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Section 3: Diseases of the Ear

Part 4: Inner Ear

Chapter 52: Implantable Hearing Devices: State of the Art

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Despite modern microsurgical techniques in the temporal bone and advances in electronic technology in the field of hearing aids, the vast majority of hearing-impaired patients are yet to be helped. In the USA, about 20 million people suffer from conductive as well as sensorineural hearing loss. Worldwide the number is estimated to be more than half a billion. These numbers certainly will grow because the population is increasing and living longer.

While the great majority of these patients are candidates for conventional hearing aid use, in the USA, only 15 per cent become users of amplification devices, ostensibly because of such different factors as sound distortion, discomfort of fit, and cosmetic appearance.

Conventional Hearing Aid

The conventional hearing aid is not an efficient system of conversion of energy. Acoustic energy is picked up by the microphone; it is then transformed into an electric signal and amplified. Through the receiver (speaker), electrical energy is transformed into mechanical energy (sound), which vibrates the tympanic membrane and ossicular chain. Acoustic hearing aids have characteristics that limit their effective use in patients with hearing loss.

The receiver of the hearing aid is the main limiting factor in amplification with minimal distortion. High frequency must be limited because of acoustic feedback. Small receivers have high susceptibility to low-frequency distortion. The proximity of the microphone to the receiver increases the electroacoustical and mechanical feedback. Feedback, sound distortion, ringing, and the necessity to have an earmold that is tightly fitted discourage many people who need amplification from wearing these devices on a permanent basis. Sound distortion is responsible for the breakdown of speech understanding, especially in hearing aid users subject to a noisy environment. There is an inherent social stigma that discourages needy patients from wearing such devices. Although in reality the device is rather inexpensive, owing to marketing policies it is offered to the public at a price three to four times higher than the actual cost of the apparatus. Unfortunately, many patients are not properly fitted or become nonusers after a trial period.

The useful life of a conventional hearing aid is only a few years. Periodic replacement is necessary. Digital and computer averaging technology is recently improving the efficiency of these devices. The conventional hearing aid has contributed greatly to aural rehabilitation; it is

here to stay and will continue to serve the needs of millions of patients who suffer from hearing losses. Technology is advancing. An inexpensive "third world" hearing aid must be developed. It is hoped that this hearing aid would cost ten times less than the conventional hearing aid in the USA. A battery, rechargeable either by electric, solar, or heat energy, would minimize maintenance. Microchip amplifiers, when mass produced, can be very inexpensive.

Implantable Hearing Devices

Possible Advantages

An implantable hearing device *ideally* should have the following advantages:

1. Cosmetically totally concealed.

2. High fidelity (broader frequency response and lower distortion).

3. Adequate acoustic gain.

4. Reduction of sound distortion. Improved performance in a noisy environment.

5. Elimination of ringing feedback.

6. Improvement of speech discrimination.

7. Efficient sound transmission mechanism, ideally digital, solid state without moving parts, driving the ossicular chain directly.

8. Trouble-free, with many years or even lifetime durability.

9. Applicable to adults and children with acquired and congenital conductive and sensorineural hearing losses that cannot be corrected by conventional surgery.

The physiologic, psychological, and social implications of hearing loss affect especially children; an implantable hearing aid device would represent a tremendous breakthrough in aural rehabilitation, thus improving the quality of life of millions of patients.

Possible Disadvantages

Possible disadvantages of an implantable hearing device include the following:

1. Insertion would require a surgical procedure, although this could be performed under local anesthesia in suitable patients.

2. Possibility of complications such as foreign body tissue reactions, infections, and damage of normal anatomic structures with further deterioration of hearing.

3. Expensive cost, which would involve the purchase of the device and professional and facility fees for surgery.

4. Possibility of need for reoperation to periodically insert batteries or to correct electronic mechanisms or coupling the ossicular chain.

5. Down time if the device malfunctions and reoperations have to be done.

6. Contrary to heart pacemakers, an implantable hearing aid would require much more electric power to function properly. Ideally, the electronic system should have maximal efficiency and use minimal electric power.

Probably the totally concealed and semi-implantable mastoid/middle ear hearing devices offer the best of both worlds.

Advantages and Disadvantages of a Totally Implantable Hearing Device

The concept of a totally implantable middle ear hearing device is very appealing. It has been discussed for the past two decades. Great technological problems are still unresolved, especially as they relate to a totally implantable, highly efficient microphone that is feedback-free. Options for microphone placement include (1) implantation under the ear canal skin; (2) implantation in the attic, coupled to the malleus, which would transmit the mechanical vibrations to the microphone receiving membrane; and (3) implantation in the middle ear, again coupled either to the malleus or incus, using the eardrum as a pressure transducer. Still, research must be done in order to solve these engineering and otologic problems. The idea of having all the hardware implanted and powered by a battery recharged transcutaneously by radio frequency is fascinating. Is if feasible? Perhaps, with the advent of future technology?

A totally implantable middle ear hearing device would have many disadvantages, such as (1) requiring a more intricate surgical procedure; (2) requiring more complex hardware to be implanted within the temporal bone; (3) requiring possible reoperations to correct malfunction and for readjustments; (4) having more possibilities of complications such as foreign body tissue reaction, infection, and damage to normal anatomic structures; (5) requiring increased maintenance and surgical costs; (6) having adverse power consumption, necessitating frequent transcutaneous radio frequency recharging of the battery, or periodic battery changes through outpatient surgery, even if done under local anesthesia; and (7) having more frequent down time if the unit malfunctions, until repairs can be made through reoperation. Additionally, a period of healing would be necessary to restore optimal functioning of the aid.

Types of Implantable Hearing Devices

There are currently three types of implantable hearing devices under investigation and with potentially wide clinical application.

Middle Ear Implantable Coupled to the Ossicular Chain

Either a partially implantable hearing device (PIHD) or a totally implantable hearing device (TIHD) may be based on piezoelectric or electromagnetic principles to drive and vibrate the ossicular chain. In the PIHD, the microphone, microchip, amplifier, and battery are located externally. An external induction coil through the skin activates an internal induction coil that stimulates the transducer coupled to the ossicular chain of the implanted unit. In the TIHD, the whole unit, including microphone, microchip, amplifiers, and battery, is totally concealed under the skin and within the temporal bone.

Temporal Bone Stimulator

With a temporal bone stimulator direct stimulation of bone conduction occurs through an oscillator coupled to titanium fixtures, percutaneously through the postauricular skin. Another possibility is a transcutaneous stimulator that uses external and internal induction coils to activate an internal titanium bone screw-magnet assembly. Bone conduction is activated via this telemetry system.

Otic Capsule Stimulator

With an otic capsule stimulator a transducer is anchored in or close to the otic capsule. The battery, microphone, and amplifier are connected to a percutaneous coupling.

Review of the Literature

The concept of using electricity to improve hearing is very old. Volta, Stevens, Djourno, and Simmons introduced concepts to stimulate the auditory nerve, which eventually led to the development of the cochlear implant with wide clinical use.

In 1935, Wilska was the first investigator to introduce the concept of an implantable middle ear hearing device. He developed a hearing aid by attaching small pieces of soft iron, weighing about 10 mg, to the tympanic membrane of a human subject. He then applied electric current to a variable frequency oscillator and a coil placed in the ear canal. The alternating electromagnetic fields resulted in movement of the eardrum, and the subject was able to hear pure tones. The tone pitch was double compared with that of the electromagnetic field. He then used a small coil attached to the eardrum to introduce a superimposed constant magnetic field. This eliminated the doubling effect by creating sinusoidal current through the coil, resulting in excellent tone perception. However, the coil got hot and caused discomfort and pain due to burning.

In 1959, Rutschmann attached a 10-mg magnet (Cunico) to the umbo of the malleus of three patients. Audio-frequency alternating current was introduced to an oscillator and a coil was worn externally. An alternating magnetic field was produced, driving the magnet and resulting in periodic displacement of the eardrum. The subjects reported that sound production was satisfactory.

In 1967, a patent was granted to the University of Pittsburgh, Department of Electrical Engineering, on a design of an electronic ear. This totally implantable hearing device, which was to be inserted in the mastoid antrum, used a silver-cadmium battery that would be rechargeable by an induction coil unit. The patent has now expired and no report of the performance of the device has yet been published. In the 1970s, Goode, Glorig and colleagues, Vernon and colleagues, and Fredrickson and associates made important contributions in this field. In spite of these research efforts, no device was developed with clinical applications.

In the 1980s, advances in technology have led to the development of an implantable hearing device using a piezoelectric vibrator of bimorph design; these studies were published by Suzuki and colleagues and by Yanagihara and coworkers. In 1985 and 1987 the same authors published a report on the clinical application of this device, apparently with good results, in patients who have experienced good amplification and high-fidelity sound transmission. Indeed, the effort of the Japanese group represents a major breakthrough in the clinical application of the partially implantable middle ear hearing device.

A new type of bone conduction hearing device was developed by Tjellstrom and colleagues. This device was based on the concept of osseointegration of titanium and bone. The same principle is applicable in the technology of implanted teeth. Under certain conditions, titanium will attach to bone directly without an intervening capsule. Drilling a hole in the bone must be done with constant irrigation in order to avoid heating and necrosis. Threads are made in the bone, under optimal conditions, avoiding tissue damage.

The concept of a percutaneous bone-anchored hearing device was introduced. Two procedures are necessary. The first operation consists of insertion of a titanium fixture 3 to 4 cm into carefully prepared threads in the postauricular bone. The periosteum and skin are closed and a period of 3 months is allowed for osseointegration. During the second procedure, the fixture is exteriorized percutaneously and then the hearing aid is attached to a titanium abutment. About 100 patients have been submitted to such procedures, reporting satisfactory results. The patient selection is based on a pure-tone bone conduction average of 45 dB or better and a speech discrimination score of at least 60 per cent. Newer designs, still under investigation, combine the percutaneous connector attached to an osseointegrated titanium implant to the piezoelectric vibrator (ceramic bimorph, Japanese design). Also, this same percutaneous implant is coupled to a transducer implanted in or close to the otic capsule.

In 1986, Hough and associates modified Tjellstrom's technique developed in Sweden. Using technology applicable to cochlear implants, transmission of sound transcutaneously through telemetry, Hough and his group were able to stimulate the temporal bone by vibrating an

osseointegrated titanium screw. A samarium-cobalt magnet secures the hearing aid in place. External and internal induction coils use radiolinking to transfer the electric signal transcutaneously to vibrate the screw-magnet assembly. The advantage of this technique is the absence of a percutaneous fixture. The disadvantage is that, at least of this stage of technological development, only patients with 25 dB or better bone conduction are eligible surgical candidates.

In 1987 and 1988, Hough and coworkers reported designs and preliminary reports of an implantable middle ear hearing aid using the electromagnetic principle. Ko and associates and Maniglia and associates have been working in this field since 1985. In 1987 and 1988, they presented their investigative results of an electromagnetic implantable middle ear hearing device of the ossicular stimulating type. In 1987, Gyo and Goode studies stapes vibration driven by a piezoelectric system in human temporal bones.

Bojrab and associates and Heide and associates have been testing an electromagnetic unit placed in the ear canal that drives a magnet glued to the tympanic membrane in humans. The principle is similar to Wilska's and Rutschmann's pioneer work. Suzuki and several other authors in 1988 have set forth the state of the art on middle ear implants. It is hoped that advances in technology will lead to the development of different devices approved for wide clinical application.

Description of the Devices with Clinical Application

Some of these newer devices are still under clinical investigation. Yanagihara and coworkers have designed two types of implantable hearing devices: (1) a partially implantable hearing device (PIHD), and (2) a totally implantable hearing device (TIHD).

These authors use a ceramic piezoelectric vibrator that provides a limited gain of about 20 to 30 decibels. In the PIHD the microphone, battery, and amplifier are located externally in the postauricular area and radiolinked to an induction coil. The electrical energy is transmitted to the connector in the mastoid, activating a piezoelectric vibrator that is coupled to the head of the stapes. In the TIHD, a device with no clinical application as yet, a microphone is inserted under the skin of the external ear canal, and the amplifier and rechargeable battery are placed in the mastoid cavity. A connector links the amplifier to the piezoelectric vibrator, which is set in the same manner as in the PIHD. The transmission of sound is done through the microphone implanted under the skin of the external ear canal. Sound vibration through the skin activates a very fine membrane of the miniature microphone.

Several patients have been implanted with the PIHD with apparent good results. More clinical application of this type of implantable hearing aid is needed. Yet to be tested is the long-term possibility of a breakdown of the electronic-mechanical device, tissue reaction to foreign materials, and the effect of the piezoelectric vibrator on the stapes and inner ear.

Hough and colleagues, on the other hand, have used a very simple device (Audiant-Xomed) that consists of a bone conduction vibrator attached to the mastoid bone. There are no

electronics involved with this system except induction coils to transmit sound to the temporal bone vibrator transcutaneously. It is only applicable on patients with 25 dB or better bone conduction. The original "body type" receiver, with a hanging wire, is not acceptable to most patients. Miniaturization of the behind-the-ear receiver has improved cosmetic appearance but resulted in gain reduction. More research is necessary to improve electronics and achieve better gain. This device is receiving considerable clinical application in the USA and abroad. It has US Food and Drug Administration (FDA) approval. According to Hough and his group, it is applicable as an amplification device in several types of patients with the following conditions: bilateral congenital or surgically created stenosis, possibly severe unilateral sensorineural deafness with a normal hearing opposite ear, open mastoid cavities with chronic otorrhea, congenital ear malformations that are not amenable to surgical repair, and massive middle ear tympanosclerosis and atelectasis.

The Swedish device of Tjellstrom and coworkers is under investigation in the USA and probably will also be granted FDA approval. Currently it is a more efficient system if compared with Audiant-Xomed. Transcutaneous transmission of electric signals to stimulate the temporal bone vibrator is much less efficient if the hearing aid oscillator is attached directly to the titanium fixture abutment. Perhaps for some patients in whom cosmesis is not an important factor, the Swedish device is a better choice. Risk of infection of the percutaneous device is reported to be negligible. The Swedish device can be used in patients with 45 dB or better bone conduction and a 60 per cent or better speech discrimination score.

Current Research and Designs

For the past 3 years at Case Western Reserve University School of Medicine, Department of Otolaryngology - Head and Neck Surgery, in cooperation with the Case Institute of Technology, Electronics Design Center, principles have been tested, designs described, and experiments conducted on an implantable middle ear hearing device, both in the laboratory and in animals.

Partially Implantable Middle Ear Hearing Device: Proposed Design Alternatives

In considering the important advantages and rick factors, it appears that the idea of a *totally concealed but partially implantable hearing device* probably is the most viable at this stage of scientific development. Three designs are described: (1) the all in the ear electromagnetic device, (2) the partially implantable totally concealed ear canal/mastoid hearing device, and (3) the partially concealed well-hidden external unit.

All in the Ear Electromagnetic Unit

An external ear canal unit consisting of an electret microphone, microchip amplifier, and an electromagnetic driving coil is used to vibrate a magnet attached to the malleus. The speaker is eliminated. Although Gyo and Goode and Bojrab and colleagues have tried this system in human volunteers with favorable results, they have encountered difficulties in adequately fixing

the magnet onto the tympanic membrane. Different adhesives have been used with rather disappointing results. Eventually, the magnet becomes dislodged and the system malfunctions.

We propose to circumvent this problem through the use of a Laser KTP 532, which would allow for the creation of the two microcavities in the malleus handle. These cavities would be receptacles for two titanium self-taping screws, biointegrated and attached to a samarium-cobalt magnet. The screws would be inserted in the malleus and allowed to solidify and biointegrate until ready for use.

After 2 months, the all in the ear canal electromagnetic unit packaged in a silicone mold would then be used. The medial end of the ferrite core of the driving coil would be positioned 3 to 5 mm away from the magnet implanted on the malleus. The distance between the magnet coil interface is critical for efficiency; it is inversely proportional to d^3 (cube of the distance). For example, if the distance is doubled (5 to 10 mm), at 10 mm from the magnet the force from the driving coil to vibrate the magnet is reduced eightfold. The ear canal device would be inserted with the use of a nonmagnetic forceps similar to those used in bronchoscopy for foreign body removal. A samarium-cobalt magnet would be implanted in the external bony canal wall under the skin to be fitted in juxtaposition with another magnet in the ear canal unit to secure stability.

The patient would be trained to insert the device in the ear canal and to remove the inserter without disturbing the position of the device in the ear canal, one he or she noticed optimal hearing improvement. The unit could be removed by a reverse maneuver using the same inserter. Canalplasties could be done in order to comfortably accommodate the device in patients with narrow canals. The driving electromagnetic coils are very efficient, with 3000 turns of the wire around the core (ferrite-alloy compound). The battery could be changed as needed by the patient. If a repair was needed in the ear canal component, a spare unit would be worn in the interim, thus eliminating down time.

Partially Implantable Totally Concealed Ear Canal/Mastoid Hearing Device

Another device under consideration is the partially implantable but totally concealed ear canal/mastoid hearing device. It employs a similar unit in the ear canal as in the first design but contains an electret microphone, microchip amplifier, battery for power, and an external induction coil (the radio signal transmitting antenna). The electrical signal would be transcutaneously transmitted by AM radio frequency to an internal induction coil, which is the receiving antenna. Radio-frequency transmission of signals allows for about 60 per cent efficiency.

The external unit would be placed in the ear canal in the same way as previously described but would be held in position by two samarium-cobalt magnets, one located in the unit and the other implanted through a mastoidectomy approach under the skin of the ear canal, laterally lodged in the posterior bony external ear canal wall. The internal induction could then be wired via passive electrical components to the electromagnetic driving coil. A cylindrical samarium-cobalt magnet would be implanted on the head of the stapes for individuals with special cases of conductive hearing loss. The samarium-cobalt magnet would not be glued

directly to the stapes head but rather to a biocompatible Plastipore cup, which is directly glued to the stapes head. In case removal is necessary, a simple cutting of the plastipore would detach the magnet completely off the head of the stapes. The attachment of the magnet directly to the head of the stapes has the advantage of consuming less power because it requires less driving forces.

Another variation is the electromagnetic-mechanical device. An electromagnetic driving coil activates a metal membrane (diaphragm) connected to a titanium spring coil, which is attached to a cup bumper sitting on the head of the stapes. However, it is desirable not to disconnect the ossicular chain in sensorineural hearing loss. An alternative approach is proposed for these cases. A magnet would be attached to the body of the incus through a pin (T-shaped) cemented with methyl methacrylate in a laser-made cavity. The driving coil (2000 turns) is inserted through the attic, with the allow ferrite of the driving coil positioned 2 mm away from the magnet. Another device consists of an electromagnetic-mechanical system connected to a titanium spring-coupling attached to the body of the incus. A titanium self-tapping screw could secure a loop at the end of the spring.

In either approach, the driving coil must be properly secured to a titanium plate-shaft (L-shaped) with titanium screws applied to the squamous portion of the temporal bone. The use of an adjustable telescoping shaft fixed in position by set screws and bracket would permit optimal coupling distance, allowing for differences in anatomy and for firm fixation.

Partially Concealed Well-Hidden External Unit

Another alternative to design No 2 is to have this variation, a partially concealed well-hidden external unit functioning in a similar fashion but located externally and hidden medially to the upper portion of the pinna instead of in the ear canal. A samarium-cobalt magnet would keep the unit well secured against the retroauricular skin. A transparent hook on the auricle would further stabilize the unit behind the ear. This unit should be suitable for patients without good manual dexterity.

Fresh Temporal Bone and Animal Research

Our research was directed toward accumulating experimental and laboratory data on the requirements of the partially implantable middle ear hearing device of the stapedial type (design No 2) with considerations of its feasibility for eventual human implantation. The general goals of the research were to determine optimal surgical techniques and ossicular coupling requirements and to develop an efficient circuit design believed to be suitable for patients with radical mastoid cavities that can be reconstructed.

In the acute phase of animal experimentation, we specifically attempted to explore whether an implanted device using direct stapedial coupling and radio-frequency transmission could provide sufficient *implant gain* with *low* power consumption in the animal with a surgically altered middle ear. The study was organized in two phases: the first phase was structured to

evaluate the coupling efficiency of the output transducer to the stapes, and the second phase was directed toward the evaluation of the radio-frequency circuit.

In laboratory experiments, we sought to specify the microvibrational chraracteristics of the magnet-weighted ossicles of fresh cat and human temporal bones. The goal in this experiment was to determine the optional type of vibratory stimulator for implantation. Specifically, we attempted to determine whether an electromagnetic or a piezoelectric circuit would produce a significantly different frequency response of stapedial vibration. The piezoelectric device tested in our laboratory showed a peak frequency response of 1.9 kHz, whereas the electromagnetic system was characterized by a uniform flat and broader frequency response. Perhaps improved piezoelectric systems, especially when coupled to the stapes, may give a flatter frequency response. Nevertheless, based on our data, we decided to adopt the electromagnetic principle in order to develop our middle ear implantable hearing device.

Two versions of the middle ear stimulator using electromagnetic principles were developed: (1) miniaturized driving coil, 2.25 mm in diameter by 13.5 mm long (1300 turns of AWG No 45 copper wire), and a cuplike samarium-cobalt magnet; and (2) special fine diaphragm or metal membrane, 6 mm in diameter, excited by electromagnetic components. A 5-0 stainless steel wire was soldered to the center of the metal membrane to be crimped to the ossicles. For comparison, a piezoelectric stimulator of bimorph design attached to the head of the stapes was also evaluated in the laboratory. The electromagnetic coil with the magnet on the head of the stapes was found overall to be more efficient and have more advantages. The systems were tested in fresh human temporal bones and fresh cat cadavers.

Ossicular microvibration below 1 micron was measured using an optoelectronic laser beam system. The displacement of the stapes or incus in the middle ear of fresh cat cadaver (less than 8 hours after death) was measured in response to the activation of the different types of implantable middle ear hearing devices. Also, the characteristics of the two types of electromagnetic stimulators and the piezoelectric stimulator driving the isolated stapes of anesthetized cats were compared. The electromagnetic stimulator has a more uniform flat and broader frequency response and does not require direct contact with the stapes.

For these reasons, we decided to select the electromagnetic minicoil after the preliminary engineering testing to be used in acute animal experiments. Seven anesthetized adult cats were used. This experiment and results were described in detail previously. In essence, auditory brain stem potentials (ABP) were elicited and recorded preoperatively. An atticotomy was performed and the incus was removed to create a conductive hearing loss. After incus removal the hearing was again tested using ABP. A silicone-coated ferrite core transducer coil (13.5 mm long by 2.25 mm in diameter) with AWG No 45 copper wire (1300 turns) was placed approximately 2 mm from the stapes-samarium-cobalt magnet assembly. A telemetry system consisting of an external conduction coil (transmitting antenna) and an internal induction coil (receiving antenna) transmitted by AM (amplitude modulation), with passive electronic signal, was transmitted to the driving coil. The driving coil was assembled in a contactless manner with the stapes-magnet assembly. The electromagnetic coil, powered either by direct wiring or by telemetry, was used

to stimulate the stapes. The experimental findings showed that the device is functional with good gain (35 dB average) and consumes low current (0.6 mA) with telemetry.

The experimental data, particularly the significant improvement noted with the telemetric circuit in place, support the original research objectives: (1) to provide sufficient acoustic gain and (2) minimal power consumption of the implant device. The mean acoustic gain of 35 dB was achieved with the telemetry unit, and this can be further increased by providing additional amplification. The external unit can very well be built with a more powerful, adjustable amplifier that can be controlled by the user.

The power consumption of the implanted portion of the device was efficient, consuming only 15 microwatts at 0 dB (electronic level), which is 27.14 dB (mean value) above the threshold measured in this condition. This small power requirement made possible the design of the described telemetric system. The power consumption of the external telemetry unit was 2.4 milliwatts (4 V, 0.6 mA). As this represents our first prototype unit, additional technological refinements in progress can be expected to decrease power consumption by a factor of three (0.8 milliwatts, 1.3 V, 0.6 mA).

This device appears to compare favorably with a medium-power hearing aid with respect to acoustic gain and power requirements. With the present prototype, a 40-mA-hour battery can last for 2 weeks on an 8-hour per day usage basis. With the improved electronics, the battery life can be increased threefold. Although no measure of discrete frequency ABP thresholds in the live animal was done, our optoelectronic laboratory data show a broad, flat frequency response from 100 to 5000 Hz. This type of frequency response is expected to provide good sound fidelity and, with the added telemetry unit, can be further modified (shaped) to the specific needs of the patient, as in the conventional hearing aid.

The energy conversion system of this device is very efficient owing to its design. Acoustic energy picked up by the microphone is transformed into an electrical signal, which is amplified and delivered directly to the transmitting (external) antenna, avoiding the need for acoustic energy conversion typical of the conventional hearing aid. The conventional hearing aid requires a second conversion of energy (electrical to acoustic) by the speaker. The acoustic energy delivered to the eardrum must be transferred through air molecules, which, in turn, leads to a further depletion of energy due to impedance mismatches and conduction losses. Not only does the elimination of a speaker lead to a better conversion of energy in the system but it also avoids the well-known problem of feedback.

The electronics of the implanted portion of the system are completely passive and simple in design, and the components are very inexpensive. They contain no transistors. They are composed of a coil, two diodes, one capacitor, and a driving electromagnetic coil with associated wiring. This implanted system requires no battery for operation. It is designed to be hermetically sealed. The components should last indefinitely, requiring no revision surgery for electronic malfunction. If there is no need for a battery, reoperations are not necessary for battery changes. Hermetic sealing avoid corrosive interactions between the hardware and body fluids. The

electromagnetic forces are transmitted to the ossicular chain on a contactless basis, thereby avoiding wear and tear of the ossicular chain.

The external portion of the system has two variants, depending on the specific needs of the patient. One variation can be totally concealed in the ear canal for patients with motivation and the good manual dexterity required for insertion and care. Older patients, especially those with limited manual dexterity, would be candidates for a miniaturized and well-hidden postauricular unit. We feel that this system in either of these variations provides simplicity in electronics and excellent cosmetic advantages. Should the external unit malfunction, there would be no down time, as the patient can replace it immediately with a spare unit. The pacemaker industry has already demonstrated the reliability with which electronics can be implanted. In additional preliminary studies on three animals, we also tested the efficiency of our system using a ring-shaped $SmCO_5$ magnet that was inserted through the long process of the incus. The incudostapedial joint was again cemented after disarticulation prior to testing. While results were encouraging, further studies have to be done in order to better evaluate this coupling method.

Certainly in patients with sensorineural hearing loss the removal of the incus is not desirable. Therefore, the magnet should be implanted on the lateral aspect of the body of the incus, which would be activated by a more powerful coil with 2000 turns. Our system coupling directly to the stapes would be more suitable for a patient who requires reconstruction of a radical mastoid cavity and who has a mobile and intact stapes superstructure. The requirement of a good eustachian tube function in such a case would not be mandatory, because the coil would drive the stapes efficiently and the minimum space of the round window niche should be sufficient for round window displacement in the scala tympani.

Future Goals

Improvement in the efficiency of the electronics and miniaturization of our system are ongoing. Laboratory analysis and testing will be performed and a prototype will be built that is applicable to human implantation. Chronic animal experimentation will begin in the dog (beagle), selected because of its anatomic and physiologic similarity to humans. Thirsty-six beagles will receive implants, divided into two groups: (1) a conductive hearing loss group (that is, with removal of the incus) and (2) a sensorineural hearing loss group with the stapes intact and hearing loss produced by ototoxicity, using aminoglycoside drugs. The magnet in this case will be implanted on the incus and a more powerful electromagnetic driving coil will be employed. Six subsets of six dogs each will be evaluated to test the different proposed designs. The animals will be evaluated using ABP tone-burst stimuli (500 to 10.000 Hz) in a threshold paradigm. Perhaps cochlear potentials with a carbon electrode at the round window could facilitate measures of acoustic distortion.

After the animals receive the implants, a period of 3 months will be allowed for biointegration. Each animal will be evaluated periodically at 3 months, 6 months, and 9 months. At 9 months, the animals will be sacrificed and the middle ear/mastoid will be inspected under the microscope to evaluate potential ossicular problems, infection, granulation tissue, and other

reactive tissue changes. The temporal bones will then be harvested and histologic studies using light microscopy will be performed. If this experiment proves to be feasible and appropriate for human application, then clinical trials will be started.

This exciting area of research is indeed just beginning. Future developments should enrich the field of otology and improve the quality of life for many patients.

The Future of Implanted Hearing Devices

The implantable hearing device is still in its infancy. More electronic, animal, and human research is necessary in order to develop efficient prototypes to test acoustic efficiency of transmission of sound to the inner ear and to study tissue tolerance using minimal electric power. Several years of follow-up are necessary in order to really evaluate the efficiency and analyze the complications of implantable hearing devices before it can be established as a good substitute for the conventional hearing aid with its current technology of development. The main technological problem lies in the development of a high gain, trouble-free, totally implantable hearing device. The biggest challenges are the development of an efficient implantable microphone (feedback-free) and a solid state system with high gain but using minimal electrical energy. Should the microphone be located under the skin of the external ear canal (as in the Japanese device), in the middle ear attached to the tympanic membrane, or in the epitympanum attached to the head of the malleus? Probably several years of research and development are on the horizon before this goal is achieved. Nevertheless, the partially implantable hearing device will probably receive wide clinical application in the near future. However, the conventional hearing aid industry is a multibillion dollar business. It is constantly active in research and development. Improved conventional hearing aids certainly will be tested and compared against implantable devices. Only time will tell which technology will serve our patients best. Probably, the implantable hearing device will play an important role to improve the quality of life of suitable patients. Nevertheless, the conventional hearing aid will continue to be used by a large percentage of patients with sensorineural as well as conductive hearing losses.