

# Totally Implantable Hearing Devices

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## Abstract

Hearing aids are the principal means of auditory rehabilitation for patients with moderate to severe sensori-neural hearing loss. Although technical improvements and modifications have improved the fidelity of conventional aids, hearing aids still have many limitations including the inherent self consciousness and social stigma attached to visible hearing aids. The recently introduced totally implantable hearing aids offer patients with hearing loss several potential advantages over conventional hearing aids. This article reviews the indications, surgical procedure, advantages and the current status of totally implantable hearing devices.

**Keywords:** Moderate to profound SNHL, totally implantable hearing device (TIHD).

## INTRODUCTION

The many dramatic advances in microscopic ear surgery in recent decades have given relief to individuals with deafness be it sensorineural or conductive hearing loss. The largest group of individuals with hearing impairment, are those with moderate to severe sensorineural hearing loss (SNHL). They are often disappointed to find that amplification with external hearing aids is the only treatment option available. Despite the many improvements in hearing aid technology, conventional hearing aids continue to have significant limitations. These limitations of conventional hearing aids led to advancing interest in implantable hearing devices. The search for methods of transmitting amplified sounds into the inner ear by direct vibration of an implant attached to the ossicular chain involves a choice between two basic technologies: electromagnetic and piezoelectric coupling.<sup>1</sup>

The piezoelectric crystal was first investigated as a middle ear driver by Vernon. The piezoelectric implantable hearing aid functions by connecting the ossicles to an amplifier using a piezoelectric crystal vibrator. Piezoelectric materials are bioelectric materials with coupled electrical and mechanical properties. Applying a voltage across an appropriately designed piezoelectric rod cause it to bend or lengthen, with a predictable change in deflection based on the voltage applied. As this rod vibrates in response to the converted auditory signals, it lies in direct contact with the ossicles, thus the sound waves are transferred directly to the ossicles, which then travel along the normal auditory pathway. This is the basic principle involved in the functioning of totally implantable hearing aid. There are at present two popular

TIHDs available—‘The Envoy Esteem’ (piezoelectric device) and ‘The Otologics Carina’ (electromagnetic device).<sup>2,3</sup>

## INCLUSION CRITERIA FOR TIHD

Participant must meet all of the following criteria to be eligible for TIHD:

- Participant is 18 years old and above.
- Participant is willing and able to comply with specified follow-up evaluations, for a minimum of one year, and understands the audiological test procedures and use of the Esteem™ System.
- Participant has mild to severe sensorineural hearing loss between 500 Hz and 4000 Hz in the ear to be implanted with pure tone air-conduction threshold levels within the limits of a hearing aid (HA) as follow:

Frequency (Hz)	500	1000	2000	3000	4000
LL* (dBHL)	25	25	30	30	30
UL* (dBHL)	80	80	80	85	90

\*LL = Lower level; UL = Upper level.

- Participant’s air-bone gap is no greater than 10 dB at 4 of the 5 following frequencies: 500, 1000, 2000, 3000 and 4000 Hz.
- Participant has an unaided maximum word recognition score of greater than or equal to 60% with recorded delivery using a phonetically balanced word list at SRT + 40 dB or at maximum tolerable presentation level.
- Participant is a current user of a properly functioning and appropriately fit hearing aid. This is defined as the

participant has used this aid for at least four (4) hours (average) per day (in the ear to be implanted) for at least three (3) months for a new aid or one (1) month for an adjusted aid.

- g. Participant has a normally functioning Eustachian tube in the ear to be implanted.
- h. Participant has a normal tympanic membrane and normal middle ear anatomy with intact ossicular chain in the ear to be implanted.
- i. Participant has adequate space for Esteem System implant determined via fine cut, preoperative, temporal bone CT scanning.

### OPERATIVE PROCEDURE

The procedure as done for an Envoy Esteem TIHA (Figs 1 to 7) involves cortical mastoidectomy with utmost care not to expose the dura or the sigmoid sinus in order to minimize the auditory feedback. Posterior tympanotomy is done such that it allows complete exposure of body of incus and the stapes with careful preservation of the incus bridge in contrast to posterior tympanotomy of cochlear implantation where it involves complete exposure of round window. A bed for speech processor is then made on the skull just behind the mastoid cavity. Titanium reflectors are placed on the posterior crura of stapes and body of incus. The mobility of stapes is confirmed with the help of Laser Doppler Vibrometer as this is an important prerequisite for the surgery.

Incudostapedial joint is disarticulated and the long process is resected using KTP/532 laser. The stapes head is completely denuded of mucosa. The stapes is precoated with glass ionomer cement (envoycem). Glasscock stabilizers are then secured. The transducers are placed on the body of incus (sensor) and on the head of stapes (driver). Gelfoam is then placed as a barrier. Hydroxyapatite cement (Medcem) is applied to the transducers. The stabilizers and the gel foam removed. The envoycem is applied first to the stapes and then to incus. The capacitances, sensor/ sensitivity test, driver test, feedback test and noise floor test are all checked with the help of laser reflectors placed on the posterior crus of stapes using the microphone secured in the external auditory canal at the very beginning of surgery. The second Medcem is applied to the transducers. The speech processor is then placed on the bed created and connected to the transducers and switched “on”. Feedback

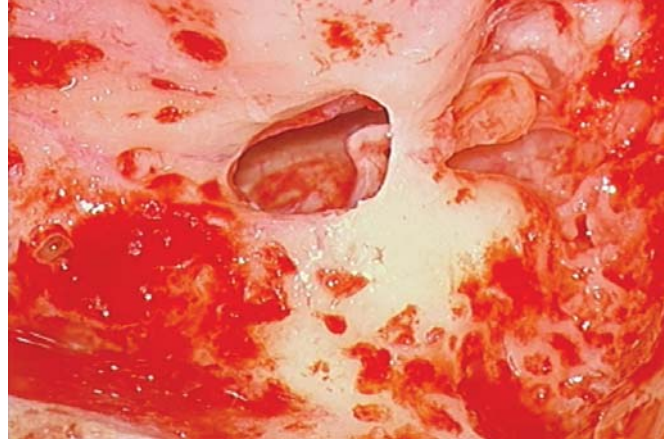


Fig. 1: Picture showing posterior tympanotomy

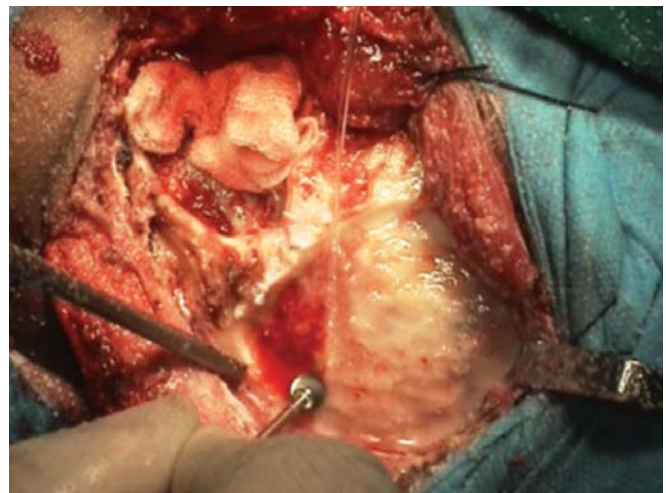


Fig. 2: Bed for speech processor

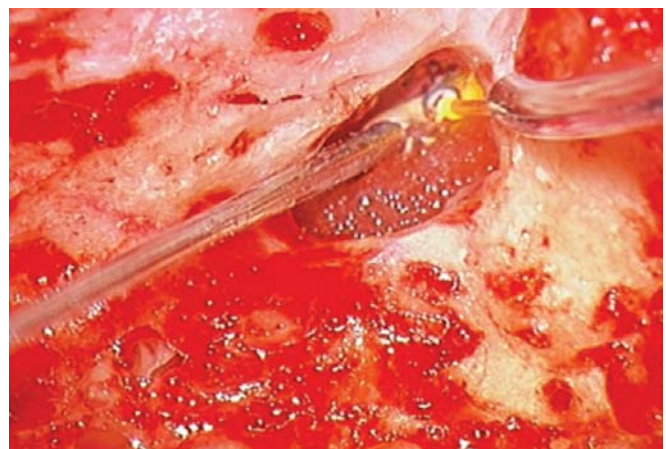
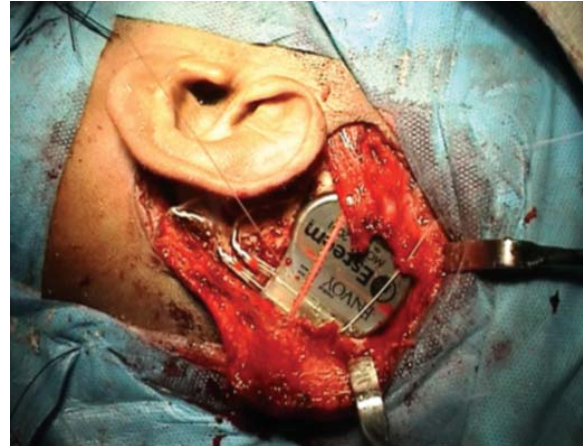


Fig. 3: Resection of long process of Incus using KTP/532 laser

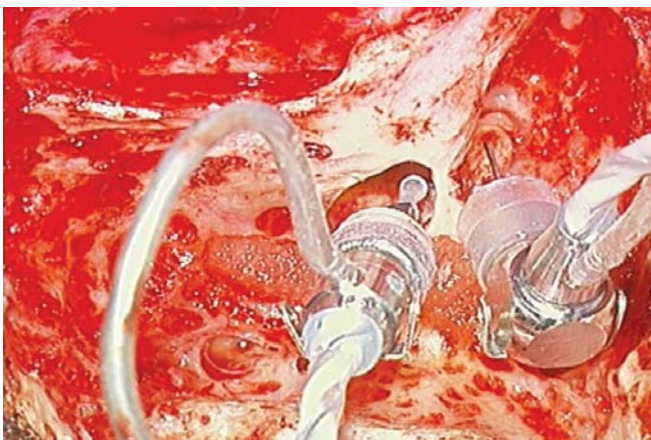




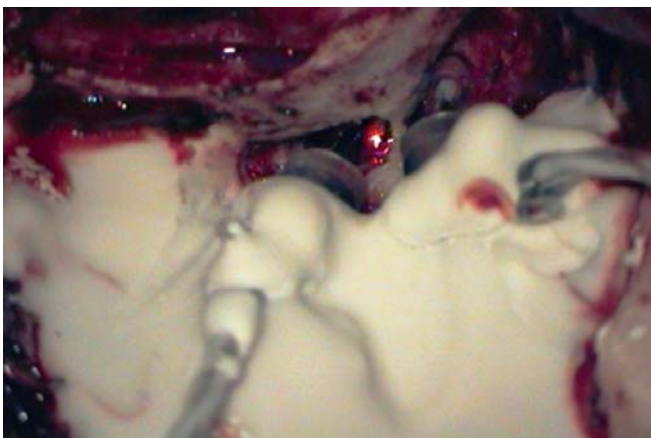
**Fig. 4:** Envoycem being applied on the stapes and incus



**Fig. 7:** Totally implantable hearing device *in situ*



**Fig. 5:** Sensor and driver in place with stabilizers



**Fig. 6:** Titanium laser reflectors being used to verify the function of the device after placement of Medcem

test and system test performed with the help of titanium reflectors. The speech processor is then switched “off”. Thus the functioning and integrity of the system was confirmed on table before closure of the wound. The “turn

on” of the device is done 8 weeks after surgery as this is the time on an average is required for complete healing.

### OUR EXPERIENCE

Madras ENT Research Foundation, Chennai a premier Implant Institute in India was the first center in South Asia to perform TIHD surgeries. Our three adult TIHD recipients were implanted in July, 2008 with the Envoy Esteem II Device. All three patients have dramatic improvement in their auditory skills using the TIHD and it has been a gratifying experience for the entire team of professionals involved in this procedure.

### DISCUSSION

The totally implantable piezoelectric device 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 signals are identical to those received by a person with normal hearing. This mechanical signal is detected from a piezoelectric transducer at the head of the incus (the sensor) and converted to an electrical signal by using existing transducer technology. The electrical signal is amplified, filtered, and converted back to a vibratory signal. The processed vibratory signal is then delivered by means of a piezoelectric transducer (the driver) attached to the stapes capitulum. The signal is then delivered via the stapes bone to the inner ear where it is converted into nerve impulses and translated into words or sound by the brain. The incus lenticular process is removed to prevent feedback to the sensor. The newly designed piezoelectric transducer can provide an output close to 110 dB sound pressure level.

An audiologist programs the implant 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 advantages of such a device are notable. Without any appliance in the external auditory canal, the occlusion effect is eliminated. Uncoupling of the sensor and driver eliminate most feedback. Even more important for some is the fact that the device is completely concealed in the body.

Battery life is an issue with totally implantable devices. The battery has an estimated life of 5 to 7 years depending on use and can be replaced under local anesthesia. In addition, removal of a portion of the incus permanently alters the ossicular mechanism and prohibits full recovery of hearing to preimplantation baseline levels if the device fails or is in the off position. Modern ossicular reconstruction techniques may effectively restore hearing to within 10 dB. Speech discrimination was markedly improved over hearing-aid by 17% as per the *Phase One trial of Envoy Implantable System from St. Croix Medical Inc.*<sup>4</sup> Functional gain and speech reception thresholds were similar for the Envoy device and for the hearing aids.

The technology platform of the TIHD is different from all other microphone-based hearing devices (hearing aids, other middle ear implants or cochlear implants). The TIHD uses the eardrum to process the incoming sound and thereby preserving a natural way of hearing that particularly benefits patients in noisy environments in contrast to Totally Integrated Cochlear Amplifier (TICA) in which the microphone is implanted subcutaneously in the external ear adjacent to the tympanic membrane. Main Outcome

Measures would include, subjective patient benefit, aided sound field thresholds, and speech discrimination with the subject's own, appropriately fit, walk-in hearing aids and the prosthesis are usually assessed.<sup>5</sup>

## CONCLUSION

The totally implantable hearing device is completely invisible. It uses the body's natural anatomy to provide optimal hearing and is not affected by acoustic feedback. This device allows patients to live normal active lifestyles with no occlusion effect and no social stigma. There is absolutely no auditory feedback and the sound quality is proved to be excellent. Successful outcomes in more than 100 patients who wear the TIHD device world over, have been published in reputed indexed journals and stand as proof to the arrival of this state of the art implant technology, as a significant milestone in the future of hearing solutions.

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