Review Article

Restoration of hearing by hearing aids

conventional hearing aids – implantable hearing aids – cochlear implants – auditory brainstem implants

R. Leuwer[1*], J. Müller[2]

[1]Klinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde, Universitätsklinikum Hamburg-Eppendorf

[2]Klinik und Poliklinik für Hals-, Nasen- und Ohrenkranke, Universität Würzburg

GMS Curr Top Otorhinolaryngol Head Neck Surg 2005;4:Doc03

Abstract

Aim of this report is to explain the current concept of hearing restoration using hearing aids. At present the main issues of conventional hearing aids are the relative benefits of analogue versus digital devices and different strategies for the improvement of hearing in noise. Implantable hearing aids provide a better sound quality and less distortion. The lack of directional microphones is the major disadvantage of the partially implantable hearing aids commercially available. Two different clinical studies about fully implantable hearing aids have been started in 2004. One of the most-promising developments seems to be the electric-acoustic stimulation.

Keywords: hearing in noise partially and fully implantable hearing aids electric-acoustic stimulation

1. Introduction

In 2000 Zenner presented an outstanding review about implantable hearing devices [1]. The reader will probably ask, why again a review partially deals with this topic. As an explanation the authors wish to give three reasons:

1. The main topic of the 2005 reviews is the restitution of function in ENT. In this context hearing should not be excluded.

2. During the recent five years technical developments have shown a tremendous progress. In addition, the focus of research has shifted and the patients` efforts to improve their deficits are still the same.

3. If we look at such topics as the bilateral cochlear implantation and the electric-acoustic stimulation the current concepts of hearing restoration are gradually changing. That is why the current potentials should again be precisely depicted.

It was owing to Zenner to give a standardized definition of terms concerning implantable hearing aids.

[*]**Corresponding Author:**
Prof. Dr. R. Leuwer, Klinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde, Universitätsklinikum Hamburg-Eppendorf, Martinistr. 52, 20246 Hamburg, eMail: leuwer@uke.uni-hamburg.de

We want to review the clinical situation and research at present.

In Germany, 14 million people suffer from sensorineural hearing loss. With children, primary consequence of untreated hearing loss is an impaired development of speech. In the elderly, however, it is increasing social isolation. The only means to treat sensorineural hearing loss are electronic hearing aids [2]. The aim of the hearing restoration is an improvement of the understanding of speech.

2. Conventional hearing aids

Conventional hearing aids function by receiving environmental sounds with a microphone, converting these sounds into electrical signals, process and amplify these signals and return it to the ear as acoustic energy [3]. The evolution of conventional hearing aids was mostly influenced by the technical progress of electronics and physical acoustics rather than the advancements in the knowledge of hearing physiology. After the introduction of semiconductors and miniaturization this progress mainly provided a better amplification and sound quality, the adaptation of dynamic range, the directionality of microphones, the Bluetooth technology as well as the storage of different strategies for environmental hearing situations. All of these improvements can satisfactorily be accomplished by *analogue hearing aids* thus still having their place on the market [4].

In 1996 *digital hearing aids* were commercially introduced [5]. In addition to the microphone, the amplifier and the receiver of analogue hearing aids these digital instruments contain an analogue-to-digital converter (ADC) before the amplifier and a digital-to-analogue converter (DAC) before the receiver [6]. The conversion of analogue into digital signals allows their mathematical processing. Between ADC and DAC there is a special computer, a digital signal processor (DSP). Speech processing in this DSP is accomplished by programmable algorithms, giving additional perspectives for speech recognition performance.

It is well known that patients with sensorineural hearing loss do not only suffer from a raised hearing threshold but also from an altered loudness perception, reduced temporal and frequency resolution and impaired localization ability [7], [8]. Hearing impaired patients who are looking for an improvement of their hearing ability often depict their inability to hear in a noisy environment as their most urgent problem [9]. Hence, strategies for separating speech and noise are the most important parameters for the evaluation of hearing aids.

In fact, there are two different concepts for noise reduction: speech-sensitive processing and - more successfully - the *directionality of the microphones* [10], [11]. In fact, directionality can also be obtained using analogue technique. The first inefficient attempts in the early seventies disappeared from the market after ten years. Advancements in the technical development of hearing aids during the last decade show that concerning the directionality analogue hearing aids now are equivalent to digital ones. One technique is the use of the *dual- or twin-microphone-technique*. Directionality to the front is gained using the frequency-dependent phase-shift and the overlapping of the microphone signals. Yet, the physiological directivity of the Concha should never be neglected meaning that the best placement of the microphone is in the ear and not above the ear [11].

Digital sound processing has further potentials that cannot be realized by analogue technique: different algorithms such as Fast-Fourier-Transformation (FFT) enable spectral and temporal analysis of the signal, selective amplification, frequency attenuation etc. [6]. Simpler additional functions of digital hearing aids using these algorithms for example are the in-situ-adaptation or the use of broad-band noise for tinnitus-masking. More complex algorithms are the recognition of *feedback and frequency-shift*. This technique makes it possible to reduce the feedback in a way that the ear mold can be replaced by a soft space maintainer leaving an unobstructed outer ear canal (e.g. ReSound AIR™, GN Resound). In addition this algorithm shows higher amplifications without feedback (e.g. OpenEar Acoustics™, Otikon). Furthermore by the recognition of feedback the hearing aid can adaptively react on changes of the present acoustical situation for example if the earmold gets out of place.

Another aspect of digital sound processing is the easy implementation of computer interfaces. The

Bluetooth technology for example allows hearing aid programming as well as direct sound transfer. One advantage of this technique is that Bluetooth is a standard technology e.g. in cell phones. All modern wireless communication techniques are also suitable for the size reduction of hearing aids: the remote control of programs and amplification facilitates their handling especially for the elderly.

Successful *suppression of noise* requires efficient noise detection. If there is simple and constant background noise such as engine noise this is an easy task. One example is the "fast-attack and slow decay" - technology that rapidly reacts on a noise source and gradually returns to the basic sensitivity after this source has disappeared. There are a lot of different examples for noise reduction techniques on the market. At this point the authors refer to the information material of the different companies. The quotation of companies and of their products should only be understood as an example without claiming completeness.

Hearing aids with a marked directionality show one disadvantage: To keep the noise signals low, the signal sensitivity only covers a small space angle. This means that the source of information can only be detected, when it is exactly in this space angle. Only little shifts lead to a loss of loudness. If a sound source is outside of this angle, e.g. information from a loudspeaker, the information cannot be understood or even be heard. One daily life situation for people with sensorineural hearing loss is to be addressed from behind or from different lateral positions. Thus some hearing aids allow the manual adaptation of directivity. A more elegant solution is the *triple-microphone-technique* (e.g. Triano™, Siemens). The hearing direction is automatically shifted after the direction of the speech signal source has been detected.

This example also shows a basic problem of adaptive hearing aids. The speech has to be recognized in order to recognize the speaker. If the noise signal is speech (e.g. party noise) this is an almost impossible task. This situation requires the physiologic ability of a healthy hearing system allowing to "listen". As a solution for this non-trivial problem some modern hearing aids already use the implementation of *artificial intelligence (AI)* and *neuronal networks*. Principle of these technologies is to rebuild or replace central auditory processes such as *directivity of hearing* (sound localization) and *separation of signal sources* (hearing in noise) in the hearing aid. Yet, as long as basic principles of neurophysiology and the psychoacoustic of speech recognition are still fairly unknown at present these developments are just first steps [8].

Although signal processing, selective amplification and noise reduction can be improved by digitalization the evidence of clinical advantage of digital over analogue aids is still lacking [5], [12]. It has to be considered that even the labelling of "digital" and "analogue" may influence the results of questionnaires [13]. Thus only double-blind-testing yields reliable study results [14].

It has to be pointed out, that not only the technically feasible, but more and more the costs will have an influence on the future developments of conventional hearing aids. Besides the special challenges of hearing aids depicted above, there are basic inherent disadvantages that reduce their public acceptance, such as

- stigmatization by the visible prosthesis
- feedback and canal infections due to the earmolds
- distortion of sound quality
- risk of damage [15]

These disadvantages as well as the high costs of hearing restoration by modern hearing aids and the anosognosia especially of the older patients entail that the majority of the hearing-impaired not using hearing aids [16].

It remains questionable if the implantable hearing aids depicted below will be able even partially to overcome this problem in the future.

3. Implantable hearing aids

Differently from conventional hearing aids in implantable hearing aids the amplified sound signal is transmitted as vibrational energy directly to the ossicular chain using an implanted vibrational transducer [1], [3]. At present there are two different principles of such transducers available,

1. the electromagnetic transducer
2. the piezo electric transducer

The basic principle of *electromagnetic transducers* is an electromagnetically induced vibration of a permanent magnet [3], [17]. Two different configurations of electromagnetic transducers have been developed, the extra-coil transducer with the permanent magnet which is located at some distance along the axis of the coil and the intra-coil transducer. The electromagnetic transducer has a high amplitude output, low distortion and low energy consumption. Due to the limited mass of the electromagnetic transducer, its impact on residual hearing is minimized.

The property of *piezoelectric materials* also is the reversible electromechanic transduction. Common principle of all piezoelectric materials is the change of dimension of a ceramic element with the application of electrical voltage [18]. In this context reversibility means two different things: First of all mechanical energy applied to the piezo-material results in electrical voltage as well as electrical voltage applied to the same material results in mechanical movements [3], [19]. Secondly reversibility means that the hysteresis is negligible: after the interruption of the driving voltage the element goes back to its starting position.

The advantage of piezoelectric transducers is their particularly low energy consumption and distortion [20]. But - on the other hand - the change of dimension per applied voltage is also small. The small amplitude of vibration can be increased using several piezos (so-called stacks). It is important to note that an unpowered piezoelectric transducer is rigid. Hence, in quiet it always impedes the normal acoustically driven middle ear and to a certain degree affects residual hearing [3].

In comparison to conventional hearing aids implantable hearingaids are a promising tool to give a substantial reduction of distortion and thus an improved sound quality and speech recognition. The indication and choice of an implantable hearing aid crucially depends on several criteria, such as

- full age
- hearing loss according to the indication range in the pure tone audiogram (Figure 1 (Fig. 1))
- normal middle ear morphology and function
- symmetrical and non-progressive hearing loss
- corresponding results of pure tone and speech audiometry
- long-term experience with conventional hearing aids

At present there are 4 different implantable hearing systems commercially available, of which 3 are sold in Europe:

1. the Bone-anchored Hearing Aid (BAHA™) after Tjellström and Branemark of Entific
2. the Vibrant Soundbridge™ of MedEl
3. the Middle Ear Transducer™ (MET) of Otologics

and for the US-American market

4. the Soundtec Direct Drive System™ of Soundtec.

All of these systems are partially implantable meaning that at least microphone, battery and sound processor are external parts.

Another piezoelectric implant, the Rion Device E-type was developed in Japan since 1978. It is suitable for patients having mixed hearing loss after chronic middle ear disease. Up to now about 90 patients have received this system [21]. Its approval is limited to University hospitals in Japan. That is why the Rion device will not be explained in this short context [22]. The authors refer to Zenner`s

review [1].

Recently Zenner and co-authors [23], [24] published their good clinical results of the Phase III study of the Implex TICA™ fully implantable device. After the bankruptcy of the Implex company the patents were sold to Cochlear and Phonak companies. Yet, the TICA device being unavailable at present will not be a topic for this review.

Although there have been interesting suggestions for the direct mechanical stimulation of the inner ear without transmission to the ossicles [25], [26] the authors again refer to Zenner`s review [1].

3.1 The Bone-anchored Hearing Aid (BAHA™)

The BAHA-system is consisting of an external component containing microphone, sound processor, battery and electromechanical transducer that is attached to a percutaneous, osseointegrated titanium implant screw. The implantation of the titanium screw into the mastoid process of the skull usually is performed in a one-step-technique in local anaesthesia. Basic principle of the implantation is to remove subcutaneous tissue and hair roots around the screw`s position. At least eight weeks after the implantation the osseointegration is completed and the external component can be attached. After 20 years there are more than 15,000 patients fitted with the BAHA worldwide [27]. Thus, it is a very well established technique [28]. The BAHA uses the direct conduction of vibrational energy to the inner ear via the osseointegrated screw. Patients with a bilateral ear canal atresia or with chronic persistent otorrhoea are candidates for the BAHA [29]. It is suitable for patients with conductive hearing loss, with a mixed hearing loss and with a sensorineural hearing loss and chronic external otitis. Depending on the extent of sensorineural hearing loss there are two different systems on the market, the BAHA Classic 300™ for patients with a maximum sensorineural hearing loss of 45 dB and the more powerful BAHA Cordelle™ for patients with a maximum sensorineural hearing loss of 60 dB. Preoperatively it is possible to check candidacy with a special teeth-conduction device. Patients with a symmetrical bilateral hearing loss should preferably undergo bilateral implantation [27], [30]. After Bance and colleagues [31] the BAHA provides an audiometric performance similar to conventional air conduction hearing aids (ACHA) with little major benefit from the BAHA over the ACHA. There is no general recommendation concerning the minimum age for implantation. Looking at the poor thickness of the infantile skull and thus the higher risk of screw extrusion (adults about 1%, children about 10%) we should hesitate to implant before 5 years of age [30], [32].

Recently two different groups [33], [34] published a new indication for the BAHA: adults with unilateral deafness, for example due to an acoustic neuroma. The BAHA, when placed on the deaf side is able to overcome the head shadow effects thus yielding greater benefit for speech understanding in noise than standard contralateral routing of signals. Yet, it must be pointed out that this new aspect still is not a standard indication in Germany and will at present not be paid by the health insurances.

3.2 The Vibrant Soundbridge™ of MedEl

The Vibrant Soundbridge has both external and internal components. The *internal component*, the Vibrating Ossicular Prosthesis (VORP) consists of

a) a receiver unit with a coil, a magnet and a processor element, that breaks down the transcutaneously transferred electrical signal to the appropriate drive signal for the Floating Mass Transducer™ (FMT)

b) a conductor link that connects the implanted receiver unit to the FMT and

c) an electromagnetic transducer, the so-called FMT itself

and an external Audio Processor with a microphone, battery, sound processor, magnet and a coil.

Common principle of partially implantable hearing aids is to pick up sound from the environment, process and amplify this signal and to transfer it transcutaneously to the implant, where the radio frequency signal is demodulated. In the Vibrant Soundbridge this signal produces vertical movement of the FMT that are transferred to the long process of the incus. Because of the low weight of the FMT

its impact upon the sound conduction is below 5 dB [3], [26].

The surgical approach resembles to the cochlear implant procedure: A retrauricular incision is performed in full anaesthesia, followed by a mastoidectomy and a posterior tympanotomy between the facial nerve and the posterior wall of the outer ear canal. It has to be pointed out that the posterior tympanotomy has to be done in a more cranial position than in CI. Furthermore the size of the FMT requires a wider approach. Then the FMT is positioned near the incudostapedial joint parallel to the stapes and fixed to the incus with a titanium clip (Figure 2 (Fig. 2)). The forces needed for the fixation of the crimp are the same as needed for the fixation of a stapedial prosthesis. If the incus body in the antrum is cautiously touched with a needle the FMT should move together with the incus.

Finally the implant is placed in a parietal bony recess and fixed to the bone with sutures. The ossicular chain remains intact. After four weeks the Audio Processor can be activated [35].

Fisch was the first to implant the Vibrant Soundbridge in Zürich in 1996. Up to now about 1000 patients have been operated. The Soundbridge received the CE-approval in March 1998 and the FDA-approval in September 2000.

After the bankruptcy of the Symphonix company that had developed the implant in July 2003 the MedEl company took over the further development and marketing of the Vibrant Soundbridge.

The Vibrant Soundbridge is suitable for patients with a (mild [36] to) moderate to severe sensorineural hearing loss [37], [38]. The upper threshold limit for a successful application is at about 80-85 dB HL. It should be used for patients with a fairly normal threshold in the lower frequencies and a high frequency ski slope hearing loss preferably [39]. The highest gain of threshold level ("functional gain") can be seen between 1 and 2 kHz. In a cohort of 125 patients [36] the gain measured with warble-tones was at about 28-37 db under free field conditions. Other publications show similar results [38], [40]. There is a decline of power of the FMT at higher and at lower frequencies. In comparison to conventional hearing aids patients are not more comfortable with a higher loudness of the signal but due to a better sound clarity and a lacking feedback and obstruction of the outer ear canal. The common disadvantages of partially implantable hearing aids are described below.

3.3 The Middle Ear Transducer™ (MET)

Like the Vibrant Soundbridge the MET consists of an external component and of an implantable electromagnetic transducer. Contrary to the Vibrant Soundbridge the power transmission of this transducer does not correspond to the principle of "actio = reactio" of an accelerated mass but to the repulsion forces that are absorbed by the fixation of the implant to the bone.

The implantation is also performed in full anaesthesia via a retoauricular incision. Both malleus head and incus body are widely exposed by an atticotomy. The transducer tip is placed in a laser-ablated hole in the incus body that is performed with a wire-guide Diode-Laser [41]. The transducer itself is placed and secured using an titanium alignment system that is closely fitting into the atticotomy (Figure 3 (Fig. 3)). After fixation of the transducer the position of the tip of the driver can be corrected using a micromanipulator. Intraoperatively the optimum position of the tip can be evaluated using Laser Vibrometry or - easier - by measuring the post stimulatory sound pressure in the outer ear canal by a preoperatively placed microphone [42]. After fixation of the transducer the connecting wire is introduced into the processor component and hermetically sealed with medical adhesive. Finally this component is placed in a parietal bony recess and fixed to the bone with sutures. The ossicular chain remains intact. Although the surgical approach is quite atraumatic, the availability of an appropriate laser is inevitable. Due to the small mass of the transducer postoperative sound conduction loss is negligible. Activation of the sound processor is recommended 8 weeks after surgery [43]. After the first implantation in 1999 about 300 patients underwent this surgery [43]. The MET received the CE-approval in June 2000.

The MET is suitable for patients suffering from moderate to severe sensorineural hearing loss. The highest gain of hearing threshold is between 1 and 3 kHz. In a cohort of 205 patients it was about 40 dB. The results of speech audiometry of the US trial group corresponded to the previous fitting with conventional digital hearing aids [43].

Both Vibrant Soundbridge and MET can be surgically removed without impairment of residual air conduction.

3.4 The Soundtec Direct Drive System™ (only available in the USA)

Similar to the BAHA with the Soundtec system only a passive element is implanted. The internal portion of the implant is a rare earth magnet encapsulated in a titanium canister with a lateral attachment ring. After tympanotomy in local anaesthesia and exposure and temporal disarticulation of the incudostapedial joint this ring is placed on the stapes head [44]. Activation of the sound processor is performed 6-8 weeks after surgery [35]. Due to the small mass of the permanent magnet postoperative sound conduction loss is negligible. The earmold contains the coil that has to be placed exactly 2 mm lateral to the tympanic membrane. There are two different models of the sound processor available, one as a BTE- and one as an ITC-device [45], [46]. Thus, the Soundtec system has an electromagnetic extra-coil transducer [3]. This implant is suitable for patients with a moderate to severe sensorineural hearing loss. The results of the phase-II clinical trial with 103 patients showed an average gain of hearing threshold in comparison to the preoperative conventional hearing aid fitting of 7.9 dB between 0.5 and 4 kHz [46]. This gain was more distinct at higher frequencies. One reason for this gain was that most conventional hearing aids capable of providing higher gain had feedback and distortion restrictions at louder volume levels. Additionally patients reported a better sound quality. Since September 2001 the Soundtec Direct Drive System has the FDA-approval.

Advantages of this implant in comparison to the Vibrant Soundbridge and the MET are the simple surgical procedure and the lower expenses. Disadvantage is the persisting occlusion of the outer ear canal although the electromagnetic transduction does not produce feedback. As with all implantable devices there is a contraindication for MRI [47]. It is questionable whether the Soundtec system will be available in Europe in the future.

4. Disadvantages of present implantable hearing aids

Apart from the high costs of hardware and operation the main disadvantage of implantable hearing aids is the implantation. Patients tend to accept the risks of surgery as long as they know in advance that their personal situation will be improved. Yet, except for the BAHA system at the moment the technical predispositions for a preoperative simulation of implant performance are not available [48].

But there are additional problems caused by the unilateral implantation of partially implantable devices without directional microphones (see [11]) The capacity of the devices at the upper limits of indication still leaves much to be desired. After Snik and colleagues [49] the MET is more powerful than the Vibrant Soundbridge at lower frequencies.

Because of the non-directionality of the retroauricular microphones assessment of hearing in noise from different directions (Bird-test or OLSA) should be part of the preoperative diagnostics.

5. Current developments: fully-implantable hearing aids

Because the totally implantable hearing devices are already technologically feasible the value of continued research on partially implantable devices is now questionable [21]. The fully-implantable device offers aesthetic advantages and hermeticity and thus can even be worn in a dusty or wet environment. Furthermore there is no additional loss of power by the transcutaneous transfer of signals.

5.1 The St. Croix Envoy™ System

Since March 2000 11 patients in 5 German centres and 7 patients in two US-American centres underwent implantation of a fully implantable Envoy hearing system developed by St. Croix Medical, Minneapolis, Minnesota during a phase-I clinical trial. To sum up the results of the phase-I trial, half of the patients showed stable amplification over a period of about two years whereas one patient suffered from fluctuating hearing loss after implantation that cannot be clearly attributed to the Envoy

System. The experiences gained during this phase-I trial resulted in technical improvements to the system. The Phase II trial being conducted in Germany and the USA began in mid 2004. Although at present only preliminary results can be reported. Currently there have been 4 implants performed in the US, and 1 implant in Germany. Two of these first implants have been activated and excellent results are being reported that indicate that the Phase I issues appear to have been overcome.

One special feature of the Envoy System is that the device takes advantage of the gain from the natural ear anatomy by using the pinna, external ear canal and tympanic membrane to conduct sound [21]. After a mastoidectomy and posterior tympanotomy the long process of the incus is cut using a CO2-laser. Then the piezoelectric Sensor is fixed to the widely exposed incus body. A glass ionomer-cement is used for fixation. After hardening of the cement the incus body is carefully mobilized thus creating a neo-joint between the incus and the Sensor. Then a piezoelectric Driver is firmly fixed to the stapes head using the same cement. This connection is not mobilized (Figure 4 (Fig. 4)). The connecting wires of the Sensor and Driver are introduced into the Sound Processor-battery-component and hermetically sealed. Finally this Sound Processor component is fixed in a parietal bony recess. The intra-operative system integrity check is performed using a Laser Doppler Vibrometer.

The vibrational energy from the tympanic membrane is transferred to the Sensor thus producing an electrical signal. This signal is filtered and amplified and transferred to the Driver. The Driver itself returns this energy to the stapes generating equivalent mechanical energy.

The principal advantage of the Envoy System is the utilization of the directionality of the pinna and the amplification of the outer ear canal. Moreover the full implantability of the system means a tremendous gain in a person's quality of life. Yet, in comparison to the other systems described here the implantation of the Envoy System obviously is the most invasive procedure (fixation of two transducers, disarticulation of the ossicular chain) and should be restricted to especially experienced ear surgeons at present.

5.2 The Fully Implantable Ossicular Stimulator (FIMOS™) by Otologics

Based on the MET-system Otologics has been developing an electromagnetic fully implantable hearing aid that is going to be object of a clinical trial in the end of 2004 after having finished experimental studies [42]. Preliminary results of this trial cannot be reported at present. The surgical approach is very similar to the partial implantation. Nevertheless the device additionally contains a rechargeable battery, sound processor and subcutaneous microphone. Intraoperatively this microphone is placed underneath the retroauricular skin. The FIMOS has the favourable effect that we already now the efficiency of the device, that the ossicular chain remains intact and that it is possible to "up*grade*" the partially implantable hearing aid without manipulations on the transducer to a fully implantable device. The lacking directional microphone is a disadvantage of the system.

6. Summary: future demands on implantable hearing aids

From the authors' point of view the future implantable hearing aids will be fully implantable, because only the full implantation provides hermeticity as well as infertility. The surgical procedure in the future has to be simple, the implants have to be cheaper in order to provide bilateral fitting. Regarding the directivity of the pinna and the amplification function of the outer ear canal the microphone has to be near to the tympanic membrane as it has been already implemented with the TICA device [11]. Also in the future it is doubtful, whether the disarticulation is inevitable. If on the other hand alternative techniques for vibrational energy transmission [25], [26] other than the ossicular chain will be developed remains unclear. This would enable us to treat patients with deformations of the middle ear who are - except for the BAHA system - not suitable for implantation today.

7. Implantable hearing aids for patients with impaired sound conduction

As described above the Vibrant Soundbridge, the MET as well as the fully implantable hearing aids

are not suitable for patients with disrupted air conduction. Many of those patients after Tympanoplastiken are not content having conventional hearing aids for their mixed or sensorineural hearing loss. For those patients Cayé-Thomasen and colleagues [50] presented the long-term results of an approach similar to the Soundtec Direct Drive System with a magnetic TORP or PORP and an extra-coil in the outer ear canal. Short-term results being excellent, but after ten years no patient was using his implant.

8. The electric-acoustic stimulation

The electric stimulation of the auditory system using cochlear implants is a well established procedure for the rehabilitation of patients with profound sensorineural hearing loss or deafness. A relatively great number of patients (von Ilberg is estimating their share at 3.4% of the German population [51]) do not correspond to the indication criteria for CI, on the other hand depending on their marked high frequency hearing loss do not have a satisfactory rehabilitation of their speech perception by conventional hearing aids. V. Ilberg estimated the indication threshold for this group being 70 dB (SPL) at 1 kHz and suggested a new concept of a combined electric and acoustic stimulation by CI and conventional hearing aids [51]. Their basic assumption was that the human auditory system is able to simultaneously process electrical and acoustical signals. A second assumption was that it is possible to introduce the CI-electrode without further damage to the resting hair cells in the cochlear apex [52]. Gstoettner and his group recently published the results of 21 patients: With 18 of these patients the hearing could at least partially be preserved [53]. The crucial difference between a conventional electrode insertion and their approach was a restriction of the depth of insertion to 360° or 18-24 mm. After their preliminary results the synergistic effect of electric-acoustic stimulation seems to have advantages concerning hearing in noise.

Despite these encouraging results the risk of complete hearing loss due to the electrode insertion is high. That is why Gantz and Turner [54] suggested the insertion of a shorter modified Nucleus CI-24-electrode. They published the results of 9 patients with an insertion depth of 6 and 10 mm (Figure 5 (Fig. 5)). The residual hearing could be preserved in all cases. They observed a better performance concerning monosyllables in their hybrid group.

At this point of experience it is not possible to finally evaluate both techniques or to compare their results. With respect to the future developments of implantable hearing aids the electric-acoustic stimulation is an interesting new aspect.

References

1. Zenner HP. Implantierbare Hörgeräte - aktueller Stand. In: Jahnke K (Hrsg). Verhandlungsbericht der Deutschen Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie. Stuttgart: Thieme, 2000, 141-161
2. Dazert S, Shehata-Dieler WE, Dieler R, Helms J. Das Mittelohrimplantat "Vibrant Soundbridge" zur Hörrehabilitation bei sensorischer Schwerhörigkeit. Laryngo-Rhino-Otol 2000; 79: 459-464
3. Spindel JH. Middle ear implantable hearing devices. Am J Audiol 2002; 11: 104-113
4. Wood SA, Lutman ME. Relative benefits of linear analogue and advanced digital hearing aids. Int J Audiol 2004; 43: 144-155
5. Parving A. The hearing aid revolution: facto r fiction. Acta Otolaryngol 2003; 123: 245-248
6. Mudry A, Dodelé L. History of the technological development of air conduction hearing aids. J Laryngol Otol 2000; 114: 418-423
7. Baguley DM, Luxon LM. The future of audiological rehabilitation. J Laryngol Otol 2000; 114: 167-169
8. Derleth RP, Dau T, Kollmeier B. Modeling temporal and compressive properties of the normal and impaired auditory system. Hear Res. 2001; 159: 132-149
9. Dhar S, Humes LE, Calandruccio L, Barlow NN, Hipskind N. Predictability of speech-in-noise performance from real ear measures of directional hearing aids. Ear Hear 2004; 25: 147-158
10. Boymans M, Dreschler WA. Field trials using a digital hearing aid with active noise reduction and dual-microphone directionality. Audiology 2000; 39: 260-268
11. Olsen HL, Hagermann B. Directivity of different hearing aid microphone locations. Int J Audiol 2002; 41: 48-56

12. Taylor RS, Paisley S, Davis A. Systematic review of the clinical and cost effectiveness of digital hearing aids. Br J Audiol 2001; 35: 271-288
13. Bentler RA, Niebuhr DP, Johnson TA, Flamme GA. Impact of digital labeling on outcome measures. Ear Hear 2003; 24: 215-224
14. Prinz I, Nubel K, Gross M. Digitale versus analoge Hörgeräte bei Kindern. HNO 2002; 50: 844-849
15. Todt I, Seidl RO, Gross M, Ernst A. Comparison of different Vibrant Soundbridge audioprocessors with conventional hearing aids. Otol Neurootol 2002; 23: 669-673
16. Gussekloo J, de Bont LE, von Faber M, Eekhof JA, de Laat JA, Huls JH, van Dongen E, Westendorp RG. Auditory rehabilitation of older people from general population - the Leiden 86-plus study. Br J Gen Pract 2003; 53: 536-540
17. Stieger C, Wäckerlin D, Bernhard H, Stahel A, Kompis M, Häusler R, Burger J. Computer assisted optimization of an electromagnetic transducer design for implantable hearing aids. Comput Biol Med 2004; 34: 141-152
18. Leysieffer H, Baumann JW, Müller G, Zenner HP. Ein implantierbarer piezoelektrischer Hörgerätewandler für Innenohrschwerhörige. HNO 1997; 45: 792-800
19. Javel E, Grant IL, Kroll K. In vivo characterization of piezoelectric transducers for implantable hearing aids. Otologie Neurootol 2003; 24: 784-795
20. Zenner HP, Leysieffer H, Maassen M, Lehner R, Lenarz T, Baumann J, Keiner S, Plinkert PK, McElveen JT. Human studies of a piezoelectric transducer and a microphone for a totally implantable electronic hearing device. Am J Otol 2000; 21: 196-204
21. Maniglia AJ, Murray G, Arnold JE, Ko WH. Bioelectric microphone options for a totally implantable hearing device for partial and total hearing loss. Otolaryngol Clin North Am 2001; 34: 469-483
22. Yanagihara N, Sato H, Hinohira Y, Gyo K, Hori K. Long-term results using a piezoelectric semi-implantable middle ear hearing device: The Rion Device E-type. Otolaryngol Clin North Am 2001; 34: 389-400
23. Zenner HP, Limberger A, Baumann JW, Reischl G, Zalaman IM, Mauz PS, Sweetow RW, Plinkert PK, Zimmermann R, Baumann I, De Maddalena H, Leysieffer H, Maassen MM. Phase III results with a totally implantable piezoelectric middle ear implant: speech audiometry, spatial hearing and psychosocial adjustment. Acta Otolaryngol 2004; 124: 155-164
24. Zenner HP, Leysieffer H. Total implantation of the Implex TICA hearing amplifier implant for high-frequency sensorineural hearing loss. Otolaryngol Clin North Am 2001; 34: 417-446
25. Spindel JH, Lambert PR, Ruth RA. The round window electromagnetic implantable hearing aid approach. Otolaryngol Clin North Am 1995; 28: 189-205
26. Hüttenbrink KB. Middle ear mechanics and their interface with respect to implantable electronic otologic devices. Otolaryngol Clin North Am 2001; 34: 315-335
27. Priwin C, Stenfeldt S, Granström G, Tjellström A, Hakansson B. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. Laryngoscope 2004; 114: 77-84
28. Tjellström A, Hakansson B, Granström G. Bone-anchored hearing aids. Otolaryngol Clin North Am 2001; 34: 337-364
29. Snik AFM, Bosman AJ, Mylanus EAM, Cremers CWRJ. Candidacy for the bone-anchored hearing aid. Audiol Neurootol 2004; 9: 190-196
30. Federspil PA, Plinkert PK. Knochenverankerte Hörgeräte immer beidseitig! HNO 2002; 50: 405-409
31. Bance M, Abel SM, Papsin BC, Wade P, Vendramini J. A comparison of the audiometric performance of bone anchored hearing aids and air conduction hearing aids. Otol Neurootol 2002; 23: 912-919
32. Mißfeldt N, Braun A, Zwirner P. Beidseitige BAHA-Versorgung bei Kindern mit Ohrmuscheldysplasie und/oder Gehörgangsatresie. HNO 2002; 50: 495-499
33. Niparko JK, Cox KM, Lustig LR. Comparison of the bone anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. Otol Neurootol 2003; 24: 73-78
34. MacLarnon CM, Davison T, Johnson IJM. Bone-anchored hearing aid: comparison of benefit by patient subgroups. Laryngoscope 2004; 114: 942-944
35. Weber PC. Medical and surgical considerations for implantable hearing prosthetic devices. Am J Audiol 2002; 11: 134-138
36. Sterkers O, Boucarra D, Labassi S, Bebear JP, Dubreuil C, Frachet B, Fraysse B, Lavieille JP, Magnan J, Martin C, Truy E, Uziel A, Vaneecloo FM. A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. Otol Neurootol 2003; 24: 427-436
37. Snik AFM, Mylanus EAM, Cremers CWRJ, Dillier N, Fisch U, Gnadeberg D, Lenarz T, Mazolli M, Babighian G, Uziel AS, Cooper HR, O`Connor AF, Fraysse B, Charachon R, Shehata-Dieler WE. Multicenter audiometric results with the Vibrant Soundbridge, a

semi-implantable hearing device for sensorineural hearing impairment. Otolaryngol Clin North Am 2001; 34: 373-388
38. Snik AFM, Cremers CWRJ. Vibrant semi-implantable hearing device with digital sound processing. Arch Otolaryngol Head Neck Surg 2001; 127: 1433-1437
39. 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 Neurootol 2003; 24: 775-783
40. Fraysse B, Lavieille JP, Schmerber S, Enée V, Truy E, Vincent C, Vaneecloo FM, Sterkers O. A multicenter study of the Vibrant Soundbridge middle ear implant: Early clinical results and experience. Otol Neurootol 2001; 22: 952-961
41. Fredrickson JM, Coticchia JM, Khosla S. Ongoing investigations into implantable electromagnetic hearing aid for moderate to severe sensorineural hearing loss. Otolaryngol Clin North Am 1995; 28: 107-120
42. Waldmann B, Maier H, Leuwer R. Indicators for efficient coupling of the Otologics MET ossicular stimulator. 3 rd symposium of middle ear mechanics in research and otology. Matsuyama, Ehime, Japan, 9.-12.07.2003
43. 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
44. Hough JVD, Dyer RK, Matthews P, Wood MW. Early clinical results: Soundtec implantable hearing device phase II study. Laryngoscope 2001; 111: 1-8
45. Roland PS, Shoup AG, Shea MC, Richey HS, Jones DB. Verification of improved patient outcomes with partially implantable hearing aid, the Soundtec direct hearing system. Laryngoscope 2001; 111: 1682-1686
46. Hough JVD, Matthews P, Wood MW, Dyer RK. Middle ear electromagnetic semi-implantable hearing device. Otol Neurootol 2002; 23: 895-903
47. Dyer RK, Dormer KJ, Hough JVD, Nakmali U, Wickersham R. Biomedical influences of magnetic resonance imaging on the Soundtec direct system implant. Otolaryngol Head Neck Surg 2002; 127: 520-530
48. Hoth S, Lohaus M, Waldmann B. Frühe akustisch evozierte Potenziale bei direkter mechanischer Stimulation der Gehörknöchelchenkette. HNO 2003; 51: 550-557
49. Snik A, Noten J, Cremers C. Gain and maximum output of two electromagnetic middle ear implants: are real ear measurements helpful? J Am Acad Audiol 2004; 15: 249-257
50. Cayé-Thomasen P, Jensen JH, Bonding P, Tos M. Long-term results and experience with the first-generation semi-implantable electromagnetic hearing aid with ossicular replacement device for mixed hearing loss. Otol Neurootol 2002; 23: 904-911
51. Von Ilberg C, Kiefer J, Tillein J, Pfenningsdorff T, Hartmann R, Stürzebecher E, Klinke R. Electric-acoustic stimulation of the auditory system. ORL 1999; 61: 334-340
52. Adunka O, Kiefer J, Unkelbach MH, Lehnert T, Gstoettner W. Development and Evaluation of an improved cochlear implant electrode design for electric acoustic stimulation. Laryngoscope 2004; 114: 1237-1241
53. Gstoettner W, Kiefer J, Baumgartner WD, Pok S, Peters S, Adunka O. Hearing preservation in cochlear implantation for electric acoustic stimulation. Acta Otolaryngol 2004; 124: 348-352
54. Gantz BJ, Turner C. Combining acoustic and electrical speech processing: Iowa/Nucleus hybrid implant. Acta Otolaryngol 2004; 124: 344-347

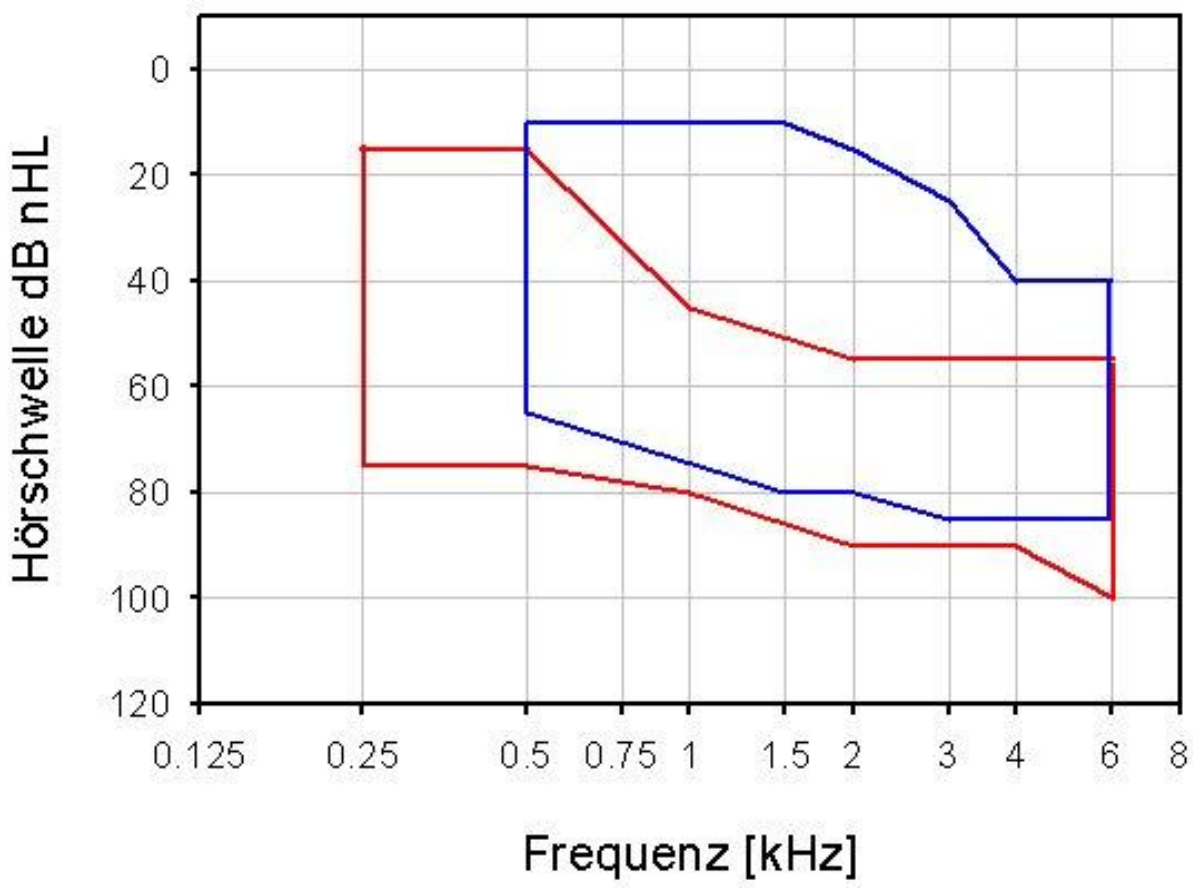

Figure 1: Indicational range of the Vibrant Soundbridge and of the MET according to the pure tone audiogram

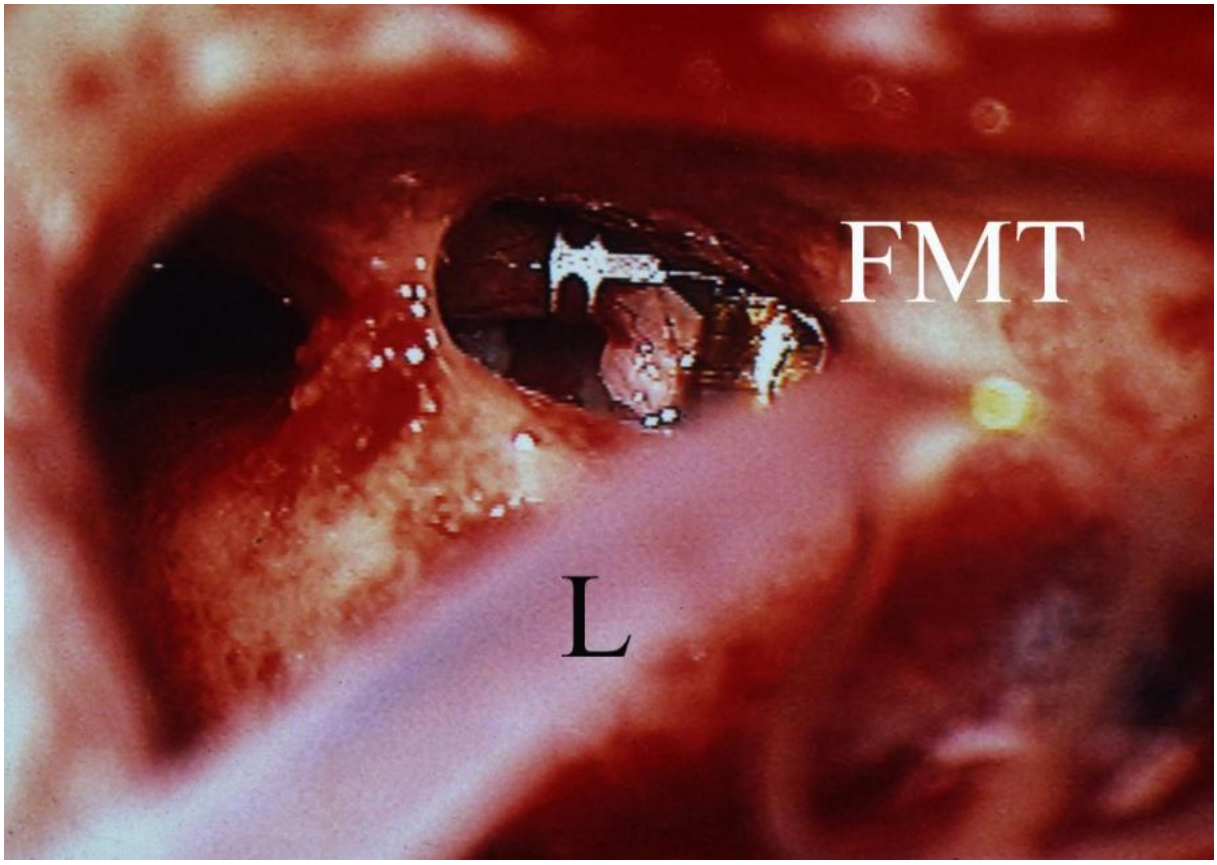

Figure 2: MedEl Vibrant Soundbridge: the Floating Mass Transducer (FMT) is attached to the long process of the incus by a titanium clip. L = conductor link

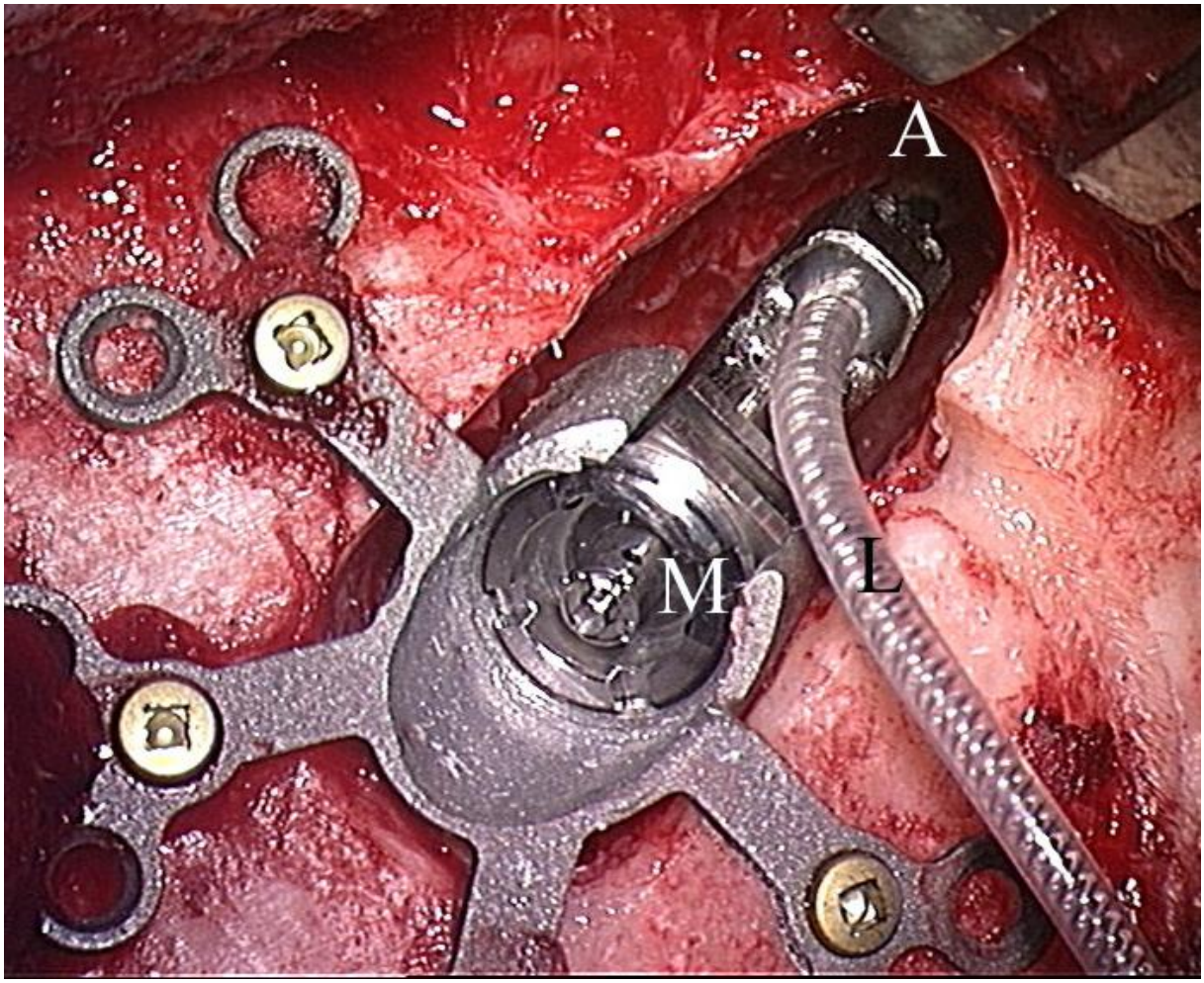

Figure 3: Otologics MET: titanium alignment and micromanipulator (M) are visible; the tip of the transducer is placed in a laser-ablation hole in the incus body (A). L = conductor link

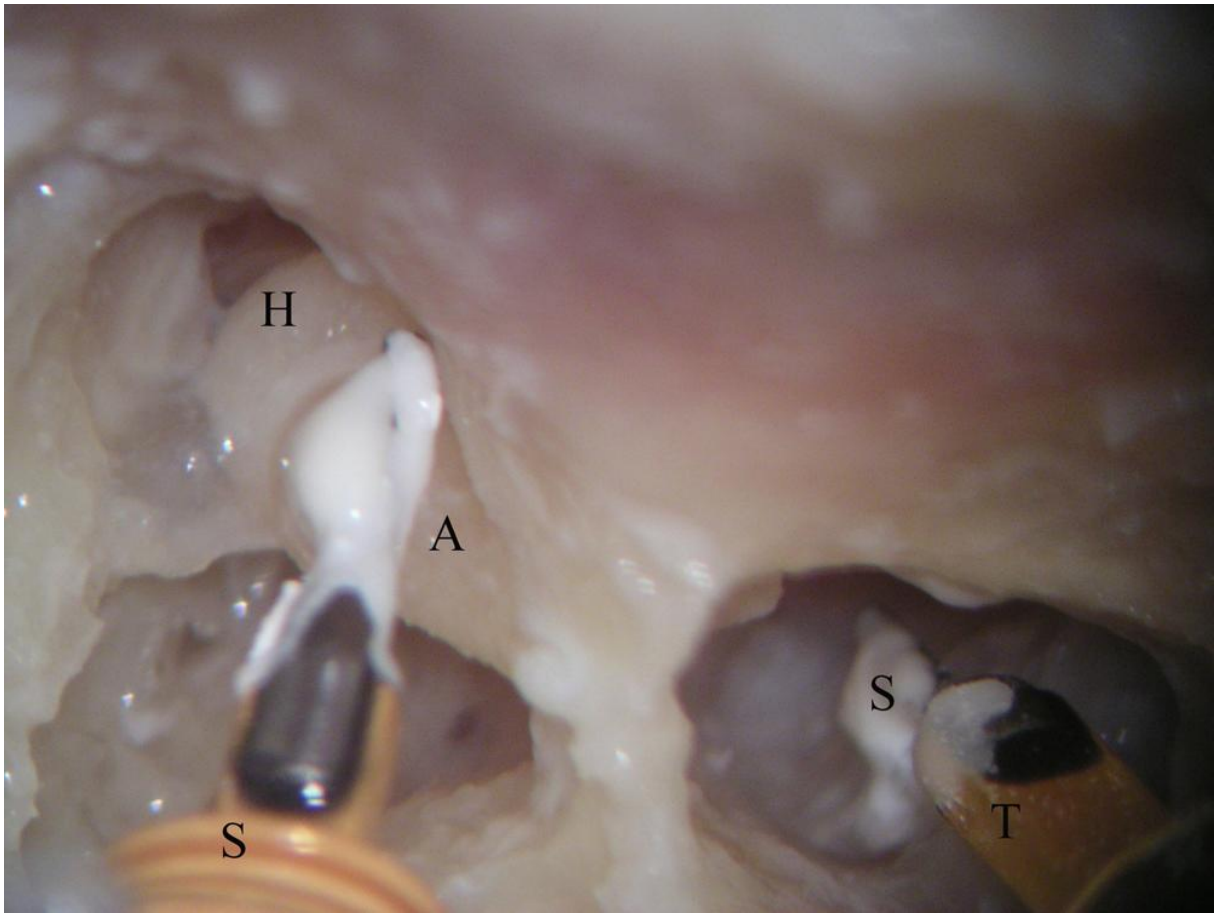

Figure 4: St. Croix Envoy (for better understanding implantation in a corpse temporal bone): the piezoelectric sensor (S) is fixed to the incus body (A) by glasionomer-cement, the driver (T) is fixed to the stapes head; H = malleus head

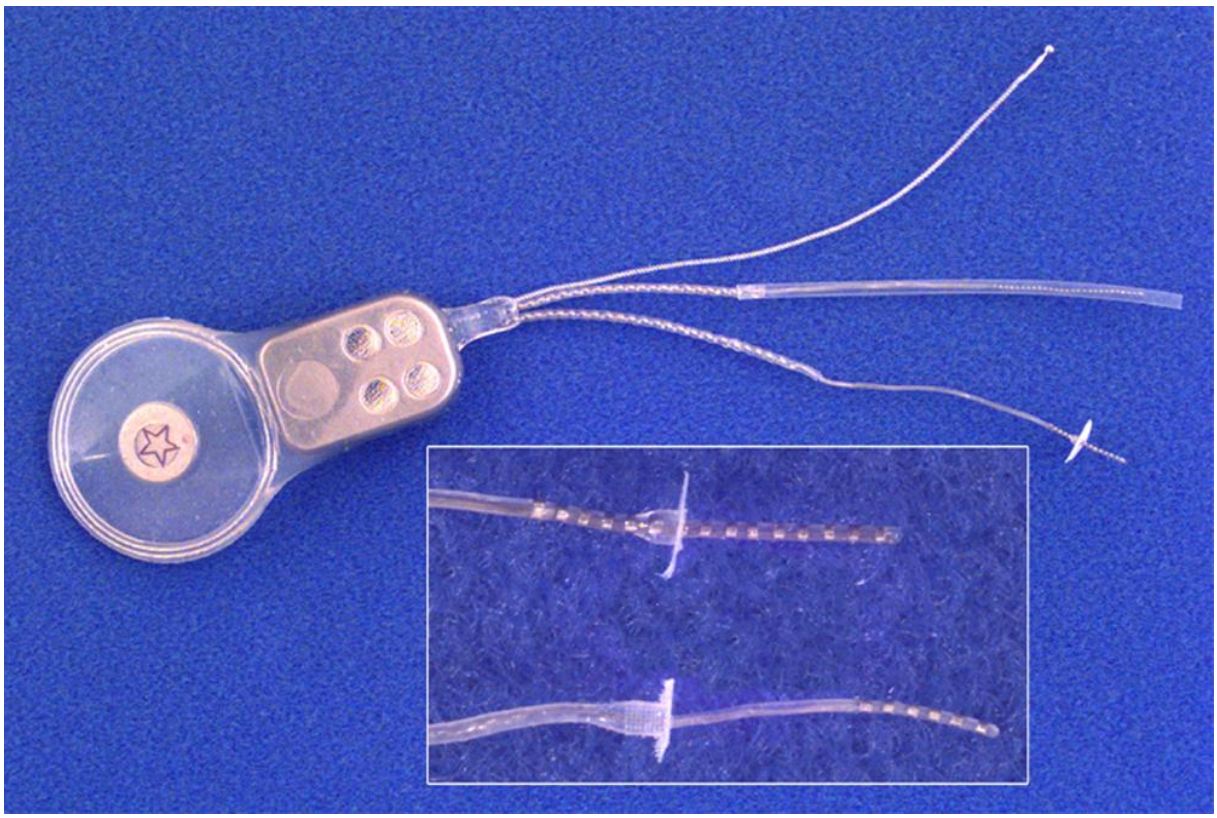

Figure 5: Iowa/Nucleus Hybrid Cochlear Implant System: the 6 and the 10 mm electrode are visible in magnification. After personal communication Gantz now only uses the 10 mm

electrode (with kind permission of B. Gantz, University of Iowa, Iowa City, IA, USA)