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A one-size disposable hearing aid is introduced

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INTRODUCTION

A disposable hearing aid has been developed to overcome many of the hurdles that have caused the vast majority of mild-to-moderately hearing-impaired individuals to delay or decide against wearing hearing correction.

The product, which uses proprietary technology, is designed to compete in quality with the industry's best and most expensive instruments. Developed by Songbird Medical Inc., of Cranbury, NJ, in conjunction with the Sarnoff Corporation (formerly David Sarnoff Research Center and RCA Research Labs) in Princeton, NJ, the device is called the Songbird Disposable Hearing Aid. It is sold and distributed by Songbird Medical.

One of the core strategies in the development of this new product was that it should be of a single physical size that can be successfully fitted by a professional from office inventory on a large majority of adult ears in just one office visit. The Songbird disposable instrument will be easy to obtain, simple to use, and available at a very low cost of entry—$39 for an estimated 40 days of usage.

Our expectation is that the introduction of this new device will result in significant numbers of people visiting a hearing aid professional for the first time, thereby substantially expanding the market for hearing aids.

BACKGROUND

The Songbird device (Figure 1) has been designed to follow the fitting trend of existing custom-molded hearing aids—to fit totally in the concha of the ear and/or in the ear canal. Such instruments constitute approximately 80% of all hearing aids sold in the U.S. and Canada[1] and continue to be a rapidly growing percentage in the remainder of the world.

Cosmetic and acoustic advantages are well documented for the custom family of in-the-ear (ITE) instruments, and it is certain that the trend toward smaller instruments that fit more deeply in the ear will continue. However, the traditional deep-fitting instruments present issues that a disposable hearing aid may solve.

The list of "problems" with custom hearing aids includes, but is not limited to:

- repeated remakes—approximately 15% within the first 90 days
- acoustic feedback
- comfort issues
- retention in the ear
- the occlusion effect
- poor or no telephone use
- repairs and the lost use of hearing aids during these times
- the management of hearing aid cells
- appropriate ear impressions.

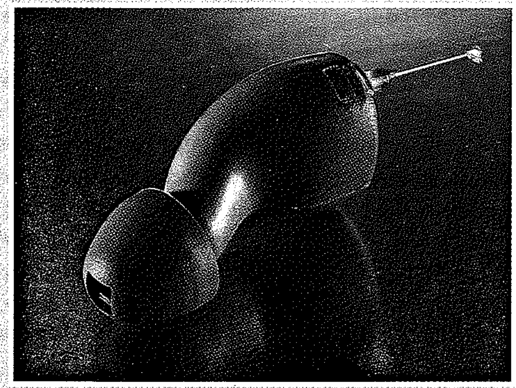

Figure 1. *The Songbird Disposable Hearing Aid.*

In response to many failed attempts to solve these problems, the concept of a disposable "uni-ear" hearing aid—a single unit that fits both ears—was developed.

DESIGN ISSUES

Overall design considerations

The goal was to design a hearing instrument that could be used easily by a high percentage of individuals who had mild and moderate hearing losses; be purchased repeatedly by consumers at very low cost; require minimal involvement for entry into the system; be repair-free; eliminate battery replacement/maintenance; be cosmetically appealing; and be automated for assembly—all without compromising quality and performance.

The design issues related to automation and disposability are unique and will be addressed in forthcoming publications, as are issues related to the electroacoustics of the instrument. The device components are entirely different from those in any other hearing aid, including the new microphone and receiver and the non-accessible power source designed specifically for this instrument.

A deep-fitting hearing instrument has proven to be a good idea, but has been difficult to implement successfully with earshells of hard acrylic or even with most "soft-tipped" earshells. One reason is that the bony structure of the ear canal is extremely sensitive to pressure at the depth to which a deep fitting earmold must penetrate. Pressure on the bony canal wall as little as 0.5 grams per square mm (the weight of a piece of paper) has been reported to cause pain.[2] Any movement or force caused by mandibular action passed on by the earshell is transmitted to the bony canal wall.

The solution used by the conventional hearing aid industry has been to taper and/or shorten the length of the earshell to avoid such contact and to facilitate insertion, until many completely-in-the-canal (CIC) units are now more like mini-canal instruments (Figure 2). Also, many audiologists/dispensers find it difficult to take appropriate ear impressions for a deeply fitting instrument, or the ear impressions are not of sufficient quality to make an accurate earshell.

Although the original plan was not for a uni-ear instrument, after numerous approaches to determine the ideal size and fit and to maximize comfort, the Songbird/Sarnoff design team made the decision to design the instrument to fit both the right and left ears. A benefit for the professional of a uni-ear design is that it simplifies fitting since the same unit can fit either ear and does not require an ear impression to obtain a deep-fitting instrument.

The objective was to develop a design that realizes as many of the acoustic and fitting advantages as possible from deep-canal hearing aid technology. These include greater overall real-ear sound pressure, especially in the high frequencies; reduced or no acoustic feedback problems; cosmetic acceptance; a reduction of the occlusion effect; maximum usability with a telephone; wind noise reduction; security of fit; and improved performance in noise.[3]

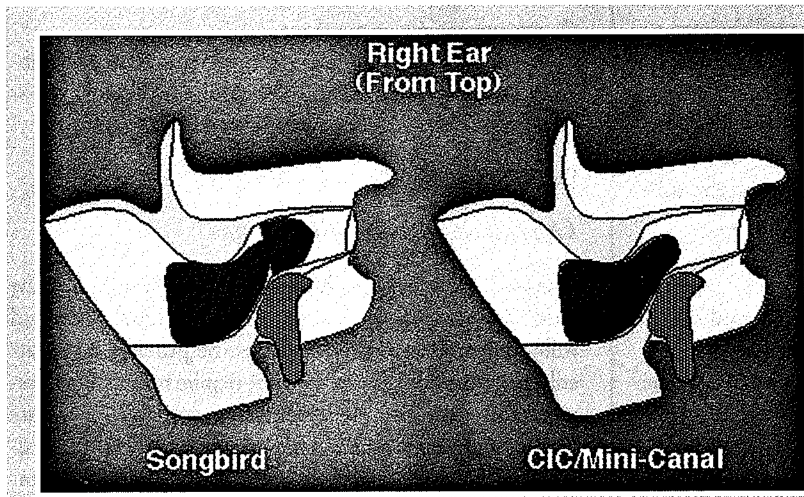

Figure 2. *The right ear canal as visualized from above. This shows a comparison of the fit of the uni-ear instrument as designed versus CIC and mini-canal instruments. Note that CIC and mini-canal instruments are tapered anteriorally to facilitate insertion and posteriorally to avoid contact with the canal wall and discomfort. They do not make good contact in the bony section of the canal to control feedback and often do not take full advantage of the acoustic benefits of a deep canal fitting.*

Physical fit and comfort

The movement of the condyloid process of the ramus of the mandible is responsible for many hearing aid fitting and comfort problems (Figure 3a). This process is identified as forming the anterior wall and first turn of the auditory canal.

Measurements made by Edwards and Harris[4] show jaw movements during speech to be from 2.5 mm to 14.4 mm in a horizontal translation of the axis of rotation and from 1.2 mm to 4.2 mm in the vertical translation of the axis of rotation (Figure 3b). MRI measurements[5] and physical measurements of ear impressions made during open and closed jaw positions[6] confirm this horizontal movement.

Ear canal expansion of up to 100% in the anterior-posterior dimension of the cartilaginous ear canal has been reported by Termeer when making ear impressions with a low-shore versus a high-shore hardness material and of different viscosity silicones.[7] In reality, a horizontal movement of approximately 2 mm (mostly forward from the position of rest) can be expected. This movement can contribute to an opening anteriorally between the hearing aid and the ear canal wall that can lead to feedback or slippage from the ear when the wearer is speaking or chewing.

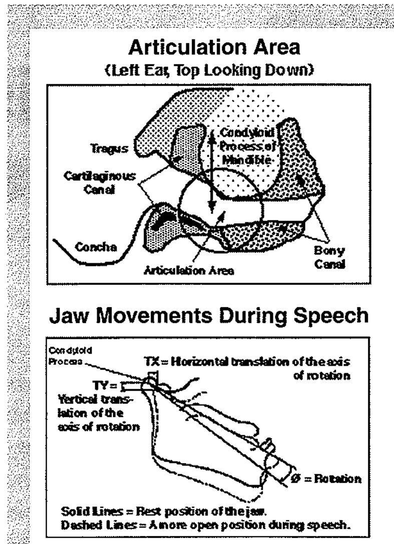

Figure 3. *The articulation area. The top drawing (a) shows the best view (top looking downward) to evaluate the ear canal and its critical turns and associated structures. The arrow at the condyloid process indicates that this structure moves forward and backward—mostly forward during speech—and as a result changes the shape of the ear canal substantially. The bottom drawing (b) is a two-dimensional rigid-body model of jaw movement during speech. Jaw movement is described as a combination of three components: TX, horizontal translation of the axis of rotation; TY, vertical translation of the axis of rotation; and Ø, rotation. (Drawing (3a) is adapted from "Rotation and translation of the jaw during speech" by Edwards and Harris.[4]*

Generally, hearing instruments are more comfortable when they do not fit deeply into the ear canal and when they have a loose fit. The disadvantage in such a design is that the fitting contributes to increased acoustic feedback, slippage from the ear, and an increased occlusion effect.

Primary solutions to these problems with small hearing instruments involve appropriate placement more deeply into the ear canal. Unfortunately, this can lead to fit and fabrication problems that demand more accurate ear impressions, critical attention to the physical fit of the hearing aid, and concerns about the "hardness" of the hearing aid shell material or tip causing discomfort.

Contributors to physical comfort that were considered in the design of the Songbird Disposable Hearing Aid included the relationship of the bony to the cartilaginous portions of the ear canal and to the "articulation" action that occurs where these meet; the skin thickness of the external auditory meatus; the movement of the condyloid process of the mandible during speaking and mastication; and the sensitivity of the bony canal. All of these tend to be interrelated.

The skin thickness related to the cartilaginous and bony sections of the ear canal is an important consideration involving the design, comfort, and fit of a uni-ear design. The cartilaginous ear canal accepts "imperfect" fits to a certain extent, suggesting an earshell design that does not have to conform closely to a particular size. On the other hand, the skin lining in the bony structure is approximately 0.1 mm in thickness, has no subcutaneous layer, and is sensitive and prone to irritation, which can result in excretions, swelling, or redness.[8]

The thinness of the skin in the bony canal requires a design that does not try to expand the bony canal. Any "drag" or unusual pushing or pulling on the skin in this area can lead to the creation of a hematoma or to skin tearing. This suggests that the device must slip into the ear without undue friction, and that merely providing a "soft flexible tip," as some are advocating, may not be the solution.

THE UNI-EAR DESIGN

In the development of the uni-ear design, existing CIC and other approaches not fully using the deep-canal approach were not considered. The design needed to be robust and inexpensive to manufacture, but at the same time of high quality, free from repair and remakes, and with exactly the same performance characteristics from one unit to the next.

Over the course of almost 4 years, approximately 400 people had numerous prototype insert designs of different shapes placed in their ears, and their reactions were observed and recorded. These designs were derived using the three-dimensional PRO-Engineering computer-aided-design (CAD) software.

The primary issues in the initial stages of development were related to physical fit and not to electroacoustics. Among these were: Could an individual insert the instrument properly? Would it be cosmetically acceptable? Was it comfortable to wear? Was it secure in the ear? Could the occlusion effect be minimized? Could it be removed easily from the ear? And would it fit acceptably into more than 70% of adult human ears?

Parameter	Total (n=280) (mm)	Male (n=160) (mm)	Female (n=120) (mm)
Pinna			
Longest diameter	63.5±12.0 (a)	63.0±12.9	59.0±11.2
Shortest diameter	36.3±6.1	38.0±7.2	35.0±6.7
EAC (b)			
Length	23.5±2.5	25.2±2.6	22.5±2.3
Longest diameter	9.3±0.9	9.7±1.1	8.5±0.7
Shortest diameter	4.8±0.5	5.1±0.7	4.4±0.3
TM			
Longest diameter	9.4±1.5	9.7±1.8	9.2±1.2
Shortest diameter	8.6±0.9	8.9±1.0	8.4±0.7
	(degree)	(degree)	(degree)
TM-AICW angle	19±2	18±2	20±2
TM-CCA angle	43±4	42±3	45±4

(a) values are expressed as mean ±SD
(b) Abbreviations: EAC, external auditory canal; TM, tympanic membrane; AICW, antero-inferior canal wall; CCA, central canal axis.

Figure 4. *External ear canal and drum head measurements (in millimeters) compiled from 280 silicone impressions from 140 cadavers. Adapted from "The external ear and the tympanic membrane" by Salvinelli et al.[9]*

The basic configuration of the hearing aid's earshell design was modified following each evaluation session. Some of these sessions were rather informal while others were highly structured. Several major design changes to the instrument occurred during this time period as a result of these evaluations.

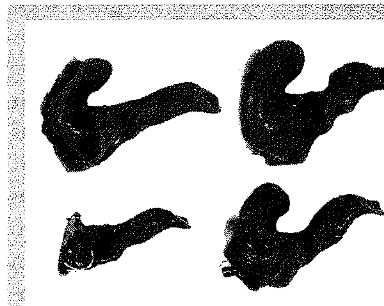

Figure 5. *Ear impressions of four complete ear canals showing variations in configurations, including the complete eardrum imprint, the annulus, and umbo.*

Earshell design

A starting point for the earshell size and shape came from a number of published data, such as those from Salvinelli et. al.[9] (See Figure 4.) However, because the published data did not diagram the actual shape of the ear canal, samples were made from ear impressions of the full length of adult ear canals to the tympanic membrane (Figure 5). These provided more specific information about the most appropriate way to terminate the instrument within the ear canal and how the shape desired and the electronic components could be incorporated best. The earshell of the device had to fit a large percentage of the population but still house the required hearing aid components and be cosmetically acceptable.

Tip design

The tip design and its method of attachment to the earshell created the greatest challenge. It had to be of an appropriate size and shape to provide easy insertion by being able to work around the ear canal bends; be comfortable in texture, shape, and hardness and exert very low pressure on the canal wall; provide flexibility without slippage from the ear; manage the variation in the shape of the ear canal during speaking and mastication; direct sound properly toward the tympanic membrane and not the canal wall; provide a good seal regardless of mandibular movement to control acoustic feedback; be durable for repeated insertions and removals; and allow for easy removal.

A critical feature was that the tip allow for full contact in the bony structure to take advantage of acoustic benefits of deep-fitting canal technology but have the ability to slide smoothly and self-guide itself against the canal wall.

More than 40 different tip designs were evaluated or considered. Some had designs similar to many in use today but when tested were very uncomfortable or provided almost no control over feedback. Some tip designs that appeared massive and were expected to provide high attenuation were ineffective in controlling feedback. Finally, a mushroom-shaped tip was selected as providing the best seal and being most comfortable.

Feedback management

A requirement for this instrument was that acoustic feedback not be a problem. A final selection of tip design was made on almost 200 subjects. Using a special test unit to determine the maximum electrical gain allowable before feedback oscillation occurred, different size mushroom-shaped tips were evaluated (Figure 6). Subjects and/or the evaluator increased the level of amplification to the point of feedback oscillation and the electrical gain was recorded.

Fullness of ear

Fullness of ear can be expressed in at least two ways—occlusion and the occlusion effect. These are not to be confused with each other.

Occlusion is caused by the plug effect of an object closing off the normally open ear canal. This is loss of sound contact with the environment and is overcome with hearing aids when they are turned on.

The occlusion effect is an increase in the loudness of one's voice when speaking as a result of occluding the ear canal. The origin of the occlusion effect is expressed by von Békésy as follows: "...throughout the skull by bone conduction, low-frequency vibration is transmitted through the soft tissues of the cartilaginous part of the ear canal and also from vibrations transmitted by the condyloid process of the mandible, vibrating out of phase relative to the movement of the skull, and, therefore, generating sound pressure in the ear canal."[10]

Management of the occlusion effect has been most efficient with the use of large vents (larger than 2 mm) or by full contact of the unit within the bony structure of the ear canal.[11,12] The uni-ear is designed to fit deeply in the ear canal and make full contact with the bony structure. Recorded comments by test subjects did not indicate that either of these issues was of major concern with the design, even though the instrument is not vented.

The final design of the uni-ear is shown in Figure 1. The design allows independent movement of the tip from the instrument earshell. This minimizes the transmission of mandibular action movement from the cartilaginous to the bony ear canal and allows the unit to bend around the ear canal turns during insertion.

SUMMARY

This article is a brief introduction of a new concept in hearing instruments that is intended to expand hearing aid use in the non-user market.

The uni-ear, disposable hearing aid described is expected to offer consumers the advantages of being of very high quality but very inexpensive to purchase. Being disposable means that not only is there no need for repairs or replacement of batteries, but it also eliminates the concern of purchasing soon-to-be outdated technology. The consumer can be upgraded easily to the latest disposable technology available.

Advantages to the hearing professional are that the disposable hearing aid will fit a very high percentage of adult ears and hearing losses and offers the promise of greatly expanding the existing hearing aid market. (HJ)

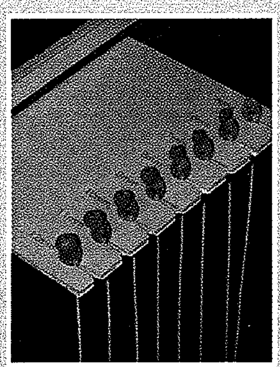

Figure 6. *The level at which feedback occurs was measured on adult subjects using this hearing aid electrical signal generator that connects to different test tips. The subject or tester turned up the calibrated dial on the test unit until feedback occurred. This level was plotted.*

ACKNOWLEDGMENTS

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