

# TOTAL IMPLANTATION OF THE IMPLEX TICA HEARING AMPLIFIER IMPLANT FOR HIGH-FREQUENCY SENSORINEURAL HEARING LOSS

The Tübingen University Experience

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Hearing devices may be classified as sound-producing hearing aids (SPHAs), electrically stimulating devices (cochlear implants, CIs), and vibratory hearing aids (VHAs).<sup>51</sup> Because patients may lose physiologic cochlear amplification (positive recruitment, loss of otoacoustic emissions [OAE] hearing devices for the treatment of sensorineural hearing loss (SNHL) are used as signal amplifiers. Sound-producing hearing aids are not in contact with the ear drum, whereas VHAs (e.g., Entific BAHA) are directly coupled to the patient's skull or ossicular chain (e.g., Rion-MEI, Symphonix Vibrant, Implex TICA). VHA is designated a vibratory amplifier implant (VAI).

The totally implantable communication assistance (TICA) device is a European-approved totally implantable vibratory amplifier implant. It picks up the sound signal transcutaneously from the external auditory canal (EAC) near the ear drum, amplifies the signal, and transduces the signal into microvibrations that are delivered to the ossicular chain. Development, technical details,<sup>21-23, 25</sup> surgical technique, patient selection criteria, and clinical results of the version LZ 3001 have been published<sup>55, 56</sup> and are reviewed in this article. Since 1998, the TICA device has been used for the surgical treatment of moderate to severe high-frequency SNHL in Europe.<sup>55</sup>

International research that led to the present-day vibratory hearing aids began as early as 1935.<sup>1, 4, 6-17, 29-31, 34-44, 46, 49, 50</sup> These research efforts have shown that replacing sound stimulation of the ear by vibratory stimulation of the ossicular

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chain may result in a surprisingly clear (low-distortion) hearing impression that is matched only by high-performance loudspeakers.

There are various ways, other than a loudspeaker, to drive the ossicular chain by a vibratory device. Rather than placing the vibratory part of a VHA on the ear drum, the TICA uses an ossicular chain coupling (OCC) to implant the actuating vibrator. The implantation of all parts of the VHA results in a totally implantable (TI) VAI coupled to the ossicular chain. A TI-VAI may be helpful to hearing-impaired persons who cannot benefit from sound-producing hearing aids for medical, psychologic, audiologic, or professional reasons.

In some patients, conventional hearing aids may have fundamental disadvantages that prevent patients from using them.<sup>45</sup> The ear mold can create an unpleasant sensation of ear occlusion and pressure. In some patients the ear mold can induce inflammation of the EAC. To prevent the sensation of occlusion, the ear mold may be inserted loosely, leading to unwanted feedback or to reduced efficacy of the hearing aid. In addition, some patients find the acoustic distortion produced by the closure of the EAC and the resulting low intelligibility of speech to be intolerable. Certain professions or jobs (e.g., in music, sports, or telephone centers) do not allow the use of hearing aids. Hearing aids are at increased risk of loss or destruction in work environments associated with heat, water, dust, steam, sweat production, or hard physical work. Finally, the patient may fear social or professional discrimination.

## DESIGN AND DEVELOPMENT

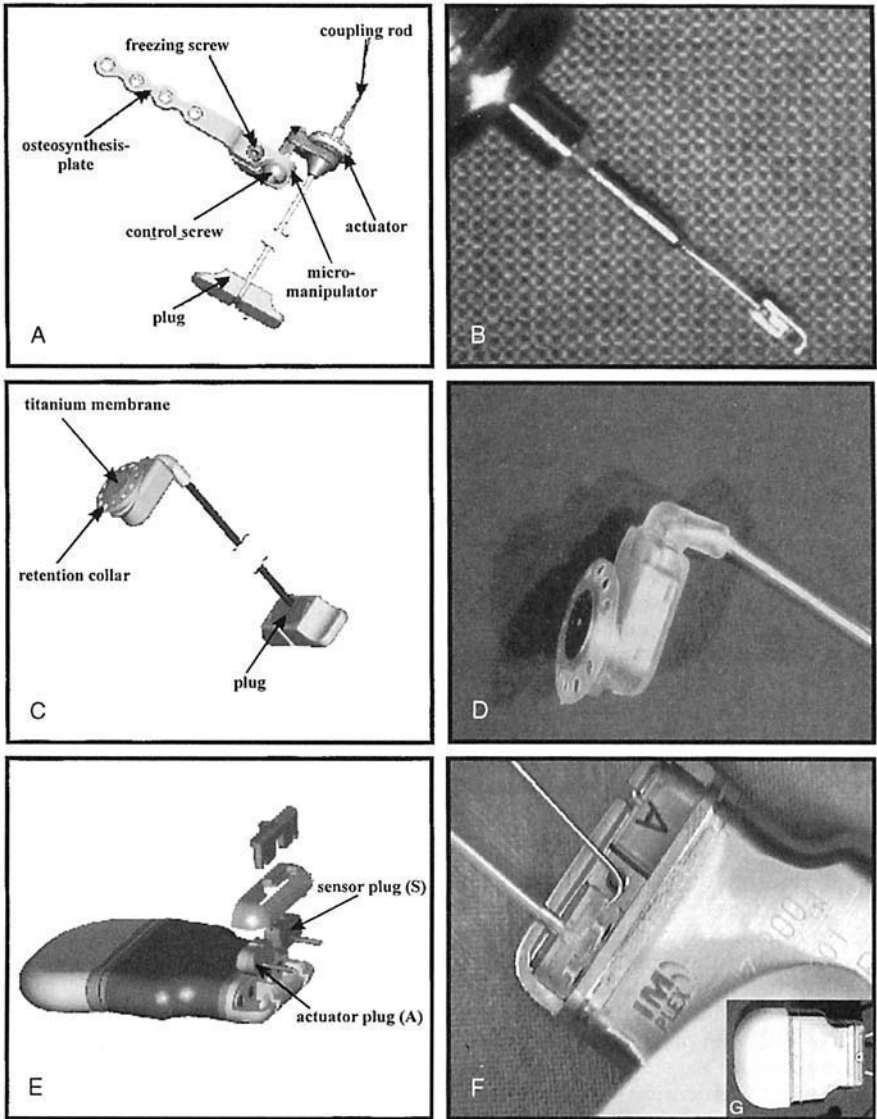
The fundamental concept of the TICA device was developed by Leysieffer and Zenner<sup>24</sup> between 1990 and 1992 at the University of Tübingen, Germany. From 1993 to 1997, after a technology transfer agreement, further development took place in a cooperation between teams from Tübingen University and from Implex AG Hearing Technology. The goal of the interdisciplinary research and development teams was a fully implantable hearing amplifier that can be used for patients with sensorineural hearing loss with intact middle ears and for patients with mixed hearing loss and interrupted ossicular chains.

### Design of Actuator and Sensor

#### *Actuator*

To develop fully implantable VAIs, most research teams looked to the development of high-performance batteries that are suitable for implantation and can supply the high energy output required by the implant for several years. The authors instead sought to create an actuator with low energy consumption (LEC) that would allow the use of present battery technology (Fig. 1). Mathematic modeling demonstrated that the power consumption of a piezoelectric transducer is much less than that of electromagnetic devices.<sup>2</sup> The TICA heteromorph piezoelectric actuator prototype was designed accordingly. Unlike the biomorph piezoelectric transducer described by Suzuki and Yanagihara's groups,<sup>38-41, 49, 50</sup> the TICA transducer does not use a rod-shaped bimorph. The TICA is a circular heteromorph system that consists of a piezoceramic disk that is intimately linked with a titanium disk. This technology offers:

- Minimal power consumption with sufficiently high stimulation levels. (The electrical power consumption at full volume and broadband signals is in the



**Figure 1.** TICA (Implex, Munich, Germany) components. Piezoelectric actuator (A) with rod for coupling to the incus body and clip (B) for coupling to the long incus process. C and D, Membrane sensor with retention collar. Actuator and sensor possess plugs to be inserted into the (E and F) main module with digitally programmable 3-channel audio-processor. Note pressure connector assembly (PCA) opened for sensor and actuator plugs. G, PCA closed.

range of  $1 \mu W$  and is therefore lower than that of electromagnetic transducers and is even significantly less than that of the electronic components.)

- Minimal nonlinear distortions
- A hermetically sealable and biocompatible casing

Because of its calculated diameter the actuator was designed for implantation in the mastoid. To transfer the actuator's mechanical vibrations the design included a 0.5 mm thin titanium probe to be coupled to an ossicle in the middle ear.

### *Sensor*

As described by Kodera et al,<sup>17</sup> a membrane sensor was designed to be implanted subcutaneously in the EAC near the ear drum. This implantation site uses the positive acoustic and audiologic characteristics of the EAC and auricle.<sup>3,17</sup> Behavioral and physiologic evidence suggests that the perceived sound spectrum, as modified by an external ear, provides important cues for horizontal and vertical sound localization. The external ear complements the incoming sound signal (e.g., with specific resonance patterns that correlate with the localization of a sound source). The resulting transfer functions encode spatial information about sound sources for input signals for the middle ear. After these signals are processed in the inner ear, the central auditory system can decode this information by evaluating the monaural cues. Ubiquitous background noise may result in different cues from specific directions, contributing to central noise suppression.

The sensor design consists of a hermetically sealed titanium cylinder with a stiff but flexible titanium membrane to be placed under the meatal skin. With a membrane diameter of only 4.5 mm, the cylinder is designed to be implanted in the posterior bony EAC. Sound-induced movements of the meatal skin drive the membrane. The stiffness of the membrane allows the membrane operation to be largely independent of the skin mass. The cylinder houses an internal microphone to transduce the motion of the membrane into electrical energy. Integrated electronics provide preamplification. Mathematical modeling predicts a sensitivity of approximately 1.5 mV/PA and a high spectral transmission bandwidth of as much as 10 kHz.

## **Development of Actuator and Sensor**

### *Actuator*

Critical to the success of any totally implantable hearing device is the space within the temporal bone that is available for implantation. The final shape of the newly designed actuator and the sensor had to allow implantation into the human mastoid. The functional geometry of a consecutive series of six actuator prototypes was evaluated in 50 human temporal bones.<sup>27</sup> The resulting final actuator (clinical actuator) could be inserted in 78% of the cadavers examined (confidence interval 61.5%–89.2%). A preoperative Schuller radiograph allows the exclusion of patients whose ears are too small for implantation.<sup>19</sup> The heart of the 0.4 g clinical actuator is a 3-mm thin titanium disk that seals the titanium casing (medical grade 2, ASTM F67) hermetically (gas-proof according to MIL-STD 883 D). The electromechanically active piezoceramic disk is located on the inside of the titanium disk. A titanium coupling probe 0.5 mm in diameter is mounted in the center of the exterior of the titanium disk.<sup>21,22</sup>

### *Sensor*

The design of the clinical sensor was developed in a similar manner as the actuator.<sup>23</sup> Extensive temporal bone studies with four prototypes resulted in an

*L*-shaped clinical sensor housing allowing the 4.5-mm sensor membrane to be inserted under the skin into the posterior wall of the EAC. The larger portion ( $8.5 \times 5.6 \times 4.5$  mm) of the sensor, however, is placed in the mastoid and is directed away from the sigmoidal sinus towards the tip of the mastoid. The *L* shape also allows coimplantation with the actuator in 78% (confidence interval 64.0%–88.0%) of the temporal bones investigated. A Schuller radiograph allows patient selection before surgery.<sup>28</sup>

The small total mass (0.4 g) lessens the sensitivity to mechanical vibrations or knocks from the exterior. The sensor is protected to a large extent against the influences of external electromagnetic influences because of the total titanium encapsulation. For further protection against electromagnetic influences, the sensor possesses electronic elements that ensure safe operation even in the presence of intense electromagnetic fields, as may occur, for example, during mobile telephone operation. Pure titanium also renders the module insensitive to a large extent to strong, static magnetic fields which can occur during MR imaging. The TICA is radiograph compatible (see Fig. 14D). The intramastoidal part of the casing, which is aligned vertically, contains the electrical feedthrough. The electrical supply is connected perpendicularly to the feedthrough so that the leads can be handled without creating kinks or bending radii that are too small. The sensor can be rotated around the axis of the cylindrically shaped part as desired, to the degree the anatomy of the mastoid requires it.

## TECHNICAL PERFORMANCE

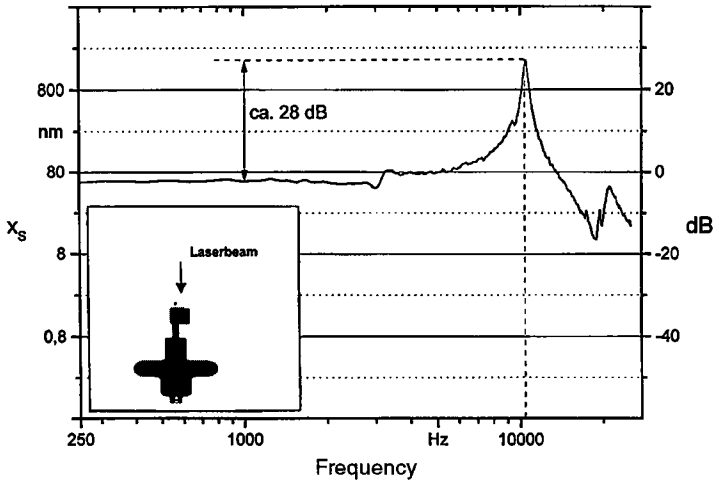
The technical performance of the implant was determined by *in vitro* measurements.<sup>21–23</sup>

### Mechanical Impedance

Mechanical output impedance  $Z_w$  of the transducer lies 1 decade (20 dB, 5 kHz) to 2 decades (40 dB,  $\leq 1$  kHz) above the mechanical input impedance  $Z_c$  of middle ear and cochlea. Thus, the ossicular mass (80 mg) should not impair the transducer output level below the first resonance: mass influence is restricted to a shift of the resonance frequency to lower values. Furthermore, based on the actuator's high mechanical impedance level in a large frequency range, the transducer displacement should be largely independent of individual variations in coupling load, up to the first resonance frequency. Thus, changes of load impedance (e.g., by connective tissue growth at the coupling site) is expected to have no significant influence on transfer frequency response.

### Spectral Bandwidth, Displacement, and Equivalent Sound Pressure Level

The transducer was calculated and optimized so that the first mechanical resonance frequency lies at about 10 kHz. Figure 2 shows the resulting frequency response in the range of 250 Hz to 25 kHz of the transducer displacement amplitude  $x_s$  in the mechanical idle mode (no-load condition). The remarkable transfer function, with an amplitude increase instead of a decrease in the high frequency range, was designed to cope with high-frequency SNHL. Transducer displacement was smooth, with a ripple of less than  $\pm 1$  dB, to about 6 kHz. Displacement was about 60 nm. Resonance was 10.25 kHz with a Q-factor of about 28 dB. Thus,



**Figure 2.** Actuator displacement ( $X_s$ ) versus frequency in a no load condition (insert) using laser doppler vibrometry.

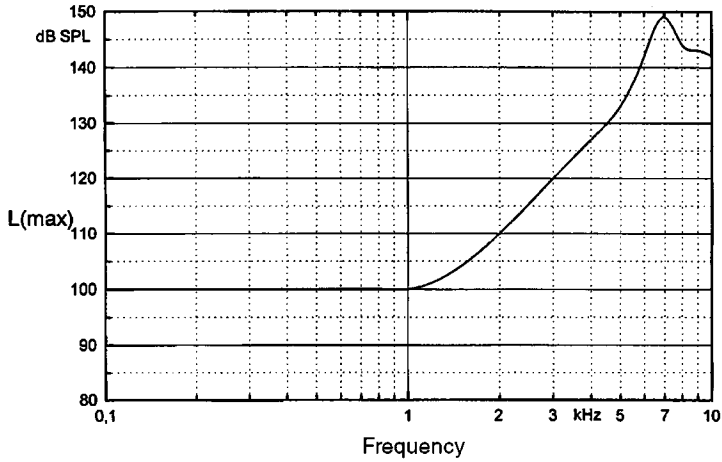
displacement amplitude increased by this factor, reaching about  $1.5 \mu\text{m}$  at 10 kHz. Up to about 1 kHz, displacement is equivalent to a sound pressure level (SPL) of about 100 dB. In the higher frequency range, the unique constancy of the output displacement results in a considerable increase in equivalent SPL. Explanation is the physiologic displacement amplitude drop of the oval window membrane above 1 kHz if the middle ear is driven by sound. Sound possesses a low output impedance.

By contrast, because of its high output impedance, the vibratory action of the implant should partly overcome the amplitude drop of the footplate. Based on these assumptions the equivalent SPL is calculated to be 128 dB at 5 kHz. At the resonance frequency the calculated maximum value lies above 160 dB equivalent SPL (Fig. 3).

Further investigations simulated the situation under the mechanical load of middle and inner ear after implantation (Figs. 4, 5). As expected, because of the greater mass being moved, the resonance frequency decreased to 7.25 kHz. Displacement, however, does not drop off dramatically. Except for the resonance frequency, the displacement of 60 nm remains the same. The Q-factor of the first resonance (corresponding to 25 dB) decreases only slightly when compared with the idle mode (about 28 dB). Thus, with load, displacement amplitudes in the range of  $1 \mu\text{m}$  are reached at frequencies around 7 kHz. The influence of encapsulating the coupling components *in vivo* (e.g., by connective tissue) was also simulated *in vitro* (Fig. 5). As expected, simulation of a mechanical frictional resistance influenced only the vicinity of the resonance.

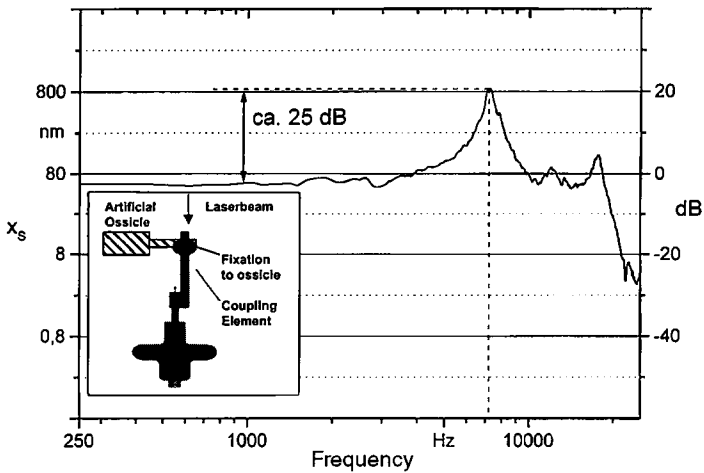
## Distortions

Low nonlinear distortions (harmonic distortion), unwanted resonances, and a minimal ripple displacement of the frequency response are important in producing a high-quality transfer, especially for speech and musical signals. The frequency response described previously was characterized by a flat curve with a small ripple

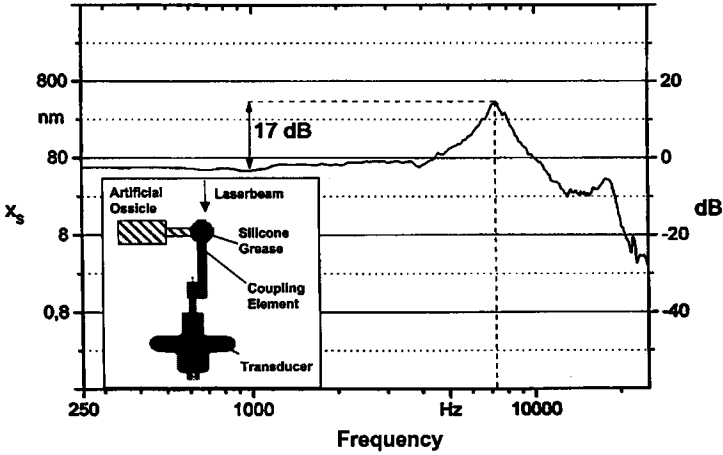


**Figure 3.** Estimated equivalent sound pressure level. Equivalent sound pressure level (SPL) was estimated for the actuator at maximum driving voltage (1.0 V<sub>RMS</sub>).

indicating linear distortions below 2.5 dB with a TH distortim (THD) of 0.1% or less. Similar results were obtained for nonlinear harmonic distortions (Fig. 6) during maximum signal levels at 500 Hz to 4000 Hz. At very low stimulus frequencies (160 Hz), the harmonic distortion factor was as low as THD 0.05%. Achieving low harmonic distortions is important because nonlinear distortions may create problems for electromagnetic transducers (e.g., in conventional hearing aids) when operating at high output levels.



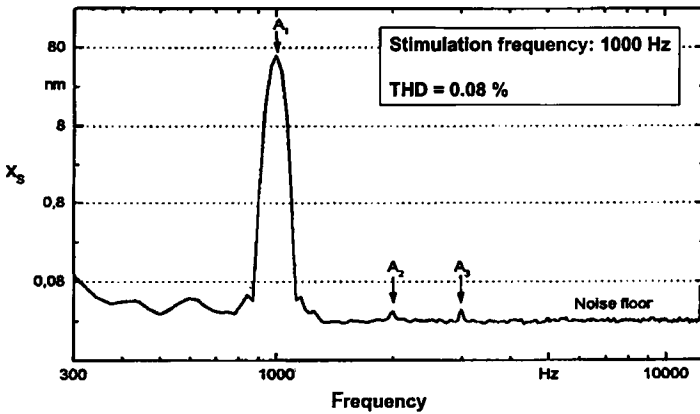
**Figure 4.** Actuator displacement under load. Displacement ( $X_s$ ) versus frequency in a simulated middle ear coupling condition. The insert shows the invitro coupling condition using an artificial ossicle made of stiff Silastic.



**Figure 5.** Actuator displacement in the presence of load and friction. Displacement ( $X_s$ ) versus frequency in the same coupling condition as shown in Figure 3. In this case the influence of possible tissue growth around the coupling area to the ossicles was simulated by using a little drop of silicone grease (insert).

**Dynamic Behavior**

Apart from a large, spectral bandwidth with low resonance and minimal non-linear distortion, the dynamics (i.e., the velocity of changes in frequency and amplitude) in the time domain of an implantable hearing aid transducer is of paramount importance for the transfer quality. Specifically, speech recognition and music involve the recognition of certain learned patterns of the signal envelope among which the onset phases are important. Signal dynamics are also relevant when the



**Figure 6.** Nonlinear distortion of the actuator. Experiments were performed using contactless laser doppler vibrometry in the in vitro simulation corresponding to Figure 3. The transducer was driven with a sinusoidal voltage at 1000 Hz and 1.0  $V_{RMS}$ .



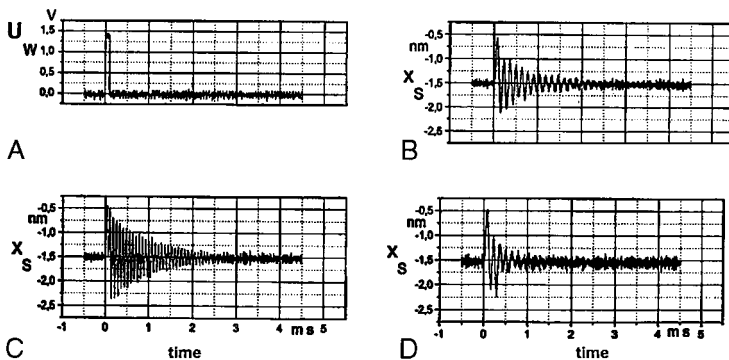
envelope of a speech signal changes drastically within an extremely short period of time (e.g., with plosives). In Figure 7, the transducer reaches a displacement amplitude value of about 80 nm extremely quickly (in less than 50  $\mu\text{s}$ ) and then vibrates to its resonance frequency. When the stimulation impulse (see Fig. 19A) stops, after about 3 ms, the displacement envelope subsides totally. Under load, the transducer also reaches the maximum amplitude very swiftly (in about 50  $\mu\text{s}$ ). Release time is below 1 ms. The results suggest that the transducer has short onset times and a decay behavior that lies within the range of the minimal time resolution capacity of healthy ears.

### Sensor Transfer Function

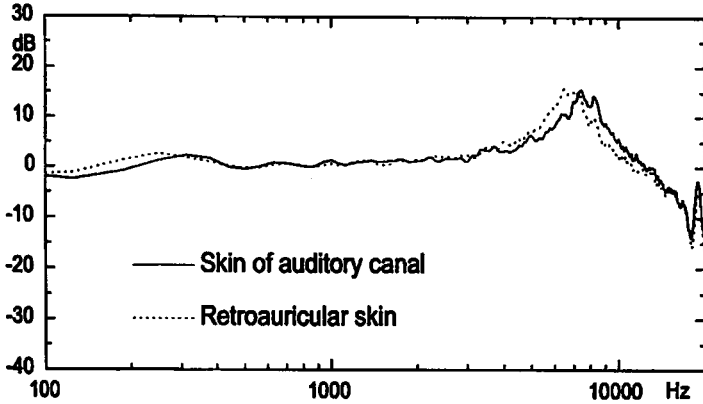
Experiments both in the idle mode and with skin and fascia coverings were carried out (Fig. 8). The idle mode transfer function is virtually frequency-independent in the total frequency range up to 8 kHz and shows a minor ripple (linear distortion) of only about  $\pm 2.5$  dB. The results suggest the highly tuned system with improved transfer function at high frequency, an advantage for patients with high-frequency SNHL. Furthermore, the first resonance frequency lies at the upper end of the transmission range. The system is governed by the stiffness of the titanium membrane below the resonance, indicating that an additional skin mass load reduces the resonance frequency but does not affect the absolute transfer function value and thus does not affect the sensor sensitivity below the resonance. This hypothesis was confirmed by laser doppler vibrometry (LDV) measurements carried out with a coating of fascia, 0.5 mm of human auditory canal skin, and 1 mm of human full skin. As expected, the resonance frequency shifted down by about 1 kHz with a full skin coating. The sensitivity and the smoothness of the response below the resonance remained the same, however.<sup>23</sup>

### Spatial Hearing

Directionality of the implanted sensor was measured using a KEMAR head. Figure 9 shows results similar to those obtained with a 2-cm<sup>2</sup> coupler,



**Figure 7.** Temporal resolution of the actuator. A, Actuator driven with an electrical unipolar pulse of 100  $\mu\text{s}$  of 1.4  $V_{\text{peak}}$ . Impulse response was measured using laser doppler vibrometry. B, Transducer response in a mechanical no load condition (compare with Figure 2). C, Impulse response corresponding to the mechanical load simulation of Figure 3. D, Impulse response corresponding to the load condition as in Figure 4.

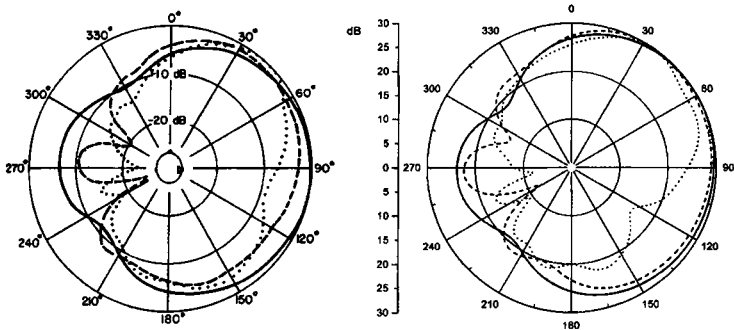


**Figure 8.** Frequency response of the sensor with the membrane covered by skin. Experiments were performed in an acoustic free-field condition.

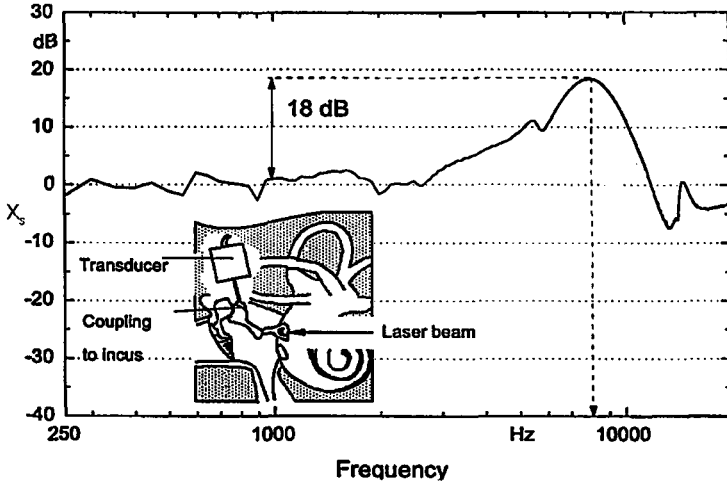
indicating that the sensor benefits from the unique acoustic properties of the external ear.<sup>25</sup>

**TEMPORAL BONE STUDIES**

Figure 10 shows the transducer coupling rod fixed to the incus body in a fresh human cadaver. Using an intracochlear approach LDV was carried out with the laser beam aiming at the center of the stapes footplate. As in the in vitro simulation (see Figs. 2, 4, 5) the first resonance frequency was at 8 kHz. Below this resonance, the frequency response is smooth down to the lower frequencies, with a maximal ripple of  $\pm 2.5$  dB. Thus, the transfer function of the actuator coupled to the ossicular chain is more or less unchanged in the footplate. Because of the high tuning of the actuator, a significant middle and high frequency increase in the equivalent SPL is also achieved. Up to about 1 kHz, the equivalent SPL  $L_{max}$  is about 100 dB



**Figure 9.** Directional characteristic of the sensor. Sensor was positioned in an artificial ear canal of a KEMAR head (right). Directional characteristic of the KEMAR® head using a standard 2 cm coupler (left). Frequencies: line = 1 kHz; dashed line = 2 kHz; dotted line = 4 kHz. Measurements were done in an anechoic chamber in free-field conditions.



**Figure 10.** Stapes displacement. Qualitative frequency response of the stapes displacement ( $X_s$ ) in a fresh temporal bone with transducer coupling to the incus body. The displacement measurement was done using a contactless laser doppler vibrometer centered on the stapes footplate through an intracochlear access from the cranial side.

SPL. Above 1 kHz, the value increases and at 4 kHz reaches approximately 125 dB. In the resonance range of 7 kHz, values reach 150 dB SPL, and at 10 kHz the equivalent SPL still reaches more than 140 dB. This range of output level and the spectral transmission bandwidth are within the parameters required for adequate treatment of moderate to severe sensorineural hearing losses.

Figure 11 shows a fresh temporal bone after implantation of the sensor. Subsequently, the meatal skinflap was laid back and soaked with Ringer's solution. The resulting frequency response ( $L_{mic}(f)$ ) of the implanted microphone in an unechoic chamber (Fig. 12) was strikingly similar to the in vitro transfer function (see Fig. 8).

## ANIMAL STUDIES

Plinkert et al<sup>32</sup> and Weber<sup>47</sup> performed acute and chronic studies in cats and dogs. In cats after preoperative (acoustic) determination of the auditory brainstem response threshold, the middle ear was opened and the piezoelectric transducer was coupled to ossicles or perilymph. Auditory brainstem responses (ABRs) were recorded following stimulation at the malleus, long in-process, stapes head, stapes footplate, or in the vestibulum. There was good correlation between the acoustically and mechanically evoked thresholds, including latencies. An electrical transducer voltage of 1  $V_{RMS}$  produced responses equivalent to sound pressure levels of 100 to 128 dB SPL at the tympanic membrane.

Chronic implantations of actuator and sensor were performed in 22 dogs,<sup>47</sup> and their performance was followed for 6 months after surgery. Hearing threshold was monitored using ABR procedures under anesthesia. Posttrial histologic studies of the inner ears did not show adverse effects caused by the chronic long-term stimulation induced by the electromechanical transducers.

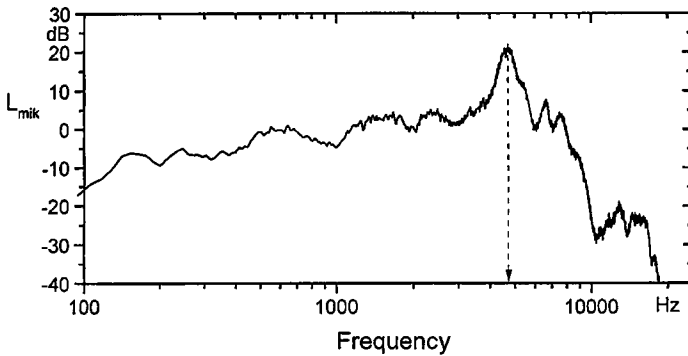


**Figure 11.** Sensor implanted in a fresh temporal bone. This situation was used for determination of acoustic free-field frequency response in Figure 12.

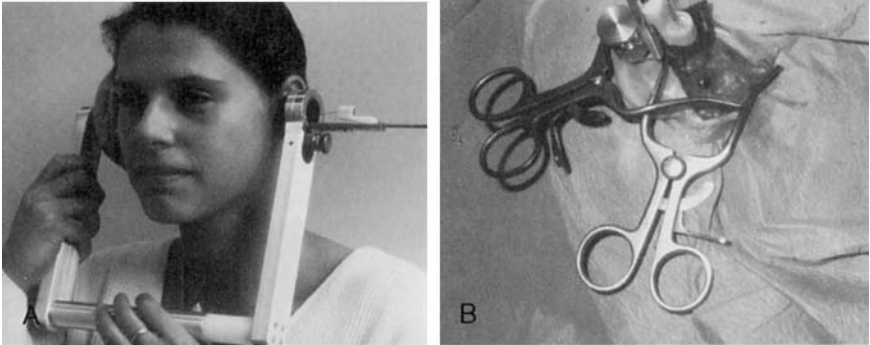
## ACUTE CLINICAL STUDIES

### Studies in Volunteers with Normal Hearing

Transducers were inserted into EACs of individuals with normal hearing (Fig. 13). For this purpose, a manipulator was fixed to a head holder. With the manipulator the transducer coupling rod was attached to the malleus in the intact ear drum. Then music from a compact disk (CD) was played. Initially, the high-frequency range was too high, an effect which could be attributed to the first mechanical resonance frequency as being around 10 kHz. This effect could be reduced



**Figure 12.** Acoustic free-field frequency response of the sensor. Sensor was implanted in a fresh temporal bone (see Fig. 11).  $L_{mik} = 0$  dB corresponds to a sensor sensitivity of 3 m V/Pa.



**Figure 13.** Human studies. A, Phase I study. B, Acute study during tympanoplasty.

with a low-pass limitation of 8 kHz; the resulting sound quality could then no longer be distinguished from the free-field presentation of the CD.<sup>33</sup>

### Studies in Patients with Hearing Loss

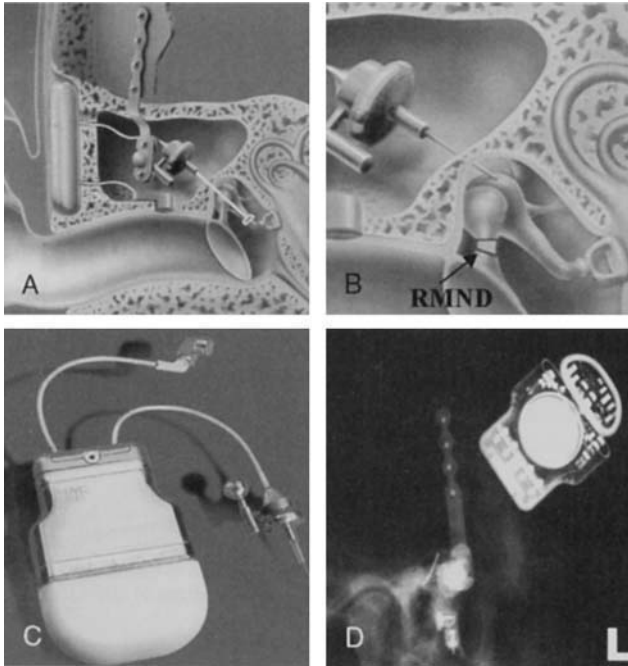
In routine tympanoplasties, actuators were acutely coupled to the ossicular chain of 28 patients (Fig. 13). In five patients a sensor was implanted together with the actuator beneath the skin of the EAC, allowing the skin to cover the microphone membrane completely.<sup>53</sup> Pure-tone thresholds in a broad frequency range (250 Hz–8 kHz) and presentation of music allowed psychoacoustic evaluation of the transfer properties. The piezoelectric transducer reached an equivalent SPL of 145 dB up to 10 kHz. Dynamics reached 32 dB, similar to preoperative controls using high-fidelity headsets (33 dB). Eighty-four percent of the patients involved gave a positive evaluation of the sound quality. Using the sensor all patients could hear with the system. When speech and music were presented under free-field conditions (65 dB SPL), understanding of the phonetically balanced speech material was 100%. Presentations of music were judged as “clear and undistorted with all broadband components.” One patient declared the music to be “slightly unnatural.”

### CLINICAL EXPERIENCE

Since 1998 the TICA version LZ 3001 has been in use in Europe.<sup>55</sup> It is approved (CE certification) for routine surgery of moderate to severe high-frequency SNHL.

### The Clinical Implant

The TICA LZ 3001 consists of three implantable modules (Fig. 14): piezoelectric actuator with broadband transmission and low energy consumption, an implantable membrane sensor, and the processor module that includes an implantable



**Figure 14.** Clinical TICA implant according to Leysieffer-Zenner. *A*, Coupling to long incus process. *B*, Coupling to incus body and optional reversible malleus neck dissection (reversible malleus neck dissection (RMND), Fig. 16). *C*, Implant with actuator (right), sensor (top) and main module (includes battery and microprocessor). *D*, Radiograph of TICA implanted in a patient.

battery and an implantable, digitally programmable, three-channel audioprocessor. The transducer, placed in the mastoid cavity, is coupled to the incus, and the sensor is implanted subcutaneously in the posterior bony wall of the auditory canal. The processor module is implanted subcutaneously behind the ear in a recess created in the squamosal portion of the temporal bone. Suitable titanium coupling elements transfer the mechanical oscillation to the incus.

#### *Effect of Total Implantation*

The purpose of total implantation is to help patients enjoy more freedom in everyday life (e.g., in taking a shower, walking in the rain, hearing the baby during the night). Sporting activities (swimming, diving, and so forth) are possible with the implant in use. As discussed earlier, total implantation may have a strong effect on professional life.

#### *Actuator*

The heteromorph, piezoelectric 0.4 g actuator (see Figs. 1, 14) is highly tuned with a resonance frequency in the range of 7 to 10 kHz, depending on the dynamic mass load.<sup>21</sup> Below this resonance and down to the low frequencies, the frequency response is flat, with a small ripple of less than  $\pm 1$  dB. Vibration amplitude at low

to middle frequencies is about 80 nm with a transducer voltage of 1 V. Nonlinear distortions at maximum volume (1 V) are small (THD < 0.1%) throughout the whole transfer range. Because of the short attack (< 50  $\mu$ s) and release time (approximately 1 ms), the dynamic properties of the transducer may contribute to clear transmission of audio signals with fast changes in the time domain (i.e., plosives in speech signals). Electric power consumption at full volume and broadband signals is in the region of 1  $\mu$ W.

### *Sensor*

The hermetically sealed implantable 0.4 g sensor (see Figs. 1, 14) possesses a sound-pressure transfer function that shows a small ripple.<sup>23</sup> Bandwidth is approximately 10 kHz. Because of its high tuning and high no-load resonance frequency, the sensor is remarkably insensitive to postsurgical changes of the loading mass on the microphone membrane caused by the skin's covering the auditory canal. The sound-pressure transfer factor at 1000 Hz is approximately 3 mV/Pa. Because of the reduced mass, the sensor is also insensitive to most environmental influences. Implantation of the sensor in the auditory canal allows the patient to take advantage of the directional functions of the outer ear and contributes to the suppression of background noise signals.<sup>3</sup>

### *Processor and Battery*

The processor module (Fig. 14) contains the signal-processing electronics and an integrated battery.<sup>25</sup> Basic audiologic features are provided by a flexible, digitally programmable three-channel system with an automatic gain control (AGC) with a peak-clipping function. Total bandwidth is around 10 kHz. Because of its limited lifetime, the battery must be changed after 3 to 5 years. Leaving the transducer and microphone in situ, the processor unit with the battery can be replaced during minor surgery under local anesthesia. This isolated replacement of the processor module is made possible by coimplanted plug connections. With technical progress, the battery lifetime will probably be prolonged from 5 years to 10 years.

### *Fixing the Actuator*

Conventional miniosteosynthesis plates (1-mm thick, 2-mm wide) were modified to create a fixing system for the actuator (see Fig. 1). The system should be placed above the mastoid cavity and should deviate no more than 30° (frontal or nuchal) from the 0° direction (cranial).<sup>20</sup>

### *Integrated Micromanipulator*

For safe manipulation of the actuator probe tip to the ossicular chain, a 0.7-g titanium micromanipulator was integrated between the fixing plate and actuator. The micromanipulator includes a ball-and-socket joint combined with a linear axis (see Fig. 1, 14). The ball is kept between the fixing plate and a clamp plate. In the resulting ball-and-socket joint, three rotational degrees of freedom can be effected with an Allen wrench. The linear axis is attached to the moveable ball. A sliding carriage can be conducted precisely along the linear axis. The actuator is elastically fixed to the sliding carriage. The sliding carriage can be positioned manually with a screwdriver. With the resulting four degrees of freedom, the manipulator allows highly secure and safe positioning of the transducer's probe tip to the ossicular chain under nearly stereotactic conditions.<sup>20</sup>

### *Coupling the Actuator to the Auditory System*

The intended sites for coupling the actuator to the auditory system include the long incus process or incus body, the head of the stapes when the incus is missing, and the perilymph when the stapes suprastructure is missing.

For coupling to the long incus process, several coupling elements have been developed.<sup>19</sup> The clinical version is a bendable titanium rod with an elastic titanium clip at its end (see Fig. 1). A ball-and-socket joint allows operation of the clip. A bell-shaped element is under development for coupling to the head of the stapes that was derived from the Tübingen titanium prosthesis (TTP) (Kurz, Dusslingen, Germany) for ossiculoplasty when the incus is missing. If the stapes suprastructure is missing, the coupling rod is inserted as an artificial long incus process through a posterior tympanotomy into the oval niche. After perforation of the footplate, a conventional piston prosthesis may be positioned as in stapedotomy and fixed to the coupling rod. Clinically, coupling to the stapes head and perilymph is not yet possible. For coupling to the incus body, two methods seem to be suitable. The microapplication of minute amounts of CE-approved surgical cement (e.g., Biocem) creates a firm connection between the coupling rod and the incus body. The rod can be also be led into a depression in the incus<sup>5, 18</sup> that is created with a laser (CO<sub>2</sub>, Erb:YAG, or KTP) (see Figs. 1, 14).

### *Biocompatibility and Biostability*

All TICA components are made of certified, biocompatible materials. Both transducer and sensor are sealed by welding and checked for hermetic gas tightness according to MIL STD 883 D. This technology corresponds to that used in modern pacemakers and cochlear implants. Corrosion effects are therefore not expected, even many years after implantation. Microphone and transducer are thus designed for lifelong use in the patient.

### *Resistance Against Environmental Influences Including MR Imaging and Roentgenograms*

The transducer weighs no more than 0.4 g and thus has a very low dynamic mass. This low mass makes it resistant to external mechanical influences such as vibrations and knocks. Because the transducer is made of pure titanium with a magnetic susceptibility of 1, no mechanical forces or torques are produced under the influence of large static magnetic fields. Thus, the device is insensitive to high magnetic fields arising in modern MR tomographs. Computed tomography (CT) scans and radiographs are possible (Fig. 14D). Impairment in the piezoceramic electromechanical activity can be expected only in the presence of high temperatures or excess mechanical strain. Because the transducer is run at a constant, and, for this material, low temperature (body temperature), without any extreme strain being imposed, no reduction of the electromechanical transduction factor and thus loss of the equivalent output level is foreseen, even after 10 years. There is likewise little risk of electrical depolarization, because the transducer is used with a maximum signal voltage of 1 to 2 V only at electrical field strengths that are well below the depolarizing maximum field strength. Because the transducer does not contain active electronic components, any risks arising through external electromagnetic influences can be almost completely ruled out. The piezoceramic is insensitive to electrostatic discharge because of its capacitive behavior, so a danger potential during implantation (contact with the electrical connection poles in the conductor) can also be ruled out.



The transducer has an inner volume that is hermetically sealed by a metal membrane and is gas-filled. Air pressure variations in the mastoid cavity can lead to a displacement of the casing membrane. With measuring techniques that take into consideration the construction, the thickness of the membrane, and the material used, it was demonstrated that the displacement of the membrane held within a 1- $\mu\text{m}$  range at external pressure changes equivalent to a depth of 5 m in water as well as up to about 4000 m above sea level. Thus, a risk for either the piezoceramic material and the mechanically coupled inner ear can be ruled out.

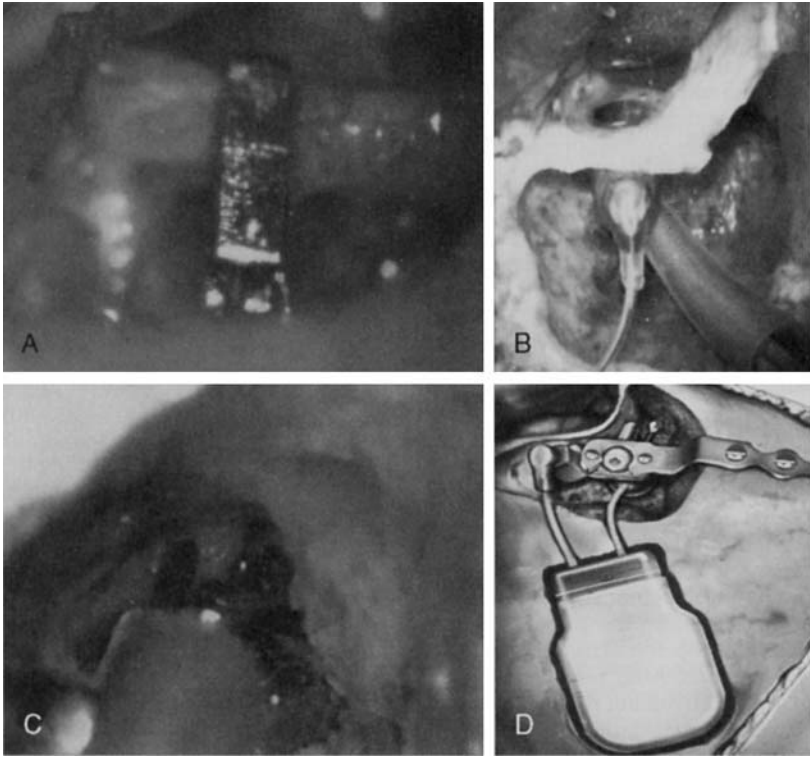
### Implantation Technique

The TICA is implanted through a retroauric approach. Starting 1 cm above the tip of the mastoid a basally stemmed retroauric C-shaped skin flap is created avoiding the processor module to be positioned directly beneath a skin suture (see Fig. 2). Subsequently, an apically based periosteal flap is formed. Mastoidectomy is performed in the usual manner. For incus coupling, the surgeon has two options: coupling to the long incus process or coupling to the incus body. For coupling to the long incus process, a typical posterior tympanotomy with or without preparation of the facial nerve is required. Then, a bony recess is created in the squamosal portion of the temporal bone behind the ear, leaving the tabula interna intact. In addition, a trepanation is created in the posterior wall of the bony external auditory canal, allowing the subcutaneous insertion of the sensor membrane (Fig. 15B).

When placing the actuator in the mastoid, the surgeon uses the positioning system to keep the actuator away from the incus, thus minimizing risk for the ossicular chain. After screwing the fixing plate to the skull, the actuator module is firmly fixed. By using the integrated positioning system, however, the transducer itself can be manipulated precisely. To couple the transducer to the long incus process (Fig. 15), the clip is maneuvered into a position just over the long incus. Holding the incus with a 90° needle the surgeon affixes the clip to the long incus process. To couple to the incus body (Fig. 15) a conical indentation of approximately 0.5 × 0.5 mm is created in the incus body. Using the positioning system, the surgeon slowly inserts the transducer until the conical tip of the coupling rod fits into the newly prepared conical hole in the incus. Forward movement of the coupling rod is halted when a slight movement of the incus is seen that results in a pretension of the ossicular chain. A drop of liquid ionomeric cement is recommended to secure the coupling.

Finally, the electronic module is introduced into the bony recess in the squamosal portion of the temporal bone (Fig. 15) and fixed by surgical suture as in a routine CI procedure. The leads from transducer and sensor are then connected with the electronic module by plug connections (see Fig. 1).

To optimize the micromechanical inner ear stimulation by an active vibratory hearing implant (i.e., the TICA) coupled to the ossicular chain, a reversible malleus neck dissection (RMND) offers a microsurgical option (Zenner et al, unpublished data). In selected patients RMND may result in significantly increased loudness because sound energy is no longer lost through the ear drum (an intact ossicular chain, when vibrating, will also vibrate the ear drum). Instead, energy may be focused to the inner ear. Reversible malleus neck dissection may also effectively suppress unwanted feedback. The RMND procedure is reversible, because the resulting interruption may easily be reconstructed at any time using a specifically shaped piece of bone or ceramic material or by using bone cement. Usually RMND is performed as a secondary procedure (i.e., weeks or months after primary surgery). It involves the creation of a tympanomeatal flap, followed by cutting of the malleus neck near

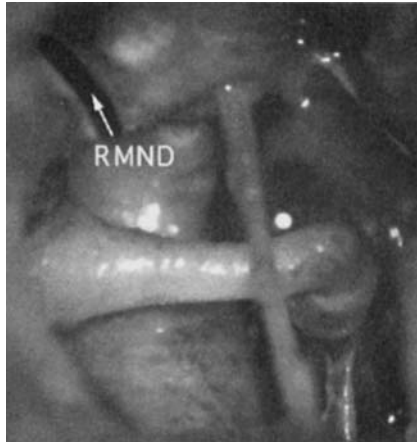


**Figure 15.** Surgical procedure. *A*, Coupling to the long incus process. *B*, Insertion of membrane sensor. *C*, Coupling to incus body. *D*, Final view of implant coupled to incus body.

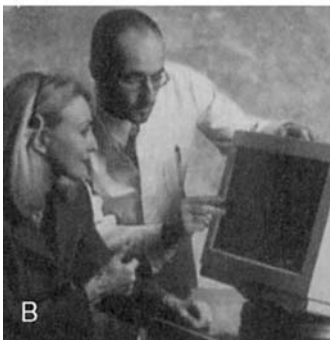
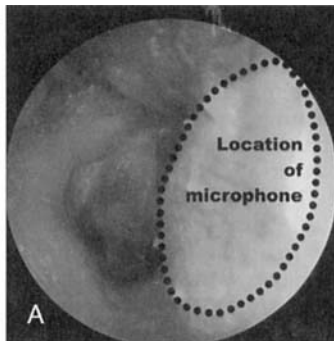
the malleus head using a laser (Erb:YAG, CO<sub>2</sub>, or KTP) or a cutting instrument (Fig. 16). Subsequently, 1 to 1.5 mm of bone from the malleus handle is resected, followed by relocation of the tympanomeatal flap.

### Handling by the Patient

A wireless, inductive remote control (Fig. 17) allowing a selection of four programs, volume adjustment, and the possibility of switching the device on and off gives the patient a number of options.<sup>25</sup> The battery in the processor unit is an accumulator cell that can be recharged inductively through a transmission coil transcutaneously using a portable recharging unit. For a running time of 50 hours, recharging for approximately 2 hours is necessary. The time course is not fixed. A patient who uses the implant can decide when and for how long to recharge the battery and can plan the day accordingly (most patients recharge 45 minutes daily while watching television). Internal safety features prevent the individual recharging process from leading to overcharging or to acute depletion of the implanted accumulator cell. During the recharging process, the patient can still hear with the TICA system.



**Figure 16.** Reversible malleus neck dissection (RMND). May be performed using a CO<sub>2</sub> laser (Sharplan, Tel Aviv, Israel). RMND may be restored using a drop of liquid cement (*From Zenner et al, 2000; with permission*).



**Figure 17.** Postoperative care. *A*, Microscopy of external auditory canal. *B*, Telemetrical fitting of the implant using a PC-based adjustment software. *C*, Wireless, battery-driven remote control for the patient.

## Audiologic Fitting

Fitting of the implanted, digitally programmable, three-channel audioprocessor to the individual impairment of the inner ear by the audiologist is performed by means of the same inductive, transcutaneous data interface used for the remote control (Fig. 17). Data are transmitted through the intact skin to a receiving coil in the implanted processor unit. The interface is connected to a personal computer. Fitting starts no earlier than 8 weeks after implantation, and several sittings are usually required for fine tuning. Before surgery patients must be informed that weeks or months may be required before they adjust to the new pattern of sound and learn new recognition cues. The TICA system allows repeated programming to accommodate hearing alterations that may arise later (e.g., a need for greater functional gain required by a progressive hearing impairment).

## Clinical Study Results

In a controlled prospective clinical study the TICA version LZ 3001 was totally implanted in 20 patients with moderate to severe SNHL (Zenner et al, unpublished data).<sup>56</sup> All patients had suffered from chronic bilateral moderate to severe SNHL and had not benefited from hearing aids. Nineteen patients were per-protocol (PP) patients after a 6-month follow-up. In selected patients binaural pure-tone hearing threshold levels (HTL) in the free-sound field revealed maximum functional gains of 40 dB at 2 kHz, 50 dB at 3 kHz, and 55 dB at 4 kHz (Fig. 18). For daily use, however, the TICA implants were adjusted to the most comfortable loudness levels (MCLs) using categorical loudness scaling. Thus, median functional gain was lower. Median functional gains at 2000 to 4000 Hz were to 20 dB with an upper interquartile limit of 30 dB at 3 kHz. In a subgroup of 17 patients for whom preoperative loudness scaling was available, pre- and postoperative comparisons were performed. In 14 patients the desired shift in the characteristic loudness curves could be seen in the frequencies involved in conversational speech (between 1000 and 4000 Hz). The gain was most obvious at 3150 Hz, at which frequency a normalization could be observed in 12 patients (71%).

Median HTLs from 1.5 to 4 kHz that did not fall into the long-term speech spectrum (LTSS) when the implant was switched off all tallied with the LTSS of normal conversational speech after the TICA was turned on. The resulting articulation index (AI) that establishes a patient's speech energy revealed a statistically significant increase (Wilcoxon,  $P \leq 0.05$ ) from 14% (median +17%, -12%) with the implant off to 32% (median +16%, -16%) with the implant switched on.

Using Freiburg phonetically balanced monosyllables (Fig. 18B) a statistically significant increase (Wilcoxon,  $P \leq 0.05$ ) of the average word recognition score (WRS) from 42% (median +27, -12) to 72% (median +19, -14%) was observed. Eighteen patients (95%) showed improvements of the SPL of the best preoperative WRS ( $\text{dB}_{\text{opt}}$ ). In 11 patients (58%)  $\text{dB}_{\text{opt}}$  had the ideal level of 65 dB. Of the 16 patients who had suffered from a preoperative speech discrimination loss (with a median value of  $20\% \pm 10\%$ ), 14 (88%) showed an improved ability to discriminate monosyllables at the end of the study. Eleven patients (69%) with a preoperative discrimination loss reached a word recognition ability of 100% after the operation. When investigating conversational speech from the front in the Göttingen sentence test, 10 patients (56%) exhibited a 100% sentence recognition in quiet at a signal level of 65 dB, rising to 14 patients (78%) at a SPL of 75 dB. In the presence of noise from the front 13 patients (72%) reached sentence recognition thresholds (50% correct) at signal-to-noise ratios between -2 dB and +1 dB. A 90°

spatial separation of the speech signal from the noise (with the noise directed to the unaided ear) resulted in a significant increase (Wilcoxon,  $P \leq 0.05$ ) of sentence recognition from 50% (median +13, -23) to 86% (median +10, -13). The results indicate that in these patients a speech intelligibility adequate for rehabilitation was achieved.

Of further interest was the determination of directional hearing ability in a low-reflection room (Fig. 18C). Perfect spatial orientation in the room was possible in 89.5% of the tasks (persons with normal hearing reached 99.8%). Almost all the errors occurred in discriminating front from back. Close inspection revealed that faults occurred mainly on the contralateral (unaided) side, whereas the ear aided by TICA made mistakes in only 3% of the cases.

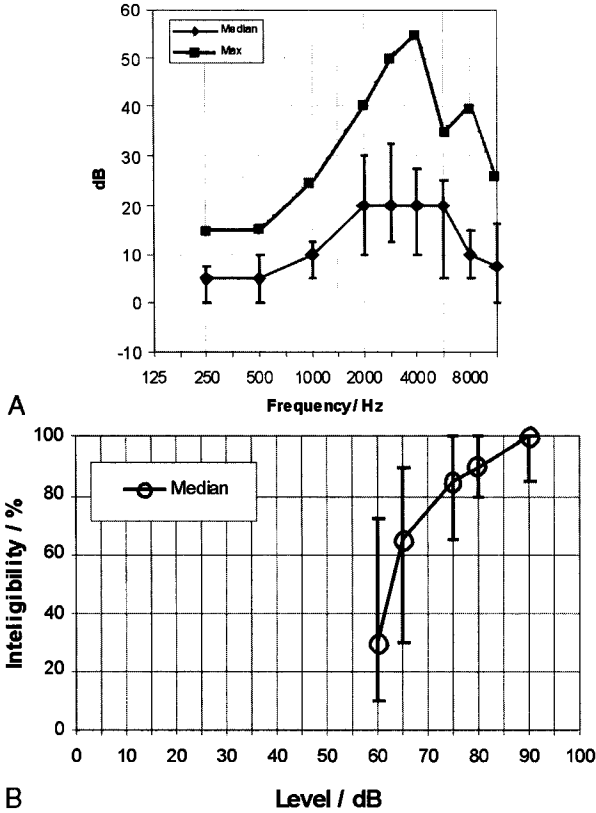
Visual analog scales (VASs) revealed a median sound quality (i.e., spectrum, pitch) that improved from a median of 70% (-40%, +30%) preoperatively to an optimum of 100% (+0%, -20%) postoperatively. The clarity (absence of distortion) of the sound perception improved from a median of 60% (-35%, +30%) preoperatively to a remarkable median value of 95% (+5%, -10%) postoperatively. The subjective loudness impression was described postoperatively as normal in 62% of patients, as too low in 22%, and as too loud in 16%. In the standardized Gothenburg profile (Fig. 18D), patients reached average values of 80% to 88% (preoperative values were 52%-60%) of the maximal scores possible for comprehension, localization, social communication, and self-confidence. Thus the reduction of impairment in social relationships and self-confidence are as great as the gain in speech comprehension and directional hearing. This statistically significant result (Wilcoxon,  $P \leq 0.05$ ) is remarkable and is unlike the results in patients who have been supplied with conventional hearing aids. Social retreat may be halted, and the quality of life seems to have risen to a large degree. Interestingly, the average daily use of the TICA, amounting to  $15.5 \pm 3.4$  hours in the per-protocol patients, clearly exceeds the 5 to 6 hours that patients use conventional hearing aids, arguing for the efficacy of the TICA.

### Adverse Effects

Adverse effects caused by the implant occurred but were minimal. These effects were correctable scar formation in the auditory canal, postoperative seroma, temporary threshold shift of bone conduction, reinstatable interruption of the incudo-stapedial joint, and cases of partial skin necrosis above the microphone membrane that could be treated with fascia. Complications, either moderate, severe (such as permanent threshold shift or facial paralysis), life-threatening, or fatal, brought about by implant or surgery did not occur. Termination of the therapy because of safety or tolerance problems was not necessary. Any adverse effect measured against the benefit for the patient could be justified and did not affect the protection of the patients' health and safety.

### STUDY SUMMARY

The study demonstrated the clinical efficacy of the totally implantable TICA in most of the patients treated, none of whom had benefitted from conventional hearing aids. The study showed efficient transmission of the signal emitted by the TICA to the middle ear ossicles right up to the cochlea in most, but not all, patients. Further clinical experience and better understanding of the best way to couple



**Figure 18.** Results of prospective clinical study (n = 20). *A*, Functional gain (difference of postoperative unaided and aided binaural free-field thresholds) with TICA programmed for a most comfortable setting (n = 19 patients). Thin line = median values and interquartile ranges; Thick line = maximum functional gain. *B*, Six months' postoperative speech discrimination results using a monosyllabic test (Freiburg test), n = 19 patients, median values and interquartile ranges.

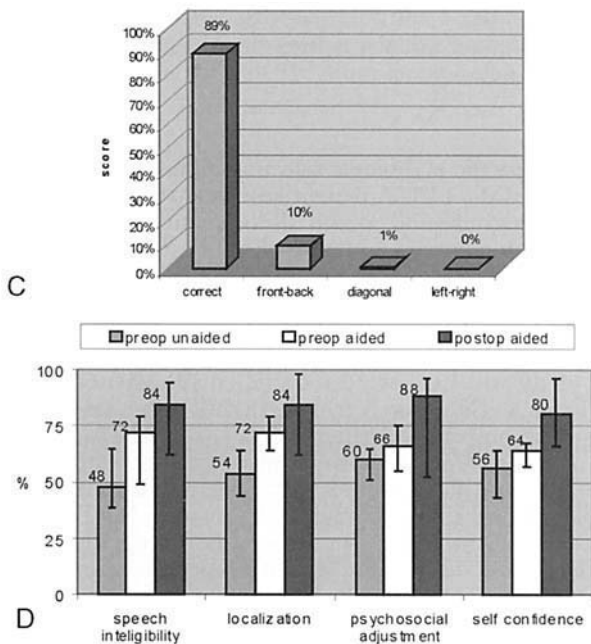
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an implant to the auditory system are needed to improve the overall success rate and specifically to improve the percentage of patients achieving hearing at normal volume.

**PATIENT SELECTION**

**Lack of Benefit from Conventional Hearing Aids**

Patients who benefit from conventional hearing aids do not need a hearing amplifier implant. There are, however, hearing-impaired patients whom hearing aids do not help. A recent investigation (Table 1) of patients possessing hearing aids showed underlying problems such as pressure-induced skin lesions, skin



**Figure 18 (Continued).** C, Spatial hearing: left column shows correct answers, right 3 columns show errors. D, Quality of life evaluation (Gothenburg profile) for the preoperative unaided, preoperative aided (conventional hearing aids) and postoperative aided (TICA) condition.

inflammations, feedback, strong background noise, uncomfortable loudness levels, insufficient amplification, low speech comprehension, too frequent use of remote controls, or hearing aid defects.<sup>45</sup> Furthermore, a study was performed in which hearing aid nonusers underwent fittings of high-performance hearing aids. Audiometry and structured interviews allowed investigators to collect data as to

**Table 1.** FREQUENCY OF PROBLEMS WITH HEARING AIDS

Problem	Percentage Encountering Problem		
	Very Often	Seldom	Rare
pressure-induced skin lesions	6	22	28
skin inflammation	6	10	9
feedback	15	34	26
strong background noise	34	32	17
uncomfortably loud	16	26	24
too quiet	12	29	24
low speech comprehension	13	25	24
too frequent use of remote control	15	20	25
difficult handling	8	5	12
device defects	5	17	31

Data From Test Z, Leserumfrage. 12:88-91, 1999.

why some of these patients could not benefit from fitting a hearing aid (unpublished data). Results are summarized later.

### Audiologic Criteria

To determine specific audiologic selection criteria, a prospective clinical investigation compared three TICA patient groups (A, B, and C) (Table 2) based on their pure-tone audiograms and speech discrimination scores. The audiologic assessment tests included speech audiometry (monosyllables) as primary efficacy variables and sentence recognition, pure-tone audiometry, functional gain, articulation index, auditory orientation, and subjective evaluation using standardized questionnaires and visual analog scales as secondary efficacy variables (Fig. 19).

In group A the main efficacy variables revealed more than 90% median word recognition at 65 dB and 100% word recognition at higher SPLs. When the  $dB_{opt}$  was shifted to lower levels, group A achieved a shift to the speech SPL of 65 dB in all cases. In all groups a previous discrimination loss could be completely eliminated. Average WRS of groups A and B showed a median increase from 42% (+27, -12%) to 93.5% (+3, -5%) and to 92.5% (+3, -7%) respectively. Among the secondary efficacy variables, almost all the standardized sentences were understood in quiet. In the presence of background noise, the sentence-recognition threshold ranged from -2 to 1 dB signal-to-noise ratio. Maximal functional gain was 55 dB at 3 kHz. The articulation index doubled. In the horizontal plane, directions were localized correctly by 89.5% of patients. In groups A and B, visual analog scales revealed maximum scores of 100% for both natural sound impression and clarity. Before surgery sound impression had reached no more than 70% and clarity no more than 62.5% (group A) or 70% (group B) of the maximal rating. With the standardized Gothenburg profile subjective evaluation of hearing, orientation, social behavior, and self-confidence, group A reached values of 96% to 98%, group B reached 92% to 96%, and group C reached 84% to 92% of the maximum score. The results suggested that the preoperative audiometric pure-tone parameter of group A could be used as a patient selection criterion.

### Imaging Criteria

Implantation of a TICA requires a minimum mastoid volume. Thus, using conventional radiographs and CT scans, the authors analyzed 50 cadaver specimens of the temporal bone before total mastoidectomy. After total mastoidectomy, the volume of the mastoid cavity was measured using CT scans and water volume determination. Finally, the TICA device was implanted into those temporal bones

**Table 2. PATIENT GROUPS**

Group Designation	Group Characteristics
A	High-frequency SNHL, maximum low-frequency HL 30 dB at 0.5 kHz. 30 dB difference between 0.5 kHz and 2 kHz.
B	Minimum of 10% word recognition at 60 dB. Maximum discrimination loss of 30%.
C	Word recognition at 60 dB plus word recognition at $dB_{opt}$ result in a minimum value of 90%.

SNHL = sensorineural hearing loss; HL = hearing level.



that were large enough to house it. The results demonstrated that the degree of pneumatization in the conventional Schuller's radiograph was a reliable parameter for preoperative evaluation.<sup>28</sup> For TICA implantation, normal pneumatization is required.

## Summary

A TICA implantation may be indicated when a patient fulfills three selection criteria: lack of benefit from conventional hearing aids, moderate to severe high-frequency SNHL, and adequate space in the mastoid for implantation.

### *Lack of Benefit from Conventional Hearing Aids*

Medical and psychosocial problems include

- Intolerance of the occlusion of the auditory canal by the ear-fitting device
- Ear-mold-induced repeated inflammation and pressure-induced skin lesions of the external auditory canal
- Manual motor impairment (e.g., from tremor or paralysis) making the daily use of tiny hearing aids or the use of tiny elements impossible
- Discrimination resulting from use of a visible hearing aid

Auditory problems include

- Intolerable feedback
- Distortion, low speech comprehension, strong amplification of background noise
- Reduced ability to communicate in the presence of background noise (party effect)
- Steep slope of hearing loss

Professional problems can be experienced by

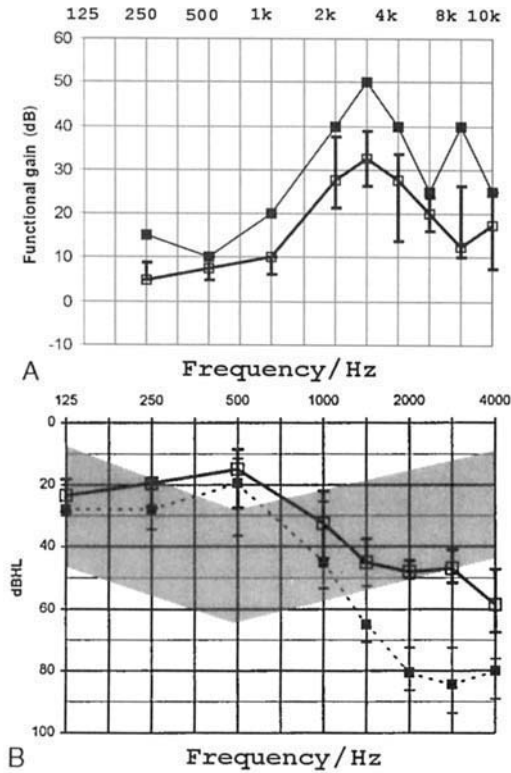
- Musicians
- Professional athletes, sports instructors
- Language professionals (translators, language teachers)
- Persons whose work requires the use of earphones or stethoscopes
- Persons whose professional activities require telephone use and who cannot conduct telephone conversations using a conventional hearing aid
- Persons whose activities are associated with heat, sweat production, fat production, steam production, or dust production that can result in loss or damage to conventional hearing aids.

### *Moderate to Severe High-frequency Sensorineural Hearing Loss*

Maximum high frequency hearing loss ( $\geq 3$  kHz) may be 90 dB (Fig. 20). Maximum low-frequency hearing loss should be no more than 30 dB at 0.5 kHz. In addition, the slope of hearing loss between 0.5 and 2 kHz should be 30 dB or more. The difference between the two ears should be no more than 20 dB (Zenner et al, unpublished data).

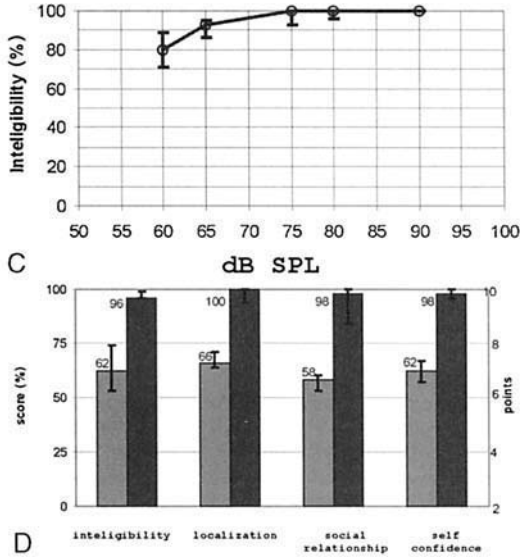
### *Schuller's Radiograph*

The Schuller's radiograph should display normal mastoid pneumatization.<sup>28</sup>

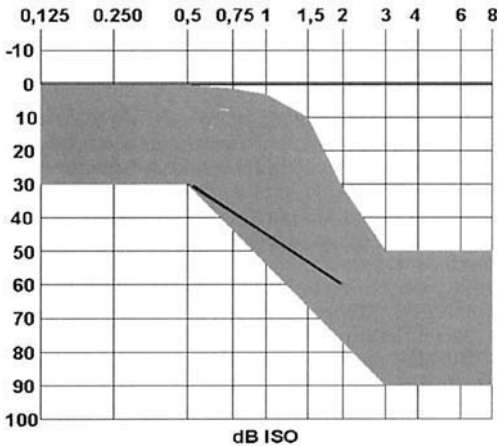


**Figure 19.** Results of patients selected according to the criteria in Figure 20. *A*, Functional gain (difference of postoperative unaided and aided binaural free-field thresholds) with TICA programmed for a most comfortable setting. Thick line = median values and interquartile ranges; thin line = maximum functional gain. *B*, Threshold transfer into long-term speech spectrum.

*Illustration continued on opposite page*



**Figure 19 (Continued).** C, Word recognition. D, Gothenburg profile before and after surgery.



**Figure 20.** Indications for TICA LZ 3001. Moderate to severe high frequency SNHL up to 90 dB at  $\geq 3$  kHz. Maximum low frequency hearing loss should be no more than 30 dB at 0.5 kHz. In addition, the slope of hearing loss between 0.5 and 2 kHz should be 30 dB and more. Missing benefits from conventional hearing aids include medical problems, psycho-social problems, audiological problems, professional problems. Mastoid with normal pneumatization.

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