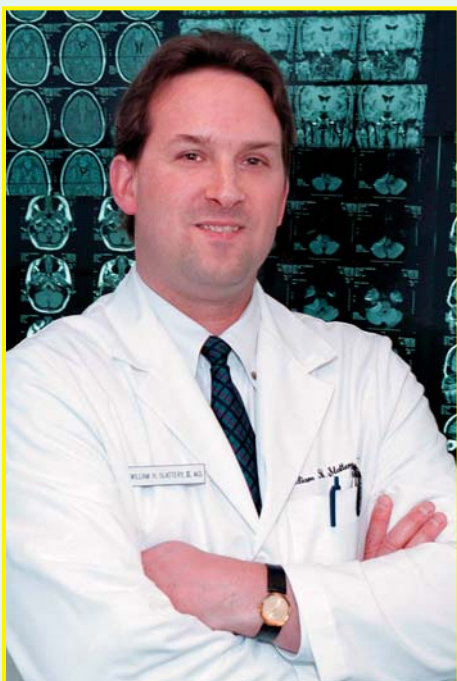


A New Alternative to Hearing Aids

Dr. Slattery Discusses Implantable Middle Ear Hearing Devices



William H. Slattery, III M.D.

Chances are great that at some point in the near future, you or one of your loved ones will need to consider wearing hearing aids or some other type of assistive listening device. Until recently, conventional air conduction hearing aids were the only choices available for many people needing sound amplification. One common complaint, however, is that they do not provide enough amplification of sounds that the user wants to hear and over-amplify the distracting background noises they wish to avoid. Acoustic feedback is another problem. While improvements in electronic circuitry have helped reduce much of the feedback in today's hearing aids, it remains a

source of irritation for most long-term wearers.

In response to these limitations, several manufacturers have developed what some experts foresee as a promising new alternative for hearing aid wearers – implantable middle ear hearing devices.

HEI's Clinical Studies Department is performing clinical trials on some of the new implantable middle ear hearing devices that manufacturers hope will gain FDA approval in the near future.

We recently spoke with William H. Slattery III, M.D., who heads the Institute's Clinical Studies Department, to shed some light on the implantable middle ear hearing technologies that either are on the market or in clinical trials.

Q What are implantable middle ear hearing devices?

A They are fully and semi-implantable devices that are attached to the hearing bones of the middle ear chamber [see anatomy diagram on page 16]. The middle ear placement enables the device to transmit sound vibrations directly to the bones that prepare and send the sound energy along to the inner ear. This is in contrast to conventional hearing aids, which amplify and present sound to the tympanic membrane [ear drum] before it enters the middle ear system.

On semi-implantable devices, the external portion consists of a battery, microphone, speech processor and electrical transmitter. The internal

portion includes a receiver, transmitting coil and mechanical vibrator, which are embedded under the skin and inside the middle ear space.

The implantable devices vary in terms of the type of transducer [energy converter] used and the way in which they are attached to the bones of the middle ear.

Q How do these differ from conventional air conduction hearing aids?

A Implantable middle ear hearing devices are advantageous in several ways. They eliminate outer ear occlusion [the feeling of having a plugged ear canal] and feedback problems that are common with hearing aids. These devices also have the potential to provide former hearing aid users with greater amplification at higher frequencies and improve speech perception in the presence of background noise. Wearers describe the devices as providing a more natural sound than they have experienced with conventional hearing aids.

Q Are semi-implantable devices hidden from view when they are worn?

A Semi-implantable devices contain both externally and internally worn parts. The external parts are placed behind the ear, so they can be hidden underneath the patient's hair.

Q *Based on clinical trials to date, who are the best candidates for implantable middle ear hearing devices?*

A The best candidates are people with moderate to severe sensorineural [permanent nerve-based] hearing loss, who are dissatisfied with their conventional hearing aids. At present, only adults can be considered for these devices. Candidates should consult with their licensed otolaryngologist [ear doctor] or audiologist to determine what's best for their individual needs.

Q *What is the average cost?*

A The current costs range from \$15,000 to \$20,000. Insurance typically does not cover costs associated with the device or implantation procedure.

Q *Tell us about the types of technologies currently on the market or in the clinical trial phase.*

A At this time, only one semi-implantable device is available in the United States. SOUND-

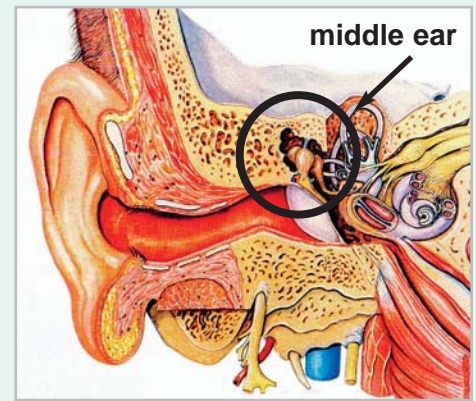
TEC's Direct System™; was approved by the FDA and is commercially available. Two other manufacturers have devices that are undergoing or pending a clinical trial phase this year: Otologics LLC's Middle Ear Transducer™; SOUND-TEC's Direct System™; and St. Croix Medical's Envoy™.

Q *How effective are middle ear devices in amplifying sound?*

A Patients describe a more natural sound with the implantable devices, which have been compared with the current digital hearing aids.

Q *How do patients replace or recharge the batteries?*

A The current semi-implantable devices have batteries in the external processor, and are easy to replace without surgery. Fully implantable devices will either contain a rechargeable battery requiring recharging every three to five days or a non-rechargeable battery requiring replacement every three to five years.



Q *In your experience, what is the most common patient concern with the new devices?*

A The most common concern is the need to undergo surgery to implant the device.

Q *Is electromagnetic interference an issue for wearers who use cell phones?*

A At this point, some of the devices can be used with cell phones without causing electromagnetic interference.

Q *Do you see the devices becoming a popular alternative to conventional hearing aids in the future?*

A It is anticipated that they will become popular once they are fully implantable, and will present both functional and cosmetic improvements for the patient. ❖

About the Institute's Clinical Studies Department

The House Ear Institute's Clinical Studies Department integrates scientific research with patient application. Under the direction of William H. Slattery III, M.D., the department is known in the field of hearing research for its clinical trial expertise involving auditory devices and medications. As such, it frequently provides consultation and educational services to other facilities to improve the quality of fact-based studies and information. The department staff also conducts frequent workshops on clinical trial protocols for the American Academy of Otolaryngology (AAO).

William H. Slattery III, M.D., is Director of the Clinical Studies Department at the House Ear Institute, Associate of the House Ear Clinic, Inc., and a Clinical Professor at the University of Southern California.