

Fully Implantable Hearing Aid

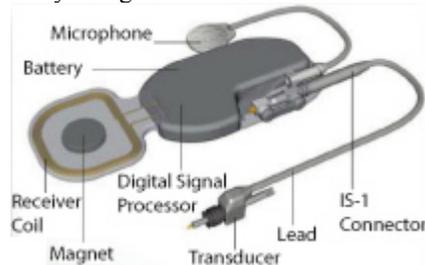
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Currently in the U.S. there is an estimated 28 million people who suffer from hearing loss. Two forms of hearing loss are conductive and sensorineural. Conductive hearing loss occurs when there is failure in efficient conduction of sound waves through the outer ear, eardrum or middle ear. It produces reduction in sound level. Sensorineural hearing loss occurs when there is damage to the cochlea or the nerve pathways to the brain. It produces reduction in sound level as well as the loss of clear hearing and ability to understand speech. Some form of hearing aid is usually worn by those who suffer from hearing loss. Hearing aids prevent full enjoyment of activities such as swimming or aerobic activities because they have to be taken out most of the time, leaving the patient with bad hearing. Otologics Inc. of Colorado has developed a fully implantable hearing aid that is completely concealed, which will make life much more enjoyable for patients with hearing loss.

The first form of this device, developed in 2005, was only a partially implantable acoustic prosthesis called the Middle Ear Transducer (MET). There was an internal receiver and an external transmitter. The internal receiver was implanted in the mastoid bone, behind the ear. It extended to the incus bone in the middle ear where the transducer was implanted. The external transmitter, which was behind the ear, is button like with a diameter of 1.2 inches. The two parts were connected by a magnet. General anesthesia was used for the procedure. There was about an 8 week healing period. This device works by a microphone picking up sound, which is processed and then transmitted to the receiver. The receiver extends to the transducer, which is attached to the Incus bone. The transducer causes the middle ear bones to move. This simulates the eardrum, which causes the middle ear bones to vibrate in response to sound waves. An experimental study was conducted with human cadaveric temporal bones and the (MET). The vibrations which were transmitted were measured with laser-Doppler vibrometry. This study not only proved that this device is safe for patients, but also that optimal transfer function between the MET transducer and oval window was achieved.

After modifying the transducer, the surgical instruments and the operative technique, otologics successfully developed the fully implantable hearing aid. The new device is very similar to the previous except that there is nothing external. A capsule is implanted behind the ear, just under the skin. The

capsule contains a microphone, battery, transmitter and processing components. The transducer is implanted into the middle ear. The microphone picks up the sound, which is processed and then sent to the transducer, causing the middle ear bones to move, simulating the eardrum. A remote control turns the device on and off. It also controls volume. The battery is charged by placing a charging device over the skin of the implant. A clinical research study is currently being conducted for this device.



The Criteria that must be met in order to participate in this study are:

- At least 18 years of age.
- Speak English.
- Suffer from moderate to severe sensorineural hearing loss.
- Currently using a hearing aid.
- In good health with normal middle ear bones.

Requirements in order to participate are to:

- Have the outpatient surgery.
- Attend five audiological visits during the study period, which is 1 year.
- Pay for the device, which costs \$12,500.

The surgical and physician costs are covered by a sponsor. After patients underwent surgery and had the device activated it was reported that patients experienced an improvement of sound-field thresholds up to 50 dB. The clinical study is not yet complete but this new form of rehabilitation is very promising.

Sources:

- <http://www.asha.org/public/hearing/disorders/>
- <http://www.otologics.com/unitedstates.htm>
- <http://oto.wustl.edu/met.htm>
- Rodriguez, Jorge Jesus, et al. "In Vitro Model for Intraoperative Adjustments In An Implantable Hearing Aid (MET)." *Laryngoscope*. 116.3: 473-481, March 2006.
- Siegert, Ralf, et al. "Fully Implantable Hearing Aids In Patients With Congenital Auricular Atresia." *Laryngoscope*. 117.2: 336-340, February 2007.