Basing Amplification Recommendations on Evidence

Improving Water Resistance for Hearing Instruments

Verification of Prescriptive Fitting through a Hearing Aid

Interaction of Hearing Loss with Psychological, Sociological, and Cognitive Behaviour
We would like to express our sincere thanks to Starkey Laboratories Canada for their generous support in making this supplement possible.
I know that I may be accused of being a nerd, but I actually have Robyn Cox’s 2005 article on evidence-based practice on my bedside table, and I don’t read it in order to fall asleep. Well, maybe I am a bit of a nerd, but Dr. Cox’s work is seminal to this field and should permeate any clinical program.

Evidence-based research and evidence-based practice means that it is the clinician who must have be the arbiter of what has been demonstrated in the literature to be useful and what may only be marketing. Often, a great sounding idea is just that, but unless it has independent object support that is free from confounding factors, clinical caution must be exercised.

This is a supplementary issue of the Canadian Hearing Report that has been sponsored by Starkey Laboratories. Starkey, like many other manufacturers, has placed a lot of time, money, and effort into ensuring that any innovation is well supported by the literature and this issue is a selection of some interesting well-supported, technologies and ideas.

Dr. Tim Trine is the guest editor for this supplementary issue and he brings with him a wealth of knowledge, both from the clinical and the manufacturing arenas. Under the guidance of Dr. Trine, some fascinating articles are in this issue, led off with a clear statement of the issue at hand, by Dr. Catherine Palmer. This is followed by articles on the prevention of moisture contamination (Dr. Weili Lin), and a novel method for the verification of a hearing aid prescription (Dr. Jason Galster and Dr. Elizabeth Galster). Finally where would an issue on evidence-based practice be without input from Dr. Brent Edwards, who probably knows more about Canada than anyone else I have ever met (except for our current prime minister, the right honourable Jack Harper).

Together this issue stands alone as a reasoned and informative issue that is a must to read and would be quite useful as a supplement to any university course on evidence-based research or clinical practice.

Marshall Chasin, AuD., Reg. CASLPO, Aud(C),
Editor-in-Chief
Canadian Hearing Report

Reference:
It’s a privilege to bring you this special issue of Canadian Hearing Report. Because an evidence-based approach has been the singular foundation of Starkey’s research and development approach over the past dozen years, I thought it would be useful to provide a sample of the diversity of our on-going efforts to establish a strong basis for the product decisions we make. Most readers will be familiar with the strong evidence base we have established for our best-in-class features such as adaptive feedback cancellation, directional processing, and noise performance because our marketing department does an excellent job of keeping that data visible and the details accessible – just take a peek at StarkeyEvidence.com if you’re in doubt. Perhaps not quite as visible but certainly as important, however, are the efforts across many disciplines taken to ensure that every critical aspect of our design is validated and well-supported by evidence. So, following Dr. Palmer’s excellent introduction to the concept of evidence-based practice and the roles and responsibilities therein, we have included three topics that represent a cross-sectional sampling of our approach – from device quality, to clinical utility, to hypothesis-driven research.

It might seem axiomatic that medical device product development would be founded on an evidence based approach; however, I think most clinicians will admit that it doesn’t take long to find examples of features that have been over sold or for which evidence simply doesn’t exist. Ironically, it is frequently the case that the features that have the least-proven efficacy are the features that are most often requested by customers. Single- or multi-channel adaptive directionality illustrates this point perfectly. Although most hearing aid companies have embraced this feature and have marketed it aggressively for several years, there is yet to be a single publication in the peer-reviewed literature or in trade journals demonstrating the efficacy of such processing (see Bentler 2005 for a meta-analysis) in anything other than contrived laboratory environments and these contrivances don’t represent the acoustics of everyday life (Woods and Trine 2004). The likely explanation for this demand is threefold:

1. The adaptive directional story fits with our intuition despite the reality of everyday life acoustics; that is, it’s easy to imagine that noises we can localize might be attenuated more if we aim a directional null at them.
2. Adaptive directional systems don’t perform substantially poorer than a directional system that has a fixed pattern.
3. The story is easy to sell to patients; that is, the same intuition that clinicians have can easily be passed along to the patient.

As Dr. Palmer points out in this issue, however, “evidence-based practice is a team effort.” If we truly want to support evidence-based practice, then our approach to product development must not only be dependent upon including those features that have proven efficacy but must also depend on the exclusion of features for which evidence does not exist. This also, of course, puts a burden on the clinician to keep abreast of the literature and to demand the data from manufacturers proving the efficacy of our designs.
As I was preparing for this special issue, I returned to an article I co-authored several years ago (Trine and Van Tasell, 2002) and I believe the closing words we used then, still apply:

“…hearing professionals should expect from manufacturers:

1. hearing aid design that is based on established scientific evidence of effectiveness
2. accurate and honest portrayal of the benefits of new technology
3. flexible fitting systems that will acknowledge potential differences among users in their desire for advanced features, and that will assist hearing professionals to achieve the best possible fit of advanced products to their customers.

I hope you enjoy the issue!

Timothy D. Trine, PhD
Chief Technical Officer
Starkey Laboratories, Inc.

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Basing Amplification Recommendations on Evidence

By Catherine V. Palmer, PhD

Evidence-based practice is a group effort. Evidence-based amplification decisions start with the basic scientists who continue to define the normal and damaged auditory system. The process continues with the research and development teams associated with hearing aid manufacturers who use these data to produce signal processing techniques, algorithms, and hearing aid features designed to mitigate the problems caused by a damaged auditory system whether that includes issues of audibility, frequency resolution, temporal resolution, or tolerance issues (to name a few). Ultimately, the responsibility sits with the clinician who is the hearing aid wearer’s connection to the evidence base. Individuals pursuing hearing aids have every reason to believe that clinicians will use their expertise to sort through the evidence to select the appropriate technology to meet the individual communication and listening needs of the patient. In addition, the consumer of hearing health care expects the provider to use the evidence and patient data to recommend the most cost-effective solution. In essence, the clinician is responsible for using the evidence base to match technology to each individual patient.

Anyone interested in evidence-based practice in audiology should become familiar with Robyn Cox’s work. Two of Dr. Cox’s articles will assist the clinician on the pathway to evidence-based practice. According to the Centre for Evidence-Based Medicine, evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The focus on the individual patient is the key to the appropriate application of evidence-based practice. Evidence-based practice does not imply that there is some type of formula that should be followed in the care of individuals seeking communication assistance. It does, however, put the burden on the clinician to know the current evidence and apply that to recommendations within the context of an individual patient who has a particular hearing loss etiology, configuration, site of lesion, and individual communication needs, abilities, and demands.

The underpinning of the clinician’s ability to engage in evidence-based amplification recommendations comes from the manufacturers’ participation in evidence-based design and further from the manufacturers’ dissemination of this information. Haynes provides a framework in which to think about what research a clinician will be most interested in when trying to find individual solutions for patients. Haynes focused on health care interventions (e.g., amplification recommendations) and indicated that there typically are three questions that one might ask: Efficacy (Can it work?).
Effectiveness (Does it work?), and Efficiency (Is it worth it?). The question of efficacy is the larger question that is asked before a hearing aid feature is introduced into the market. This is the extent to which an intervention does more good than harm. Evidence-based design deals with the question of efficacy. An amplification example would include an evaluation of a fixed directional microphone in a sound booth with fixed noise sources at the nulls. This type of investigation answers the question of whether a directional microphone can work given the correct set of circumstances. If the findings in this type of study are negative, then there would be no reason to pursue the particular technology. On the other hand, just because the findings in this type of investigation are positive, does not mean that the feature will be useful in real-life listening situations (e.g., where one cannot completely control where the noise is coming from).

Effectiveness is the critical question for the clinician and this assesses whether the intervention does more good than harm when used in typical practice. An example might be an examination of the performance of an adaptive directional microphone response compared to a fixed polar pattern directional response in real-world listening conditions. The concept of effectiveness has to be applied specifically to the patient at hand. Will this intervention be effective for this particular patient given their needs and abilities and specific communication demands and environments?

Efficiency asks whether the effect of an intervention is worth the additional cost that may be incurred. For example, automatic adaptive feedback control may be shown to be effective, but if hearing aids with this feature cost more, is the additional cost to the patient worth the benefit obtained? This is where the clinician is called upon to evaluate the level of evidence (and alternative treatments, e.g., occluded earmold to deal with feedback) in light of the patient’s needs including their financial constraints or financial constraints of a larger system of reimbursement.

A systematic review or meta-analysis of treatment options (e.g., feedback management, directional microphones, noise reduction) is a gift to the clinician who is trying to implement evidence-based practice. The Journal of the American Academy of Audiology devoted an entire edition of the journal to systematic reviews related to amplification and auditory rehabilitation (JAAA, 2005, June Supplement). Ideally, we will see more systematic reviews appearing in our journals. A systematic review is a summary of the scientific literature in which explicit methods are used to perform a comprehensive search and critical appraisal of individual studies. A meta-analysis is a type of review where the studies could be combined in order to provide a higher level of evidence for a particular recommendation. A published systematic review or meta-analysis should be a powerful tool for the clinician. This provides the clinician with the evidence levels and grades for various treatment recommendations that can be directly applied to clinical practice.

Because systematic reviews are not always available on specific topics of interest, clinicians need to become critical consumers of the research related to efficacy and effectiveness. They must make decisions based on the evidence available at the time. Robyn Cox provided an easy to follow protocol for answering specific clinical questions. In summary, she suggests

(1) Ask an answerable question,
(2) Conduct an efficient search of the literature to locate the available evidence relevant to the question,
(3) Evaluate the quality of the evidence,
(4) Decide how the evidence applies to this particular patient and generate your recommendations for treatment,
(5) Evaluate the outcome of the treatment and seek ways to improve next time. This process can be empowering for clinicians when they find evidence to support clinical recommendations. It is rewarding to talk to patients about technology options based on the evidence as it
applies to their particular circumstance (hearing ability, lifestyle, etc.).

Unfortunately, good evidence is often deficient in many areas, but a lack of evidence is not the same as a lack of benefit. A lack of evidence in the area of efficiency is often a problem for clinicians. New hearing aid signal processing schemes and features come out quickly and new features seem to be in the marketplace before the previous set has been submitted to rigorous evaluation in terms of effectiveness. This is one problem associated with careful evaluation and peer review of publications. This process takes time and generally the timeline is longer than the signal processing or features’ shelf life. Therefore, clinicians are routinely required to evaluate data directly from manufacturers when trying to make evidence-based recommendations. Considering this position, the manufacturer must be responsive to what the clinician needs to critically evaluate the evidence-based design and the clinician must be comfortable to demand adequate detail in order to make sound judgments. Palmer et al (2008) provide a tutorial in being critical consumers of research. The clinician should be familiar with five aspects of a study or research report: (1) level of evidence, (2) rationale for the sample size chosen, (3) variability in the data, (4) determination of statistical significance, and (5) practical significance of the findings. These are all items that should be included in the study report. For detailed information about each area, the reader should access this tutorial at www.audiology-online.com. The level of evidence refers to the design of the study. Table 1 and 2 provide a common set of descriptions and grade levels for study designs. Ideally, one would require evidence with grades of B or higher when making clinical decisions. When presented with data, the clinician should always ask if a power analysis was conducted to determine the appropriate number of subjects to answer the question under investigation. When viewing results, all graphs displaying mean data should be accompanied by standard deviation (or standard error) bars. This is the only way for the consumer of data to see how variable the findings were which speaks to how confident one can be that the outcomes were different for two treatments. Figure 1 displays data without standard deviation bars and the same data with standard deviation bars are displayed in Figure 2. The data in Figure 1 might make the clinician eager to recommend Hearing Aid #3 while the data in Figure 2 would help the clinician realize that there is significant overlap in performance between these hearing aids. Clinicians should make it clear that they cannot accept manufacturer data (or anyone else’s data) without the variability displayed. Investigations typically provide information related to statistical significance, but for the clinician, this is only the first step in testing significance. Statistical significance indicates that there is a difference between treatments – a test of practical significance (e.g., effect size) tells the clinician if the difference will likely be meaningful to patients. Hopefully, we will see more and more manufacturers going beyond a measure of statistical significance and supplying data related to practical significance.

Table 1. Describing the quality of the design (from Cox, 2004)

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<td>1</td>
<td>Systematic reviews and meta-analyses of randomized controlled trials</td>
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<td>2</td>
<td>Randomized controlled trials</td>
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<td>Non-randomized intervention studies</td>
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<td>4</td>
<td>Descriptive studies (cross-sectional surveys, cohort studies, case-control designs)</td>
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<td>5</td>
<td>Case studies</td>
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<td>Expert opinion</td>
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Table 2. Grades of recommendations (from Cox, 2004)

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<td>A</td>
<td>Consistent level 1 or 2 studies</td>
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<tr>
<td>B</td>
<td>Consistent level 3 or 4 studies or extrapolations from level 1 or 2 studies</td>
</tr>
<tr>
<td>C</td>
<td>Level 5 studies or extrapolations from level 3 or 4 studies</td>
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<tr>
<td>D</td>
<td>Level 6 evidence or troubling inconsistencies or inconclusive studies of any level</td>
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While being a critical consumer of research is an important part of the clinicians’ professional life, one must also be cognizant that some recommendations do not require an evidence base – they are in essence acoustic or physical facts. Examples would include issues like the need to correct pediatric hearing aid fittings with real-ear-to-coupler difference. The fact is that infants and young children’s ears are smaller than average couplers and therefore this discrepancy must be accounted for in a hearing aid fitting. One does not need a comparative study to identify this as an important clinical practice. If the goal of hearing aid verification is to know the output of the hearing aid in the ear canal, then one can recommend real ear probe microphone measures. A study is not needed to prove that this is a way to measure output, it is an acoustic fact. One does not need an evidence base to recommend locking battery doors for a pediatric fitting. A study with some children receiving locking battery doors and some children receiving standard battery doors would be inappropriate if not unethical. It is a fact that a locking battery door makes it less likely that a battery will be swallowed. As we see the pendulum swing and more clinicians demand an evidence base for clinical decision making, we need to be careful not to overlook acoustic and physical facts that should be applied directly without looking for an unneeded evidence base.

Evidence-based design which is the focus of this special issue is a critical component of evidence-based practice. There is not one best hearing aid but there is a best solution for each individual patient. The evidence base and clinical decision making should lead the clinician there. Manufacturers are essential partners in this process through evidence-based design of amplification systems and through adequate reporting of these data that is conducive to critical analysis by the interested clinician.

References
Improving Water Resistance for Hearing Instruments

By Weili Lin, PhD

One of the recurring problems with hearing aids is the frequent exposure to moisture, wax, and other foreign materials that can degrade and eventually hinder their performance. This issue may be exacerbated as the demographics of the hearing impaired shifts to hearing aid wearers with more active lifestyles (such as baby boomers and children).

The common reasons for failure due to the ingress of moisture, sweat, and other foreign materials include the following:

- Blockage of acoustic paths (such as acoustic ports and pathways);
- Damage to transducers and mechanical components such as switches;
- Leakage and corrosion of zinc air battery; and
- Circuit malfunctions due to compromising the protective layer and solder joints.

Many design techniques have been used to provide protection against the ingress of foreign materials. For example, acoustically transparent but water repellent fabrics and foams have been applied in front of the acoustic ports to reduce the amount of unwanted substances that can reach the transducers. Their effectiveness, however, has been found to be insufficient through laboratory evaluations and field return data. In addition, there are several limitations to this technique, and they include the following:

- Moisture barriers degrade in performance over time and need to be replaced frequently.
- It can be difficult to attach acoustic fabric reliably and cost effectively due to the miniature nature of the protective mechanism.
- The in situ performance of a hearing aid could suffer from the degradation in acoustic transparency due to the condensation of water droplets on the fabric surface.

Traditionally it has also been difficult to protect the battery (and to a lesser extent, the electronic circuits) from moisture ingress. For example, o-ring seals have been designed to minimize moisture ingress around battery compartment and case seams; however, this technique has not been very practical for most products. As a result, the build-up of wax, moisture, and other materials continues to be a challenge for some devices. A different method needs to be developed to provide enhanced protection against foreign materials and to address the limitations of the traditional techniques.
HYDROPHOBIC AND SUPERHYDROPHOBIC NANO COATING

The solution for many of these issues lies in the application of thin moisture repellent coatings to hearing devices as an alternative and/or enhancement to the traditional approaches.

Water repellent phenomena can be found in many plants. The lotus plant, for example, has leaves with an exceptionally non-wetting surface as the basis of its self-cleaning mechanism; water droplets completely roll off the leaves and carry the dirt and mud with them at the same time. This self-cleaning or lotus effect is caused by both the hierarchical roughness of the leaf surface (composed of micrometer-sized papillae), and the intrinsic hydrophobicity of the waxy surface layer covering these papillae. The roughness enhances the natural non-wetting nature of the surface, leading to even greater repellence to a liquid drop on the surface.

How a solid surface repels a liquid, therefore, mainly depends upon two factors: surface energy and surface morphology.

The surface energy affects the liquid-solid surface interface by influencing the attractive forces between the liquid and solid at the molecular scale. When liquid contacts a surface, the liquid molecules may have a stronger attraction to the molecules of the solid surface than to each other due to a low surface tension. The degree of water repellence of a surface, or hydrophobicity, can be characterized by measuring the contact angle of a small water droplet on a level surface (as shown in Figure 1). The contact angle $\Theta$ can be determined in simple cases by Young’s equation:\(^{1,2}\)

$$\cos \Theta = (\gamma_{SV} - \gamma_{SL}) / \gamma_{LV}$$

Where, $\gamma_{SL}$, $\gamma_{SV}$, and $\gamma_{LV}$ are the interfacial free energies per unit area of the solid-liquid, solid-gas, and liquid-gas interfaces, respectively.

![Figure 1. Illustration of liquid contact angle on a solid substrate](image1)

Alteration of surface morphology, on the other hand, at the micro- and/or nanoscale can allow an air layer to be formed in the spaces between the surface texture features during liquid contact. This surface roughness/texture is crucial in producing superhydrophobic surface, which can be described by two distinct states as shown in Figure 2.\(^2\) A water droplet that completely wets a textured surface is in the “Wenzel state” and tends to leave a water trail as it slides and spreads. Conversely, a water droplet that rests on the layer of air within a textured surface is in the “Cassie state,” which can have far less droplet adhesion and a far greater contact angle. A surface is deemed hydrophobic if the water contact angle $\Theta$ (WCA) is between 90° and 150°, and superhydrophobic if WCA is above 150°.

![Figure 2. Comparison of behaviours for a liquid droplet on a textured surface](image2)

This lotus effect, shown as the “Cassie state” above, can be achieved artificially by introducing textures on a surface of interest at the nano scale (such as a nano tube forest, nano particles, or etching) through photochemical or plasma treatment. A surface coating resistant to both water and oil wetting (a.k.a., omniphobic) would be ideal for preventing or minimizing ingress from a number of contaminants simultaneously. This work only focuses on utilizing nano coating technology to produce non-wettable surfaces that achieve water resistance for hearing devices.
WATER RESISTANCE
The term water resistant commonly describes objects capable of limiting the ingress of water. For electronic devices, several standards have been established to characterize the degrees of water resistance, with some methods more relevant to hearing aid applications.

SALT FOG
The salt fog or spray test is an accelerated corrosion test that produces a corrosive attack to the Device-Under-Test (DUT) in order to predict its long-term performance under challenging working environments associated with humid and salty conditions. These are the conditions that behind-the-ear (BTE) and receiver-in-the-canal (RIC) devices are exposed to regularly due to their close proximity to the sources of sweat and moisture from active users in highly humid environments.

Many standards call out the salt fog test, such as ASTM B117, IEC 68-2-11, MIL-STD-810G (method 509.5), etc. Although there are substantial variations among these standards in terms of test duration and the way results are interpreted, the test setup and delivery are essentially the same. The MIL standard has been adopted during Starkey’s evaluations due to its well-defined test cycles and clear acceptance in the consumer electronic industry. During the test, a 5% salt solution concentration was used to create a salt atmosphere at a temperature of 35°C. The test consists of 48 hours of salt atmospheric exposure followed by 48 hours of drying time under ambient conditions.

IMMERSION
In the watch industry, water resistance is usually accompanied by an indication of the static test pressure (such as the depth of water) that a watch was exposed to during a leakage test. Similar testing can be conducted on any electronic device that may be exposed to partial or complete immersion to assess if it is watertight. Both the Ingress Protection (IP) rating from IEC and MIL-STD-810G (Method 512.5) describe the requirements and processes for an immersion test.

IP Rating
The IP Code, as defined in IEC 60529, is a system for classifying the degree of protection against the intrusion of solid objects, dust, and water provided by an electrical equipment enclosure. Here are two numbers in the IP code, with the first digit indicating the level of protection against the ingress of solid foreign objects, and the second digit representing the level of protection against the harmful ingress of water. The water ingress levels consist of protection against dripping water (levels 1 and 2), spraying/splashing water (levels 3 and 4), water jets (levels 5 and 6), and immersion (levels 7 and 8). In terms of the degrees of protection against immersion, levels 7 and 8 correspond to a submersion of up to 1 meter and an immersion beyond 1 meter, respectively.

MIL-STD-810G (Method 512.5)
This standard requires a DUT to be submerged to a depth of 1 meter in water for 30 minutes to assess if the unit can survive temporary immersion, such as being dropped in a puddle. As a result, it is comparable to the test associated with level 7 under the IP rating. For simplicity, the MIL standard was adopted in this work to understand the performance of hearing aids under immersion.

EVALUATION OF NANO-COATED HEARING AIDS
In order to evaluate the feasibility of improving water resistance for hearing aids using nano coating technology, experiments were conducted with the following device types, evaluation processes, and assessment methods.

SALT FOG TEST
Two groups of hearing devices with different coating treatments were used to perform this test. The first group consisted of BTE modules constructed of cases and microphones in order to evaluate the effectiveness of nano coating in protecting the microphones. They were treated with superhydrophobic coating, on the cases around the acoustic ports and on the inner walls along the acoustic path (as shown in Figure 3).

Figure 3. Coated areas on a BTE module
A total of 10 BTE modules (five control units and five coated devices) were positioned inside the salt fog chamber as shown in Figure 4, and were exposed to a salt atmosphere for a total of 256 hours. The microphones' frequency responses were measured periodically throughout the experiment prior to the salt exposure, after each removal from the salt fog chamber (labelled as “Wet” condition), and after being dried out in the ambient (“Dry” condition).

**IMMERSION TEST**

Only devices from group 2 were used along with fresh control units in performing the immersion test per MIL-STD-810G (Method 512.5). Electro-acoustic measurements were performed before and after the immersion to identify any impact from the exposure.

**TEST RESULTS**

**SALT FOG TEST FOR GROUP 1 MODULES**

Figure 5 shows the frequency responses of directional microphones prior to salt fog experiment. After the modules were exposed to salt mist for 256 hours, all five coated devices (shown as solid lines in Figure 6) still exhibited directional characteristics and fair sensitivities under the wet condition, and recovered fully under the dry condition. In contrast, all untreated units (shown as dashed lines in Figure 6) lost directionality and showed significant sensitivity loss under the wet condition. Only one untreated device recovered fully under the dry condition (three control units are shown since the others had failed to perform earlier).

![Figure 4. Device setup in a salt fog chamber](image)

![Figure 5. Frequency responses of directional capsules for group 1 BTE modules before salt fog test](image)

![Figures 6a and 6b. Directional frequency responses for group 1 BTE modules after 256 hours in salt fog](image)
SALT FOG TEST FOR GROUP 2 DEVICES

Eighteen RIC devices (nine treated and nine untreated) were subjected to a 48 hour salt fog test. After the devices were retrieved from the salt fog chamber, visual inspection was performed on the battery itself and on a 3M moisture detector installed inside the device. It is evident that nano coating was able to prevent the batteries from discharge and corrosion (Figure 7), and deter salt residue from entering the devices (Figure 8).

Figures 7a and 7b. Batteries used in RIC device after 48 hour salt fog exposure

Figures 8a and 8b. Internors of RIC devices after 48 hour salt fog exposure

In order to analyze the performance after salt fog exposure more thoroughly, it is necessary to evaluate the microphone and the rest of the hearing aid (which includes the circuit and receiver) separately. To facilitate this evaluation, audio input wires from the circuit and microphone wires were routed out of the cases for eight devices (four control and four coated units), which enabled the testing of the microphone itself and the circuit and receiver sub-assembly (with an electrical input signal).

The post-salt fog results under both the wet and dry conditions are shown in Tables 1 and 2, the smaller the values, the better the performance after salt fog exposure.

<table>
<thead>
<tr>
<th>Table 1. Results of RIC Devices under Wet Condition after 48 Hour Salt Fog Test</th>
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<tr>
<td>Visual Inspection</td>
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<td>Moisture Inside Device</td>
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<tr>
<td>Control (9)</td>
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<td>Coated (9)</td>
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<tr>
<th>Table 2. Results of RIC Devices under Dry Condition after 48 Hour Salt Fog Test</th>
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<tr>
<td>Performance under Dry Condition</td>
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<tr>
<td>Device Too Noisy To Be Audible</td>
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<tr>
<td>Control (9)</td>
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<td>Coated (9)</td>
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The following observations were made based on the above results:

- The vast majority of the nano-coated devices (~90%) performed properly even under the wet condition, whereas all the control units failed to perform wet.
- The root causes of failures for the untreated devices under the wet condition were found to be: Deteriorating performance in untreated microphones (100% failure rate) and Degradation in untreated circuit and receiver sub-assemblies (50% failure rate).
- Under the dry condition, no failures were found for the coated devices. In contrast, the control units were not able to recover and function properly.

Subsequently, similar results were observed during additional salt fog experiments on other coated devices. It was also noticed that the coating can withstand multiple cycles of Salt Fog exposures without degrading its effectiveness significantly. This bodes well for long-lasting protection for Starkey hearing aids featuring this type of nano coating.

### IMMERSION TEST FOR GROUP 2 DEVICES

Two experiments were conducted. During the first experiment, two RIC devices, with one control and one nano coated, were subjected to multiple immersion cycles. The immersion duration was 30 minutes for each of the first two cycles, but was doubled for each of the subsequent cycles and reached 4 hours for the 5th cycle. Both devices were then placed underwater for 18 hours during the 6th cycle to assess any long term impact. The 2 cc output from each device was measured during each cycle in both the wet and dry states. The output changes in directional mode under the wet condition in all six cycles are shown in Figure 9. It is evident that the nano-coated device preserved its performance even in the wet state after extensive immersion, whereas performance of the control unit deteriorated.

**Figures 9a and 9b. Output changes in directional mode for two RIC devices after multiple immersion cycles**
During the second experiment, ten RIC devices (five control and five nano-coated) were submerged for 30 minutes per the MIL standard. The changes in omni-directional output under the dry condition are shown in Figure 10. It is apparent that all nano-coated devices retained their performance, while the control units did not fully recover.

- Treating the whole device provided excellent protection against moisture ingress for battery and the interior of the product.

In addition, the durability of the nano coating was also revealed through extensive exposures to the salt fog environment.

Overall, the hydrophobic nano coating offers a more effective and comprehensive solution to moisture resistance than traditional techniques; this represents a paradigm shift in improving the durability and longevity of hearing instruments in the field. The Starkey S Series RIC products, released this past spring, feature Advanced HydraShield, a moisture resistance solution that consists of an advanced hydrophobic nano coating. This technology has already helped thousands of hearing professionals and patients experience the comfort of knowing that their hearing instruments are moisture resistant and will maintain their performance throughout years of ownership.

Future work will be focused on improving the durability of the nano coating even further and enhancing the resistance to other foreign materials.

**CONCLUSIONS**

This study demonstrated the effectiveness of superhydrophobic and hydrophobic nano coatings in improving water resistance for BTE and RIC devices in the following key areas:

- Nano-coated devices were able to retain electro-acoustic performance in both the wet and dry conditions; whereas the traditional techniques were shown to be inadequate.

**References**


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**Figure 10.**

Output changes in omni mode for RIC devices after one immersion cycle
Verification of Prescriptive Fitting through a Hearing Aid

By Jason A. Galster, PhD and Elizabeth A. Galster, AuD

Evidence-based practice (EBP) has become the cornerstone of quality for patient care. Many fields, including medicine, pharmacy, and audiology are examining existing standards of practice to evaluate procedures and improve upon them. An example of EBP is the Guidelines for the Audiologic Management of Adult Hearing Impairment developed by the American Academy of Audiology. This standard of practice uses a review of evidence-based literature to recommend a clinical protocol for the prescriptive fitting of hearing aids. A fundamental recommendation made within this standard is that hearing health care professionals must verify and validate hearing aid fittings in order to ensure that the treatment will provide adequate benefit for each patient. The equipment required for clinical real-ear measurement has been available for more than 20 years. With two decades of availability and strong recommendations supporting the use of real-ear measures in clinical practice, one may expect that their use has become a standard of clinical practice. In countries such as the United Kingdom and Australia this is the case. The respective health care systems in those countries have mandated objective verification of the hearing aid fitting. For instance, the Australian Government Hearing Services Program specifically outlines forms of evidence that may be used to document the results of the hearing aid fittings: “Example of evidence: records of the prescriptive target, and verification of the actual output of the gain-frequency response and SPL/MPO to target; real ear measurements.” In cases such as these, the hearing care professional must complete the mandated objective verification in order to receive financial reimbursement from the government-funded health care service. In contrast, countries without such regulations show grossly different trends.

Unfortunately, this is not the case in the United States. A 2003 survey of 165 hearing care professionals in the United States showed that 74% of
audiologists have access to real-ear equipment. Based on this number, it is reasonable to assume a majority of practicing audiologists routinely perform real-ear measures. However, a study in 2004 showed that only 35% of respondents were routinely using real-ear equipment. Another survey conducted in 2006 of practicing audiologists showed that less than 20% of audiologists always use real-ear measures and almost 30% never verify their fittings with in situ measures. The question, of course, is why are audiologists not routinely using real-ear measurements in spite of the recommended guidelines and the obvious advantages for improved hearing aid outcomes? Some professionals have tried to rationalize their lack of compliance with best practice standards to complete real-ear measures by citing cost of equipment and time constraints. Apparently, many professionals feel as though they are achieving successful patient outcomes without the use of real-ear measures.

Ricketts reviewed data that offers insight into the discrepancy between what patients perceive as success and what qualifies as a prescriptively appropriate fitting. In this study, patients were asked to rank order gain configurations based on their perceived “pleasantness.” Ricketts found that the fittings patients judged to be “most pleasant” may not provide them with much, if any, gain, specifically 0 dB of low-frequency insertion gain and only 5 dB of high-frequency insertion gain. Based on this information, it can be concluded that it is insufficient to verify a fitting simply by asking the patient how the devices sound as this may result in a hearing aid fitting with inappropriate hearing aid gain settings. Given that the primary goal of a hearing aid fitting is to improve audibility, it is critical to verify that speech sounds are indeed audible for the patient. Real-ear measures are the most efficient way of doing this.

To compound the topic of patient perception, other researchers have found that prescriptive fittings as determined by hearing instrument manufacturers may not match the targets prescribed by the programming software. The findings of these studies reflect inaccuracies in the predictions of programming software. Because all hearing aids must initially be programmed to a predicted patient response, there are several stages where the predicted response or gain displayed in the manufacturer’s software deviates from actual hearing aid performance in the patient’s ear. One source of this error is an inability to accurately predict residual ear canal volume without a measurement performed in each individual’s ear canal(s). Therefore, an average measure, quantified as the real-ear to coupler difference (RECD), is used to predict the acoustic effect of the outer ear after insertion of the hearing aid. However, this measure may be inaccurate and result in a hearing aid response that is different than that prescribed by the programming software, unless patient-specific RECDs are used. Real-ear measurement will quantify in situ acoustics and allow for the hearing aid to be programmed appropriately for each individual patient.

Realizing the time and cost constraints of traditional real-ear verification, Starkey Laboratories introduced a real-ear measurement system, termed Integrated Real-Ear Measurement, in the Destiny and Zôa lines packaged within each hearing aid. Released in 2007, the Integrated Real-Ear technology was introduced so that clinicians could easily and accurately use this integrated system to improve the match to prescriptive target in all Starkey hearing aid products. Integrated Real-Ear Measurement uses a measure of the patient’s RECD to derive a prediction of the real-ear aided response (REAR). This technique was shown to improve the match to the selected prescriptive target. Although the use of the measured RECD improves the accuracy of the initial match to prescriptive targets; the
use of the REAR measured in dB SPL values is clinically more intuitive and offers significant advantages over the RECD measure. For instance, reporting real ear aided responses in SPL for the hearing aid output allows for direct comparison to a patient’s audiometric data, as well as to the long-term average speech spectrum.

To take full advantage of the REAR measurement, Starkey Laboratories introduced a new feature called “Live Real-Ear” in the S Series line of hearing aids. This development replaces the Integrated Real-Ear Measurement with a new system that performs a real-time measurement of the patients’ REAR. With “Live Real-Ear,” the Inspire 2009 software program presents a speech-shaped noise stimulus generated by the hearing aid’s signal processor. This allows validation, in real-time, of the in situ effects of the device’s gain and compression parameters for any of the six prescriptive targets (i.e., NAL, NALr, DSL 5.0, etc.) available in the Inspire 2009 software.

The Starkey S Series Live Real-Ear procedure allows for two options: (1) “Measure and Match” is used to automatically adjust the hearing aid response to the selected prescriptive targets and (2) “Measure Only” is used to verify the current settings after fine-tuning adjustments. Each of these Live Real Ear measures automatically deactivates advanced signal processing, such as digital noise reduction, which may interact negatively with real-ear measurement signals.

**LIVE REAL-EAR CLINICAL PROTOCOL**

1. At the initial hearing aid fitting, the S Series hearing aid is “Best Fit” using average ear data to the patient’s audiogram through the Inspire 2009 software. After otoscopic examination of the patient’s ear canal, the hearing aid is placed in the patient’s ear, along with the Live Real-Ear probe tube (Figure 1). The probe tube should extend a minimum of 5 mm beyond the end of the hearing aid receiver or tubing.

![Figure 1. Starkey S Series In-The-Canal (ITC) shown “real-ear ready” with probe microphone tube.](image)

2. When the Live Real-Ear “Measure and Match” routine has been started, the hearing aid will generate a 65 dB SPL speech-shaped noise from the hearing aid receiver into the patient’s ear canal. Using the proprietary Live Real-Ear probe tube, the hearing aid microphone measures the REAR as a function of frequency and sends that data back to the Inspire 2009 software. An example of this initial measurement is shown in Figure 2a. For this patient, high-frequency output was 5 dB above NAL-NL1 targets. If the “Measure Only” option had been selected the software driven program would stop at this stage, displaying only the in situ hearing aid output.

![Figures 2a and 2b. The real-ear aided response for two Live Real-Ear measurements is shown as measured through the Inspire 2009 software. Figure 2a shows the Measure Only response at Best Fit settings. Figure 2b shows the results of the Measure and Match routine.](image)
3. Following this initial measurement, the “Measure and Match” program will calculate the difference between the prescribed targets and the now-measured REAR. The Inspire 2009 software automatically adjusts the device settings to reduce the difference between the “Best Fit” settings and the prescribed output targets. After the automatic gain adjustments have been completed, a second speech-shaped noise is presented to verify that the automatic adjustments result in a match to prescriptive targets. This second REAR is the customized hearing aid response provided for review on the screen of the Inspire 2009 software, as shown in Figure 2b. The prescribed gain has been reduced by approximately 5 dB in order to match the prescribed output targets.

The adjustments required for a prescriptively appropriate fitting are stored in the Inspire 2009 software. In the event that follow-up visits are needed for fine-tuning, these stored data will ensure that an accurately-calibrated response is displayed on the software screen. The entire “Measure and Match” process described above is completed in 90 seconds with three mouse clicks.

**CLINICAL EXAMPLE**

An example of a patient fitting using Live Real-Ear is provided in Figure 3. The hearing aid fitting was done using an S Series 11 in-the-canal hearing aid. The data shown in each figure were collected using an Audioscan Verifit real-ear measurement system. The Audioscan Verifit was used to independently verify the Live Real-Ear feature that is built into all S Series hearing aids. This patient has a mild-to-severe sloping, high-frequency hearing loss. The NAL-NL1 prescriptive targets, in black, are shown for both the Inspire 2009 software and the Audioscan Verifit. The light blue response shows the hearing aid response before the Measure and Match routine, and the dark blue response shows the improved match to target after Measure and Match was performed. This example illustrates a case in which the residual ear canal volume is smaller than the average used in the prediction of Best Fit settings, as reflected in increased in situ output levels. The Measure and Match routine in Live Real-Ear quantified the difference between the measured Best-Fit response and the prescriptive targets then automatically decreased gain in the appropriate channels, improving the match to the patient’s prescriptive target.

![Figure 3. Two real-ear aided responses, as measured via the Audioscan Verifit system, are shown as a function of frequency (Hz). The light blue line shows the real-ear aided response for Best Fit settings using an S Series 11 in-the-canal hearing aid. The dark blue line is the aided response after completing the Measure and Match routine.](image)

The Live Real-Ear measurement not only improves the accuracy of initial fitting, it is also a repeatable measurement. Figure 4 provides test-retest data from the Measure and Match routine, which was performed twice using the Audioscan Verifit system, by the same tester and during the same visit. After the first measurement, the hearing aid was removed from the ear and the Live Real-Ear assembly was uncoupled from the instrument. After reinserting the hearing aid, the settings were returned to the average best-fit and a second Measure and Match was completed. The difference between the two measurements was less than 1 dB on average, with a maximum difference of 2.2 dB at 470 Hz.
References


SUMMARY

Recommendations of best clinical practices will continue to motivate the design of evidence-supported hearing aid features. There is little doubt that the routine verification of hearing aid fitting will be always be a focal component of these best clinical practice recommendations. With Live Real-Ear in the Starkey S Series, clinicians have the opportunity to verify patients’ real-ear aided response (REAR) without the concerns of additional cost or time commitments associated with manual adjustments and external real-ear equipment.
Interaction of Hearing Loss with Psychological, Sociological, and Cognitive Behaviour

By Brent Edwards, PhD

People typically associate hearing loss with having a harder time hearing sounds. The potential impact of hearing loss on a person’s life is far worse than that – more insidious and more profound. This paper will detail the consequences that hearing loss has on many aspects of a person’s life, and focus in detail on the complex interaction between cognition and hearing, and the impact that hearing aids can have on that interaction.

Psycho-social consequences
Communication is what makes us uniquely human and is an important aspect of everyone’s lives. Most people take communication for granted, and the loss of the ability to communicate with one’s family and friends can be profound. People who were once socially active often find themselves withdrawn because of their inability to participate in communication. Additionally, the impact of hearing loss on overall physical well-being cannot be ignored. Research has shown that self-perceived physical functioning declines with hearing loss. Depression, anxiety, emotional instability, lower self-esteem, and avoidance of social activities are all associated with hearing loss. The negative impact of these physical and psychological effects of hearing loss ultimately leads to an overall lower quality of life for the hearing impaired.

Hearing aids have the ability to alleviate many of the effects described above. Hearing aids can improve the wearer’s psychological well being by reducing emotional instability, depression, and anxiety. Hearing impaired people who wear hearing aids appear to have fewer instances of confusion, disorientation, and inability to concentrate compared to those who do not wear hearing aids. Research has demonstrated improvement to perceived physical health from wearing hearing aids. The overall impact of all of these effects is that hearing aids, in addition to improving hearing, can improve the overall quality of life of the hearing aid wearer.

Cognition: Top-down effects
Hearing aid research and development over the past century has focused on audibility, an issue of whether the acoustic signal produces a detectable signal in the auditory nerve. Auditory perception, however, is much more complicated than the representation of what occurs at the auditory periphery. The mid-brain and auditory cortex perform complex functions to separate the components of the received acoustic signal into component sources, creating auditory objects that allow the listener to focus on the acoustic source of interest such as a single talker in a room of many talkers. When listening to speech, the cortex applies knowledge of context, linguistics, and grammatical rules to interpret speech sounds that are not heard due to masking, hearing loss or inattention.

Pichora-Fuller et al. have shown that elderly listeners with hearing loss are better able to use contextual information to understand speech in noise than an age-matched group with normal hearing, suggesting that the hearing loss group has habituated to using context information more than the normal hearing group because they use it more often due to their hearing loss. In other words, those
with hearing loss exercise their cognitive “muscle” more than normal hearing listeners and therefore that cognitive ability is more effectively utilized by those with hearing loss.

Evidence also suggests that cognitive ability affects how well people can benefit from hearing aid technology. Lunner and Sundewall-Thorén have shown a correlation between cognitive ability and benefit from fast-acting compression, where subjects who scored higher on a visual diligence task understood speech better with fast-acting compression compared to their speech understanding with slow-acting compression.9

These results and other evidence demonstrate that cognition affects auditory perception in a top-down manner, and we have much more to learn about how cognitive ability can be used as a diagnostic to improve counselling and hearing health solutions for people with hearing loss. McCoy et al. demonstrated that hearing loss can result in poorer memory.10 This can happen because sensorineural hearing loss degrades speech signals during the transduction process in the damaged cochlea, resulting in a distorted signal reaching the auditory processing regions of the cortex. Current models of working memory suggest that it has a limited amount of resources available to perform all of its many functions. Since working memory may have to work harder to interpret what is being heard from the degraded signal received from the damaged auditory periphery, fewer resources will be available to perform other tasks such as storing information in long-term memory or comprehending what is being heard. The implication of this is that degraded memory function may be a symptom of increased hearing loss rather than degraded cognitive ability, yet it may be misdiagnosed as resulting from cognitive decline with the hearing left untreated. Of critical interest is whether hearing aids, by improving the quality of the auditory signal received by the auditory cortex, can reduce the cognitive load required to interpret the auditory signal and thereby improve the ability of working memory to perform other critical cognitive functions. In other words, an important research question is whether wearing hearing aids can result in improved memory and other cognitive ability by reducing the cognitive effort to understand speech.

An interaction between hearing loss and cognitive function that is apparent to most clinicians who interact with hearing loss patients is in the area of listening effort. Most practitioners who fit hearing aids understand that people with hearing loss are more mentally fatigued after communicating in a noisy environment that someone with normal hearing.11 Continuously struggling to understand speech in a noisy restaurant, for example, appears to require greater cognitive effort because of the hearing loss, and after a short period of time people with hearing loss become fatigued and withdraw from conversations, eventually altering their lifestyle to avoid noisy social situations. We were interested in whether hearing aids could mitigate such mental fatigue and reduce the cognitive effort required for listening to speech in noise. More specifically, we wanted to develop an objective measure of listening effort for speech in noise rather than rely on hearsay and self-assessments from questionnaires because of the unknown criterion by which people assess their own listening effort. When asked to compare the effort of listening to two different passages, for example, people may rate the passage that was more intelligible or had better sound quality as being less work to listen to, regardless of whether there was a difference in effort or not.

Sarampalis et al. investigated the effect of hearing aid technology on listening
effort using dual-task paradigms, a classic approach in the cognitive science field for measuring cognitive effort. Dual-task experiments take advantage of the limited capacity of working memory by having subjects perform two different tasks at the same time: a primary task that is the target of the effort measure, and a secondary task that is sensitive to changes in the effort applied to the primary task. The amount of effort being applied to the primary task is estimated by measuring performance on the secondary task. The assumption behind this paradigm is that the cognitive system has a limited capacity to perform tasks, so if the amount of cognitive resources being applied to the primary task increases, then the amount of resources available for the secondary task decreases and results in poorer performance in the secondary task. Thus, while performing the primary and secondary task simultaneously, if performance on the secondary task improves, then the effort being applied to the primary task is assumed to have decreased.

The effects of a fast-acting noise reduction algorithm and of directional microphones were investigated using this dual-task paradigm. To determine the effect of noise reduction on effort, conditions with and without the application of the noise reduction at different signal-to-noise (SNR) ratios were compared. To determine the effect of directional microphones on effort, conditions with SNRs that differ by 4 dB were compared, simulating the difference between a directional microphone being on and off in a diffuse noise situation.

For the primary task, subjects heard IEEE sentences at four different SNRs and were required to repeat what they believe was said in each sentence. Their accuracy at correctly identifying words were scored and the results shown in Figure 1. Increasing the SNR increased word recognition performance, as expected, with the 4-dB increments representing improvements one expects to receive from a directional microphone. The solid line shows results with noise reduction inactive and the dashed line shows results for noise reduction active. There is no statistically significant difference between the two conditions, indicating that the application of noise reduction did not have an effect on speech intelligibility.

The secondary task that was conducted simultaneously with the speech task was a visual monitoring reaction time task. Subjects monitored a computer screen that exhibited two empty squares, one on the left and one on the right. Every few seconds, a digit appeared in one of the squares. If the number was even, the subject had to press an arrow pointing towards the digit. If the number was odd, the subject had to press an arrow pointing away from the digit. The subjects were instructed to perform this task as quickly as possible, and the reaction time from the appearance of the digit to their pressing an arrow button was measured as their performance on this secondary task. Subjects performed this visual reaction time task while also conducting the speech-in-noise task.

Figure 2 shows the reaction time data. The dark-shaded bars show reaction time when noise reduction was inactive at the different SNRs. The reduction in reaction time as SNR increased suggests that the speech task became less effortful with increasing SNR, thereby allowing more cognitive resources to be applied to the visual task as SNR increased and resulting in fast reaction times. The fact that listening effort reduces as speech intelligibility improves is perhaps not surprising – one has to spend less effort interpreting what was said when there is less noise to interfere with the speech – but having proven this with established objective measures from the cognitive.
The light-shaded bars in Figure 2 show the reaction times when noise reduction was active. There is no significant difference between the reaction times for noise reduction on versus off for the higher SNRs. There is, however, a significant reduction in reaction time at the lowest SNR when noise reduction was activated. This result suggests that while noise reduction did not improve speech understanding (see Figure 1), it did reduce listening effort for the speech understanding task in the most difficult listening condition. Similar results were obtained with a different dual-task paradigm described in Sarampalis et al., reinforcing this conclusion.

These experiments provide objective proof that directional microphones and noise reduction technology found in modern hearing aids can reduce the effort necessary to listen to speech understanding in noisy situations. Research is underway in our research center to use similar listening effort measures on subjects with hearing loss wearing hearing aids to determine the effect of amplification and different hearing aid technologies in situ on the amount of effort necessary to understand speech in noise.

CONCLUSIONS
Auditory perception is a complex function involving not just the auditory periphery but also the mid-brain and cortex. All stages interact with each other, and the nature of those interactions is important to investigate so that we can understand the impact of hearing loss and hearing aids on those interactions. Scientific evidence is accumulating that proves hearing loss can affect psychological and sociological behaviour, while also affecting the cognitive ability of functions typically thought to be unrelated to hearing. We are just beginning to understand the impact that hearing aids have on mitigating these effects and improving the lives of people with hearing loss who have experienced behavioural detriments beyond issues of audibility.

Understanding these effects, and the impact that hearing aid technology can have on them, is important in order to properly counsel clients with hearing loss. Being able to explain to people what the full impact of their hearing loss is having on their lives could make them more likely to seek help with their hearing. Being able to explain the full impact that hearing aid technology has on improving their lives could also make them more willing to purchase and wear hearing aids. And finally, having additional measures beyond speech intelligibility and sound quality with which to assess hearing aid technology and other hearing health solutions, such as aural rehabilitation, will help to guide the development of new technologies to benefit those with hearing loss.

References
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