

Implantable electro-mechanical devices for sensorineural hearing loss

J. Claes and P. H. Van de Heyning

University department ENT, Antwerp University Hospital, University of Antwerp

Key-words. Hearing loss; treatment; implantable devices

Abstract. *Implantable electro-mechanical devices for sensorineural hearing loss.* Implantable electro-mechanical devices are a valuable solution for patients with sensorineural hearing loss who do not tolerate a conventional hearing aid. The currently available devices are the result of technological progress and clinical experiments over the last 30 years. The advantages observed during early clinical trials are nowadays confirmed. Some issues – specifically the coupling of the device to the human auditory system – are still open for improvement.

Introduction

Conventional hearing aids have important limitations, even for properly selected patients and after rigorous adaptation. Many patients with sensorineural hearing loss (SNHL) avoid the use of a conventional hearing aid despite their needs for better hearing. Apart from psychological factors, distortion of the amplified sound is often cited as a major reason for this attitude. Also, the presence of a hearing aid in the external ear canal is experienced as uncomfortable, cosmetically unacceptable, and stigmatizing. Occlusion of the external ear canal may cause external otitis and wax accumulation. Acoustic feedback phenomena occur at high frequencies and high intensities. A small receiver, inherent to the design of a hearing aid, heavily distorts low frequencies. These phenomena degrade speech understanding and limit hearing gain achieved with conventional hearing aids. Many of the limitations of conventional hearing aids are related to the physics of sound, and hence fundamental and difficult to overcome.

A hearing aid that does not involve the delivery of amplified sound in the external ear canal, and that is totally hidden would probably meet the needs of a large group of patients with hearing loss. Middle ear implants offer these advantages and have successfully remediated hearing loss of patients with SNHL and conductive or mixed hearing loss.

Advantages over conventional hearing aids and principles of functioning

Implantable electro-mechanical devices transduce sound into mechanical vibration that, in most cases, is directly applied to the ossicular chain. They are therefore often referred to as “direct drive” transducers. The mechanical vibration can be generated by a piezoelectric element, an electromagnetic coil, or even hydrostatic force. These transducers are implanted in the middle ear, and do not imply use of an occlusive ear mould and a small speaker, and therefore appear user-friendly and promise better quality of hearing.

Direct application of force to the ossicular chain is a relatively

new project in otologic clinics, and many questions with practical implications arose. How does the normal human ossicular chain vibrate? What is the effect of a mass load on this vibration? What should be the optimal direction of the force applied to the ossicular chain? How well, on the long term, will the implant integrate in the tissues of the ossicular chain? These notions are equally or even more important than considerations of technical and surgical feasibility when a coupling system is designed, and are currently under evaluation.

Types of implants currently available in Belgium for clinical implantation

Two types of implants are currently available in Belgium for clinical use under FDA and/or CE approval. The Vibrant Soundbridge (VSB, Vibrant MED-EL Hearing Technology, Innsbruck, Austria – Figure 1) is a semi-implantable device consisting of three parts: an external audio processor, an internal receiver, and an electromagnetically driven

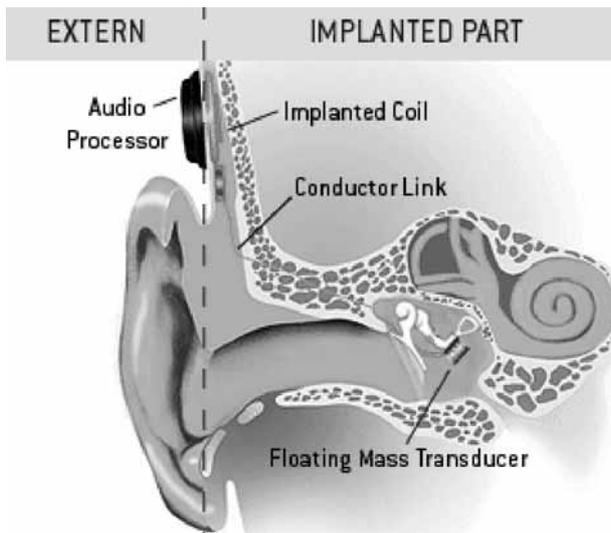


Figure 1
The Vibrant Soundbridge system

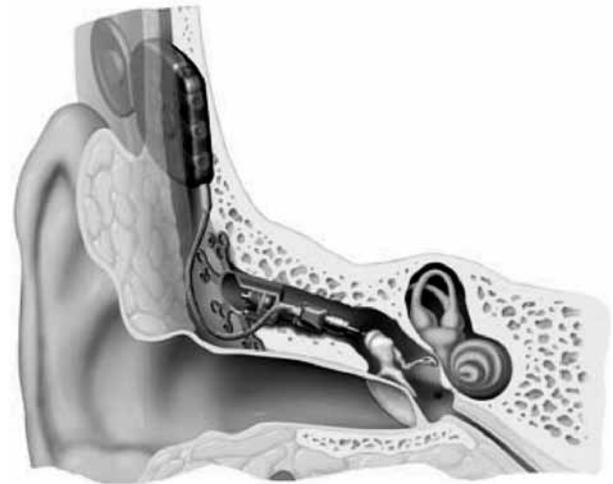


Figure 2
The MET system

transducer, which is attached to the long process of the incus. The transducer of the VSB is also called a floating mass transducer; it contains a mass that can freely move within the coil. The internal receiver of the device is implanted in a recessed seat in the temporal fossa, similar to a cochlear implant. A wire links the internal receiver to the floating mass transducer. A mastoidectomy with posterior tympanotomy is necessary for exposition of the long process of the incus, to which the floating mass transducer is attached. The audio processor is worn externally like the external coil of a cochlear implant, it is coupled to the internal receiver by a transdermal telemetry system.

The Otologics Middle Ear Transducer (MET, Otologics, Boulder, Colorado, USA – Figure 2) consists of an external audio processor which is worn on the skin behind the ear, and an internal receiver-transducer that drives an aluminum oxide probe that is coupled to the incus body. The electromagnetic transducer is

mounted into an atticomastoidectomy cavity, and acts as a piston on the ossicular chain via a hole that is made in the body of the incus with a laser. The receiver is embedded in a temporal fossa seat much like is done in cochlear implant surgery.

Otologics has recently developed a fully-implantable ossicular stimulator named Sonäta. The system uses the same direct drive on the incus body as the MET, but it has a microphone that is positioned subcutaneously, and a battery and sound processor that are also implanted under the temporal skin. The battery can be charged transcutaneously.

A third system, DACS or Direct Acoustic Cochlear Stimulation (Cochlear Acoustics, Lausanne, Switzerland) is in phase IV post approval investigation in Europe. The system has an implantable part that provides an artificial incus process on which a stapes prosthesis, comparable to those used in stapedotomy, can be attached. An external sound processor drives the implant.

A fourth system, the Soundtec Direct Hearing System (Soundtec Inc., Oklahoma City, Oklahoma, USA), currently only available in the USA, consists of an external and an internal portion. The external part carries a microphone and a sound processor connected to an electromagnetic coil, it can be worn in the ear canal or behind the ear with a custom ear canal mold in which the coil is incorporated. The internal part is a magnet that is attached to the incudo-stapedial joint. It can be implanted through a transmeatal tympanotomy.

Patient selection criteria

Today, only adult patients are selected for Vibrant Soundbridge implantation. They should have a sensorineural hearing loss, which is not of retrocochlear origin. Middle ear anatomy must be normal and there should be no air-bone gap greater than 10 dB at two or more frequencies at 0.5, 1, 2 and 4 kHz. The hearing loss must be stable in time. The use of a conventional hearing aid must be

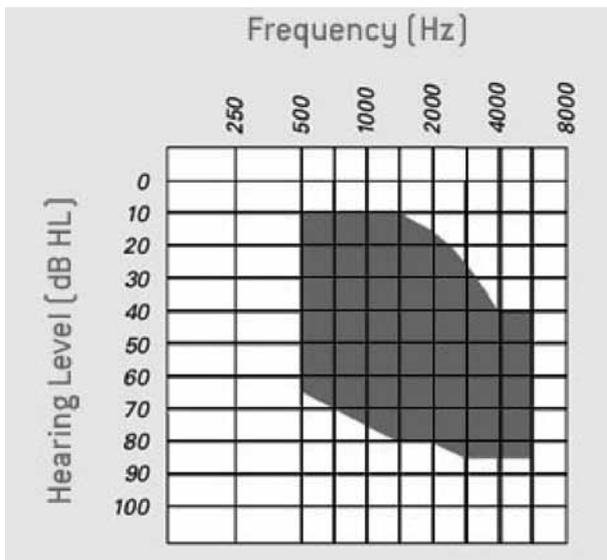


Figure 3

Audiologic selection criteria for Vibrant Soundbridge

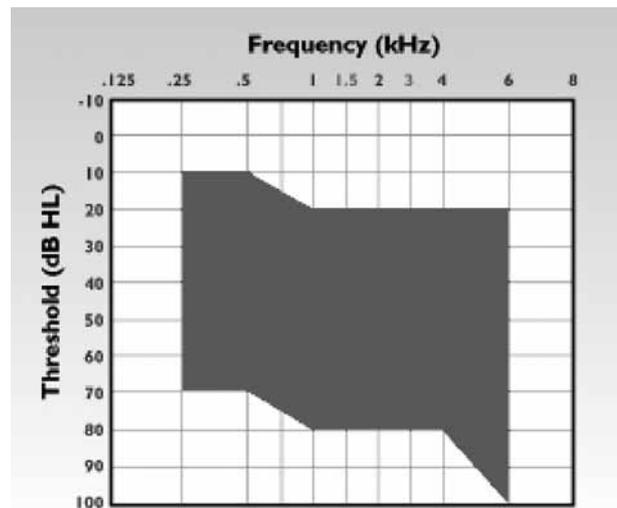


Figure 4

Audiologic selection criteria for MET system

contraindicated for medical reasons or rejected by the patient after optimal fitting and a reasonable period of use. The pure tone unaided hearing levels of the fitted ear must lie within the boundaries given in Figure 3. Speech understanding should be at least 50% in open-set word tests at the most comfortable listening level. A combination of the Vibrant Soundbridge floating mass transducer with a stapedotomy prosthesis is under investigation. This modification would extend the selection criteria to mixed type hearing losses. A number of personal communications have been made by several surgeons who apply the floating mass transducer to the round window niche in difficult-to-treat middle ear cases. (Colletti V, MEMRO 2006, Zurich, personal communication).

The selection criteria for the MET implant include adult patients with SNHL, no signs of conductive or retrocochlear hearing loss, and no history of recurrent otitis media. The hearing loss

must be stable, of post-lingual onset and lie within the limits given. Patients should have realistic expectations of their hearing gain (Figure 4). The range of hearing loss that can be remediated by the Sonäta is identical to that of the MET system. A combination of the system with a partial ossicular replacement prosthesis in titanium is under investigation. This combination would extend the indications to mixed hearing loss with a normally functioning stapes, such as certain congenital malformations of the ear and certain post-surgical chronic otitis cases. No results of these latter options have been published today.

The DACS system does not require a functional middle ear, and can be implanted without compromise to residual hearing or residual middle ear function. It would therefore be applicable to sensorineural as well as mixed type hearing losses. Clinical experience with the system, however, is limited today.

As in all prosthetic rehabilitation of hearing, selection of patients must also take into account the effect of “dead regions” in the cochlea, where the absence of hair cells precludes successful amplification of sound, be it acoustic or by direct vibration of the ossicular chain.¹ Also, normal hearing at low frequencies may contra-indicate a middle ear implant since a low frequency and low intensity rumble may, as it does in conventional non-digital hearing aids, disturb the user.

Results

Several studies by different centers in the USA and in Europe report the results after implantation of the Vibrant Soundbridge (VSB) system.²⁻⁴ These reports conclude that most of the patients clearly benefit from the VSB, with however a subgroup of patients experiencing low gain (at threshold or at conversational sound level) that could not be explained by their amount of preoperative

hearing impairment. Speech recognition scores after implantation are comparable to those obtained with conventional hearing aids, with however a large spread of results. A large French multicenter clinical study with 125 VSB implantees reports that 83% of the patients were either satisfied or very satisfied with the device.⁵ Unsatisfactory results in some of the patients are attributed to problems with positioning and fixation of the floating mass transducer,⁶ as well as to suboptimal programming of the audio-processor. By measuring sound in the external ear canal, a reverse transfer function can be established, and the proper functioning of the implant and its coupling to the ossicular chain can be objectively assessed during or after the operation.⁷ The sound quality after implantation is generally rated as undistorted, and hearing with the implant results in better speech understanding even in situations with loud background noise.⁴

Also the long term results seem to be very interesting as the first implanted patients in 1996 continue to be satisfied with their device.⁸ Studies comparing patient satisfaction between the VSB and the conventional hearing aids seem to favor the first.^{9,10} The fixation site of the floating mass transducer at the lenticular process of the incus appears to show changes comparable to those after stapes surgery.¹¹ We must however accept that selection criteria for implantable hearing devices do not only depend on pure audiometric selection criteria.¹²

Experimental acoustic studies found that a floating mass transducer reduces stapes displacement in the temporal bone model. This might have an effect on high fre-

quency hearing function, especially when the device is switched off.¹³

The evidence level of conclusions found in the literature on VSB implants can be classified as level II.

For the MET implant system, the first results of multicenter clinical studies are now available. For 282 patients implanted in Europe and the USA, group mean postoperative bone and airconduction thresholds (unaided) did not change significantly from preoperative levels. Postoperative air conduction thresholds decreased slightly in some patients, due to the mass loading effect of the coupled transducer. Sufficient gain was achieved to reach target prescription levels for patients with moderate to severe hearing loss. Audiometric and subjective assessment indicates that patients do as well or better with the MET Ossicular Stimulator than with their conventional hearing aid.¹⁴ However, at this time (August 2005) only one multicenter study with this device is available. We therefore classify the results studies of the MET system at level III of evidence.

Conclusion

After a long period of experimental studies and research, the implantable electro-mechanic hearing devices for SNHL are now on the verge of broad clinical application. The first clinical results are very promising and the currently used devices are safe and functional. They will probably become a good alternative for those patients who are dissatisfied with their conventional hearing aid. It is also clear that some changes in technical aspects of

implantation – especially in the design of the ideal coupling between transducer and ossicular chain – are needed before these hearing aids will become widely accepted.

References

1. Baskent D, Shannon RV. Frequency transposition around dead regions simulated with a noiseband vocoder. *J Acoust Soc Am.* 2006;119:1156-1163.
2. Snik AF, Mylanus EA, Cremers CW, *et al.* Multicenter audiometric results with the Vibrant Soundbridge, a semi-implantable hearing device for sensorineural hearing impairment. *Otolaryngol Clin North Am.* 2001;34:373-388.
3. Dazert S, Shehata-Dieler WE, Dieler R, Helms J. "Vibrant Soundbridge" middle ear implant for auditory rehabilitation in sensory hearing loss. I. Clinical aspects, indications and initial results [in German]. *Laryngorhinootologie.* 2000;79:459-464.
4. Lenarz T, Weber BP, Issing PR, *et al.* Vibrant Sound Bridge System. A new kind hearing prosthesis for patients with sensorineural hearing loss. 2. Audiological results [in German]. *Laryngorhinootologie.* 2001;80:370-380.
5. Sterkers O, Boucarra D, Labassi S, *et al.* A middle ear implant, the Symphonix Vibrant Soundbridge: retrospective study of the first 125 patients implanted in France. *Otol Neurotol.* 2003;24:427-436.
6. Snik A, Cremers C. Audiometric evaluation of an attempt to optimize the fixation of the transducer of a middle-ear implant to the ossicular chain with bone cement. *Clin Otolaryngol Allied Sci.* 2004;29:5-9.
7. Winter M, Weber BP, Lenarz T. Measurement method for the assessment of transmission properties of implantable hearing aids. *Biomed Tech (Berl).* 2002;47 Suppl 1 Pt 2:726-727.
8. Luetje CM, Brackman D, Balkany TJ, *et al.* Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. *Otolaryngol Head Neck Surg.* 2002;126:97-107.

9. Uziel A, Mondain M, Hagen P, Dejean F, Doucet G. Rehabilitation for high-frequency sensorineural hearing impairment in adults with the symphonix vibrant soundbridge: a comparative study. *Otol Neurotol.* 2003;24:775-783.
10. Todt I, Seidl RO, Gross M, Ernst A. Comparison of different vibrant soundbridge audioprocessors with conventional hearing AIDS. *Otol Neurotol.* 2002;23:669-673.
11. Todt I, Seidl RO, Mutze S, Ernst A. MRI scanning and incus fixation in vibrant soundbridge implantation. *Otol Neurotol.* 2004;25:969-972.
12. Junker R, Gross M, Todt I, Ernst A. Functional gain of already implanted hearing devices in patients with sensorineural hearing loss of varied origin and extent: Berlin experience. *Otol Neurotol.* 2002;23:452-456.
13. Needham AJ, Jiang D, Bibas A, Jeronimidis G, O'Connor AF. The effects of mass loading the ossicles with a floating mass transducer on middle ear transfer function. *Otol Neurotol.* 2005;26:218-224.
14. Jenkins HA, Niparko JK, Slattery WH, Neely JG, Fredrickson JM. Otologics Middle Ear Transducer Ossicular Stimulator: performance results with varying degrees of sensorineural hearing loss. *Acta Otolaryngol.* 2004;124:391-394.

J. Claes
Univ dept ENT
Antwerp University Hospital
University of Antwerp
E-mail: jos.claes@uza.be

CME questions

1. Middle ear implants are applicable for:
 - A – patients with middle ear conductive hearing loss
 - B – patients in whom the chronic otitis precludes the use of conventional hearing aids
 - C – patients with unilateral total deafness
 - D – patients with sensorineural hearing loss and a normal middle ear
 - E – patients with bilateral total deafness

2. An advantage of MEI over conventional hearing aids is:
 - A – receivers can be larger because they do not have to fit in the external ear canal
 - B – there is no feedback phenomenon (Larsen's effect)
 - C – they are invisible since they are implanted
 - D – they perform better in the high frequency range

3. The widespread application of MEI is limited by:
 - A – the cost
 - B – the surgical procedure that is necessary
 - C – the incompletely resolved issue of coupling the device to the ossicular chain
 - D – the limited number of indications for their use

4. When an implanted MEI it is switched off, the hearing of the patient when compared to the pre-implantation levels:
 - A – is identical
 - B – is much worse
 - C – is probably worse in the high frequency range
 - D – is probably worse in the low frequency range

5. The functional results of MEI are, in comparison to conventional hearing aids:
 - A – systematically worse
 - B – systematically better
 - C – partly unpredictable because of technical shortcomings in the frequency characteristics of direct drive systems
 - D – partly unpredictable because of technical shortcomings in the coupling of devices to middle ear structures

Answers: 1D; 2B; 3C; 4C; 5D
