Totally implantable hearing aid surgical technique and the first Indian experience with Envoy esteem

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Abstract Hearing aids are the principal means of auditory rehabilitation for patients with moderate to severe sensorineural hearing loss. Although technical improvements and modifications have improved the fidelity of conventional aids, hearing aids still have many limitations. Implantable hearing aids offer patients with hearing loss several potential advantages over conventional hearing aids. This presentation will highlight our first experience, the indications, the procedure, the advantages and the current status of totally implantable hearing aids.

Keywords Moderate to profound sensorineural hearing loss (SNHL) · Totally implantable hearing aid (TIHA) · Envoy esteem

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 [1]. 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. The piezoelectric crystal was first investigated as a middle ear driver by Vernon [2]. 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 [3]. This is the basic principle involved in the functioning of totally implantable hearing aid (TIHA).

Case history

Case 1

A 22-year-old lady presented with a history of progressive hearing loss following an attack of chicken pox and

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jaundice at the age of 10 years. Hearing loss has been stable currently and pure tone audiogram showed bilateral 75 dBHL and speech discrimination score was 60 % for words and 70 % for sentences. Patient was reluctant to use hearing aid due to cosmetic reasons and because she did not like the “occlusal effect”. CT scan temporal bone showed well pneumatized mastoid with medially placed facial nerve. Patient underwent right TIHA implantation surgery on 22/07/08. The procedure involves cortical mastoidectomy with facial recess exposure, with adequate and complete exposure of ossicles with careful preservation of the incus bridge. The sensor and driver piezoelectric crystals were respectively placed on the body of incus and the head of the stapes. The intricate detail of the surgery is discussed subsequently. The postoperative period was uneventful.

Case 2

A 26-year-old young man presented to us with history of progressive hearing loss noticed at the age of 11 years, insidious onset with no significant past history except for the history of ear discharge in right ear for which he underwent mastoidectomy in right ear recently. Pure tone audiogram showed 90 dBHL in the right ear and 60 dBHL in the left ear and SDS was 65 % for words and 70 % for sentences (Fig. 1). Patient used hearing aid in the left ear for 2 years but was unhappy with the sound quality perceived and the occlusal effect. CT scan temporal bone showed well-pneumatized mastoid and medially placed facial nerve (Fig. 3). Patient underwent left TIHA implantation surgery on 23/07/08. The operative procedure involves cortical mastoidectomy with adequate and complete exposure of ossicles with careful preservation of the incus bridge. The sensor and

driver piezoelectric crystals were respectively placed on the body of incus and the head of the stapes. The entire detail of the surgery is discussed subsequently. In this patient, the second genu of the facial nerve was found to be dehiscence which was securely separated from the stapes head and the transducer with the help of temporalis fascia placed on the dehiscence portion of the facial nerve. The postoperative period was uneventful except for facial weakness Grade III which recovered completely one week after surgery.

Case 3

A 38-year-old man presented to us with a history of progressive hearing loss noticed at the age of 5 years. There was no past history of ear discharge or an attack of exanthematous fever. Patient started using hearing aid at the age of 18 years in the left ear for a period of 9 years, after which he discontinued using it. Since the last 2 years he has been a reluctant user of digital hearing aid in his left ear. Current PTA of the patient is 65 dB HL for right ear and 70 dBHL for left ear and SDS was 70% for words and 75% for sentences. Patient was unhappy with the aid because of poor sound quality. CT scan temporal bone showed much contracted mastoid with medially placed facial nerve (Fig. 4). Patient underwent right TIHA implantation surgery on 24/07/08. The operative procedure involved cortical mastoidectomy with adequate and complete exposure of ossicles with careful preservation of the incus bridge. The sensor and driver piezoelectric crystals were respectively placed on the body of incus and the head of the stapes. The intricate detail of the surgery is discussed subsequently. The procedure in this patient was more challenging to the surgeon as

Fig. 1 Preoperative pure tone audiogram

the antrum was very contracted and hence there was difficulty in placing the driver on the stapes, as the most important prerequisite for a better outcome is that the transducers should not be in contact with any other structure other than the incus body and the stapes head (near contact) to prevent auditory feedback. Postoperative period was uneventful.

Inclusion criteria

As per the manufacturers of Envoy Esteem implantable system.

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

- Participant is 18 years old and above

Fig. 2 Postoperative pure tone audiogram of the same patient

Fig. 3 HRCT Temporal Bone of Case 2 showing well pneumatized mastoid

Fig. 4 HRCT temporal bone of Case 3 showing poorly pneumatized mastoid and contracted antrum

- b) 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.
- c) 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:

Freq (Hz)	500	1000	2000	3000	4000
LL* (dB HL)	25	25	30	30	30
UL* (dB HL)	80	80	80	85	90

*LL = Lower Level; UL = Upper Level

- d) 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.
- e) 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.

- f) 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

Procedure 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 in such a way that it allows complete exposure of body of incus and the stapes with careful preservation of the incus bridge in contrast to the posterior tympanotomy of cochlear implantation where it involves complete exposure of round window (Fig. 5). In particular the corner between the annulus and incus bridge is emphasized in the procedure to maximize the exposure of the long process and the body of the incus. A bed for speech processor is then made on the skull just behind the mastoid cavity (Fig. 6). 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. Incudo-stapedial joint is disarticulated and the long process is resected using KTP/532 laser (Fig. 7). The stapes head is completely denuded of mucosa. The stapes is pre-coated with glass iontomer cement (Envoycem) (Fig. 8). Glasscock stabilizers are then secured. The transducers are placed on the body of incus (sensor) and on the head of stapes (driver) with the help of the stabilizers (Fig. 9). Gelfoam is placed as a barrier. Hydroxyapatite cement (Medcem) is applied to the transducers. The stabilizers and the gel foam are then 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 checked with the help of Titanium reflectors placed on the posterior crus of stapes, using microphone secured in the external auditory canal at the very beginning of the surgery (Fig. 10). The second Medcem is then applied to the transducers. The speech processor is then placed on the bed created (Fig. 11) and connected to the transducers and switched "on". Feed back test and system test are next performed with the help of laser reflectors. The speech processor is then switched "off". Thus the functioning and integrity of the system is confirmed on the table before clo-

Fig. 5 Picture showing posterior tympanotomy

Fig. 7 Resection of long process of incus using KTP/532 laser

Fig. 6 Bed for speech processor

Fig. 8 Envoycem being applied on the stapes and incus

sure of the wound. The connectivity of the speech processor with the transducers is confirmed intraoperatively with the help of C-arm (Fig. 12). The “turn on” of the device is done 8 weeks after surgery as this is the average time required for complete healing.

Discussion

Totally implantable piezoelectric device used by us is the Esteem by Envoy Medical (originally St. Croix Medical). This 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

Fig. 9 Sensor and driver in place with stabilizers

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 (SPL).

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

Fig. 10 Titanium laser reflectors being used to verify the function of the device after placement of Medcem

Fig. 11 Totally implantable hearing device in situ

Fig. 12 Intraoperative C-arm image showing the connectivity between the speech processor and the transducers

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.

The Envoy device faces some hurdles as it is further developed. Its battery life is an issue, as with any totally implantable device. The battery has an estimated life of 5–7 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 [4]. Functional gain and speech reception thresholds were similar for the Envoy device and for the hearing aids.

As of 2007, the US Phase II trial is underway. Over 70 patients have been implanted in this part of the trial. Overseas, the Esteem received the C.E. mark in 2006, and it is currently being used in several countries. The technology platform of the Envoy System is different from all other microphone-based hearing devices (hearing aids, other middle ear implants or cochlear implants). The Envoy 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 [5].

In our institution, switch-on of the device was done 8 weeks after the surgery. The outcome was measured by pure tone audiogram with Envoy Esteem device and speech discrimination scores (Fig. 2). Postoperative SDS on an average for all three patients for closed set and open set are 100% and 95% respectively. There is absolutely no auditory feedback and the sound quality is excellent. Patients could carry out telephonic conversation comfortably.

Postoperative complications usually anticipated are similar to any mastoid surgery, in addition to device failure. In our patients, one had transient facial paresis due to dehiscence of facial nerve canal.

Conclusion

The totally implantable hearing device is completely invisible. It uses the body's natural anatomy to provide optimal hearing and not affected by acoustic feedback. This device allows patients to live normal active lifestyles with no occlusion effect. There is absolutely no auditory feedback and the sound quality is excellent. There is no maintenance of batteries for up to 5 to 7 years.

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