Over the last ten years, the hearing industry has seen very little growth in sales. Historically, the largest increases in sales have come with the introduction of small hearing aids including in-the-canal (ITC) and completely-in-the-canal (CIC) hearing devices. Today, however, the largest segment of hearing instrument sales is the behind-the-ear (BTE) market, which now accounts for approximately 67% of all hearing aids sold (Strom, 2010). One of the major contributors to this segment is the receiver-in-the-canal (RIC) style product which makes up approximately 28% of the standard product market and might be considered a nice compromise between the cosmetically appealing custom products and the reliability of BTE products. Considering the now stagnant growth in sales, we must ask ourselves the following question: Is a behind-the-ear product really the best solution for everyone?

In the spring of 2010, Starkey Laboratories, Inc. released a new product style termed the invisible-in-the-canal or IIC. This product is designed to sit beyond the aperture of the ear canal and ideally as deep as the second bend of the ear canal (Van Vliet & Galster, 2010). The SoundLens (IIC) is a premium technology product including Starkey’s industry leading feedback canceller and patented Voice IQ fast-acting noise reduction system. With the realized success of the SoundLens, and the success of the instant fit RIC, Starkey Laboratories wanted to create a small, open, instant-fit in the ear device that would appeal to both market demands.

From a mechanical design perspective, creating a small, open, instant-fit product that could be deeply inserted into the ear canal fit a majority of ears? After analyzing the anatomy of the ear canal and carefully considering that the device had to include the basic components of a hearing aid (e.g., a microphone, a battery, a circuit and a receiver), the minimum size of the device was determined. The device also had to be as open as possible, yet accommodate larger ear canals and ear canals that exhibit large amounts of movement while talking or chewing. With this in mind, a two piece concept was designed. This concept (Figure 1) consists of a modular hearing aid that is inserted into a sleeve, which accommodates for multiple ear canal sizes and ear canal movement. This two-piece concept not only met the basic requirements but also included innovative design features to protect against microphone and receiver failure. The following paper will describe the basic design features, as well as the safeguards put in place to protect and improve the overall functionality of the device known as the AMP.

Figure 1: Line drawing of modular hearing aid and sleeve.
Module Design Features

The design of the AMP module began with an in-depth study of ear canal geometry and a review of conventional designs. In the past, these designs gravitated toward curved or bent housings with sharp corner transitions. These transitions provide an efficient use of internal space and theoretically make sense with the natural bends in the ear canal. However, the inherent flaw with this decision is that sharp corner transitions on a hearing instrument require precise placement and orientation in the canal to avoid concentrated pressure points, ultimately reducing comfort and overall physical fit rate. To reduce or even eliminate concentrated pressure points, the AMP was designed with a circular cross section (Figure 2a). To accomplish this circular cross section, the receiver had to be fundamentally re-engineered. In traditional custom devices, a stock receiver is selected and added to the rest of the product based on the desired gain and frequency response. In contrast, one of the first steps of this project was designing and building a receiver to meet the needs of the AMP product. Not only does this reduce the physical size without compromising performance, it allows for a few important and innovative design features including: placing the microphone and receiver diaphragms orthogonal to each other in completely separate compartments therefore reducing mechanical vibration; creating a curved off-axis 5mm long acoustic channel for enhanced bandwidth (Figure 2b); and providing a 360° sound inlet port (Figure 2c) to ensure an un-occluded path to the microphone regardless of variations in ear anatomy.

Sleeve Design Features

The second important hardware design innovation of the AMP product is the removable liquid injection molded (LIM) silicone sleeve. Before placing the AMP module into the ear canal, it must first be inserted into the LIM silicone sleeve. The LIM sleeve serves 4 main functions: 1. as an agent to aid in the comfort and retention of the device, 2. to protect against moisture, 3. as a wax barrier, and 4. to aid in the removal of the device. LIM silicone was selected over other materials as it balances a range of physical properties necessary to withstand continued use within a complex environment. Properties such as chemical resistance, environmental stability, durometer retention and superb tear resistance were essential components and considerations. To accommodate comfort and retention in a wide range of ear canals, as well as a wide range of hearing losses, the LIM silicone sleeve was designed with 4 different sizes including small, medium, large, and occluded (Figure 3).

Although the LIM silicone sleeve has excellent tear resistance, there was mild concern that the sleeve could tear during removal of the device from the ear canal. In an effort to validate the theoretical tear strength, Starkey engineers performed a statistical analysis of typical forces.
applied during removal of the devices. These data were used to develop a mechanical stretch test at a threshold of three times the typical required removal force. Multiple sleeves were subjected to tens of thousands of stretch cycles and exhibited minimal to no indication of damage, wear or tearing. To further test the tear resistant properties of the sleeve, cuts were induced in the sleeves and after tens of thousands of cycles no additional damage, wear or tearing was seen. The design and LIM silicone material lived up to and even surpassed initial expectations.

Wax and Moisture Protection

To address wax and moisture protection, a moisture-blocking liquid polymer that cures and conforms across all internal connections was applied. The AMP was also designed to be self contained, meaning that the need for additional wax and moisture protection systems were eliminated through a combination of multiple design features.

For the receiver, wax protection is afforded by a two-fold design. 1) The sleeve itself has a redundancy of 4 small boomerang shaped ports (Figure 4). This shape creates a small slit and flap mechanism. Should wax ingress force the flap mechanism downward, it naturally springs back lifting the wax back to the exterior of the sleeve. 2) In the case that wax force its way past these boomerang shaped ports, it would accumulate in the curved acoustic channel on the exterior of the hearing aid module. Because this acoustic channel is relatively long at 5mm, it greatly reduces the chance of wax or other debris actually entering the receiver port. Traditionally, microphones in canal products are exposed to wax and other unwanted debris during insertion and removal from the ear canal as it is common to push on the faceplate of the device. To protect the microphone of the AMP, Starkey designed a 360° sound inlet leading to five redundant internal ports (Figure 5). This redundancy virtually assures a clear path to the microphone even in the harshest conditions and regardless of ear anatomy. Internally, the five ports provide access to a hydrophobic (moisture resistant) and oleophobic (oil resistant) microphone protector consisting of an acoustically transparent fabric.
weave. The moisture repellant nature of the fabric weave is naturally increased by the fact that moisture is entering through the side (smaller surface area) rather than through the face of the fabric weave. The collection cavity itself can be cleaned with the typical wire loop provided with custom products without fear of damaging the filter media.

**Clinical Validation of Physical Fit Rate, Comfort and Retention, Fit, and Acoustic Transparency**

Over the course of 6 months, a clinical evaluation was completed to validate the design goals of overall physical fit rate, comfort, retention, and openness or acoustic transparency of the AMP device. The results are reported below.

**Physical Fit Rate**

To determine the physical fit rate of the AMP, 53 people including 28 males and 25 females, who ranged in age from 23 to 83, were tested. The physical fit, as judged by a Research Audiologist, was divided into five categories: Ideal, Good, Acceptable, Unacceptable, and Did Not Fit. Figure 6 illustrates examples from each category, respectively. As shown in Figure 7, 88% of the 105 ears examined fell into the acceptable to ideal range.

**Acoustic Transparency**

After completing and understanding how the AMP physically fit into the ear canal from a visual perspective, a more in-depth study was completed to understand how the end user perceived their experience with the AMP. The first step involved measuring the acoustic transparency or “openness” of the device. To do this, the real-ear unaided response (REUR) and the real-ear occluded response (REOR) were measured on 18 research participants. Figure 8 shows that the average difference between the REOR and the REUR with the AMP product is similar to average data from a traditional CIC with an I/O or open vent (McCabe & Galster 2010), suggesting that...
the devices were non-occluding in the majority of ears and thus unlikely to lead to the perception of feeling occluded or “plugged”.

**Comfort and Retention**

Once the physical fit rate and the acoustic transparency had been determined, comfort and retention ratings during typical use were completed. Again, using data collected from 19 research participants with Ideal or Good fit ratings, it was found that the majority of participants rated the AMP as comfortable and reported that the device was staying in their ears most or all of the time. These results are shown in Figures 9 and 10.

**Summary**

In order to provide more options for individuals with hearing impairment, Starkey Laboratories, Inc. has developed multiple product offerings for those patients who desire a more compact, more discrete hearing instrument. These offerings include the SoundLens (IIC) and the product described in this paper called the AMP. Both products offer an effectively invisible solution that meets different needs. While the SoundLens is a premium custom fit product, the AMP is a non-custom, relatively open, instant-fit hearing aid designed as a product for those new to the hearing aid market.

The AMP has not only been designed to reduce known field issues with deep fitting products but also to solve common problems associated with current instant fit non-custom products. The innovative features described in this paper have led to a very exciting non-custom product that physically fits a large percentage of ears, is relatively “open” in most ears, and has been shown to have high average comfort and retention ratings. Yet, it must be stressed that this is a non-custom product and candidacy based on hearing loss, dexterity, and comfort and retention must be evaluated prior to determining whether or not this is the most appropriate product for your patient.
References


