BASIS FOR A NEW SEMI-IMPLANTABLE ELECTRO-MAGNETIC MIDDLE EAR HEARING AID

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Dedication:

This work is dedicated to my dear wife Cecilia Britt àWengen-Juhlin for her continuing support and encouragement as well as for her sobering criticism and perspective, and to our wonderful sons Raffael Anders and Linus Felix who constantly remind me of the priorities in life.

1. Introduction

1.1 Aim of this work

The aim of this work is to present the current state of research in the field of electronic middle ear implants. Furthermore, this work provides data on ongoing research in the development of a new electromagnetic middle ear implant. Several aspects of this implant, however, are yet unsolved and will be discussed.

This thesis presents the status of research and current developments including experimental work, new ideas and designs.

1.2 Structure of this work

The thesis is structured in two major parts. Chapters 1 to 3 are reviews and chapters 4 to 8 consist of original work. The section on the stapes superstructure (Ch.3.5.1.) is also original work.

After background information in chapter 1, chapter 2 discusses the history of implantable devices for hearing impairment. Middle ear anatomy and physiology (chapter 3) are essential for the development and concept of any implantable device. Research has led to new insight in the vibration mode and displacements as well as to precise measurements of physical properties of the ossicles.

Chapter 4 presents the concept of this semi-implantable hearing aid with its internal and external units. Attention is given to titanium screws for osseointegration because a percutaneous titanium screw is also proposed for this implant acting as an electrical plug to connect the external hearing aid with the implanted transducer. Chapter 5 summarizes basic research and experiments with this new transducer. The concept and further details on this implant are provided in chapter 6. Chapter 7 presents various designs for different pathologic conditions of the middle and inner ear in possible implants applying this new technology.

The thesis concludes with a discussion on aspects of this implantable device (chapter 8), implications for the future (chapter 9), and final conclusions (chapter 10).

Appendix I contains background information on the use of magnets in medicine, Appendix II supplies research on patents issued for implantable hearing devices, and Appendix III provides technical definitions for magnets.

1.3 Background information

The hearing impaired population is insufficiently served by conventional acoustic hearing aids. This is especially true for patients with moderate-to-severe and severe hearing impairment.

1.3.1 Hearing impairment

Hearing impairment is a limiting factor to the quality of life. Hearing impairment is considered the most common sensory deficit in the world today.[1] In the United States of America (USA) in 1989, the number of hearing impaired people was estimated to be 15 to 20 million or about 8% of the population. Most of these people have a mild, moderate or moderate-to-severe hearing loss. About 1.4% of the total population or 3 million suffer from severe and profound hearing loss. One third of these patients are deaf and for part of them the only treatment option would be a cochlear implant. The remaining one percent or 2.5 million severely hearing impaired patients are poorly served by acoustic hearing aids. Currently, they are forced to wear powerful hearing aids that help the most poorly impaired read lips better and the less impaired in this group hear what is most likely bad sound with disturbing amplification of background noise. Because of the enormous gain required, feedback is a constant problem. Cochlear implants are not a suitable alternative for the severely hearing impaired because the surgical procedure with insertion of the electrode into the cochlea might destroy the organ of Corti. Patients eligible for cochlear implants must have a profound hearing loss with no benefit from conventional hearing aids to qualify for this irreversible procedure.

Hearing impairment results in vocational and recreational limitations, social isolation, and inter- and intrapersonal frustrations.

1.3.2 Conventional hearing aids

Conventional hearing aids have been used for many decades. Advantages of these commercially available aids include ease of use, exchangeability and variability of programming. Disadvantages include cosmetic problems, acoustical feedback, sound distortion, insufficient signal-to-noise difference, and local infections of the external ear canal.

The evolution of modern hearing aid technology can be traced from carbon devices (1880) through the vacuum tube period (1920) to the early transistorized models (1952).[2] The first electronic hearing aids became possible with the development of the transistor and consisted primarily of a microphone, amplifier, and speaker. These initial devices left a lot to be desired in terms of sound quality and appearance. Hearing aids have been reduced in size. Most hearing aids are still

quite large and cosmetically unattractive due to the molds that must be worn in the ear canal.

Information on the distribution of conventional hearing aids is available from the USA, where nearly 80 percent of all hearing aids now purchased are of the custom in-the-ear (ITE) type.[3] In a recent survey in Germany, the rate of fitting of ITE aids ranked at only 20%.[4] Some hearing aids use digital technology and remote controls. Programmable hearing aids allow the user to choose among individually tailored listening strategies.[5],[6]

Early placement of conventional hearing aids is the single most important rehabilitative measure for the hearing impaired child. Traditional fitting protocols are applied because data used for individual fittings require verbal communication.[7]

In a survey of 18-year-old students with moderate to severe hearing impairment only 58 percent wore their hearing aid regularly.[8] As much as 39 percent were ashamed of wearing their hearing aid in public. Among the major negative factors were the degree of noise disturbance and problems with cerumen accumulation. A fourth of these young adults would prefer another type of hearing aid.

Switching between programs might be beneficial for some hearing aid users. In a model with eight programs users were found to choose primarily two programs: one for "spot-light" or directed listening, one for "broad" listening.[9] The concept of changing between directional listening for personal communication and wide field listening for ambient sound is also chosen for the Phonak PICS system that uses two different microphones in each side.[10] The directional microphones significantly reduce disturbing noise. Binaural hearing allows an improvement of speech reception thresholds of up to 6 dB.[11]

Other hearing aid users prefer a single best listening program that leaves them independent of a remote control which can be lost, misplaced or underpowered by low batteries.[12]

ReSound™ describes their sound processing called "multiband full dynamic range compression", where by amplification of bass and treble, sounds can be continuously and automatically adjusted and matched to the impaired patient's loudness profile.[13] This technology was developed at AT&T Bell laboratories.

In earlier years only one ear was fitted with a hearing aid. Modern hearing aid research stresses the benefits of binaural amplification.[14-20] Patients with symmetrical hearing loss aided binaurally report improvements in speech understanding ability, sound quality, spatial balance and localization.[21],[22] Unilateral hearing aid fitting in the severely hearing impaired might lead to auditory deprivation.[23],[24] Severely hearing impaired persons benefit from binaural amplification. However, speech perception in noisy environments might be better with a monaural fitting.[25]

Feedback has been a problem with electronic aids since the first one was built. Even with optimal molding of the earpiece, a complete and permanent seal often cannot be achieved. When eating or yawning the mold moves and permits annoying feedback. Feedback may also loop through the vent of the ear mold.[26] Feedback is the result of placing a microphone too close to a speaker or turning up the volume high enough allowing at least 40 dB of sound pressure to reach the microphone causing an acoustical path between the microphone and speaker to be activated.[27] This results in a squeal with a dominant frequency of 2 to 3 kHz. This frequency is influenced by the resonance of the concha and the external ear canal. Attempts to minimize feedback with electronic feedback suppression have been somewhat successful by preventing the feedback loop from being established.[28,29] Regulation of frequency amplification may be beneficial.[30,31] Extensive research for further feedback reduction is currently done by hearing aid companies.[32-35] Acoustic feedback can be compensated by applying an electrical feedback signal to an electrical path including an amplitude limiting device between the microphone and the receiver. But even with digital feedback equalization results have suggested that listeners with hearing impairment are indeed limited by acoustic feedback.[36] Because of the feedback problem, acoustic devices for moderately severe and severely hearing impaired persons become increasingly difficult to design as the gain required for their amplification increases.

For the hearing aid user the most important and primary requirements are good sound fidelity, improved speech recognition performance, and enhanced self-perception of communication abilities.[3] Future hearing aid users benefit from counselling before fitting for improved acceptance and better outcome. Results are far from ideal.[37] Most conventional hearing aids of the acoustic type suffer from low sound quality with distortion and amplification of background noise. The recent development of acoustic devices that feature digital technology, advanced compression, Automatic Gain Control (AGC) techniques, and multi-channel processing improve sound quality to a certain extent. Conventional hearing aids are currently capable of peak output levels of 140 dB SPL. The maximum level provided to the ear is 130 to 135 dB SPL to prevent further damage to the inner ear by acoustic trauma.[38] The functional gain of conventional powerful behind-the-ear (BTE) hearing aids is currently up to 65 dB.

Cosmetics are much improved by the small in-the-canal hearing aids. The completely-in-the-canal hearing aids (CIC) require deep impressions from the bony external ear canal.[39] Occlusion effects are not generally tolerated. Feedback is a concern, especially with in-the-ear and in-the-canal aids.

Conventional hearing aids are limited not only by their technical specifications but also by proper use of the hearing aid wearer.[40] Conventional hearing aids are rejected in the majority of patients.[41,42] A survey by the US Food and Drug Administration (FDA) revealed surprising tendencies in the hearing aid

market. Sales of hearing aids have declined by more than 90'000 from 1993 (1'555'034) to 1994 (1'463'859) with fewer new users of hearing aids. The FDA is supporting efforts to provide hearing aids to a wider number of potential recipients.[43] At the same time regulatory actions have been prepared to improve quality hearing aid fitting in the US.

Goldstein[44] cited inappropriate claims by hearing aid companies, that hearing aids

1) are a means of treating hearing loss
2) can reverse hearing loss, prevent progression of hearing loss, or stimulate the auditory nerve to recover
3) can eliminate background noise
4) can provide normal clarity of speech or restore hearing of speech to normal levels under all listening conditions for all listeners
5) can benefit all users equally.

Conventional hearing aids require a mold in the external ear canal, which often leads to local problems including discomfort, wax accumulation, skin infection and a disturbing occlusion effect. Repeated external otitis because of the use of a hearing aid may lead to an inability to wear the aid. In chronically draining ears of patients with incurable middle ear infections and large radical cavities, only open tube amplification may be possible. In this set-up feedback is an even more frequent problem. The problem of chronically draining ears has been successfully treated with the Swedish bone-anchored hearing aid of Brånemark that bypasses the external ear canal (EAC).[147]

Individuals with profound hearing loss who are not yet candidates for cochlear implants are currently not served well enough by hearing aids. Vibrotactile devices in conjunction with their hearing aids might improve their communication ability only to some degree.[45-47]

The greatest challenge for any hearing aid is to provide the user with good sound-to-noise difference in noisy environment.[48] Hearing aid tests in free-field noise differentiate this ability best. Noise is mostly low frequency that can be partly filtered out. This however reduces the spectrum of amplified frequencies. Even with individually fitted digitally programmable hearing aids, physical limitations of sound amplification by air cannot be overcome.[49]

In conventional air-conduction hearing aids, amplification is restricted to certain frequencies.[50] The peak of amplification is reached around 1 kHz with a sharp drop at frequencies above 3 kHz.[51] For improved speech differentiation these higher frequencies are important even though for some patients perception of high frequency signals is not possible by amplification. In conventional hearing aids low frequencies are better amplified than are high frequencies.[52] Noise reduction strategies in hearing aids reduce low-frequency gain.[53] Improved

amplification of frequencies of up to 8 or 10 kHz would improve speech perception. Patients have stated that clarity of sound ranks the highest in importance in amplified listening.[54] In a double blind cross-over study, patients with noise-induced hearing loss preferred the hearing aid with high-frequency amplification over the aid with a flatter response curve.[55]

The above mentioned problems motivate the identification of better solutions for the hearing impaired population. Implantable hearing devices might solve some of these problems. The implant is expected to provide the wearer with significantly improved amplification with better signal-to-noise ratio, less distortion and better sound fidelity. Furthermore, cosmetics should be improved as well as local infections of the EAC decreased. As such, the number of potential recipients for a middle ear implant is large when considered in global terms.

The electromagnetic middle ear implant that is proposed here has excellent amplification of frequencies up to 10 kHz. Speech differentiation in noise is expected to be superior to conventional hearing aids.

1.3.3 Aging population

With increasing age, more patients will need hearing amplification. Conventional hearing aids often are not beneficial for the elderly.

The most recent US census in 1990 recognized 31 million adults older than 65 years of age.[56] This number is expected to increase to more than 40 million by the year 2000 and to exceed 65 million by the year 2030. Estimates are that approximately 30% of patients between 65 and 74 years of age have some degree of hearing loss. This increases to 50 % and more in patients of 75 years of age and older.[57]

In our society, patients with presbycusis are demanding a higher standard of living than previous generations did. Mulrow et al.[58,59] tested quality-of-life changes in a randomized trial in an elderly population. They concluded that subjects provided with hearing aids significantly improved their emotional function, their communication function, their depression, and their cognitive function. In a survey in Denmark on hearing aid quality, the median age in 4450 patients was 71 years.[60] However, for some of the elderly patients with moderate-to-severe and severe hearing impairment, conventional air conduction hearing aids often do not compensate for the loss. Acceptance is hampered by annoying sound distortion.[61,62] Amplification of background noise leads to rejection of the hearing aid in the elderly especially when the aid is not constantly worn.[63] Furthermore, auditory processing disorders increase with age leading to poorer performance with hearing aids. Enhanced signal-to-noise ratio might be successful to help overcome the debilitating effects of auditory processing disorders in elderly people. However, with careful instruction even patients of 90 years of age and older can be fitted with a hearing aid even though problems

handling the device increase in this age group.[64] With higher age, ease of use becomes more and more important.[65]

Because hearing aids are not paid for by most conventional health insurance programs in the USA, the majority of patients have to purchase their own hearing aids.[66] In other countries like Switzerland, social or medical insurances pay for the major part of the cost of hearing aids. Nevertheless, many of these patients are not satisfied with the quality and quantity of their hearing restoration. Studies have shown that 50 to 80% of hearing aids are not worn regularly. Inconstant use leads to more discomfort and less benefit.[67]

In an elderly population a cross-modality study to evaluate satisfaction revealed, that denture wearers reported the highest satisfaction, followed by eyeglass wearers. Hearing aid wearers reported the lowest satisfaction.[68] Among subjects with hearing aids, satisfaction was inversely related to age.

1.3.4 Influence and success of the cochlear implant

One of the reasons, that success of an implantable middle ear hearing aid can be anticipated, is the good acceptance and fine results of patients implanted with a cochlear implant.

The cochlear implant is an acoustic nerve stimulator that helps patients suffering from profound hearing impairment by providing the cochlear nerve with electrical stimulation. Practice and specialized training are required to improve performance. Because the insertion of the electrode into the cochlea disrupts inner ear structures, it is a procedure with no possible return to regular acoustical or mechanical stimulation of the ear. The highest success with cochlear implants has been achieved in children who have lost hearing after speech development. This is especially true if the cochlear implant is inserted with only a short delay. The second group to profit most from a cochlear implant are postlingually deaf adult patients who lost their hearing at some later stage in life. The cochlear implant and similar developments have increased awareness and interest in the field of implantable hearing devices.

Recently, segments of the American deaf community have opposed the surgical implantation of cochlear implants, which was discussed widely in the media.[69-72]

1.3.5 Middle ear reconstruction

An important factor in the decision making of hearing rehabilitation is the state of the ossicular chain. The middle ear implant connects to the ossicular chain. As such, the implant ties into problems encountered with middle ear ossicles. There is an ongoing discussion among otologists concerning the indications, techniques and results of middle ear reconstruction for ossicular problems. This discussion is of relevance to potential recipients of implantable devices, where the ossicles have been partly or totally destroyed by disease.

Various potential designs of implants to correct these problems will be provided in Chapter 7.

There is continuing criticism of any kind of electronic middle ear implants by some otologists as Niehaus, Helms et al.[73] discussed in 1995.

In conventional middle ear reconstruction, the tympanic membrane is repaired in tympanoplasty. Conventional middle ear prostheses are connected between the ossicles as an interposition or in direct contact with the tympanic membrane as a columella.[74,75] The transformation of sound to the cochlea depends on the closure of the air-bone gap and as such on the efficient sound conduction of the ossicular prosthesis. Commonly used prostheses include Partial Ossicular Replacement Prosthesis (PORP), Total Ossicular Replacement Prosthesis (TORP)[76] in a variety of designs.[77-80] Efforts are made to find the best shape and material among the many prostheses on the market.[81-86]

Reconstruction of the middle ear following otologic disease or trauma is a common otologic operation.[87,88] These procedures, however, do not produce reliable results. In over one third of post-operative results reported, the surgeon fails to close the air bone gap to less than 20 dB at 0.5, 1.0 and 2.0 kHz.

No single alloplastic material fulfills all the criteria of biocompatibility, stabilization and incorporation.[89] Homologous and autologous material like cartilage[90-92] and bone[93] are also used for middle ear reconstruction.[94] Even teeth have been shaped and used for ossiculoplasty[95] but long-term stability has been questioned.[96] Some otologists intend to replace the entire middle ear by an artificial middle ear.[97,98] However, there are physical limitations to all of these stiff prostheses even in the best placement technique and under optimal conditions in the middle ear cleft.[99] Gross middle ear abnormalities also limit the possibilities of ossicular reconstruction.[100]

Ionomer cement may be useful in the reconstruction of the middle ear.[101] Ionocap® is a polymaleinat ionomeric cement of alkaline glass powder and polyalkenoic acid that is mixed in the operating room.[102] This cement can also be used for device fixation in the mastoid or middle ear.

In an intact incus-stapes connection, the electromagnetic implant can be attached to the long process of the incus. This facilitates the use of a larger implant, as the incus can support more mass than the stapes head alone. In the case of incus destruction or severe incus-stapes disruption, the electromagnetic implant will have to be placed directly on the stapes head and shoulders.[103] There are no significant differences in relation to age as the ossicles already have almost their full size at birth. If the stapes superstructure is destroyed, then the electromagnetic implant might have to be connected directly to the stapes footplate.

Therefore, several electromagnetic implant models for chronic ear disease will be needed to provide for these various situations.

1.4 Basic ideas for middle ear implants

Middle ear implants act as mechanical drives of the ossicular chain to transmit vibrations to the cochlea. Ideally, the middle ear implant is placed in a healthy middle ear.

Two electronic systems have been used as mechanical drives. They are the electromagnetic transducer and the piezoelectric transducer. In order to be effective, these transducers have to overcome the impedance of the cochlea and they have to vibrate with a peak-to-peak displacement of up to 15 µm. Furthermore, their frequency response should be flat without major resonance peaks, or their disturbing resonance frequencies should not be within the main speech frequencies of 0.250 to 4 kHz.

These basic ideas have been known for more than twenty years. Up to now it has not been possible to construct a middle ear implant that fulfilled all of these expectations with the exception of the Japanese piezoelectric implant. That type of middle ear implant will be discussed in detail in the following chapter.

The main problem of all middle ear implants has been to power the transducer with enough energy to excite the ossicular chain with adequate displacements. Energy consumption of these mechanical drives is high compared to cochlear implants with their electrical stimulation.

The fixation of the implant onto the ossicular chain also causes problems. A destruction of the chain should be avoided in order to preserve hearing by the tympanic membrane and thus by conventional air conduction hearing aids.

2. History of implantable hearing devices

This chapter discusses implantable hearing devices for patients with sensorineural or conductive hearing impairment. Cochlear implants are not included in this thesis.

For several decades otologists have experimented with possibilities to excite the cochlea by mechanical transmission of some kind.[104] The reasons for this effort are the inefficiency and still unsatisfactory quality of conventional air and bone conduction hearing aids. The purpose of implantable hearing aids is to improve the quantity and quality of amplification of sound waves. The operating principle is based on the existence of a transducer of some kind that transforms the electrical signal into a mechanical wave. This transducer can either act onto the ossicles of the middle ear or onto the mass of the temporal bone by short-circuiting the middle ear. The latter device is then called a bone conduction implant. There are currently two types of bone conduction implants available.

Transducers acting directly onto the middle ear ossicles are called middle ear implants. Several devices of these are under intense research and clinical investigation. No device is yet commercially available. The longest experience stems from the Japanese piezoelectric middle ear implant of Suzuki-Yanagihara (Rion).

2.1 History of bone–conduction implants

Conventional bone-conduction hearing aids serve a special group of hearing impaired patients who suffer from a conductive hearing loss. Patients with aural atresia are part of this group.

Conventional bone-conduction hearing aids transmit acoustic energy by mechanical vibration to the skull. For this, they need a firm pressure on the skin of the skull. This pressure is applied by a spring band worn around the head or by special eyeglasses. However, it is this pressure that causes discomfort and pain as well as unreliable sound transmission depending on the contact of the vibrator. Furthermore, efficiency is limited for these hearing aids. All of these factors led to the development of alternative methods to bridge the gap of conductive hearing loss.[105]

2.1.1 Brånemark titanium screw

In the 1960's, experimental studies of Brånemark et al.[106] showed the possibility of direct anchorage of titanium implants in bone. This work was based on extensive animal experiments and the term *osseointegration* was coined.[107],[108] In 1985, Brånemark[109] suggested a new definition of osseointegration: "A direct

structural and functional connection between living bone and the surface of a load-carrying implant".[110]

A large body of literature has been published on the topic of titanium dental implants.[111-127] This technique is considered safe and more than 300,000 implants have been inserted in humans. Most of them remain lifelong. The interface between the titanium implant and bone was one of the main topics of interest.[128-143]

In the meantime, a large body of literature mostly from Scandinavian countries has been published on the topic of the percutaneous bone anchored hearing aid (BAHA).[144-186]

The first patients were implanted 1977. In a review of the first 100 patients with a follow-up of 8 to 16 years, ninety percent of implants were found to be stable.[187] The long-term success is due to a combination of implant material and minimal trauma to the tissue. In 1991, Tjellström reported on 750 patients implanted with the Brånemark hearing aid implant. Of these, only 10 implants had to be removed due to insufficient integration and all were in younger patients with a thickness of the outer cortical bone layer of less than 3 mm.

Tjellström described in detail the surgical procedure for insertion of the titanium screw for the bone anchored hearing aid. The initial two-stage procedure for implantation was changed to a one-stage procedure.[188-191]

Infection of tissue is a major concern in any procedure that permanently interrupts the skin surface leaving a fistula. In most cases, these skin reactions cause minor problems. They can be solved with local cleaning and disinfecting procedures. Disinfecting mouthwashes also improved gingivitis and periodontitis after dental implantation.[192-194] Tjellström[195] analyzed more than 800 patients where skin perforations for attachment of the Brånemark titanium screw were performed. No reaction was found in 92.5%, redness in 4.1%, moisture in 1.8%, granulation tissue in 1.5% and infection leading to removal of the percutaneous implant in only 0.1%. With increasing time, these skin reactions neither increased nor decreased in frequency. Thinning of the subcutaneous tissue around the percutaneous plug remains an important step to prevent skin infection.[196] The skin around the abutment then lies closer to the skull and is allowed less lateral motion. The cover screws of retrieved titanium screws have been investigated for soft tissue reaction, which revealed a significantly larger number of contaminants and macrophages.[197] This contamination however is physiological and does not lead to soft tissue infection in the majority of patients.[198] Skin infection was most commonly caused by Staphylococcus aureus.[199] None of the patients had delayed hypersensitivity towards titanium.[200] Insertion of a percutaneous implant might be contraindicated in patients with a history of previous skin infections.[201]

Electromicroscopic evaluation of soft tissue around percutaneous titanium implants reveals close contact of the implant to the surface and minimal to no inflammatory process.[202] In irritated skin, an increased number of inflammatory

cells, mainly polymorphonuclear cells, B-cells, and plasma cells but not T-cells suggested a response directed against exogenous agents rather than an allergic reaction against the implant per se.[203] Significant irritations only occurred in less than 4% of the observations.

Craniofacial epistheses are mounted on titanium implants around the orbit and nose as well as at the lateral skull.[204] Collaboration of the surgical team with the prosthetic team determines the beneficial result for the patient.[205]

Analysis of the torque applied in insertion and removal of titanium screw implants was provided among others by Ueda et al.[206,207.] Insertion of the screw in the outer cortical layer of the skull resulted in insertion torque of 50 Ncm and insertion into both layers in insertion torque of 70 Ncm. This difference of 40% was also observed in long-term stability. For successful osseointegration, the screw should be left free of load for at least 3 months.[208] In dental implants, immediate loading with overdentures has been tried in a selected group of patients.[209,210]

Comparison between titanium implants and hydroxyapatite implants revealed similar clinical behavior but the titanium implants were easier to remove from bone if necessary.[211] Coated and uncoated titanium screws proved success rates exceeding 95%.[212,213] Bioactive coatings may not lead to improved fixation of implants.[214]

The safety and stability of the percutaneous titanium screw depends largely on the thickness and quality of the skull bone. Bone thickness of the skull of less than 3 millimeters has led to implant loss in young children.[215] In carefully selected cases in children, Jacobsson et al.[216] reported a 96.6% fixture survival rate. Skin reactions were more frequent in auricular prostheses (25%) than in the BAHA (8%). The temporal line superior and posterior to the auricle provides the thickest bone close to the cochlea. Preoperative CT scanning to judge the thickness of bone is helpful to evaluate safe positioning of the screw,[217] whereas preoperative radiographic misjudgement might lead to implant loss.[218] Furthermore, sterile and atraumatic handling of the titanium screw before insertion is of major importance for safe osseointegration.[219]

Safe anchorage of the titanium screw in the skull bone was found in 97% in a longterm follow-up of up to 16 years and one loose screw occurred out of 68 implants.[220,221]

The use of the Brånemark bone conduction hearing aid implant is now increasing also outside of Scandinavia.[222-232] The device has been implanted by more than 150 ENT departments worldwide.[233] Cremers recently reported on 180 BAHAs implanted in Nijmegen, Proops reported on 140 BAHAs in Birmingham, Portmann on 42 in Bordeaux and Häusler in Bern on 28 BAHAs.

The technique of percutaneous titanium screws is also applied for fixation of auricular or facial episthesis.[234-238] Raivio et al.[239] combined aural episthesis

with the bone anchored hearing aid in children with bilateral microtia. Telescopic titanium magnets for flexible extension in episthesis are also in use.[240]

Snik et al.[241] evaluated the BAHA in the acoustic free-field in a group who previously used conventional bone conductor hearing aids. The aided thresholds and speech discrimination scores were substantially better with the BAHA due to higher volume settings chosen by the patient. Patients reported fewer problems with saturation and less distortions with the BAHA. However, the results in patients who had previously used an air-conduction hearing aid were ambiguous.[242]

Abramson et al. assessed patient satisfaction by questionnaire and found that all patients fitted with the BAHA preferred the bone-anchored hearing aid over their previously worn hearing aids.[243] In a study comprising the first 65 patients to receive a BAHA by Tjellström's team in Gothenburg, 74% of patients stated that they were very pleased with what they regarded as improved sound transmission.[244]

The bone anchored hearing aid is also advocated for pure sensorineural hearing loss.[245] Use for this indication is still limited. Bone conduction levels by pure-tone audiometry have to be better than 50 dB SPL in the speech frequencies. This however is substantially different from the levels needed for the Audiant Bone Conductor which requires bone conduction levels of 20 dB SPL or better.

The incidence of potential candidates for the BAHA hearing aid is estimated to be 1:200,000 persons per year. This would yield about 30 patients per year in Switzerland. To collect data on the experiences of this limited population, otologists in Denmark have formed a nation-wide study group.[246]

In a comparison between conventional air conduction hearing aids and bone-anchored hearing aids for pure sensorineural hearing loss, the results with the BAHA were poorer.[247] This was ascribed to volume settings set too low by the patients in order to prevent saturation of the hearing aid amplifier and associated distortion. In a comparison of the BAHA with conventional bone conduction hearing aids, none of the patients had poorer results with the BAHA.[248] Speech recognition was improved, which was ascribed to better performance of the BAHA in the high frequency range (above 2 kHz) and to relatively less distortion.[249] Skin attenuates high frequency transmission. This is true in conventional bone conduction aids as well as in the Audiant®. In the percutaneous coupling, these high frequencies are transmitted better than in conventional bone conduction hearing aids.

Browning and Gatehouse[250] tried to predict the value of the BAHA for previous hearing aid users. All patients who previously used bone conduction hearing aids were delighted with the BAHA. However, only two thirds of patients who previously used air conduction hearing aids were equally pleased with the BAHA. One third reverted back solely to their air conduction hearing aid.

Browning and Gatehouse could not find predictive information to separate the two groups preoperatively. These findings are also supported by results of a multicenter study of Mylanus et al.[251] in the Netherlands, where all previous bone conduction hearing aid users profited best by the BAHA. Also in the fitting with the super-bass bone-anchored hearing aid HC 220, patients with previous experience of air conduction hearing aids did not profit as much.[252] Furthermore, hearing in noise was more difficult due to stronger low frequency amplification by this device.

Measurements of the thickness of skin to predict successful fitting with the BAHA safely in patients with a conventional bone conduction hearing aid have been found to be unsuccessful.[253]

2.1.2 Xomed Audiant®

In 1980, Hough and Vernon[254] joined in a project on the development of an implantable electromagnetic hearing device. The project was based on experience with cochlear implants and their transcutaneous induction system. The alignment across the intact skin was achieved by rare-earth magnets on either side of the skin.[255],[256] This research resulted in the Audiant® system.

Xomed has constructed the Audiant®[257-266] which is a bone conduction system designed for the hearing impaired with no sensorineural hearing loss and only mild conductive loss. The bone conduction levels have to be 20 dB or better in the speech frequencies of 0.5 to 4 kHz in order for the Audiant® to provide the patient with some help.[267] In these cases, the average improvement in threshold was found to be 36.0 +/- 13.3 dB.[268] Selection of patients seems to be crucial for the success of the Audiant® system.[269]

The device has met with limited success. The Xomed Audiant® has not kept its promised role in hearing rehabilitation.[270],[271] Browning[272] reported on the British experience with the Audiant where only 59 per cent of the patients use their Audiant® aid. The major reason for rejection was lack of power. Whitehead[273] however reported success in five out of six patients fitted with the Audiant®. Four of the five patients used the ear level processor.

In patients with unilateral profound hearing loss 72% were no longer wearing their Audiant® Bone Conductor after a mean follow-up of 3 years and 25% had the device removed. It was recommended that the Audiant not be used in patients with unilateral profound hearing loss. Pulec[274] however published indications and results of the use of the Audiant® for just this indication. Pulec implants the Audiant® in patients with total hearing loss on one side due to various reasons. Bone conduction thresholds on the hearing ear must be 20 dB SPL or better. The implant then acts as a cross for sound transmission by bone conduction. He claims excellent patient satisfaction for this indication. This approach has not been supported by others thus far.

Essentially, the Audiant® Bone Conductor consists of a coil magnet configuration that vibrates the skull. Bone conduction transmits the signal to the cochlea. The electromagnetic middle ear implant proposed here only vibrates the ossicles directly.

Skin necrosis at the level of the Audiant® implant due to the pressure of the external unit has been observed.

The first series of the Audiant® system was hampered by limited energy output. The new Audiant® AX-II implant provides higher output.[275,276] It can be combined with a behind-the-ear processor, an at-the-ear processor or a body level device. Dunham and Friedman[277] reported on the success of the implanted device, which was preferred by children over the conventional bone conduction hearing aid.

Long term results with the Xomed Audiant® were presented by Jack Hough[278] in 1993. He claims that socially adequate hearing can be obtained if proper guidelines for indication are used. More than sixty Xomed Audiant® devices have been implanted by Causse.[279]

In clinical comparisons between the transcutaneous bone conduction implant Audiant® and the percutaneous bone conduction implant BAHA, the latter provided higher output levels and better patient satisfaction.[280]

2.2 History of middle ear implants

Prior to 1960 there is no evidence in the literature suggesting an implantable hearing aid placed into the middle ear.

A patent was filed in the USA in 1971 to use a hollow tooth for implantation of devices.[281] This has recently been attempted again.

Only in 1991 did it become apparent that research in the field of implantable middle ear hearing aids has been carried on for more than 30 years when Mahoney[282] reported on his work started in 1961. Due to restrictions applied by the contracting company Medtronics, Minneapolis, no information prior to 1991 was published in the medical literature. Furthermore the CIA (Central Intelligence Agency) was interested in the possibility of implanting an audio tape into the mastoid cavity using some of Mahoney's knowledge. The concept of this project was a totally implantable hearing aid. The microphone would be placed under the skin covered with a thin silicone membrane, a rechargeable battery would be sealed in epoxy and charged externally by electromagnetic loop induction. Volume and pitch control as well as on-off could be controlled externally by magnetic reed switches. A US patent was filed in 1967 and granted in 1971.[283] The technique uses a direct ossicular coupling that was initially connected to the body of the malleus and later the incus acting on a push-pull principle. Clinical intraoperative trials on ossicles of patients operated on under local anesthesia were conducted with hearing gains of 16 to 38 dB. Set screws would anchor the transducer to the mastoid. The body of the malleus and later of the incus were drilled to precisely fit the oscillating rod.

According to Mahoney, the high frequency drilling of the ossicles did not result in sensorineural hearing damage. No audiometric data are provided to confirm this claim. There is substantial evidence that any kind of drilling on the ossicles or touching the ossicles with the burr causes substantial cochlear damage. Audiological data with high frequency hearing loss after conventional stapedectomy with stapes footplate removal led to the finer and more sophisticated techniques of stapedotomy where only a small opening into the stapes footplate is needed. Slow speed skeeter drills have been advocated for this purpose. Other surgeons propose the use of handheld microperforators.[284] Lately, the use of lasers has been proposed to reduce the mechanical trauma to the cochlea further.[285 -295]

Short battery life limited the success of the project of Mahoney. Projects with totally implantable hearing aids are still not to be realized due to insufficient energy supply by implanted batteries. Rechargeable batteries would demand long waiting time. Ideas of recharging batteries while a patient sleeps have been abandoned due to potential side effects of electromagnetic fields.

Stimulation of the inner ear has also been tested via the semicircular canals in a fenestration procedure but was not successful over the longer term.[296]

2.2.1 Piezoelectric middle ear implants: Yanagihara/Suzuki

This semi-implantable hearing device is a piezo-electric bi-morph developed at Ehime University in Matsuyama, Japan. The project is supported by Rion, a hearing aid company, and by large grants from the Japanese Health System.[297] In 1983, the first 5-year project on this middle ear implantable hearing aid (MEI) was completed.[298] Extensive research has led to the development of this device and audiological testing has led to better understanding of the effects of an implanted device.[299-301] In 1987, Yanagihara et al.[302] published results of the first human applications of this device. By 1995 several papers on this device were presented.[303-307]

This transducer drives the stapes directly. For this, the device requires disarticulation of the ossicles with removal of the incus and thus destruction of conductive hearing. The device reportedly produces up to 50 dB of gain. However, implantation is surgically challenging. The reason for the difficulty is the need for fixation of the base of the piezo-electric bimorph in the middle ear serving as a resting point. This point must be chosen at a precise distance in order for the bimorph to reach the head of the stapes at the correct angle and distance. Because stapes movements of only 1 to 10 micrometer are needed in stimulation of the cochlea, the positioning of the device is critical. A hydroxyapatite tube is interposed between transducer and stapes head. A 1 Volt peak-to-peak input was equivalent to that produced by a sound stimulus of 90 dB sound pressure level at the tympanic membrane.[308]

The first implantation of a partially implantable device was undertaken in 1984. In 1993, long-term results on 30 patients were presented by Yanagihara[309] and Suzuki.[310,311] In 6 patients the device failed, leading to a 20% failure rate. In 2 cases, problems with wires led to malfunction, in 2 cases skin fistulas occurred, in one patient amplification was insufficient, and in one patient the connecting hydroxyapatite tube dislocated. The best amplification was found at 0.5 kHz with long-term hearing gains of 30 dB.

For a new series of patients to be implanted, Suzuki suggested reducing the required bone conduction levels from 40 dB to 30 dB HL. This substantially reduces the number of potential recipients. With this bone conduction level, the Japanese implant is almost as restricted as the American Xomed Audiant®. Furthermore, the Japanese implant destroys the middle ear by removal of the incus.

Suzuki also advised implanting only patients with a spacious middle ear. One of the problems seen with this implant is tympanic membrane perforation. This was due to erosion of the tympanic membrane by the piezoelectric vibrator that sits atop the stapes head and on a hydroxyapatite tube. Even in normal ears, the distance between the stapes head and the TM is within 3 to 5 millimeters.

Thus, it is contraindicated in any patient with tympanic membrane retraction. Chronic middle ear infections are a contraindication to implantation.

A case was reported where manipulation in the ear canal led to accidental disruption of the wire to the piezoelectric transducer.[312]

The microphone used for the external unit is an Electret-microphone. The frequency response of the piezoelectric bimorph is flat below 5 kHz. Preconditions include bone conduction thresholds of 50 dB or better in speech frequencies with speech discrimination scores of 70 percent or better.

The Japanese team of Suzuki tried to solve the problems of the totally implantable hearing aid. The Electret condenser microphone would be placed under the skin. This was successfully tested in cats for over one year. The response is best at 2 to 4 kHz. The thicker the skin the less the high frequency transmission. The primary batteries were MnO_2/Li, which were designed to last for 2 years. The second batteries were rechargeable NiCd. The number of recharges is limited at this point. Currently the volume of the batteries is 4.8 milliliters.

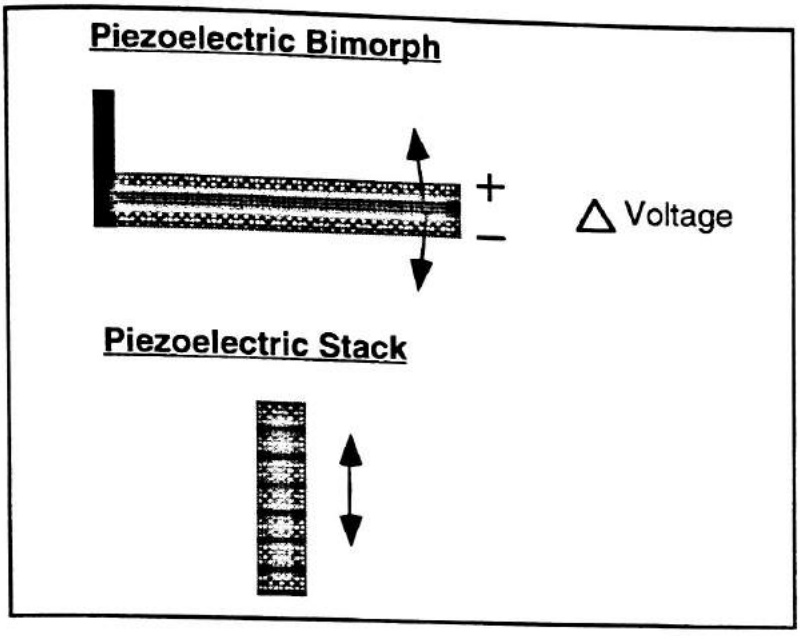
Yanagihara discussed driving the incus directly without destruction of the ossicular chain. However, the piezoelectric transducer was too weak for that task.

The future of this Japanese piezoelectric implant is unknown. It has played a major role in the thinking of middle ear implants and the development of other ideas. This implant however is fraught with major drawbacks such as the destruction of the middle ear, the need for a good cochlear reserve with bone conduction levels of 40 dB HL or better and the requirement of large mesotympanic spaces.

Olivier, Sanguy, and Cannoni[313] reported on a single patient implanted in Marseilles with the piezoelectric implant of Yanagihara/Suzuki. To their knowledge it was the first successful implantation of this device outside of Japan. No other patient was implanted at their center. The reasons for not implanting any other patients include the improvements of conventional hearing aids, the need for surgery with destruction of the ossicular chain and the need to wear an external part behind-the-ear. Rion has restricted the distribution of this implant and they are no longer exported. Sixty-five patients have been implanted in Japan with this device as of June 1995.

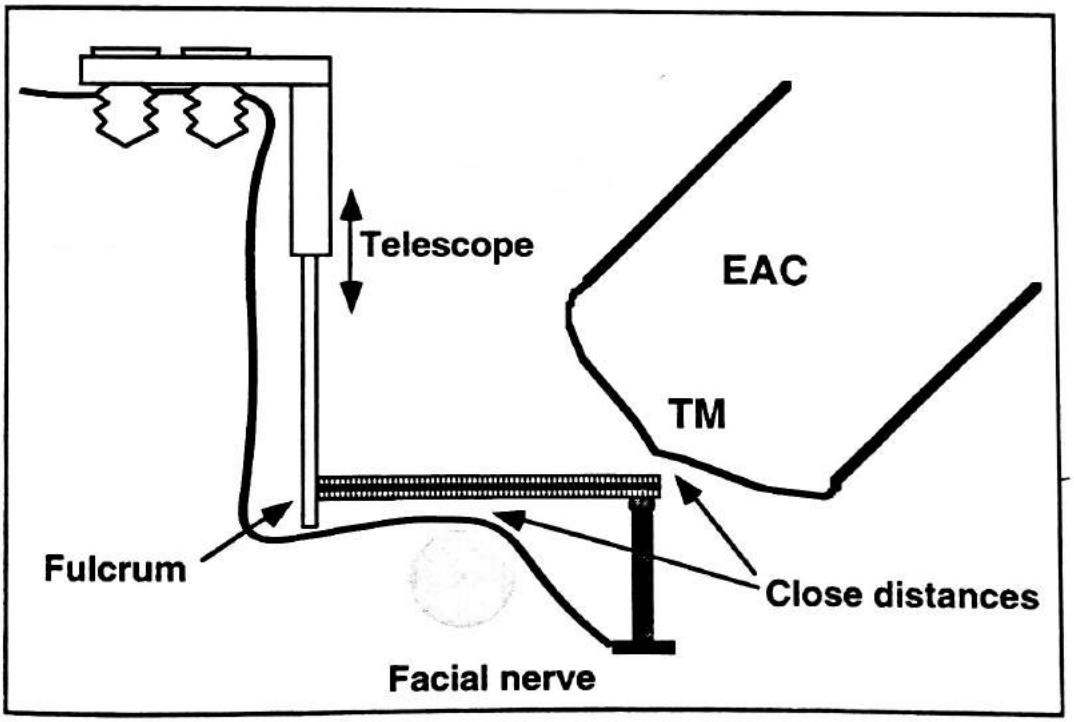
Efforts have been made to diminish the energy transfer across the skin. A titanium screw should act as an electrical plug, much as planned for the device proposed in this thesis.

Fig. 1: Piezoelectric transducers:
Amplification of displacement by bimorph or stack construction.



The individual crystals of piezoelectric transducers allow only a limited displacement. To augment displacement, several combinations of piezo crystals are possible that multiply displacement. Among these combinations the bimorph design and the stack design are the most common.

Fig. 2: The piezoelectric implant Yanagihara/Suzuki:

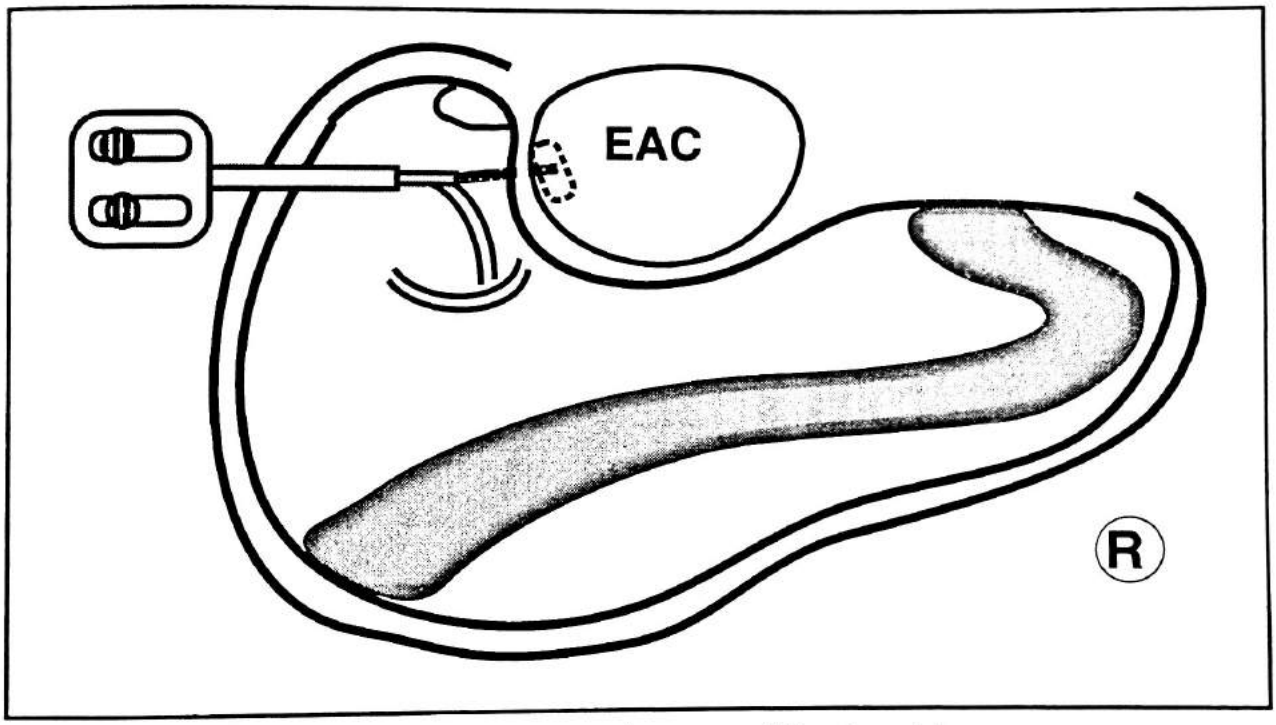


TM = Tympanic Membrane, EAC = External Auditory Canal

For the Japanese implant, the bimorph set-up was chosen. The ceramic piezoelectric bimorph is brittle. It breaks easily under stress. After resection of the incus the piezoelectric bimorph is connected to the head of the stapes. The length of the pole from the skull surface to the fulcrum can be adjusted by a telescope. The implant then needs to rest on the pole to act as the fulcrum. Close distances are between the ridge of the tympanic portion of the facial nerve and the ceramic bimorph as well as to the tympanic membrane. To adjust the distance to the stapes, various cylinders of hydroxyapatite can be interposed.

In an attempt to improve sound quality in patients implanted with the piezoelectric implant, three different types of frequency responses were tested. The program with a wide frequency response and a peak at 4 kHz was preferred by 83% of patients.[314]

Fig. 3: Location of the Japanese piezoelectric implant in the mastoid:



Fixation of the implant in cortical bone along the temporal line in a right ear. Telescopic extension to the epitympanum. EAC = External Auditory Canal

Lateral surgical view in a right ear after mastoidectomy. The posterior wall of the external auditory canal is intact. The transducer is led through a posterior tympanotomy opening into the mesotympanum after removal of the incus.

This implant requires destruction of an otherwise healthy ossicular chain. This is one of the reasons, why this implant has been used almost exclusively within Japan.

2.2.2 Electromagnetic hearing aid

In 1935, Wilska[315,316] was the first researcher who tried to stimulate the middle ear with electromagnetic induction. The magnets were attached to the eardrum stimulated by the use of alternating electromagnetic fields.

The first experiments using the electromagnetic technique for middle ear structures including the tympanic membrane were published by Rutschmann[317] in 1959. He placed "small pieces of soft iron of about 10 mg" on the tympanic membrane of human subjects. An electromagnetic induction field was induced by a large coil over the external ear and various frequencies generated by an oscillator were provided. The subjects described the sound as similar to the sound by acoustic energy.

In the past 30 years, a substantial body of basic research and development of new concepts on various ideas of the electromagnetic implant have been published by Goode.[318 -333]

Other important papers on the topic of electromagnetic middle ear implants have been published by a number of scientists and clinicians.[334 -344]

2.2.2.1 Previous concept

In an electromagnetic drive, the coil generates an alternating electromagnetic field that drives a permanent magnet. Until July 1992, it was common practice to have the coil detached from the magnet. That was the original concept of a loudspeaker where the membrane with the magnet swings and the coil remains stable thus allowing a constant field. This concept was later replaced in loudspeakers with a system in which the coil became the moving part, the so-called *moving coil technique*. The advantage of this change was the lighter weight of the coil compared to the magnet. However, in middle ear implants all research was based on the coil and magnet located at some distance apart. Research teams tried to optimize this configuration by improving the coil design and by using stronger magnets.

2.2.2.2 Major problem

The unresolved problem in electromagnetic hearing aids has been the inefficiency of the electromagnetic induction system where the magnet was placed on an ossicle and the field was induced by a coil at a distance from the magnet.

The coil has been placed at various locations, including the external auditory canal, the mastoid and the middle ear space. Any location of the coil at some distance from the magnet renders it ineffective because the electromagnetic field becomes increasingly weaker due to a logarithmic decrease by a distance factor exponential d^3. The influence of distance on the decrease of power in a coil-magnet set-up is discussed in chapter 5.3.2.

It was therefore suggested that the magnetic field be placed as close to the magnet as possible. One of the problems has been to position the coil close to the magnet without direct physical contact, which would cause distortion. Furthermore, contact might lead to mechanical breakdown of the thin wires of the coil.

2.2.3 Current research on implantable middle ear hearing aids

Several groups of researchers are currently working on the realization of an electromagnetic middle ear implant.

2.2.3.1 Oklahoma City

Xomed has funded research by Hough's group of otologists in Oklahoma, USA, who invented the Xomed Audiant® system. The success with the implanted rare-earth magnets led to a system to stimulate the ossicular chain directly. Initial animal testing used implantable magnets applied to various portions of the ossicles in guinea pigs.[345] Positioning of the induction coil in the external ear canal or the mastoid was crucial in the ABR measured effect on the cochlea. The single most important factor was distance of the coil to the magnet.[1]

According to a senior official of the company, Xomed has stopped their support of the project.[346] Research is continued with support from a private foundation. Hough[347-349] has placed magnets at several locations on middle ear ossicles driving them with an induction coil placed in the mastoid and the external ear canal.[450] These placements included among others, the handle of the malleus, the body of the incus, the long process of the incus, as well as on the incudo-stapedial area after disconnecting the incudo-stapedial joint. In 1972, Glorig et al.[350] reported on their experiments with kangaroo rats and human subjects in magnetically coupled stimulation of the ossicular chain.

Extensive research has been conducted by the Oklahoma group of Hough to find the most efficient coil design. However, the major problem is still the loss of energy caused by the distance between coil and magnet with the closest distance of more than 3 millimeters. Results of animal experiments led to temporary clinical trials with human volunteers in 1985. Intraoperative testing was performed on patients in surgery for otosclerosis. In a first series of implanted magnets onto the incudostapedial joint in a human trial patients reported the sound to be of high fidelity. The best gains were achieved at 3 and 4 kHz and were as much as 30 dB.[450]

Magnetic implants were studied in temporal bones for their stability in magnetic fields of MR scanners. After exposure of these bones to magnetic fields of 1.5 Tesla apparently no damage to the ossicular chain could be found.

Under a clinical trial research protocol supervised by the FDA, five patients were implanted with the annular doughnut shaped magnet inserted between the

incudostapedial joint. All five patients showed excellent gains at 3 to 4 kHz. The sound was described by the patients as pleasing and of high fidelity (Baker et al. 1995). After three months, the neodymium-Iron-Boron magnets ceased to work and explantation revealed leaking into the implants leading to corrosion of the ferrous magnet. [351] The magnets were changed to samarium-cobalt magnets that are resistant to corrosion. The energy product is less in Sa-Co and magnets had to be larger. This led to dampening of unaided hearing by a mass effect. For that reason, the magnets were explanted.

Baker et al. (1995) offered six conclusions from their middle ear implant program:

1. The human cochlea responds best to amplification provided by vibrations of magnetic implants attached at the incudostapedial (IS) joint.
2. The IS-joint appears to be a good anatomic location for implantation.
3. Surgical removal and reimplantation can be accomplished without loss of normal ossicular chain function.
4. Neodymium-Iron-boron should not be used in an implant until long-term stability of its magnetic strength can be assured.
5. Samarium-cobalt is presently the magnet of choice.
6. When an implant of excessive mass is attached to the IS-joint, audiometric effects on the ossicular chain are seen.

2.2.3.2 St.Louis

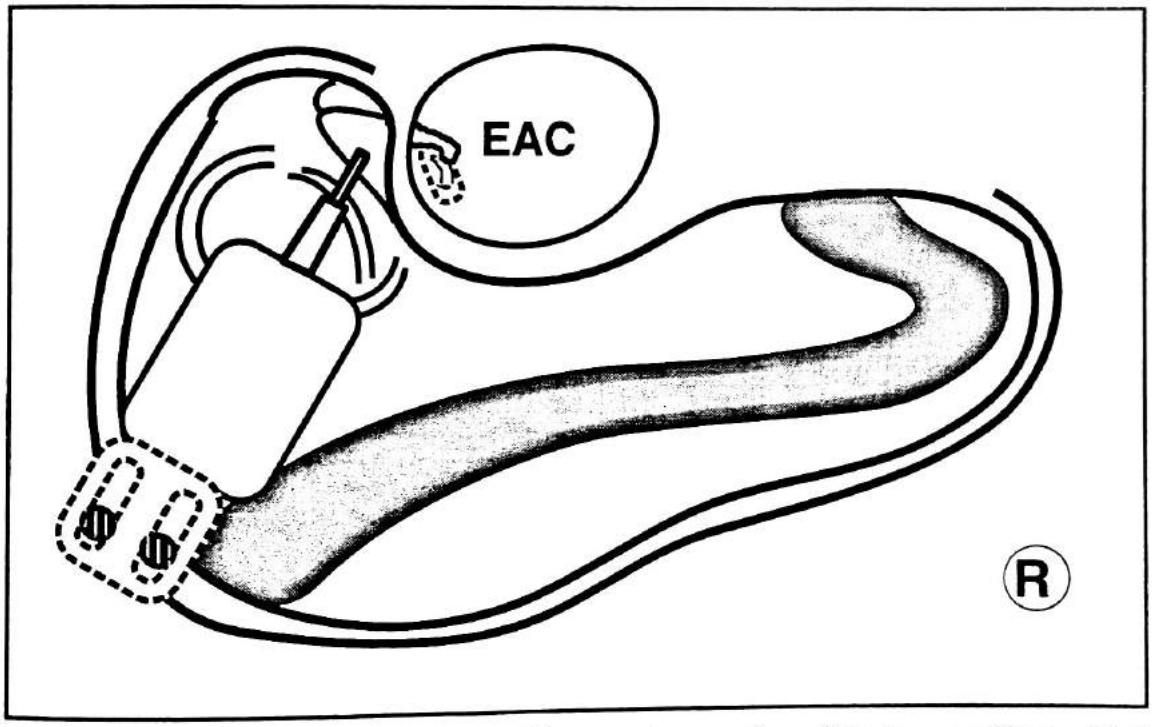
Fredrickson has been working on electromagnetic implants for the past 20 years with partial support by Storz Company. He was granted Canadian and American patents in 1973 on an electromagnetic middle ear implant using a percutaneous plug in the skull for power delivery.[352] The middle ear implant described in these patents consisted of a magnet attached to the head of the stapes. The incus was removed for this placement. An induction coil was placed above the magnet and fixed in the mastoid area. This system never came to fruition probably due to technical problems associated with this concept. The negative aspects of this surgery were the necessity removing the incus and as such a disconnection of natural sound conduction. Furthermore, the coil was placed at some distance from the magnet. Additionally, the coil had to be attached in the mastoid area requiring precise and safe attachment in order to approach the magnet as closely as possible.

Fredrickson is currently working on another concept. This is very similar to the approach described by Mahoney in stimulating the incus by a rod connection from an electromagnetic transducer placed in the mastoid. However, the hole in the incus body is drilled with a laser, which facilitates the delicate drilling

substantially. This will be a totally implantable hearing aid. The effect of skin thickness on the implanted subcutaneous microphone was measured in a porcine model.[353] To minimize attenuation and exploit the sound collecting qualities of the external ear, the deep meatal skin appears to be a favorable position for implantation. Animal testing has apparently been successful. Experiments with monkeys led to the conclusion that the load on the ossicles must be minimized for optimal sound transmission.[354] In 1993 Fredrickson presented his concept for the first time.[355] The electromagnetic transducer is mounted in the squamous portion of the temporal bone and extends through the attic to the incus body. A mechanical transducer coupled to the malleus measured output levels equivalent to 140 dB SPL with a flat frequency response beyond 10 kHz. This device has been implanted in Rhesus monkeys in acute and chronic experiments.

The probe tip of the transducer contacts the body of the incus in an epitympanotomy approach with intact ear canal wall. Testing up to 1995 included 6 monkeys.

Fig. 4: The Fredrickson transducer in the mastoid bowl extending to the incus.



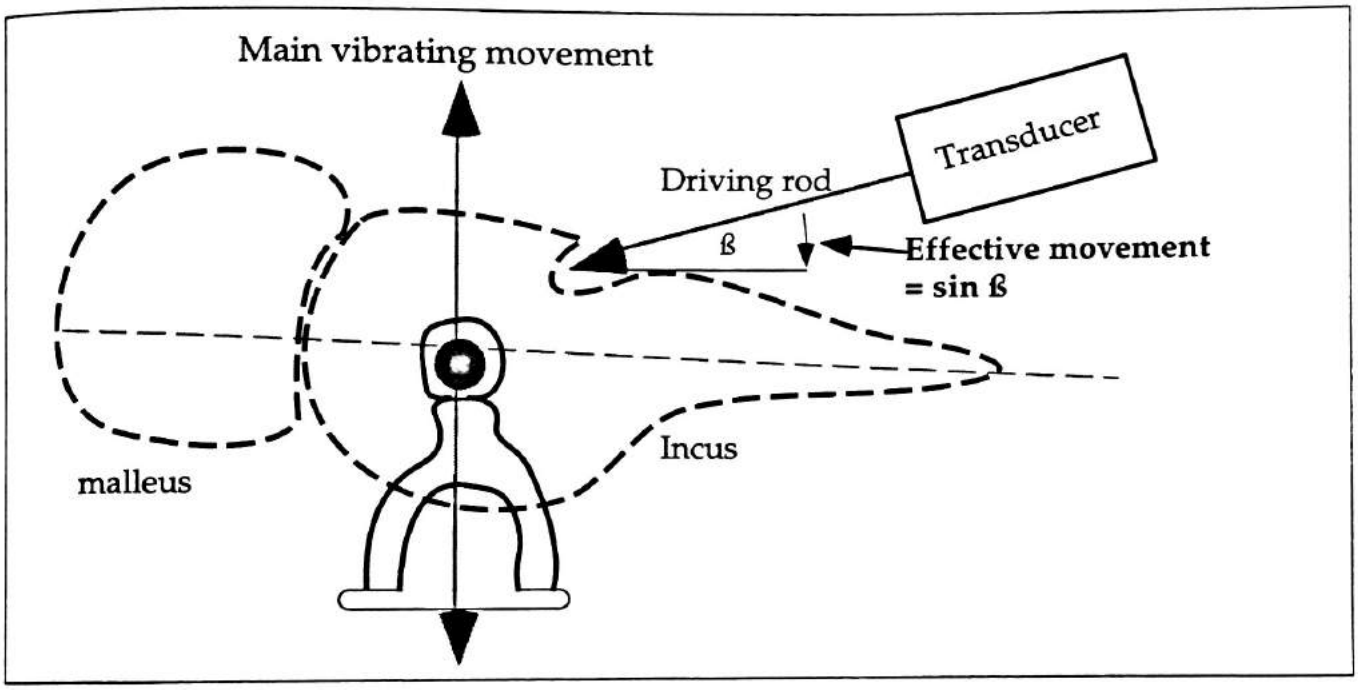
Fixation of the transducer in the cortical bone at the crossing of the temporal line with the sigmoid sinus in a right ear. Driving rod to the body of the incus.
EAC = External Auditory Canal

The advantage of this implant is the volume available in the mastoid bowl that can hold the transducer. The distances are estimated to be in the 10 x 15 x 3 mm range giving this implant a potential volume of about 450 mm^3.

The drive technology is electromagnetic with a push-pull drive chosen for its proven linear frequency response.

The main disadvantage of this set-up is the angle between the driving rod and the natural axis of rotation of the incus. Because the transducer is located in the mastoid bowl, it reaches the body of the incus from the side thus causing more of a lateral movement than the desired movement in the axis of the incudo-stapedial joint.

Fig. 5: Direction of the driving rod to the incus: reduction of potential movement



The effective movement of this drive depends largely on the angle ß. The larger ß the more effective the movement where the effective movement is proportional to the sinus of angle ß. With the position of the transducer in the mastoid, angle ß remains small. To place the transducer at an optimal position it would have to be reduced in size to two to three millimeters to be fitted superior to the external auditory canal close to the temporo-mandibular joint.

2.2.3.3 Cleveland: Maniglia

At the Case Western University in Cleveland Ohio, USA, Maniglia has been working on an electromagnetic middle ear implant with a research group at the University School of Engineering.[356-358] A supplement of the Annals of Otology, Rhinology and Laryngology of 1988 was dedicated entirely to the project of Maniglia.[359] A patent on the partially implantable hearing aid device was granted to Maniglia in 1991.[360] The International Symposium on Electronic Implants in Otology and Conventional Hearing Aids in Orlando, Florida, USA in November 1993 was organized by Maniglia and papers were published in the February 1994 issue of the *Ear, Nose and Throat Journal*. The February 1995 volume of the Otolaryngologic Clinics of North America on *Electronic Implantable Devices for Partial Hearing Loss* was edited by Maniglia. In his chapter, the *contactless semi-implantable electromagnetic middle ear device* is presented in detail.[361]

The corporate partner is Wilson Greatbach Ltd., Clarence, New York. This project is supported by an NIH Grant and by the Head and Neck Medicine and Surgery Foundation.

The central concept of Maniglia's transducer relies on a close distance of 1 millimeter between coil and magnet so they are not in contact. Thus the device is termed "contactless".[362,363] An air-core coil is used to drive a neodymium-iron-boron (NdFeB) magnet that is fixed to the body of the incus. The driving coil consists of 52 AWG copper wire with 2669 turns and with 875 ohms resistance. Initial illustrations showed a screw drilled into the incus body to hold down a magnet. To the best of the author's knowledge nobody had demonstrated that a screw could be drilled into the incus without splintering this delicate ossicle or causing severe cochlear damage.[364] According to Maniglia, trials with the KTP and CO2 lasers were also not effective. The fixation has been changed to a cement. The cement is called Metabond® and is used in dental surgery in Japan (Sun Medical Co., Kyoto, Japan). The US Food and Drug Administration (FDA) is in the process of evaluating Metabond® for use in the middle ear.[365] Metabond® is currently approved by the FDA as a Class II dental device for cementing titanium to dentine in dental surgery only.

Signal transmission through the intact skin is achieved by AM radio frequency. The RF receiver and electronic circuitry lie beneath the external antenna.

All parts of this implant system are encapsulated into titanium, laser welded and hermetically sealed. The Neodymium-Iron-Boron magnet weighing 28 milligrams is hermetically sealed in a helium atmosphere in the titanium case. The system allows a maximum gain of 45 dB. The gain measured in cats by ABR was 40 dB at most.

The transducer acts only in a push mode. The restitution of the incus is left to the elastic forces of the ossicular chain. The driving coil is in a titanium

housing with a diameter of 5 millimeters. A device of 5 mm width in the epitympanum appears to be the uppermost limit. One would rather choose a size of 3 to 4 mm because the tegmen often prolapses inferiorly narrowing the access to the ossicles.

In animal experiments with cats, the normal sound conduction was dampened by 5 dB in ABR click thresholds by the placement of the Neodymium-Iron-Boron magnet of 28 milligrams.

Initially, the external part was to be placed into the external ear canal. This concept was abandoned due to the limited volume of the canal as well as to potential skin problems related to occlusion. Now the external part is to be put into a retroauricular skin pocket. It remains to be proven that this pocket will not result in chronic skin problems. The retroauricular crease easily leads to infections and the formation of sebaceous cysts.

Human trials have not been initiated yet due to technical problems with the antenna of the device.[366] In the chronic cat experiments, the polytetrafluoroethylene-coated platinum iridium antennas broke at the feedthrough connection. The titanium encasements were covered with a thin layer of middle ear mucosa. No leakage had occurred.

Maniglia also discussed the possibility of a percutaneous plug that would eliminate the need of the transmission electronics with radiofrequency. That would lead to an increased power supply to the implant. However, the Swedish BAHA titanium screw must be approved by the FDA first before any percutaneous plug would be tried.

The FDA has approved this device for limited clinical trial.The contactless electromagnetic implant system has been described at several conferences including the conference on Transplants and Implants in Otology in Bordeaux, June 1995.[367]

Cleveland: Lenkauskas

Another active group in Cleveland Ohio was founded by Lenkauskas, who also teaches at the Case Western University in Cleveland Ohio. He presented his concept of a totally implantable hearing aid in 1991.[368] This interesting set-up consists of a motion sensor, an electromagnetic silicon actuator, and an implanted amplifier. The battery is placed in the neck or in the axilla until a way is found to use the electric energy generated by the body. The motion sensor is connected to the incudo-malleal joint to pick up vibrations.[369,370] The actuator drives the inner ear fluids of the posterior semicircular canal. This has been tested in dogs' ears. The device has not been constructed for implantation in human temporal bones, nor in human ears.

The actuator chosen for this set-up has also not been tested in temporal bones. In the dog model, a voltage of 4.6 V yielded an output level monitored by

ABR of 105 dB (HL). At lower voltage levels 0.8 V rendered 90 dB (HL) and 0.01 V still 60 dB (HL).

The Company involved in the production of coils and magnets is Wilson Greatbach LTD of Clarence, New York.

Phase shifts and interference with this device have not been discussed. The delay of sound pick-up to vibration of the labyrinth fluid travelling to the cochlea will be substantial.

2.2.3.4 Detroit/Copenhagen

Kartush of the Michigan Ear Institute and Tos of the Gentofte Hospital in Copenhagen together with the company Smith-Nephew-Richards have also been active in the invention of an electromagnetic hearing aid. In 1990, a US patent by Ashtiani and Cendes was assigned to Richards Medical Company.[371] A disc shaped magnet is inserted into the head of a PORP residing on the stapes head. The magnet is driven by a coil in the external ear canal.

Another patent assigned for Richards is an ear level device.[372] The coil is located in the ear canal with the magnet attached to the tympanic membrane or with the magnet incorporated into a TORP or PORP. Again, the coil and magnet are far away from each other which requires enormous power for a gain that will help the hearing impaired. Kartush et al.[373],[374] presented preliminary results of clinical trials. Kartush[375] also presented findings, which led to approval by the FDA to start a pilot study with 10 patients with sensorineural hearing loss. The target magnet was implanted beneath the tympanic membrane.

In Denmark, Tos[376] implanted nine patients with magnetic TORPs and PORPs by 1993. Reports could only be given on six patients because one patient suffered a stroke and could not comply, and in two patients the implant was extruded. Gains of up to 60 dB were measured. The frequency range included 125 Hz and 8 kHz permitting amplification in frequencies where conventional air conduction hearing aids are less effective. The patients reported excellent sound quality. Their use in profoundly hearing impaired patients is anticipated.

This magnetic implant incorporated in a PORP or TORP might be indicated in the diseased middle ear where ossiculoplasty is needed anyway. These infected ears, however, are prone to reject implants of any type and material. Due to their chronic ear disease, including ventilation problems, they might cause tympanic membrane retractions and middle ear effusions leading to repetitious infections of the middle ear cavity. In the healthy middle ear with intact ossicular chain, one would need to be careful not to destroy the chain in order to preserve the conductive apparatus for conventional air conduction hearing aids.

Any technology that follows this approach will be more successful than the types of magnetic implants in PORPs and TORPs.

Furthermore, in the small group of implanted patients, two implants were already extruded. PORPs and TORPs are prone to be extruded and with additional vibration acting on them by the driving coil, these implants are expected to be extruded in an even higher percentage. These patients will also never be able to undergo any MRI examination. These implants are only wedged in the ossicular chain and are not fixed to it.

One of the major benefits for patients implanted with these magnetic devices is the total lack of feedback.[377] This allows higher output levels, especially in the higher frequencies. Gains at 4 and 6 kHz were significantly better compared to the previously used conventional air conduction aids. Performance in noise was also found to be superior in the implant group. All patients preferred their implant over their air conduction hearing aid.

2.2.3.5 Stanford

Two leading otologists at Stanford, Perkins and Goode are also involved in the company ReSound that produces high quality digital hearing aids. ReSound is concentrating its efforts and resources on a new product called the EarLens®. Results presented in 1992 on the first seven patients showed a maximum gain of 30 dB. In the ear lens project the coil is positioned in a neck loop at a substantial distance from the TM. This distance requires an energy input of about 1 Ampère in order for the electromagnetic field to reach the magnet on the ear drum.

Experiments with magnets on umbo and magnets in a disc placed on the central part of the TM around the umbo are currently in clinical trial in the EarLens® system.[378-381] Magnets placed on the tympanic membrane have been carried by individuals for over a year.

The device in its current form will only help people with mild or mild to moderate hearing loss. Placement of the disc causes hearing loss due to attenuation by the mass effect. This loss ranges between 5 to 10 dB. Goode and Perkins present a regular course at the yearly American Academy of Otolaryngology-Head and Neck Surgery[382,383] on the progress of these electromagnetic implantable devices.

Initially the coil was to be placed in an in the ear-canal hearing aid after widening of the osseous canal. Perkins termed this surgery "The Canal Recontour Procedure".[384,385] However, severe problems with cases of cochlear damage by drilling forced a halt to this project. According to Goode's presentation in 1993 various locations of the driving coil have been tested. In order for the device to be effective it must be placed within 4 mm to the magnet with the coil in the external ear canal. The skin of the ear canal is increasingly sensitive the closer the distance to the tympanic membrane. Any device in the EAC cannot be placed closer than 3

to 4 millimeters lateral to the TM without causing significant discomfort. Patients wearing In-the-ear hearing aids that are placed deep in the EAC report unpleasant sensations not only due to the occlusion effect, but also due to close proximity to the TM. Furthermore the TM is not in a rectangular plane to the axis of the EAC. It is tilted and shifted anterior and medial leaving the fibrous annulus of the TM in the posterior two quadrants at a closer distance to any device in the EAC than the annulus of the anterior two quadrants.

Placement of the driving coil in the mastoid area was not efficient due to limited size and ineffective direction of the coil to the magnet. The coil was then placed into the necklace described above, which allows heavy material and a forceful electrification.

The ear lens maintains position stability on the tympanic membrane by residing on a film of mineral oil.[386] The patient needs to spray mineral oil into his ear canal on a daily basis. The ear lens can be kept on the tympanic membrane for an extended period of time without causing discomfort or myringitis. The occlusion effect of the ear canal is avoided with the induction coil in the necklace. The EarLens® is not visible from the outside providing good cosmetics for the patient. The main drawbacks are attenuation by the mass effect when not stimulated by the coil and limited amplification. The latter may limit success.[387]

2.2.3.6 Hannover

At the Medizinische Hochschule Hannover Germany, Thomas Lenarz is testing a piezoelectric middle ear implant. This implant is currently placed into dog ears. It drives the long process of the incus through a posterior tympanotomy opening. No research data have yet been published. The project was started in Tübingen at the time when Lenarz was cooperating with Plester. The transducer is located in the mastoid cavity and fixed by cement.

2.2.3.7 Dresden

At the University clinic of Dresden Hüttenbrink is experimenting with a drive to stimulate the round window membrane. Research in this project is ongoing. Previous research was achieved in Münster. A large body of knowledge of middle ear physiology was accumulated in collaboration with Hudde.

2.2.3.8 Bordeaux

A piezoelectric vibrator for a middle ear implant is currently being evaluated by otologists and scientists in Bordeaux. In 1993[388] and 1995 a group of the University clinic of Bordeaux[389] with Bébéar and Darrouzet presented their work on a piezoelectric drive. Their research program was started in 1989 stimulated by the results of the Japanese piezoelectric implant and first results were published in the French literature in 1991 and 1993.[390-392] The piezoelectric implant was chosen over the electromagnetic implant for its structural simplicity, excellent frequency fidelity, and low energy consumption. The bimorph assembly consists of lead, zyrcon, and titanium.

In a first stage, the Bordeaux team tested the piezoelectric drive in guinea pigs with implantation onto the round window membrane.[393] Measurements of ABR confirmed frequency response from 250 Hz to 16 kHz. In vitro tests confirmed a flat frequency response for this frequency range in stimulation levels from 30 to 1000 mV. The energy consumption is high.

This group has chosen a piezoelectric ceramic with a resonance beyond the frequency range of 250 Hz to 10 kHz because these drives have an inherent resonance that can be disturbing. This resonance was the major reason for Maniglia and his group to prefer the electromagnetic over the piezoelectric drive.

In the Bordeaux system, the piezoelectric bimorph is passed through a posterior tympanotomy.[394] The incudo-stapedial joint is separated and the drive is slipped in-between. In guinea pigs, no cochlear damage could be recorded after implantation of the device. No human testing has been performed yet. The piezoelectric bimorph has a length of 5 millimeters. The entire length of the device will be 13 millimeters, with a width of 1.6 millimeters, and a thickness of 0.6 millimeters. The drawings provided (1995) display a rather crude model of the bayonet-shaped implant without any possibilities for adjustment of length or direction. For testing of the transducer, a hydrophone is used. Frequencies ranged from 0.5 kHz to 8 kHz with Voltages from 250 mV to 2.5 Volts compatible with biomedical use. 250 mV resulted in an equivalent sound pressure level of 85 dB SPL and a maximum of 110 dB SPL with stimulation by 2.5 V with a linear increase.

Energy transfer to the piezoelectric transducer will be by a percutaneous connection. Technical shortcomings have limited their success so far. The main limitation of this system is the small size of the transducer.

2.2.3.9 Charlottesville, Virginia

At the University of Virginia, USA in Charlottesville[395,396] basic research on stimulation of the round window membrane was started in 1989. A small permanent magnet is placed on the round window in an animal model leaving the ossicular chain intact.[397] An electromagnetic stimulation coil is placed behind the

ear. Evoked brainstem responses are measured. Ossicular problems are circumvented with this approach. No further information is available at this point.

2.2.3.10 Columbus, Ohio

At the Ohio State University College of Medicine in Columbus, Welling and Barnes have tested the possibility stimulating the cochlea by acoustic stimulation of the semicircular canals.[398] This approach is similar to the fenestration procedure popularized by Lempert in the 1950s. A piezoelectric vibrator is attached to the fenestration. The piezoelectric driver in this program displays a resonance frequency at 3 kHz. This is unfavorable for use in humans where frequencies between 1 and 4 kHz are most important for speech recognition. The implant has been tested in cats by measuring cochlear microphonics.

A single patient was implanted with the transducer when undergoing surgery for intractable benign paroxysmal positioning vertigo. There are only preliminary data provided and the authors voice concern for sensorineural hearing loss due to fistulization as well as bony closure of the fenestration.

2.2.3.11 Others

In Zagreb, Croatia, Matutinovic and Matutinovic[399] experimented with implanted magnets on the tympanic membrane in humans. They also presented a case with magnet placement onto the stapes footplate. However, their report is anecdotal.

At the University Clinic of Köln Germany, Stennert is exploring possibilities to replace the entire middle ear by an artificial middle ear. This project is called CoMEP, which stands for Complete Middle Ear Prosthesis. The tympanic membrane is made of Goretex. A rod within a metal cylinder acts as a columella to drive through the stapes footplate. This is only hypothetical and many problems will have to be solved. The crucial tolerance for a piston to reach into the vestibule should not be more than 0.5 mm.[418] Once an artificial middle ear of this sort becomes usable, fitting it with a transducer would become a possibility.

There may be several other scientists working to solve the problems of driving the middle ear. Due to the overwhelming financial benefit of a successful product, secretive behavior without publications has been commonplace in the field of implantable middle ear hearing devices.

3. Anatomy and physiology of the human middle ear

The basis for any surgery or implantation of a device into the middle ear is thorough knowledge of middle ear anatomy and physiology.

3.1 History of middle ear anatomy

According to Wever and Lawrence[400] it was Berengaro da Carpi who discovered two of the three ossicles in 1514. Later they were described in detail by Vesalius in Basel, Switzerland in 1543. He gave the malleus and incus their present names. Then Ingrassia (1546) discovered the stapes and the oval and round windows of the cochlea. Fallopius (1561) carefully described the ossicles and their articulations, and also distinguished the two principal divisions of the inner ear and gave them their present names of cochlea and labyrinth.

Eustachius (1564) described the tensor tympani muscle and the tube connecting the tympanic cavity with the pharynx, now known by his name. The stapedial muscle was first accurately described by Varolius in 1566.

The first systematic account of the transmission of sound by the ear was presented by Coiter in 1566 in his book *De auditus instrumento*. In 1683 it was the French anatomist and surgeon Joseph Guichard DuVerney who described physiological details in his book *Traité de l'organ de l'ouie* based upon his experiments with sound. He strongly favored the ossicular route of sound conduction over the previous theory of the aerotympanic pathway. He also described bone conduction correctly tracing vibrations from the jaw bones to the temporal bones. Only in 1760, Cotugno discovered that the cochlea and labyrinth are filled with fluid and not with air as thought before. Then around 1830 the compound microscope, which had long been known in principle, was made into a practical instrument for research through improvements in the art of lens making. Reissner now discovered the membrane named after him and Corti in 1851 described the complex sensory structure lying on the basilar membrane.

3.2 Tympanic membrane

The tympanic membrane is an oval shaped structure separating the external auditory canal from the middle ear. It transmits airwaves into mechanical vibrations of the ossicular chain. The membrane consists of an outer squamous epithelium, a middle layer of connective tissue and an inner layer of mucous lining. In sensorineural hearing loss the tympanic membrane is without pathology.

3.2.1 Measurement of vibrations

The recent development of the OLIT (Optical Laser Interferomic Tympanometer) coupled with the software TYMPTEST which uses FFT and multi-averaging techniques through a standard AT compatible computer facilitated the development of a new implant.

First, the OLIT has facilitated the rapid accumulation of vast amounts of data on the physiologic characteristics of the hearing mechanism.

Second, the OLIT is capable of measurements in the magnitude of nanometers. Such previously unheard of dimensions of measurements have made scientists well aware that the making of an implant capable of transmitting such small movements to the cochlea is within theoretical and practical possibility. This theory was validated with the construction of relatively crude prototypes of electromagnetic middle ear implants.

A previous system used to measure vibrations of the middle ear is the video measuring system as described by Guinan and Peake in 1967.[401]

3.2.2 Vibration pattern of the tympanic membrane

The tympanic membrane moves most in the posterior-superior quadrant. The anterior-superior quadrant is next, followed by the posterior-inferior quadrant and leastly by the anterior-inferior quadrant and the pars flaccida. This pattern of vibration is greatly dependent upon frequency. The acoustic information is only transmitted, however, by the malleus handle led by the vibrations of the tympanic membrane.

The umbo presents a substantially higher peak-to-peak displacement than the short process of the malleus. This supports the theory of a rotational axis in the epitympanum or higher (Hüttenbrink 1992). Hüttenbrink's measurements have led to a new understanding of movements of the ossicles.[402],[403] He differentiates between large movements due to static pressure changes where sliding movements of the ossicles prevent damage to the cochlea, and micromovements for sound transmission.

Movements of the tympanic membrane in changing sound pressure levels can be studied using Laser-Doppler technology. Previously, other interferometry technology was used.[404] Kurokawa recently published results on movements of the tympanic membrane and treatment of flaccid areas by Holmium Laser in an experimental temporal bone study.[405] In live human experiments, Laser beams can not only be directed onto certain points on the tympanic membrane, but also they can be directed in a sweeping movement over large areas of the tympanic membrane. Modern Laser technology allows reflection on the squamous epithelium of the tympanic membrane without the need for reflective substances. Previously, reflective points such as 3M-reflective tape had to be used for points of reference. This artificially stiffened the tympanic membrane. The collected

information can then be analyzed. The fast movements of the membrane can be slowed down to simulate the action of the membrane, similar to the visualization of vibrations of the laryngeal vocal folds by stroboscopic technique.

Volume displacement of the entire tympanic membrane measured under static pressure changes agrees well with volume displacement data in the literature on tympanometry. There is a linear relationship between umbo displacement and volume displacement.[406]

3.3 Malleus

The malleus is attached to the tympanic membrane. It receives the vibrations from the tympanic membrane and conducts them to the incus with which the malleus articulates in a true joint.

The three ossicles are joined by means of articular ligaments and the system is suspended in the middle ear by eight other ligaments. Two of these ligaments lead to muscles: the stapedial muscle and the tensor tympani muscle.

3.4 Incus

The incus connects with the malleus and the stapes. In chronic middle ear disease the incus is the ossicle with the most common destruction. The incus is ideal for connection of a middle ear implant because of its location within the middle ear. It lies towards the mastoid and antrum as well as towards the superior-posterior quadrant of the tympanic membrane.

3.4.1 Malleus-incus relationship

Early physiological studies on middle ear mechanics stated, that the malleus and incus rotate around an axis within the ossicles. Recent research has revealed that this is only true for low frequencies where the axis of rotation points from the anterior mallear ligament to the short process of the incus.[407] The vibration of the incus is not parallel to the malleus for all frequencies. At lower frequencies of up to 1 kHz, the vibrations are mainly parallel. Above 1 kHz, the incus vibrations do not follow the movements of the malleus due to slippage in the malleo-incudal joint. Various measurements have proven this slippage. This difference of amplitude has to be taken into account if an implant would be wedged between the malleus and incus. Phase shifts could hamper sound transfer to the stapes. If the implant is squeezed between the malleus and incus with increased tension this slippage might be reduced. Recent measurements by Goode et al. show slippage in the ossicular lever system explaining part of the "roll-off" above 1 kHz (Fig.24).[408]

This would explain some of the findings of earlier physiologists. The tip of the long handle of the malleus - the umbo - does not move in a translational displacement. Interferometry and three dimensional analysis have instead revealed

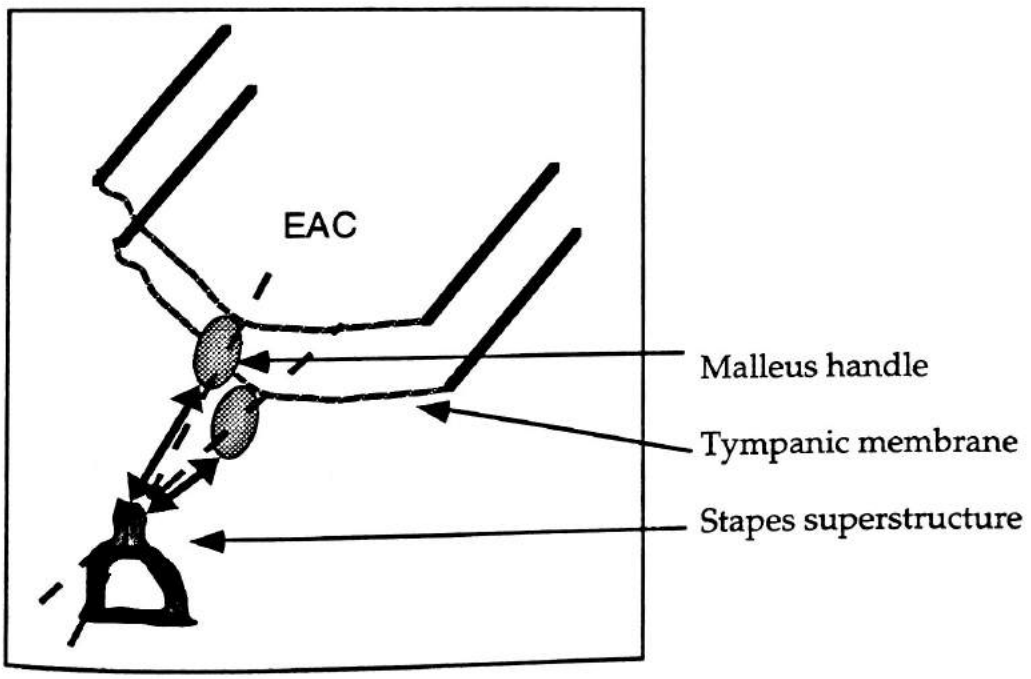
an elliptical path.[409] The shape and inclination of this plane changes with frequency.

Recent experimental studies on the function of the incudo-malleal joint highlighted the importance of using fresh and moist temporal bones. The incudo-malleal joint seems to be especially sensitive to a dry atmosphere when the joint capsule tightens. This leads to loss of the sliding movements within the incudo-malleal joint. The malleus and incus then act as one block. This would explain many of the earlier findings of middle ear physiologists.

Hüttenbrink[410,411] showed the importance of the gliding action within the incudo-malleal and the incudo-stapedial joints. These gliding actions decouple the inner ear from the middle ear and thus protect the inner ear from destructive excessive movements of the tympanic membrane and malleus. Hüttenbrink[412,413] also showed that the incudo-malleal joint is of importance in reducing the translation of static air-pressure changes onto the stapes. In temporal bone experiments, artificial fixation of the joint led to increasing pressure on the stapes footplate. The same phenomenon happens when temporal bone specimens become too dry.

Anatomical distances between malleus handle and long process of the incus vary substantially depending on the degree of pneumatization of the temporal bone. The crucial distance most often is 2.5 mm but it may be as short as 2.0 mm.

Fig. 6: Variations of distances and angles between malleus handle and stapes superstructure.



EAC = External Auditory Canal

3.5 Stapes

The stapes superstructure is of paramount importance in the concept for a middle ear implant because middle ear implants may be attached onto the stapes superstructure - as in the Japanese piezoelectric implant system - or in the incudostapedial joint. In order to develop a middle ear prosthesis that attaches to the stapes, exact measurements of the stapes superstructure must be known.

It has been proven that direct stimulation of the stapes yields the highest cochlear input (Goode 1994). Data collected on measurements of the stapes superstructure have appeared in a separate publication by the author of this thesis.[414]

3.5.1 Anatomy of the stapes superstructure

In previous works of anatomy details of the stapes superstructure are not included in the 1992 revised edition of Donaldson et al.'s[415] *Surgical Anatomy of the Temporal Bone*, as well as in Sarrat et al.[416] and Olszewski[417]. Common interest in anatomy and morphology of the stapes revolves either around the footplate as the link to the inner ear, or the stapes head as part of the incudo-stapedial junction.[418,419] Gundersen[420] (1971) described detailed information on the movement and function of the ossicular chain and Hough[421] on a wide variety of middle ear malformations seen during surgery of the stapes.

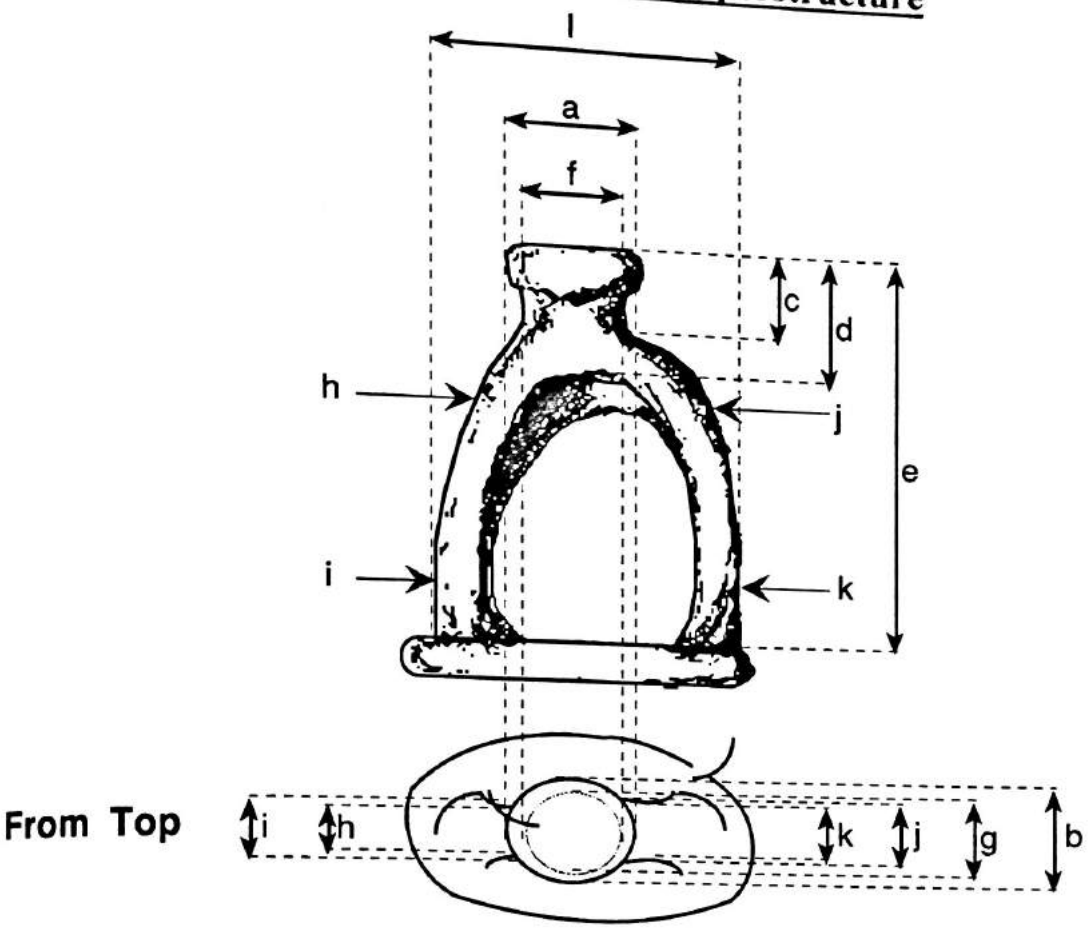
According to Schuknecht, the distance between the medial surface of the long process of the incus to the surface of the stapes footplate is 4.0 mm in males and 3.75 mm in females.[422] The position of the stapes in the oval window is of importance to the surgeon.[423,424] In PORPs and incus replacement prostheses, only the dimensions of the stapes head are necessary such as for the clothespin shaped Krause modified Schuring ossicle-cup prosthesis.[425,426] Hüttenbrink has developed a new PORP of gold that fits precisely around the stapes superstructure.[427] The flanges embrace the stapes crura and can be gently clamped around them.

In the process of designing an electromagnetic middle ear implant, further information on dimensions of the stapes head, its neck, the width of the shoulders, and the bases of the anterior and the posterior crura, as well as the width of the entire superstructure had to be acquired.

3.5.1.1 Material and methods

Ten human stapes were extracted from fresh temporal bones. All specimens were from male patients with an average age of 70 years ranging from 62 to 81 years. Measurements were obtained under the microscope with a precision caliper of Mitutoyo Company, Japan with accuracy to one hundredth of a millimeter. For each site two measurements were obtained and the mean value recorded.

Fig. 7: Measurements of the stapes superstructure



Legend

a : diameter of stapes head parallel to axis of footplate
b : diameter of stapes head perpendicular to axis of footplate
c : surface of head to shoulders
d : surface of head to opening of superstructure
e : surface of head to surface of footplate
f : diameter of stapes neck parallel to axis of footplate
g : diameter of stapes neck perpendicular to axis of footplate
h : thickness of anterior crus at shoulder
i : thickness of anterior crus near footplate
j : thickness of posterior crus at shoulder
k : thickness of posterior near footplate
l : maximum width of superstructure

3.5.1.2 Results

1. Stapes head:

The stapes head displays a wide variety of shapes. It can be small and flat and not wider than the neck, or it can be tilted and wide with a rim of excessive bone.

Commonly, only the distance from the head to the undersurface of the stapes footplate is measured for height. It was felt that the height of the superstructure to the surface of the footplate is more important than to the undersurface of the footplate because ossicular reconstruction with a TORP or interposition in the replacement of the stapes depends on the distance to the lateral surface of the footplate. This mean distance is 3.19 mm (2.91-3.45) with a standard deviation of 6%. This distance was the most constant among all the measurements obtained.

2. Stapes neck:

The stapes neck consists of the bony structure between the head and the crura. In some specimens the neck is less distinguishable than in others.

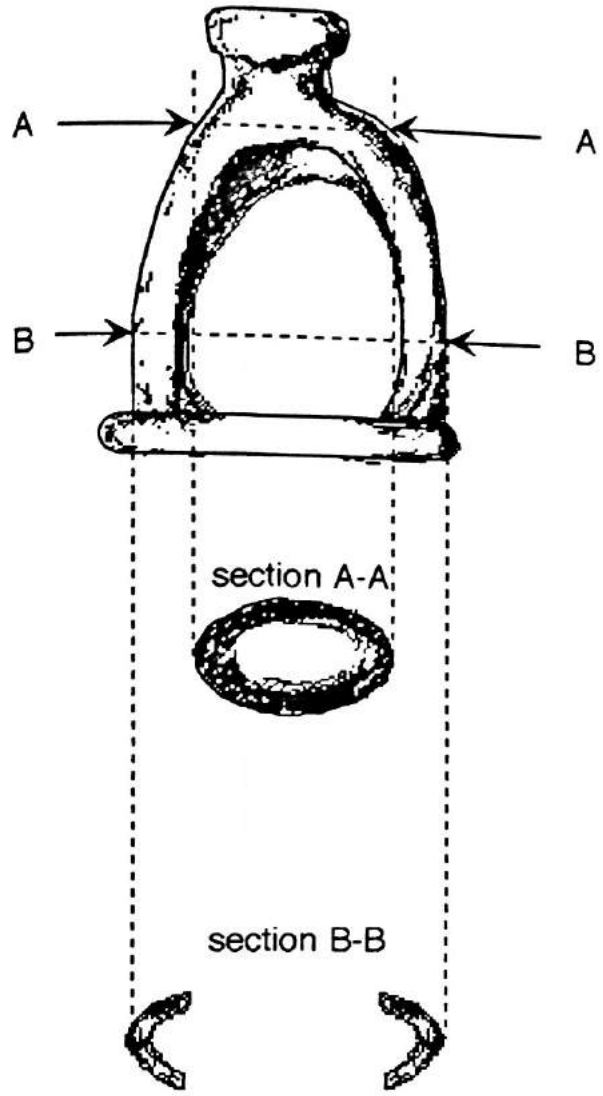
The neck displays a long oval diameter. On average, the neck is 0.19 mm thinner than the head in the short diameter.

3. Stapes crura:

The anterior and posterior crura form a hollow arch that connects the head and neck of the stapes to the footplate. The crura are not symmetrical. The anterior crus is straighter and more delicate and the posterior crus is more curved and stronger. In crossection, the crura show a half-moon shaped architecture that is hollow towards the opening (Fig.8).

This asymmetry of the anterior and posterior crus might be due to unequal stress put on the stapes. The long process of the incus does not act in a precise right angular axis to the axis of the stapes superstructure but it leans more toward the posterior crus. Furthermore, the axis of peak-to-peak displacements does not seem to act in an axis through the stapes head and through the middle of the stapes footplate but rather more inferior towards the annular ligament near the ponticulus. This theory would explain the unequal strengths of the superior and inferior arches of the superstructure (Fig.9). In conclusion, the main stress on the stapes acts posterior and inferior.

Fig. 8: Crossections of crura



Section A-A : hollow arch of superstructure
Section B-B : hollow crura

Fig. 9: Superior and inferior crural arches of stapes superstructure

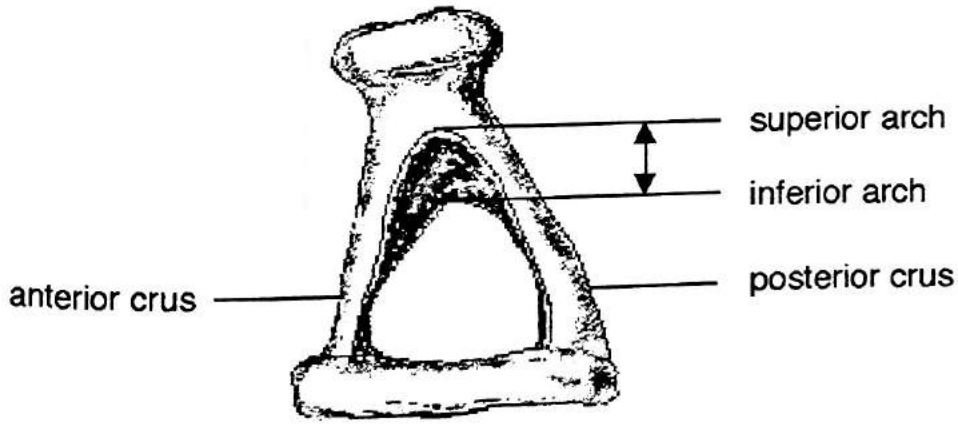
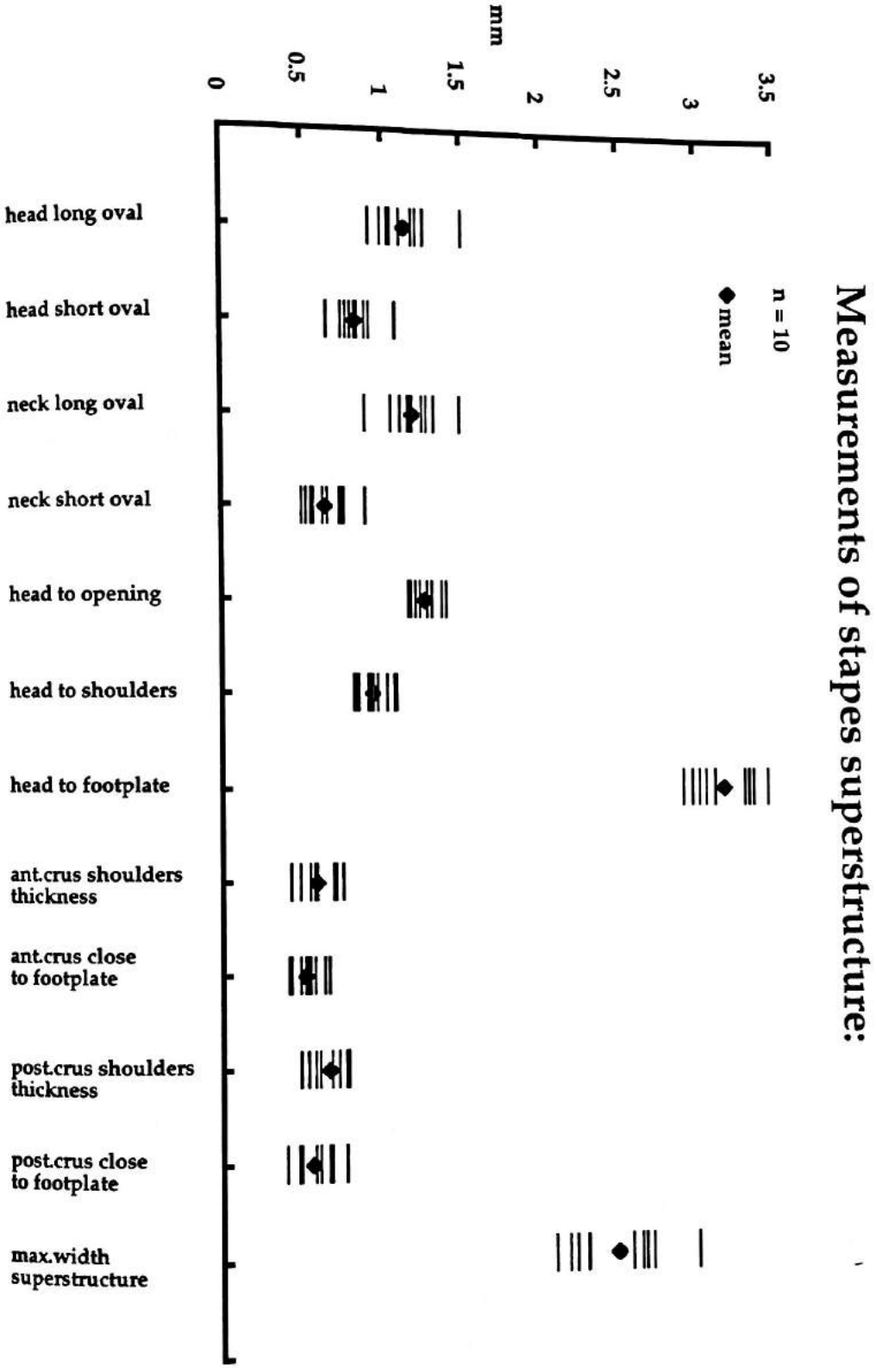


Table 1: Measurements of the stapes superstructure



The dimensions of parts of the superstructure are:

1. Stapes head 1.14 mm (range 0.91-1.49) in diameter parallel to the axis of the footplate and 0.83 mm (range 0.65-1.08) perpendicular to it.
2. Stapes head to shoulders 0.93 mm (range 0.81-1.07), head to foramen 1.26 mm (range 1.15-1.39), and head to lateral surface of stapes footplate 3.19 mm (range 2.91-3.45).
3. Neck width parallel to the axis of the footplate 1.18 mm (range 0.88-1.47) and 0.64 mm (range 0.48-0.88) perpendicular to it.
4. Anterior crus 0.58 mm wide (range 0.41-0.74) at the shoulder of the arch, 0.51 mm (range 0.39-0.65) closer to the stapes footplate.
5. Posterior crus 0.65 mm wide (range 0.46-0.77) at the shoulder of the arch and an average of 0.55 mm (range 0.38-0.75) closer to the stapes footplate.
6. Maximum width of entire superstructure near footplate 2.48 mm (range 2.06-2.98).

3.5.2 Discussion on the measurements of the stapes superstructure

The stapes superstructure is the most delicate part of the ossicular chain. In high-resolution CT-scanning in only 70% of middle ears was the stapes visible depending on the air surrounding it. Due to the superstructure's small volume and bone density, detection and differentiation of pathological situations in CT-scanning remains limited.

In their paper in 1988, Sarrat et al. described morphological variations of the ossicles.[428] They found a great variety of individual shapes with more variations in the malleus and the stapes than the incus. The geometrical parameters show distinct differences between the anterior and posterior crus. This would confirm our findings as discussed above. We found an asymmetry of the arches that form the opening with a stronger arch on the inferior side compared to the superior side in 8 out of 10 specimens. Anson and Donaldson[415] also describe the superior crural arch as somewhat greater in circumference than the inferior one (Fig.9).

The incudo-stapedial joint is a true diarthrodial articulation. According to Marquet (1981), the ligaments of the joint are unequal with more laxity and smaller dimensions in the antero-inferior part than in the postero-superior part.[429] These differences might be due to uneven exertion in the incudo-stapedial joint, which supports the theory of uneven stress on the stapes by the incus.

In 1992, Sarrat et al. analyzed the histologic pattern of the bone in human ossicles.[416] The stapes is made of a delicate bone, whose most compact structure corresponds to the head and tip of the crura. Cartilaginous nodules were found in the crura as well as the footplate, but more so in the incus and malleus. Cavitations with bone lacunae were found to increase with age. Anson and Donaldson describe an increase of variations of the stapes with age. In a retrospective study on stapes surgery, we found age-related differences in

functional outcome that might be due to previously unknown age-related structural differences of the ossicles.[430-432]

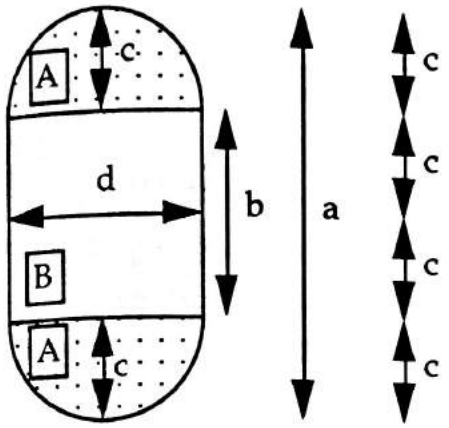
Measurements of the stapes superstructure vary with standard deviations between 6% and 23%. The least variations were found in the distance from the surface of the stapes head to the shoulders, to the foramen, and to the upper surface of the stapes footplate. The most variations were seen at the posterior crus near the footplate.

The position of the attachment of the stapedius tendon is variable according to Marquet. In 6 percent of specimens, it is attached to the lenticular process of the incus, in 29 percent to the capsular ligament, in 62 percent to the head of the stapes, and in only 3 percent to the posterior crus of the stapes. In this work we did not include data on the stapedial tendon.

3.5.3 Stapes footplate

The anterior and posterior crus stand on the stapes footplate like an arch of triumph on a platform. The footplate is suspended in the oval window by the annular ligament. The area of the stapes footplate is of interest in the design of any implant or TORP that connects directly to the footplate. Furthermore, the footplate relates to the cochlear impedance because it connects the air filled space of the middle ear with the fluid filled space of the inner ear.

Fig. 10: Area of stapes footplate:



Assuming that:
- the stapes footplate is divided into four equal parts
- the ends of the stapes footplate are semi-circles
- one part equals the radius of the semi-circle at each end

Then:
$a = 2b = 4c$
$b = 2c$
$c = a/4$
area $A = (\pi r^2) / 2 = (\pi c^2) / 2 = (\pi (a/4)^2) / 2$
area $B = b\,d = 2\,c\,d = a/2\,d$

Total footplate area $= 2A + B$

Values in millimeters: (*values* a *and* d *from Kirikae, 1959*)[103]

$a = 2.96$ $b = 1.48$ $c = 0.74$ $d = 1.33$
area $A = \pi (a/4)^2 / 2 = 0.86\ mm^2$
area $B = a/2\,d = 1.96\ mm^2$

Total footplate area
$= 2A + B = 2\ (0.86\ mm^2) + 1.96\ mm^2 = \mathbf{3.69\ mm^2}$

3.5.4 Vibration mode of stapes

The vibration mode of the stapes is still controversial. According to Békésy[433], the main vibration mode of the stapes is a rotation around an axis at the posterior portion of the annular ligament in a hinge-like movement in experiments when the sound intensity is kept moderate. This corresponds to the anatomical finding that the posterior portion of the annular ligament is thicker and narrower than the anterior portion.[434] At input sound levels of above 140 dB SPL, the vibration mode changes and the stapes moves around an axis corresponding to a line connecting the anterior and posterior crus in a lengthwise axis. Kobrak[435]

noted the same findings at high intensities. However, there is minimal clinical relevance to these findings at high intensities, because such high sound pressure levels would damage the ear.

By contrast, Kirikae (1959) described the vibration mode of the stapes as a combination of three motions: a piston-like movement, a hinge-like movement around the posterior axis that Békésy had demonstrated, and a rotatory movement around the long axis of the footplate. Kirikae further showed that the ratio of displacement amplitudes between the anterior and posterior edges of the stapedial footplate was 3:2 at 0.4 and 0.8 kHz. Gundersen (1971) studied stapes vibration in temporal bones with intact cochleas using a contacting electro-magnetic device and found that the stapes moves like a piston up to 2 kHz. Above 2 kHz the stapes moves in a "mere uneven manner" with significant individual variations.

In order to apply to these physiological movements of the stapes, the axis of vibration transmitted by an implantable transducer should direct in the main axis of the stapes and less in a hinge-like fashion like the piezoelectric device of Yanagihara and Suzuki.

In order to measure changes of sound transmission produced by middle ear surgery Hüttenbrink and Hudde[436] used a hydromechanical system for laboratory use that is implanted into the cochlea. This hydrophone transmits waves between 100 Hz and 10 kHz.

Manipulations on the stapes, as in removal of cholesteatoma matrix in the oval window niche, might cause disruption of the annular ligament.[437] A leakage of perilymphatic fluid only occurs after a complete rupture of all fibers at one location. Loading of the stapes with 35 mg as proposed in the electromagnetic implant in this thesis should not cause disruption of the fibers of the annular ligament.

Excessive drilling in the temporal bone might cause temporary threshold shifts.[438] These may have already resolved by the time the packing is removed from the ear. For the implantation of an electromagnetic middle ear implant, drilling will not exceed drilling for conservative mastoidectomy.

Changes of static air pressure causes displacement of the stapes footplate.[439] This displacement is limited in the intact ossicular chain to a mean of 232 microns induced by static air pressure changes in the external ear canal of plus-minus 400 mm H_2O. These movements however can be substantially larger in implanted stapes prostheses.

3.6 Axis of rotation of the ossicles

Kirikae (1959) described the axis of rotation of the ossicles to run from the lowest portion of the ligamentum mallei anterius adjacent to the tympanal wall through the malleus-incus-complex to the short process of the incus. Thus, the long process of the incus with its connection of the lenticular process to the stapes

travels the greatest distance in vibration. When attaching an artificial vibrator to the incus, it should therefore be positioned as distally on the long process as possible (Fig.35).

Hüttenbrink[440] challenges the previous concept that the ossicles rotate around the axis running through the short process of the incus. This axis is only important in changes of static ambient air pressure when the malleus rotates around this axis. In acoustic vibrations, however, the imaginary rotational axis lies outside the ossicular chain. Thus the malleus-incus-stapes complex moves in a more piston-like action. From his research on micromechanics of the middle ear, Hüttenbrink[441] derived its significance for middle ear prostheses. He stressed the importance of a firm coupling of implants to the ossicular chain for optimal sound transfer.

3.7 Impedance of the cochlea

Any mechanical middle ear implant will have to consider the impedance of the cochlea in order to judge the energy required to drive the cochlea. The fluid filled space of the cochlea leads to resistance other than the conduction system of the ear drum and the ossicles that are surrounded by air.

Lately, it was Goode (1994) [442] who measured the impedance of the stapes and the cochlea to be approximately 0.5 million acoustic ohms (cgs) above 1 kHz. Below 1 kHz the impedance is less than this. He also found that the spring constant for the cochlea is 7.0×10^2 N/m.

3.8 Action of the middle ear muscles

Hüttenbrink[443-445] among others has studied the anatomy and physiology of the human middle ear. In his experiments with fresh human temporal bones, he imitated action of the tensor tympani muscle and the stapedial muscle and measured ossicular displacement. The tensor tympani muscle pulls the umbo inwards for a distance of about 100 micrometers. Due to the gliding motion in the malleo-incudal joint, the stapes is pushed inwards for about 10 microns. Additionally, the stapes is displaced anteriorly, antagonistic to the pull of the stapedial muscle. Thus the tensor tympani muscle stiffens the ossicular chain.

The stapedial muscle pulls the stapes backwards, lifting the anterior crus outwards and pushing the posterior crus inwards. Contraction of the stapedial muscle pushes the malleus-drumhead complex outwards. As such, the stapedial muscle counteracts the tensor tympani muscle. The stapedial muscle thus causes a shift in the incudostapedial joint which in turn reduces sound conduction to the cochlea.

4. Development of a new electromagnetic hearing aid

4.1 Planning

4.1.1 Aims for the semi-implantable middle ear hearing aid

In the planning and development for a new middle ear hearing aid, the following aims were chosen:

1. Frequency response: flat response by transducer, minimal resonance within amplified frequencies, good signal-to-noise ratio
2. Efficiency: high efficiency transducer
3. Energy consumption: low to prolong battery life
4. Transmission external to internal unit: with minimal attenuation
5. Sound: high fidelity
6. Otologic surgery: simple, straightforward, reliable
7. Price: as low as possible, to allow insurance coverage and to make it available to a large number of patients

4.1.2 Questions

Initial questions to be answered in the research for an implantable hearing aid included, among others, the following:

- Material of magnet: Samarium-Cobalt or Neodymium-Iron-Boron
- Size and weight of magnet
- Type of induction system
- Shape and material of coil
- Location of induction coil: in ear canal, behind the ear, or at further distance
- Relationship of coil to magnet
- Improvement of performance by improved coil-magnet concept
- Energy delivery to the implant
- Type of fixation of the device on the ossicles
- Necessity of incus removal
- Combination of implantation of device with middle ear surgery
- Power sources
- Performance of electromagnetic induction systems
- Involvement of a hearing aid company
- Patent situation in the US and worldwide
- FDA-regulations for clinical testing
- Possibility for clinical trials in Europe

4.1.3 Choice of transducer system: magnet and coil

One of the most frequent applications of an electromagnetic technique is in loudspeakers. Initially, the magnet in a loudspeaker was fixed to the speaker membrane, which was then moved by the field of a fixed coil. The distance between coil and magnet should be as small as technically possible preferably in the range of 1 micrometer. The parts should not touch because this would cause distortion of the sound produced and would lead to the disruption of the coil wire destroying the speaker. The drawback of the moving magnet was the weight and bulk of the magnet itself. Inertia increases with added weight and results in decreased energy output. The alternative technique was therefore developed keeping the magnet in its place and moving the coil around it. This "moving coil" system is now widely applied in speakers. The coil is lighter than the magnet, which decreases inertia.

In a middle ear implant, dimensions are very limited. After removal of the incus an implant of 9 millimeters in diameter could theoretically be placed in the middle ear cleft between the stapes and the malleus. This however would be far too large to be supported by the small stapes. A reasonable size for a middle ear implant would be within 3 mm in diameter. Furthermore, the ossicular chain should be left intact to permit physiological sound transmission as provided by a conventional hearing aid. Within the limited dimension of 3 mm, the magnet, coil and encasement will need to be incorporated. Technical difficulties arise in the construction of such an implant. The distances in a moving magnet or a moving coil system would be very small with very limited tolerance for surgical variations. It was therefore one of the goals in development of the electromagnetic implant to keep it as simple and safe as possible.

4.2 Internal unit

4.2.1 The magnet

4.2.1.1 Rare earth-cobalt permanent magnets

The use of permanent magnets based upon rare earth-cobalt alloys has increased steadily in the last few years. The quality of these magnets has been improved reaching a maximum energy product of up to 32 (no unit). New alloy composition may substitute for $SmCo_5$.[446]

4.2.1.2 Magnet-coil sizes: mass effect

The mass of the stapes itself is 3.38 ± 0.48 mg (Kirikae 1959). To be effective in driving the stapes, the vibrator of the electromagnetic implant system should be as large as can be tolerated. However, the stapes cannot be overloaded. Loading of the incudostapedial joint with magnets of up to 50 mg has been shown not to destroy the ossicular chain. A total weight of 35 to 40 mg appears to be the

upper limit within safe margins. The specific weight of Samarium-Cobalt is 8.0 g/cm^3.

Furthermore, the mass effect has to be taken into account. More mass causes energy loss in the high frequencies resulting in a roll-off of the stapes displacement curve. Nishihara, Aritomo, and Goode[447] proved that the addition of mass onto the stapes produced a high-frequency decrease in stapes displacement. More mass however improves the energy transfer in the lower frequencies. This is especially true at 0.5 kHz and lower. For high frequencies of 4 kHz or greater, less mass is preferable. A compromise between these two effects has to be found.

4.2.1.3 Effect of size of stapes footplate on frequency response

The size of the stapes footplate is an average of 2.96 ± 0.15 mm in length and 1.33 ± 0.11 mm in width.[103] The area of the footplate thus covers 3.69 mm^2. (Fig.10)

This small area of 3.69 mm^2 results in good energy transfer of high frequencies but poorer transfer for low frequencies. The impedance of the fluid filled cochlea is estimated to be 1:1x10^6 in relation to the impedance of the middle ear. The coil-magnet system is more effective in higher frequencies. Thus it does not correct this imbalance, and correction by external amplification is necessary. Lower frequencies will have to be boosted.

4.2.1.4 Maximum energy product

The maximum energy product describes the strength of a magnet. Only a few years ago, the strongest magnets used to reach 20 to 22 (no unit).[448] The energy product $(B \times H)_{max}$ is used as a means of expressing the quality of magnetic materials for use in static systems. Now, the highest energy product reaches 32 and further increase to 35 and 40 is expected within the next few years. (See also Appendix III)

4.2.1.5 Magnets with high energy product

Permanent magnets with a high energy product can be made from materials with a high saturation magnetization, which can also be magnetically hardened, which produces a strong magnetic field. A high degree of magnetic anisotropy is necessary for a potential magnetic material.

It has been found that intermetallic compounds of rare earths (RE) and cobalt (Co) possess these characteristics. Those with the formula RE-Co5 using the rare earths Y, La, Ce, Pr, Nd, Sm and mixtures of them, offer the best prospects. These compounds have a high saturation magnetization, a high Curie point and a pronounced crystalline anisotropy. These are the properties that make them ideal as materials for the production of excellent permanent magnets. They have a high remanence combined with a powerful coercive field strength.

The magnetic hardness ensures that the magnet retains its magnetic field strength. As a result of the strong and almost rigid magnetization of the Samarium-Cobalt magnet, the stray field is greatly reduced and the usable field in the close vicinity of the magnet is considerably larger than that of ferrite magnets or AlNiCo-magnets.[449]

4.2.2 Coil

The ideal coil wire might be a bifilar copper coil of 42 to 48 Gauge thickness or smaller in a very densely wired coil. The denser the coil the more flux can be produced. Modern technology using photographic application of a coil system can produce very efficient, flat and light coils.

4.2.3 Encasement

The encasement of the implant shields the transducer from body fluids that would cause corrosion. The encasement could be made of silastic or titanium. Gold has not yet been approved by the FDA for use in the middle ear. The major concern with any magnet that contains iron is its propensity for corrosion (Hough 1993). The Neodymium-iron-boron magnet has this disadvantage compared to the non-corrosive Samarium-cobalt magnet.

The biocompatible housing encases the coil, magnet and membrane that is affixed to the middle ear ossicular chain or can be placed within a PORP (partial ossicular replacement prosthesis) or TORP (total ossicular replacement prosthesis).

The Xomed Audiant® Bone Conductor is covered by Parylene-C, a biocompatible coating produced by Union Carbide.[450] In addition, an undercoat of gold is electroplated on the prosthesis. These Parylene-C and gold-coated magnets have been tested in compatibility studies in guinea pig and dog models.

Titanium can also be used for Laser welded encasement.

4.2.4 Wire

The middle ear implant is connected to the induction coil or the percutaneous plug by a wire system. This wire is protected at its insertion point into the implant by a ceramic sheath to prevent leakage into the case. This connection is most delicate. Maniglia's team saw disruption of the insertion of the wire into the case. The wire itself is a high-grade copper wire coated with silastic as used in cochlear implants.

4.3 Percutaneous Plug

The connection of the external amplifier to any implanted middle ear device or cochlear implant has always been a topic of concern. Current systems use transcutaneous induction with external and internal coils like the Japanese implant of Yanagihara/Suzuki and other systems. An alternative to the transcutaneous coil-to-coil induction is direct electrical coupling using a plug. To avoid the attenuation of transcutaneous coil-to-coil induction, the electromagnetic implant can be connected directly to an implanted electrical plug.

The multichannel cochlear implant system Ineraid® [451-462] uses a percutaneous connection. The plug in the Ineraid® system consists of a pyrolized graphite and was fixed to the bony surface of the skull by three screws.[463] Loosening of the screws has led to pedestal loss.[464] Parkin (1994) claims that in 63 patients implanted by 1994, only one pedestal had to be removed due to problems with infections. However, the percutaneous connection proved to be at risk for bacterial infection. Severe local infection seems to be difficult to control and plugs had to be removed.[465],[466]

The major advantage of a pedestal is a stable and reliant electrical transfer for the implanted electrodes without significant energy loss by attenuation. Furthermore, it allows the volume of the implant to be reduced by placement of the amplifier in the external unit and by avoidance of transmission parts such as coils or RF receivers.

Nobelpharma has been approached to construct a solid percutaneous titanium plug for use in cochlear implants. The basic idea was to reduce the cost of implant production and to make the cochlear implant available to a larger number of patients.[467] The project has not yet been realized.

4.3.1 Attenuation by transcutaneous induction

According to Yanagihara et al.[312] a loss of 20 dB is initially sacrificed to transfer energy through the intact skin. This equals an efficiency of 1%. Efficiency can be raised to about 30% by applying improved conventional electromagnetic induction. Currently, RF techniques are under investigation to improve transduction further. A major problem is the interference of magnets that are used to hold the external part in alignment with the internal part to line up the coils. Further refinement of the RF technique might decrease this interference as well.

The Swedish Brånemark system has shown that a percutaneous plug can be safely applied for their bone vibration hearing aid using a titanium screw. The screw is firmly drilled into the outer and inner cortical layer of the skull. Even under mechanical stress by the vibrating hearing aid it remains firmly attached. There seem to have been few problems with local skin irritations, and these can be managed with local antiseptics.

The location of the screw proposed here will be behind the ear in the hair bearing area. This will conceal the attached hearing aid and will improve the cosmetic aspect. Furthermore, the attachment will be firm and safe due to the placement of the screw through the outer cortical layer of the bone and into the inner cortical layer without penetration into intracranial space.

4.3.2 Surgical procedure for the percutaneous plug

- A standardized drill system drills the socket and thread for the screw.
- A connecting channel to the middle ear is carved out with a hand held drill.
- The hollow titanium screw is inserted.
- An insert that is in connection with the implant by a wire is placed into the hollow screw.
- A cap screw is mounted into the titanium screw holding the insert and sealing the screw to prevent contiguous infection from the external ear to the middle ear.
- The skin around the screw is thinned down and allowed to heal directly to the periosteum.
- The screw is allowed to osseointegrate for at least six weeks before the external hearing aid is placed.
- The hearing aid is then plugged in the hollow screw by direct electrical connection.
- The external hearing aid consists of an electrical connector to the screw, a microphone, an amplifier, a battery compartment, volume control and program control all of which is incased in a housing. The outer design will be flat to fit along the skull of the head. Depending on the energy requirements, the size can be miniaturized more and more until the entire apparatus can be placed into the hollow screw.
- The diameter of the screw can be wide enough to house the entire external part. There is no limitation of size due to static considerations because the bony skull in the temporal area can be reduced without causing any problems in statics. The sole limitation will be cosmetics. Which size of a screw will be tolerated by patients will have to be explored further.

The Swedish Brånemark system with its percutaneous titanium screw has been highly effective and secure. The main differences of a percutaneous coupling to the above mentioned Inner aid® plug are :

1. The implant material is titanium.
2. The screw is tightly fixed into the skull bone.
3. The surrounding skin is thinned out to adapt to the periosteum and to permit free access to the surface of the screw.

Extensive literature has been written about the technique to implant titanium screws into the body including its use for a bone-conduction hearing aid (See chapter 2). Current application of this titanium fixation system are dental implants, bone conduction hearing aids, and facial and auricular epistheses.

The author proposes the use of a hollow titanium screw as an electrical connector. Hollow screws have been used for dental implants where osseointegration was improved by additional perforations of the titanium screw permitting the bone to grow through the hollow screw.[468 -471]

4.3.3 Concept of the percutaneous plug

The percutaneous plug designed for this implant consists of a large caliber hollow titanium screw of 5.3 mm diameter with an electrical coupling to the implant.

The external part of the hearing aid is snapped into the hollow insert. Ideally, the volume of the hollow screw would be large enough to hold the entire external part consisting of microphone, battery, amplifier and housing. This, however, would require a titanium screw that would be too large to implant.

4.3.4 Location of the screw

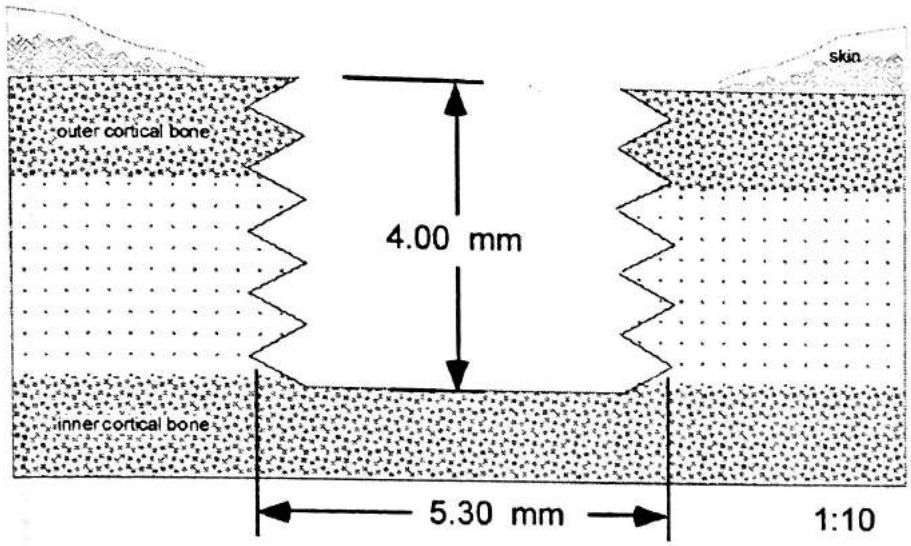
The location of the screw will be in the temporal area of the skull above the line of the attachment of the auricle, superior to the area, where glasses are worn. It will be posterior to the attachment of the pinna in the hair bearing part of the skull. This provides positioning of the microphone in an anterior direction without the disadvantages of a sound shadow caused by the pinna.

A possible disadvantage is the partial loss of the temporalis muscle attachment as well as partial loss of temporalis fascia. The exact positioning will have to be determined to avoid these drawbacks which are considered to be minor. Fascia can also be harvested from other locations.

4.3.5 Graphs for the new percutaneous plug

4.3.5.1 Drill out for percutaneous screw: through skull bone in the temporal line

Fig. 11



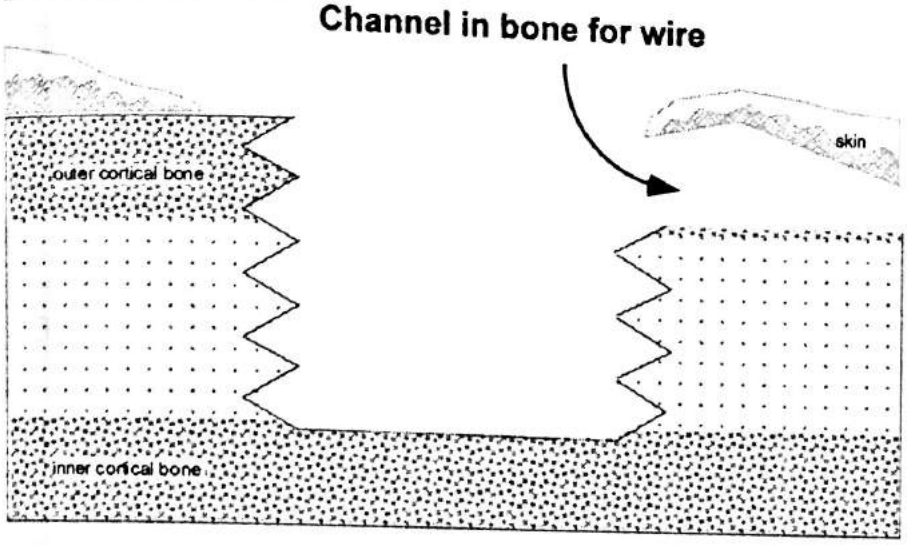
At the temporal line superior to the external ear canal the temporal bone provides a thickness ranging between four and six millimeters. This site has been chosen for the Brånemark titanium implant for its strongest cortical layers near the ear. Drill-out for the socket of the percutaneous screw leads through the outer cortical layer and the cancellous bone into the inner cortical layer for a depth of 4 mm. The diameter of the burr is 5.3 mm. The skin around the implant is thinned down to let it adhere to the periosteum. This technique has reduced the number of soft tissue reactions according to the experience in the Swedish group.

The experience with the Brånemark screw has shown, that even exposure of the dura does not cause serious sequelae.

4.3.5.2 Channel in bone for wires

Partial drill-out of the outer cortical layer for a channel will permit the wires to be lead from the percutaneous plug to the implant in the middle ear and will be fixed with sutures or with a few drops of a bone cement such as Ionocap. The skin covers the channel. The diameter of the wires will be 0.5 mm so that a one millimeter groove will be sufficient.

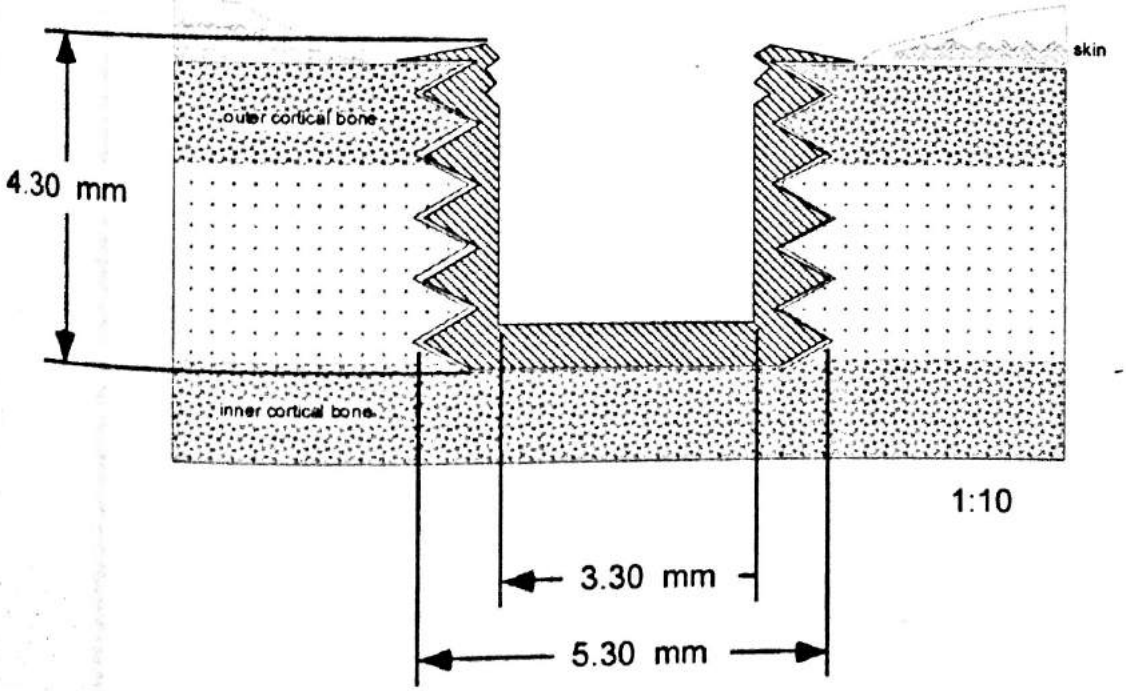
Fig. 12: Channel



4.3.5.3 Insertion of the hollow titanium screw

The hollow titanium screw is screwed carefully into the drill-out. During this phase it is important to preserve a clean surface of bone and metal to provide optimal conditions for osseointegration.

Fig. 13: Hollow screw

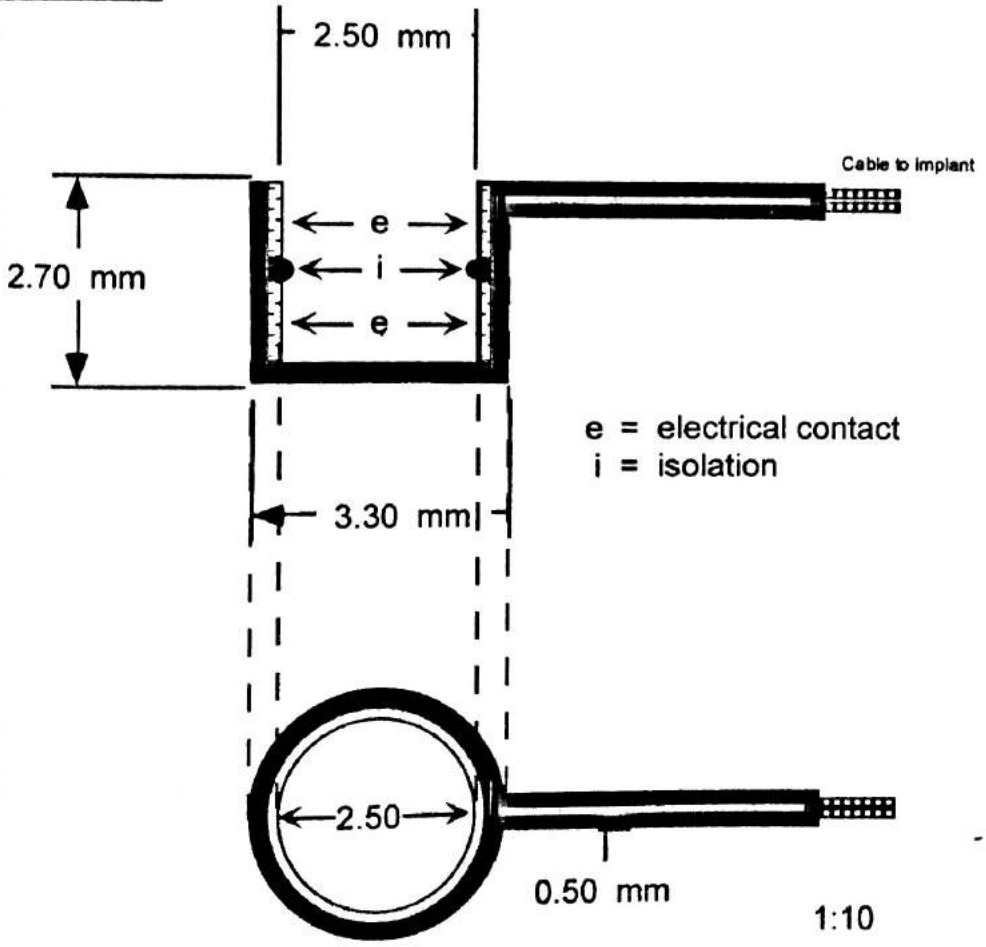


The hollow titanium screw will undergo osseointegration with an intimate connection to bone. The length of the screw will be standardized to 4.3 mm. The outer diameter of the screw will be 5.3 mm. The hollow socket for the plug is 3.3 mm. This will contain the insert.

The diameter of the entire screw and as such the hollow part could be designed larger to hold more of the external unit within the socket. The outer diameter now set at 5.3 mm could be increased up to about 10 mm. This however would result in more removal of soft tissue and a wider opening of the percutaneous plug when the external unit is not worn. This opening however could again be covered by a plastic cap. Swimming and other sports activities will still be possible.

4.3.5.4 Insertion of the connector

Fig. 14: Insert



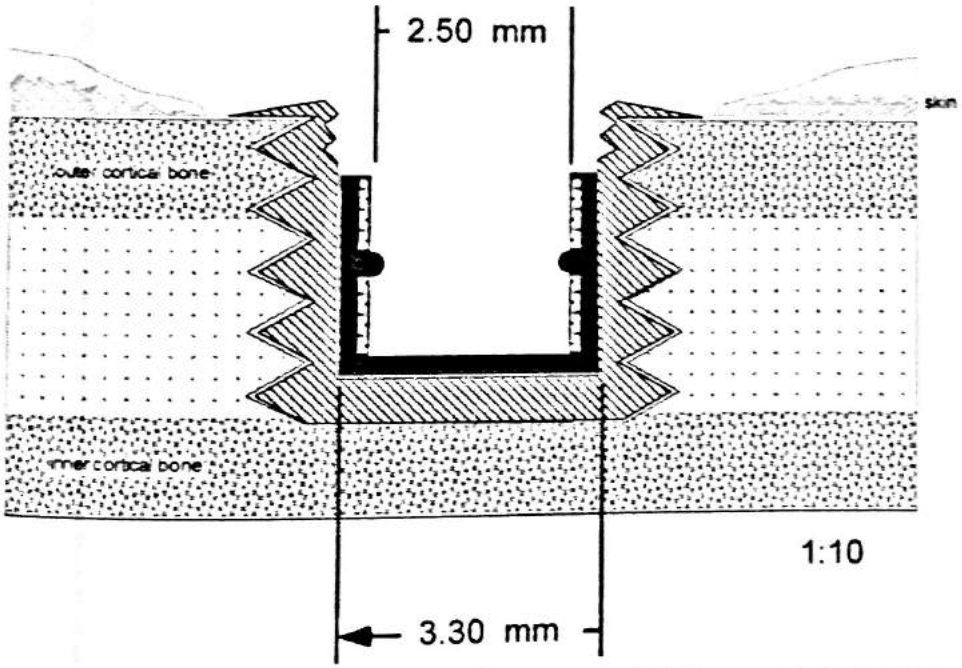
The outer diameter of the connector is 3.3 mm and the connecting part harboring the wires is 0.5 mm.

The connector contains the surfaces for the electrical contact for the external unit. The outgoing wires connect the plug to the middle ear implant of the hearing aid. The plug is a commercial jack-plug of 2.5 mm diameter, which is also used for ear phones in walkmen. This will need to be shortened to the depth of the socket.

The connector is constructed in continuity with the middle ear implant connected by wires. No plugging or manipulation of the wires will be necessary.

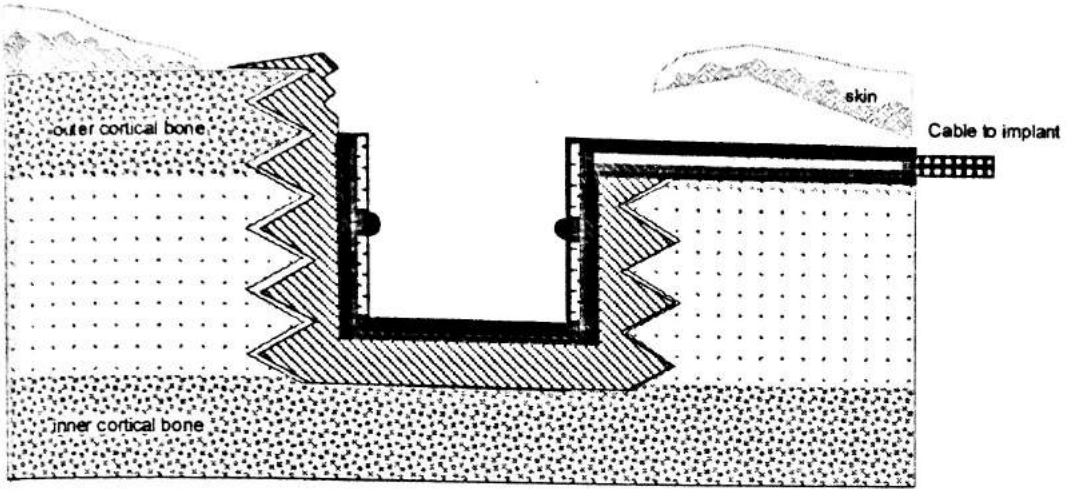
Excess wire length can be coiled within the mastoid cavity. This might be important in children where a displacement of cochlear electrodes by growth of the skull in cochlear implants has been assumed.

Fig. 15: Insert in hollow screw



The connecting insert has an outer diameter of 3.3 mm. It leaves an open space of 2.5 mm. Above it is the inner thread for the cap screw.

Fig. 16: Insert and connecting part with wires



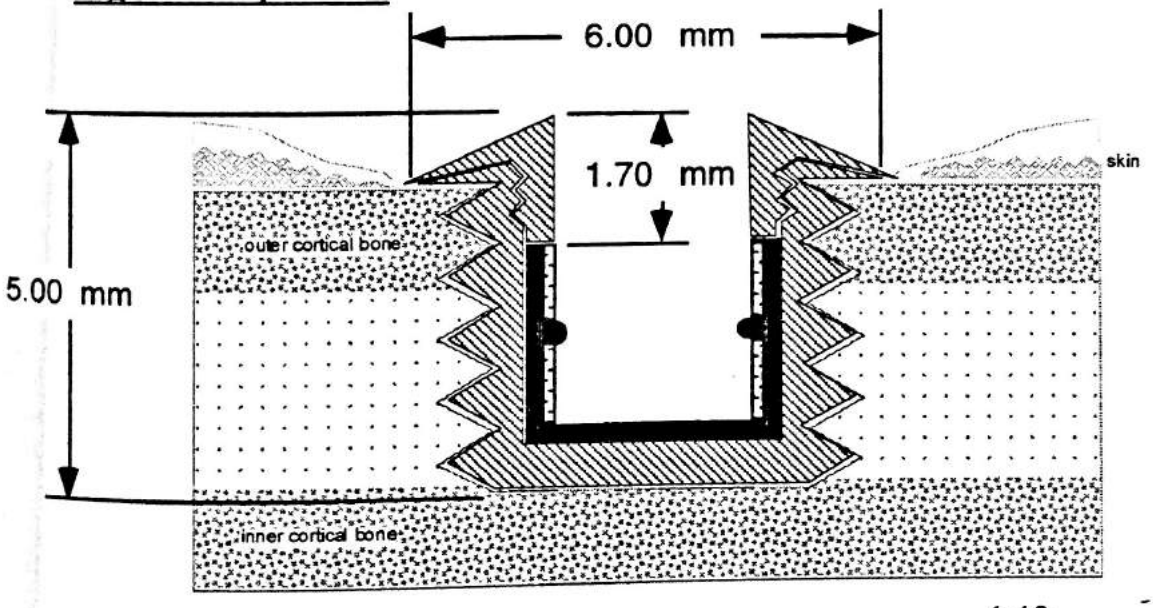
1:10

Insert at the level of the connecting part with the wires.

4.3.5.5 The cap screw

A cap screw is screwed into the inner thread of the hollow screw. The purpose of this cap screw is to hold the insert tightly and safely within the screw.

Fig. 17: Cap screw



1:10

The cap screw has an outer diameter of 6 mm, an inner diameter of 2.5 mm, and a hight of 1.7 mm. Altogether, the composition of the percuatenous plug is 5 mm high. Four millimeters are implanted into the bone and one millimeter extends laterally.

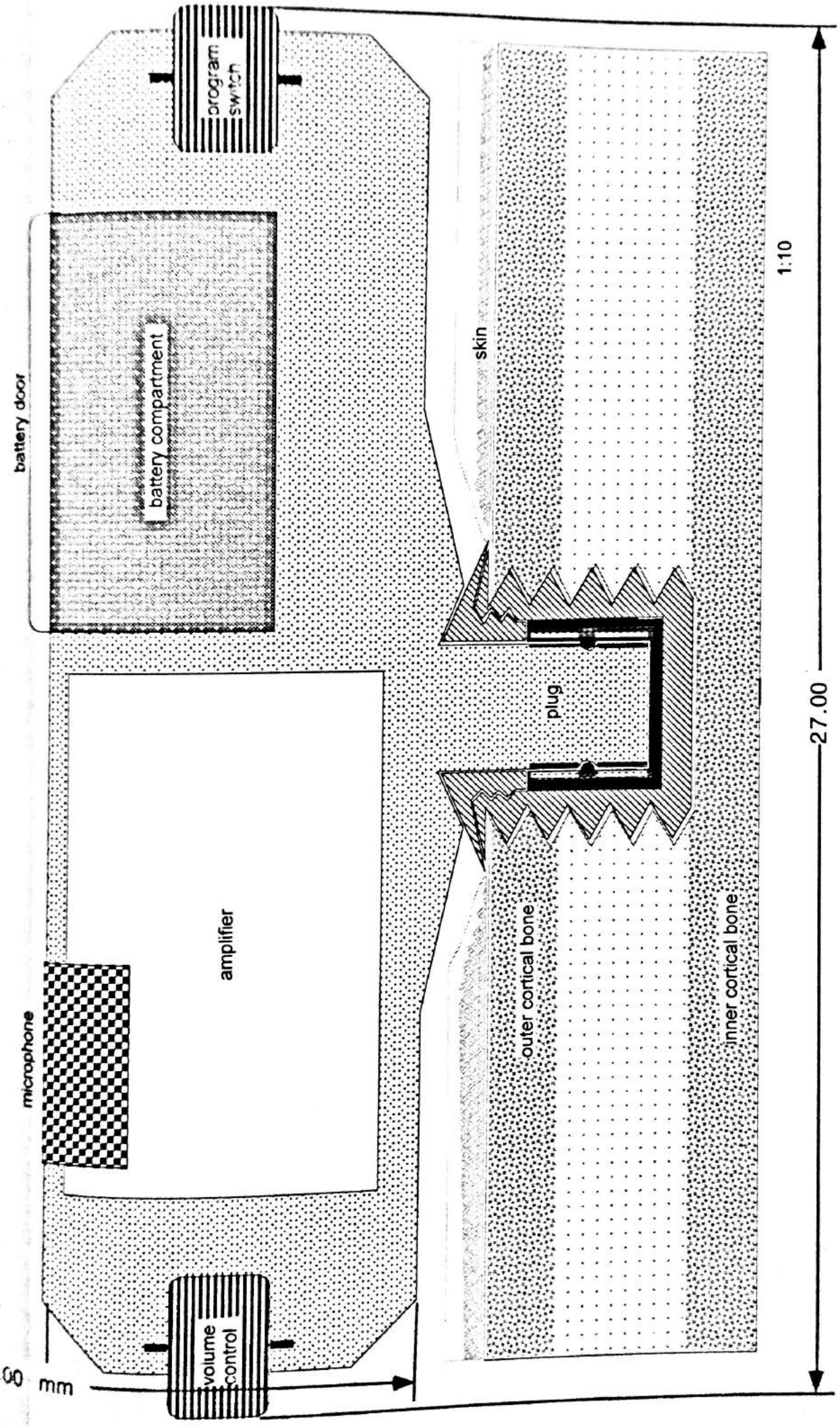
4.4 External unit

The external unit consists of several parts that cannot yet be implanted. In the Japanese concept of the totally implantable hearing aid the microphone is placed beneath the skin of the external ear canal. [472] Pick-up of sound was found to be unreliable due to interindividual thicknesses of ear canal skin. To avoid any such problems, a the concept of the semi-implantable set-up was chosen.

The external unit contains the power supply and controls of the semi-implantable hearing aid. The battery is kept in a battery compartment that can be opened by a flip door. The microphone picks up sound waves that are integrated and modulated by the amplifier. Controls include a volume-control wheel and a program switch available to the user.

4.4.1 External unit plugged into percutaneous screw

Fig. 18 (Next Page)


program switch
battery door
battery compartment
skin
1:10
plug
amplifier
outer cortical bone
inner cortical bone
27.00
microphone
volume control
7.00 mm

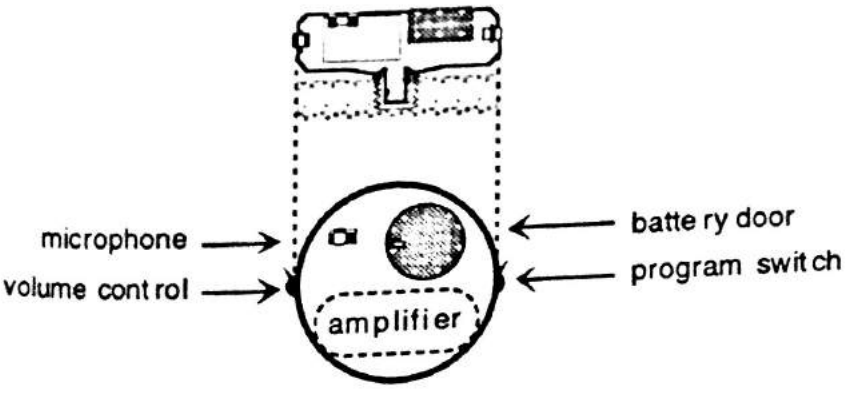
The external unit connects to the insert in the implanted titanium screw by the jack-plug, which harbors electrical contacts. The external unit can be easily plugged in and out of the hollow screw. It rides on the shoulders of the cap screw.

The limited size and volume of the external unit demands little force on the osseointegrated screw. The screw is not vibrated such as in the Brånemark bone-conduction implant. A predesigned breaking point at the neck of the external unit will protect the osseointegrated screw from breaking loose in the event of a blunt trauma to the external unit. The jack plug will be hollow to enable removal of remaining parts should a break occur.

The electromagnetic hearing aid will be semi-implantable because the microphone has to be in contact with air for optimal function and because batteries will need to be replaced frequently. Even though batteries with a long life span have been developed (Mahoney 1992) and transcutaneous loading of a battery is possible, it is highly impractical.

Any kind of vibrating implant requires an adequate power supply. A system requiring only 1 Milliwatt in a 1 Volt and 1 Milliampère system would be preferable. At this point, it is more probable that the implant will run on a 1.5 or even 3 Volt system. Frequent battery changes will be necessary. It is estimated that one battery will last for about 48 hours. This energy requirement is still low compared to the massive power supply for the EarLens® system that needs 1 Ampère of current to provide the magnet on the tympanic membrane with an adequate electromagnetic field from the neck loop.

Fig. 19: Real size of the external unit with plug:



1:1

The external unit has a diameter of 27 mm and a height of 7 mm.

The volume is:

$(r^2 \pi)$ height = ((diameter/2)π) height = ((27/2) 3.14) 7 = 400 mm^3 = 4.0 cm^3.

This is approximately equal to the height of four stacked Swiss 2-Frank coins. Recent achievements in technological miniaturization enable the construction of an external unit of this volume.[473]

4.4.2 Microphone

The microphone will be miniaturized and of highest quality. Advances of miniaturization of microphones as used by Knowles microphones have led to new fields of inner ear research permitting the recording of otoacoustic emissions. Hearing aid companies such as Phonak already use several types of microphones within their hearing aid units.

4.4.3 Amplifier and signal processing unit

Miniaturization of microchips has led to further decreases of hearing aid volume.[474] This technology can be applied readily to our electromagnetic implant. With further decrease in volume, the whole external part could be put into the hollow titanium screw. This would render the hearing aid practically invisible because the screw will be placed in the hair bearing part of the temporal area of the skull.

The signal processing unit will be programmable to allow an individual setting for each patient according to the patient's audiological needs. Several programs may be preset to permit quick changes in various surroundings. Preset programs are used in several conventional hearing aids.[475]

4.4.4 Battery

The volume of the battery will depend on the Voltage requirements of the implant. A 1.5 Volt system would be preferable over a 3 Volt system. Exchange of the battery will be easy for the patient. This is an important detail, because most patients who will be using this implant will be older and have decreased dexterity.(see Ch.1.3.3.)

4.4.5 Exchange of the external unit

The external unit is readily exchangeable in case newer models are produced in the future. Major breakthroughs are to be expected in further miniaturization of computer chips and battery sizes. This will allow further reduction of the overall size of the external unit. As mentioned above, a cosmetically favorable situation would be to hide the entire external unit into the hollow screw leaving a flat surface at the level of the skin of the skull.

Daily insertion of the external unit is facilitated by visualization of the screw in a mirror. Visual impairment might hinder this insertion.

4.5 Otologic surgery for implantation

The surgical procedure for implantation of the incus clip (Ch. 7.1.) includes the following steps.

In order to insert the implant into the middle ear, an access has to be drilled. After a cortical mastoidectomy, the facial nerve is identified and the facial recess is opened to visualize the incudo-stapedial joint. To improve visualization, a transcanal approach as used in stapedectomy raises the tympanomeatal flap and exposes the incus and stapes after curettage of the scutum.

The implant is inserted through the mastoid and the facial recess into the middle ear where it is clipped on the long process of the incus. This procedure is controlled through the posterior tympanotomy as well as through the transcanal view.

The wires lead from the implant to the mastoid area. Depending on the connection system chosen, the wire either connects the implant to the receiving coil of the transcutaneous system, which is fixed in a cavity of the outer cortical layer of the skull, or it leads to the insert of the percutaneous plug (Ch. 4.3.).

Because the surgery can be performed under local anesthesia, the implant can be tested in the operating room to assure correct and safe connection to the ossicles and good functioning of the system. After skin closure, the wound is allowed to heal and the screw to osseointegrate for six weeks before any testing will be performed.

5. Experiments

Békésy[476-482] and Frank[483] demonstrated that elasticity of ligaments, capsules and the tympanic membrane in fresh temporal bones is identical within several hours postmortem when compared with that of living persons. The majority of the following experiments were conducted with fresh human temporal bones.

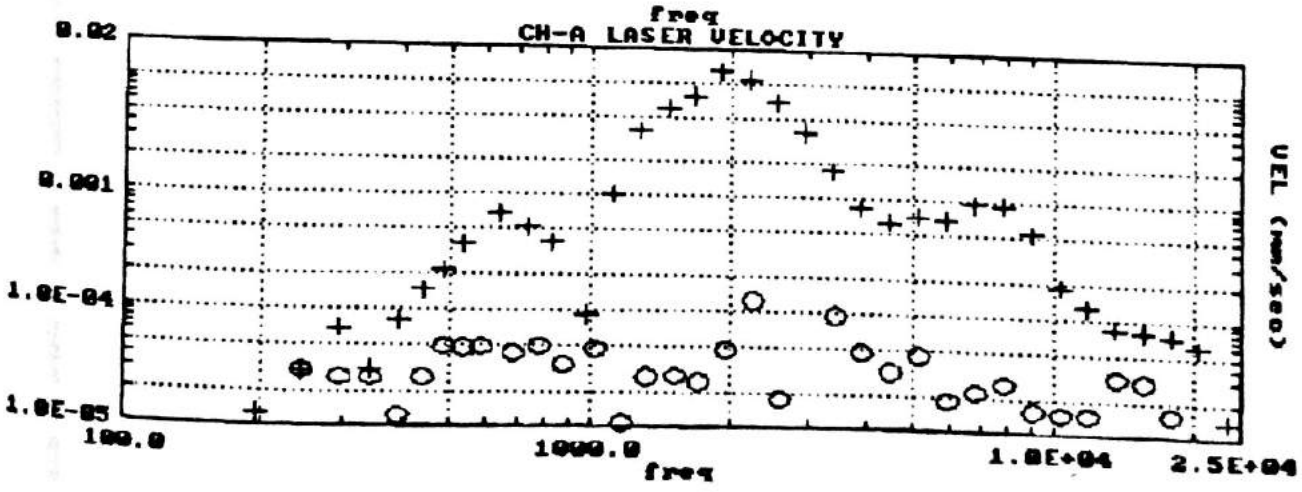
5.1 Tools for experiments

5.1.1 Optical Laser Interferometry:

The movement of a target can be precisely followed by a new laser guided instrument constructed by Ball.[484] A laser interferometer Polytech #2500 with a #350 sensor head, 10-µm spot size is aimed at a small target consisting of 3M reflective tape. This tape is applied to the magnet-coil system as well as to the stapes footplate. Once a good laser lock is achieved, the target velocity is traced and recorded with a special computer program. Peak-to-peak displacements of as small as 0.0001 µm (10^{-10} m) can be recorded. The system has also been used for eardrum measurements displaying umbo displacements. The frequency range of 0.25 to 20 kHz with 5 data points per octave was measured.

In the studies reported, footplate displacements as well as vibrations of the magnet–coil system in temporal bones were recorded.

Fig. 20: Example of a plot of target velocity recorded with Laser Doppler Vibrometer



The figure above displays velocity of the target (+) on the stapes footplate of a fresh human temporal bone with intact fluid filled inner ear spaces, and the noise floor (o). The transducer consisted of a 35 mg Samarium-Cobalt magnet surrounded by a copper coil of 42 gauge with 50 turns. Data were recorded with the laser Doppler interferometry system. These raw values were later converted to peak-to-peak displacements as shown in Chapter 5.2.

In this tracing, the target velocity is below 10^{-4} mm/sec in frequencies below 500 Hz. At 1 kHz, the velocity reaches 10^{-3} mm/sec and is highest at 2 kHz with 10^{-2} mm/sec. Velocity then decreases to 10^{-3} mm/sec again for frequencies between 5 and 10 kHz. Velocity can be measured well beyond 10 kHz.

There is an attenuation at 1 kHz of unknown origin. This might have been caused by this individual temporal bone.

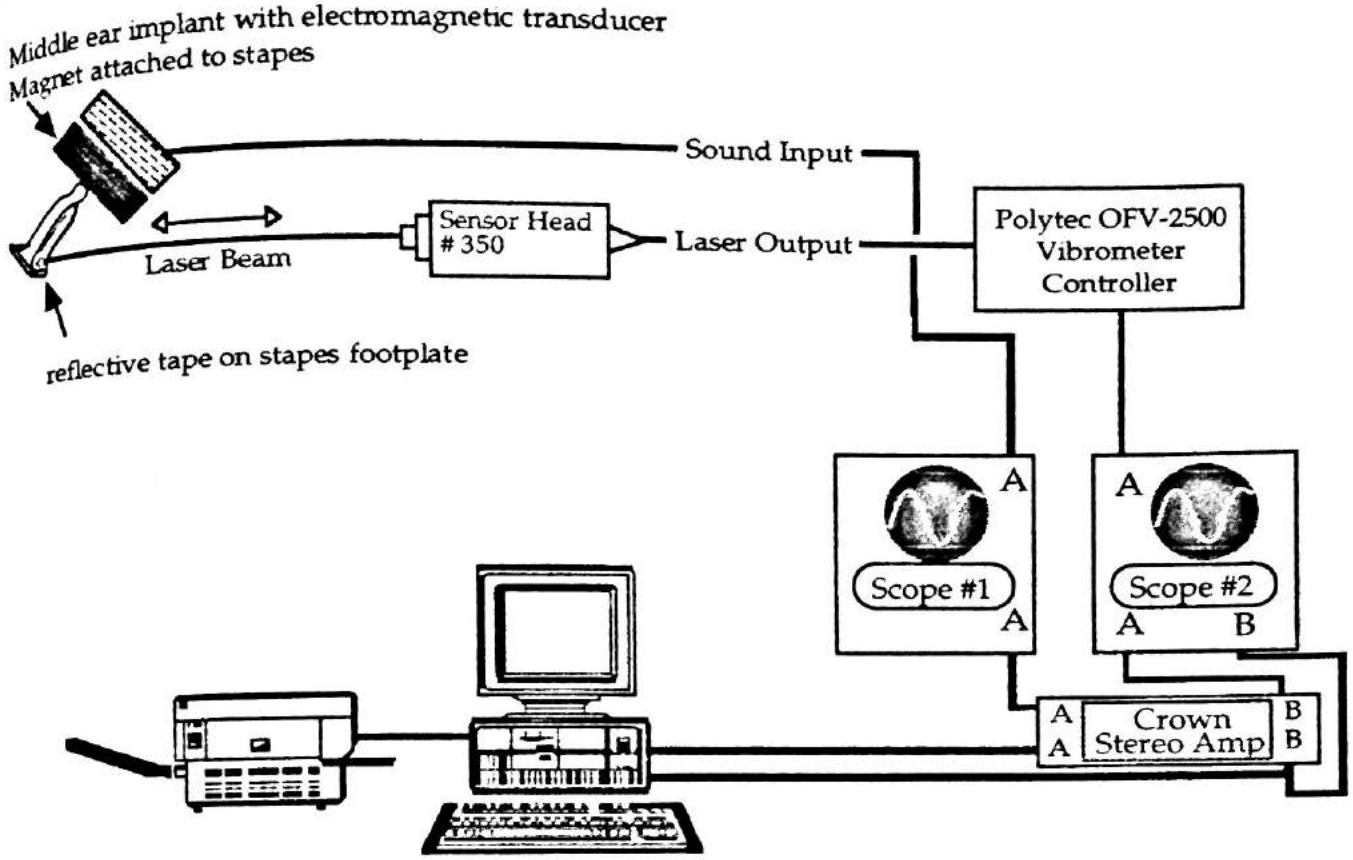
The intention of this graph is to show the frequency response of this electromagnetic implant with a constant power input. The values derived from this figure are not subject to discussion of maximal values in target velocity.

These values present a surprisingly high velocity up to 10 kHz compared to conventional acoustic hearing aids, which are hampered by the limitation of high-frequency gain. This implant has its highest amplification around the essential frequencies of 1 to 5 kHz. Understanding of speech greatly depends upon the detection of sibilants,which are composed primarily of high-frequency energy. Furthermore, hearing loss is most prominent in high frequencies in presbycusis, as well as in cochlear damage due to noise, ototoxic lesion and mechanical trauma. Increased amplification of higher frequencies appears desirable.

5.1.2 Laser Doppler System (LDS):

Vibrations of the human tympanic membrane can be studied without anesthesia or analgesia with the laser Doppler vibrometer.[485] Potential future applications include the diagnosis of inefficient tympanic membranes as well as judgement of tympanoplasties for effectiveness and success.

Fig. 21: Laser Doppler Vibrometer:



5.2 Normal values for ossicular displacement

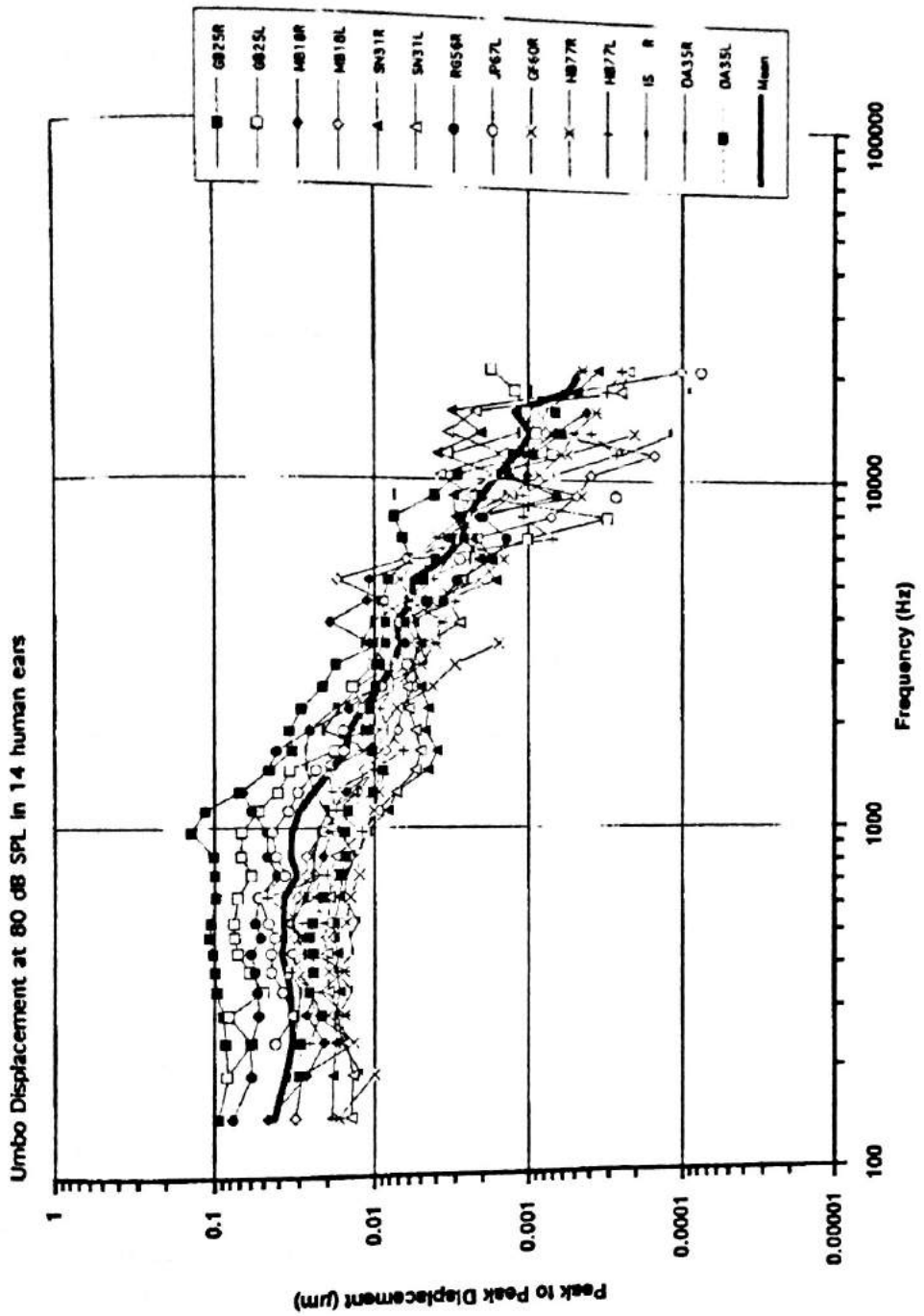
5.2.1 Umbo displacement

Knowledge of the vibration mode of the tympanic membrane provides basis for comparison with stapes footplate displacements. The following figure displays peak-to-peak displacements of the umbo in fourteen live human ears at calibrated sound pressure levels of 80 dB.

The reflective target was placed on the umbo under the microscope and the laser beam was constantly monitored during the measurement period to remain on the reflective tape. Between 0.1 and 1 kHz, peak-to-peak displacement is linear at a level of 0.04 micrometers. Above 1 kHz there is a logarithmic decline in displacement in all ears.

The following graph displays peak-to-peak measurements in 14 humans with normal tympanic membranes and normal middle ears.

Fig. 22: Tympanic membrane displacements in live human ears

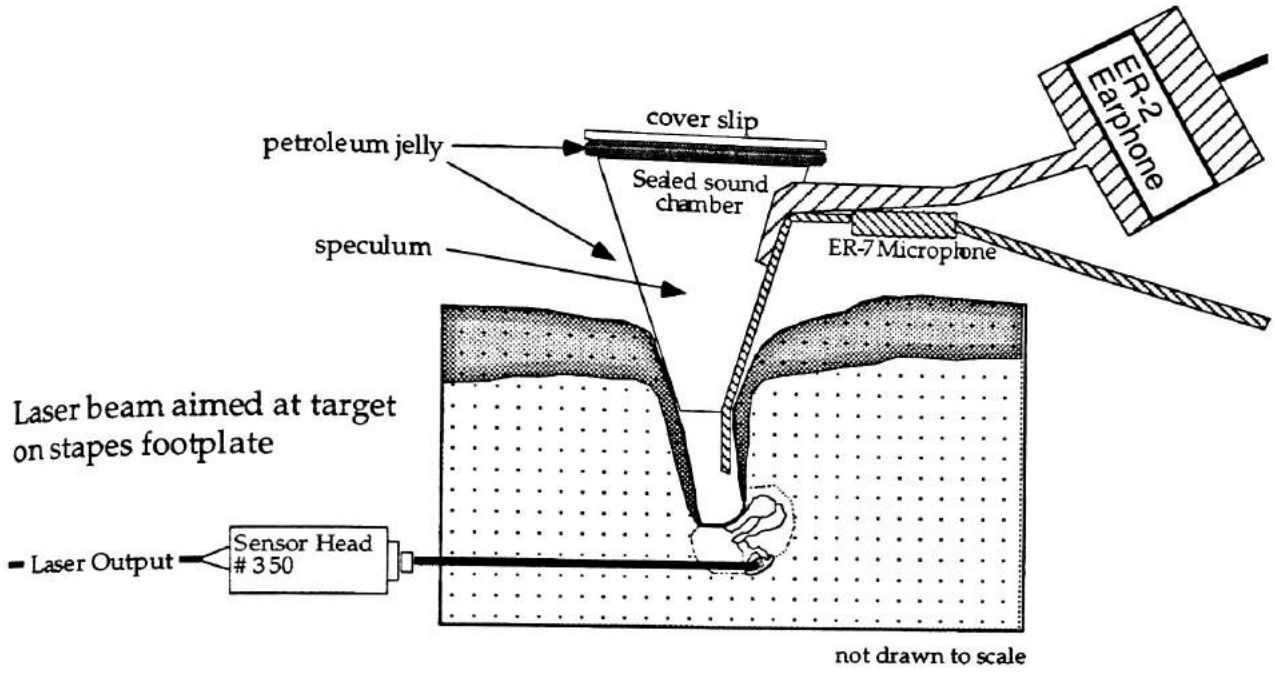


5.2.2 Stapes displacement

The following set-up was chosen for calibration of measurements of peak-to-peak displacements of the stapes footplate. The laser beam is aimed directly at the target on the stapes footplate. The target is positioned between the crura of the stapes superstructure. To aim at the target on the footplate in a straight line, the mastoid and tympanic portion and the inferior knee of the facial nerve have to be resected from the temporal bone. It is important to contain the integrity of the fluid filled spaces of the inner ear to keep the cochlear impedance as high as

possible. Other researchers have measured stapes footplate displacements through the opened vestibule from the undersurface. This however reduces the impedance and causes an artificial situation.

Fig. 23: Measurement of stapes footplate displacement with Laser Doppler Vibrometer in calibrated sound pressure levels:



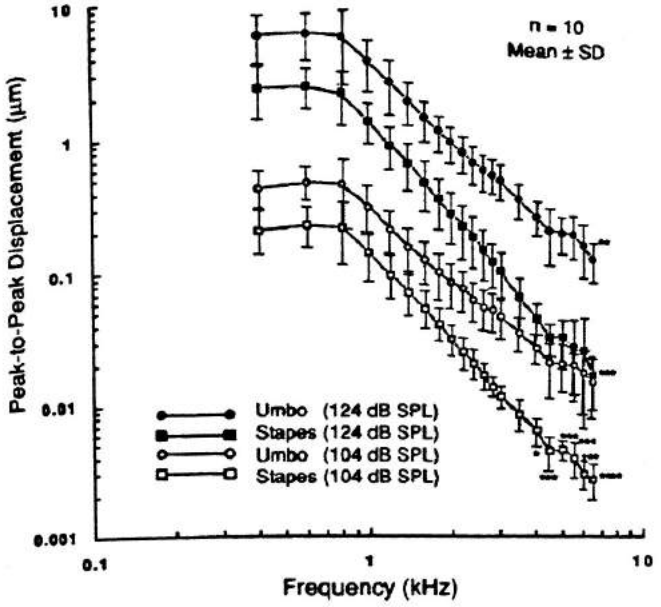
Sound pressure to the tympanic membrane is applied by the ER-2 earphone in a sealed sound chamber consisting of an ear speculum and a cover slip. Application of sound was calibrated with an intracanalicular microphone. The sound pressure level was kept at 80 dB SPL for all frequencies. Calibration of sound was achieved by real-time measurements with ER-7 microphones 3 mm lateral to the tympanic membrane in the sealed off external ear canal (Ch. 5.2.2.). An acoustic seal is provided by petroleum jelly.

A reflective tape is set on the stapes footplate. The laser beam aims at the footplate after resection of the facial nerve. The cochlea is intact and filled with fluid. Cochlear impedance is higher in live patients due to blood pressure.

Displacement of the stapes footplate in fresh human temporal bones was recorded with calibrated sound pressure levels. This data were then used as a frame of reference for the displacement achieved by electromagnetic transducers.

5.2.3 Comparison between umbo and stapes footplate displacements

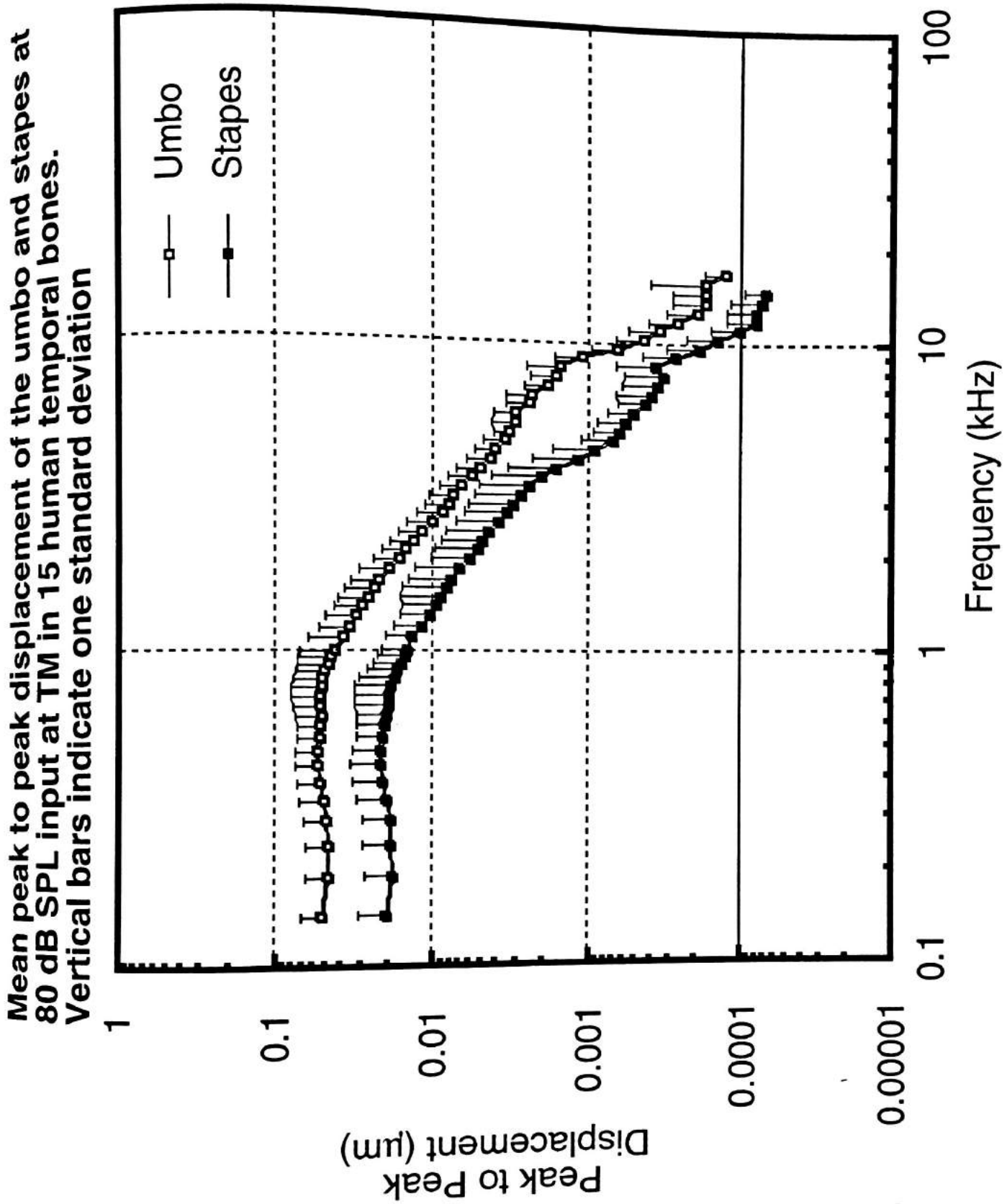
Fig. 24: Umbo and stapes footplate displacement in ten human temporal bones (TB) at 104 and 124 dB SPL inputs at the tympanic membrane.



Mean age at death: 72.0 years, range 65 - 80 years.
(* = 9 TB, **= 8 TB, *** = 7 TB, ****= 6 TB)

These data were collected from the research group at Stanford (Goode et al. 1994). This figure reveals a roll off of the mean umbo displacement at -10.4 dB per octave from 1 kHz to 4 kHz, whereas, stapes displacement rolls off at -13.4 dB per octave. The lever ratio had a mean value of 2.2 below 1.4 kHz rising to 5.2 at 4.0 kHz reaching a peak at 6.0 kHz. The increasing difference between umbo and stapes in the higher frequencies are due to slippage in the inter-ossicular joints mainly the incudo-malleal joint (Goode et al. 1994).

Fig. 25: Peak-to-Peak displacements of umbo and stapes in human temporal bones:

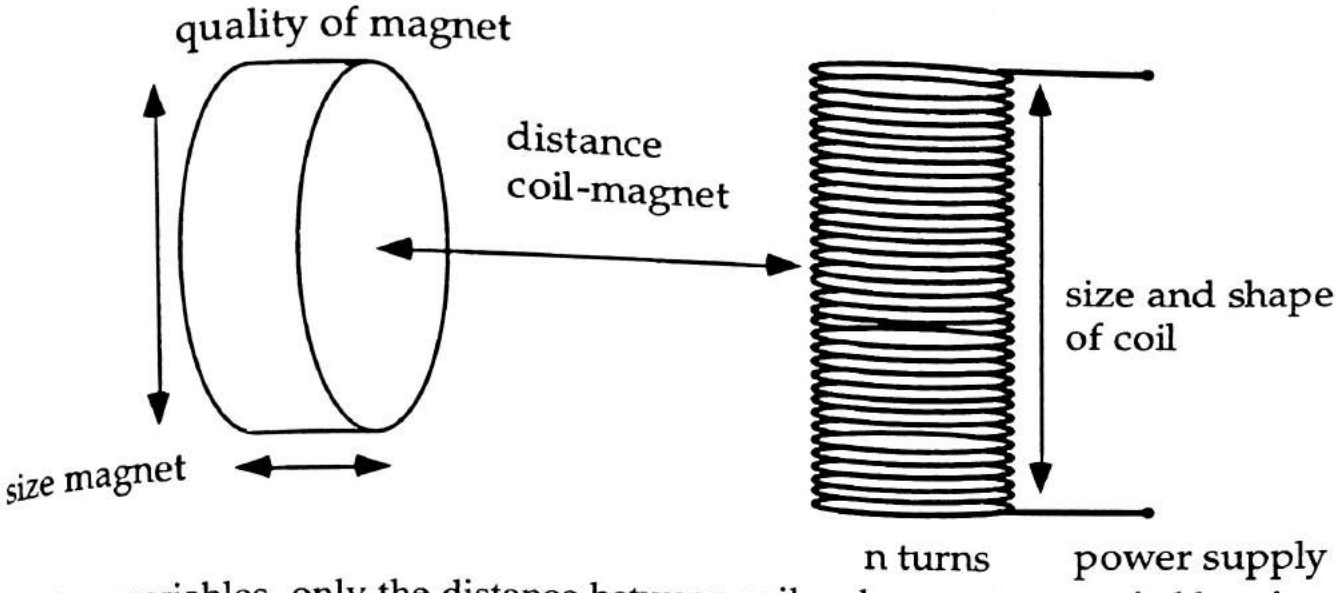


This graph on *Mean peak-to-peak displacement of the umbo and stapes at 80 dB SPL input at the TM in 15 human temporal bones* was provided by Nishihara from the paper *Effect of changes in mass on middle ear function* by Goode and Nishihara, 1992.

5.3 Variables in electromagnetic induction

In electromagnetic induction, several parameters can be varied including those displayed in the next graph.

Fig. 26: Variables:



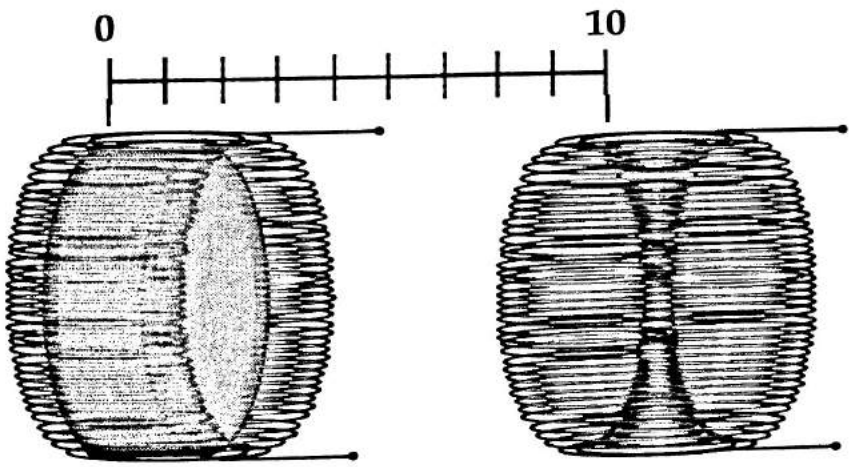
Of these variables, only the distance between coil and magnet was varied keeping all other values stable.

5.3.1 Distance coil to magnet

In electromagnetic physics, the influence of distance on the force of an electromagnetic field is well known. The force decreases exponentially with distance. In a set-up with a human temporal bone, we wanted to show the effect of increasing distance between coil and magnet. This experiment should answer the question of which distance between coil and magnet can be allowed without losing too much power.

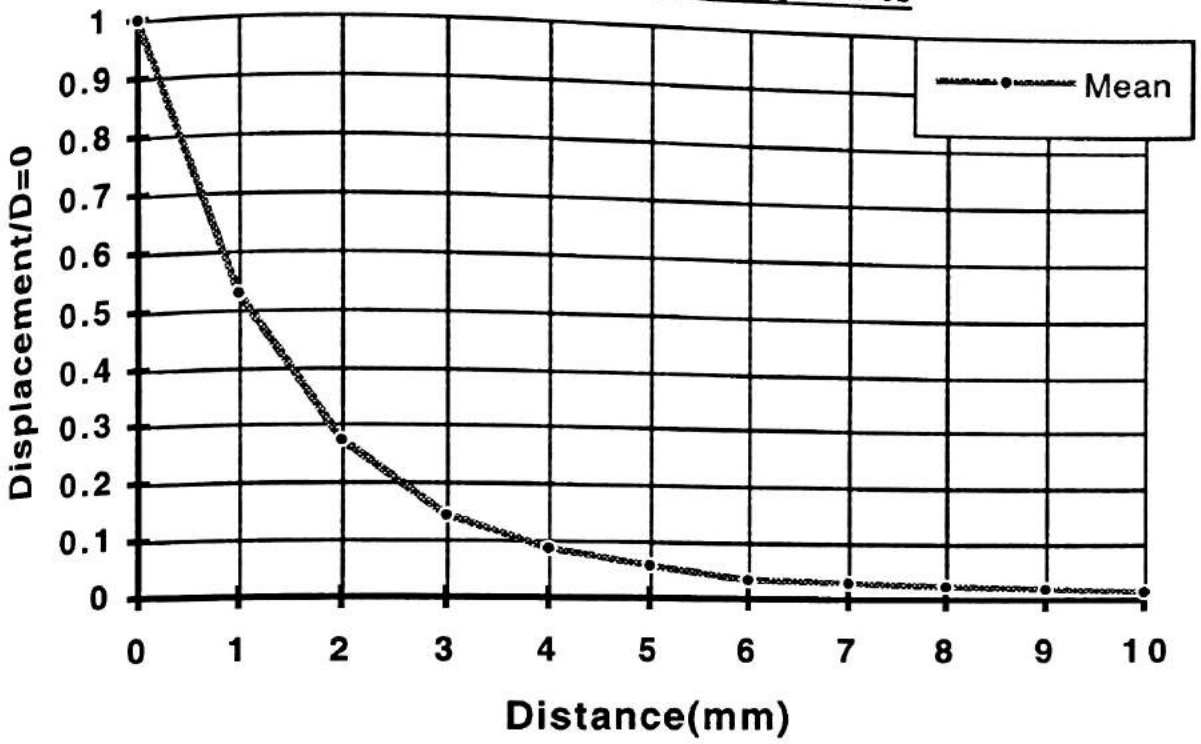
5.3.2 Variation of distance coil-magnet: 0 to 10 mm

Fig. 27:



A copper coil of 48 G wire was wound to encircle a disc shape magnet of neodymium-iron-boron without touching the magnet. The laser was aimed at a reflective tape on the magnet's surface and peak-to-peak displacements were measured starting at the distance of 0 mm. The coil was moved millimeter by millimeter away from the magnet to as far as 10 millimeters distance keeping all other parameters constant.

Fig. 28: Peak-to-peak displacement in relation to distance magnet to coil: mean value of all frequencies



Displacement is plotted using a non-logarithmic scale.

The above graph displays the largest displacements at zero millimeters distance between coil and magnet. With increasing distance, the peak-to-peak displacement decreases at a fast rate. At one millimeter distance the displacement reaches only 53 percent of the maximum value. At two millimeters it decreases to 28 percent, at four millimeters to 10 percent.

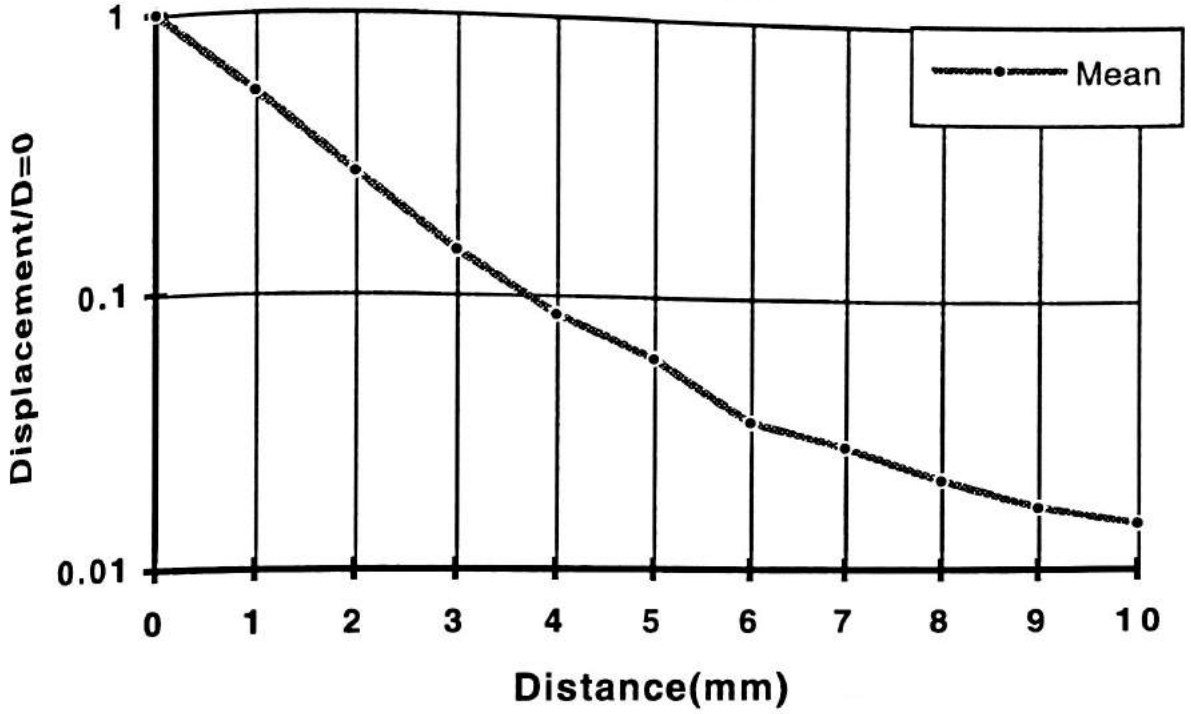
Comment:

Any distance between magnet and coil greatly reduces its efficiency. Whenever possible, this distance should be kept very small. In Maniglia's *Contactless Electromagnetic Transducer,* the distance between the induction coil in the attic and the magnet on the incus body is ideally 1 millimeter. This must lead to a loss of energy of about 50 percent. Furthermore, Maniglia does not describe a technique for the accurate placement of the coil above the magnet. The distance of one millimeter might well be increased to 1.5 or 2 millimeters by the

surgeon rendering that implant system quite weak. Maximum amplification by his system is described to be around 35 dB SPL.

In our transducer, the distance between coil and magnet is kept at zero millimeters. The coil surrounds the magnet in one compact housing.

Fig. 29: Peak-to-peak displacement in relation to distance magnet to coil: in logarithmic scale



The decrease of stapes footplate displacement in relation to increasing distance between coil and magnet is displayed above.

In this experiment the curve is perfectly straight in the first four millimeters. The curve crosses the 10^{-1} at 3.7 mm.

The decrease in this individual experiment was :

$$y = 10^{-x/3.7}$$

where y = displacement (D) / displacement (D=0)
x = distance

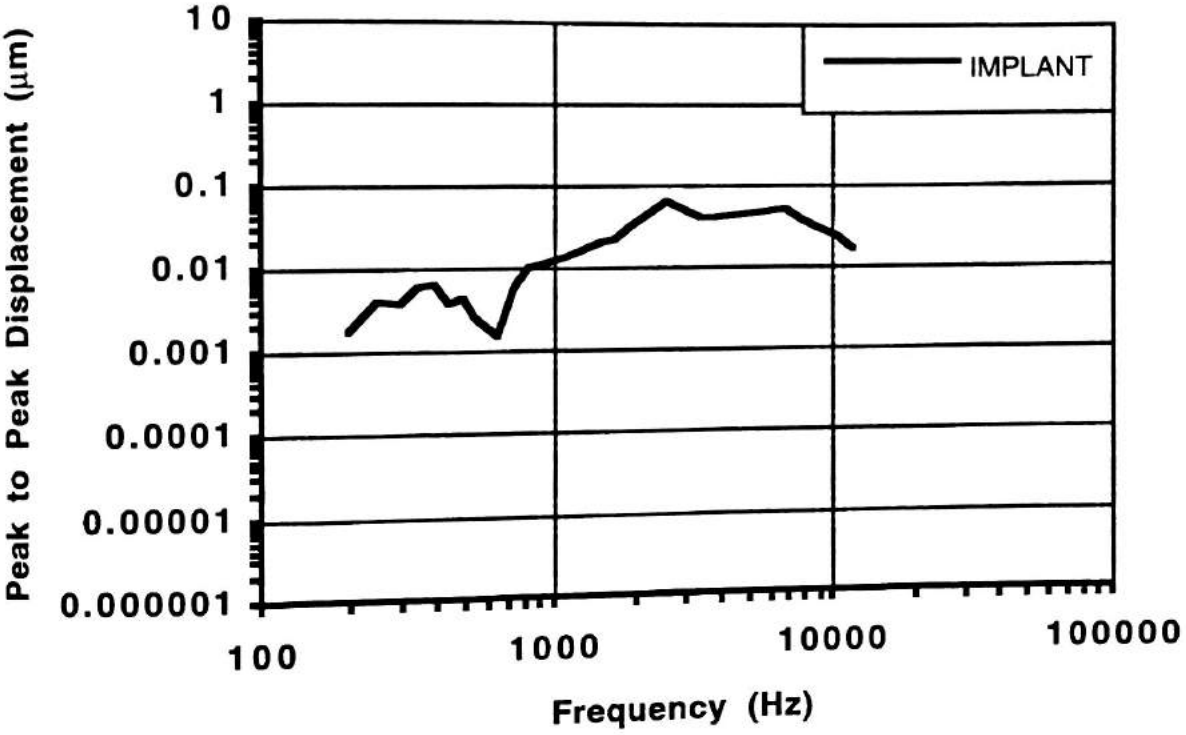
5.4 Middle ear implant on stapes head

The data provided in this thesis were collected using hand crafted transducers. Manufacture of close tolerance transducers using micro-machining and photographic technology similar to the kind used in integrated circuit design will improve the transducer's efficiency. That way the size of the transducer can be further reduced to fit into even smaller volumes. This will facilitate surgical placement. It will also permit the integration of the transducer into various middle ear implants (See Ch. 7).

5.4.1 Stapes displacement by MEI

One of the middle ear implants was glued to the stapes head in a fresh human temporal bone. Displacements were measured from the surface of the stapes footplate.

Fig. 30: Middle ear implant: stapes footplate displacement



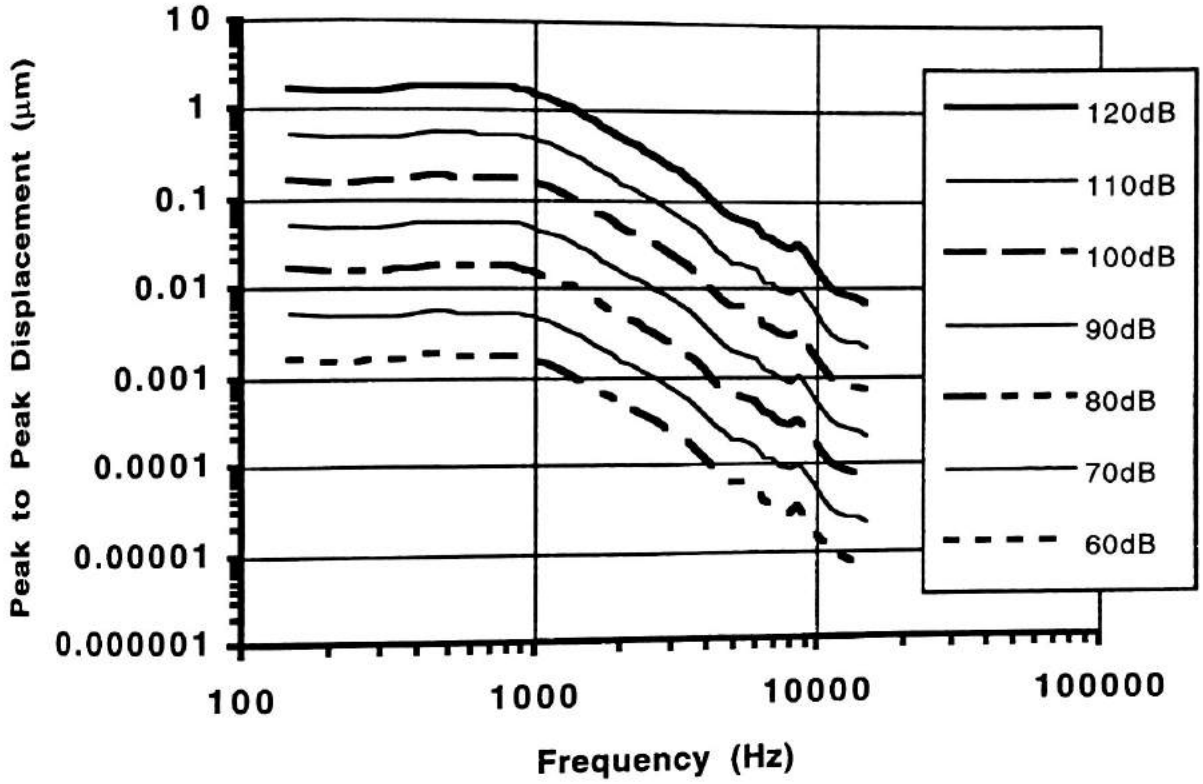
Input to the implant was 20 mA on 2.5 V yielding 50 mW.
Peak-to-peak displacement is measured on the stapes footplate.

5.4.2 Stapes displacement for calibrated sound pressure levels

Normal values for sound pressure levels from 60 to 120 dB.

Normal values were obtained using 28 fresh human temporal bones. Calibrated sound pressure levels of 80 dB SPL were applied with a sound chamber to the tympanic membrane of these specimens. Stapes velocity was measured at the stapes footplate between the crura and values were converted to peak-to-peak displacement. The 80 dB line in this chart is the mean value of measurements on 28 temporal bones. As the sound pressure scale measured in decibels is logarithmic, the values down to 60 and up to 120 dB were extrapolated from this curve at 80 dB

Fig. 31: Stapes displacement (n=28)

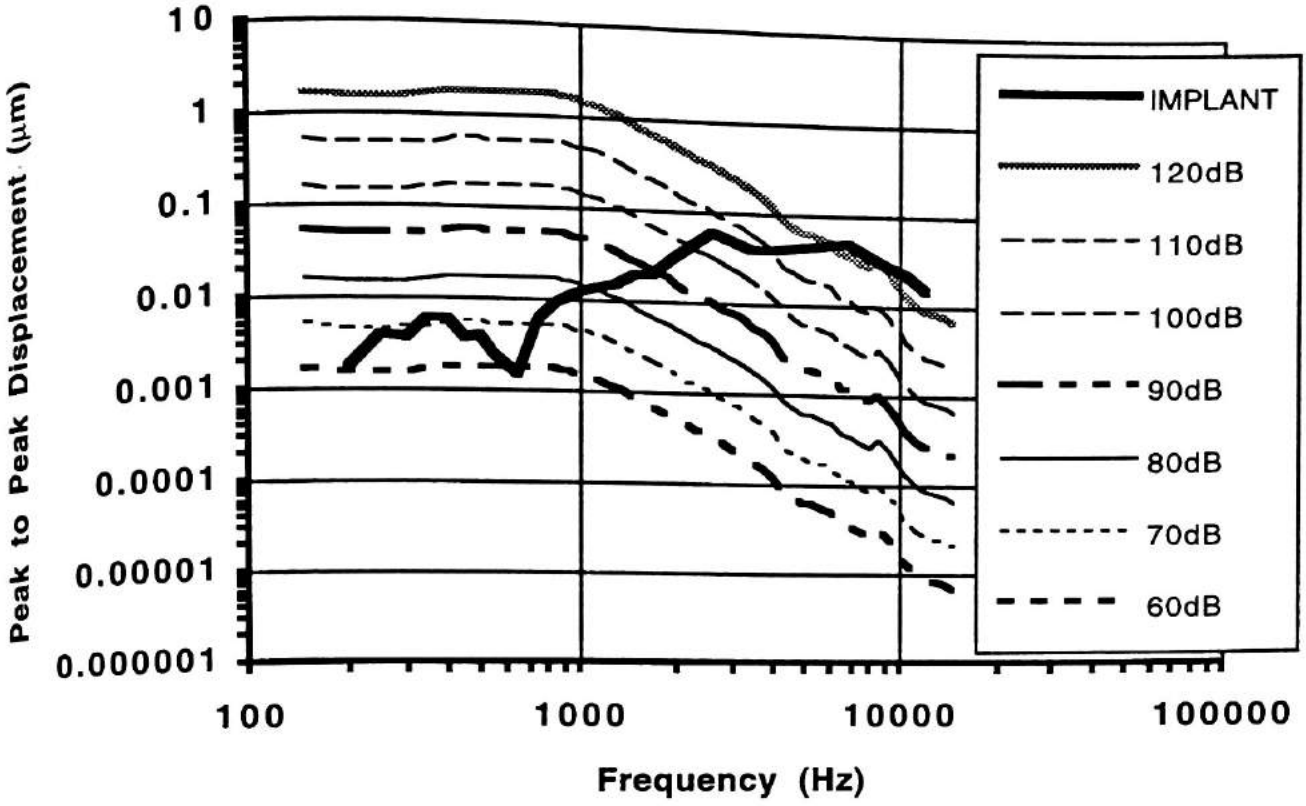


The measurements for this normative chart were obtained by Shinsei Nishihara, Research Fellow from Ehime University Japan, at the Veteran's Administration Medical Center Palo Alto, California.

5.4.3 Efficacy of an Electromagnetic Middle Ear Implant

Peak-to-peak displacements of the stapes footplate as induced by the MEI are compared to normal values at calibrated SPL.

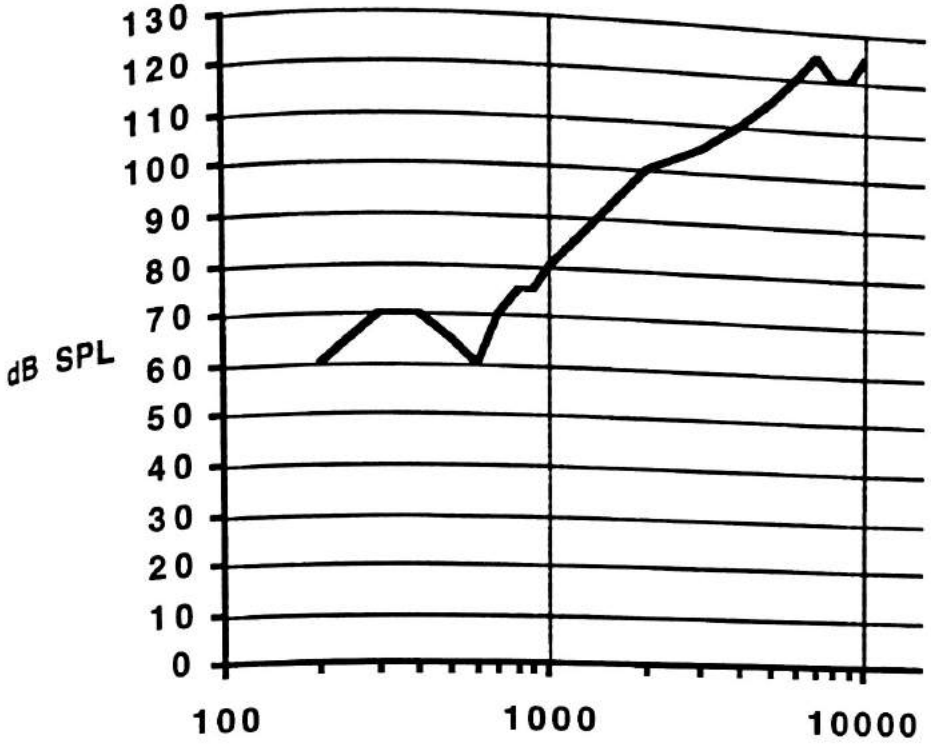
Fig. 32: Middle ear implant on stapes head: Stapes displacement



Displacements achieved by the electromagnetic implant were superimposed on the normal values of stapes displacement.

5.4.4 Sound Pressure Levels with MEI

Fig. 33: Frequency response of MEI on stapes



In logarithmic display the sound pressure levels produced by the MEI are almost linear between 0.8 and 8 kHz. Above 8 kHz artifacts influence the values. Below 0.8 kHz values do not respond in a logarithmic pattern.
These findings confirm the prediction that the MEI will be powerful in the middle and high frequencies and will have less again in the low frequencies. For stronger low frequency output, a larger electromagnetic device would be necessary. This, however could not be attached to the small ossicles. The weight of the stapes is only 3 to 5 milligrams. The effect of mass on various locations on the ossicular chain (Nishihara 1994) rules that an implant of 40 to 50 mg appears to be the maximal tolerable weight but a weight of 20 to 30 mg appears preferable.

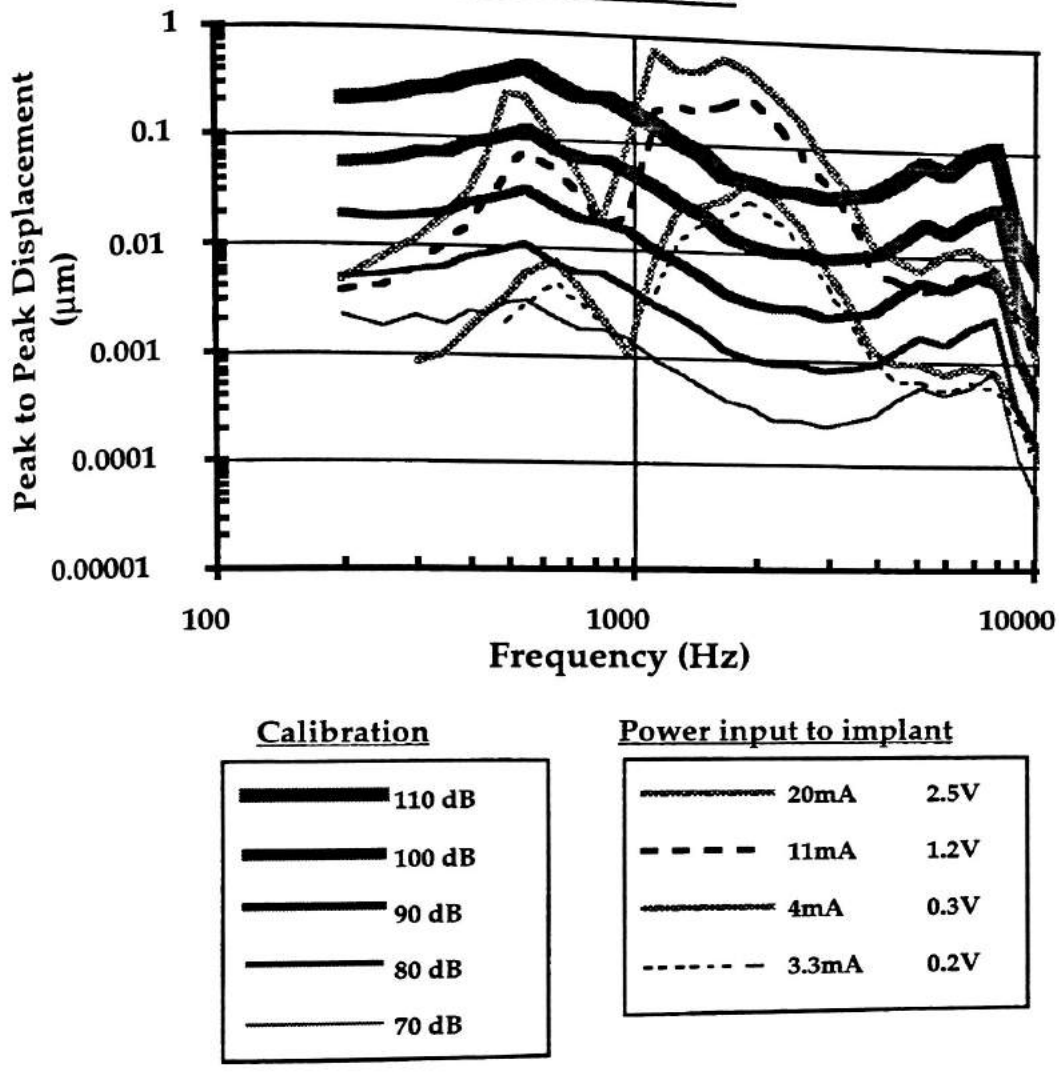
A study of power decrease with increasing distance and with preliminary results of the efficacy of the electromagnetic transducer was presented.[486,487]

5.5 Various input of power: performance

5.5.1 Set-up: variation of current

A human temporal bone was calibrated for sound pressure levels of 70 to 110 dB SPL at the level of the tympanic membrane. Stapes displacement for these levels was recorded and displayed as peak-to-peak displacement curves.

Fig. 34: Electromagnetic drive: Various input. MEI on long process of incus



The electromagnetic implant is set on the long process of the incus, lightly wedged between incus and scutum.

Input:

Various arbitrary levels of power input are provided.
Voltage and current are measured in RMS.
A 10 ohm resistor was used for stabilization.

Output:
Stapes peak-to-peak displacement curves were projected on the calibration curves to judge sound pressure levels. Maximum equivalent sound pressure levels were obtained at 2 kHz.

Table 2: Levels of the above stated arbitrary power settings:

Current in mA	Voltage in V	Power in mW	Maximum SPL at 2 kHz
20	2.5	50	125
11	1.2	13.2	120
4	0.3	1.2	110
3.3	0.2	0.66	105

5.5.2 Efficiency

This middle ear implant has proven an output of up to 125 dB SPL at an energy input of 50 milliwatts. This compares favorably to a regular acoustic hearing aid taking the improved sound quality into account.

5.5.2.1 RMS

RMS stands for root-mean-square. The RMS voltage is 70.7% of the peak value.[488] The voltmeter reads the effective value and as such the RMS value and not the peak value.

5.5.2.2 Peak-to-peak displacement

This is derived from target velocity.
Velocity is divided by $2 \pi f$ f = frequency

5.6 A new transducer

On 8-18-92, an experiment implementing the concept of very close contact in the electromagnetic induction in a transducer consisting of a magnet surrounded by a coil was successfully completed. The intention was, to show the potential energy transfer onto the ossicles of the middle ear by a transducer using this technology.

5.6.1 Set up of the transducer

1. Small magnet of Samarium-Cobalt :
   35 mg, disc size 1.2 mm diameter x 1.0 mm height
2. Coil around it:
   two bifilar wires
   42 G
   50 turns
   impedance of 6.5 ohms

The coil is not tightly fixed to the magnet. The coil was first wound onto a plastic tube and the magnet was then stuck into it leaving a space of 0.2 mm around it. The measuring target of 3M-reflective tape is placed on the footplate.

5.6.2 Results

Maximum output: gain as demonstrated by the logarithmic chart in Fig. 32 "Frequency response by MEI" in Ch. 5.4.3

Table 3: Sound pressure levels by MEI:

At frequencies below 1 kHz:	60 dB
at 1 kHz:	80 dB
at 2 kHz:	90 dB
at 4 kHz:	110 dB
between 4 and 10 kHz:	120 - 125 dB

The sound pressure levels obtained with this transducer as listed in chapter 6.4. display maximum levels of 125 dB SPL with 50 milliwatts input and minimum levels of 105 dB SPL with 0.66 milliwatts input.

5.6.3 Comment on the transducer

1. In this experiment the transducer was not glued or otherwise fixed to the incus. It was merely sitting on it. This connection might explain the lower displacement levels at the lower frequencies.

2. The calibration curves of the temporal bone of Fig. 34 (Ch. 5.5.1.) are somewhat different from the mean curve obtained from 28 temporal bones. The reason for this flat curve might be the stiff quality of the tympanic membrane and the ossicles. This does not influence the result of the measurements because this temporal bone was calibrated individually.

3. The transducer used in this experiment was more efficient than the one used in previous experiments. It requires less power for equal sound pressure levels. However, it was hand made and an industrially machined transducer with high precision parts will be substantially more efficient.

4. The SPLs correspond well to various power inputs. A 10 dB increase in SPL requires about a tenfold increase in power.

5. The ideal power consumption of hearing aids using microchip technology is 1 milliwatt equal to 1 Volt and 1 milliampere. At this level of power input, this crude transducer produced maximum SPLs of 105 to 110 dB.

6. Concept of the Semi-implantable Hearing Aid

The semi-implantable hearing aid consists of external and internal parts:

1. External part:
   - Microphone
   - Battery
   - Amplifier
   - Induction coil or connector to plug

2. Internal part:
   - Internal coil or percutaneous screw
   - Wire connection from coil to transducer
   - Transducer in middle ear

6.1 Transducer

The central parts of all middle ear implants described in this thesis are the transducers, whether they are of piezoelectric or electromagnetic design.

6.1.1 New concept

Previous concepts of electromagnetic transducers included the placement of the coil as close as possible to an implanted magnet. This caused great technical and surgical difficulty. In particular, the fixation of the coil in the correct position over the implanted magnet was uncertain. As the implantable hearing system should be used by the majority of otologists, its construction and set-up should be as safe and simple as possible.

It was estimated that power delivery could be provided by 1 or 2 batteries with 3 or possibly 1.5 Volts.

The weight of the magnet might be reduced to as low as 10-20 mg and the weight of the coil to around 5 mg.

This transducer contains a coil-magnet setup that permits a very efficient energy transfer to the ossicle to which it is attached to.

Due to pending patent applications in various countries no detailed information on the construction of the transducer can be provided at this time.

6.1.2 Explanation of function of the transducer

The permanent magnet of this transducer system moves in response to the changing AC field produced by the coil. The magnet is held in position by a structure that permits mobility in the north-south direction. The magnet moves away from or towards the coil in response to the alternating electromagnetic field.

The key concept of this design is this: although the magnet tends to move away from or towards the coil, the coil also tends to move towards or away from the magnet. This is due to the law of physics of conservation of energy where there is an equal and opposite reaction to every action. In this case the equal and opposite reaction is the coil movement juxtaposed to the magnet movement.

In absolute terms, the resulting loss from this design is equivalent to 6 dB, however, because the design is so efficient in terms of configuration within the middle ear, this loss is acceptable.

The transducer uses inertia to set the entire case in motion. The inner motion of the magnet relative to the coil transmits this vibration onto the whole transducer to let it vibrate.

The polarity of the permanent magnet remains the same throughout time. The field caused by the coil changes in an alternating mode. If the plus field opposes the plus side of the magnet, it pushes it away. The negative field on the other side however attracts the magnet. Changes of the AC-current then cause an attraction that brings the magnet back. The movement of the magnet in relation to the changing field causes the entire transducer to vibrate because of the mass of the magnet. Resonances will have to be ruled out in the final transducer. No effort has been made in these preliminary transducers to analyze potential resonance frequencies and amplitudes.

This transducer has no outer part that is mobile as in most of the other transducer concepts currently used. The case is stiff and does not flex. The movement of the entire case makes this transducer unique. This concept also allows a variety of designs that fit the respective needs of middle ear problems as in partial loss of ossicles: see chapter 7 on various designs of this implant.

6.1.3 Interface between coil and magnet

In this transducer, the coil engulfs the magnet closely. A relative movement between coil and magnet is possible. The kind of fixation of the magnet on a pliable membrane must be decided by engineers. The closer the distance between the coil and the magnet, the higher the power transmission.

6.1.4 Placement of the transducer on incus or stapes

Whenever possible, an intact ossicular chain should not be interrupted for attachment of a middle ear implant. Without disruption, the device therefore needs to be attached to the incus or the malleus. The handle of the malleus is covered by the tympanic membrane and the head of the malleus is less available than the body of the incus or the long process of the incus. Attachment of the device is therefore most probable on the incus itself and most probably on the long process of the incus.

In order to place an implant on the stapes, the incudo-stapedial joint would have to be separated temporarily. This is also proposed in the doughnut transducer (Ch. 7.1.2.).

6.2 Middle ear implant

The transducer is incorporated into a biocompatible housing. Pacemaker technology has proven that electronic implants can be sealed off effectively from body fluids. The transducer might be covered by laser welded titanium. Several layers of biocompatible substances could further make up the housing. The outermost layer will be silastic. A long-term study by Ng and Linthicum[489] from the House Ear Clinic has shown the lack of foreign body reaction to silicone in the middle ear in histologic work-ups of patients supplied with silastic sheets in their middle ear cavity.

Any middle ear implant that touches the tympanic membrane will require a cover of hydroxyapatite or cartilage to prevent extrusion. Hydroxyapatite is currently used in several middle ear prostheses such as the PORP of Black[490] with its egg shaped head.

This middle ear implant has no external moving parts. As such it is less prone to cause middle ear irritation or infection. Furthermore, the risk for mechanical break-down of the transducer itself is reduced. This transducer does not need a resting point from which the action is directed to the ossicles as do other middle ear implants. This implant can be mounted directly onto an ossicle.

Various designs of middle ear implants will be provided once clinical testing has proven the efficiency and safety of the semi-implantable hearing aid for sensorineural hearing loss (Ch. 7.1.).

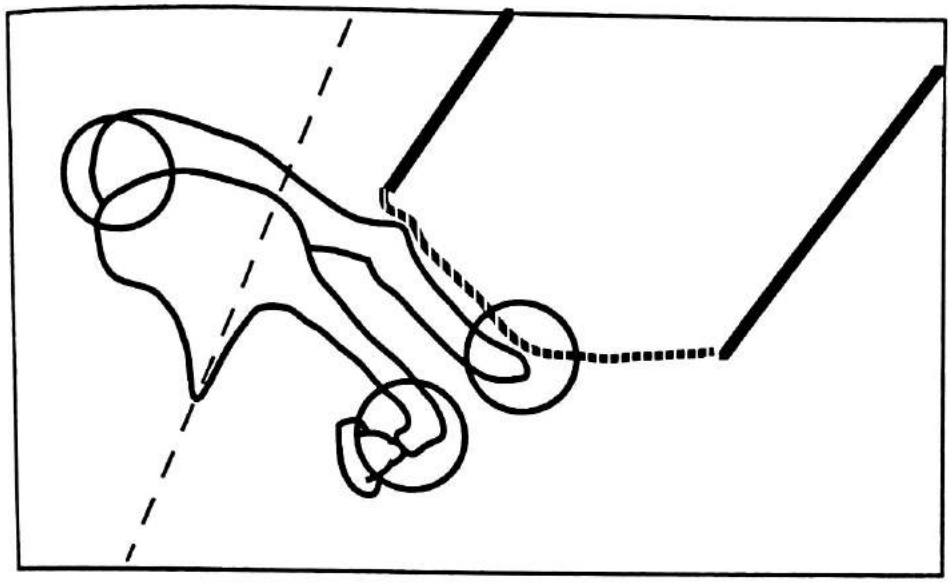
6.2.1 Attachment of the implant

The attachment to the middle ear ossicles can be achieved in a variety of ways. A platinum or titanium clip to hold the implant on the long process of the incus will be the most probable way of fixation (Chapter 7). This technique has been applied successfully in a variety of stapes prostheses. In order not to cause necrosis of the long process of the incus, the clip will not be a wire but rather a band to distribute the stress onto a larger surface. The blood supply to the lenticular process is provided by the vessels of the periosteum of the long process of the incus as well as along the stapedial tendon and the stapes superstructure. In the implant with the incus clip, the incudostapedial joint is not separated and the blood supply to the stapes superstructure is not threatened.

In order to use the maximum lever arm, any implant should consider the law of levers. The longer the lever arm, the less the force needed. For middle ear anatomy this means placement of the implant as far away from the axis of rotation

as possible. Location on the lenticular process would therefore be more efficient than on the long process of the incus.

Fig. 35: Locations on ossicular chain with most peak-to-peak displacements:

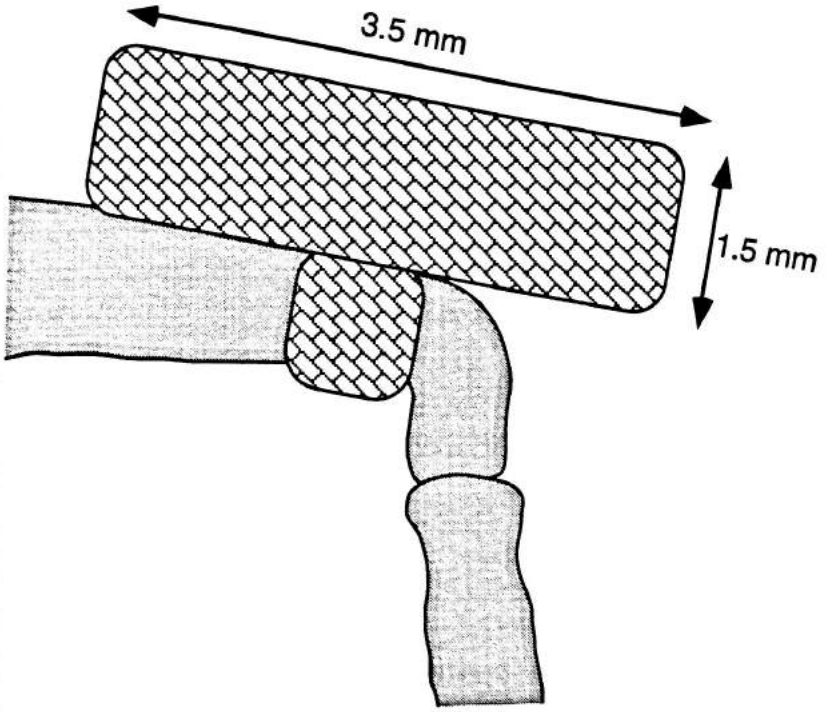


Circles: umbo, lenticular process of incus and incudostapedial joint in mesotympanum, malleus head and incus body in epitympanum.

Several implants follow this rule. The EarLens® system of ReSound attaches to the center of the TM. Smith Nephew Richards tested an implant that was attached at the medial side of the malleus handle. The contactless device of Maniglia drives the body of the incus. The epitympanum is also addressed by the electromagnetic device of Fredrickson where the incus body is driven by a rod connection.

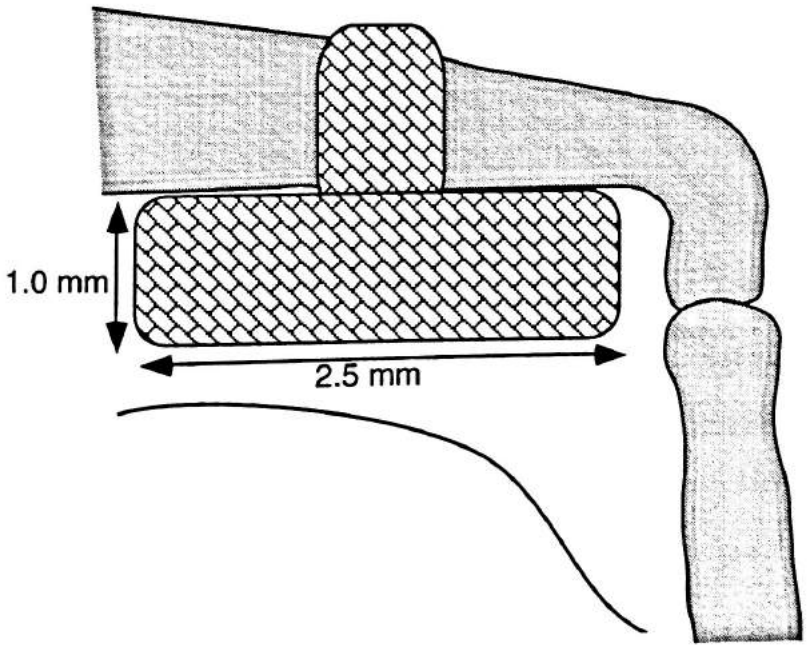
In the system described in this thesis, the implant will most probably be placed onto the long process of the incus but not hanging parallel to it. Placement in the axis of the long process of the incus is important to avoid rotation of the implant around the long process. The reason for this location is its accessibility in middle ear surgery as well as the familiarity of otologists with stapes surgery.

Fig. 36: Middle ear implant on long process of the incus:



An implant placed on top of the long process of the incus could have a diameter of 3.5 mm in a disc shape with a weight of 35 mg. Height should not exceed 1.5 mm in order not to touch the mucosal surface of the tympanic membrane.

Fig. 37: Middle ear implant suspended on long process of the incus:



An alternative location for placement of the device is the space between the long process of the incus and the tympanic portion of the facial nerve. This location allows for limited implant dimensions of about 2.5 to 1.0 millimeters due to the close proximity of the facial nerve. The weight would be limited to about 20 mg.

6.2.2 Removal of the middle ear implant

Removal of the implant is possible by spreading the clip. The possibility of removal is important if replacement should become necessary in the advent of a technical problem. Due to the solid design of the implant with no external moving parts, the transducer is expected to perform properly over many years. However, exchange must be possible.

The silastic coating will prevent the implant from fixation to the middle ear by fibrosis or ossification. The surgery for exchange of the implant will be fast because the approach through the mastoid as well as the drilling of the cortical bone in the retroauricular area to hold the internal coil will have already been achieved by the initial surgery.

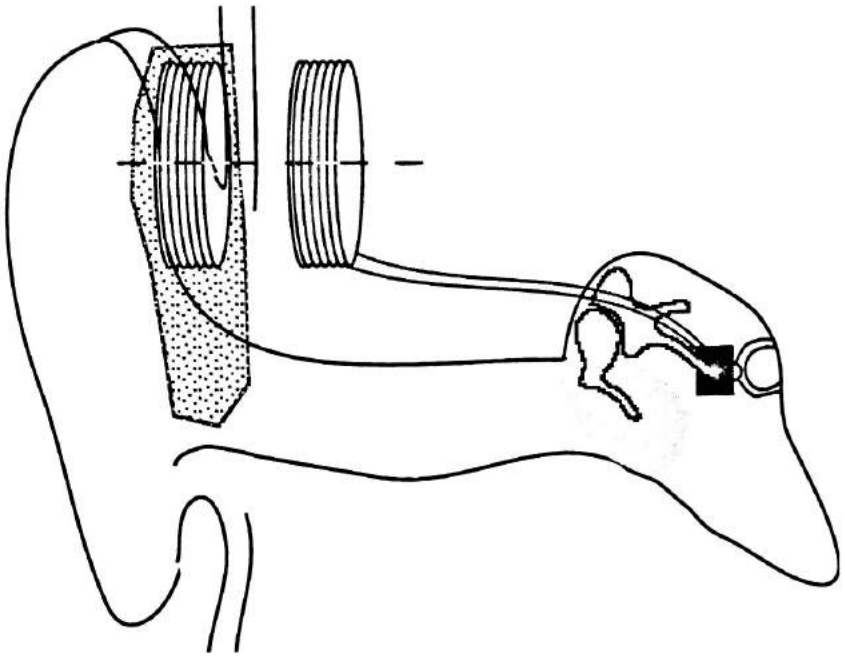
6.2.3 Residual hearing

To place this type of implant into the middle ear does not require disruption of the ossicular chain. Hearing through acoustic waves along the external ear canal and the conductive system of the middle ear will only be hampered mildly due to the additional weight resting on the incus. A dampening effect of 10 to 15 dB is to be expected.

6.3 Transcutaneous induction

In transcutaneous conduction, the power to the implant is delivered by a transcutaneous coil-to-coil system (Fig.38) as it is used in several cochlear implants. In order to provide exact alignment of the two coils, two magnets are placed in the center of each coil to allow an ideal position as well as to hold the external part in place. With this, the speaking coil is located parallel to the implanted receiving coil. This mode of alignment and technique of energy transfer through the intact skin is used in cochlear implants as well as in the Audiant® Bone Conductor.

Fig. 38: Transcutaneous induction:



Alignment of coils is crucial

The internal coil connects to the transducer in the middle ear by wires. In the case displayed here, the transducer is positioned between the incudostapedial joint as in the doughnut design.

6.4 Percutaneous connection

As explained in chapter 4, the alternative to transcutaneous induction is a direct electrical coupling using a percutaneous plug. This direct connection would eliminate the loss by attenuation that can be as high as 20 dB. Recent technologies have shown improved efficiency for transcutaneous induction. The application of radio frequency (RF) transmission might lead to further improvement. At this time, no final decision has been made between the two systems. It is quite possible that both will be pursued to a later stage of development.

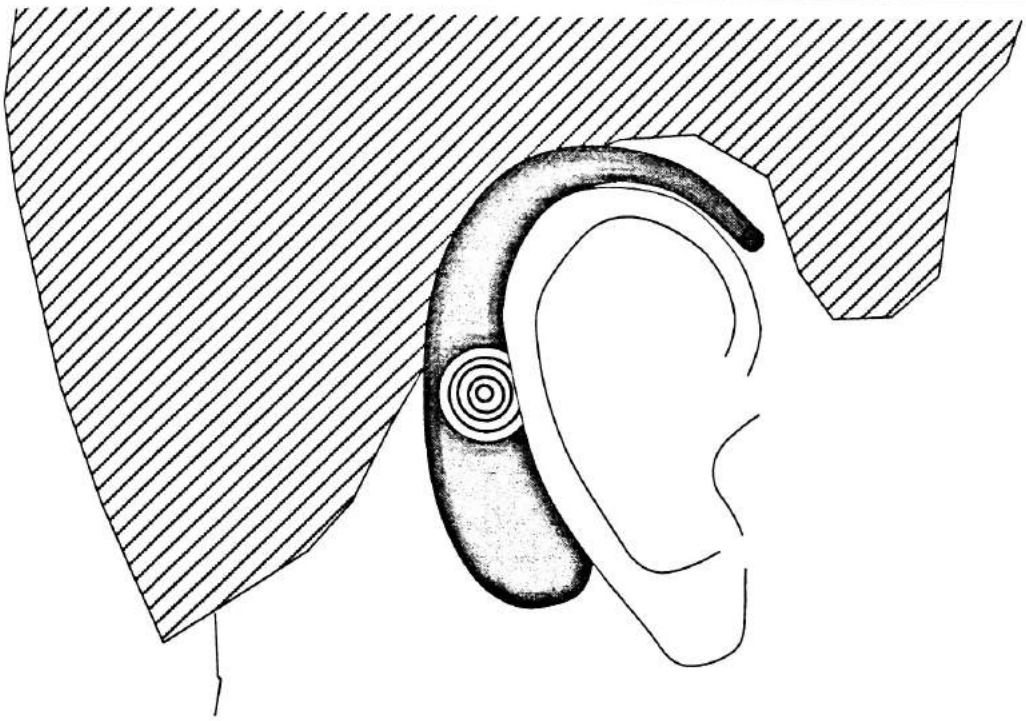
6.5 Designs of the external unit

The external unit will be crucial for acceptance by the general public because this is the only part seen by the patient and the family.

6.5.1 Behind the ear location in transcutaneous induction

This set-up is applied by the Japanese piezoelectric system of Rion. Alignment between induction coils needs to be achieved in surgery because the external device is dependent on the positioning around the auricle. The microphone lies above the pinna for improved acoustic pick-up of sound.

Fig. 39: Transcutaneous induction by Behind-The-Ear hearing aid:



Concentric circles: location of the induction coil in the external part of the hearing aid.

With a behind-the-ear (BTE) device, cosmetics is not improved compared to a conventional hearing aid design. Furthermore, this external device can shift and move around leading to problems in transmission to the implanted coil.

The microphone still needs to be placed in an acoustically favorable situation that is above the pinna. The best location acoustically would be the external ear canal but the ear canal is not well reached with a BTE device.

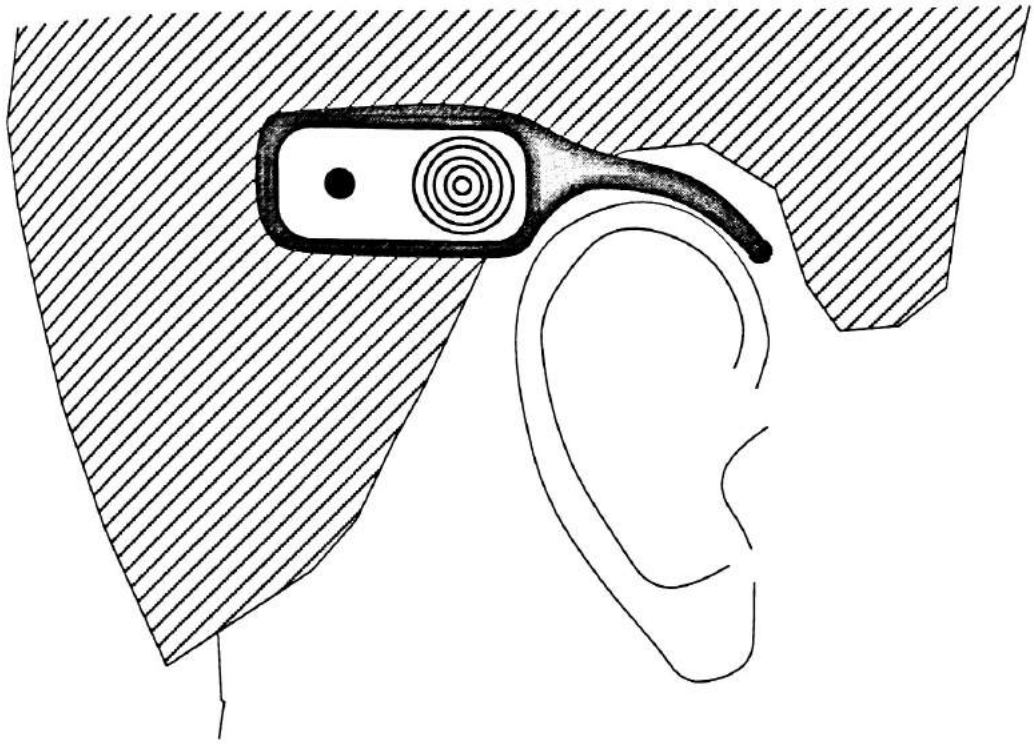
This location of the microphone above the pinna is also used in the next design, where the external device is better hidden in the hair bearing scalp.

Cosmetic concerns with a BTE device are less favorable than with an ITE device or one that is hidden by hair. Furthermore, the effectiveness of the transcutaneous induction is a major factor for the performance of the implant as experience with various cochlear implants has demonstrated.

6.5.2 In hair-bearing retroauricular skin in transcutaneous induction

The receiving coil is placed in the hair bearing skin of the retroauricular area. Alignment is achieved by magnets. The microphone needs to be positioned above the pinna for ideal acoustic reception.

Fig. 40: Transcutaneous induction by hearing aid attached by magnetic force in temporal hair-bearing skull:



This set-up is used in one model of the Xomed-Treace™ Audiant® system. In order for the device to remain on the head, a strong attraction by magnetic attraction is necessary. This can lead to skin irritation, local pain and headache. The device also falls off easily rendering it prone to destruction by mechanical trauma.

Among other reasons, these disadvantages have led to further evaluation of the possibility of a firm connection of the external device to the skull.

6.5.3 Percutaneous connection

The above mentioned disadvantages of cosmetics, insecure transmission of information, and danger of falling off were all taken into consideration. Correction was sought in the percutaneous coupling. In the proposed device, the external part might be small with an estimated volume of 4 cm^3. With improved electronics, it will be miniaturized further.

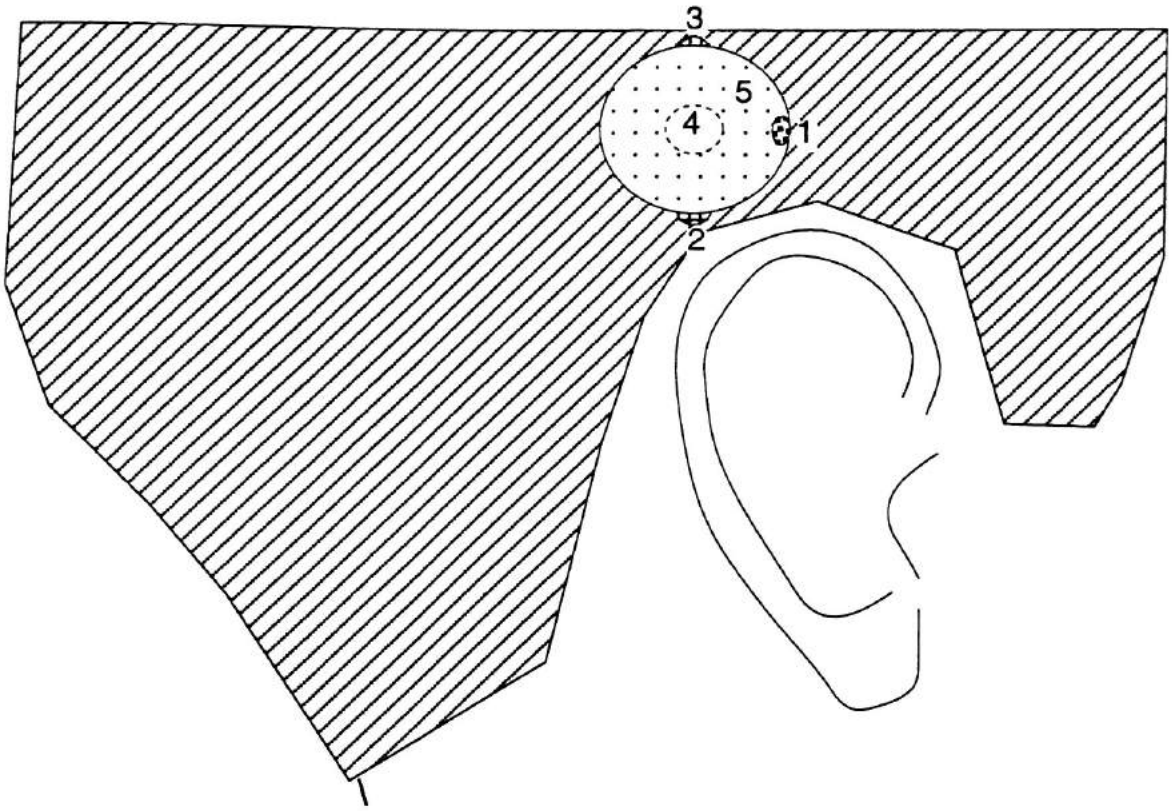
The plug is placed in the hair bearing part of the temporal squama. This allows safe insertion of the titanium screw into the skull bone, easy access for patient handling and forward direction of the microphone.

The Brånemark titanium screw has proven the excellent cosmetics of this location and there is minimal friction or noise by hair. Furthermore, the external

unit is secured firmly by a plug-in system. Security of fixation will be similar to the Brånemark system.

The external unit (Fig. 41) consists of a microphone (1), volume (2) and program (3) control. All are integrated in a compact housing (5) holding the battery and the sound amplifier. This external hearing aid part is plugged into the socket of the percutaneous titanium screw by the connector (4) (Ch.4.3.).

Fig. 41: Proposed percutaneous plug:
External part of the semi-implantable hearing aid:
Plugged in



Legend:

1	Microphone	4	Plug
2	Volume Control	5	External Hearing Aid
3	Program Control		

For further information on the percutaneous plug see chapter 4.

7. Designs

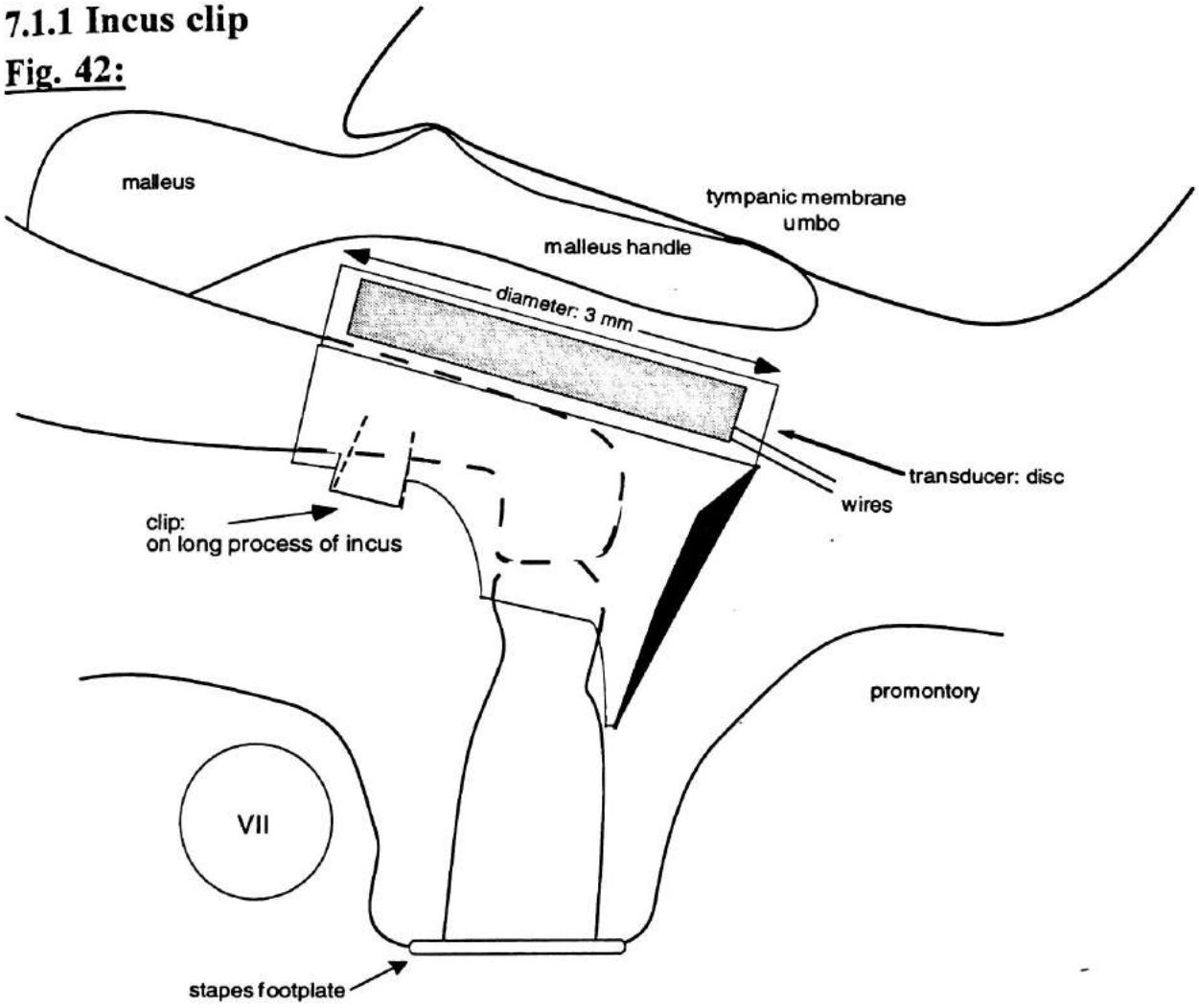
The transducer of the electromagnetic middle ear implant may be incorporated in several different designs depending on indication and use.

7.1 For sensorineural hearing loss

In pure sensorineural hearing loss, the middle ear is intact and functioning well. The sound conducting apparatus must not be impaired in order to keep the possibility for the use of an acoustic hearing aid. The piezoelectric device of Suzuki/Yanagihara removes the incus permanently to attach their transducer to the stapes head. As such, the acoustic chain is severed and interrupted leaving an air-bone gap of 50 to 60 dB. This is to be avoided.

7.1.1 Incus clip

Fig. 42:



Attachement of the implant on the long process of the incus by titanium clip.

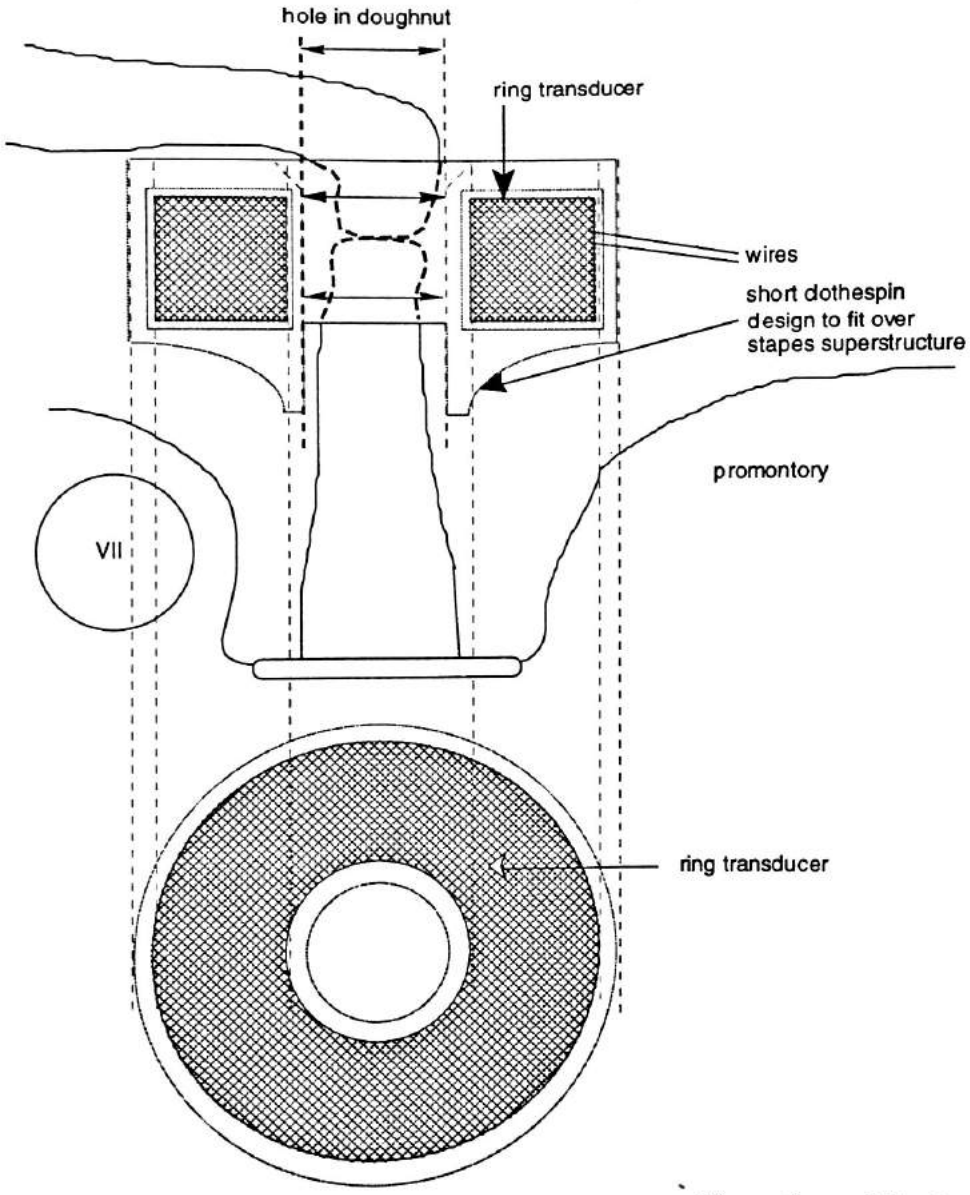
A possible design for sensorineural hearing loss is the incus clip. The implant is riding on the long process of the incus and the stapes superstructure.At this site, the diameter of the long process of the incus is 0.8 to 1.0 mm. Currently

the author is working on a new stapes prosthesis that will use a similar clip with an attachment at this location.[491]

7.1.2 Doughnut shape

Another possibility for placement of the transducer is the location between the incus and stapes. After disconnection of the incudo-stapedial joint, a ring transducer is slipped onto the neck and shoulders of the stapes superstructure and the incudo-stapedial joint is realigned and allowed to heal. This results in safe placement without danger of dislocation. The need to disconnect the incudo-stapedial-joint temporarily might be a disadvantage.

Fig. 43: The doughnut transducer:

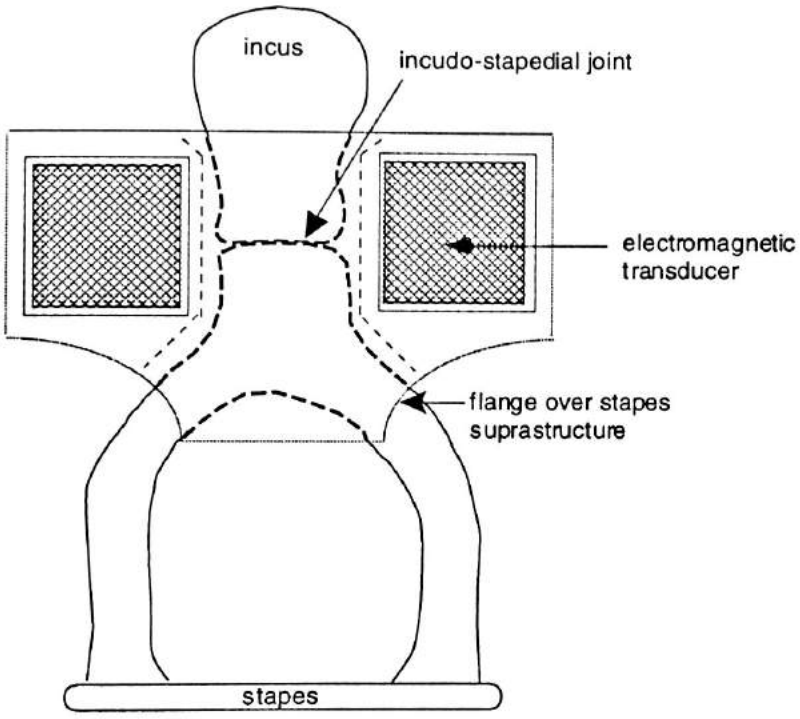


Insertion of the doughnut implant by temporary disruption of the incudo-stapedial joint.

The location on the incudo-stapedial joint limits the size of the ring transducer to 1.5 mm in height and 2 mm in diameter. Due to the opening in the implant, the central part of the magnet is also lost for energy transfer. This, however, results in a diminished weight. Because inertia is the driving part of this transducer, any reduction of weight of the magnet will result in decreased output. For moderate and moderate-to-severe hearing losses, this mode of implantation might still be adequate.

Studies of Hough et al. (1988) have shown that a ring magnet placed on the incudo-stapedial joint will withstand the pull by the magnetic field of an MRI machine.

Fig. 44: The doughnut transducer:
Section parallel to the stapes superstructure:



The doughnut transducer rides on the shoulders of the stapes.

7.2 For conductive hearing loss

7.2.1 Incus replacement prosthesis

In chronic middle ear disease, the incus is affected most often resulting in partial or total destruction. The part most often affected is the long process leading to disconnection in the incudo-stapedial joint. A fibrotic connection might still transduce part of the sound energy. In total disruption, the air-bone gap is 50 to 60 dB. In order to establish sound conduction, an incus replacement prosthesis (IRP) may be inserted. If the body of the autologous incus is intact it can still be used for an interposition between malleus and stapes or a columella between stapes and tympanic membrane.

Otherwise, an incus replacement prosthesis or a partial ossicular replacement prosthesis (PORP) may be implanted. Audiologic results are often disappointing leaving an average air-bone gap of 15 to 25 dB or more. To the best of this author's knowledge there is no moving IRP available that amplifies or generates mechanical waves.

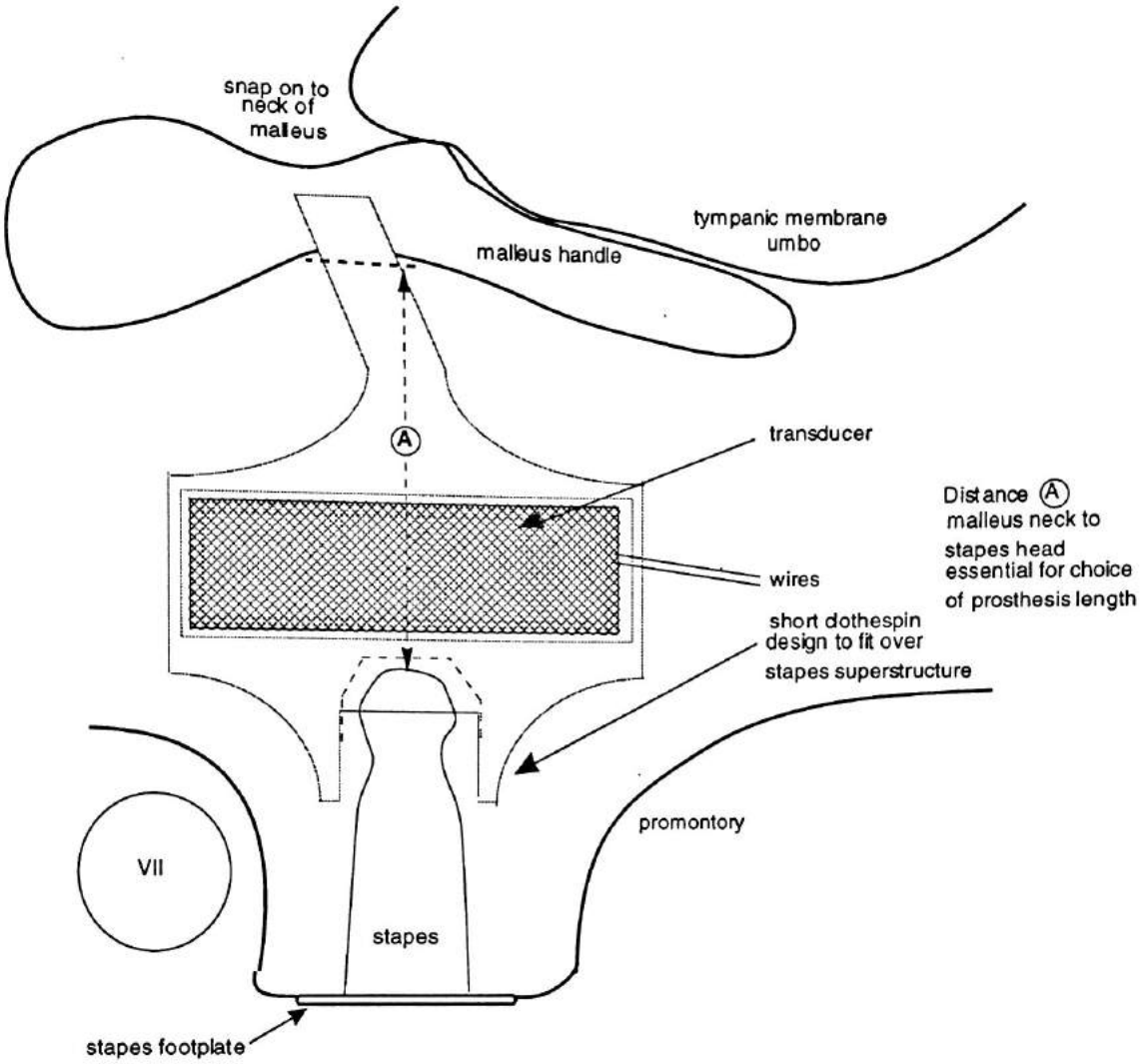
The electromagnetic transducer proposed herein can also be encased into an IRP that changes it into a vibrating prosthesis. This concept is purely hypothetical and has not yet been tested.

Amplification might be jeopardized by phase shifts leading to decreased sound quality or even uselessness of this set-up. Phase relationships have not been determined yet and further laboratory testing will have to prove the viability of an electromagnetic IRP. One clinically tested electromagnetic implant is that of Kartush (Ch.2.2.3.4) where PORPs and TORPs have been considerably profitable to the patient apparently without significant problems of phase shifts or distortion.

The IRP might be fixed to the neck of the malleus. Shea has designed a similar IRP and TORP with this mechanism. According to Smith this results in a very effective and safe connection.[492] Other incus replacement prostheses are interposed between the stapes and the malleus handle. Because of its defined anatomical site, the neck of the malleus allows for a safer connection than the malleus handle.

The connection between malleus and stapes is reinstalled and energy transfer from the tympanic membrane to the cochlea is possible. The location of the IRP at the neck of the malleus is not the most favorable site acoustically. The additional sound transfer might be important in the low frequencies as the maximum output of the MEI is only 60 dB at 0.5 kHz and 80 dB at 1 kHz.

Fig. 45: Incus replacement prosthesis:



The IRP implant is wedged between the stapes head and the malleus neck.

For optimal sound transmission, the ossicular chain must be able to vibrate without restraint. Any interposed prosthesis replacing an ossicle should therefore be similar in weight and be attached firmly to the remnants of the ossicular chain. Hüttenbrink[493] reported on the influence of fixation of ossicular replacement prostheses. For optimal sound transmission, the connections should be tight. Repositioning of an IRP down along the malleus handle towards the umbo increases sound transmission by the tympanic membrane, but it also increases stress.[494,495]

7.2.2 Partial Ossicular Replacement Prosthesis: PORP

More destruction of the middle ear that might include the incus, part of the malleus as well as the tympanic membrane (TM), a partial ossicular replacement prosthesis (PORP) may be inserted. The head of the PORP is commonly in contact with the tympanic membrane as a columella.

The main obstacle in surgery of middle ear defects using PORPs or TORPs has been the persistent air-bone gap that remains after surgery as well as a continuous danger for extrusion of the implant. This conductive loss occurs in addition to the sensorineural loss that is often present in these ears. In combination, the patient is left with a substantial hearing loss. Furthermore, many of these patients have a history of infection and irritation of the external ear canal. Conventional hearing aids provoke these local infections and patients tend not to wear their hearing aids at all. Patients would benefit from a technique leaving the external ear canal open, such as in the proposed middle ear implant.

A vibrating PORP can also be constructed using this transducer technology. The head of the PORP can be in contact with the TM. This requires a coating of hydroxyapatite. In a middle ear that is deep enough, the electromagnetic transducer can also be placed without contact to the TM.

An estimated 25,000 TORPS and PORPS are surgically implanted in the USA alone each year. The advantage of an electromagnetic implant over a stiff rod is obvious.

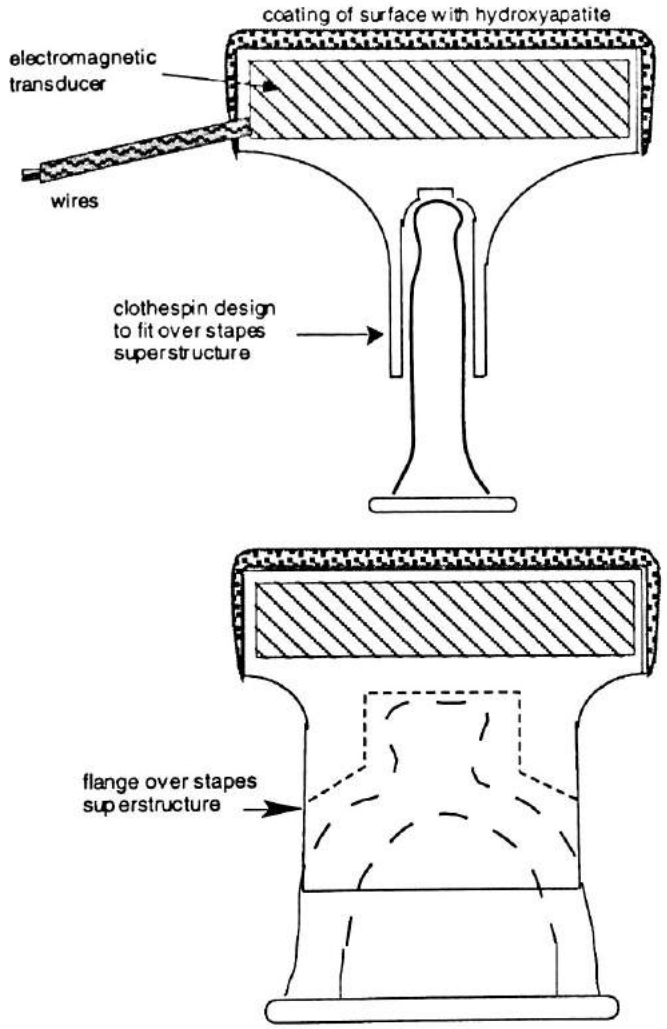
The flanges of the PORP proposed here straddle the stapes superstructure. This concept was developed by Schuring and Lippy in 1978 and termed the "clothespin" design.[496-498] In 1992, Krause presented a modification of the Schuring implant at the American Academy of Otolaryngology - Head and Neck Surgery in Washington D.C. produced by Smith&Nephew Richards Inc.[499] Hearing results were presented as a preliminary report on this prosthesis. The design decreases the pivoting of the PORP prosthesis on the stapes capitulum. It helps to prevent inferior-superior displacements by straddling the stapes superstructure. The part of Krause's PORP that is sitting on the stapes is derived from a tube making it a circular structure in diameter. The flanges extend almost to the level of the footplate. Hüttenbrink has invented a PORP of gold (*Dresden prosthesis*)that may be gently clamped onto the stapes superstructure.[500]

The superstructure of the stapes has variations (Ch. 3.1.5). The space in the oval niche is limited. When the stapes superstructure tilts towards one side, this space becomes even smaller. The design of the flanges of the implant proposed here, which straddle the stapes superstructure, must take this into account in order not to attenuate sound conduction by friction. Instead of the curved and long flanges of the Krause modified Schuring prosthesis, the flanges are flat and short and sit just on the shoulders of the prosthesis without reaching down towards the footplate. This permits contact over a greater length and prevents contact with the

facial nerve or the promontory. This concept has also been applied in an experimental IRP developed by the author and produced by Microtek.[495]

The Krause modified Schuring ossicular implant is made of Fluoroplastic (Teflon®). It connects to a hydroxyapatite cap of 3.8 mm diameter, which is placed under the tympanic membrane.

Fig. 46: Partial ossicular replacement prosthesis:



Cover of the PORP surface with hydroxyapatite to allow direct contact with the tympanic membrane.

7.2.3 Total Ossicular Replacement Prosthesis

In severe middle ear disease with further ossicular destruction, not only the incus might be eroded but also the stapes superstructure leaving only the malleus and stapes footplate intact. A total ossicular replacement prosthesis (TORP) may be used for reconstruction. The audiological results are commonly worse than with PORP or IRP. According to Black[501] and Goldenberg,[79] air-bone gaps are closed to within 20 dB in only 50 to 60% of these ears.

Shelton and Sheehy[502] followed 466 ears after ossicular reconstruction with PORPs or TORPs and reported slightly better results. The air-bone gap was closed to within 20 dB in 76% of cases reconstructed with PORP and 69% of those reconstructed with TORP. Closure within 10 dB was achieved in 52% and 39%, respectively. Extrusion occurred in 5.3% of cases and was usually related to poor Eustachian tube function.

Sanna et al.[503] reviewed 247 cases with TORPs and PORPs in a long-term study with minimum follow-up of 5 years. Hearing results decreased over time. Initially an air-bone gap to within 25 dB was achieved in 66.6% in TORPs and 62.5% in PORPs. The extrusion rate was 7.7%. Their group[504] also reported on better hearing results using an autologous fitted incus for interposition versus Plastipore PORP.

A vibrating TORP would be most helpful for this situation.

There are drawbacks to the use of a TORP. Due to the long distance to be bridged and the small area of the stapes footplate, these TORPs tend to be unstable and fall out of position easily. A permanent solution to this problem has not yet been found. A clip-on holder that connects the lateral part to the malleus might improve stability. The part connected to the stapes footplate can be shaped in an oval form to fit inbetween the remnants of the crura of the stapes superstructure. However, there is no doubt that this field of ossicular reconstruction will require future work.

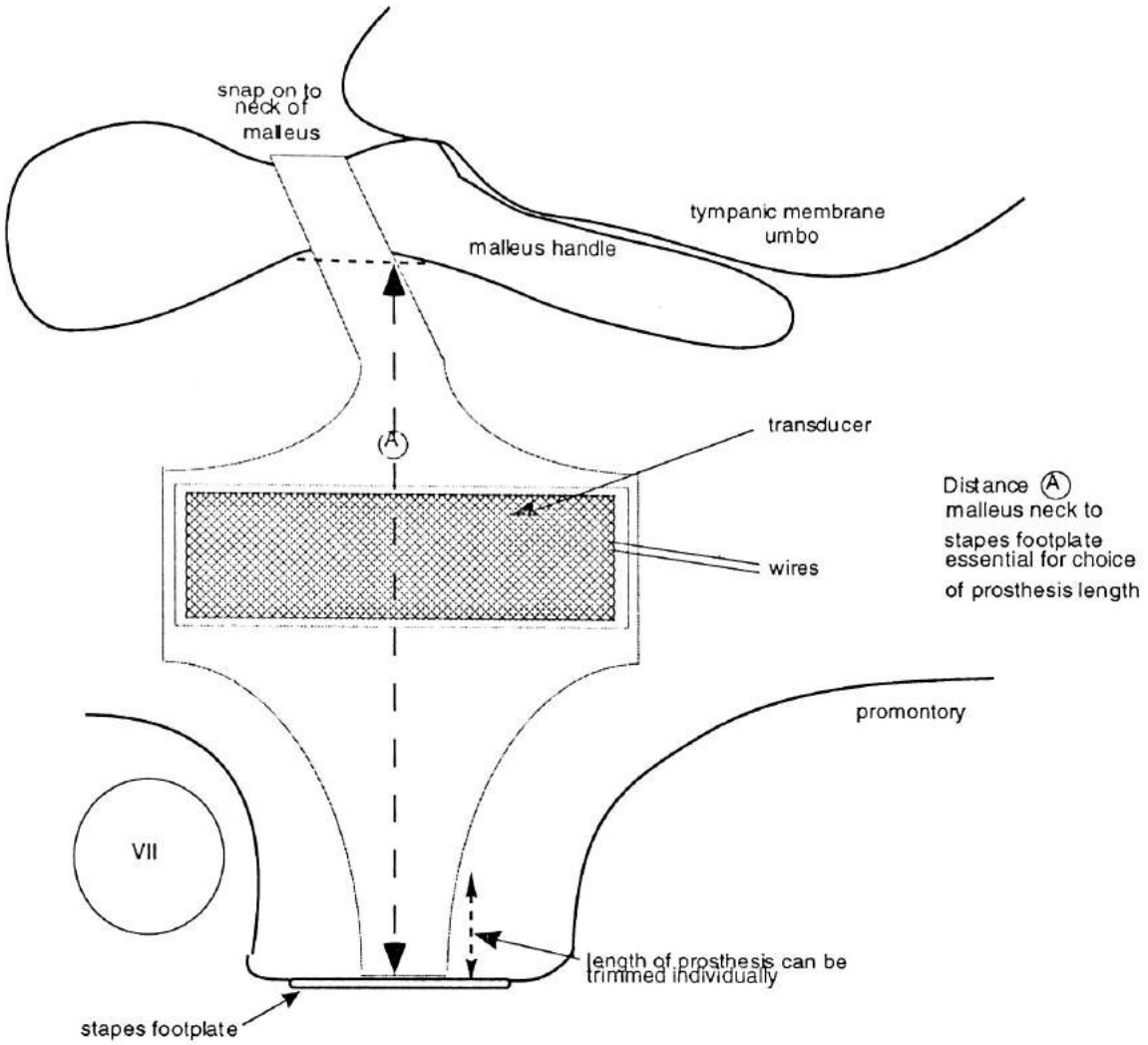
Hüttenbrink[505] has studied the changes of pressure exerted on the stapes footplate by a TORP as compared to an intact ossicular chain. Not only sound pressure but also static pressure is transmitted by this connection. The conducted pressures that we measured were ten times higher with a TORP on the footplate than in the physiologic situation. Thus, the risk for destruction of the stapes footplate increases and rapid changes of surrounding pressure, such as in diving, must be avoided by these patients.

A drum-to-footplate prosthesis (TORP) not only conducts vibrations to the inner ear but also static pressures. The stapes footplate can be fractured by forces that are too high.[419, 506]

The electromagnetic transducer can be incorporated into a TORP as it is into an IRP or PORP. A possible design is displayed in Figure 47.

The connection to the malleus neck is equal to the one used for the IRP (Ch. 7.2.1.). The length of the TORP is measured from the undersurface of the malleus neck to the stapes footplate. The length of the prosthesis is then trimmed at the lower portion taking care not to injure the delicately coated wire system.

Fig. 47: Total ossicular replacement prosthesis:



The TORP implant is wedged between the stapes footplate and the malleus neck.

This two dimensional drawing does not illustrate that the malleus is not positioned directly above the stapes footplate but more anterior to it. This distance is bridged in some TORPs by an inverted L-shaped form. This implant is planned to consist of one column that stands somewhat tilted on the stapes footplate. With the clip on the malleus neck, this implant should remain stable in position.

The length between the stapes footplate and the malleus neck will be one of the critical factors of this implant. Tight coupling should improve stability as well as sound conduction. However, a coupling that is too tight might stiffen the stapes footplate reducing its vibrational properties.

7.2.4 In subtotal petrosectomy and lateral skull base surgery

In ablative surgery of the middle ear with resection of the stapes superstructure, the tympanic membrane, and the external ear canal, reconstruction that allows air-conducted sound transmission is no longer possible. In this case, stimulation of the cochlea might be achieved with a device that connects to the stapes footplate. The middle ear cleft is then obliterated with a temporalis muscle flap or with fat.[507, 508]

The electromagnetic transducer could be encased into an implant that rests on the footplate. The main problem is to determine the best method for fixation onto osseous structures. This might be possible with short titanium screws of micro-plating of rigid internal fixation of 1.0 mm diameter. Location of this screw will have to be determined. The location over the tensor tympani muscle might be safer than on the promontorial bone.

7.2.4.1 Design

Fig. 48: MEI on stapes footplate:

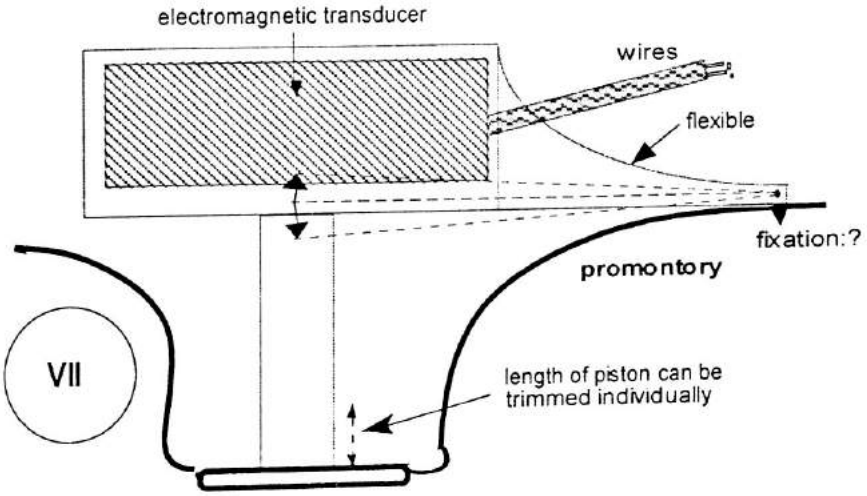
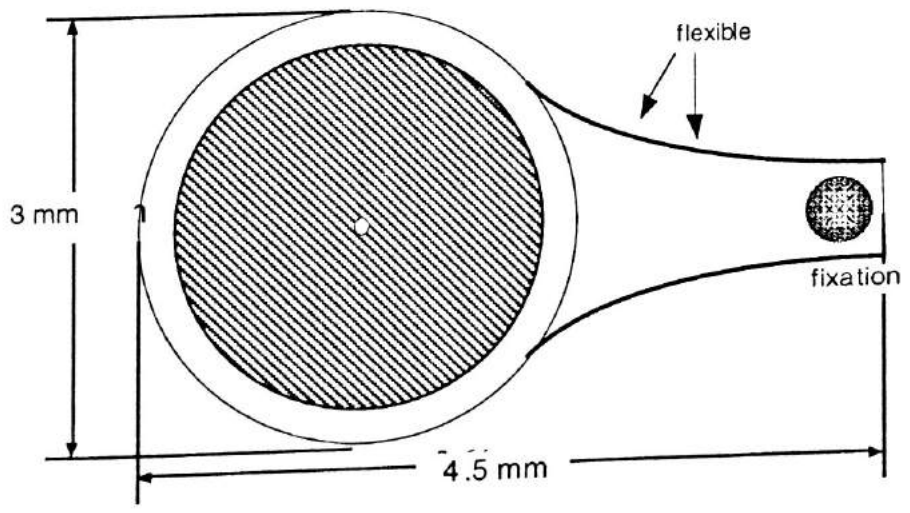


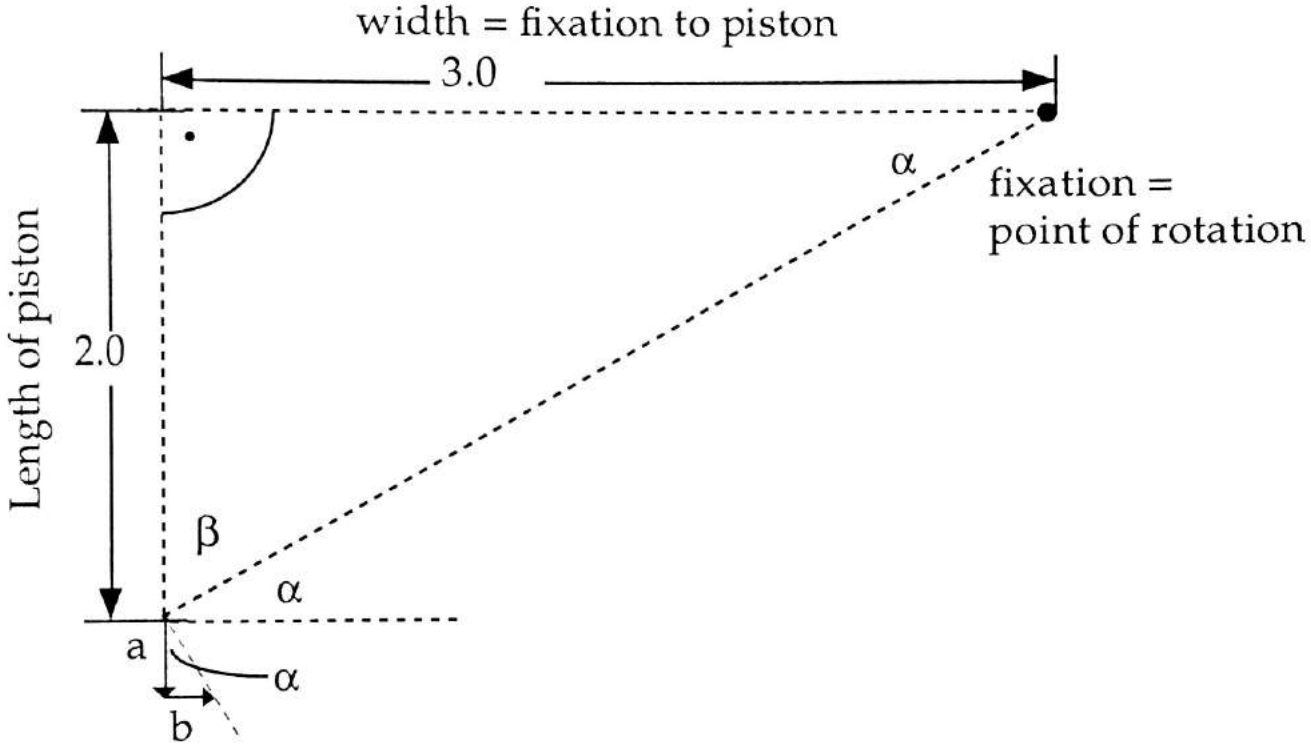
Fig. 49: View from top:



This implant was designed to stimulate the remaining stapes footplate in an otherwise destroyed middle ear of patients suffering from a complete air-bone gap. This design is entirely hypothetical.

7.2.4.2 Lateral shift of piston on stapes footplate

The vibrating piston standing on the stapes footplate might cause irritation. Due to a lateral shift discussed below further osteolysis might occur. A trigonometric drawing helps to judge the degree of lateral movement of the piston on the stapes footplate. This lateral shift might rub on the thin footplate and might eventually result in osteoclastic activity due to pressure leading to a perilymph fistula.



$\tan \beta = 3.0 / 2.0 = 1.5$

$\beta = 56^{o}$

$\alpha + \beta = 90^{o}$

$\alpha = 90^{o} - 56^{o} = 34^{o}$

$\tan \beta = b/a$

$b = \tan \beta \cdot a$

Lateral shift of piston on stapes footplate in this situation
= 33% of peak-to-peak displacement

In this situation, the lateral shift equals 33% of the downward movement. In a stiff implant, this energy loss would be significant. The connection to the fixation of the implant must therefore be flexible enough to allow the fulcrum to move rather than staying constant.

7.3 Future designs

Future work on the most preferable design of the middle ear implant has to be continued. The designs proposed in this work are to be considered as basic designs from which better ones are to emerge. Once close tolerance machining is available, the physical size of the transducer will become known. Constant improvement of the transducer design will also have to be sought in order to find the most efficient set-up.

8. Discussion

Despite modern hearing aid technology, conventional acoustic hearing aids are still flawed by low fidelity, feedback problems and cosmetic disadvantages. Over the last 33 years, researchers in the fields of otology and audiology have worked on implantable hearing devices that could overcome these and other disadvantages of acoustical hearing aids.

There is a limit to acoustic amplification that is dictated by physics. A large proportion of patients wearing acoustical hearing aids are quite unhappy with them despite of all the immense efforts to improve technology. The hearing impaired are the largest disability group in the developed world. New thinking has to come into the field addressing new ways of energy transfer to the cochlea to help these patients. This thesis discusses the invention of a new semi-implantable hearing aid that is inserted into the middle ear and attached to the ossicles.

8.1 The Invention

Recently, individuals of the research team in the Division of Otolaryngology - Head and Neck Surgery at Stanford University in California, USA including the author, invented a transducer for a new semi-implantable hearing aid. Transducer prototypes have been built and tested and demonstrated characteristics that give the device potential in addressing the needs for a successful semi-implantable hearing device that might help the moderate-to-severe and severely hearing impaired.

The implant promises the following features:

1. No direct acoustical feedback
2. Enhanced sound quality due to direct drive technology
3. Implantable by a trained otologist.
4. Efficient with a peak power consumption of less than 10 mA.
5. Output levels of 130 dB SPL.
6. Cosmetically acceptable and/or virtually invisible.

The components are isolated from the body chemistry by a laser welded titanium seal covered with biocompatible layers of silicone. Knowledge of this technology can be adapted from pacemakers as well as cochlear implants.

The conventional relationship between the electromagnetic coil and the permanent magnet is reversed in this implant. Although this is not the easiest or most efficient way to build a loudspeaker or earphone, it is an effective way to

make a miniature vibrating device capable of driving the ossicles in the middle ear.

The transducer of this device can be incorporated in several different designs of middle ear implants. It could also be incorporated into already existing middle ear prostheses. The current size of implant prototypes has been a disk of 3 mm in diameter and 2 mm in thickness. It consists of a coil/magnet combination encased in a button. The magnet is suspended on a surface that allows it to move independently from the coil. The coil is attached to the inside of the button. The case itself does not flex. The whole implant vibrates due to the inertia of the magnet driven by the alternating electromagnetic field. As such, the implant has no outer moving parts such as a piston, membrane, or lever that would move relative to the rest of the implant. Instead, the case of the implant is of one solid surface. This prevents potential complications like leakage, break down of moving parts, attenuation by fibrosis or other influences by physiological or pathological processes in the middle ear.

8.2 Theory of Operation

An amplifier of a standard hearing aid connected to the device produces an Alternating Current (AC) field in the coil. As the coil produces an electromagnetic field, it causes a relative movement between coil and magnet. Due to the heavier weight of the magnet, it is the coil that moves away or towards the magnet. This is due to the law of inertia. Because the coil is connected to the case, this relative movement also moves the entire case. The case then is connected to the middle ear, where it transforms the vibration onto the ossicles and produces a travelling wave in the cochlear fluid.

The net result of this coil-magnet configuration produces 6 dB less output than a standard driver configuration. However, because the movement needed to produce the equivalent of 134 dB in the human hearing mechanism is less than 20 microns and the middle ear is a perfectly balanced system by nature, the 6 dB loss might not be relevant. The relationship of electromagnetic transfer between coil and magnet could be further optimized.

The device is implanted in the middle ear through surgical techniques that are, for the most part, already common otologic techniques. This implant also profits from ideas that have been incorporated into cochlear implants or into similar devices from other areas such as pacemakers.

8.3 Energy loss due to distance between induction coil and magnet

In one experiment (see Ch.5), the loss of energy with increasing distance between coil and magnet was determined. This deleterious effect has hampered previous inventions in the field of electromagnetic middle ear implants. At a distance of 1 mm the field of the electromagnetic induction drops to 53% of the induction at 0 mm distance, at 2 mm to 26%, at 3 mm to 14%, at 4mm to 9% following a logarithmic curve. Therefore, a transducer, in which the coil and magnet are placed apart at some distance cannot be as efficient as a close design like the one proposed.

8.4 Advantages of the semi-implantable hearing aid

8.4.1 Sound quality

According to patients who have been fitted with acoustic hearing aids, the sound quality of an electromagnetic implant is markedly improved because the device drives the middle ear directly thus maximizing sound quality potential (Kartush 1991). Direct driving of the ossicular chain without the necessity of sound amplification and output in air as in conventional hearing aids is thought to offer superior sound quality.

The author has worn this novel transducer on his tympanic membrane. Sound transmission was crisp and clear with excellent intelligibility.

Because the device is implanted in the middle ear space, the danger for feedback is limited. High levels of energy can cause the tympanic membrane to vibrate and transmit acoustical energy through the external ear canal (EAC). The EAC and the concha act as a horn with a resonance of 2 to 3 kHz. The sound emitted could theoretically reach the microphone that is located above the ear causing a feedback loop to become established. The probability for this feedback loop is low according to experts of middle and external ear physiology.[509]

8.4.2 External auditory canal

In the proposed magnetic middle ear prosthesis, the sound input is not via the tympanic membrane but via a microphone on the external part of the hearing aid worn on the temporal hair area. Thus the sound modulation effect of the concha and the external ear canal with its resonance at 3 kHz remains unused because the EAC and the TM are bypassed. The concha and EAC are free of material. This results in improved cosmetics because the external part is hidden in the retro- and supra-auricular area. The lack of an insert in the EAC also reduces common irritation and discomfort including allergy of the sensitive ear canal skin to ear molds and chronic infections of the EAC.[510] Substantial improvements of chronic EAC problems was noted in the Brånemark device after leaving the EAC free of inserts and molds.[511,512] Discussions concerning the maximum usable real-ear insertion gain depending on the design of the ear mold will no longer be

required.[513] The electrical plug will allow loss-free energy delivery to the transducer.

8.4.3 Anchoring

This device is unique in several aspects. This implant does not have any parts that move relative to the rest of the implant. It also does not flex. The body of the implant remains stable and intact throughout. As such it does not need anchoring in a second place in order to provide relative movement of one of its parts as in several other designs.

The electromagnetic transducer of John Fredrickson for instance is fixed in the mastoid area. A rod connection is then made to a small hole in the incus body. The main problem with this and any anchoring device is the dependence on the safe and secure fixation of the base. Only the cortical bone of the mastoid area is capable of holding such a base in place. This is at a substantial distance from the incus. The displacements of the stapes necessary for sound conduction to the cochlea are 0.1 to 10 µm requiring very close tolerance. It remains questionable whether otologic surgeons can regularly achieve as precise an alignment as would be needed.

In this system, there is no base or fixation. The implant only needs to be attached to the ossicle itself. This is one of the major advantages of this concept. The attachment might consist of a platinum or titanium band, similar to the ones used in stapes surgery. Titanium has the advantage of shape memory.

The device does not destroy residual hearing. Implantation of the incus clip does not require disarticulation of the ossicular chain as in some other middle ear implants. In this proposed implant the patient could return to a conventional acoustic hearing aid with minimal negative effect, if any, should the device fail. If the implant is left on the incus, the negative mass effect would decrease sound transmission to a certain extent. Studies on the influence of mass at various locations of the middle ear have been conducted by this research team at Stanford University.[514] Increasing mass will diminish vibration in higher frequencies.

8.4.4 Choice of side

The choice of the side to be implanted depends on audiological work-up and the patient's preference and dexterity. In intra-individual studies, patients invariably preferred to wear the monaural hearing aid on their better ear. According to Swan, Browning, and Gatehouse[515-517] patients try to minimize their disability in the most disadvantageous listening situations. As in cochlear implants, it is generally expected to implant a patient unilaterally. Further improvement of the device, reduced cost and proven safety for the cochlea might lead to binaural implantation in the future.

8.4.5 External Amplifier

There is no need to redesign the present-day hearing aid amplifier system. The implant is going to be built around an already existing amplifier system. A hearing aid company has already agreed to provide the external part of this system.

8.4.6 Biocompatibility

The implant can be readily made biocompatible using existing technology from the pacemaker and cochlear implant industries. With no moving parts on the outside the compact design facilitates establishment of a biocompatible housing.

The Audiant Bone conductor of Hough is sealed by Parylene-C (Union Carbide), which seals it effectively from body fluids.[450]

8.4.7 Severely hearing impaired patients

The severely hearing impaired population is the target group for implantation. These patients are not candidates for a cochlear implant, but are poorly served by conventional acoustic hearing aids.

8.4.8 Frequency response

To understand speech, the 2 to 3 kHz frequency range is very important and sound pressure gain here is more useful than at 6 kHz. In telephone transmission, the lower frequency limit is as low as 0.3 kHz. The limiting factors for transmission in the lower frequencies in our tested electromagnetic implants are the size of the device and the weight of the magnet. The device acts like a small speaker with its membrane diameter of 2 mm. The limited weight of 35 mg also decreases vibration in the low frequencies. However, in tests with the proposed device, frequencies as low as .125 kHz were amplified. The signal-to-noise ratio was less favorable than in middle and high frequencies. The absolute low frequency limit has not yet been determined.

The sound conduction system of the human ear has its limitations. The external ear reaches its resonant peak at 2.5 to 3 kHz. The ossicular chain has its resonant peak at 1 kHz. It is at or near these frequencies that the external and middle ear have their greatest effect on sound transmission.[518] The electromagnetic implant however, has a sound transmission that reaches up to 10 kHz and higher.

In human ears, the resonance of the air-conductive system greatly influences its performance. The size and shape of the concha is a factor, as the normal concha has a resonant peak at 5 to 6 kHz. It extends the high frequency gain of the ear canal and lowers the canal resonant frequency from 3.5 to 2.7 kHz in an average EAC length of 29 mm.[519] The deeper the concha the lower its resonance frequency and the lower the canal resonance. The presence of a collapsed ear canal

under conventional earphone cushions is known to appear as a predominantly high frequency conductive loss.[327]

8.5 Fixation of the implant in the intact middle ear

A vibratory device with a magnet-coil configuration enclosed in a small-sized box can only vibrate sufficiently if the magnet incorporated is of substantial weight to act and if the device is fixed tightly to the ossicular chain. The tighter the adaptation the better the vibratory efficiency and the better the energy transfer to the ossicles and the cochlea.

In the process of development of an MEI, several locations on the ossicular chain were evaluated.

8.5.1 Device lateral to the tympanic membrane

Hearing devices might be placed onto the tympanic membrane such as in the EarLens® system from ReSound . One of the disadvantages of this set-up is the multi-layered epithelium of the tympanic membrane that desquammates cells from its surface. This debris gets stuck under the ear lens, which is worn continuously. In patients with a propensity for infections of the tympanic membrane and external ear canal, external otitis might require discontinuation of use of the ear lens. This has been a problem in some patients using the EarLens®.

8.5.2 Fixed to the handle of the malleus

A clip fitted onto the malleus handle from the middle ear is possible because the tympanic membrane connects to the handle by a fold. However, the clip is then in contact with the undersurface of the tympanic membrane and as such is at risk for extrusion. At the neck of the malleus, between the head and short process, placement is safest due to the indentation in the bone that promises a tight grip for a clip.

8.5.3 Fixation between malleus and incus

The distance between the incus and malleus is affected by age. In children, it is significantly smaller than in adults. In the fetus, these ossicles are parallel to each other. Their spreading apart depends on the development of the air cell system of the temporal bone. Well pneumatized bones have larger distances than ones with little pneumatization, where ventilation is impaired leading to retention and infection.

Another issue that has to be solved is a possible phase shift due to a transmission from the malleus handle directly to the incus and stapes. The vibration of the device will have to be adjusted precisely to result in optimal output and to diminish any part of harmful phase shift that would diminish the

signal transmission to the cochlea. Further testing might provide evidence that could abolish this location altogether.

8.5.4 Fixation on the long process of the incus

The device can be attached on top of the long process of the incus without touching the malleus. This requires a flat implant with a maximum thickness of 2 mm (Fig.36) because the distance between the long process of the incus and the tympanic membrane can be as little as 3 mm. The device might be secured by a flange on the inferior side of the stapes for improved attachment.

An alternative location for fixation on the long process of the incus is to hang the device directly on the process (Fig.37). This requires an even smaller device. Its location would be ideal because a clip could surround the long process much the same as the clip used conventionally in stapes surgery. This would provide a tight connection.

The fixation of implants on the ossicular chain could also be achieved with ionomeric bone cement.[520] In Europe, Ionomer cement has been used for ossicular repair.[521-524] Ionos cement has also been shaped as ossicles for ossiculoplasty.[525] However, Ionomer cement could have potential lethal effects when in direct contact with dura. For this reason, the cement is no longer available for ear surgery.

8.5.5 Doughnut device on stapes

To attach a doughnut shaped device to the stapes, the incudo-stapedial joint must be disconnected. The ring shaped device is then slipped in to sit on the shoulders of the stapes superstructure. The lenticular process of the incus is then allowed to connect to the stapes head again. Healing requires two to three weeks. The device is not activated until the fourth week after surgery and healing can be assumed. Precise measurements of the stapes superstructure (Ch.3.1.5.) that are needed to develop this device have been obtained for a series of human temporal bones.[414]

Exposure to MRI- fields of a 1.5 Tesla magnet will have to be tested to prove the stability of this implant in the human middle ear. Experiments with human temporal bones are planned and will be carried out as soon as implants are manufactured. A safe connection of the incudo-stapedial joint is essential in sound transmission as well as for improved safety in MRI exposure. Hough et al. (1988) showed in animal experiments that a magnetic ring on the stapes superstructure was not altered by MRI if three weeks of healing allowed the joint to reattach.

One of the limitations of this design is the small size of the ring magnet and the coil due to the limited space in the oval niche.

8.5.6 Location of the transducer

The space around the stapes is limited in the oval niche. Also, the space between the stapes and the long process of the incus is limited. This restricts the size of an implant to 2 mm in diameter and 1 mm in thickness, which is very small considering the parts needed, including magnet, coil, and housing. However, we still consider a doughnut shaped implant as a viable alternative.

Another location for placement of the transducer is between the incus and the malleus. The implant would ride on the long process of the incus straddling the superstructure of the stapes. It would be wedged between incus and malleus.

Several considerations have to be evaluated:

1. The malleo-incudal joint (MIJ) has typical characteristics:
   - diminution of peak-to-peak displacement of stapes compared to umbo
   - the difference is constant in low frequencies
   - the difference increases at frequencies above 2 kHz,
     which is termed "slippage" of the MIJ

2. An implant wedged between malleus and incus leads to:
   - added mass: mass effect
     → increased amplitude in low frequencies
     → decreased amplitude in high frequencies
   - possible reduction of the slippage effect due to stiffening of the MIJ

3. Influence on angles of malleus and incus-stapes:
   - malleus is lateral to the axis of the stapes
   - lateral distance between malleus and incus varies considerably:
     → increases from children to adults
     → is decreased in poorly pneumatized middle ears
   - A decreased distance increases the unfavorable angle.

8.6 The power delivery system

There are currently two options for power delivery to the implant. One is the transcutaneous coil-to-coil induction system through the intact skin and the other is the percutaneous plug-in system using a skin perforating technique.

Both systems have their advantages and disadvantages:

Table 4: Comparison of transcutaneous and percutaneous connection;

	Advantages	Disadvantages
Transcutaneous	Intact skin Less risk of skin infection Good cosmetics when external part is not worn	Attenuation of power Inconstant power transduction Falling off of external part
Percutaneous	No power loss Secure placement Good cosmetics if miniaturized	Skin penetration Psychological effect Possible risk for infection

Future testing will be necessary to find the best power delivery system. Until now, any transcutaneous induction was impaired by power loss due to attenuation by the skin and difficulty in precise alignment of the two coils. Should RF technology overcome the power loss, then the transcutaneous technique would be superior.

The percutaneous power delivery system has distinct advantages. Foremost, it provides the implant with all the power from the external part because there is no attenuation from the electric plug. The plug also provides a safe and stable placement for the external part. Sports activity will be possible to some extent. The plug itself can be easily exposed to water as it has been proven in hundreds of patients using the Swedish percutaneous hearing aid.

The major disadvantage of the percutaneous plug is the necessity to perforate the skin and the need for daily cleaning by the patient. Infection of the skin is rare however because the scalp is well vascularized. In the Swedish experience only 0.1% of the percutaneous plugs had to be removed due to infection. Minor skin problems were seen and treated in 8%. Local disinfection was all that was needed. However, good personal hygiene seems to be a prerequisite for this type of connection.

Another restriction to the percutaneous plug is age. Children have a thinner skull bone with finer cortical layers. The plug might come loose more easily in children than in adults. All of the percutaneous screws that had to be removed due to instability in the Swedish patients were in children. The Swedish implant is a

powerful vibrator that transmits the energy by bone conduction to the cochlea. There is substantially more stress on the Brånemark percutaneous screw than in our plug, which would merely be used to hold the external part. The only mechanical stress applied to the screw would be manipulation by the patient or inadvertent blows to the head.

The psychological factor must be taken into account as well. In the Swedish experience, a few patients asked for removal of the percutaneous screw due to problems with paranoia. The idea of having a plug in one's head might not be acceptable to all patients. Exploration for tendencies towards paranoia in the preoperative work-up might reduce this risk. The Swedish experience as well as experience by other otologists who implant the Brånemark percutaneous screw describe this as occurring rarely though.

The implantable hearing aid might be more powerful than conventional air conduction hearing aids. The output peaks will have to be controlled carefully so that temporary or even permanent threshold shifts with cochlear damage are not produced.[526-528]

8.7 Cosmetics

In today's society, cosmetic considerations must be taken into account. Hearing impaired patients would prefer to conceal their impairment. The stigma of a hearing aid is still a powerful deterrent to acceptance and use.

Part of the patients fitted in Great Britain by the NHS with the standard behind-the-ear hearing aid rejected the fitting and chose to purchase an in-the-ear hearing aid on their own.[529] Cosmetic consideration was also the main reason patients chose to purchase a private hearing aid without the support of the British Health Services.[530] Ease of use with spectacles was the second most common reason. Sound quality only ranked third.

A totally implantable hearing aid would be the favorable solution to this increasing demand. This is currently not possible because of several technical problems.[531] One is that the microphone requires sound waves to reach its surface. Attempts to bury the microphone under the skin in the retroauricular area[282] or beneath the skin of the external ear canal[304] have not been entirely successful. The Japanese project has abandoned the idea of a totally implantable hearing aid concentrating instead on their semi-implantable one.

In the implant described in this thesis, the external part can be miniaturized because the power requirements will most probably be 1.5 to 3.0 Volts at 1 mA thus using only a small sized battery. The amplifier can be reduced significantly with modern chip design. The final size of the external part has not yet been decided. It will be similar to the volume control knob of modern in-the-ear canal devices. The external part could be placed completely into the hollow part of the percutaneous plug if this is chosen as the most favorable technique. The external

part would then be flush with the surface of the skin of the skull and would not protrude. This would render an excellent cosmetic effect. The external part could be removed from the plug by pulling on a small ring. The location of this plug could be above the level of the pinna in the hair bearing part of the scalp. That location will allow the microphone to pick up sound better than from the retroauricular area with its sound shadow.

8.8 Age

There are limitations to the degree of competence with which some elderly patients can handle electronic equipment. An observational study found that a majority of elderly patients made errors with simple handheld calculators and with VCR remote controls.[532] It has been concluded that remote controls for telerobots will have to be very simple and resistant to errors.

This conclusion is equally important for implantation of electronic middle ear devices. The majority of recipients of these devices will be elderly patients and simple handling will be of paramount importance. It is known already that difficulties changing in a hearing aid can lead to malfunction.[533] Behind-the-ear hearing aids are better handled by the elderly than the smaller in-the-ear hearing aids.[534] However, difficulty with insertion of the ear mold was the single most frequent reason why patients failed to use their behind-the-ear hearing aids.[535]

The external unit of the semi-implantable hearing aid proposed in this thesis will be fixed externally in a plug and will be simpler to handle than inserting the mold into the concha and external ear canal. Older patients with presbycusis will profit from the high frequency amplification of this implant which is also thought to increase speech understanding ability.

8.9 Food and Drug Administration

Progress in the development of implantable hearing aids has been hampered because of incompatible goals between manufacturers and the medical profession. In general, hearing aid companies are not familiar with otologic surgical procedures and otologists have little experience with the electronic requirements of hearing aids. To be successful, a team approach is needed so that both professions can exchange ideas.

Development is also hindered by regulatory forces like the Food and Drug Administration (FDA). Required testing and subsequent approval is an enormous obstacle that creates financial burdens that are increasingly difficult to overcome.

With the Medical Device Legislation, it is now increasingly difficult to clinically test new medical devices. This is particularly true for implantable devices. Safety and effectiveness must be demonstrated.

9. Outlook in the future

Patients implanted with electromagnetic devices face various difficulties in daily life. The potential hazards will have to be taken into account before implantation of electromagnetic middle ear hearing aids.

9.1 Electromagnetic pollution of the environment

One of the potential problems for implant wearers is electromagnetic fields. An increasing body of knowledge has accumulated on the effect of electromagnetic fields on the human body.[536-538] These fields are not noticed by the human sensory system. This pollution is sometimes referred to as *electro-smog*. The danger caused by this electrosmog is discussed publicly.[539,540]

Increasing concern about possible negative influence of electromagnetic fields has been voiced. High voltage power lines are accused of side effects on humans and animals. The discussion is carried on in national forums as recently published by the German *Bundesminister für Umwelt, Naturschutz und Reaktorsicherheit* in 1992.[541] In that publication, the possible health hazards of modern telecommunications are discussed. The level of safety is still not known and international norms have to be decided upon.

Patients wearing pacemakers are warned to avoid electromagnetic fields.[542] They cannot pass through airport metal detector frames. Microwave ovens and vacuum cleaners as well as television sets are among the most powerful generators of electromagnetic fields in the household.[543] Computer screens have been accused of emitting more than 2 Milligauss of electromagnetic emission, which is considered to be a limit for safety.[544] The strongest of these fields is caused by high-power lines. Compared to these, the fields caused by the micromagnets in an implantable hearing aid are negligible.

Two aspects of electromagnetic fields are important for this project:

1. Influence of the electromagnetic field caused by the implant itself
2. Influence of electromagnetic fields on the implant

The first aspect can be addressed without hesitation. The electromagnetic implant will be powered by a system of one to three Volts on one milliampere. This electrical energy is very small causing no significant electromagnetic fields of harm. As demonstrated in the experiment concerning influence of the distance of the coil to the magnet, the field decreases exponentially by $x^{-3.7}$.

The second aspect will have to be investigated more extensively. Strong external electromagnetic fields could be troublesome to carriers of magnetic

implants. Patients wearing the EarLens® have reported hearing several electrical apparatus. Turning on the TV set results in a strong field when the screen is degaussing. Microwave ovens, hair dryers, vacuum cleaners and computer screens are among the most often mentioned sources of electromagnetic fields. Airport security frames make a short and uncomfortable noise, antitheft devices at exit doors in stores produce a more constant field.

Due to the increasing number of electromagnetic devices and controls, electromagnetic fields appear in ever increasing numbers.[545] Cases of heart pacemaker disfunction due to various influences including the remote control of a toy car have been reported.[546],[547] Magnetic anti-theft control gates at store exits have caused problems in pacemakers of unipolar design causing dangerous effects.[548],[549]

It is not known yet whether patients with electromagnetic middle ear hearing aids would be adversely influenced by using a cellular phone. Cellular phones have caused disturbances in intensive care units and are therefore banned from around sensitive clinical equipment.[550] Cellular phones and laptop computers are not allowed during take-off and landing of air planes for the same reason. A special induction system within the telephone handle to connect to the implant by induction might be beneficial to our patients.

No negative side effects have yet been reported for patients undergoing MRI. However, various effects of MRI on metallic middle ear implants like malfunction, dislocation and warming-up are known.[551 -554]

In patients with cochlear implant, monopolar surgical instruments and electroconvulsive therapy are not to be used in order not to damage the implants as well as the cochlea. In patients after defibrillation, however, no damage to the cochlear implant has been found.[555] Whether this restriction will also apply to electromagnetic middle ear implants will have to be studied. It is anticipated that the deleterious effects are smaller because the coupling to the middle ear is mechanical and not electrical.

9.2 Future applications of the electromagnetic transducer

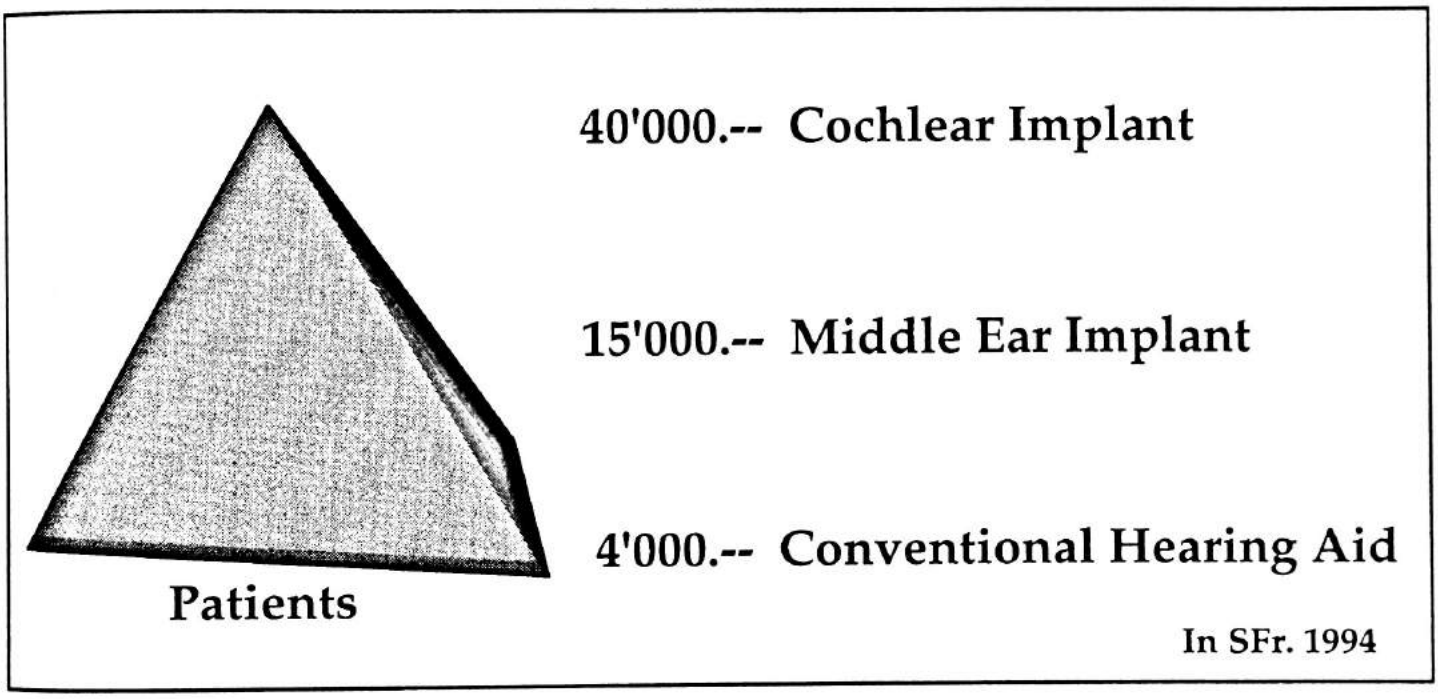
1. The main target group for this electromagnetic middle ear implant are patients with severe hearing loss. Should the implantation in these patients be successful, then the group of hearing impaired patients with a moderate to severe hearing loss might be addressed. The superior sound quality of the direct drive system and less so the need for maximum amplification will then lead to the group with moderate hearing loss.
2. Implants might be made significantly smaller in the future than described here. A transducer could then be placed directly on the flat stapes footplate in cases where there is a complete loss of the middle ear without the need for stabilization or balancing of the transducer on a piston.

3. Implants could be made to stimulate the cochlea directly through the round or oval windows. Decrease in size might allow this placement. The perilymphatic space however has to remain sealed from the middle ear space to prevent labyrinthitis and meningitis. A placement of a mechanical implant into the perilymphatic space with a wire connection is not feasible and probably never will be.

9.3 Cost

Middle ear surgery to improve hearing, such as ossiculoplasty or stapedectomy including the prosthesis is fully covered by medical insurances in Switzerland. Cochlear implants costing about 40,000.-- Swiss Francs are now fully covered by insurances under the new insurance law (Swiss KVG 1996).

Fig. 50: Cost pyramid and potential recipients:



Middle ear implants will range in cost between conventional hearing aids and cochlear implantation (Fig.50). It is anticipated that this cost will also be covered by medical insurance even though there is additional surgery and the implantable material is high cost.[556] This might not be true for the USA, where patients will have to pay privately for a middle ear implant.[509]

Ideally, implants would be inserted bilaterally, such as used for conventional hearing aid fitting where bilateral fitting leads to superior performance in difficult hearing situations.[509] Whether or not this will be possible in terms of financing as well as with respect to potential complications remains to be evaluated and discussed. The bone anchored hearing aid of Brånemark, for instance, has been fitted binaurally with increased success.

9.4 Audiology

Flawless audiologic preoperative work-up and postoperative follow-up is of utmost importance in hearing rehabilitation with a middle ear implant. Fine tuning of the programmable external part of the hearing aid will provide the patient with improved results.

9.5 Surgery

Implantation of the device will not be more difficult than ossiculoplasty. As such, it can be learned by the average otologic surgeon. A standard procedure with common surgical approaches using common microsurgical instruments will be taught. The surgery will consist of a combined approach of a transmastoid and transcanal technique.

The proper training, instruction and support will be of paramount importance for long-term success for the patient.

9.6 Biocompatibility

The problems of biocompatibility for electronic implants have been solved by long-term experience with heart pacemakers. In otology, experience with various cochlear implants is growing. The increasing number of cochlear implants that are completed without signs of rejection from the middle and inner ear prove their safety and biocompatibility. This body of knowledge provides a wide choice of biomaterials for middle ear implants.[557,558]

9.7 Future efforts

Further development of a project of this goal and magnitude cannot be carried on purely in an academic setting. Generous financial input will be necessary to bring the product to fruition.

It remains unknown when the semi-implantable hearing aid will be finally realized. Hopefully, this will be within this century. In 1977 Goode published a paper with the title *"Implantable hearing aid may be ready in five years."* Twenty years have passed since then and many problems still need to be solved. The here proposed implant might lead to a major step forward.

In a later stage of development, collaboration with a leading hearing aid company will be crucial for further improvement and for supply of the hearing aid with the external part. It is not planned to develop a new external hearing aid part. Existing technology can be adapted for this product. A miniaturized amplifier system is preferable to minimize the size of the external part.

10. Conclusions

1. The electromagnetic transducer of the middle ear implant transmits sound to the ossicles.

2. The electromagnetic implant prototypes produce excellent frequency response curves.

3. When placed on a live subject's eardrum the electromagnetic implant prototypes supply excellent sound. The quality of musical input was clear and crisp. High frequencies are transmitted better than low frequencies.

4. The electromagnetic implant has been reduced to the size of 3 mm in diameter and 2 mm in thickness without loss of high quality frequency response. It might be further reduced to a size of 2 x 1 mm.

5. Prototypes have produced high output equivalents. It is expected that refinements of the manufacturing process by micromachining will lead to significant improvement.

6. The transducer of this electromagnetic implant can be made very efficient, compact and in various shapes for various surgical indications.

7. The qualities of the electromagnetic implant include enhanced sound quality, lack of feedback, improved cosmetic appearance and improved signal-to-noise ratio with less distortion than a standard hearing aid.

8. The unique invention allows a direct attachment to the ossicles without other anchoring or stabilization.

9. There are no moving parts on the outside of the implant. The whole implant vibrates with sound.

10. Power delivery to the implantable part is by transcutaneous induction or percutaneous connection.

11. The target group for this middle ear implant will be patients with moderate to severe and severe hearing impairments. However, patients with moderate or even mild hearing loss might also profit from the improved sound quality of this direct drive system.

12. The technology can also be incorporated into middle ear implants used in middle ear reconstruction. Middle ear prostheses can be adapted by insertion of the electromagnetic transducer.

13. Post-implantation care and close monitoring will improve rehabilitation and secure long-term success of the implant.

14. The major advantages over other middle ear implants are expected to be:
    - Ease of placement by the surgeon.
    - No destruction of residual hearing.
    - Easy removal of the device with the possibility of exchange with another device or return to the use of a conventional acoustic hearing aid.
    - Vibration of the electromagnetic implant as one compact unit:
        a) Decreased potential for device failure and mechanical breakdown.
        b) Decreased incidence of middle ear infection.
        c) Simple attachment to anatomical structure of the middle ear without need for anchoring at a second location.
        d) Proper attachment on the ossicle with reduction of mechanical injury to the bone by vibration.

15. Potential longevity of the electromagnetic implant with possible exchange for a new or improved implant.

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12. Appendixes

Appendix I: History of magnets in medicine[559]

1. Widespread use of magnetic applications

1.1 Operating room

- Rubber pad with flat ceramic magnets as an instrument holder.
- Magnetic folder to be used by the scrub nurse to hold suture needles.
- Magnetic floor sweeper in the operating room to search for dropped needles.

1.2 External switching of heart pacemakers

- To change the pulsing characteristics of implanted heart pacemakers.[560]

1.3 Foreign body remover

- To remove foreign bodies of a ferrous metal from within the tracheo-bronchial tree or the esophagus and stomach.[561]
- To locate metallic foreign bodies just under the skin.
- To localize orthopedic screws.
- To localize and remove metallic foreign bodies within the orbit.[562] Metal detectors have also been used to localize metallic foreign bodies.[563]

2. Magnet applications in specialized use

2.1 Eyelid magnets

Platinum-cobalt magnets have been inserted under the skin at the edge of the upper and lower eyelids for the treatment of facial paralysis.[564] Platinum-cobalt magnets are well tolerated in human tissue[565] and it appears that samarium–cobalt is also well tolerated.[566 -572]

2.2 Colostomy closure device

Feustel and Hennig have developed a magnetic closure device that eliminates the need for an externally worn bag.[573] A samarium-cobalt ring magnet is placed under the skin around the opening of the colostomy opening, closing it, and is held in proper position by the ring magnet.

2.3 Intra-oral dental prostheses

Magnets have been used for denture retention for several decades starting in the 1950's.[574 -578] Sectional bridges can be assembled with magnets as reported by Gillings from Sydney Australia.[579],[580] He also published extensively on several aspects of intraoral application of magnets.[581 -587]

One solution has been to construct the prosthesis in two (or more) parts with magnets holding the two parts together.[588-591]

An obvious solution was to implant two or more small magnets under the gum on the lower jaw to attract magnets placed in the lower denture.[592] Behrman used platinum-cobalt magnets for this purpose, and found they were well tolerated by the tissues but had the problem of extrusion in time.[593] Magnets have been placed into tooth roots for the same purpose.[594]

Before the use of Samarium-cobalt magnets with a maximum energy product of up to 32, platinum-cobalt magnets were tested in clinical use.[595] Their magnetic force however was not sufficient enough to allow a functional adaptation of the dentures.

Since the perception and development of a stable osseointegration system by Brånemark in Sweden, the interest in magnetic retention of dentures has decreased.[596-598] However, Goode discussed the possibility of using the intermittent period between first and second stage Brånemark implants of 12 months to use magnetic attraction for denture retention.[599]

Gillings reported on magnets placed in the dental root canal for overlay dentures.[600] There is more need for stabilization for the mandibular denture than for the maxillary denture.[601]

Niparko, Tjellström and Holt presented their results on osseointegrated implants for prosthesis retention of auricular and orbital defects.[602-606]

3. Magnet applications under development

3.1 Denture retention

The problem of holding a lower denture in place in a patient who has worn a denture for many years is a common problem in dentistry. The use of magnets helps to hold the lower denture in position. The reaction of dental tissues to magnetic fields has been studied.[607,608]

3.2 Magnetic orthodontics

Alnico-V magnets have been attached to individual teeth in a cat in the attracting mode to gradually move teeth, similar to the movements performed on human teeth by orthodontists using rubber bands and springs. The experiment was felt to be successful[609] and has also been used in humans.[591]

Magnetic forces have also been used for denture retention for more than 30 years.[610] More commonly, magnets are applied to the maxilla. However, implantation has also been tested in the mandible. Maxillary obturators to cover hard and soft palate defects as in cleft palate or after tumor surgery can be fitted with magnets for improved retention. Osseointegrated implants have also been connected to magnetic attachments of complete dentures.[611]

3.3 Magnets as locators

The use of small magnets attached to surgical sponges has been suggested to minimize the possibility of leaving a sponge inside a patient during surgery. Magnets have also been used to improve techniques of orotracheal intubation.[612,613]

4. Miscellaneous applications of magnets in medicine

4.1 Tumor therapy

Magnetism has been used in the treatment of benign and malignant tumors. The aggregation of ferrite particles occludes the blood supply to the tumor, producing tumor necrosis.[614] The same type of system has also been used to concentrate chemotherapeutic drugs, attached to the ferrite in microspheres, in the tumor.[615] The risk for skin necrosis has limited this form of application.

4.2 Implantable magnetic pumps

Magnetic force has been used experimentally to power small implantable rotary pumps in the same way magnetic stirrers are powered.[616]

Implantable magnetically activated pumps are being designed to help failing hearts work better.[617]

4.3 Externally controlled magnetic catheters

Alternating current magnetic fields developed by an external electromagnet have been used to guide a magnet tipped catheter through the vascular system to perform angiography (contrast x-rays) of arteries and veins that are normally difficult to reach with conventional techniques.[618]

Magnets are also in use in the plastic surgery of the distal urethra.[619] Percutaneous stimulation of peripheral nerves by magnetic fields is used increasingly for diagnostic purposes.[620-621]

Finally, magnet quackery is a growing "use" of rare earth-cobalt magnets in paramedicine. Despite a large amount of data showing that low level magnetic fields have no significant biologic effect on tissues, the use of magnetic bracelets, necklaces and "polarizers"[622] is touted as cure alls for a variety of ailments; the evidence is unconvincing.[623,624]

Appendix II: Patent research

Patents issued by the U.S. Department of Commerce, Patent and Trademark Office:

Patent Number	Issue Date	Applicant / Patentee	Class	Subclass
5'259'033	11-93	Goodings et al.	381	68
5'258'032	11-93	Perkins et al.	381	68
5'257'623	11-93	Karasev et al.	607	27
5'163'957	11-92	Sadé et al.	128	420.2
5'094'108	3-92	Kim et al.	73	627
5'085'628	2-92	Engebretson et al.	600	25
5'061'282	10-91	Jacobs	623	10
5'031'219	7-91	Wards et al.	381	68.5
5'015'225	5-91	Hough et al.	600	25
5'015'224	5-91	Maniglia	600	25
5'003'608	3-01	Carlson	381	68.6
4'988'333	01-91	Engebretson et al.	600	25
4'969'900	11-90	Fleischer	623	10
4'948'855	8-90	Novicky	526	279
4'944'301	7-90	Widin et al	128	420.6
4'936'305	6-90	Ashtiani et al.	128	420.6
4'840'178	6-89	Heide et al.	128	419R
4'817'609	4-89	Perkins et al.	128	420.6
4'817'607	4-89	Tatge	128	419R
4'800'884	1-89	Heide et al.	128	419R
4'776'322	10-88	Hough et al.	128	1.6
4'756'312	7-88	Epley	128	420.5
4'728'327	3-88	Gersdorff	623	10
4'666'443	5-87	Portner	623	3
4'665'896	5-87	LaForge et al.	128	1D
4'662'358	5-87	Farrar et al.	128	1D
4'628'907	7-88	Epley	128	1R
4'612'915	9-86	Hough et al.	128	1R
4'611'598	9-86	Hortmann et al.	128	419R
4'606'329	8-86	Hough	138	1R
4'542'532	9-84	McQuilkin	433	78
4'540'761	9-85	Kawamura et al.	526	245
4'489'330	12-84	Motomu et al.	128	78
4'441'210	4-84	Hochmair et al.	179	107G
4'428'377	1-74	Zollner et al.	138	419R
4'369'530	1-83	Robinson et al.	3	1.7
4'357'497	11-82	Hochmair et al.	381	68.3
4'303'722	12-81	Novicky	526	279
4'281'419	8-81	Treace	623	10
4'251'686	2-81	Sokolich	381	154
4'248'899	2-81	Novicky	526	264

4'213'207	7-80	Wilson	3	1.7
4'143'661	3-79	LaForge et al.	128	419R
4'120'570	10-78	Gaylord	260	86.1
4'063'049	12-77	Pipitone et al.	179	110A
4'063'048	12-77	Kissiah, Jr.	179	107R
4'052'754	10-77	Homsey	128	1R
3'974'825	8-76	Normann	128	1D
3'919'722	11-75	Harmison	3	1.7
3'909'852	10-75	Homsey	623	10
3'882'285	5-75	Nunley et al.	179	107E
3'870'832	3-75	Fredrickson	179	108E
3'838'468	10-74	Armstrong	128	421
3'808'179	4-74	Gaylord	260	86.1E
3'842'440	10-74	Karlson	3	1
3'763'333	10-73	Lichowsky	179	107R
3'771'173	11-73	Lamb Jr.	3	1
3'764'748	1-73	Branch & Durham		
3'712'962	1-73	Epley		
3'710'399	1-73	Hurst	128	1.3
3'676'611	7-72	Stephens	179	107G
3'674'945	7-72	Hands	381	153
3'633'217	1-72	Lance	3	1
3'594'514	7-71	Wingrove		
3'557'775	1-71	Mahoney		
3'473'170	10-69	Haase et al.	128	421
3'346'704	10-67	Mahoney	179	107
2'702'354	2-55	Chorpening	128	71
2'402'392	6-46	Goldsmith		

Further information on some of these patents:

5'259'033 11-93 Goodings et al.
An electrical path to reduce the feedback loop of acoustic hearing aids.

5'258'032 11-93 Perkins et al.
Contact transducer assembly for hearing devices: the EarLens system.

5'257'623 11-93 Karasev et al.
A method for generating electric pulses for biological object stimulation.

5'085'628 2-92 Engebretson et al.
Electromagnetic transducer with connecting rod to the body of the incus.

5'015'225 5-91 Hough et al.
Implantable magnets for fixation on the ossicular chain: various locations.

5'015'224 5-91 Maniglia
The partially implantable hearing aid device: contact-less electromagnetic system.

4'988'333 01-91 Engebretson et al.
Implantable middle ear hearing device and acoustic coupler therefor.

4'969'900 11-90 Fleischer
An entire new tympanic membrane, middle ear and mastoid.

4'936'305 6-90 Ashtiani et al.
A disc shaped magnet residing in a PORP with induction coil in EAC.

4'817'609 4-89 Perkins et al.

Ear lens system with induction coil in EAC after canal recontour surgery.

4'817'607 4-89 Tatge

Magnetic PORP and TORP, induction coil in the EAC.

4'800'884 1-89 Heide et al.

Magnet on malleus handle, induction coil in EAC.

4'776'322 10-88 Hough et al.

Magnet in various locations on ossicles, induction coil in EAC.

4'728'327 3-88 Gersdorff

Artificial middle ear conduction system.

4'628'907 7-88 Epley

Magnetic attachment through the tympanic membrane to the malleus.

4'612'915 9-86 Hough et al.

Direct bone conduction hearing aid: Xomed Audiant.

4'611'598 9-86 Hortmann et al.

Multi-frequency transmission system for implanted hearing aids.

4'489'330 12-84 Motomu et al.

Electromagnetic induction coil antenna for implanted hearing aids.

4'063'049 12-77 Pipitone et al.

Piezo-electric electroacoustic transducer.

3'882'285 5-75 Nunley et al.

Totally implantable hearing aid, microphone in EAC.

3'870'832 3-75 Fredrickson

Magnet on stapes head, induction coil around it.

3'764'748 1-73 Branch & Durham

Several configurations of implantable hearing aid concepts.

3'712'962 1-73 Epley

Piezoelectric transducer to be inserted between the ossicles.

3'594'514 7-71 Wingrove

Piezoelectric ceramic sensor at the ossicles to pick up vibrations.

3'557'775 1-71 Mahoney

Implantable hearing aid in the antrum to connect the middle ear.

American patents are effective for 17 years.

Patent issued by the Canadian Patent Office:

1'440'724 6-76 Fredrickson

Magnet on stapes head, induction coil around it.

Patent issued by the German Patent Office: Deutsches Patentamt

DE 40 26 766 A1 2-92 Schmid et al.

Electromagnetic middle ear hearing device: magnet on malleus handle, induction coil behind the ear.

DE 3420244 9-86 Hortmann et al.

Multifrequency transmission system for implanted hearing aids.

Patent issued by the Japanese Patent Office:

JP 81167833 Appl.Nr. 1-81 Motomu et al.

Electromagnetic induction coil antenna for implanted hearing aids.

The above listed patents revealed no previous work that is similar to the electromagnetic device presented in this thesis.

Appendix III: Definitions for magnets

To apply magnets in a device, basic definitions of magnets are provided to understand their physical properties further.

a) Faraday's law

Defines the relationship of voltage and flux as:

$E = N d\phi/dt \times 10^{-8}$

For sinusoidal voltage conditions, it is written:

$E = 2.22\ \phi_t FN \times 10^{-8}$ or

$E = 4.44\ B_m A_c\ FN \times 10^{-8}$

where:

E	= voltage desired
B_m	= Flux density of material in gausses
ϕ_t	= Total flux capacity of core
A_c	= Effective core cross-sectional area
F	= Design frequency
N	= Number of turns
ϕ_t	= 2 Bm x Ac

b) Ampère's law

Defines the relationship between magnetizing force and current.

It is commonly written as

H = 0.4 pi NI / M1

where:

H	= Magnetizing force in Oersteds
N	= Number of turns
I	= Current through N turns
M1	= Magnetic path length of core

c) Magnetic flux

The product of the magnetic induction B and the cross–sectional area, when the magnetic induction B is uniformly distributed and normal to the plane of cross–section.

d) Maxwell
The unit of magnetic flux in the cgs electromagnetic system.
One Maxwell equals 10^{-8} Webers.

e) The Gauss
The unit of magnetic induction in the cgs electromagnetic system.
The Gauss is equal to 1 Maxwell per square centimeter.

f) Oersted
The unit of magnetizing force in the cgs electromagnetic system. One Oersted equals a magneto–motive force of one Gilbert per centimeter of path length.

g) Coercive Force
The value of magnetizing force required to reduce the flux density to zero.

h) Residual Flux
The value of magnetic induction that remains in a magnetic circuit when the magneto-motive force is reduced to zero.

i) Squareness ratio
The ratio of residual flux density to the maximum (saturation) flux density.

j) Permeability
In general, the ratio of the changes in magnetic induction to changes in magnetizing force (B to H) is called the permeability represented by the symbol μ.

k) Window area
The area in circular mils of the hole of the core. (Unit Wa)

l) Winding factor
The ratio of the total area of copper wire in the center hole of a toroid to the window area of the toroid. (Unit K)

m) Basic units in magnetism

B	Gauss	B_r = Residual Induction
ø	Maxwells	
A	Area (in cm^2)	
H	Oersteds	
		H_c = Coercive Force
		H_{ci} = Intrinsic Coercive Force
V	Generated voltage	
N	Turns	
μ	Permeability	
F	Force (dynes)	
Bn	Magnetic induction	
Ag & Am	Area air gap & magnet	
lg & lm	Length air gap & magnet	
Hm	Magnetic coercive force	
f_1	Leakage factor	
f_2	Reluctance factor	
C	Capacitance	
Bg	Air gap, Gauss	

n) Sinusoidal Waveform

in peak current or voltage

o) Magnetic induction

in Gausses = magnetic flux per area
or
in Webers per square meter = Tesla

Tesla = Weber per square meter

p) Magnetizing force: in Oersteds

Oersted = Ampère-turn per distance

q) Permeability

Gausses per Oersted or
Webers per Ampère-turn distance

r) Thermal stability

A rise in temperature above 25°C leads to reversible losses of magnetization. Irreversible changes start at above 100°C .
The temperature coefficient of remanence is:
Tk_{Br} = -0.04%/°C

In the human body at 37°C, the loss is virtually none.

s)Long-time stability

At temperatures of 100°C or less no change of flux density is observed after 4000h (=167 d)

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