ORIGINAL ARTICLES

Earlens* tympanic contact transducer: A new method of sound transduction to the human ear

RODNEY PERKINS, MD, Palo Alto, California

This article is an initial report on a new method of transducing sound to the human ear. The report describes the shortcomings of conventional acoustic amplification devices, the potential advantages afforded by the Earlens system (ReSound Corp., Redwood City, Calif.), a description of the system, and preliminary clinical results. The system is composed of two elements: a transducer that is composed of a magnet mounted on a thin, conical silicone platform and a device that generates a magnetic field which causes the Earlens to vibrate. The Earlens transducer is placed on the umbo area of the tympanic membrane and maintains its position there by floating on a droplet of mineral oil. Two configurations of the magnetic field device are described: one that is placed within the external auditory canal and another that is worn around the neck. This feasibility study was done in seven patients during a 3-month period. All patients in the study maintained the position of the transducer for the duration of the study, and the tympanic membranes showed no evidence of inflammation or other problems. The presence of the transducer caused an average 5-dB threshold depression in the speech frequencies. In the neck-worn device, maximum mean functional gain was 25 dB at 2000 Hz. Variability in the functional gain at different frequencies was noted with poorer gain above 2000 Hz. (Otolaryngol Head Neck Surg 1996;114:720-8.)

Hearing devices have long been the principal method of treatment of sensorineural hearing impairment. The earliest of these devices, the cupped hand and the hearing trumpet, whether crudely made from an animal horn or those later renditions crafted from silver and ornately engraved, provided some degree of assistance by shifting the resonant frequency to the benefit of the listener (Fig. 1). In this century we have seen the introduction of electronic devices that amplify environmental sound and present the enhanced acoustic signal to the external auditory canal. However, although these devices do provide improved hearing, they have certain inherent problems that limit their performance and acceptance.

From the California Ear Institute at Stanford.

*ReSound Corp., Redwood City, Calif.

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Reprint requests: Rodney Perkins, MD, 801 Welch Rd., Palo Alto, CA 94304.

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A new method of transducing sound to the ear has been developed that appears to eliminate many of the problems of current hearing devices and opens the possibility of a new communication pathway for linking the person to a variety of communication inputs. This method, called the Earlens system (ReSound Corp., Redwood, Calif.), uses as its key element the tympanic contact transducer. To more fully appreciate the advantages of this new system, it is worthwhile to review some important, but generally overlooked, aspects of our hearing and to discuss some of the major drawbacks of current acoustic hearing devices.

ACOUSTIC CONTRIBUTION OF THE AURICLE AND EXTERNAL EAR CANAL

Externally originated sound waves first strike the auricle and its convoluted internal curvatures. This structure and its shape provide certain directional information, resonances, and amplification (nominally 10 dB at 5000 Hz) to the sound, which then passes into the external auditory meatus (Fig. 2). As

Fig. 1. Engraved silver telescoping ear trumpet: 1800s.

Fig. 3. Canal contributes 10 to 12 dB at 3200 Hz.

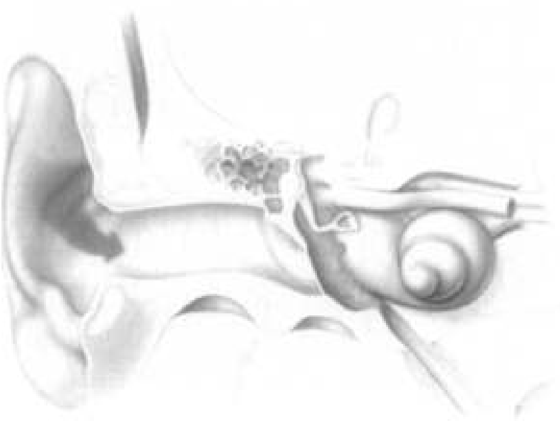

Fig. 2. Auricle contributes 10 dB at 5000 Hz.

Fig. 4. Internal sound is dissipated through the ear canal

it passes through the external auditory canal, certain frequencies are amplified. This is nominally 10 to 12 dB at 3200 Hz and is based on the length and the diameter of the canal (Fig. 3). The amplification of the combined conchal and canal contribution is nominally a 12- to 15-dB gain at 2700 Hz. Thus the original sound is modified by the auricle and canal before it impacts the tympanic membrane. It is this modification of the incoming acoustic energy that gives much of what we define as "naturalness" to what we hear.

Internally generated sounds such as speech and those resulting from chewing pass from the oral cavity and upper airway through the bony and soft tissues and are emitted into the external auditory canal. Much of this sound is normally dissipated through the open meatus (Fig. 4). We come to perceive the "naturalness" of our own voice on the basis of this along with other factors.

PROBLEMS WITH CONVENTIONAL ACOUSTIC HEARING DEVICES

Conventional acoustic hearing devices have a number of inherent problems regardless of the sophistication of the electronic sound processing used. These problems derive primarily from their physical presence in the auricle and external auditory canal.

Their position in the auricle and canal not only blocks incoming sound but also interferes with the normal resonances and frequency amplification described above (Fig. 5). Thus their very presence in the outer ear requires additional amplification and disturbs significant characteristics of the input signal to the tympanic membrane, to which the person has been accustomed for decades.

Further distortion occurs when the electronically processed signal is converted back into an acoustic signal and emitted into the ear canal through the output speaker of the device. Because the device is

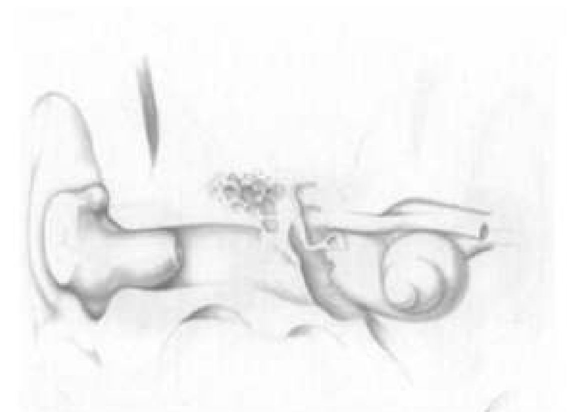

Fig. 5. Conventional devices block the concha and meatus.

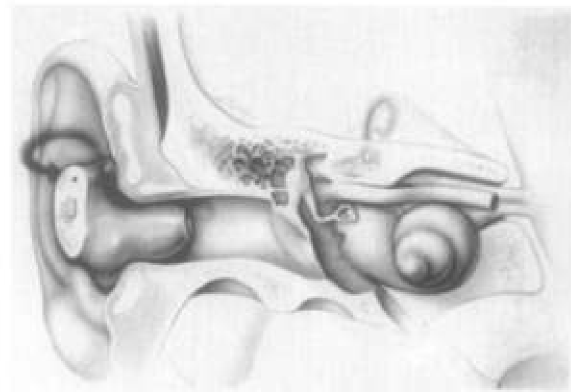

Fig. 7. Amplified sound returns to the microphone creating feedback.

Fig. 6. Postprocessing distortion occurs in the occluded canal.

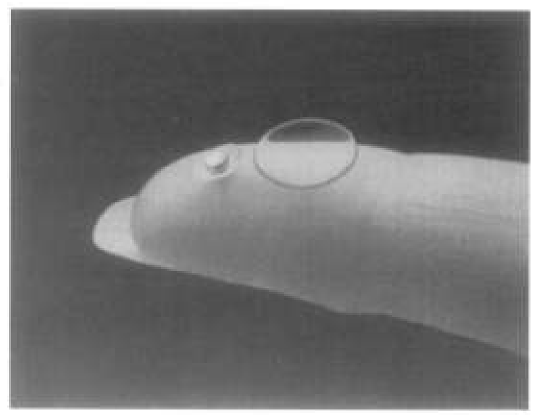

Fig. 8. Earlens transducer and an ophthalmic contact lens.

blocking the external auditory meatus, the signal enters an abnormal and artificially created closed chamber where abnormal resonances are created, distorting the signal before it reaches the tympanic membrane (Fig. 6).

Acoustic feedback is another problem with conventional hearing devices. The output from the device is picked up by the input microphone from sound leaking into it between the plastic housing of the device and the canal skin or internally through vibrations within the device (Fig. 7). Attempts to fit the device more tightly to eliminate feedback frequently result in discomfort. Conversely, a less tightly fit but more comfortable device is more prone to feedback.

Furthermore, internally generated sounds such as those from chewing and talking are emitted into the blocked external auditory canal. They cannot dissipate normally and give rise to the annoying perception of one's own voice being loud and sounding hollow. This phenomenon is commonly called the *occlusion effect.* This problem makes it almost impossible for some patients with hearing devices to carry on a conversation while eating.

And, perhaps more importantly, the cosmetic appearance of conventional devices is a great deterrent to many who could profitably use a device. The concern that others will perceive them as getting old or being defective or less intelligent prevents the acceptance of assistance in millions of people.

The Earlens system could eliminate many of the problems of conventional hearing devices for hearing-impaired persons and could potentially provide a convenient private method of communication in the normal-hearing population.

EARLENS CONCEPT

The concept involved in the Earlens system is surprisingly simple in several regards. It involves the same principle used with ophthalmic contact lenses

Fig. 9. Lateral view of Earlens transducer in place.

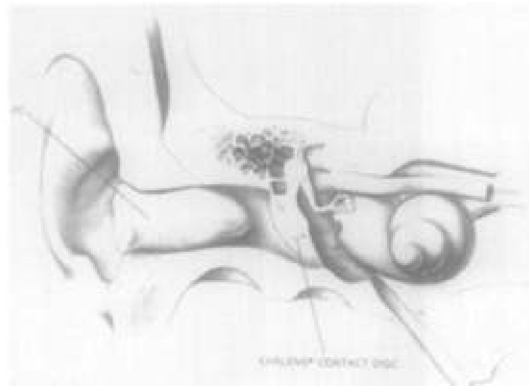

Fig. 11. ITC configuration with internal coil.

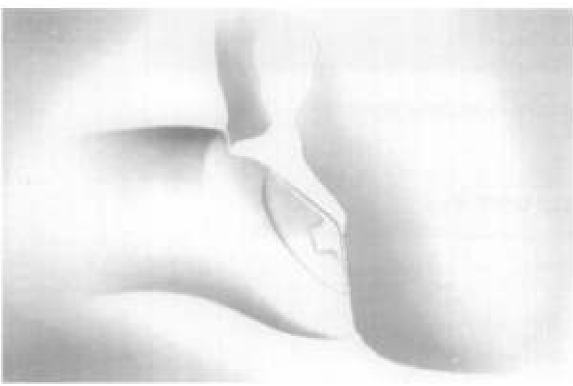

Fig. 10. Sagittal view of Earlens transducer in place.

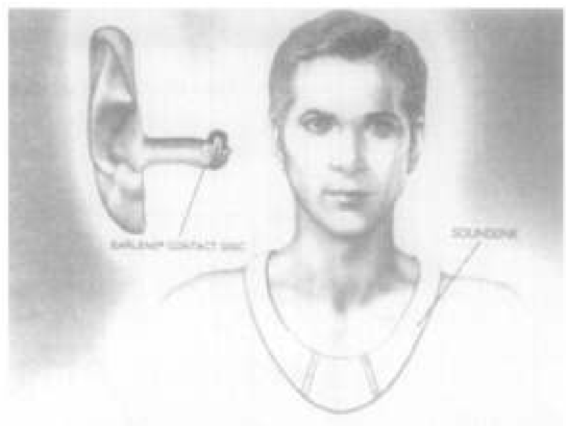

Fig. 12. SoundLink configuration.

for four decades and the same transduction concept used in acoustic speakers.

In this system an electromagnetic coil worn by the patient produces a magnetic field that vibrates a magnet embedded in a conically shaped silicone rubber film resting on the surface of the tympanic membrane. When acted on by a magnetic field, the magnet vibrates the diaphragmatic tympanic membrane and the malleus, transmitting vibrations to the remaining ossicular system and to the inner ear.

TYMPANIC CONTACT TRANSDUCER (EARLENS)

The Earlens tympanic contact transducer is composed of two elements: a magnet and a thin, cone-shaped silicone rubber platform (Fig. 8). A gold-plated sumerium cobalt magnet is captured on a biocompatible silicone rubber platform that has the shape of the central tympanic membrane. The Earlens transducer is placed on the umbo area of the tympanic membrane and maintains its position there by floating on a droplet of mineral oil (Figs. 9 and 10). The conically concave shape of the tympanic membrane and the adhesive forces provided by the mineral oil are similar to those conferred by the convex shape of the cornea and the molecular and surface tension characteristics of the lacrimal fluid, which provide position stability for an ophthalmic contact lens.

The Earlens transducer is made from a silicone impression of the patient's tympanic membrane. Therefore its shape conforms exactly to the conical umbo area of the tympanic membrane. A small droplet of mineral oil is placed on the umbo, and the Earlens transducer is transported to the tympanic membrane with a small plastic suction tip. After it is released, the exact position is attained by manipulating it with a slightly curved titanium instrument.

The patient atomizes a small amount of mineral oil into the ear canal periodically to replenish that lost by slow evaporation.

MAGNETIC FIELD DEVICE

The device that generates the magnetic field contains the sound-processing electronics and an elec-

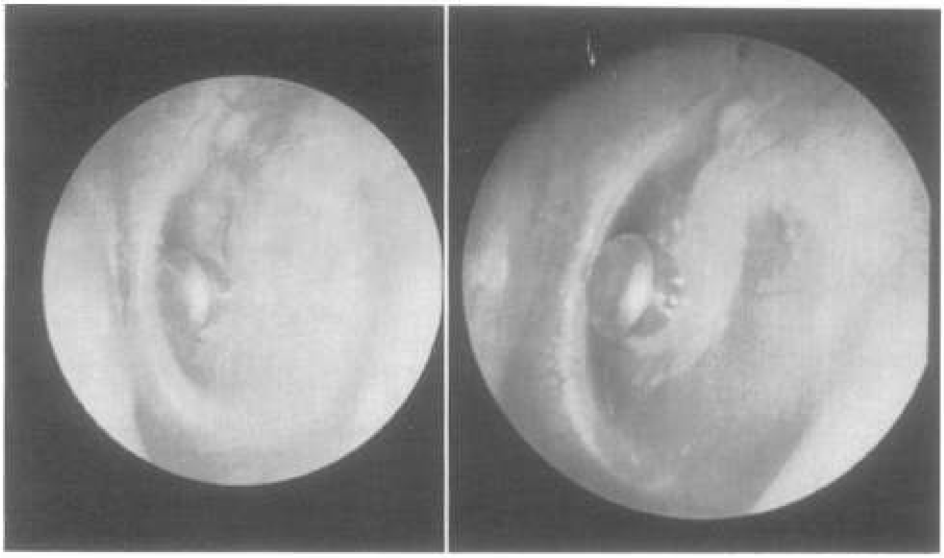

Fig. 13. Day of placement *(left)*; after 3 months *(right)*.

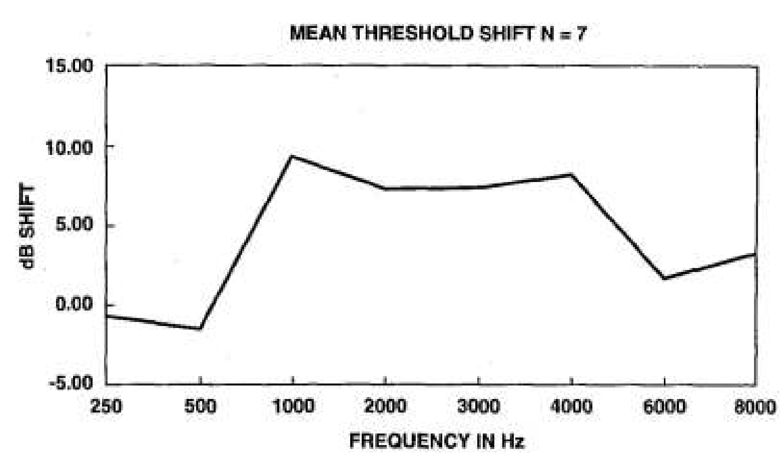

Fig. 14. Mean threshold shift after placement (n = 7).

tromagnetic coil. Two configurations of this device are being developed: one to be placed in the ear canal, the in-the-canal (ITC) configuration, and another to be worn around the neck, the SoundLink (ReSound Corp.) configuration.

ITC Configuration

This configuration combines the Earlens transducer with an ITC device that contains a microphone, sound-processing electronics, a battery, and a miniature electromagnetic coil (Fig. 11).

SoundLink Configuration

The SoundLink is a necklace under development that contains a wide-diameter magnetic coil, rechargeable batteries, sound-processing electronics, FM receiver, and a microphone (Fig. 12). Although the patient could wear the SoundLink necklace externally, another design provides for the patient to wear the SoundLink necklace under his or her clothing. A small wireless microphone and short-range FM transmitter would transmit the acoustic signal to the SoundLink necklace.

INITIAL STUDIES

An initial study primarily to assess the safety and stability of the Earlens transducer on the tympanic membrane was done at the California Ear Institute in Palo Alto. The protocol was determined to be a nonsignificant risk and was approved by a local institutional review board. In the study seven patients were evaluated during a 3-month period, and

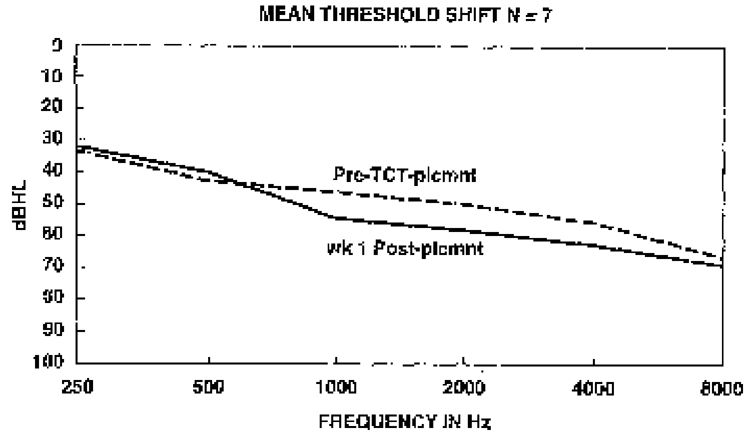

Fig. 15. Threshold shift after placement (n = 7).

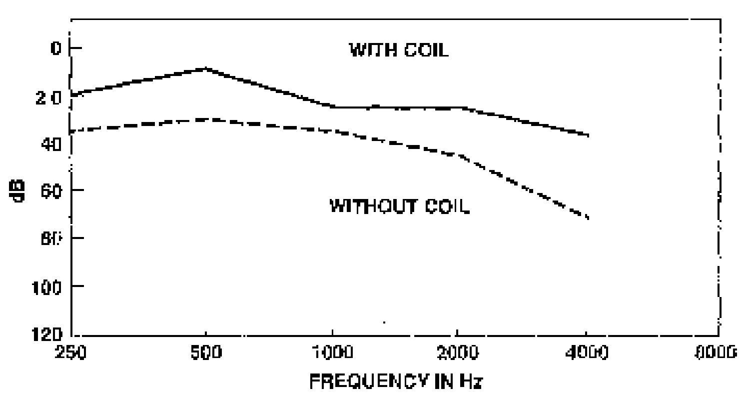

Fig. 16. Patient A: Decibel gain with ITC coil.

the Earlens transducer remained in position on the umbo throughout the study.

The patients were monitored throughout the study. Visual microscopic inspection, 35-mm, and videophotography of the tympanic membrane were carried out before placement of the Earlens transducer and after placement at intervals of 1 week, 2 weeks, 1 month, 2 months, and 3 months. Audiometric studies were carried out at appropriate intervals. Early prototypes of both configurations of the magnetic field devices were used to assess the feasibility of the concept.

All seven patients were able to wear the Earlens transducer throughout the 3-month period without displacement or inflammation (Fig. 13). The clear nature of the thin silicone rubber platform of the Earlens transducer allows the area of the tympanic membrane beneath the platform to be observed. Although some patients were aware of its presence immediately after placement, most patients were unaware of it after a short time.

Although a more complete and detailed report on audiometric studies will be reported separately, it is of particular interest to note the threshold shift after placement of the Earlens transducer and the functional gain provided by the two magnetic driver configurations.

The weight of the Earlens transducers in this group had a range of 39 to 43 mg. After placement the mean threshold shift varied at different frequencies with a minimum of −2 dB at 500 Hz and a maximum of 9 dB at 1000 Hz (Figs. 14 and 15). Average speech frequency application loss was approximately 5 dB. Although any such "loading effect" or application loss is undesirable, it must be viewed in comparison with the typical insertion loss of 15 to 20 dB associated with conventional acoustic hearing devices resulting from their blockage of the

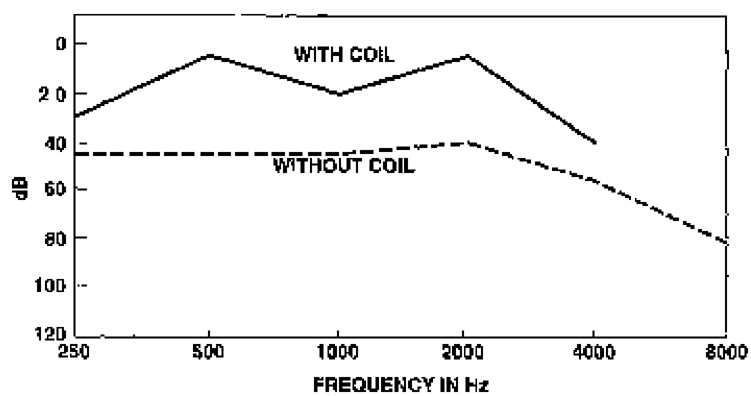

Fig. 17. Patient B: Decibel gain with ITC coil.

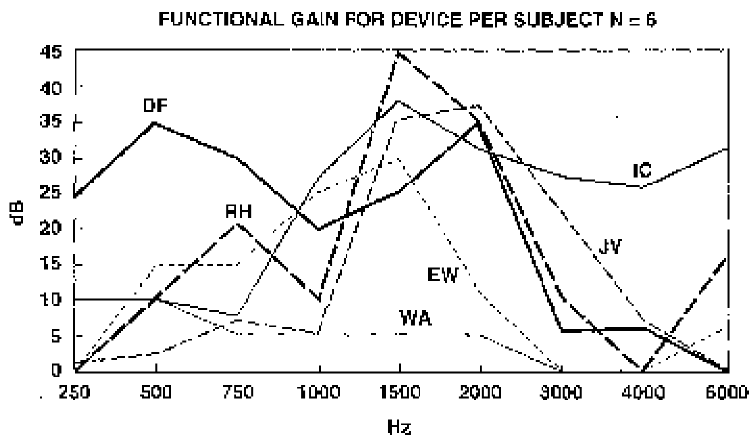

Fig. 18. Functional gain in seven patients with SoundLink.

external auditory canal. This application loss is being studied, and modifications of the platform and magnet of the Earlens transducer are being assessed in an effort to minimize this effect.

The ability of such a system to provide adequate amplification was established. The ITC configuration was studied in two patients (Figs. 16 and 17). The ITC configuration was sensitive to the coil of the device being very close to the Earlens transducer. Variations in coil and system design to improve this are in progress.

Six of the seven patients used the prototype SoundLink configuration. Variability in the functional gain at different frequencies was noted (Fig. 18). The maximum mean functional gain was 25 dB at 2000 Hz. Patients liked it subjectively. All emphasized the comfort of the unobstructed ear canal, the lack of occlusion effect, and the lack of feedback. They reported feeling less like a hearing-impaired person and freer. Another series using a significantly improved SoundLink prototype will be reported in the future.

DISCUSSION

Earlens Transducer

The principal aim of this initial study was to assess the safety and stability of the Earlens transducer on the tympanic membrane. The lack of inflammation during this 3-month period speaks well to the issue of safety and the ability of the tympanic membrane to tolerate the resident Earlens transducer. In addition, some patients in the study are part of an extended follow-up protocol and have had many more months of inflammation-free residence of the Earlens transducer.

To understand the ability of the tympanic membrane to tolerate a lengthy residence of the Earlens transducer, it is informative to make comparisons between the Earlens transducer and an ophthalmic contact lens. Ophthalmic contact lenses were first used in actors for short filming sessions. An ophthalmologist would come to the movie set, place the glass contact lens on the eyes of the actor, and after the scene was filmed, would remove the lenses. Now, several decades later, contact lenses are ubiquitous and may be worn for extended periods without removal. This has resulted from our understanding of the nature of the nutritional and oxygenation needs of the cornea. The nutritional requirements are mediated by the lacrimal fluids, and the oxygenation needs are serviced by the direct effusion of oxygen into the fluids and into the corneal epithelium. The development of gas-permeable biomaterials, which allow oxygenation of corneal cells through the lens material, was necessary for individuals to wear contact lenses safely for any extended period. By contrast the tympanic membrane is a considerably different and a more robust structure. Functional considerations dictate that the corneal epithelium be optically clear and without blood vessels. Because the external surface of the tympanic membrane does not have a similar functional requirement, its nutritional and oxygenation needs are served by a healthy blood supply emanating from the manubrial artery and the circumferential vessels flowing onto the tympanic membrane from the adjacent canal skin. Although in the future other biomaterials may be found to have more optimal characteristics for the Earlens platform, the successful residence of these lenses on the patients in this study suggests that medical-grade silicone rubber is a material that is satisfactory and safe in this application. This is not surprising because for more than two decades millions of silicone rubber ventilation tubes have been placed within the tympanic membrane and have been in contact with the epithelial surface for extended periods.

Also, it is of interest to note that in this study most of these patients continued to wear their conventional hearing devices in the ear containing the Earlens transducer during the study for audiometric assessment purposes. It is common knowledge that continual obstruction of the external canal with a conventional acoustic hearing device predisposes it to a higher incidence of external otitis than would be the case in normal open canals. The lack of tympanic membrane inflammation in this compromised environment gives further strength to the apparent safety of such a device for this extended period.

The position stability of these transducers was excellent. Only minor rotation of the Earlens transducer was thought to have occurred in one or two patients, and all seven patients maintained the devices in good contact with the central tympanic membrane throughout the 3-month study. This is particularly interesting because we know that conventional ventilation tubes move through the tympanic membrane and are extruded probably as a result of forces exerted on them by the migrating squamous epithelial surface (Fig. 19). We also know that magnets glued on the umbo area in experiments are not maintained in this position for any extended period. This probably results from the glue bond failing and/or migration of the epithelium carrying the magnet with it off the placement site. In the case of the Earlens transducer, it is theorized that the extended position stability is a function of several factors. The concave shape of the umbo area confers some degree of stability, especially in combination with the molecular adhesive and surface tension characteristics of the mineral oil. As noted above, these factors are similar to those operative in ophthalmic contact lenses. In addition, however, it is believed that the migrating squamous epithelium slides beneath the mineral oil layer, leaving the Earlens transducer in its original topographic position.

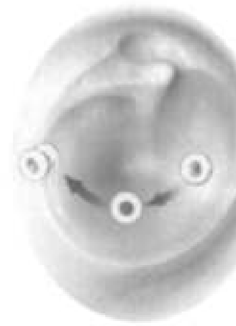

Fig. 19. Epithelial migration forcing extrusion of vent tube.

ITC Configuration

Because of the small diameter of the coil, this device needs to be in relatively close proximity to the Earlens transducer to provide sufficient magnetic field strength for adequate amplification. The strength of the magnetic field is inversely proportional to the cube of the distance between the coil and magnet. If successfully developed, the ITC configuration has the potential to offer principal performance advantages over conventional hearing devices.

Reduced feedback. Feedback would be reduced because there would be no electronic speaker producing sound.

Reduced occlusion. Occlusion would be reduced because it would not be necessary to seal the ear to reduce feedback. The device could be widely vented.

Increased reliability. Damage caused by earwax and corrosion caused by moisture buildup would be reduced because the part of the ITC device within the ear canal would be sealed.

SoundLink Configuration

It is currently thought that this configuration, if successfully developed, would address most of the mild to moderately hearing-impaired population. It is doubtful that this configuration would address the severely impaired because those patients require significantly more amplification than is provided by the SoundLink prototype as described. This is especially true in the higher frequencies where magnetic transduction is less efficient. The SoundLink configuration has the potential to offer four principal performance advantages over conventional hearing devices.

Elimination of feedback. Feedback would be eliminated because of the placement of the microphone at a distance from the ear.

Elimination of occlusion. Occlusion would be eliminated, and comfort increased, because nothing would obstruct the ear canal.

Increased reliability. Damage caused by earwax and corrosion caused by moisture buildup would be reduced because only the Earlens transducer would be placed in the ear.

Retention of normal resonances. The open ear canal provides a pathway for the conchal and canal resonances to reach the tympanic membrane, thus enhancing the "naturalness" of sound.

Improved aesthetics. Once in place, the Earlens transducer is not visible. The device that generates magnetic energy for the Earlens transducer may be designed in different configurations that would not resemble traditional hearing devices. For example, an aesthetically designed necklace.

The feasibility of including FM and/or infrared receivers in the SoundLink configuration to enable users to receive transmitted signals is being explored. These features would take advantage of already existing signal sources in some cordless telephones and in systems designed to assist hearing-impaired persons in public settings, such as theaters and church, and would assist them in listening to radio and television.

Other Potential Applications

It is believed that nonmedical applications of this technology may exist. It may be useful as a method of transmitting sound to the ear in personal communication, telephone, consumer products, voice paging, language translation, noise cancellation, and other applications in which a private and inconspicuous transmission of sound to the individual is desirable.

CONCLUSIONS

Preliminary studies on the Earlens transducer system, which uses a principle similar to that of an ophthalmic contact lens, indicate that the presence of a silicone rubber/magnetic transducer on the tympanic membrane for extended periods causes no adverse effect or inflammation.

There is slight application loss primarily in the midfrequency range, which is caused by the presence of the Earlens transducer on the tympanic membrane. It varies from individual to individual and it is thought that optimization of the Earlens design can minimize this effect.

Preliminary studies suggest that adequate amplification is feasible from two configurations of magnetic field sources. Development of these configurations is currently in progress and under study.

If successfully developed, the Earlens system is expected to have significant advantages over conventional acoustic systems for hearing-impaired persons and has potential for the transduction of sound to the normal human ear in a number of communication applications.