ll be taking a brief look at the developments that led us to where we are today.

Marshall Chasin, AuD, Guest Editor of this special section, moderated the panel session, “New developments in implantable devices,” held at AudiologyNOW! 2008. Readers may contact Dr. Chasin at Marshall.Chasin@rogers.com.

A brief history of middle ear implants

By *Marshall Chasin*

In 1935 Alvar Wilska sprinkled iron filings onto the tympanic membrane of a patient lying on his side on a medical table.¹ Dr. Wilska placed an earphone over the man’s ear that produced no sound—only an electro-magnetic signal—and the patient reported “hearing.”

In this experiment, the iron filings moved around in synchrony with the changing magnetic field (the alternating current or ac flux). These filings caused the tympanic membrane to move, which in turn transduced the vibration to the cochlea. This was the first reported example of an implantable hearing device. In this case, the iron filings took the place of the receiver. In the 1950s, it took 28,000 mA to produce an 85-dB SPL signal. Today less than 3 mA can produce this same level of signal.

Goode defined a middle ear implant (MEI) as a hearing device part or all of which is implanted in the middle ear.² MEIs offer cosmetic advantages (since they are invisible when worn), and they can also provide greater high-

frequency amplification because of the separation of the microphone from the receiver. In addition, an MEI creates little or no occlusion effect because very little, if any, of the device is situated in the ear canal.

The first MEI to come to market was designed for patients with chronic dysfunction of the middle ear, and it replaced many of the middle ear’s functions.³ Possibly because of the complicated and irreversible nature of the surgery, this MEI approach did not gain widespread use outside of Japan.

MORE RECENT APPROACHES

The 1990s saw a return to MEIs in which only the receiver transducer was placed in the middle ear. The major thrust of modern implementations of the device is for treating people with purely sensorineural hearing losses (and normally functioning ossicular chains), although some manufacturers are modifying their products for patients with

mixed or conductive hearing losses as well.

Although various approaches have been tried, most current MEIs use a receiver element situated on or near the incudo-stapedial joint, which Jack Hough, MD, and colleagues have shown to be the optimal location. It's medial enough to take advantage of the rotary characteristics of the ossicles and thus ensure sufficient high-frequency transduction, yet lateral enough to be close to the driving coil, which is situated either in the ear canal or behind the ear.⁴ Coating the implanted receiver magnet in a titanium case wards off moisture, which was a problem with earlier implants.

This type of MEI is referred to as an electro-magnetic or electro-mechanical implant. As the name suggests, it requires two parts: an implanted magnet and an external coil coupled to the microphone. Like any electro-magnetic combination, the external coil can't be too far from the internally implanted magnet. An advantage of this system is that it can achieve very high outputs (up to 130 dB SPL), although in most cases outputs have to be limited to 110 dB SPL (usually because of Food and Drug Administration regulatory concerns). A disadvantage of the electro-magnetic approach is its relatively large size. That meant that the MEI implementations of the 1990s and early 2000s could be only partially implanted.

A second approach developed in the 1990s (similar to Suzuki and Yanagihara's idea) used a piezo-electric form of

transduction. As with electro-magnetic MEIs, candidates for this more modern piezo-electric approach had purely sensorineural hearing losses.

When a piezo-electric crystal is bent or flexed, a current is generated, and the converse is also true. Thus, it could be used as a microphone and a receiver, albeit with different degrees of efficiency. An advantage of these piezo-electric MEIs is their small size, which allows them to be fully implanted in the middle ear.

However, a serious drawback is that their maximum output is typically limited to about 110 dB SPL (with maximum use gain on the order of 30-35 dB). Therefore, the devices cannot be fitted on patients with more than moderate sensorineural hearing loss, a range well within the capability of the smaller CIC hearing aids. In the piezo-electric approach, a small ceramic crystal is implanted on the ossicular chain (usually surgically placed in or near the incudo-stapedial joint). This is physically joined either to an external microphone surgically located in the (posterior) wall of the ear canal or to the patient's tympanic membrane, which serves as the microphone.

THE BAHA

The bone-anchored hearing aid (Baha[®]) has been widely used since the late 1980s. Designed primarily for patients with conductive or mixed hearing losses (with bone-conduction scores no worse than 45 dB HL), the Baha is fitted such that

only the receiver is implanted in the temporal bone and sound is sent by bone conduction to the relatively intact cochlea.

Historically, there have been both transcutaneous (over the skin) and percutaneous (through the skin) devices, the latter being the now-discontinued Xomed Audient and the former being the only Baha remaining on the market, which is made by Cochlear Corp. There were inherent problems with a transcutaneous approach because the transduced signal may be of low intensity, and in some cases could not stay in contact with the skull.⁵

In contrast, the percutaneous approach, which uses an abutment that protrudes through the skin behind the ear, has better mechanical transduction characteristics, which make it suitable for a wider range of patients.

ON TO THE FUTURE...

The rest of the articles in this special section are based on presentations given at AudiologyNOW! 2008. They discuss what is just down the road for middle ear implants. No longer are MEIs too large for a fully implantable system and, thanks to sophisticated new digital algorithms and digital processing, today's MEIs can draw on the same electroacoustic benefits that are available with conventional hearing aids.

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Soundbridge users report better sound quality

By *Tim Campos*

The Vibrant Soundbridge[®], which has been approved for use by adults in the U.S. since 2001, is intended for persons who have moderate-to-severe sensorineural hearing loss and cannot achieve success or adequate benefit from acoustic hearing aids or are unable to tolerate hearing aids due to conditions such as chronic perichondritis of the ear, chronic otitis externa, atresia of the ear canal, congenital malformations, or skin reaction from the earmold or hearing aid case.

Additional candidate selection criteria include: normal middle ear function, a speech-recognition score of at least 50% at the implant ear under headphones, no retrocochlear or central involvement, no skin conditions preventing attachment of the audio processor, and realistic expectations.

The Soundbridge consists of two primary components, as seen in Figure 1:

- ❖ a surgically implanted vibrating ossicular prosthesis (VORP) containing a magnet, receiving coil, demodulator

package, conductor link, and floating mass transducer (FMT).

- ❖ the external audio processor (AP).

The AP is worn outside the head, behind and above the pinna. It is held to the scalp by attraction between magnets in the VORP and in the AP. The AP also contains a microphone, a signal processor, telemetry electronics, and a standard 675-zinc air battery that powers the system.

The FMT is a totally enclosed transducer that uses inertial drive to impart