HIA
Hearing Industries Association

1444 I Street, NW, Suite 700
Washington, DC 20005
TEL: (202) 449-1090
FAX: (202) 216-9646
www.hearing.org

November 21, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff
10903 New Hampshire Ave.
Bldg. 66, Rm. 4425
Silver Spring, MD 20993-0002

RE: 513(e) Reclassification Petition for Wireless Air Conduction Hearing Aids (21 C.F.R. § 874.3305)

Dear Sir/Madam:

The enclosed information is submitted by the Hearing Industries Association (HIA) in support of downclassifying wireless air conduction hearing aids with certain defined attributes – described below – from Class II to Class I. This petition is being submitted under section 513(e) of the Federal Food, Drug, and Cosmetic Act (FDC Act) which allows for reclassification of a device based upon the availability of new information. The information presented is submitted in accordance with the reclassification procedures described in 21 C.F.R. § 860.123.

Wireless features have been used in hearing aids for over 30 years. There is an abundant amount of information available demonstrating that general controls are sufficient to provide reasonable assurance of safety and effectiveness of hearing aids that possess certain characteristics. In 2011, FDA cleared a 510(k) premarket notification for a wireless hearing aid through the *de novo* classification process. As a result, all hearing aids with any wireless features now fall within Class II. HIA believes that general controls are sufficient to reasonably assure safety and effectiveness of wireless hearing aids with certain attributes, and that special controls are not needed. As shown in the attached petition, the new data presented to FDA demonstrate that wireless hearing aids with definable traits do not present risks that require the establishment of special controls; for this group of wireless hearing aids, general controls are sufficient to provide reasonable assurance of safety and effectiveness. HIA is therefore requesting that currently commercially available wireless hearing aids that possess defined characteristics (*e.g.*, features encompassing transmission from one hearing aid to another for purposes of signal processing, improving signal to noise ratio, or receipt of wireless signals from an external device (including a hearing aid) to the hearing aid) be reclassified to Class I.

Wireless hearing aids that possess attributes beyond what is on the market today will be regulated as Class II, 510(k)-exempt devices. Included in the enclosed reclassification petition is a summary of information describing the safe and effective use of wireless features available in hearing aids today. This summary provides valid scientific evidence supporting downclassification of the device.

Thank you for the opportunity to submit this information.

Sincerely,

Carole Rogin
President
Hearing Industries Association

Enclosures

TABLE OF CONTENTS

513(e) RECLASSIFICATION PETITION FOR WIRELESS AIR CONDUCTION HEARING AIDS

I. Specification

A wireless air conduction hearing aid is a "wearable sound-amplifying device, intended to compensate for impaired hearing, that incorporates wireless technology in its programming or use." 21 C.F.R. § 874.3305. This product is currently classified as a Class II device exempt from the 510(k) premarket notification requirements and subject to the following special controls: (1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation; (2) Design, description, and performance data should validate wireless technology function; and (3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

FDA classified wireless air conduction hearing aids as a Class II device in June 2011 in response to a *de novo* classification petition submitted by Widex Hearing Aid Company (Widex) for the C4-PA hearing aids with WidexLink wireless technology. Air conduction hearing aids without wireless features are Class I devices. 21 C.F.R. § 874.3300(b). This reclassification petition seeks to have wireless hearing aids with certain features be regulated in the same manner as hearing aids that do not contain wireless features. As discussed below, and based on the newly presented data, the presence of these defined features does not result in an increased safety risk to patients and the effectiveness is not negatively affected.

Section 513(e) of the FDC Act governs reclassification of devices. This section provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under Section 513(e) or an interested person may petition FDA to reclassify a device. The term "new information," as used in Section 513(e), includes information developed as a result of a reevaluation of the data before FDA when the device was originally classified, as well as information not presented, not available, or not developed at that time. (*See*, *e.g.*, *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before FDA is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (*see Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in "medical science." (*Upjohn,* 422 F.2d at 951). Whether data before FDA are old or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (*See*, *e.g.*, *General Medical*

Co. v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which FDA relies must be publicly available. HIA's petition does not rely upon trade secret or confidential commercial information.

The device for which reclassification is requested is the wireless air conduction hearing aid that possesses (1) ear to ear features encompassing transmission from one hearing aid to another for purposes of signal processing and/or improving signal to noise ratio, *e.g.*, binaural processing of directional input, and/or (2) wireless input of audio or other streamed signals to the hearing aid (receipt of wireless signals from external device, including a hearing aid), *e.g.*, receiving of audio data (audio streaming). For example, ear to ear features enable a person to change the volume or other settings of a hearing aid by making adjustments to only one device. The wireless feature will simultaneously adjust the hearing aid in the other ear to better coordinate the new setting, and to make adjustments simpler for the person with hearing loss. Wireless hearing aids can also synchronize the compression settings on both hearing aids to preserve interaural cues. They can also receive microphone inputs from the opposite hearing aid to further increase its directivity index. Wireless input of audio signals allow the consumer to listen to a television or HiFi sound system directly through the hearing aids to avoid loss of sound, and to minimize the need to set the volume at a level that is uncomfortable for people without hearing loss. Some hearing aids with wireless features and related Assistive Listening Devices also allow a person to receive phone transmissions through their hearing aid instead of holding the cell phone itself up to the ear. This helps to avoid Hearing Aid Compatibility (HAC) issues that often arise when a person with hearing loss uses a cell phone or similar device. Some wireless hearing aids can transmit the audio signal from a phone to both ears when it is placed close to one ear. Also, some hearing aids with wireless features can be reprogrammed via wireless by a hearing health professional while being worn by the person with hearing loss which greatly enhances the adjustment process.

As discussed in greater detail below, these features present a very low risk for four key reasons. First, wireless hearing aid manufacturers currently conduct testing in compliance with a number of international standards demonstrating that the EMC and non-ionizing radiation levels are safe. These levels are significantly below that permitted by the Federal Communications Commission (FCC) and emitted by commonly used products such as cellular phones.

Second, though hearing aid manufacturers routinely validate the wireless technology functions of the devices, those functions are secondary to the amplification feature that makes up the basic operation of a hearing aid. If the wireless features fail to communicate between hearing aids, or between a hearing aid and an external device, the hearing aid does not stop working. The only functionality lost is that of the wireless communication. Each hearing aid would continue to work independently, as they did prior to the addition of wireless features. The hearing aid would still meet its intended use even if the wireless function failed.

Third, standard wireless hearing aid labeling includes a number of warnings and information related to the potential for interference with other wireless devices, and the potential exposure to EMC and non-ionizing radiation. And fourth, wireless hearing aid manufacturers engage in methods to protect the data security and integrity of the wireless communications.

For these reasons, wireless air conduction hearing aids with the features identified above do not require special controls.

II. Statement of Action

It is requested that FDA reclassify wireless air conduction hearing aids from Class II to Class I if the only wireless features they possess are the following: (1) ear to ear features encompassing transmission from one hearing aid to another for purposes of signal processing and/or improving signal to noise ratio, *e.g.*, binaural processing of directional input, and/or (2) wireless input of audio or other streamed signals to the hearing aid (receipt of wireless signals from external device, including a hearing aid), *e.g.*, receiving of audio data (audio streaming), or separately receiving reprogramming instructions from a hearing professional. As noted above, there are a number of reasons the wireless features do not present a high risk to the user. Perhaps most important, the wireless functionality and the amplification functionality can exist independently. The wireless features exist for ease of use, but are not necessary for the basic functionality of the hearing aid. Rather, they simply allow a user to control both hearing aids from one device, giving the user easier access to the controls. If the wireless functionality failed, the user would still gain the benefits of amplification without interruption.

Furthermore, a hearing aid professional verifies that the wireless features function properly and are suitable for the intended user. The professional has the option to disengage some or all of the wireless features if he or she concludes that would be best for the user. This demonstrates that wireless features are not essential to the critical operation of the hearing aid, and their inclusion therefore presents little, if any, added risk and are not essential to the effectiveness of the device. General controls are therefore sufficient to assure the safe use of these wireless hearing aid devices.

III. Supplemental Data Sheet

Please refer to Appendix I.

IV. Classification Questionnaire

Please refer to Appendix II.

V. Basis for Request

This petition for reclassification is based on the fact that the wireless features present in hearing aids with the defined characteristics are safe and effective without the need for special controls. General controls, in conjunction with the hearing aid specific requirements already imposed by FDA in 21 C.F.R. § 801.420, are sufficient to establish reasonable assurance of safety and effectiveness, and therefore hearing aids with wireless features that have defined parameters can be regulated as Class I 510(k)-exempt devices under 21 C.F.R. § 874.3300.

Wireless hearing aids have been on the market for many years, substantially predating the Widex 510(k) submission that led to the reclassification. In fact, FDA cleared a wireless hearing aid in January 1980, the Model 339 Telecros Wireless CROS. That device was the predecessor for "ear-to-ear" communication in more recently-introduced wireless hearing aids. Similarly, FDA cleared FM assistive listening accessories prior to 1998. *See, e.g.*, K964035, Phonak "Microlink" Personal FM Receiver. Those accessories serve as the predecessor of audio streaming to self-contained RF receivers in recently-introduced wireless hearing aids. The wireless features in today's hearing aids provide the same basic functionality as these predecessors. After 1998, hearing aids were exempted from the 510(k) requirement. Even when hearing aids with more sophisticated wireless capabilities entered the market, FDA never took the position that those features required special controls. Thus, there was a history of wireless hearing aids sold for many years without 510(k) review and before special controls were imposed. There are millions of wireless hearing aids currently in use in the United States, constituting billions of hours of device usage. Despite this wide use, the MAUDE database does not include a single Medical Device Report attributed to the wireless functionality of hearing aids in the last five and a half years. Attached in Appendix III are summaries of the limited number of complaints found in MAUDE about hearing aids since January 1, 2008, none of which relate to wireless functionality.

In addition, HIA has reviewed the published literature. Our search covered English-language articles in PubMed with the following search terms: "hearing aid" and wireless; "hearing aid" and wireless and "adverse event"; "hearing aid" and wireless and complaint; "hearing aid" and wireless and problem. We did not identify a single report of an adverse event associated with the wireless features of a hearing aid.

The Hearing Industries Association acknowledges that the special controls included in 21 C.F.R. § 874.3305 for wireless air conduction hearing aids may well be appropriate for devices with certain features in hearing aids. These hearing aids may present risks that would warrant imposition of special controls. HIA does not believe, however, that the special controls are necessary for all hearing aids simply because they have some wireless functionality. There is a long history of the safe use of certain wireless features of hearing aids predating the establishment of special controls.

Specifically, HIA believes that the following features that have been used in wireless hearing aids do not present any risks greater than those found in Class I hearing aids: (1) ear to ear features encompassing transmission from one hearing aid to another for purposes of signal processing and/or improving signal to noise ratio, *e.g.*, binaural processing of directional input, and/or (2) wireless input of audio or other streamed signals to the hearing aid (receipt of wireless signals from external device, including a hearing aid), *e.g.*, receiving of audio data (audio streaming), or separately receiving reprogramming instructions from a hearing professional. HIA notes that its members, who manufacture over 90 percent of the hearing aids sold in the United States, already meet various safety standards, comply with good manufacturing practices, and obtain ISO certification for these manufacturing activities.

A. Reclassification Petition

FDA's recent reclassification applied to all hearing aids with wireless features. In reclassifying these products, FDA issued a Federal Register notice and a letter establishing special controls. The agency also released a copy of its decision memorandum supporting reclassification. These documents do not expressly describe the basis for placing wireless hearing aids in Class II. Based on the special controls that were established, it appears that the two safety issues identified by the agency related to non-ionizing radiation and electromagnetic interference. There do not appear to be any effectiveness-related grounds for establishing special controls, and HIA is aware of no effectiveness-related reasons for special controls. HIA notes that the published literature contains multiple articles demonstrating the effectiveness of hearing aids with wireless functionality. For example, Picous and Ricketts reported that in a study of 18 adults with moderate-to-severe sensorineural hearing loss, wireless systems offer advantages to listeners in that some positioning constraints are associated with telecoil use, and that speech recognition was better with bilateral wireless routing than with acoustic coupling. J. Am. Acad. Audial 2013 Jan. (24)(1); 59-70. The special controls were intended to address these potential safety issues by requiring (1) appropriate analysis and/or testing to validate EMC and the safety of exposure to non-ionizing radiation; (2) validation of wireless technology functions through design, description, and performance data; and (3) labeling to specify appropriate instructions, warnings, and information about EMC, wireless technology, and exposure to non-ionizing radiation. 21 C.F.R. § 874.3305.

The concerns the special controls are intended to address are not necessary to improve the safety of hearing aids that contain only the identified wireless features, since, as noted above, hearing aid manufacturers already take a number of steps in the production, testing, and labeling of hearing aid products to assure safe use, and because the presence of these features will not result in the risks the special controls are designed to present. These are discussed in turn below.

B. Wireless Hearing Aid Safety

1. *Compliance with FCC, International Standards, and FDA Guidance*

In the Widex documents, FDA expressed concern about the safety of wireless emissions from wireless air conduction hearing aids and the risk of heating human tissue based on the radiated power levels of the device. Currently marketed wireless hearing aids address these concerns in the following ways. The FCC has a maximum permissible specific absorption rate (SAR) of 1.6W/kg averaged across any one gram of tissue. 47 C.F.R. § 2.1093(d)(2). Note that the FCC requires SAR testing only for devices having output power of greater than 60mW/carrier frequency in GHz. FCC Office of Engineering & Technology, *Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields*, Supplement C (Edition 01-01), at 9 (*citing* American National Standards Institute (ANSI), *Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*, ANSI/IEEE C95.1-1992 (previously issued as IEEE C95.1-1991); National Council on Radiation Protection and Measurements (NCRP), *Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields*, NCRP Report No. 86, 1986). SAR testing is therefore not required for hearing aids because they have power levels well below the 60mW/carrier frequency. A 2005 article about a then-new Siemens wireless hearing aid, Acuris, states that the SAR measurement for the hearing aid indicated that the hearing aid "had SAR values at least 478 million times lower than the U.S. safety limit. In comparison, mobile phones have SAR values 3.2 times below the U.S. safety limit." Powers, T.A., and Burton, P., *Wireless technology designed to provide true binaural amplification*, 58 THE HEARING JOURNAL 25, 26, at 30 (Jan. 2005).

Currently marketed wireless hearing aids have typical peak output power within the range permitted by the FCC. Though output power varies for each hearing aid, it is about 300,000 times less than average cell phone output power. If the wireless feature in a hearing aid were active 100% of the time, and all output power was absorbed by 1 gram of tissue, the output power would be approximately 500 times lower than the 1.6W/kg limit specified by the FCC. Therefore, there is no safety risk associated with wireless products that are below the FCC SAR limit, such as hearing aids.

In reclassifying wireless hearing aids, FDA also expressed concerns about immunity and wireless coexistence. Designing hearing aids with wireless features that will avoid interference is critical to hearing aid manufacturers. An article published in the Hearing Journal reports that "enabling the instrument to select among multiple frequency channels around the 900-MHz ISM band dramatically reduces the probability of degraded communication. For example, if the probability for interference on a single channel is 1%, the probability for interference on both channels simultaneously is 0.01%.

Such conditional probabilities across independent channels result in an overall likelihood of interference that is strikingly small." Jason A. Galster, *A new method for wireless connectivity in hearing aids*, 63 The Hearing Journal 36, 39 (2010).

Hearing aid manufacturers conduct approximately 20 tests in accordance with consensus standards, at least half of which are recognized by FDA. A list that incorporates the current consensus standards that apply to wireless hearing aids is provided in Appendix IV. These tests include the M2 immunity requirements per ANSI C63.19, and the requirements of IEC 60601-1-2, meaning they do not generate harmful interference and are immune to disturbances from electromagnetic fields and electrostatic discharges. Both of these standards are recognized by FDA. Standard testing of wireless hearing aids includes testing to assure that they can coexist with wireless interferers, such as mobile phones or Bluetooth headsets, without unacceptable loss of functions or any safety concerns for the user, *e.g.*, the hearing aid must not amplify at full strength. For example, coexistence verification tests the device's radiated emission and its immunity towards interference according to recognized standards and limits, thus verifying its ability to coexist. IEC 60601-1-2. Coexistence validation tests immunity towards relevant and strong interferences, thereby validating the hearing aid's ability to coexist in a more realistic test setup.

Additionally, in January 2007, FDA issued a draft guidance titled "Radio-Frequency Wireless Technology in Medical Devices." This draft guidance encourages manufacturers of medical devices with RF technology to consider wireless coexistence, performance, data integrity, security, and EMC during several stages of the product life cycle. These include identification, documentation, and implementation of product design requirements; design verification and validation; and risk management processes and procedures. *Id.* at 4. The guidance also discusses the considerations specific to RF wireless technology in medical devices that should be considered in addition to general medical device requirements. Manufacturers of wireless hearing aids have long complied with the terms of the draft guidance, and have incorporated that guidance into standard practice, helping to assure the safe and effective design of wireless technology.

2. *Critical Amplification Feature not Affected by Wireless Functionality*

Though wireless features provide additional applications for the user, they do not affect the basic operation of the hearing aid. In other words, if the wireless communication fails between hearing aids, or between an external product and a hearing aid, the hearing aid does not stop working. The only functionality lost is the wireless communication until the link is re-established. Each hearing aid would work independently, as they have traditionally, and each can continue to function independently while still providing amplification and communication with the outside world.

This is critically important, because the ability of the amplification feature to continue to operate even in the absence of wireless functionality means that the loss of such functionality would present no risk to the patient in, for example, an environment where the user might be driving a car or standing on the street and need to hear an emergency siren. The user would still hear an ambulance or honking horn, even if the wireless functionality was interrupted. This key safety feature demonstrates that the use of wireless functions presents an extremely low safety risk to the user.

As part of their compliance with QSR requirements, particularly those identified in the draft guidance as of critical importance to devices with wireless RF technology, wireless hearing aid manufacturers routinely conduct testing that demonstrates the continued safe use of the amplification features in the absence of wireless functionality. Wireless coexistence verification is implemented through EMC and radio testing, in which both radio immunity and radio emissions are tested against ANSI and FCC limits. Wireless hearing aids are tested for EMC and radio performance according to internationally recognized standards, such as ANSI/IEC 60601-1-2: 2007. This testing is generally conducted for radiated fields of 3 v/m at 3 meters for frequencies from 80MHz to 2.7GHz, electrostatic discharges at +/- 6KV contact discharge and +/- 8KV air discharge, and AC magnetic fields at 3A/m for both 50 and 60Hz. ANSI/IEC 60601-1-2: 2007. The testing has shown that as wireless hearing aids transmit and receive frequencies, communication disruption may occur, but the core hearing aid functionality (audio amplification) and basic safety (*e.g.*, the ability to continue to hear safety alerts) are maintained, programmed settings are maintained, and no audio artifacts occur that would cause the output of the hearing aid to exceed its programmed maximum acoustic output level as set by the hearing professional.

In short, this means that the hearing aids will not accidentally shut down due to wireless interference; there is no permanent loss of effectiveness with respect to the wireless functions of the hearing aid or any change in program mode due to disturbance from other wireless devices; no change in long-term memory settings; and no generation of loud tones. These devices therefore do not need to be placed in Class II in order to provide reasonable assurance of safety and effectiveness.

3. *Wireless Hearing Aids Contain Appropriate Warnings and Precautions*

In its Summary Review Memo responding to the Widex *de novo* petition, FDA stated that the emissions safety information was acceptable and appropriate because, in part "the design considerations and labeling warnings regarding pacemakers are sufficient." Currently marketed wireless hearing aids also contain sufficient labeled warnings with regard not only to pacemakers, but to potential interference with other wireless instruments and standard warnings about the wireless features. Below is a list of sample warnings contained on currently marketed hearing aids:

- If you wear an active implantable device keep the wireless hearing aids and hearing aid accessories such as wireless remote controls or communicators at least 15cm away from the implant.

- If you experience any interference, do not use the hearing aids and contact the manufacturer of the implant.

- Please note that interference can be caused by power lines, electrostatic discharge, airport metal detectors, etc.

- If you have an active brain implant, please contact the manufacturer of the implant for risk evaluation.

- When boarding a flight or entering an area where RF transmitters are prohibited, wireless functionality must be deactivated, as it is not allowed to radiate radio signals during flights or in otherwise restricted areas.

- Your hearing instruments are designed to comply with the most stringent Standards of International Electromagnetic Compatibility. However, it is still possible that you may experience interference caused by power line disturbances, airport metal detectors, electromagnetic fields from other medical devices, radio signals, and electrostatic discharges.

- Your hearing instruments should not be worn during an MRI procedure or in a hyperbaric chamber.

4. *Data Integrity and Security are Addressed*

Finally, FDA's concerns about data integrity and security of data exchange do not require special controls. Companies use a variety of means for controlling data integrity and security exchange of data, including: Forward Error Correction based on Reed Solomon block codes; cyclic redundancy check (CRC) to protect against bit errors; message delivery via an ARQ automatic retransmission acknowledge/request protocol; packet-based wireless communication includes an FEC encoded header and an FEC encoded payload, which are CRC checked individually for proper reception; pairing by a random security code to ensure authentication of the wireless link and minimize the risk of disturbance from other hearing aids nearby; use of various combinations of retransmission, frequency hopping, and error correction to maximize the likelihood of maintaining a good link; and disabling of wireless services when the device is in low-battery mode, which will allow primary services to remain active.

Additionally, to protect the security of wirelessly transmitted data, wireless hearing aids do not use an open system for wireless data transmission, but instead use, for example, a proprietary transmission packet protocol and a proprietary digital modulation that incorporate a data whitener based on a complex polynomial to scramble the data. These approaches prevent other commercially available devices from discovering, intercepting, interpreting, or injecting transmitted data and effectively ensure security of transmitted data. Furthermore, the low output power and antenna size limit the range at which hearing aids can establish effective wireless transmissions. For ear to ear functionality between instruments, the wireless transmission range is limited to approximately 12 inches; for receiving audio signals from other products to the hearing aid, the range is approximately 3-5 meters. This limits the ability of wirelessly transmitted data to be intercepted.

C. Conclusion

Wireless hearing aids are heterogeneous, encompassing a variety of features. The features that have specifically been identified in this petition can be safely and effectively used without special controls because of their low power, safe use with medical devices, history of safe use, adherence to QSRs and FCC standards, and data security. Please refer to Appendix V for copies of literature supporting the claim that reclassification of these wireless hearing aids from Class II to Class I will result in a device that remains safe and effective for its intended use, while ensuring that new hearing aids that incorporate new features will be subject to the special controls established by FDA.

VII. Unfavorable Data

There are no unfavorable data known to us.

VIII. Summary of New Information

Please refer to Appendix V for copies of literature discussing the safe use of wireless hearing aids.

IX. Source Documents

There are no source documents to be submitted relevant to this product.

X. Financial Certification or Disclosure Statement

This is not applicable.

APPENDIX I

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: June 30, 2015
(See PRA Statement on Page 2)

Panel Recommendation

1 GENERIC TYPE OF DEVICE
Wireless hearing aid

2 ADVISORY PANEL
Ear nose and throat

3 IS DEVICE AN IMPLANT (21 CFR 860.3)?
☐ Yes ☒ No

4 INDICATIONS FOR USE IN THE DEVICE'S LABELING
A wearable sound-amplifying device intended to compensate for impaired hearing, that incorporates wireless technology in its programming or use.

5 IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE
General No known risks to health presented by the device.

6 RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY
Classification Class I
Priority (Class II or III Only)

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

N/A

8 SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

Abundant evidence and long-term clinical experience exist demonstrating that general controls are sufficient to provide reasonable assurance of safety and effectiveness of wireless hearing aids. Data from FDA's MAUDE database as well as published literature have been included to support this petition.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE *(e.g., special labeling, banning, or prescription use)*

N/A

10 IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification/Comments

- [ ] a Registration/Device Listing
- [x] b Premarket Notification Already exempt.
- [ ] c. Records and Reports
- [ ] d Good Manufacturing Practice

11 IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- [ ] a. Exempt
- [ ] b Not Exempt

Justifications/Comments

12 EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

See Appendix IV.

13 COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO

Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Regulations Staff, WO66-4436
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

APPENDIX II

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED OMB NO. 0910-0138
EXPIRATION DATE June 30, 2015
(See PRA Statement on Page 2)

PANEL MEMBER/PETITIONER Hearing Industries Association	DATE 11/21/2013
GENERIC TYPE OF DEVICE Wireless hearing aid	CLASSIFICATION RECOMMENDATION I

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☒ NO
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☒ NO
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☒ NO
4. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☒ YES ☐ NO
5. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO
6. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS, IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II ☐ Guideline Document ☐ Performance Standard(s) ☐ Device Tracking ☐ Testing Guidelines ☐ Other *(Specify)* ______	
7. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority ______ ☐ Medium Priority ______ ☐ High Priority ______ ☒ Not Applicable ______	
8 FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☐ NO ☒ NOT Applicable
9 FOR A DEVICE RECOMMENDED FOR CLASSIFICATION/RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. ☐ Low Priority ______ ☐ Medium Priority ______ ☐ High Priority ______ ☒ Not Applicable ______	

PSC Publishing Services (301) 443-6740 EF

10. IDENTIFY THE NEEDED RESTRICTION(S)

- [ ] Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
- [ ] Use only by persons with specific training or experience in its use
- [ ] Use only in certain facilities
- [ ] Other *(Specify)* ______

11. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO

Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Regulations Staff, WO66-4436
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

APPENDIX III—MAUDE COMPLAINTS

A search for "hearing aid" in "brand name" from January 1, 2008 through June 28, 2013, revealed the following five complaints:

Manufacturer	**Brand Name**	**Description of Complaint**	**Date Report Received**
Unknown	Prototype Hearing Aid	Patient with implanted bone conduction hearing aid complained of ringing	4/23/12
Phonak	Phonak Exelia Hearing Aid	Moisture intrusion caused by sweat	10/13/11
Cochlear Americas	Cochlear BP100	Bone anchored hearing aid cracked	8/24/11
Starkey	Starkey in the Canal Hearing Aids	General complaint about hearing loss allegedly associated with use of hearing aids and teaching in noisy environments	5/15/09
Miracle Ear	Miracle Ear Hearing Aid	Design complaints	12/16/08

APPENDIX IV—Standards

Standards applicable to wireless hearing aids

1. Electrical safety under IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (2005)

2. Electromagnetic compatibility under EN 60601-1-2:2007, Medical electrical equipment, Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility –Requirements and test (2001)

3. Conformance with FCC Part 15 requirements

4. ANSI/ASA S3.22:2009, Specification of Hearing Aid Characteristics - Includes April 2007 Erratum

5. ANSI/ASA S3.35-2010, Method of Measurement of Performance Characteristics of Hearing Aids under Simulated Real-Ear Working Conditions

6. ANSI/ASA S3.36-2012, Specification for a Manikin for Simulated in situ Airborne Acoustic Measurements

7. ANSI/ASA S3.42-1992/Part 1, (R 2007) Testing Hearing Aids with a Broad-Band Noise Signal

8. ANSI/ASA S3.46-2013, Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids

9. ANSI/ASA S3.20-1973, (R 2003) Bioacoustical Terminology

10. ANSI/ASA S3.25-2009, For an Occluded Ear Simulator

11. ANSI/ASA S3.7-1995 (R 2008), Method for Coupler Calibration of Earphones

12. IEC 60118-13 ed. 3.0 b:2011, Hearing aids, Part 13: Electromagnetic compatibility (EMC) – Product standard (Ed. 2, 2004)

13. IEC 60950-1:2001; EN 60950-1:2001 + A11:2004, Information technology equipment – Safety – Part 1: General requirements (2004)

14. IEC 62209-2, Evaluation of the human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices in the frequency

range of 30MHz to 6 GHz: Human models, instrumentation and procedures (Draft 2007)

15. EN 301 489-3 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz. Harmonized EN covering essential requirements under article 3.(1) (b) of the R&TTE Directive.

16. EN 301 489-17 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems. Harmonized EN covering essential requirements under article 3.(1) (b) of the R&TTE Directive.

17. EN 300 330-1V1.7.1, Electromagnetic compatibility and radio spectrum matters (ERM); Short-range devices (SRD); Radio equipment in the frequency range of 9kHz to 25MHz and inductive loop systems in the frequency range of 9kHz to 30MHz; Part 1: Technical characteristics and test methods (2006-04)

18. EN 300 330-2V1.5.1, Electromagnetic compatibility and radio spectrum matters (ERM); Short-range devices (SRD); Radio equipment in the frequency range of 9kHz to 25MHz and inductive loop systems in the frequency range of 9kHz to 30MHz; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive (2006-04)

19. EN 300 328 V1.7.1, Electromagnetic compatibility and radio spectrum matters (ERM); Wideband transmission systems; data transmission equipment operating in the 2, 4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive (2006-10)

APPENDIX V—Supporting Literature

1. Picou, E.M., and Ricketts, T.A., *Efficacy of hearing-aid based telephone strategies for listeners with moderate-to severe hearing loss*, 24 J. AM. ACAD. AUDIOLOGY 59-70 (2013).

2. Williams, V.A., et al., *Subjective and objective outcomes from new BiCROS technology in a veteran sample*, 23 J. AM. ACAD. AUDIOLOGY 789-806 (2012).

3. Banerjee, S., *Binaural Spatial Mapping optimizes real-world hearing aid behavior*, STARKEY HEARING TECHNOLOGIES, TECHNOLOGY PAPER (2011).

4. Picou, E.M., and Ricketts, T.A., *Comparison of wireless and acoustic hearing aid-based telephone listening strategies*, 32 EAR HEAR 209-20 (2011).

5. Galster, J., *A new method for wireless connectivity in hearing aids*, 63 THE HEARING JOURNAL 36-39 (2010).

6. Kreisman, B., et al., *Improvements in speech understanding with wireless binaural broadband digital hearing instruments in adults with sensorineural hearing loss*, 14 TRENDS AMPLIF. 3-11 (2010).

7. Powers, T.A., and Burton, P., *Wireless technology designed to provide true binaural amplification*, 58 THE HEARING JOURNAL 25, 26 (Jan. 2005).

Efficacy of Hearing-Aid Based Telephone Strategies for Listeners with Moderate-to-Severe Hearing Loss

DOI: 10.3766/jaaa.24.1.7

Erin M. Picou*
Todd A. Ricketts*

Abstract

Background: Understanding speech over the telephone when listening in noisy environments may present a significant challenge for listeners with moderate-to-severe hearing loss.

Purpose: The purpose of this study was to compare speech recognition and subjective ratings across several hearing aid-based telephone listening strategies for individuals with moderate-to-severe sensorineural hearing loss.

Research Design: Speech recognition and subjective ratings were evaluated for a simulated telephone signal. The strategies evaluated included acoustic telephone, unilateral telecoil, unilateral wireless streaming, and bilateral wireless streaming. Participants were seated in a noisy room for all evaluations.

Study Sample: Eighteen adults, aged 49–88 yr, with moderate-to-severe sensorineural hearing loss participated.

Data Collection and Analysis: Speech recognition scores on the Connected Speech Test were converted to rationalized arcsine units and analyzed using analysis of variance testing and Tukey post hoc analyses. Subjective ratings of ease and comfort were also analyzed in this manner.

Results: Speech recognition performance was poorest with acoustic coupling to the telephone and best with bilateral wireless routing. Telecoil coupling resulted in better speech recognition performance than acoustic coupling, but was significantly poorer than bilateral wireless routing. Furthermore, unilateral wireless routing and telecoil coupling generally led to similar speech recognition performance, except in lower-level background noise conditions, for which unilateral routing resulted in better performance than the telecoil.

Conclusions: For people with moderate-to-severe sensorineural hearing loss, acoustic telephone listening with a hearing aid may not lead to acceptable performance in noise. Although unilateral routing options (telecoil and wireless streaming) improved performance, speech recognition performance and subjective ratings of ease and comfort were best when bilateral wireless routing was used. These results suggest that wireless routing is a potentially beneficial telephone listening strategy for listeners with moderate-to-severe hearing loss who are fitted with limited venting if the telephone signal is routed to both ears. Unilateral wireless routing may provide similar benefits to traditional unilateral telecoil. However, the newer wireless systems may have the advantage for some listeners in that they do not include some of the positioning constraints associated with telecoil use.

Key Words: Hearing aids, hearing loss, noise, speech discrimination, telephone

Abbreviations: ANOVA = analysis of variance; BTE = behind the ear; CST = Connected Speech Test; rau = rationalized arcsine unit; RSETS = simulated equivalent telephone sensitivity; SD = standard deviation; SNR = signal-to-noise ratio; SPLITS = sound pressure level for inductive telephone simulator

*Vanderbilt University Medical Center, Nashville, TN

Todd A. Ricketts, PhD, Associate Professor and Director of Graduate Studies, Vanderbilt Bill Wilkerson Center, Room 8310, Medical Center East, South Tower, 1215 21st Ave S, Nashville, TN 37232-8242; Phone: (615) 936-5258; Fax: (615) 936-6914; E-mail: todd.a.ricketts@vanderbilt.edu

Portions of this paper were presented at AudiologyNow! 2010, San Diego, CA, April 16, 2010.

This study was funded in part by a grant from Siemens Hearing.

People who have hearing loss are more likely to experience a reduced quality of life and increased risk of depression (Mulrow et al, 1990a; Carabellese et al, 1993) due to increased communication difficulties and impaired activities of daily living (Carabellese et al, 1993; Dalton et al, 2003). One activity of daily living is telephone usage, which allows users to communicate with others from remote locations for the purposes of socialization, business, or emergencies. Indeed, a large majority of people with hearing loss report moderate-to-severe difficulty using the telephone because the telephone signal was either too soft or unclear (Kepler et al, 1992).

For people with permanent, sensorineural hearing loss, the most common remediation includes the provision of hearing aids. While hearing aids can improve quality of life (Mulrow et al, 1990b, 1992; Cohen et al, 2004; Chisolm et al, 2007), psychological well-being (Dye and Peak, 1983), and general communicative efficacy (Harless and McConnell, 1982), hearing aid use often may not improve telephone listening for individuals with hearing loss (Tyler et al, 1983). In addition to a lack of visual cues, potentially limited context, and unfamiliar talkers, conversing over the telephone may be difficult for hearing aid users because coupling the telephone signal to the hearing aid may be difficult. Sometimes hearing aid use may even exacerbate difficulties communicating over the telephone (Kepler et al, 1992). As few as 40% of hearing aid users report satisfaction with their hearing aid(s) while using the telephone (Kochkin, 2002). This suggests that many hearing aid users were not satisfied with listening over the telephone given the technology available at that time.

For hearing aid users, there are several possible options for delivering the telephone signal to the hearing aid. These include acoustic and wireless routing strategies. For acoustic routing, the hearing aid user holds the telephone receiver near the desired ear and the acoustic output from the telephone receiver is delivered acoustically to the hearing aid, which amplifies the signal based on the gain in the hearing aid. While this routing technique is feasible for both landline and cellphone use, it is limited in a number of ways, particularly for listeners who require high levels of amplification due to substantial hearing loss. In such listeners, orientating the telephone closely enough to the hearing aid microphone in order to ensure adequate acoustic signal levels, while maintaining the distance necessary to limit acoustic feedback, may be difficult or impossible. Advances in feedback-reduction algorithms (Latzel et al, 2001; Chung, 2004), decreasing hearing aid gain above 3000 Hz (Stypulkowski, 1993), and use of foam pads to increase distance between telephone and hearing aid (Palmer, 2001) have all been advocated to improve the problems associated with feedback and acoustic telephone coupling. However, acoustic telephone coupling remains problematic for listeners with more hearing loss who require more hearing aid gain (Latzel et al, 2001; Palmer, 2001). Even if limitations related to feedback are eliminated, the benefits of acoustic coupling are expected to be limited in noisy environments because both noise and telephone signals will be amplified.

An alternative solution to acoustic coupling is use of one form of wireless routing: a telecoil in the hearing aid. The telecoil allows for wireless signal transmission by transducing the oscillating electromagnetic field generated by traditional loudspeakers, which include telephone receivers (Smith, 1974; Yanz, 2005). Because the hearing aid microphone may be deactivated and only the signal from the telephone is amplified, the telecoil may substantially enhance the signal-to-noise ratio (SNR) for the ear listening to the telephone. In addition, the signal from the telephone is amplified based on individualized hearing aid gain, which can improve speech recognition if the telecoil response is similar to the acoustic hearing aid response (Davidson and Noe, 1994).

Although telecoils have been shown to provide some benefits relative to acoustic coupling (Cashman et al, 1982; Sorri et al, 2003), the benefit of induction loop or telecoil usage does not always yield superior performance (Vargo et al, 1970; Tannahill, 1983; Holmes, 1985). In some cases, lack of telecoil benefit may have been related to suboptimal frequency shaping of the telecoil response (Hodgson and Sung, 1972; Rodriguez et al, 1993). Another reason for variable reports of telecoil benefits may be that the strength of the telephone signal is sensitive to the position of the telephone receiver relative to the telecoil. The electromagnetic source must be positioned very near the telecoil and at the appropriate perpendicular orientation for optimal operation, and some amount of user positioning is often needed to achieve an acceptable signal delivery level (Tannahill, 1983; Compton, 1994; Yanz and Preves, 2003). In addition to positioning constraints, telecoils are also susceptible to interference from competing electromagnetic noise from cellular telephones, power lines, and fluorescent lights (Vargo et al, 1970; Yanz and Preves, 2003). Furthermore, telecoil use is limited to landline telephones or hearing aid-compatible cell phones that emit an electromagnetic signal that may be transduced and amplified. Many newer loudspeaker technologies, including the increasingly popular silicon variety used in the majority of current mobile telephones, do not generate an electromagnetic field. Thus, although the telecoil has the potential to improve telephone listening for hearing aid users, the technology continues to exhibit practical limitations, particularly while listening to the majority of modern telephones.

A third telephone signal delivery option for hearing aid users is wireless streaming. Most major hearing aid manufacturers have introduced wireless streaming that can be paired with a variety of devices, including music systems, televisions, as well as both traditional landline and cellular telephones. Generally, wireless streaming strategies use intermediary transmitters that accept signal input from cell phones or other auxiliary sources and then route it to the hearing aids. With this technology, cellular telephone or other signals are typically routed to the transmitter using a commercially available wireless technology, such as Bluetooth, or they may be directly hardwired. When a single transmitter is used, it is typically housed within the hearing aid remote control or some other small unit which is placed on the hearing aid wearer's body (e.g., around the neck). Alternatively, multiple transmitters connected to multiple sources are used within the same system. When multiple transmitters are used, some or all of them are typically directly hardwired to the external devices (e.g., plugged directly into a telephone, television, etc.). Signals received by the intermediary transmitter are then routed directly to a wireless receiver housed within the hearing aid case using one of a variety of proprietary wireless interfaces.

Another common method is to have the intermediary transmitter send the signal to the hearing aids using near-field magnetic induction, which is picked up using a hearing aid's telecoil. A third technique is to use a small "boot" that is directly connected to the base of behind-the-ear (BTE) style hearing aid as the wireless receiver. One of the common differences seen across manufacturers is the distance between the intermediary transmitter(s) and the hearing aid(s)/receiver(s). Depending on the specific manufacturer, this distance may be limited to anywhere from a few feet or less (as is common with near-field magnetic induction) to more than 30 ft (as is common with 900 MHz and 2.4 GHz wireless technologies).

As with telecoils, newer wireless transmission systems may be beneficial for telephone listening because they may offer improved SNR by disabling the hearing aid microphone during use. Furthermore, like telecoils, wireless streaming allows for individualized amplification based on the amount of gain in the hearing aid. In addition, however, newer wireless streaming schemes have at least three potential advantages over traditional telecoil wireless transmission. First, streaming does not necessarily suffer from some of the same positioning constraints; the transmitting telephone position relative to the hearing aid is commonly only limited by the distance constraints of the wireless protocols being used. Second, the newer wireless technology is compatible with most digital cellular phones, in addition to many other devices (e.g., television and music players). This compatibility allows for improved convenience because listeners are able to easily switch between multiple audio devices. A final potential advantage to the newer wireless transmission schemes is that many manufacturers offer systems that are capable of delivering the signal wirelessly to one or both hearing aid(s).

Use of wireless streaming for a potential solution to telephone use was recently evaluated by Picou and Ricketts (2011) who found that wireless streaming has the potential to significantly improve speech recognition in noise for a telephone signal, compared to acoustic telephone coupling, for listeners with mild-to-moderate hearing loss. In addition, speech recognition performance with bilateral wireless streaming was found to always be superior to performance with unilateral wireless streaming. That is, for wireless streaming to be maximally effective, the signal should be routed to both hearing aids. However, results indicated that there are limitations to the applicability of this new technology. Most importantly, the benefits of this technology, especially compared to an acoustic telephone program, were only evident for users who were fitted with limited venting. Hearing aid users who were fitted with small vents were able to take advantage of improved SNR with wireless routing compared to an acoustic telephone. In contrast, participants fitted with maximal venting could place the telephone directly over their ear in the acoustic telephone condition allowing for the telephone signal to enter the ear canal with minimal attenuation, while at the same time blocking some of the background noise from entering the ear canal leading to enhanced SNR. Furthermore, these advantages were hampered in the wireless streaming conditions because the open fittings allowed background noise to leak into the ear canal, decreasing the SNR for the wireless condition.

Based on these previous results, one might speculate that acoustic telephone routing may be beneficial for hearing aid wearers with a wide range of hearing loss, assuming an open fitting and an effective feedback cancellation system to allow for adequate hearing aid gain. Furthermore, one might also speculate that hearing aid wearers with greater hearing loss might benefit from wireless streaming technologies as long as they are fitted with limited venting. However, it is unclear how degree of hearing loss might interact with these hearing aid-based telephone listening strategies.

More severe hearing loss is significantly associated with more psychological distress, more difficulty relating and reacting to the environment (Dye and Peak, 1983), and more social isolation (Weinstein and Ventry, 1982), likely due, in part, to increased difficulty communication via the telephone (Dalton et al, 2003). Indeed, more severe hearing loss has been associated with poorer speech recognition performance with a telecoil (Stoker et al, 1986). Therefore, it might be expected that people with more severe hearing loss may experience more difficulty using a telecoil (or wireless technologies) than their peers with better hearing. Conversely, telecoils and wireless streaming are both sensitive to venting effects. As vent size increases, more background noise is allowed into the ear canal (Dillon, 1985). People with more hearing loss often require hearing aid fittings with less venting and more gain, and thus might be more likely to benefit from telecoil and wireless streaming technologies relative to acoustic telephone listening than their peers because of an increase in amplified signal level presented through the hearing aid in comparison to the unamplified noise level present in the listening environment.

In addition to acoustic, telecoil, and wireless routing strategies, an intuitive strategy for improving communication over the telephone is to plug the nontelephone ear. Although the strategy may be awkward, plugging the nontelephone ear might have the potential to improve speech recognition in a noisy listening environment. For example, Licklider (1948) demonstrated the potential to improve speech recognition when participants were tested via headphones and the contralateral noise source was removed. He presented monosyllabic words to one or both ears and presented white noise (90 dB) to one or both ears. When the speech signal was only in one ear, Licklider reported a benefit of approximately 6% from turning off the noise to the ear with no speech signal. Therefore, it is possible that patients might improve their speech recognition over the telephone by plugging the nontelephone ear if they are in a noisy environment.

Conversely, although there was a trend for improved performance, Picou and Ricketts (2011) found that plugging the nontest ear did not improve speech recognition as compared to leaving the contralateral hearing aid turned on for hearing aid users with mild-to-moderately severe hearing loss. However, the utility of plugging the nontest ear for hearing aid users with more severe hearing loss, especially in combination with limited venting, is unclear. Perhaps removing as much distracting background noise as possible will yield bigger improvements in speech recognition over the telephone when listening in a noisy environment.

The purpose of this study was to evaluate speech recognition and subjective ratings in several hearing aid-based telephone listening strategies for individuals with moderate-to-severe sensorineural hearing loss. Specific telephone listening strategies under investigation included acoustic telephone, unilateral telecoil, unilateral wireless streaming, and bilateral wireless streaming. In addition, the effect of plugging the nontest ear was investigated for the acoustic telephone and telecoil conditions. In all conditions, participants were seated in a noisy room.

METHODS

Participants

Eighteen native-English-speaking adults (10 males) participated in this study. Participants' mean age was 70.3 yr (min = 49, max = 88, σ = 10.8). All participants were experienced hearing aid users with an average 12.5 yr of experience (min = 0.5, max = 40, σ = 14.8). Participants had symmetrical sensorineural hearing loss as evidenced by no interaural asymmetries >15 dB between 500 and 3000 Hz and also had normal middle ear function as evidenced by no air-bone gaps >10 dB and normal middle ear immittance findings. See Figure 1 for mean participant audiometric thresholds. Participants were compensated for their time and all testing was completed in accordance with the policies of Vanderbilt University's Institutional Review Board regarding human participants in research.

Procedures

Participants were seated in a double-walled, sound-attenuating room (4 × 4.3 × 2.7 m) surrounded by loudspeakers that delivered the background noise. During testing, a participant held either the telephone handset or the wireless transmitter, depending on the test condition. The remaining equipment used for testing was outside the test environment. Participants completed speech recognition testing in 12 conditions (i.e., six hearing aid configurations in two levels of background noise) using two passage pairs in each condition for a total of 24 test conditions. After each condition, participants were asked to give their subjective ratings of ease and comfort. Participants were counterbalanced for test ear in the acoustic, telecoil, and unilateral wireless conditions (right or left). All participants were tested with speech presented to both ears in the bilateral condition. To avoid effects of learning and fatigue, the order of conditions was counterbalanced within a given noise configuration.

Hearing Aid Fitting

Participants were fitted with either Siemens Nitro (N = 4) or Siemens Motion 700 P (N = 14) BTE hearing

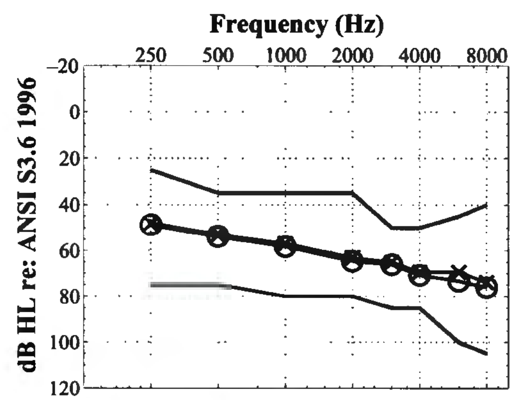

Figure 1. Mean pure-tone audiometric thresholds for the right (O *symbols*) and left ears (× *symbols*) of all study participants. *Solid lines* represent the minimum and maximum thresholds obtained.

aids, depending on gain requirements based on a participant's hearing loss. A single pair of each instrument type was used across all participants. All participants were fitted with the accompanying Siemens Tek Connect. The Tek Connect is both a remote control and a wireless transmitter. It can be synchronized to a Bluetooth device or programmed to accept an auxiliary input. The signal from the Tek Connect can then be transmitted wirelessly to the hearing aid(s). For all fittings, participants were fitted with custom earmolds with standard no. 13 tubing and clinically appropriate venting.

During the hearing aid fitting, digital noise reduction, speech enhancement, and wind management were disabled. Digital feedback suppression was activated for all conditions in order to limit feedback. All participants were fitted using the National Acoustic Laboratory-Non-Linear 1 (NAL-NL1; Byrne et al, 2001) prescriptive method. With the hearing aid input set to omni-directional, real ear verification using an Audioscan Verifit indicated that all targets were matched within +7 and −4 dB for frequencies 250–4000 Hz for all participants and the average match to target was excellent (Fig. 2).

Four programs all with identical software gain, but differing by signal routing, were generated for each listener. Signal routing included acoustic (omni-directional microphone), telecoil, and Tek Connect with external microphone muted (both unilateral and bilateral routing). For the test hearing aids, there were multiple settings encompassing 6 dB cut to a 6 dB boost for the Tek Connect as an input. For all Tek Connect conditions, the hearing aid was programmed for maximum Tek level (6 dB boost) because this setting led to the greatest similarity in real ear output for the Tek connect in comparison to acoustic fittings. Specifically, the real ear-aided response measured in a KEMAR using the Verifit for the average Tek-connect and acoustic conditions differed by no more than 4.5 dB from 300 to 3000 Hz. The telecoil

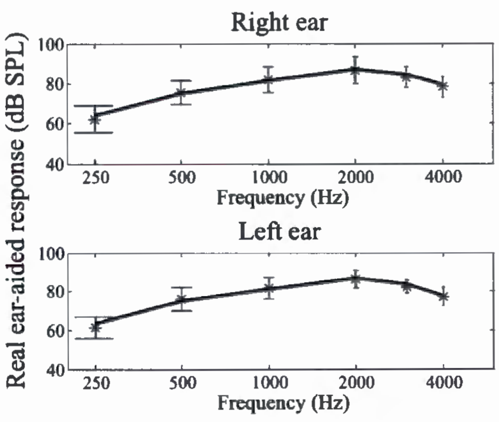

Figure 2. Mean NAL-NL1 (Byrne et al, 2001) prescribed REAR targets *(solid line)* and measured hearing aid responses *(asterisks)* across all study participants. The error bars represent ±1 standard deviation (SD).

in all hearing aids was oriented in the horizontal plane as is recommended for telephone use. To verify that the telecoil and acoustic programs had similar gain, the sound pressure level (SPL) in an inductive telephone simulator (SPLITS) was measured for all participants. The concomitant relative simulated equivalent telephone sensitivity (RSETS) values ranged from −1.0 to 2.3 dB ($\bar{X}$ = 0.8 dB), indicating that the acoustic microphone and telecoil gains were similar.

Hearing Aid Conditions

The six experimental hearing aid conditions for this study varied based on the telephone signal routing configuration and on the configuration of the nontest ear. There were three unilateral conditions wherein the speech signal was delivered only to the test ear either via acoustic coupling (microphone input), wireless telecoil coupling (telecoil input), and wireless routing (Tek connect input). During these unilateral conditions, the contralateral hearing aid was turned on amplifying background noise. During the wireless routing conditions, participants did not use a telephone receiver because the speech signal was routed directly to the Tek Transmitter. During the acoustic and telecoil conditions, the participants held a telephone receiver. All participants were instructed to hold the telephone receiver in a position where they could hear best, and were counseled that this position was likely behind the ear near the hearing aid microphone. In addition to these three unilateral conditions, there was a bilateral speech condition (bilateral Tek connect input) wherein an identical speech signal was delivered simultaneously to both ears. The hearing aid microphone was disabled for all wireless transmission conditions (both wireless streaming and t-coil) because previous work revealed that activation of the hearing aid microphone for environmental monitoring during wireless streaming significantly decreased performance essentially eliminating any potential speech recognition benefit this technology may provide (Picou and Ricketts, 2011).

Two final conditions were included to evaluate the effect of plugging the nontest ear. These conditions were similar to the acoustic and telecoil conditions, except the contralateral hearing aid was removed and an E.A.R. foam earplug was inserted. In summary, speech recognition in six listening conditions was evaluated. These listening conditions included: acoustic coupling with contralateral hearing aid active (acoustic), acoustic coupling with contralateral ear plugged (acoustic-plugged), telecoil coupling with contralateral hearing aid active (telecoil), telecoil coupling with contralateral ear plugged (telecoil-plugged), unilateral wireless routing with contralateral hearing aid active (unilateral), and bilateral wireless routing (bilateral).

Target Speech Stimuli

To simulate realistic telephone listening conditions, the Connected Speech Test (CST) was chosen as the test material because it is highly contextual. The CST contains 24 passage pairs derived from a children's encyclopedia. Each passage contains 10 sentences on a topic and the passage pairs are approximately equally intelligible. Key words were scored to derive a percent-correct speech recognition score (Cox et al, 1987, 1988). For each hearing aid configuration and noise-level combination (12 conditions total), two passage pairs were used. The presentation level of the speech was measured to be 65 dBA in an IEC 711 artificial ear simulator with 0 dB insertion hearing aid gain as programmed on a Knowles Electronics Manikin for Acoustic Research (K.E.M.A.R.).

During testing, recorded speech stimuli were played from one channel of a DVD player (Pioneer DV-563A) and routed to an audiometer (Madsen Electronics Orbiter 922) for level control. From the audiometer, speech stimuli were routed through a multi input-output processor (System 3 Tucker Davis Technologies RX8) that allowed for filtering of speech signals controlled by a custom computer program. The I/O processor was used to filter the speech. All speech signals were bandpass filtered (300–3400 Hz; 800th order FIR filters) to simulate telephone transmission signals. Pilot data confirmed that telephone signals are bandpassed from approximately 300–3400 Hz. After processing, speech signals were routed to either the Tek Connect via auxiliary input for the wireless routing conditions or to a telephone handset for the acoustic and telecoil conditions.

Competing Signals

In each of the six hearing aid conditions, the speech signal was transmitted with background noise at a + 15 dB SNR. Background noise was mixed with the speech signal to simulate a listening situation where the talker is in a noisy background. During testing, recorded multitalker babble was played from the second channel of a DVD player (Pioneer DV-563A) and routed to the second channel of the audiometer (Madsen Electronics Orbiter 922) for level control. From the audiometer, the noise stimuli were mixed with the speech stimuli and routed to the multi I/O processor and subsequently to the Tek Connect or telephone handset.

In addition, all test conditions included background noise present in the listener's environment. Background noise in the listener's environment was a multitalker babble with the same long-term average spectral shape as the CST speech stimuli. During testing, four uncorrelated samples of this noise were used as background noise in the listener's environment. Each sample was played using Adobe Audition (version 1.5) and routed using a multichannel soundcard (Echo Layla) to four loud speakers placed at a distance of 1 m at equal eccentricities around the participant (45°, 135°, 225°, and 315°). Each of the six hearing aid conditions was tested in two background noise levels. A noise level of 55 dBA was used because it is representative of the average levels commonly found in department stores, general office environments, and hospitals (Pearsons et al, 1977). A level of 65 dBA was used to assess telephone listening in environments with higher levels of background noise. Pilot data demonstrated that this level is representative of restaurants, airport terminals, and shopping malls during nonpeak hours.

Subjective Ratings

Subjective reports were gathered for each condition based on a scale similar to one described by Richards et al (2006). Participants were asked to rate subjective comfort and ease of listening following each test condition. They were presented with the questions, "How easy were those sentences to listen to?" (ease of listening) and "How comfortable were those sentences?" (comfort). In addition, they were given a magnetic white board with two marked lines, one for ease and one for comfort. Each line had 11 numbered tick marks, with 0 corresponding to "less easy" and 10 corresponding to "most easy," and 0 corresponding to "least comfortable" and 10 corresponding to "most comfortable," for ease and comfort, respectively. Participants indicated their rating by placing a magnet on a number line drawn on the magnetic white board. After a set of six conditions, all magnets were cleared from the board.

Data Analysis

The speech recognition scores from the two CST passage pairs in each condition were combined and transformed into rationalized arcsine units (rau) in order to limit the potential ceiling and floor effects on variance (Studebaker, 1985). A mixed model overall analysis of variance (ANOVA) was completed with one between-subject factor (test ear) and two within-subject factors (hearing aid condition, noise level). Follow-up testing using post hoc Tukey HSD comparisons were completed. However, given the potential effects of interest (hearing aid condition within a given noise level), all possible pairwise comparisons were evaluated only within a given background noise level. Comparisons between noise levels were ignored.

For analyses of subjective data, the ratings from the two runs in each condition were averaged. A Levenne's ANOVA revealed that these subjective ratings did not violate the assumption of homogeneity of variance. Therefore, a within-subjects ANOVA was completed with two within-subjects variables (hearing aid condition, noise level). Follow-up analyses using post hoc Tukey HSD comparisons were completed as well. Similar to speech recognition results, all possible pairwise comparisons were only evaluated within a given background level.

RESULTS

Speech Recognition

Figure 3 displays the mean speech recognition performance (rau) on the CST for the six hearing aid conditions in background noise of 55 dB (*top panel*) and 65 dB (*bottom panel*). Overall ANOVA revealed a main effect of noise level ($F_{1,\,6} = 33.171$, $p < 0.001$, $\omega^2 = 0.225$) and a main effect of hearing aid condition ($F_{5,\,80} = 58.595$, $p < 0.001$, $\omega^2 = 0.567$). In addition, there was a significant noise × hearing aid interaction ($F_{5,\,80} = 9{,}273, p < 0.001, \omega^2 = 0.010$). The main effects revealed that speech recognition performance was worse with higher-level background noise and there was a difference between the hearing aid conditions. There was no main effect of ear tested. Therefore, follow-up analyses of the significant interaction were completed after collapsing the data across ear tested.

Follow-up testing was completed using Tukey HSD pairwise comparisons of speech recognition performance in both background noise levels. Results indicated that, in a background noise of 55 dB (see Figure 3, *top panel*), acoustic telephone was not significantly different from acoustic telephone with nontest ear plugged. Similarly, telecoil condition was not significantly different from acoustic telephone with nontest ear plugged. Finally, telecoil with the nontest ear plugged was not different than the unilateral wireless routing condition. All other comparisons were significant ($p < 0.05$). Results were similar when the background noise was 65 dB (see Figure 3, *bottom panel*). The effect of plugging the nontest ear was not significant in the acoustic or telecoil conditions. In contrast to the lower-level noise condition, however, the unilateral wireless condition was not different than either of the telecoil conditions. All other comparisons were significant ($p < 0.01$).

Taken together, these results indicate that there was no speech recognition benefit to removing the contralateral hearing aid and plugging the nontest ear. Furthermore, speech recognition performance was poorest with acoustic coupling to the telephone, and best with bilateral wireless routing. Telecoil coupling resulted in better speech recognition performance than acoustic coupling, but was significantly poorer than bilateral wireless routing. Furthermore, unilateral wireless routing and telecoil coupling generally led to similar speech recognition performance, except when background noise was 55 dB when unilateral routing resulted in better performance than the telecoil.

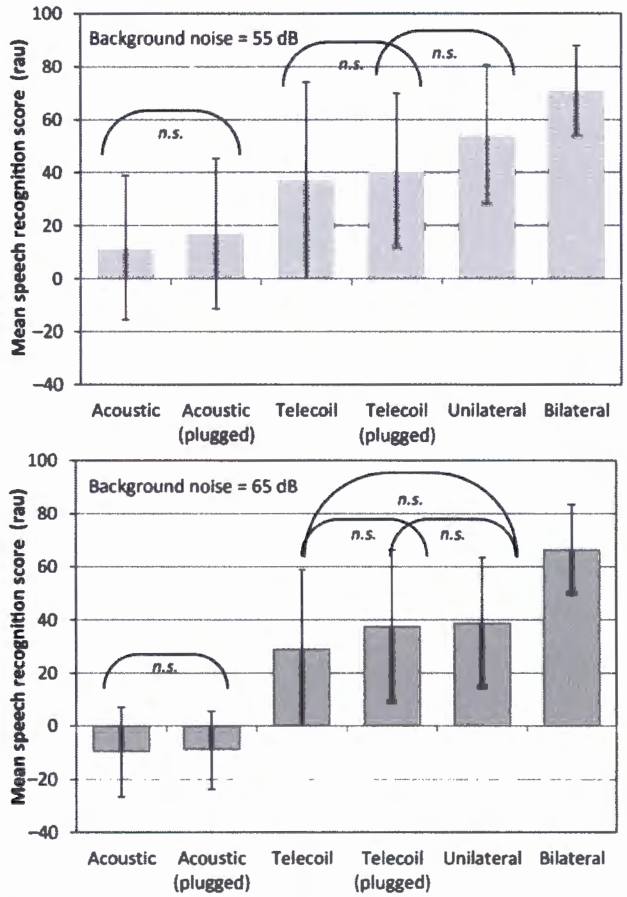

Figure 3. Mean speech recognition scores (rau) measured via the CST. *(Top panel)* Results with the 55 dB SPL background noise. *(Bottom panel)* Results with the 65 dB SPL background noise. The error bars represent ±1 SD. All pairwise comparisons were significant $p < 0.05$, except where indicated.

Subjective Ratings

Ease of Lstening

Figure 4 (*top panel*) displays the subjective ratings of ease of listening in all hearing aid conditions. An ANOVA with two within-subject variables (hearing aid, noise) revealed significant main effects for hearing aid ($F_{5,\,85} = 27.318, p < 0.001$) and noise ($F_{1,\,17} = 12.694$, $p < 0.001$). In addition, there was a significant interaction between noise and hearing aid ($F_{5,\,85} = 2.64$, $p < 0.05$), suggesting that the effect hearing aid configuration differed based on background noise level. To further explore these main effects, Tukey HSD pairwise comparisons were completed separately for each background noise level. Post hoc comparisons revealed a similar pattern of results in both background noise levels. Specifically, results revealed that plugging the nontest ear did not change ratings of ease of listening in either the acoustic telephone or telecoil conditions. In addition, the telecoil conditions yielded ease of listening ratings that were not significantly different from unilateral wireless routing conditions. All other comparisons were statistically significant ($p < 0.05$). These results suggest that bilateral wireless routing resulted in the greatest ease of listening when compared to all other hearing aid conditions, while acoustic telephone resulted in the least ease of listening compared to all others. However, telecoil and unilateral wireless routing yielded similar ratings of ease of listening.

Comfort

Figure 4 (*bottom panel*) displays the subjective ratings of comfort in all hearing aid conditions. An ANOVA with two within-subject variables (hearing aid, noise) revealed significant main effects for hearing aid ($F_{5,\,85} = 21.605$, $p < 0.001$) and noise ($F_{1,\,17} = 38.052$, $p < 0.001$). However, there was no significant interaction noise and hearing aid. Follow-up analyses using Tukey HSD pairwise comparisons revealed an identical pattern of results as the subjective ratings of ease of listening.

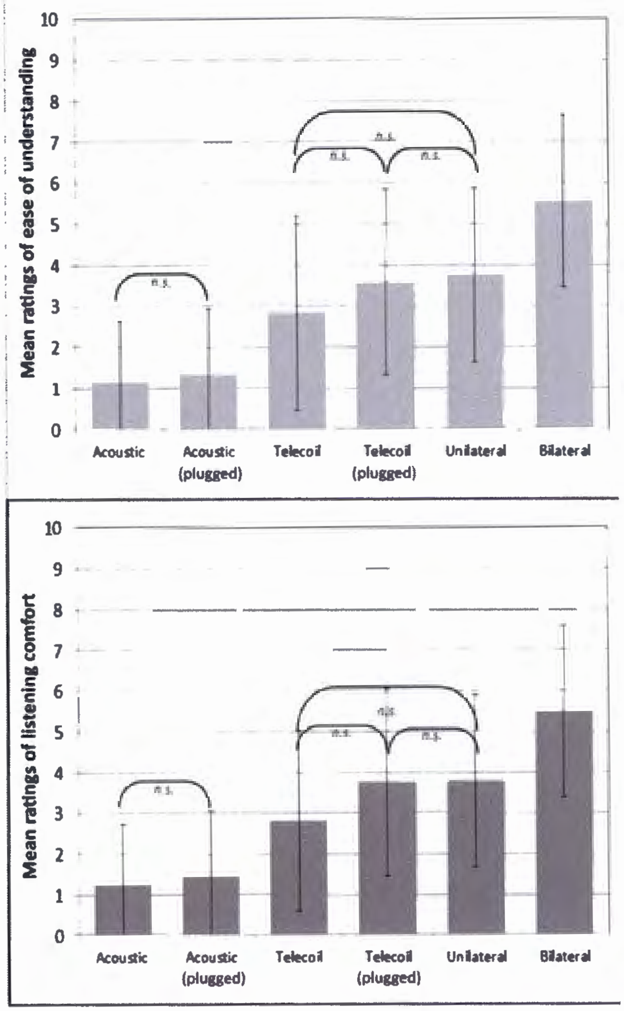

Figure 4. Mean ratings of participants' subjective ratings of "ease of understanding" *(top panel)* and "listening comfort" *(bottom panel)*. Participants' ratings could range from 0 to 10. Higher values indicate higher rating of ease or comfort. Error bars represent ±1 SD from the mean. All pairwise comparisons were significant $p < 0.05$, except where indicated by "n.s."

DISCUSSION

Unilateral Strategies

Results indicated that performance and subjective ratings were poorest in the acoustic telephone condition. Even in the lower noise condition, the average speech recognition performance was <20% with an acoustic telephone. Indeed, 16 of 18 listeners were unable to repeat >50% of target words in the lower noise condition. These results provide additional support for the contention that acoustic telephone listening through a minimally vented or unvented hearing aid is a poor solution for telephone communication in noise for listeners with moderate-to-severe hearing loss. These results are consistent with those reported by Cashman et al (1982). Specially, these authors demonstrated that, for listeners with severe hearing loss in listening conditions similar to those in the current study, average speech recognition performance was approximately 10%.

The finding that performance for the telecoil condition was significantly better than the acoustic telephone condition was also consistent with the results reported by Cashman et al (1982) who reported significantly better word recognition performance in noise with a telecoil than an acoustic telephone setting for listeners with severe hearing loss. This advantage is expected because the use of a telecoil (or any similar wireless transmission technique) allows for signals to be directly routed from the sound source to the ear, bypassing much of the noise present in the listening environment.

Since both unilateral wireless routing and unilateral telecoil route the test signal to a single ear, it was expected that both strategies would lead to similar speech recognition in noise performance. This hypothesis was generally supported as similar performance was found for the 65 dB SPL background noise conditions. Although performance was similar, wireless streaming yielded superior speech recognition performance than telecoil routing in the lower-level noise condition (55 dB). The factors underlying this finding are explored in more detail in the following section.

In addition to examining differences between telephone listening strategies, it was of interest to examine the effect of plugging the nontest ear in the acoustic telephone and telecoil conditions. Results indicated that removing the contralateral hearing aid and plugging the nontest ear did not affect speech recognition performance or subjective ratings of ease of listening or comfort. These results are consistent with previous literature that suggested altering the noise level for the contralateral ear when no speech signal is present does not influence speech recognition (e.g., Holmes et al, 1983; Picou and Ricketts, 2011). Therefore, muting or removing the contralateral hearing aid does not enhance telephone communication compared to leaving the hearing aid turned on, even when listening in background noise. However, as speculated previously (Picou and Ricketts, 2011), there may be some other benefit that patients derive from plugging the nontest ear, such as decreased listening effort.

SNR and Performance

The pattern of speech recognition performance across the unilateral conditions was expected to result, at least in part, from the SNRs participants were listening to during testing. To evaluate the potential effects of SNR, the SNRs during testing were measured as a function of frequency across all unilateral test conditions. To do this, steady state noises with the same long-term average spectral shape and overall level as the speech and noise signals were played through the same signal delivery system as used during testing (e.g., loudspeakers for background noise, and telephone receiver or the appropriate wireless system for the test signals). The signal and noise levels were then measured in each participant's ear canal using and ER7C probe microphone system. Figure 5 displays the mean SNR as a function of frequency during testing for all participants.

As displayed in Figure 5, the SNRs for the acoustic telephone condition were very poor, consistent with poor speech recognition performance and subjective ratings of ease and comfort. During the acoustic telephone conditions, the background noise levels in the room were 55 or 65 dB SPL; however, in the acoustic telephone condition, the hearing aid microphones were active, amplifying the background noise. In addition, the limited hearing aid venting precluded natural acoustic telephone transmission, so listeners were reliant on the hearing aid to amplify the acoustic telephone signal.

Also evidenced in Figure 5 are improved SNRs relative to acoustic telephone condition for both the telecoil and unilateral wireless streaming conditions, consistent with improved speech recognition performance in these two strategies relative to the acoustic telephone strategy. In addition to being improved relative to acoustic telephone condition, the SNRs for both these unilateral strategies were very similar to each other, consistent with similar speech recognition performance. Both strategies resulted in very favorable SNRs in both background noise levels.

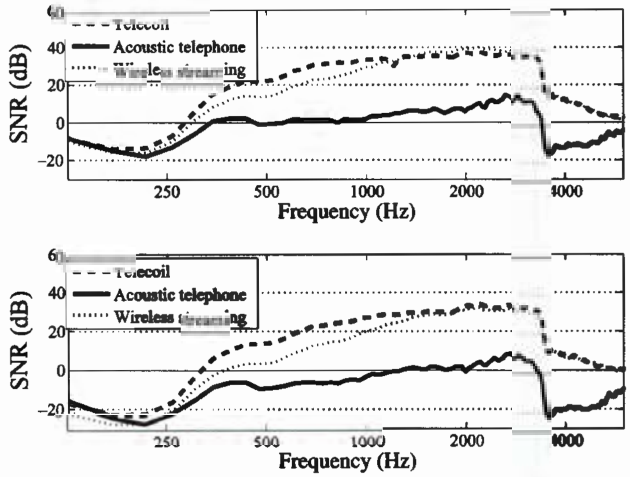

Figure 5. Mean SNR as a function of frequency during testing as measured in the ear canal for all participants. *(Top panel)* Results with the 55 dB SPL background noise. *(Bottom panel)* Results with the 65 dB SPL background noise.

The factors leading to better speech recognition in the wireless streaming condition in comparison to the unilateral telecoil in the lower background noise level (55 dB SPL) conditions are unclear. However, we speculate that it may be related to difficulty maintaining optimal positioning of the telecoil. Specifically, while participants were instructed, and reminded, to move the telephone receiver to a position where they could hear best, they were likely variable in receiver placement. Evaluation of the SNR was completed in a short session just prior to speech recognition testing. That is, the average SNR values for the t-coil measures reflect the levels obtained for a few seconds immediately after the subjects were instructed to hold the telephone receiver in the position where the signal level was optimal. During testing, participants were asked to hold the telephone receiver in position for the duration of testing, which encompassed several minutes. In contrast, the transmitter for the wireless streaming was always within the critical distance for optimum transmission, and the signal strength was not sensitive to orientation relative to the hearing aid.

In addition, some participants may not have been skilled at telephone receiver positioning. Figure 6 displays the SNR measured for two separate participants, one who successfully positioned the telephone receiver and one who was less successful. This finding is consistent with previous literature that suggests that many patients experience difficulty taking the necessary steps for successful telephone use via telecoil, even after training and years of experience. For example, Desjardins and Doherty (2009) found that 75% of experienced hearing aid users were not able to take the appropriate steps necessary for telephone use with their hearing aid, including proper telephone receiver positioning. Therefore, because wireless streaming is not sensitive to orientation constraints, provided it is placed near enough to the hearing aid for appropriate transmission, it is proposed that a potential advantage of this technology over traditional telecoil strategies is consistency of signal strength. Modern wireless strategies may be technologically difficult for some users and may require additional setup and training during clinic time. However, the tradeoff for this effort may be a signal that is consistently delivered and not as dependent on a very specific orientation of the telephone receiver as is the case with telecoil routing.

Bilateral Routing

Bilateral wireless streaming yielded the best performance and subjective ratings of ease of listening and comfort compared to all other telephone listening strategies. These results are consistent with previous research with closed fittings, our previous research with closed fittings (Picou and Ricketts, 2011), in addition to several lines of evidence that suggest listening with two ears yields better results than listening with only one. Often, this bilateral benefit is attributed to binaural summation (or binaural redundancy) and binaural squelch.

On average across noise levels, participants in the current study benefited approximately 22% from a bilateral speech signal compared with a unilateral speech signal. This was quite similar to the approximately 20% we measured previously for listeners with mild-moderate hearing loss fitted with closed venting configurations (Picou and Ricketts, 2011). Together, these results support a similar and significant bilateral advantage across a wide range of hearing loss. As discussed in a previous manuscript, the speech signal for wireless presentation is not truly diotic. The bilateral advantage measured is assumed to reflect the combined benefit of a diotic advantage due to binaural summation (e.g., Plomp and Mimpen, 1981; Hawkins et al, 1987; Davis et al, 1990) as well as binaural squelch (Zurek, 1992). Specifically, the competing environmental noise surrounds the listener, affording some binaural cues which may allow the listener to differentiate it more easily from the dichotic wireless signal for which binaural cues are absent. As suggested previously (Picou and Ricketts, 2011), this binaural squelch advantage is consistent with the "cross-over" effect. If a patient has better hearing at some frequencies in one ear, and better hearing at different frequencies in the other ear, fitting two hearing aids may allow for better overall hearing at the combination of those frequencies than fitting either ear with a single hearing aid (Byrne and Dermody, 1974). Similarly, if the SNR is better at some frequencies in one ear and better at other frequencies in the opposite ear, listeners will likely perform better listening bilaterally than monaurally.

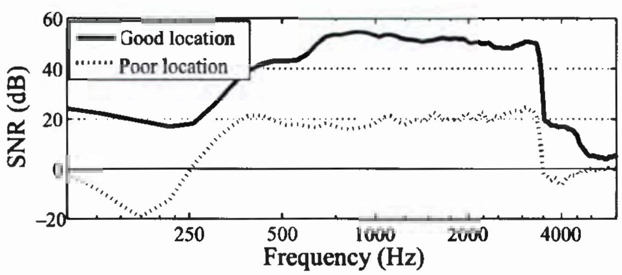

Figure 6. Example SNRs for two participants, one who was more successful at telephone receiver placement ('Good Location') and another who was less successful at telephone receiver placement ('Poor Location').

Although not evaluated in the current experiment, we speculate that any technology that is able to route a telephone signal bilaterally, including bilateral telecoil routing, will provide significant speech recognition in noise advantage over unilateral techniques. However, wireless techniques that are not sensitive to the exact orientation limitation exhibited by the telecoil may provide more consistent benefit. Clinically, however, other factors must be considered when choosing the optimal routing solution for an individual listener. These factors include, but are not limited to the cost (telecoil is generally considerable cheaper than newer wireless solutions), and how much technical support the patient will need to effectively implement the solution. In addition, these results only apply when listening to the telephone in noise. It is unknown whether a similar pattern of results would emerge in quiet listening situations.

In addition to yielding superior speech recognition performance and subjective ratings compared to unilateral wireless routing, bilateral wireless routing also yielded significantly better performance than the acoustic telephone condition. This result is consistent with previous literature that suggests bilateral wireless routing allows for better speech recognition performance than an acoustic telephone (Picou and Ricketts, 2011). However, in the previous study, the advantage for bilateral wireless routing was only evident when participants were fitted with minimal venting. Furthermore, participants in the previous study had mild-to-moderately severe sensorineural hearing loss.

It was of interest to examine the possible effects of degree of hearing loss on benefit of bilateral wireless routing compared to acoustic telephone. Because hearing aid gain influences the SNR that a patient will listen to using wireless streaming, it is possible that patients with more hearing loss are more likely to benefit from bilateral wireless routing because they will have a more favorable SNR. To evaluate the potential effects of hearing loss, a correlation analysis was completed between average pure-tone audiometric threshold (0.5, 1.0, 2.0, 4.0 kHz) and bilateral wireless benefit compared to acoustic telephone (difference between speech recognition performance in the bilateral wireless condition and acoustic telephone condition). To include a wider range of hearing loss, data collected from previous work were included (Picou and Ricketts, 2011). Figure 7 displays benefit from bilateral wireless routing compared to acoustic telephone as a function of pure-tone average. Although the data are displayed separately for two background noise levels (55 and 65 dB), a similar pattern of no significant relationship was seen for both noise levels. Specifically, a consistent magnitude of bilateral advantage was demonstrated over a very wide range of hearing loss when compared to acoustic signal delivery.

When evaluating the data from these two studies in combination, we conclude that venting is the primary factor that contributes to limiting the additional benefit for bilateral wireless benefit compared to acoustic telephone listening. That is, bilateral signal routing is expected to provide significantly better speech recognition than acoustic telephone listening across a wide range of hearing losses as long as venting is limited.

CONCLUSIONS

Generally, for people with moderate-to-severe sensorineural hearing loss, acoustic telephone listening with a hearing aid is not a desirable strategy when listening in noisy environments. Although unilateral routing options (telecoil and wireless streaming) improved performance, speech recognition performance and subjective ratings of ease and comfort were best when bilateral wireless routing was used. These results suggest that wireless routing is a potentially beneficial telephone listening strategy for listeners with moderate-to-severe hearing loss who are fitted with limited venting if the telephone signal is routed to both ears. However, wireless routing is not generally superior to traditional telecoil routing when routed to only one ear, except that it is not sensitive to the positioning constraints of a telecoil.

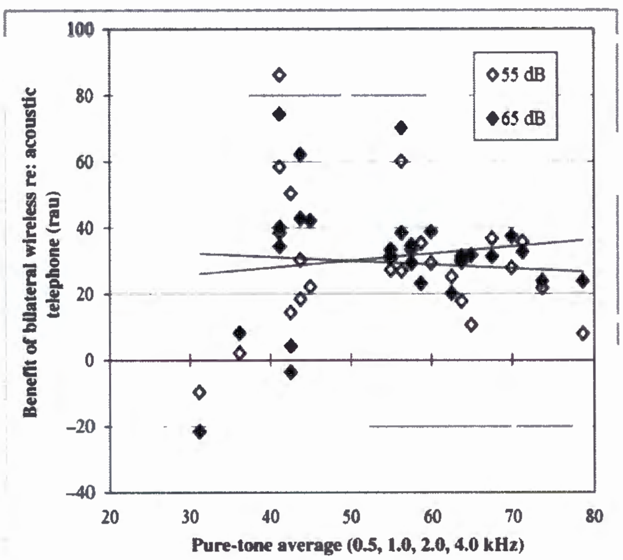

Figure 7. Speech recognition benefit of bilateral wireless routing compared to acoustic telephone as a function of pure-tone average (0.5, 1.0, 2.0, 4.0 kHz). Data points represent participants in the current study (pure-tone averages >50 dB hearing level) and participants fitted with occluding domes who participated in a previous study (Picou and Ricketts, 2011). Data are displayed separately for conditions where background noise levels were 55 and 65 dB.

Acknowledgments. The authors thank Steven Marcrum and Elizabeth Aspell for their assistance in data collection and preparation. The authors also thank Siemens and the Dan Maddox Foundation for their support.

REFERENCES

Byrne D, Dermody P. (1974) An incidental advantage of binaural hearing aid fittings the "cross-over" effect. *Br J Audiol* 8(4):109–112.

Byrne D, Dillon H, Ching T, Katsch R, Keidser G. (2001) NAL-NL1 procedure for fitting nonlinear hearing aids: characteristics and comparisons with other procedures. *J Am Acad Audiol* 12(1):37–51.

Carabellese C, Appollonio I, Rozzini R, et al. (1993) Sensory impairment and quality of life in a community elderly population. *J Am Geriatr Soc* 41(4):401–407.

Cashman MZ, Rossman RN, Abel SM. (1982) A comparison of three modes of hearing aid-telephone coupling. *J Otolaryngol* 11(4):239–247.

Chisolm TH, Johnson CE, Danhauer JL, et al. (2007) A systematic review of health-related quality of life and hearing aids: final report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults. *J Am Acad Audiol* 18(2):151–183.

Chung K. (2004) Challenges and recent developments in hearing aids. Part II. Feedback and occlusion effect reduction strategies, laser shell manufacturing processes, and other signal processing technologies. *Trends Amplif* 8(4):125–164.

Cohen SM, Labadie RF, Dietrich MS, Haynes DS. (2004) Quality of life in hearing-impaired adults: the role of cochlear implants and hearing aids. *Otolaryngol Head Neck Surg* 131(4):413–422.

Compton C. (1994) Providing effective telecoil performance with in-the-ear hearing instruments. *Hear J* 47:23–26.

Cox RM, Alexander GC, Gilmore C. (1987) Development of the Connected Speech Test (CST). *Ear Hear* 8(5 Suppl):119S–126S.

Cox RM, Alexander GC, Gilmore C, Pusakulich KM. (1988) Use of the Connected Speech Test (CST) with hearing-impaired listeners. *Ear Hear* 9(4):198–207.

Dalton DS, Cruickshanks K, Klein B, Klein R, Wiley T, Nondahl D. (2003) The impact of hearing loss on quality of life in older adults. *Gerontologist* 43(5):661–668.

Davidson SA, Noe CM. (1994) Programmable telecoil responses: potential advantages for assistive listening device fittings. *Am J Audiol* 3(2):59–64.

Davis A, Haggard M, Bell I. (1990) Magnitude of diotic summation in speech-in-noise tasks: performance region and appropriate baseline. *Br J Audiol* 24(1):11–16.

Desjardins JL, Doherty K. (2009) Do experienced hearing aid users know how to use their hearing aids correctly? *Am J Audiol* 18(1):69–76.

Dillon H. (1985) Earmolds and high frequency response modification. *Hear Instruments* 36:8–12.

Dye C, Peak M. (1983) Influence of amplification on the psychological functioning of older adults with neurosensory hearing loss. *J Acad Rehab Aud* 16:210–220.

Harless EL, McConnell F. (1982) Effects of hearing aid use on self concept in older persons. *J Speech Hear Disord* 47(3):305–309.

Hawkins DB, Prosek RA, Walden BE, Montgomery AA. (1987) Binaural loudness summation in the hearing impaired. *J Speech Hear Res* 30(1):37–43.

Hodgson W, Sung R. (1972) Comparative performance of hearing aid microphone and induction coil for a sentence intelligibility test. *J Aud Res* 12:261–264.

Holmes A. (1985) Acoustic vs. magnetic coupling for telephone listening of hearing-impaired subjects. *Volta Review* 87(4):215–222.

Holmes AE, Frank T, Stoker R. (1983) Telephone listening ability in a noisy background. *Ear Hear* 4(2):88–90.

Kepler LJ, Terry M, Sweetman RH. (1992) Telephone usage in the hearing-impaired population. *Ear Hear* 13(5):311–319.

Kochkin S. (2002) MarkeTrak VI: 10-year customer satisfaction trends in the US hearing instrument market. *Hear Rev* 9(10):14–25, 45.

Latzel M, Gebhart TM, Kiessling J. (2001) Benefit of a digital feedback suppression system for acoustical telephone communication. *Scand Audiol Suppl* (52):69–72.

Licklider JCR. (1948) The influence of interaural phase relations upon the masking of speech by white noise. *J Acoust Soc Am* 20: 150–159.

Mulrow CD, Aguilar C, Endicott JE, et al. (1990a) Association between hearing impairment and the quality of life of elderly individuals. *J Am Geriatr Soc* 38(1):45–50.

Mulrow CD, Aguilar C, Endicott JE, et al. (1990b) Quality-of-life changes and hearing impairment. A randomized trial. *Ann Intern Med* 113(3):188–194.

Mulrow CD, Tuley MR, Aguilar C. (1992) Sustained benefits of hearing aids. *J Speech Hear Res* 35(6):1402–1405.

Palmer CV. (2001) Ring, ring! Is anybody there? Telephone solutions for hearing aid users. *Hear J* 54(9):10–18.

Pearsons KS, Bennett R, Fidell S. (1977) *Speech Levels in Various Noise Environments*. Washington, DC: US Environmental Protection Agency.

Picou EM, Ricketts TA. (2011) Comparison of wireless and acoustic hearing aid-based telephone listening strategies. *Ear Hear* 32(2):209–220.

Plomp R, Mimpen AM. (1981) Effect of the orientation of the speaker's head and the azimuth of a noise source on the speech reception threshold for sentences. *Acustica* 48:325–328.

Richards VM, Moore BCJ, Launer S. (2006) Potential benefits of across-aid communication for bilaterally aided people: Listening in a car. *Int J Audiol* 45(3):182–189.

Rodriguez GP, Holmes AE, DiSarno NJ, Kaplan H. (1993) Preferred hearing aid response characteristics under acoustic and telecoil coupling conditions. *Am J Audiol* 2(3):55–59.

Smith GM. (1974) The telephone adapter and other telephone aids for the hard of hearing. *Volta Review* 76:474–484.

Sorri M, Piiparinen P, Huttunen K, et al. (2003) Hearing aid users benefit from induction loop when using digital cellular phones. *Ear Hear* 24(2):119–132.

Stoker RG, French-St George M, Lyons JM. (1986) Inductive coupling of hearing aids and telephone receivers. *J Rehabil Res Dev* 23(1):71–78.

Studebaker GA. (1985) A "rationalized" arcsine transform. *J Speech Hear Res* 28(3):455–462.

Stypulkowski PH. (1993) Fitting strategies for multiple-memory programmable hearing instruments. *Am J Audiol* 2(2):19–28.

Tannahill JC. (1983) Performance characteristics for hearing aid microphone versus telephone and telephone/telecoil reception modes. *J Speech Hear Res* 26(2):195–201.

Tyler RS, Baker LJ, Armstrong-Bednall G. (1983) Difficulties experienced by hearing-aid candidates and hearing-aid users. *Br J Audiol* 17(3):191–201.

Vargo SW, Taylor G, Tannahill JC, Plummer SA. (1970) The intelligibility of speech by hearing aids on inductance loop and microphone modes of signal reception. *J Speech Hear Res* 13(1):87–91.

Weinstein BE, Ventry IM. (1982) Hearing impairment and social isolation in the elderly. *J Speech Hear Res* 25(4):593–599.

Yanz J. (2005) Phones and hearing aids: issues, resolutions, and a new approach. *Hear J* 58(10):41–42, 44, 48.

Yanz JL, Preves D. (2003) Telecoils: principles, pitfalls, fixes, and the future. *Semin Hear* 24(1):29–42.

Zurek PM. (1992) Binaural advantages and directional effects in speech intelligibility. In: Studebaker GA, Hochberg I, eds. *Acoustical Factors Affecting Hearing-Aid Performance*. Boston, MA: Allyn & Bacon, 255–276.

J Am Acad Audiol 23:789–806 (2012)

Subjective and Objective Outcomes from New BiCROS Technology in a Veteran Sample

DOI: 10.3766/jaaa.23.10.5

Victoria A. Williams*†
Rachel A. McArdle*†
Theresa H. Chisolm†*

Abstract

Background: Patients with single-sided deafness (SSD), where one ear has an unaidable hearing loss and the other ear has normal or aidable hearing, often complain of difficulties understanding speech and localizing sound sources, and report a higher self-perceived hearing disability. Patients with SSD may benefit from using contralateral routing of signal (CROS) or bilateral contralateral routing of the signal (BiCROS) amplification. Dissatisfaction of previously available (Bi)CROS devices has been reported, such as, interfering transmissions, low-fidelity sound quality, poor "user-friendly" set-up, and a bulky and cosmetically cumbersome appearance.

Purpose: Recent advances in hearing aid technology have improved (Bi)CROS hearing aids; however, these devices have not been experimentally evaluated. We hypothesized that newer technology with reports of improved digital signal processing, wireless transmission, and physical design would be as good, or better than, our participants' previous-generation BiCROS systems.

Research Design: A within-subjects, pretest-posttest design was executed.

Study Sample: Thirty-nine veterans (one female, 38 males; mean age = 74 yr, range = 49–85 yr) from the Audiology Section of the Bay Pines Veterans Affair Healthcare System participated. All participants were previously experienced BiCROS hearing aid users with varying degrees of sensorinerual hearing impairment in their better ear.

Intervention: Participants were provided at least 4 wk of consistent use with the new BiCROS.

Data Collection and Analyses: Participants completed three research visits. At Visit 1, with their previous BiCROS, and at Visit 3, with their new BiCROS, the following objective and subjective measures were obtained: (1) soundfield speech-in-noise testing using the Words-In-Noise (WIN) test; (2) speech, spatial, and qualities of the hearing scale (SSQ) questionnaire; (3) selected questions from the MarkeTrak questionnaire; and, (4) three open-ended questions. Data were analyzed using parametric and nonparametric statistics.

Results: Overall, the objective (WIN) and subjective (SSQ, MarkeTrak, and open-ended questions) measures indicated that the new BiCROS provided better outcomes than the previous BiCROS system. In addition, an overlap of favorable results was seen across measures.

Conclusions: Of the 39 participants, 95% reported improvements with the new BiCROS and chose to utilize the device regularly. The favorable objective and subjective outcomes indicate that the new BiCROS system is as good, or better than, what was previously utilized by our sample of veterans.

Key Words: Hearing aids, hearing loss, single-sided deafness, unilateral

---

*Bay Pines VA HealthCare System, Bay Pines, FL; †Department of Communication Sciences and Disorders, University of South Florida, Tampa, FL

Victoria Williams, AuD, Bay Pines VA HealthCare System, Audiology (126), PO Box 5005, Bay Pines, FL 37710; Phone: 727-398-6661 ext 4862; Fax: 727-319-1209; E-mail: vawilli2@mail.usf.edu

Phonak Hearing Systems, Inc. supported this work through a donation to the Bay Pines VA Foundation that covered costs of participant compensation and materials. The VA Office of Academic Affiliations supported this work through a Pre-Doctoral Fellowship (to V. A. Williams). The Rehabilitation Research and Development Service, Department of Veterans Affairs, supported this work through a Career Development Award (to R. A. McArdle).

The contents of this paper do not represent the views of the Department of Veterans Affairs or the US Government.

Abbreviations: ANOVA = analysis of variance; BAHA = bone-anchored hearing aid; (Bi)CROS = (bilateral) contralateral routing of signal; BPVAHCS = Bay Pines Veterans Affairs Healthcare System; BTE = behind the ear; FS = full shell; HL = hearing level; HS = half shell; ILD = interaural level difference; ITC = in the canal; ITD = interaural time difference; ITE = in the ear; LTASS = long-term average speech spectrum; REAR = real-ear aided response; RMS-D = root-mean-square difference; sd = standard deviation; SL = sound level; SNR = signal-to-noise ratio; SPL = sound pressure level; SSD = single-sided deafness; SSQ = speech, spatial, and qualities; TCROS = transcranial CROS; UHL = unilateral hearing loss; VA = Veterans Affair; WIN = Words-in-Noise Test

INTRODUCTION

Collectively, across all types and degrees of hearing loss, approximately 28 million Americans have hearing impairment, with 90% classified as sensorineural in type. Most sensorineural hearing losses are bilateral in nature, but a recent report indicated that about 60,000 new cases of unilateral hearing loss (UHL) occur annually (Popelka et al, 2010). UHLs can vary in degree from mild to profound and can be conductive or mixed, as well as sensorineural. The present work is concerned with the subgroup of patients with UHL who exhibit a nonmedically treatable and unaidable hearing loss in the "poorer" ear, with either normal hearing or an aidable hearing loss in the "better" ear. Such individuals are often classified as having single-sided deafness (SSD). Due to inconsistencies in terminology and methodological differences across studies, the prevalence of SSD within the adult population is difficult to determine, but is considered to be relatively infrequent. SSD can result from numerous etiologies, including sudden idiopathic insult, neoplasms, demyelination, vertebrobasilar stroke, trauma, ototoxicity, infection, Meniere's disease, and autoimmune disease (Voelker and Chole, 2010). Regardless of the etiology, nonmedically treatable SSD can negatively impact functioning in daily life by eliminating the advantages associated with binaural hearing.

Advantages associated with hearing with two ears include binaural summation of loudness and binaural release from masking (Bergman, 1957; Dirks and Wilson, 1969; Bess and Tharpe, 1986). Binaural summation is an additive effect, resulting in improved audibility, of about 3 dB when processing sound with two ears (Levitt and Rabiner, 1967a, 1967b). The effect increases as a function of sensation level, with advantages of 6–10 dB observed at 30 and 90 dB sensation levels, providing approximately 18% improvement in word recognition ability in quiet (Bess and Tharpe, 1986). Binaural release from masking is the phenomenon thought to be responsible for the "cocktail party effect" (Cherry, 1953; Bronkhorst, 2000), or the ability of the listener to focus on a single talker amid a background of other conversations and noise. A release from masking occurs as a result of the differences in the time and intensity of the signal and noise sources that reach both ears, allowing the listener to segregate the signal from the background masking noise (Dirks and Wilson, 1969; Flynn et al, 2010).

The two primary binaural cues that make it possible to detect speech in noise in typical listening situations are interaural level differences (ILDs) resulting from the head-shadow effect and interaural timing differences (ITDs) of signals reaching the ears. These cues are also responsible for localization abilities too. The ability to localize sounds in space occurs when sound is perceived as louder and arrives first at one ear compared to the other. Furthermore, ILDs and ITDs are frequency dependent. For example, as a result of the head-shadow effect, a signal with mid- and high-frequency energy reaching one ear will be attenuated by 15–20 dB when it reaches the opposite ear (Shaw, 1974). The head-shadow effect not only results in ILDs for mid- and high-frequency sounds, but also differences in the time of arrival of the sound at both ears, which is particularly important for localization of lower frequency sounds.

A person with SSD loses the advantages associated with binaural summation of loudness and binaural release from masking, as well as the ability to localize sounds in space. Indeed, research data are available demonstrating that individuals with SSD have poorer speech understanding in quiet (Giolas and Wark, 1967) and in background noise (e.g., Harford and Barry, 1965; Giolas and Wark, 1967). And, as would be expected, with only one ear able to receive the sound, localization abilities are negatively impacted (e.g., Viehweg and Campbell, 1960; Häusler et al, 1983). Perhaps it is not surprising then, that without binaural hearing abilities, individuals with SSD have reported reduced occupational productivity (Dimmelow et al, 2003), and increase in self-reported handicap and decrease in health-related quality of life (Giolas and Wark, 1967; Rosenbaum, 1976; Newman et al, 1997). The self-reported perception data indicate that patients reported an increase in embarrassment, confusion, and helplessness due to UHL (Giolas and Wark, 1967; Rosenbaum, 1976; Dimmelow et al, 2003).

To remediate some of the negative effects of SSD, a traditional amplification strategy can be utilized where the signal arriving at a microphone worn on the poorer ear is transmitted to a receiver worn on the better ear. Hearing aids utilizing this contralateral routing of signal (CROS) approach have been available for more than four decades (Harford and Barry, 1965). While a simple

CROS strategy can be used if an individual has normal hearing in the better ear, if a hearing loss is present in the better ear, a bilateral contralateral routing of signal (BiCROS) approach is utilized. A BiCROS system not only allows for transmission of sounds arriving at the poorer ear to the better ear, but also provides amplification to the better ear (Pumford, 2005). While early devices used a hardwire connection to transmit the sound from the poorer to the better ear, both amplitude modulation (AM), and, more recently, frequency modulation (FM) have allowed for wireless connectivity between the poorer and better ears.

(Bi)CROS devices do not restore binaural hearing, but they do provide a "two-sided hearing environment," where the intensity difference and time delay provided from the transmission makes a "pseudo head-shadow" effect (Ericson et al, 1988; Taylor, 2010). Indeed, (Bi)CROS users appear to have temporal cues that aid in sound source localization (Hol et al, 2010). Additionally, improvements in laboratory tested speech-in-noise performance were reported with utilization of (Bi)CROS systems (Lin et al, 2006). And, equally important as the laboratory evidence, improvement in self-reported performance and satisfaction in most listening environments with utilization of a (Bi)CROS device were documented (Hill et al, 2006; Hol et al, 2009).

Even though there are data documenting that the use of a (Bi)CROS device can improve problems associated with SSD, there are also several other reports of poor success rates and dissatisfaction from (Bi)CROS users (Cashman et al, 1984; Ericson et al, 1988; Hayes et al, 2005; Flynn et al, 2010; Taylor, 2010). Reports of low satisfaction among (Bi)CROS users have been associated with: (1) interfering transmissions; (2) low-fidelity sound quality; (3) poor "user-friendly" setup; and, (4) a bulky and cosmetically cumbersome appearance. With regard to interfering signals, there were reports of audible AM radio stations along with interfering noise produced by other electromagnetic fields such as computer monitors, fluorescent lights, and security systems (Hayes et al, 2005). The reports of low fidelity of sound may be related to inferior digital signal processing in the devices. Some previous (Bi)CROS systems lacked programming flexibility, therefore limiting the access to fine-tune compression and frequency responses of the devices. The lack of fitting flexibility could have caused under- or overamplification as the devices could only be adjusted according to low-, mid-, and high-frequency outputs without being able to manipulate small changes in gain needed for varying hearing loss configurations. As for ease of use, some devices had multiple attachments, switches, push buttons, and sometimes wires making accessing and ensuring proper functionality of the (Bi)CROS difficult; therefore, patients reported them as not "user-friendly" (Hayes et al, 2005). As a final point, the previous (Bi)CROS devices were considered bulky and even cosmetically unappealing because the smallest in-the-ear (ITE) style aid was a full-shell (FS) product enclosing the entire concha bowl of the ear. And, similarly, the smallest behind-the-ear (BTE) style was a traditional-sized device with a standard ear hook and tubing. Both previous ITE and BTE BiCROS systems did not take advantage of the recent advances in hearing aid miniaturization along with receiver in the canal technology for BTE devices.

In addition to the patient-reported complaints, there is controversy in the literature regarding the benefits of (Bi)CROS systems (Hill et al, 2006; Hol et al, 2010; Taylor, 2010). This may have allowed other forms of remediation options to develop and flourish for some patients with SSD. Different options include other forms of amplification like the transcranial CROS (TCROS) (Bishop and Eby, 2010; Valente et al, 1996), osseointegrated implantable devices (e.g., bone-anchored hearing aid [BAHA]) (Snik et al, 2005; Flynn et al, 2010), and unilateral cochlear implantation (Baguley, 2010). The TCROS is similar to the (Bi)CROS system as it uses traditional amplification, but, dissimilar because it uses a power (high gain/output) device that stimulates the better ear by a transcranial crossover of the mechanical and vibratory energy via bone conduction (Sullivan, 1988; Valente and Oeding, 2010). The TCROS must sit very snug and deep within the ear canal and it has been reported to be uncomfortable and also unfavorable due to audible feedback (Valente and Oeding, 2010). Another form of bone-conduction stimulation is the osseointegrated implantable devices that send direct vibrational energy from the implant to the bone of the skull which transduces the signal to the better ear. Furthermore, another option requiring surgery is the unilateral cochlear implant. The cochlear implant is placed in the inner ear of the poorer ear which provides direct electric stimulation to residual nerve cells. Osseointegrated and cochlear-implanted devices can be contraindicated due to lack of audiological and/or medical candidacy and considered unfavorable by some patients due to the invasive procedure needed to place the device. Although these other options might be considered for some patients with SSD, each of these approaches also have limitations; therefore, (Bi)CROS devices are the initial and still most commonly used method to rehabilitate SSD.

Recent advances in technology and miniaturization have resulted in at least two new (Bi)CROS devices becoming commercially available for patients with SSD. The Unitron Tandem™ and the Phonak CROS™ are reported to have improved digital signal processing allowing improved frequency response programming, improved transmission with a wider range and stronger transmission strength while decreasing or eliminating interference, improved feedback suppression, improved usability, and improved cosmetics. No study to date, however, has examined outcomes with the newer (Bi)CROS technologies.

Additionally, a recent review of the (Bi)CROS literature reported a paucity of experimental evidence investigating the benefits of (Bi)CROS systems utilizing proper assessment tools and the most up-to-date technology with proper verification (Taylor, 2010).

The goal of the present study was to evaluate the subjective and objective outcome measures associated with the use of a new BiCROS system. It was hypothesized that the newer technology with its reports of a fully digital signal processing scheme, advanced processing algorithms, and improved handling and cosmetic appeal would be as good, or better than, the participants' current BiCROS system based on subjective and objective outcome measures. Specifically, we addressed the following questions: (1) Are there improvements in objective measures of speech understanding in noise with the new compared to previous-generation BiCROS devices? (2) Are there improvements in self-report of benefits related to speech, spatial, and quality of scores with new compared to previous-generation BiCROS devices? and (3) Are there improvements in self-reported satisfaction with the new compared to previous-generation BiCROS devices?

METHOD

Design

A convenience sample, one-group pretest-posttest, within-subjects design was used to explore the differences in objective and subjective outcomes from new compared to previous-generation BiCROS systems.

Participants

The Bay Pines Veterans Affairs (VA) Healthcare System (BPVAHCS) Institutional Review Board approved all experimental and recruitment procedures. Participants were recruited from the Audiology Section of BPVAHCS, located west of the greater Tampa Bay area in Florida. Recruitment was completed in two ways. First, the BPVAHCS dispensing records between 2007 and 2010 were reviewed for previous BiCROS fittings. This review revealed 67 patients who currently wore a BiCROS device. These 67 veterans were mailed a letter discussing the study and 37 responded and agreed to participate. Second, three additional participants were recruited through direct referral from the clinic staff. These three participants were seen for a replacement BiCROS system. Initially, a total of 40 veterans (one female, 39 males) were enrolled in the study. One male participant withdrew prior to research Visit 2 because he was no longer able to drive to the facility secondary to an eye operation. The remaining 39 participants were between the ages of 49 and 85 yr old (mean age of 73.86 yr, standard deviation [sd] = 8.76). All participants were enrolled for VA healthcare benefits and received all audiological services including previous and new BiCROS free of charge.

Participants had sensorineural SSD with varying degrees of sensorineural hearing loss in their aidable (better) ear. The audiometric data for the participants' better and poorer ears are shown as a function of hearing [dB hearing level (HL); American National Standards Institute, 2004] in Figure 1, panels A and B, respectively. In Figure 1A, the minimum, maximum, and mean audiograms for the better ear (represented by triangles) are displayed; in

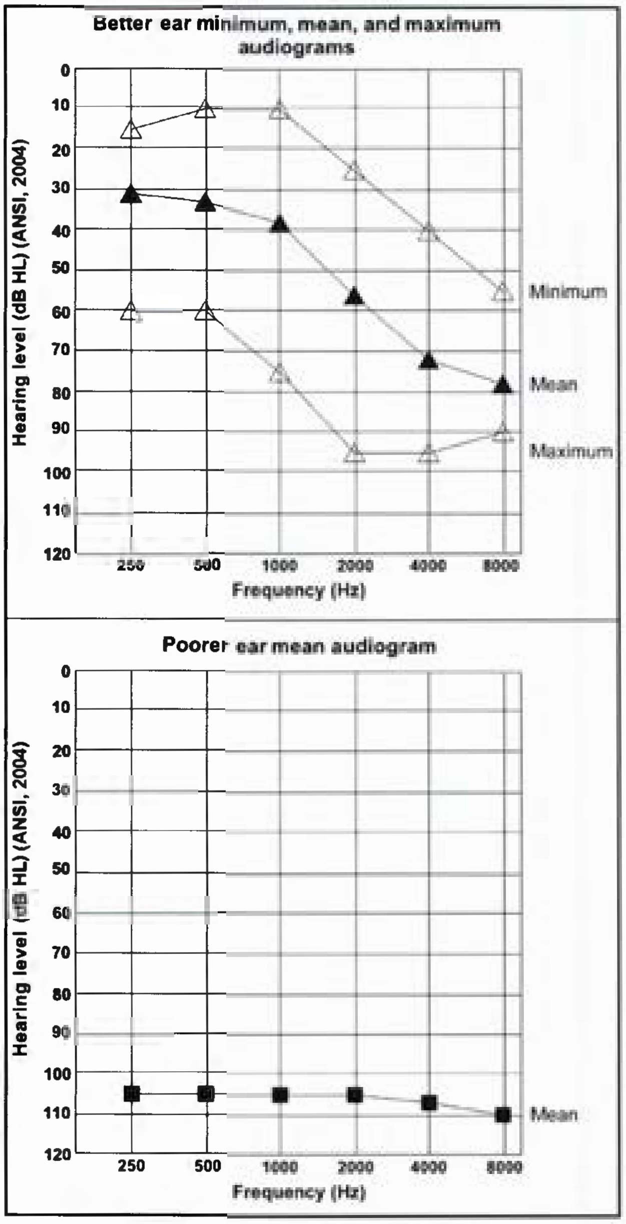

Figure 1. *(Top panel, 1A)* The mean audiogram and lower and upper ranges of hearing thresholds for the participants' better ear. *(Bottom panel, 1B)* The mean audiogram for the participants' poorer ear.

Figure 1B, the mean audiogram for the poorer ear (represented by solid squares) is shown. The right ear was the better ear for 24 participants, while the remaining 15 participants had aidable hearing in their left ears. Participants' word recognition in quiet (NU-6; Tillman and Carhart, 1966) performance obtained at 40 dB sensation level regarding the participants' speech recognition threshold for spondaic words ranged from 0 to 100% for the better ear with an average of 76.1% (sd = 23).

Previous BiCROS

Table 1 shows the BiCROS devices used by the participants at the time of recruitment into the study. These devices are referred to as the participants' previous BiCROS. As a criterion for the study, all participants were experienced BiCROS users; however, as shown in the fifth column in Table 1, the length of experience varied. On average, participants utilized their

Table 1. Participants' Previous BiCROS Manufacturer, Model of Aid, and Style

	Previous BiCROS					
Ss No.	Make	Model	Style	Experience(mo)	RMS-D (.5–4 kHz)	Target
1	PHONAK	EXELIA + CROSLink	BTE	23.27	2.06	On
2	INTERTON	IQ-CM WLXX	FS	35.07	9.23	Under
3	PHONAK	EXELIA ART M + CROSLink	BTE	4.50	15.69	Under
4	INTERTON	IQ-CM WLXX	FS	23.90	7.91	Under
5	PHONAK	EXELIA ART M + CROSLink	BTE	10.30	5.45	Under
6	RESOUND	IQ-CM-WLXX	FS	5.03	10.32	Under
7	PHONAK	ELEVA 211 + CROSLink	BTE	49.70	5.70	Under
8	INTERTON	IQ-CM WLXX	FS	26.47	5.55	Under
9	PHONAK	EXELIA ART + CROSLink	BTE	13.53	5.55	Over
10	INTERTON	IQ-QUANTUM MULTICROS	BTE	14.03	4.39	On
11	INTERTON	IQ-CM WLXX	FS	14.90	10.09	Under
12	PHONAK	NAIDA IX + CROSLink	BTE	15.13	5.74	Over
13	PHONAK	SAVIA ART 211 + CROSLink	BTE	42.73	11.51	Under
14	PHONAK	EXELIA ART M + CROSLink	BTE	4.87	6.60	Under
15	PHONAK	EXELIA ART M + CROSLink	BTE	3.30	9.33	Over
16	INTERTON	IQ-QUANTUM MULTICROS	BTE	23.33	10.22	Under
17	PHONAK	EXELIA + CROSLink	BTE	14.90	5.24	Over
18	PHONAK	EXELIA ART M + CROSLink	BTE	6.57	5.59	Under
19	RESOUND	IQ-CM-WLXX	FS	8.53	4.92	On
20	PHONAK	EXELIA ART + CROSLink	BTE	13.33	3.67	On
21	INTERTON	IQ-CM WLXX	FS	16.47	15.39	Under
22	PHONAK	EXELIA ART M + CROSLink	BTE	4.67	7.60	Under
23	PHONAK	EXELIA ART M + CROSLink	BTE	11.67	2.92	On
24	RESOUND	IQ-QUANTUM MULTICROS	BTE	8.90	10.16	Under
25	INTERTON	IQ-QUANTUM MULTICROS	BTE	24.57	1.87	On
26	INTERTON	IQ-QUANTUM MULTICROS	BTE	49.30	10.43	Under
27	INTERTON	IQ-QUANTUM MULTICROS	BTE	20.97	10.14	Under
28	RESOUND	IQ-CM-WLXX	FS	9.10	7.58	Under
29	PHONAK	EXELIA ART + CROSLink	BTE	14.13	1.80	On
30	PHONAK	EXELIA ART M + CROSLink	BTE	3.67	4.15	On
31	RESOUND	IQ-CM-WLXX	FS	7.23	4.36	On
32	PHONAK	EXELIA ART M + CROSLink	BTE	5.33	2.50	On
33	INTERTON	IQ-CM WLXX	FS	51.83	10.22	Under
34	INTERTON	IQ-CM WLXX	FS	38.73	10.42	Under
35	PHONAK	EXELIA ART M + CROSLink	BTE	4.07	2.55	On
36	PHONAK	EXELIA ART M + CROSLink	BTE	4.40	8.96	Over
37	TELEX	349 MCAC	BTE	134.97	11.58	Under
38	INTERTON	IQ-QUANTUM MULTICROS	BTE	27.10	9.03	Over
39	INTERTON	IQ-CM WLXX	FS	15.67	11.02	Under
			Mean	20.67	7.37	
			sd	(23.24)	(3.59)	

Note: Participants' previous BiCROS manufacturer, model of aid, and style (i.e., BTE or FS) are listed. Duration of experience (in months) with the participants' previous device is shown. Obtained from the real-ear verification procedures, participants' RMS-D is shown along with the fit classification (i.e., On, Under, or Over) to the prescribed NAL-NL1 target. BTE = behind the ear; FS = full shell; RMS-D = root-mean-square deviation; sd = standard deviation.

previous BiCROS for 20.67 months (sd = 23.24) prior to enrollment into the study.

Furthermore in Table 1, collapsed across manufacturers, 27 participants wore a BTE BiCROS style while the remaining 12 participants utilized an ITE-FS hearing aid style. In particular, it can be seen in Table 1 that 19 participants used a Phonak CROSLink BiCROS system, 18 others wore an Interton/GN Resound BiCROS, and one participant wore a Telex BiCROS. These devices varied in digital signal processing capabilities, functionality, and physical design. Specifically, the Phonak CROSLink transmitter was housed in a standard BTE casing, with an omni-directional microphone, that transferred the acoustic signal via a 374 kHz AM signal to a CROSLink receiver that was coupled to a hearing aid with an audio shoe. The CROSLink was coupled to various BTE style hearing aids on the better ear; thus, its digital-to-analog conversion was dependent on the digital signal processing capabilities of the better ear hearing aid (participants' better ear hearing aids are also listed in Table 1). On the other hand, the BiCROS systems from Interton/GN Resound, the IQ Quantum MULTICROS (BTE), and IQ-CM WLXX (ITE-FS) had predefined paired devices and did not require a separate hearing aid for the better ear. Both Interton/GN Resound BiCROS systems are equipped with omni-directionality with the receiver having three adjustable channels for wide dynamic range compression and frequency band adjustments. For the Interton/GN Resound BiCROS systems, the signal from the transmitter to the receiver was transmitted via 1.8 MHz frequency. Finally, operating on a 374 Hz frequency transmission signal, the Telex 349 MCAC BiCROS was a large BTE device utilizing a 675 battery. This device had the most limited processing capabilities with an adjustable two channel receiver.

New BiCROS

In the present study, the Phonak CROS was selected as the experimental new BiCROS system because it was available in both ITE and BTE styles allowing more fitting options. The Phonak CROS can be configured as a CROS or BiCROS system and consists of (1) a transmitter microphone device in small casing (BTE: Audeo Smart casing, or ITE: in the canal [ITC], half shell [HS], or FS) and (2) a Phonak hearing aid (receiver) with wireless Spice Technology (Audeo Spice Smart [BTE] or Ambra platform line [BTE and all ITE styles]). Regardless of configuration, the Phonak CROS System utilizes a digitally coded, inductive transmission technology with a transmission frequency of 10.6 MHz. By creating a hearing instrument body area network, the Phonak CROS System transmits the full audio bandwidth from the transmitter to the better ear instrument. In addition to the proclaimed improvements in wireless transmission, the new (Bi)CROS is reported to have advanced directionality algorithms, improved cosmetic appeal with a "user-friendly" set-up design, and advanced acoustic indicators.

Table 2. Participants' New BiCROS (Manufactured by Phonak) Model and Style of Aid

	New BiCROS		
Ss No.	Model	Style	RMS-D (.5–4 kHz)
1	Audeo Spice Smart IX	BTE	1.50
2	Ambra	HS	4.15
3	Ambra	ITC	2.29
4	Ambra	FS	1.50
5	Ambra	HS	1.80
6	Audeo Spice Smart IX	BTE	2.06
7	Audeo Spice Smart IX	BTE	3.04
8	Ambra	ITC	3.28
9	Ambra	ITC	2.60
10	Ambra	FS	1.41
11	Ambra	FS	1.87
12	Audeo Spice Smart IX	BTE	1.80
13	Audeo Spice Smart IX	BTE	2.55
14	Audeo Spice Smart IX	BTE	2.35
15	Audeo Spice Smart IX	BTE	4.09
16	Audeo Spice Smart IX	BTE	3.24
17	Audeo Spice Smart IX	BTE	1.87
18	Audeo Spice Smart IX	BTE	1.80
19	Ambra	HS	1.80
20	Ambra	HS	1.80
21	Ambra	HS	3.81
22	Audeo Spice Smart IX	BTE	3.43
23	Ambra	FS	0.50
24	Audeo Spice Smart IX	BTE	1.80
25	Audeo Spice Smart IX	BTE	4.44
26	Audeo Spice Smart IX	BTE	1.22
27	Audeo Spice Smart IX	BTE	2.35
28	Ambra	FS	1.87
29	Ambra	HS	1.00
30	Audeo Spice Smart IX	BTE	2.35
31	Audeo Spice Smart IX	BTE	1.87
32	Audeo Spice Smart IX	BTE	1.80
33	Ambra	HS	4.03
34	Audeo Spice Smart IX	BTE	2.60
35	Audeo Spice Smart IX	BTE	1.66
36	Ambra	HS	1.66
37	Audeo Spice Smart IX	BTE	2.50
38	Audeo Spice Smart IX	BTE	1.94
39	Ambra	HS	2.50
		Mean	2.31
		sd	0.92

Note: Participants' new BiCROS (manufactured by Phonak) model and style of aid (i.e., BTE or FS, HS, or ITC) are shown. Obtained from the real-ear verification procedures, participants' RMS-D is listed. BTE = behind the ear; FS = in-the-ear full shell; HS = half shell; ITC = in the canal; RMS-D = root-mean-square deviation; sd = standard deviation.

The specifics regarding the participants' new BiCROS systems are shown in Table 2. The exact style size (i.e., ITC, HS, FS) and acoustic coupling (e.g., venting, etc.) depended on the participant's hearing loss configuration and severity. Participants, however, were allowed to choose their preferred new BiCROS system style (i.e., BTE or ITE). Thirteen participants switched styles; specifically, 10 participants changed from a previous BTE BiCROS to a new ITE and three participants selected a new BTE BiCROS compared to their previous ITE style.

BiCROS Verification

Ultimately, the goal of a successful BiCROS fitting is to provide appropriate amplification to the better ear and provide a transparent transfer of the acoustic information from the poorer ear to the better ear (Dillon, 2001; Pumford, 2005; Taylor, 2010). With this goal in mind, both the previous and new BiCROS systems were fit and verified using the same standard clinical procedures. The standard clinical procedures include three real-ear responses, which are described below, that were compared to National Acoustics Laboratory nonlinear fitting procedure version 1 targets (NAL-NL1; Dillon, 1999; Byrne et al, 2001; Dillon et al, 2007). The real-ear probe microphone measurements were obtained using a speech-mapping input signal via an AudioScan® Verifit™ real-ear analyzer (Audioscan Verifit, 2009; Dillon, 2001; Pumford, 2005).

The first of the three standard real-ear responses obtained ensured appropriateness of gain for the better ear (receiver). A 65 dB sound pressure level (SPL) input signal was presented at 0° azimuth and the long-term average speech spectrum (LTASS) real-ear aided response (REAR) was obtained. Next, to evaluate the BiCROS transmission, two responses were obtained. First, a 65 dB SPL input signal was delivered at 45° azimuth with respect to the better ear closest to the speaker. This LTASS REAR was obtained from the probe microphone in the better ear along with the reference microphone on the better ear. Next, with the transmitter activated and speaker directed to 45° azimuth with respect to the poorer ear, another REAR with the same 65 dB input signal was obtained. In this case, the reference microphone was activated on the poorer ear but the probe microphone was still positioned inside the better. The REARs from both directions should match, providing an acoustically transparent transmission of sound from the poorer ear to the better ear. Lastly, we obtained the real-ear saturation response with a maximum pressure output of 85 dB SPL to ensure that, across the frequency response, loud sounds were tolerable as indicated by being below the estimated uncomfortable loudness levels.

The root-mean-square difference (RMS-D) was calculated between the NAL-N1 target compared to LTASS REAR at 500, 1000, 2000, and 4000 Hz for the 65-dB input signal at 0° azimuth. Tables 1 and 2 show the RMS-D values for the previous BiCROS and new BiCROS systems, respectively. The RMS-D was used to assess the closeness to target for each fitting, as well as compare the fit across each participants' previous and new BiCROS devices. The average RMS-D for the previous BiCROS devices was 7.37 (sd = 3.59), whereas the new BiCROS RMS-D average of 2.31 (sd = 0.92) indicated that the new BiCROS frequency response provided a closer match to the target. Assessment with a paired samples *t*-test indicated a statistically significant difference ($p < 0.05$) in RMS-D between the participants' previous and new BiCROS devices. A RMS-D value of ≤5 is considered "on" target (Cox and Alexander, 1990; Mueller, 2005). All new BiCROS systems were on target; however, as seen in the seventh column of Table 1, only 11 of the previous BiCROS systems matched target, six were over target, and 22 were under target. The inability of the previous BiCROS system to match target successfully may be due to the inferior digital signal processing in some of the devices. The lack of programming flexibility, which can limit the access to fine-tune compression and frequency responses of the devices, could have caused under- or overamplification as the devices could only be adjusted according to low-, mid-, and high-frequency outputs without being able to manipulate small changes in gain needed for varying hearing loss configurations. For example, 15 of the 22 previous BiCROS devices that were under target were due to the device not being able to match target at 2000 Hz secondary to a precipitous hearing loss.

Objective Outcome Measure

Words in Noise. Participants completed soundfield speech-in-noise testing measured by the Words-in-Noise (WIN; Wilson, 2003) test. The WIN test involved the presentation of monosyllabic words in multitalker babble at seven signal-to-noise ratios (SNRs) from 24 to 0 dB in 4 dB decrements. The WIN recordings were played from a compact disc player (Model CDC-5090C/R; Sherwood) routed to an audiometer (Model 61; Grason and Stradler) to soundfield speakers (Model FTX Series III to GSI wall-mounted speakers; Ashley Power Amplifier). Calibration of the soundfield environment, completed weekly, utilized a substitution method using a Larson-Davis sound level meter that ensured an accurate soundfield presentation level. The WIN test was presented at 70 dB SPL for the five different listening conditions. Figure 2 shows a schematic of the different listening conditions. As seen in Figure 2A, three of the five different listening conditions tested had speech at 0° azimuth and noise at 180° azimuth for the following configurations: (1) unaided, (2) monaural receiver only, and, (3) BiCROS. Then, shown in Figure 2, panels B and C, also with the BiCROS activated, at azimuths 90° and 270° with either the (4) speech at the poorer ear (transmitter) and noise at the better ear (receiver), or (5) speech at the better ear (receiver) and noise at the poorer ear (transmitter). Performance was evaluated using the 50% point on the listeners' psychometric function, calculated with the Spearman-Kärber equation (Finney, 1952), for each condition.

As for test order, listening conditions (4) and (5) were counterbalanced, but, conditions (1) through (3) were conducted in order to ensure the most difficult condition was completed first (i.e., unaided) and difficulty decreased with postulated increase in accessibility of acoustic cues. As the WIN test has list equivalence across all four lists, randomization was completed to ensure each list was used the same amount of time. Odd-numbered participants received list one first, while even-numbered participants were presented list two first and then lists were alternated.

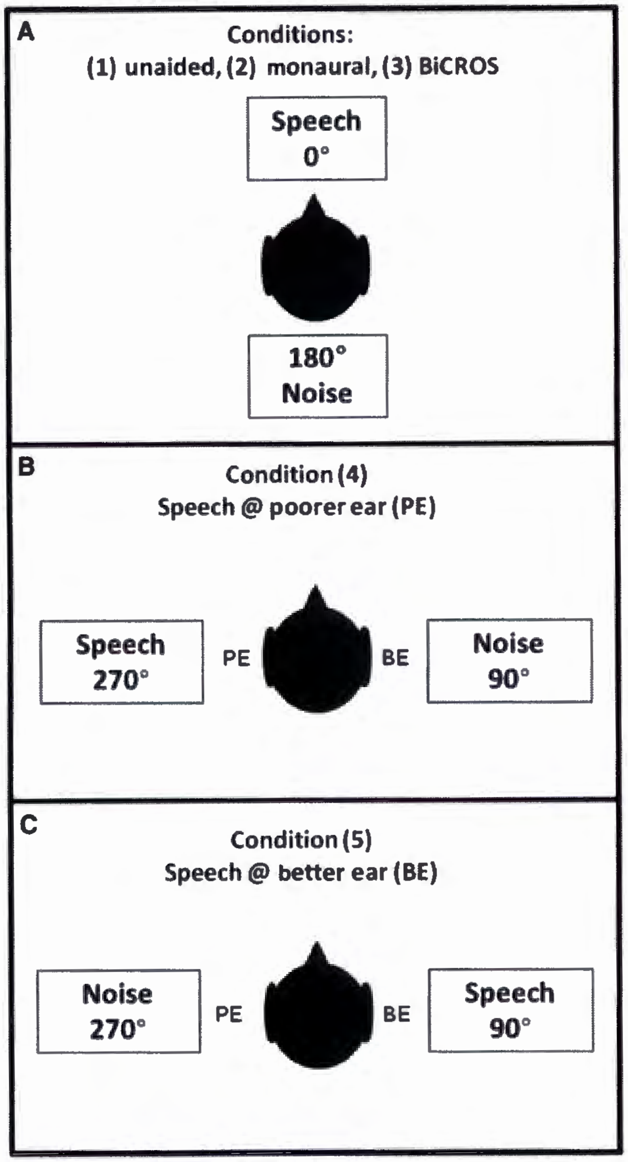

Figure 2. *(A-C)* Schmatic of the soundfield setup for the words-in-noise (WIN) testing. *(A)* The speech was presented at 0° azimuth and noise at 180° azimuth for the following listening conditions: (1) unaided, (2) monaural (receiver only), and (3) BiCROS. *(B-C)* The speech was also presented with the BiCROS activated, at azimuths 90° and 270° representing listening condition (4) speech at the poorer ear (PE) (transmitter) and noise at the better ear (BE) (receiver), or condition (5) speech at the better ear (receiver) and noise at the poorer ear (transmitter).

Subjective Outcomes Measures

Speech, Spatial, and Qualities of Hearing Questionnaire

The Speech, Spatial, and Qualities of Hearing Questionnaire (SSQ; Gatehouse and Noble, 2004) was used to evaluate influences of cochlear function on auditory disability and handicap. Participants were asked 50 questions about auditory attention, perceptions of distance and movement, sound-source segregation, listening effort, prosody, and sound quality. The self-reporting SSQ is divided into three sections for speech perception, spatial hearing, and more general qualities of hearing. The SSQ can then be further analyzed into 10 pragmatic subscales (Gatehouse and Akeroyd, 2006). In the Speech domain, there are four subscales: (1) Speech in Quiet, (2) Speech in Noise, (3) Speech in Speech Contexts, (4) and Multiple Speech-Stream Processing and Switching. In the Spatial domain, there are two subscales: (1) Localization and (2) Distance and Movement. Finally, in the Qualities category, there are four subscales: (1) Sound Quality and Naturalness, (2) Identification of Sounds and Objects, (3) Segregation of Sounds, and, (4) Listening Effort.

The questionnaire was self-administered, paper and pen mode, and had the standard 0- to 10-point ruler scaling (Gatehouse and Noble, 2004). The left side of the 10-point ruler scale (toward "0") represented complete inability or complete absence of quality. The right side (toward "10") represented complete ability or complete presence of the quality. Hence, a large number response reflects greater ability (less disability) or better quality. Additionally, if a question did not pertain, the participant was encouraged to check the "not applicable" or "wouldn't be able to hear" box that was available.

MarkeTrak

Selected questions from MarkeTrak (Kochkin, 1990) were self-administered to the participants for assessment of satisfaction and benefit. The items were specifically selected because they focused on satisfaction with the BiCROS features (e.g., overall comfort, battery life) and satisfaction in situations known to be difficult for patients with SSD (e.g., conversations in noise, in car, on the telephone). Participants were asked to rate their BiCROS experiences using a 5-point ordinal scale: "Very dissatisfied = 1," "Dissatisfied = 2," "Neutral = 3," "Satisfied = 4," and "Very satisfied = 5." Participants were also able to select not applicable, "N/A," if the feature or situation did not relate to them.

Open-Ended Questions

All participants were interviewed to examine any positive and negative attributes regarding the new BiCROS system that may have not been assessed by the other standardized closed-set questionnaires. The following three questions were asked: (1) What was the number one attribute that you liked the most about your new BiCROS system? (2) What did you like least about the new BiCROS system? and (3) Would you like to keep the new BiCROS system?

The responses were recorded by a research assistant and were later entered into a database. Responses were reviewed across participants for similar topics by two researchers independently. Then, two blind reviewers categorized the responses into the topics. There was a 96% agreement on all responses into the designated topics and any disagreements were settled by a third reviewer.

Study Protocol

Participants completed three research visits and were compensated $20.00 per visit. At Visits 1 and 3, administration of the SSQ and MarkeTrak questionnaires were counterbalanced to control for order effects. Across all visits, the BiCROS fitting, verification, and WIN testing took place in an Industrial Acoustics Company, double-walled, sound-treated booth.

Visit 1

A full audiometric evaluation was completed if the patient did not undergo an evaluation within the past 6 months. As head size can negatively affect BiCROS transmission (Punch, 1988; Taylor, 2010), the head breadth of each participant was measured (in centimeters) from above and behind the ears using a laboratory constructed caliper. Verification of the previous BiCROS fitting was completed, and subjective and objective outcome measures were obtained with respect to the participants' previous BiCROS. Participants then selected the hearing aid style preferred and earmold impressions were obtained, if necessary, for the new BiCROS device.

Visit 2

Three to 6 weeks after Visit 1, participants returned for Visit 2. The participants' new BiCROS was fit with the following program sequence: start-up program with automatic directionality ("Soundflow") and transmitter activated; Program 1 with monaural omni-directionality ("Calm situation") and transmitter disabled. Data log was initiated to monitor device usage and quantify amount of time in each program. In addition, the BTE devices were set with an automatic acoustic telephone, while the ITE had an automatic telecoil activated. Push buttons on both the BTE and ITE devices were active to allow for manual program change. Access to a volume control was only available on the ITE devices with a digital volume wheel present on the receiver device only. The new BiCROS fitting was verified using standard clinic procedures (details explained in verification section above). A research assistant instructed the participants regarding proper use and care of the new BiCROS. Participants were provided a log to record any likes or dislikes of the system and keep track of the battery life.

Interim Visit

An interim appointment between Visit 2 and Visit 3 was completed, if necessary, if the participants were experiencing difficulties. At the interim visit, the research assistant would recounsel regarding proper use and care of the device, and make any necessary programming and modifications to the device to rectify the participants' complaints. If programming changes were required, real-ear probe microphone verification was completed to ensure acoustic functionality. Fourteen participants required interim visits and the majority of these return appointments were due to cerumen impaction in the receiver. These returning participants were recounseled on proper cleaning and wax-trap replacement.

Visit 3

Visit 3 was completed at least 4 weeks after Visit 2, or at least 4 weeks post an interim visit, if the participant experienced a lapse in continued use of the new BiCROS. This assured that each participant had a minimum of 4 weeks consistent and functional use with the new BiCROS. The average trial period varied from 27–65 days with an average of 38.1 days. At Visit 3, participants completed all posttrial subjective and objective outcome measures using or with regards to their new BiCROS. The participants then decided if they would like to utilize their new BiCROS system consistently rather than their previous BiCROS system.

RESULTS AND DISCUSSIONS

The aim of the present study was to determine whether there were differences in subjective and objective outcome measures associated with the use of a new BiCROS system compared to previous-generation BiCROS systems. First, speech-in-noise performance, evaluated by the WIN test, is presented. Then, self-perceived handicap related to speech, spatial, and quality of scores, evaluated by the SSQ, is presented. And, to conclude, self-reported satisfaction and benefit, assessed with selected MarkeTrak items and open-ended questions, are presented.

Objective Outcome Measure

WIN

Figure 3 shows the mean thresholds and standard deviations obtained, per listening condition, during Visit 1 (light bars) either unaided or with the previous BiCROS system and unaided or with the new BiCROS system during Visit 3 (dark bars). Previously described in Figure 2, recall that the listening conditions evaluated were: speech presented at 0° and noise 180° while (1) unaided; (2) monaural receiver only; and, (3) BiCROS; then, also with the BiCROS activated, at azimuths 90° and 270° with either (4) the speech at the poorer ear (transmitter) and noise at the better ear (receiver); and, (5) speech at the better ear (receiver) and noise at the poorer ear (transmitter).

As seen in the Figure 3, condition (1), unaided, had the highest (poorest) thresholds at both testing sessions. Higher and unchanged SNR thresholds across Visits 1 and 3 were expected due to the severity of hearing losses. Throughout the other conditions, which utilized some form of amplification (i.e., monaural or BiCROS), it can be seen from Figure 3 that performance was better than the unaided condition and a poorer performance was observed when the listeners utilized their previous BiCROS. Specifically, in condition (2), where the participants were monaurally aided (receiver only), the mean SNR threshold from the previous to new BiCROS device showed a 3.1 dB SNR improvement.

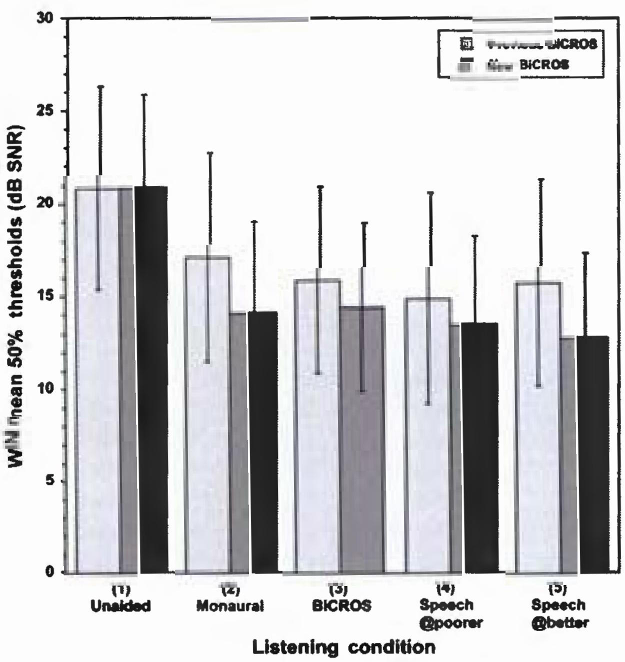

Figure 3. Words-in-Noise (WIN) test mean thresholds (dB SNR) and standard deviations obtained across the five listening conditions at either Visit 1 (previous BiCROS) or Visit 3 (new BiCROS).

This indicated that the monaural amplification provided from the new BiCROS system receiver led to improvements in speech-in-noise understanding. Similarly, condition (3), where the participants were aided with the BiCROS, there was an average improvement of 1.5 dB SNR with utilization of the new BiCROS compared to the previous BiCROS.

Condition (4), speech at the poorer ear, and condition (5), speech at the better ear, had an increased spatial separation of the speech and noise as either the stimulus was directed toward one ear or the opposite (i.e., 90° and 270° azimuth). An improved performance within conditions (4) and (5) was expected because it is well documented that spatial separation improves intelligibility (e.g., Dirks and Wilson, 1969). It can be seen in Figure 3 that performance in conditions (4) and (5) was better than all other conditions. These findings suggest that there is still a spatial release from masking with a BiCROS system as it provides a two-sided listening environment. Also seen in Figure 3, within these two spatially separated conditions, the new BiCROS provided better speech-in-noise recognition compared to the previous BiCROS device. As an example, in condition (5), speech at the better ear and noise at the poorer ear, a mean improvement of 3.0 dB SNR with the new BiCROS was observed.

Indeed, the mean SNR thresholds for the new BiCROS were lower (better) in all aided listening conditions; but, as seen in Tables 1 and 2, the new BiCROS provided better audibility, as indicated by lower RMS-Ds. The difference in audibility may explain, in part, the improvements observed from the WIN testing. Therefore, to determine whether the speech-in-noise understanding improvements were statistically significant, a repeated-measures version of the general linear model analysis of variance (ANOVA) was conducted to examine the main effects and interactions of device and listening condition with the difference in RMS-D as a covariate. Collapsed across all devices, there was a main effect for condition (5 levels) [$F(1,38) = 13.08$, $p < 0.001$]. This significant main effect was expected because with a change in amount of audibility (i.e., unaided, monaural, BiCROS) and/or change in direction in presentation of the stimuli (i.e., azimuth) differences in speech-in-noise understanding were predicted. However, a main effect of session (i.e., Visit 1 with previous BiCROS compared to Visit 2 with the new BiCROS) was not significant [$F(1,38) = 0.001$, $p > 0.05$] when the difference in RMS-D was assigned as a covariate.

Despite the lower (better) thresholds being observed with the new BiCROS across listening conditions 2–5, when audibility was accounted for, the improvements in performance failed to reach statistical significance. Likewise, the interaction between sessions and listening conditions was not significant [$F(4,38) = 0.69$, $p > 0.05$]. This implies that the improved speech-in-noise performance with the new BiCROS was due, in part, to the better frequency response provided by the new BiCROS which gave more access to the signal. It can be argued that the new BiCROS devices were able to meet target better, which demonstrates an advancement in technology. As described earlier, the digital signal processing capabilities in the previous BiCROS devices were lacking and some of the devices where restricted to only two or three adjustable channels for fine-tuning manipulations. Additionally, it was hypothesized that due to the reported improvements in digital signal processing with respect to directionality and noise-reduction algorithms, the new BiCROS system would provide improved speech-in-noise recognition. Improved thresholds were expected especially for listening conditions (4) and (5) where the speech signal and noise was spatially separated as it was assumed there would be decrease the transmission of the noise. Unfortunately, a direct comparison of the previous BiCROS to the new BiCROS digital signal processing cannot be made because of the statistically significant differences in audibility between the devices that were observed.

Subjective Outcome Measures

SSQ

The responses from the SSQ were assessed for each individual item across all three domains (i.e., speech, spatial, qualities), and also according to 10 pragmatic scales within the domains (Gatehouse and Akeroyd, 2006). Figures 4–9 show the mean score obtained for the three domains and pragmatic subscales. Specifically, Figures 4, 6, and 8 show the mean scores obtained for each item with regards to the participants wearing their previous BiCROS (open squares) or new BiCROS (filled squared). Within these figures, mean scores located toward the right of the graph indicate better performance or presence of a quality assessed. A significant improvement in self-rated perception, with the initial p value of 0.05 adjusted with a Bonferroni correction for multiple comparisons, from the new compared to the previous BiCROS is denoted with an asterisk. The corresponding p values and the number of responses per question are listed in these figures as participants whom checked "not applicable" or "would not hear" lead to questions having less than n = 39 responses.

Shown in Figure 4 are the 14 items that compose the speech domain. All speech-domain responses, with the exception of three items, showed a statistically significant improvement in rating for the new BiCROS when assessed with an adjusted paired samples t-test ($p <$ 0.004). The significant increase in perceived speech performance with regards to the new BiCROS functionality compared to the previous BiCROS indicates that in almost all environments where the participants were

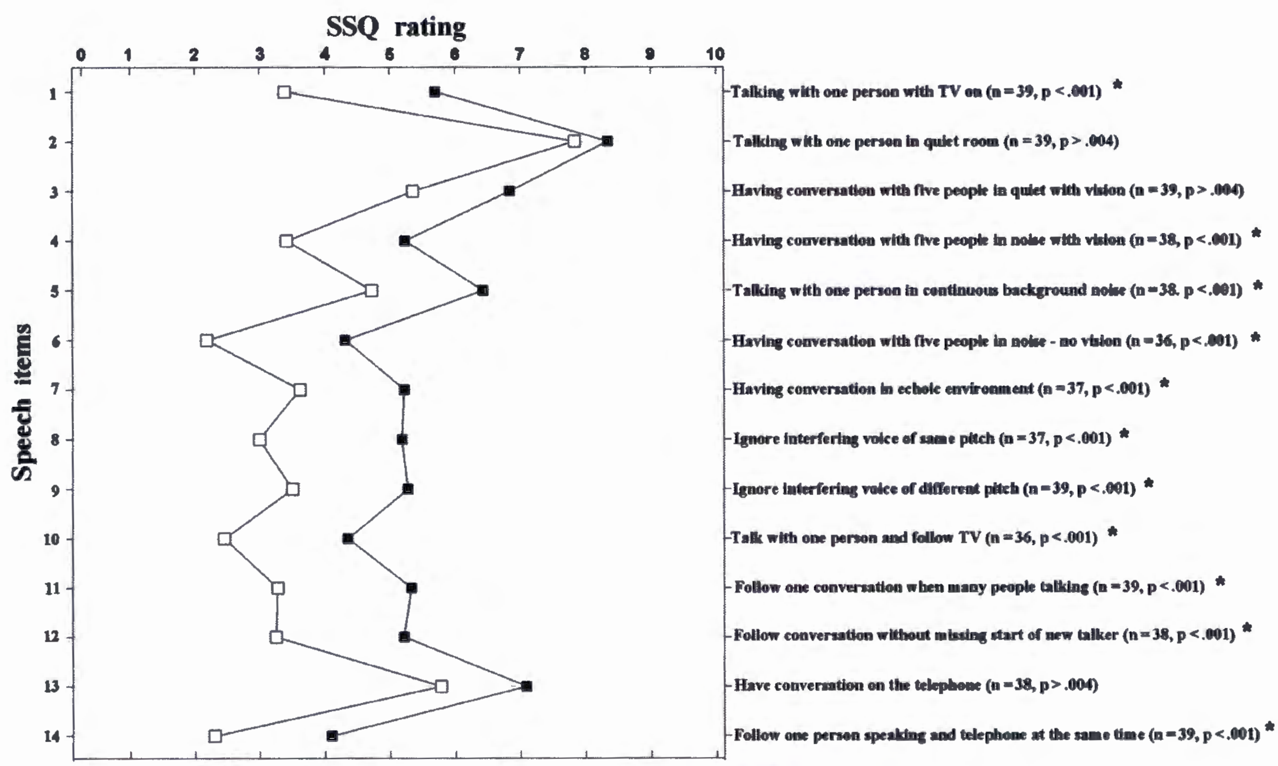

Figure 4. Mean ratings for the speech items of the speech, spatial, and qualities (SSQ) questionnaire are displayed. Statistically significant differences between responses with regards to the participants' previous BiCROS (□) compared to the new BiCROS (■) are indicated with an asterisk (*).

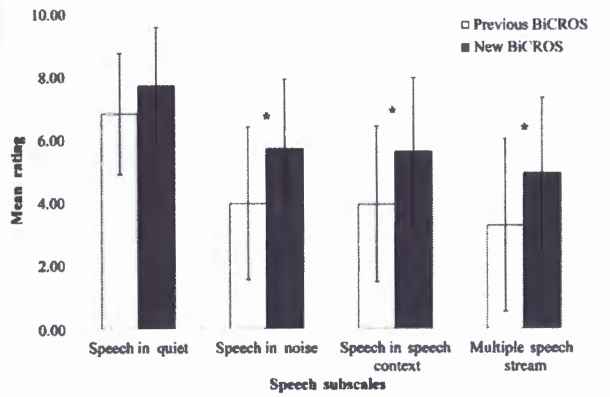

Figure 5. Mean ratings for the speech domain subscales of the speech, spatial, and qualities (SSQ) questionnaire. Statistically significant differences between responses with regards to the participants' previous BiCROS (light bars) compared to the new BiCROS (dark bars) are indicated with an asterisk (*).

asked to listen to speech they rated the new BiCROS as superior compared to their previous BiCROS systems. We further evaluated the speech domain by assessing the four speech subscales which provided additional evidence of improved self-perception of speech abilities with use of the new BiCROS. As shown in Figure 5, the mean ratings with standard deviations show the new BiCROS was rated as higher than the previous BiCROS in all four subscales. The first ("speech in quiet"), second ("speech in noise"), third ("speech in speech context"), and, lastly, the fourth subscale ("multiple speech-stream"), when analyzed with an adjusted paired samples t-test and all except for the "speech in quiet" subscale, showed statistically significant improvement in ratings with the new BiCROS ($p < 0.005$). Overall, looking at the individual speech domain items and the speech subscales, participants rated performance with the new BiCROS as better compared to their previous BiCROS.

Figure 6 shows the mean responses to the 17 items that comprised the spatial domain. The spatial domain addresses the self-perceived handicap relating to directional, distance, and movement judgments. As seen in Figure 6, the mean responses with regards to the new BiCROS are located further right (better) than the responses obtained regarding the previous BiCROS. Indeed, eight of 17 questions showed a significant improvement when analyzed using an adjusted paired

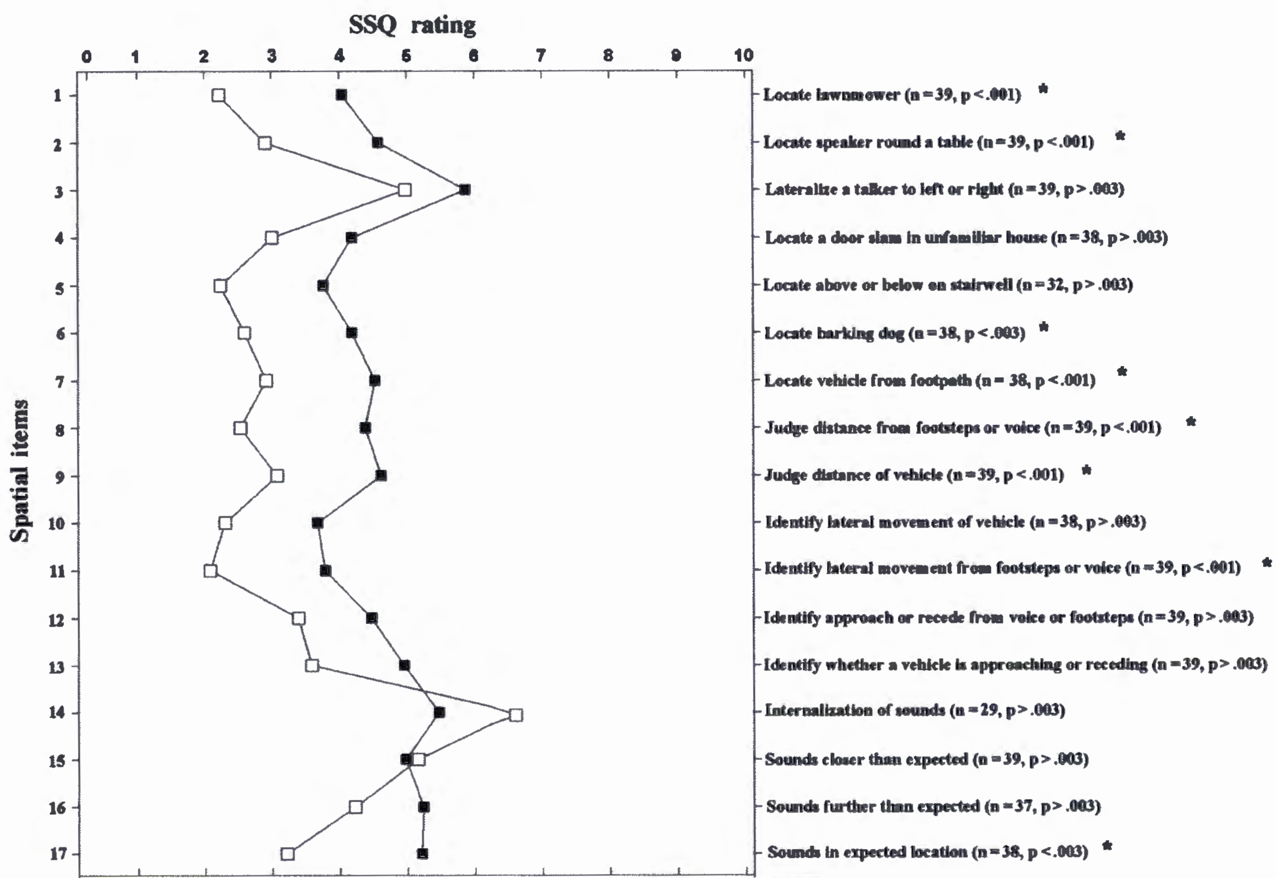

Figure 6. Mean ratings for the spatial items of the speech, spatial, and qualities (SSQ) questionnaire are displayed. Statistically significant differences between responses with regards to the participants' previous BiCROS (□) compared to the new BiCROS (■) are indicated with an asterisk (*).

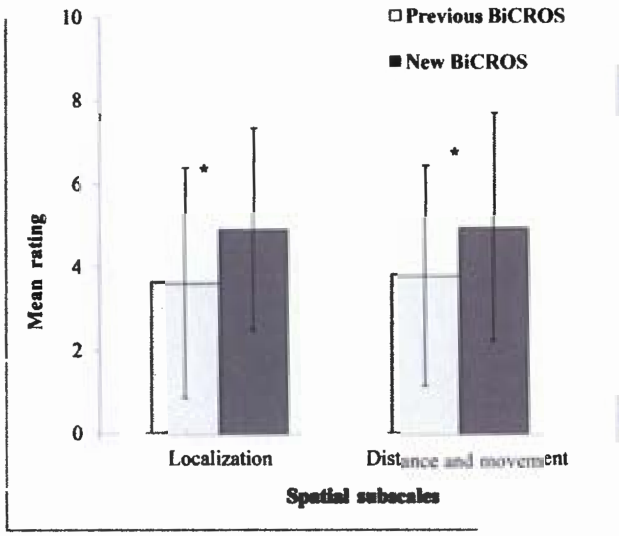

Figure 7. Mean ratings for the spatial domain subscales of the speech, spatial, and qualities (SSQ) questionnaire. Statistically significant differences between responses with regards to the participants' previous BiCROS (light bars) compared to the new BiCROS (dark bars) are indicated with an asterisk (*).

samples t-tests ($p < 0.003$). Observing a significant improvement in self-rated ability in the spatial domain suggests that the new BiCROS improved some of the biggest complaints described by our participants with SSD. To further evaluate the spatial domain, two spatial subscales, "localization" and "distance and movement," were evaluated and mean results are displayed in Figure 7. Again, the mean score obtained for the subscales for both subscales was rated superior for the new compared to the previous BiCROS. Moreover, evaluated by an adjusted paired samples t-test, both spatial subscales reached statistical significance ($p < 0.005$) indicating improved self-perception of spatial abilities. Interestingly, a preceding study did not find a positive improvement on the spatial domain of the SSQ (Hol et al, 2010). In the Hol et al study, however, the CROS devices used were considered previous-generation technology, which may provide additional support that the new-generation BiCROS can enhance self-perceived spatial awareness.

Overall, our data indicate that, within the spatial domain, self-perceived improvements were observed with the use of the new BiCROS. This finding is particularly interesting considering that the SSQ is sensitive to responses from listeners with asymmetrical hearing loss (Noble and Gatehouse, 2004). Respondents with asymmetrical hearing loss typically rate a higher self-perceived disability than respondents with symmetrical hearing loss across all domains of the SSQ, but especially for the spatial domain. This is apparent when comparing Figures 4, 6, and 8. In Figure 6, even with the new BiCROS devices, the mean score obtained within the spatial domain is rated lower on the 10-point scale than scores seen for the speech or qualities domains. To specify, for the spatial domain, the mean scores were typically ranked around 5; but, the speech and qualities domains show mean responses around 7 and 8. With that stated, the SSQ quantified the debilitating effects of SSD for our participants; however, the overall ratings were poorer on the spatial domain implying that even though the new BiCROS provided improvement it did not match the self-perception of binaural listeners.

Figure 8 shows the mean responses for the 19 items composing the qualities domain. The qualities domain includes questions assessing ease of listening, and the naturalness, clarity, and identification of different speakers, different musical pieces and instruments, and different everyday sounds. As seen in Figure 8, all items indicated better self-perceived quality while utilizing the new compared to previous BiCROS. Additionally, five questions showed a statistically significant improvement ($p < 0.003$) with the new BiCROS being ranked as more superior than the previous BiCROS. The four quality subscales (i.e., "sound quality and naturalness," "identification of sound and objects," "segregation of sounds," and "listening effort") were also assessed and mean subscale ratings can be seen in Figure 9. Two subscales, "sound quality" and "listening effort," showed statistically significant improvements between the previous compared to the new BiCROS ($p < 0.005$).

MarkeTrak

Selected questions from the MarkeTrak (Kochkin, 1990) questionnaire were used to assess for satisfaction and benefit regarding features or performance in specific listening environments with regards to wearing the BiCROS systems. As seen in Figure 10, the proportion of participants who rated satisfaction as either "very satisfied" or "satisfied" are grouped together and are represented on the right side of the figure. On the left side, however, respondents who rated satisfaction as "very dissatisfied" and "dissatisfied" were combined. The responses showed a shift in the distributions toward the right for the new BiCROS system. This pattern of results indicates that when asked about satisfaction regarding the BiCROS systems, higher levels of satisfaction were found for the new BiCROS systems than the previous BiCROS systems.

To further explore the satisfaction data for device features and listening environments, the data were examined using the Wilcoxon matched-pairs signed ranks test, a nonparametric alternative to the related t-test, which provides a Z statistic. With regards to the previous compared to the new BiCROS, the percentage of satisfied to dissatisfied participants changed significantly on all items assessed. The number of respondents, the Z statistic, and corresponding p value are

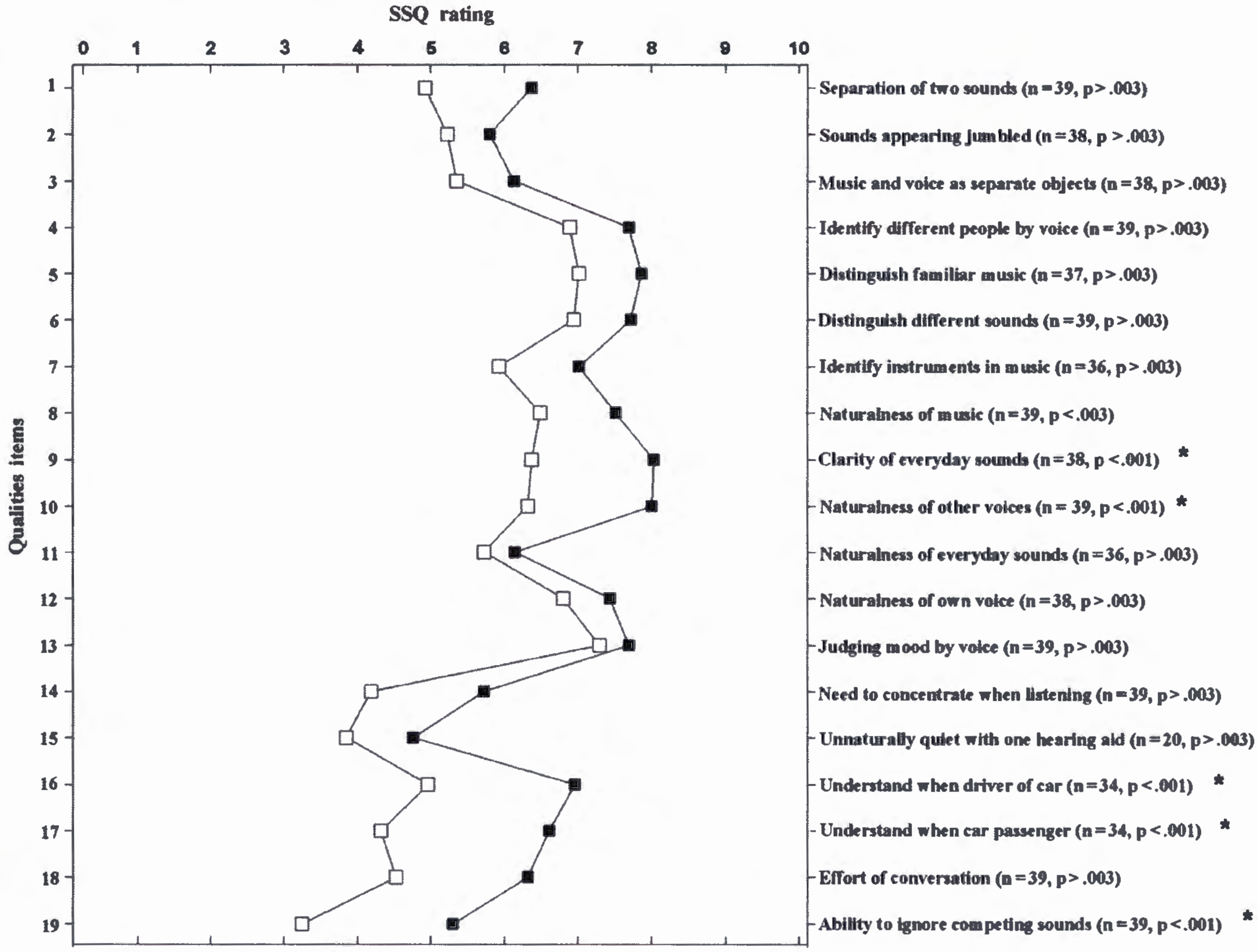

Figure 8. Mean ratings for the qualities items of the speech, spatial, and qualities (SSQ) questionnaire are displayed. Statistically significant differences between responses with regards to the participants' previous BiCROS (□) compared to the new BiCROS (■) are indicated with an asterisk (*).

also shown in Figure 10 for each item. Interestingly, all questions showed a significant increase in satisfaction rating in favor of the new BiCROS except for the item which inquired about the participants' satisfaction with battery life. Responses for the battery life question showed a switch in the distribution where the new BiCROS was rated as less satisfied compared to the previous BiCROS. Overall, despite the dissatisfaction with battery life, participants rated the new BiCROS more satisfactory than their previous BiCROS system.

Open-Ended Questions

In Figure 11, the percentage of responses per category for the three open-ended questions is shown. In Figure 11A, it can be seen that for Question (1), "What was the number one attribute that you liked the most about your new BiCROS system?," the following categories were identified: quality of sound (n = 12), improved hearing (n = 8), device physical properties (n = 11), ease of use (n = 3), and other (n = 5). The categorized responses indicated that both acoustic (i.e., quality of sound and improved hearing [n = 20]) and nonacoustic (i.e., device physical properties and ease of use [n = 14]) factors contributed to the most-liked attribute of the new BiCROS.

As for the least-liked attribute, Question (2) asked, "What did you like least about the new (Bi)CROS system?" As shown in Figure 11B, the responses were grouped into the following categories: excessive battery drain (n = 13), problems with device physical properties (n = 10), problems with manual adjustments (n = 7), other (n = 7), and nothing liked the least (n = 5). Interestingly, none of topics identified for this question directly related to the acoustic- or sound-quality features of the new BiCROS; but instead, most categories dealt with disapproval of some physical element or functionality of the device. The number one complaint about the new BiCROS was excessive battery replacement. Participants were asked to keep track of battery life

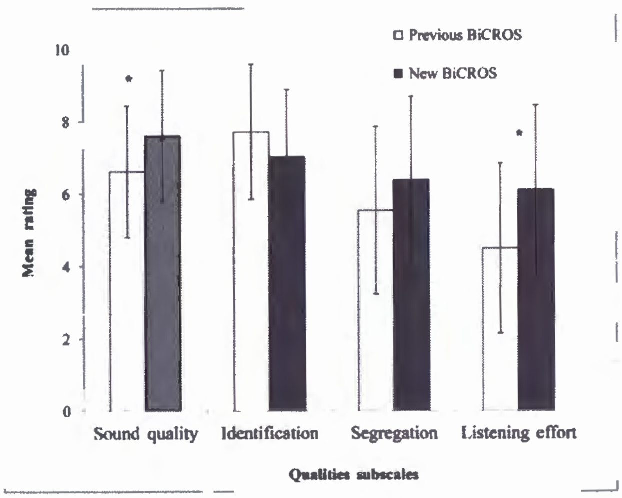

Figure 9. Mean ratings for the qualities domain subscales of the speech, spatial, and qualities (SSQ) questionnaire. Statistically significant differences between responses with regards to the participants' previous BiCROS (light bars) compared to the new BiCROS (dark bars) are indicated with an asterisk (*).

and were provided a journal to annotate the day and time they changed the batteries (e.g., total hr use per battery, acoustic indicator beeps heard, and how often, etc). It is possible that having to document the battery replacements made the participants more aware of the process and caused even more frustration. The negative opinions about battery drain were also seen in the MarkeTrak questionnaire where the distribution in satisfaction shifted toward a dissatisfaction rating for the battery life feature.

Finally, Question (3) asked, "Would you like to keep the new BiCROS?" Thirty-seven participants decided to utilize the new BiCROS on a regular basis instead of their previous devices. Factors such as uptake, retention, and usage are good indicators of approval with amplification. Participants self-reported more daily use with the new BiCROS compared to their previous device. Complimentary to the decision to keep the new BiCROS and the self-report of daily use, the data logging downloaded from the new BiCROS indicated high usage. From the data logs, the mean total hours of usage since the fitting was 365.9 hr (sd = 188.92). Additionally, the average hours per daily use collected from the devices showed participants utilized the system on average 9.94 hr/day (sd = 4.41). As a comparison, Hill et al (2006) evaluated 91 (Bi)CROS users with wired digital devices and reported similar high-satisfaction indicators (e.g., 76% retention and 3.4/5 positive scaling rating on generic self-reported questionnaire). In the Hill et al study, the participants self-purchased their (Bi)CROS devices; thus, as hearing aid outcomes obtained from VA patients are similar to private-pay patients (Smith et al, 2009), it may be reasonable to believe that the present results with high satisfaction and usage could generalize to the private sector too.

Nonetheless, the two participants that decided not to keep the new BiCROS devices were unsatisfied with the device performance for two different reasons. One participant was unsatisfied with the ITE style of the device and reported poor retention. This participant's previous BiCROS device was a BTE and she preferred the retention properties of the device being snug behind her pinna. According to the data log report, this participant wore the device for a total of 24 hr over the entire 4-week trial period (0.6 hr/day). The other participant that decided not to keep the new BiCROS device stated, regardless of being an experienced BiCROS user, he did not care for wearing two hearing aids and would rather utilize a device in his better ear only. This participant did wear the new device (i.e., data log reported 307 total hr of use and 14.8 hr/day). Overall, the majority of participants elected to keep the new BiCROS, and this can be interpreted as the new BiCROS device being good or better than the participants' previous BiCROS system.

CONCLUSIONS

The goal of the present study was to evaluate the subjective and objective outcome measures associated with the use of a new-generation BiCROS system. We hypothesized that the new BiCROS with its reported improved wireless transmission, signal processing, and physical design would be as good, or better than, the participants' previous BiCROS systems. Although several positive findings are reported in the present study, limitations of the study must be addressed. The primary limitation was in the design of the study. As this was not a controlled-randomized trial, results are to be interpreted with caution. Thus, a possible inflation of positive findings may have occurred due to a placebo effect (Dawes et al, 2011). Specifically, the subjective ratings could have been inflated because the participants were aware the study was evaluating new BiCROS technology. Next, success with amplification is known to depend on motivation and this has been shown as true for all types of hearing aids (Valente and Oeding, 2010), including (Bi)CROS systems (Harford and Dodds, 1966). As our participants self-elected to partake in the study they may have been more motivated than other patients with SSD. Finally, the results reported are limited to BiCROS systems only. Consequently, the present study cannot speculate about performance and preference of CROS users with the new-generation device, also considering that BiCROS users typically report more satisfaction and acceptance than CROS users (Harford and Dodds, 1966; Taylor, 2010; Hol et al, 2010). Further investigation is needed on CROS devices and patients without hearing aid experience as the present reported data are from experienced BiCROS users only.

Nevertheless, the overall findings from the present study were favorable as seen by an overlap of positive

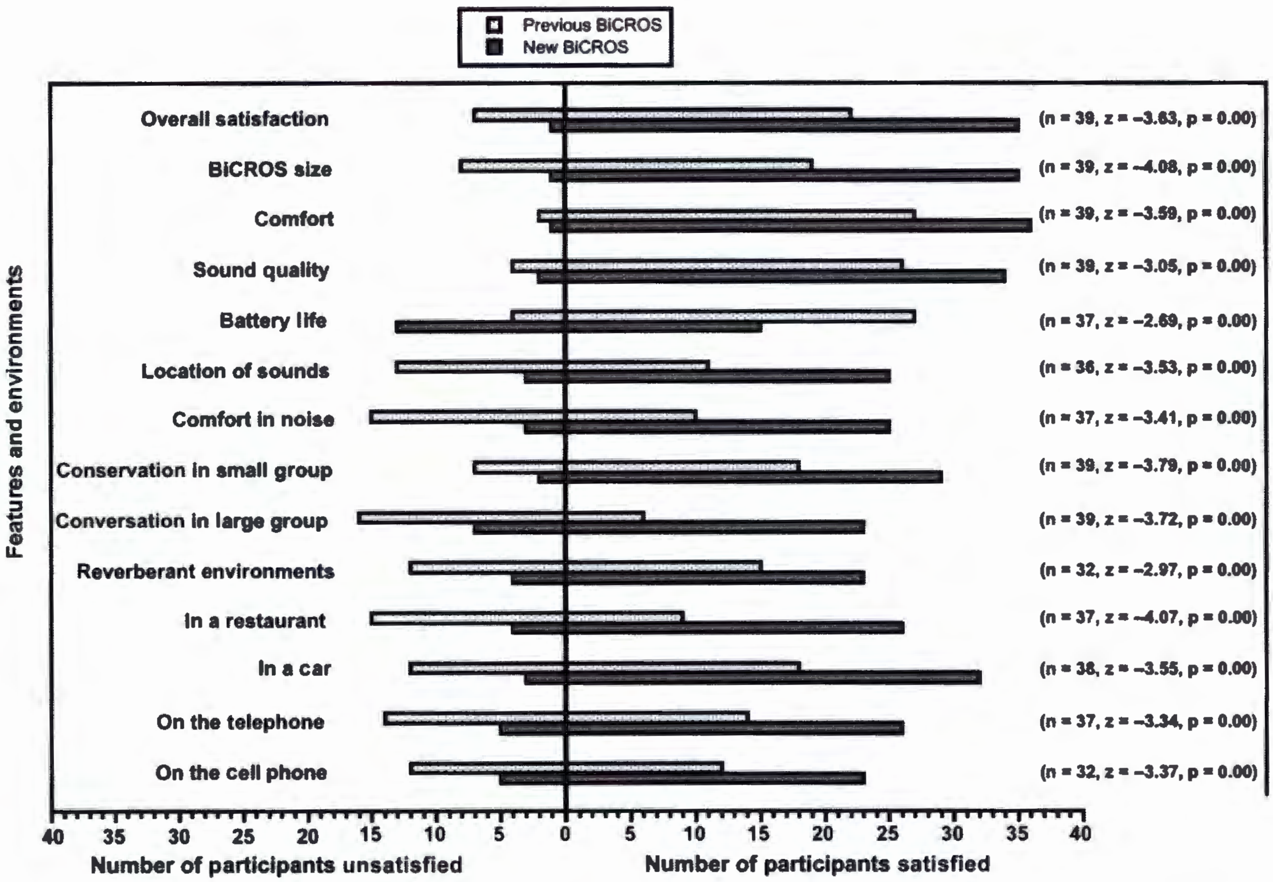

Figure 10. Number of participants who reported either dissatisfaction *(left side)* or satisfaction *(right side)* across the BiCROS features or listening environments are shown.

results from the objective and subjective measures. As an example of positive overlap, responses from the SSQ, MarkeTrak, and open-ended questions, along with WIN objective scores, indicated improved hearing in background noise with regards to the new BiCROS. Also interesting to note, a positive overlap of findings were observed for complex spatial listening environments commonly reported as extremely difficult by patients with SSD, such as listening while driving in a car. Such spatially complex environments require separation of the signal and noise similar to what was simulated by listening conditions (4) and (5) of the WIN test. These WIN results showed improved speech-in-noise recognition performance indicating the new BiCROS system provided a two-sided listening environment. Additionally, subjective findings from the MarkeTrak questionnaire and SSQ subscales of "localization" and "distance and movement" indicated improved self-perception of abilities in the complex spatial listening environments with the new BiCROS. The improved spatial awareness is similar to other findings that were found for BAHA recipients (Niparko et al, 2003) which was attributed to a possible expansion of the soundfield.

The observed similarities across outcome measures provide evidence of consistency in the positive ratings. Unlike some previous studies examining (Bi)CROS user satisfaction and performance (e.g., Hol et al, 2010; Bishop and Eby, 2010), our present results indicate that the new BiCROS systems can provide improved satisfaction and performance for patients with SSD. The previous studies with less favorable outcomes utilized devices with inferior digital signal processing schemes, therefore providing further support that the differences in outcomes obtained in the present study may be due to the improvements in technology in the new-generation BiCROS system.

In conclusion, the present study evaluated the improvements in objective and subjective measures with regards to a new- compared to previous-generation BiCROS systems. Of 39 participants, 37 reported some form of satisfaction with the new BiCROS system and wished to use the system on a consistent basis. Based on the positive subjective and objective outcomes observed, the new BiCROS System is as good, or better than, what was previously utilized by our sample of veterans.

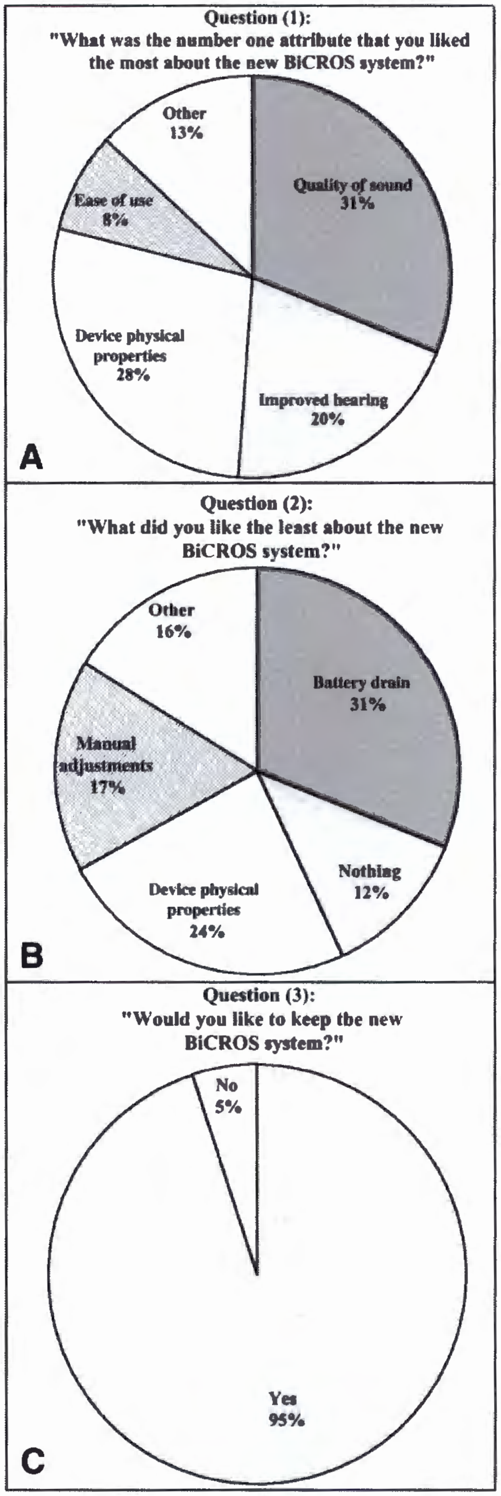

Figure 11. *(A-C)* Percentage of responses per category for the three open-ended questions.

Acknowledgments. The authors acknowledge Elizabeth Talmage, Amanda Cooley, and Julie Lewerenz for their assistance in data collection and management.

REFERENCES

American National Standards Institute. (2004) *Specification for Audiometers (ANSI S3.6 2004)*. New York: American National Standards Institute.

Audioscan Verifit. (2009) *Verifit Hearing Instrument Fitting System User's Guide Version*. Dorchester: Audioscan. 3.4.

Baguley DM. (2010) Cochlear implants in single-sided deafness and tinnitus. *Semin Hear* 31(4):410–413.

Bess FH, Tharpe AM. (1986) An introduction to unilateral sensorineural hearing loss in children. *Ear Hear* 7(1):3–13.

Bergman M. (1957) Binaural hearing. *AMA Arch Otolaryngol* 66 (5):572–578.

Bishop CE, Eby TL. (2010) The current status of audiologic rehabilitation for profound unilateral sensorineural hearing loss. *Laryngoscope* 120(3):552–556.

Bronkhorst AW. (2000) The cocktail party phenomenon: A review of research on speech intelligibility in multiple-talker conditions. *Acta Acustica* 86(12):117–128.

Byrne D, Dillon H, Ching T, Katsch R, Keidser G. (2001) NAL-NL1 procedure for fitting nonlinear hearing aids: characteristics and comparisons with other procedures. *J Am Acad Audiol* 12(1): 37–51.

Cashman M, Corbin H, Riko K, Rossman R. (1984) Effect of recent hearing aid improvements on management of the hearing impaired. *J Otolaryngol* 13(4):227–231.

Cherry EC. (1953) Some experiments on the recognition of speech with one and two ears. *J Acoust Soc Am* 25:975–979.

Cox RM, Alexander GC. (1990) Evaluation of an In-Situ Output Probe-Microphone Method for Hearing Aid Fitting Verification. *Ear Hear* 11(1):31–39.

Culling JF, Hawley ML, Litovsky RY. (2004) The role of head induced interaural time and level differences in the speech reception threshold for multiple interfering sound sources. *J Acoust Soc Am* 116:1057–1065.

Dawes P, Powell S, Munro KJ. (2011) The placebo effect and influence of participant expectation on hearing aid trails. *Ear Hear* 32 (6):767–774.

Dillon H. (1999) NAL-NL1: a new prescriptive fitting procedure for nonlinear hearing aids. *Hear J* 52:10–16.

Dillon H, ed. (2001) CROS bone conduction and implanted hearing aids. *Hearing Aids*. New York: Thieme, 434–450.

Dillon H, Ching T, Keidser G, et al. (2007) Factors affecting the prescription of hearing aids, and the NAL-NL2 prescription. http://www.nal.gov.au/pdf/NL2-etc-NE-conf-Dillon-download.pdf. Accessed May 9, 2011.

Dimmelow KL, O'Connor AF, Johnson IMJ, McKinney C, Mendelow AD, Shackleton C. (2003) Hear the other side–a report by the advisory group for single sided deafness. www.entific.com

Dirks DD, Wilson RH. (1969) The effect of spatially separated sound sources on speech intelligibility. *J Speech Hear Res* 12:5–38.

Ericson H, Svärd I, Högset O, Devert G, Ekström L. (1988) Contralateral routing of signals in unilateral hearing impairment. *Scand Audiol* 17:111–116.

Finney DJ. (1952) *Statistical Method in Biological Assay*. London: C. Griffen.

Flynn MC, Sammeth CA, Sadeghi A, Cire G, Halvarsson G. (2010) Baha for single-sided sensorineural deafness: review and recent technological innovations. *Semin Hear* 31(4):326–349.

Gatehouse S, Akeroyd M. (2006) Two-eared listening in dynamic situations. *Int J Audiol* 45(1, Suppl):S120–S124.

Gatehouse S, Noble W. (2004) The Speech, Spatial and Qualities of Hearing Scale (SSQ). *Int J Audiol* 43:85–99.

Giolas TG, Wark DJ. (1967) Communication problems associated with unilateral hearing loss. *J Speech Hear Disord* 32(4):336–343.

Harford E, Barry J. (1965) A rehabilitative approach to the problem of unilateral hearing impairment: the contralateral routing of signals (CROS). *J Speech Hear Disord* 30:121–138.

Harford E, Dudds E. (1966) The clinical application of CROS: a hearing aid for unilateral deafness. *Arch Otolaryngol* 83(5):455–464.

Häusler R, Colburn S, Marr E. (1983) Sound localization in subjects with impaired hearing: spatial-discrimination and interaural-discrimination tests. *Acta Otolaryngol Suppl* 400:1–62.

Hayes D, Pumford J, Dorscher M. (2005) Advantages of DSP instruments for wireless CROS fittings. *Hear J* 58:44–46.

Hill SL 3rd, Marcus A, Digges EN, Gillman N, Silverstein H. (2006) Assessment of patient satisfaction with various configurations of digital CROS and BiCROS hearing aids. *Ear Nose Throat J* 85(7):427–430, 442.

Hol MK, Kunst SJ, Snik AF, Cremers CW. (2010) Pilot study on the effectiveness of the conventional CROS, the transcranial CROS and the BAHA transcranial CROS in adults with unilateral inner ear deafness. *Eur Arch Otorhinolaryngol* 267(6):889–896.

Kochkin S. (1990) Introducing MarkeTrak: a consumer tracking survey of the hearing impaired market. *Hear J* 43(3):17–27.

Levitt H, Rabiner LR. (1967a) Binaural release of masking for speech and gain in intelligibility. *J Acoust Soc Am* 42:601–608.

Levitt H, Rabiner LR. (1967b) Predicting binaural gain in intelligibility and release from masking for speech. *J Acoust Soc Am* 42(4):820–829.

Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Niparko JK. (2006) Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone anchored hearing and contralateral routing of signal amplification. *Otol Neurotol* 27:172–182.

Mueller HG. (2005) Fitting hearing aids to adults using prescriptive methods: an evidence-based review of effectiveness. *J Am Acad Audiol* 16:448–460.

Newman CW, Jacobson GP, Hug GA, Sandridge SA. (1997) Perceived hearing handicap of patients with unilateral or mild hearing loss. *Ann Otol Rhinol Laryngol* 106(3):210–214.

Niparko JK, Cox KM, Lustig LR. (2003) Comparison of the bone anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. *Otol Neurotol* 24(1):73–78.

Noble W, Gatehouse S. (2004) Interaural asymmetry of hearing loss, speech, spatial and qualities of hearing scale (SSQ) disabilities, and handicap. *Int J Audiol* 43:100–114.

Popelka GR, Derebery J, Blevins NH, et al. (2010) Preliminary evaluation of a novel bone conduction device for single-sided deafness. *Otol Neurotol* 31(3):492–497.

Pumford J. (2005) Benefits of probe-mic measures with CROS/BiCROS fittings. *Hear J* 58(10):34–40.

Punch JL. (1988) CROS revisited. *ASHA* 30(2):35–37.

Rosenbaum S. (1976) Evaluation of the hearing handicap scale for individuals with monaural, mild, and moderate sensorineural hearing impairment (Unpublished doctoral dissertation). New York: Columbia University.

Shaw EA. (1974) Transformation of sound pressure level from the free field to the eardrum in the horizontal plan. *J Acoust Soc Am* 56 (6):1848–1861.

Smith SL, Noe CM, Alexander GC. (2009) Evaluation of the International Outcome Inventory for Hearing Aids in a Veteran Sample. *J Am Acad Audiol* 20(6):374–380.

Snik AF, Mylanus EA, Proops DW, et al. (2005) Consensus statements on the BAHA system: Where do we stand at present? *Ann Otol Rhinol Laryngol Suppl* 195:2–12.

Sullivan RF. (1988) Transcranial ITE CROS. *Hear Instrum* 39:54.

Taylor B. (2010) Contralateral routing of the signal amplification strategies. *Semin Hear* 31(4):378–392.

Tillman TW, Carhart R. (1966) *An Expanded Test for Speech Discrimination Utilizing CNC Monosyllabic Words. Northwestern University Auditory Test No. 6. Report SAM-TR-66-55, USAF*. San Antonio: School of Aerospace Medicine, Brooks Air Force Base.

Valente M, Oeding K. (2010) Transcranial contralateral routing of the signal as a fitting option for patient with single-sided deafness. *Semin Hear* 31(4):366–377.

Valente M, Valente M, Potts L, Vass W, Goebel J. (1995) Wireless CROS versus transcranial CROS hearing aids. *Am J Audiol* 4(1):52–59.

Viehweg R, Campbell R. (1960) Localization difficulty in monaurally impaired listeners. *Trans Am Otol Soc* 48:339–350.

Voelker CCJ, Chole RA. (2010) Unilateral sensorineural hearing loss in adults: etiology and management. *Semin Hear* 31(4):313–325.

Wilson RH. (2003) Development of a speech-in-multitalker-babble paradigm to assess word-recognition performance. *J Am Acad Audiol* 14:453–470.

BINAURAL SPATIAL MAPPING OPTIMIZES REAL–WORLD HEARING AID BEHAVIOR

Shilpi Banerjee, Ph.D.

For decades, researchers and clinicians have emphasized the importance of bilateral hearing aid fittings in minimizing disruptions to the exquisitely-tuned binaural auditory system. The availability of hearing aids with wireless features has renewed interest in the subject, and focused the discussion on signal processing. This paper describes the rationale, design and efficacy of Binaural Spatial Mapping, Starkey's wireless ear-to-ear communication protocol. Along the way, it debunks some popular notions about binaural hearing, hearing impairment, and listener preferences, arriving at a destination that optimizes real-world hearing aid behavior.

Survey Says...

Satisfaction with hearing aids is at an all-time high of 80 percent (Kochkin, 2010). Nonetheless, problems persist in adverse listening situations – such as in restaurants, cars and large groups (Kochkin, 2010). These situations are important to hearing aid wearers and typically involve communication or intentional listening (Wagener, et al., 2008).

The notion of multiple environment listening utility, proposed by Kochkin (2007), suggests a direct relationship between the number of satisfactory listening situations and overall satisfaction with hearing aids. It stands to reason, then, that improving performance in problematic listening situations would yield increased satisfaction with hearing aids. Indeed, this is the premise of many advances in hearing aid technology. Binaural Spatial Mapping is no exception.

Binaural Hearing

Binaural hearing is hearing with two ears. This is advantageous – compared to monaural hearing – when differences exist between the signals for the two ears. These advantages are greatest in complex and dynamic listening environments, such as restaurants, cars and large groups (Noble & Gatehouse, 2006).

When located directly in front of or behind a listener, the characteristics of a sound are essentially the same at the left and right ears, and binaural hearing provides no benefit over monaural hearing. Moving the sound to, say, the left side has two effects. First, the sound is louder at the left ear than at the right ear, resulting in an interaural level difference (ILD) that is most prominent at frequencies above ~1000 Hz. And, second, the sound arrives at the left ear before the right ear, resulting in an interaural timing difference (ITD) that is most prominent below ~1000 Hz. ILDs and ITDs are the primary binaural cues for spatial release from masking, a phenomenon more commonly referred to as the cocktail party effect (Cherry, 1953).

Complex listening environments are known to increase difficulty in recognizing speech. Further, greater similarity between speech and any interfering noise increases the confusion.
One relatively simple method of alleviating this difficulty is to spatially separate the speech from the noise. In persons with normal hearing, this spatial release from masking produces a 12-16 dB improvement in the speech reception threshold in noise (Beutelmann & Brand, 2006).

Signal processing in hearing aids tampers with the naturally-occurring ILDs and ITDs in many ways. For example, wide dynamic range compression could reduce ILDs by applying less gain where the incoming sound is louder and more gain where the incoming sound is softer. Similar effects can occur with other features when, for example, only one device is in the directional mode or more noise reduction is applied in one device than in the other. Directionality and noise reduction are intended to aid listening in complex environments. As such, it is important to consider how often these features are in agreement – i.e., in the same state – in everyday listening situations. According to Banerjee (2011), independent signal processing in a bilateral pair of hearing aids is in agreement – i.e., in the same state – 75-95 percent of the time. Accordingly, binaural cues are intact a large majority of the time.

Is it problematic that binaural cues could be disrupted when signal processing in a bilateral pair of hearing aids is in disagreement (as much as 25 percent of the time)? Beutelmann and Brand (2006) have shown that persons with impaired hearing obtain significantly less benefit from binaural cues compared to persons with normal hearing. Stated differently, the presence of hearing loss diminishes the ability to effectively use binaural cues.

Thus, preservation of binaural cues through forced synchronization of signal processing in a bilateral pair of hearing aids may not be the optimal solution. Could it be that asymmetric signal processing is a part of the solution rather than the problem? Consider, for example, a situation where the hearing aid wearer is engaged in a conversation with a child in the back seat en route to soccer practice (Figure 1). Ideally, the hearing aids should maintain audibility of the child's voice in one ear and minimize any interference from road noise in the other. Asymmetric signal processing – where, for example, one hearing aid remains omnidirectional while the other switches to the directional mode – would appear to be advantageous in this situation.

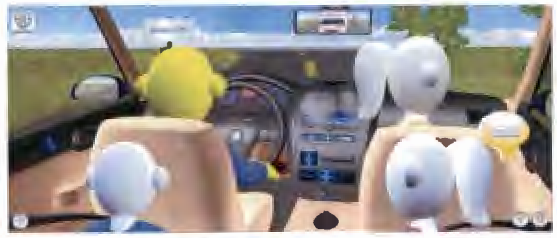

Figure 1: Hypothetical scenario in the car – hearing aid wearer in the driver's seat conversing with a child in the back seat. Speech signal is located on the rear right side with noise predominantly on the left.

The Case for Collaborative Signal Processing

Traditionally, laboratory-based hearing aid research has been conducted in symmetrical sound fields – for example, where the speech signal of interest is located directly in front of the listener and the background noise is diffuse or located directly behind the listener. As noted previously, such a configuration results in identical inputs to the two ears and requires no intervention for ensuring binaural benefit. However, the use of asymmetric test set-ups in two studies provides insight into the judicious use of collaborative signal processing with wireless capabilities.

The first study by Hornsby and Ricketts (2007) examined the effect of symmetric and asymmetric microphone modes under three listening conditions: 1) speech in front with surrounding noise, 2) speech in front with noise on the left side and 3) speech on the right side with noise on the left side. For speech located in front (conditions 1 and 2), directionality in at least one device yielded improved speech understanding in noise, and directional benefit was greatest when both devices were in the directional mode. Interestingly, noise location had no impact on directional benefit – i.e., bilateral directionality was equally beneficial with noise surrounding the listener or only on the left side. For speech located on the right side, a significant decrease in speech understanding was observed with the right device in the directional mode; the status of the left device did not affect on the outcome. The authors concluded that, when speech is located to the side, the reduction in speech audibility resulting from directional processing on that side is detrimental to speech understanding.

In the second study, Banerjee (2010) demonstrated similar results in subjective preference for directionality based on the location of the speech signal. Figure 2 shows the relative – compared to the bilateral omnidirectional (O-O) condition – likability of various microphone configurations; large, positive values indicate better outcomes. For speech located in front, listeners preferred some directionality (O-D or D-O) over none at all (O-O), and bilateral directionality (D-D) was preferred most of all. When speech was located in the rear right, however, listeners had a significant dislike for directionality on the right side; the status of the left device did not affect the results. This is interpreted as an aversion to reduced audibility of speech that occurs behind the directional hearing aid.

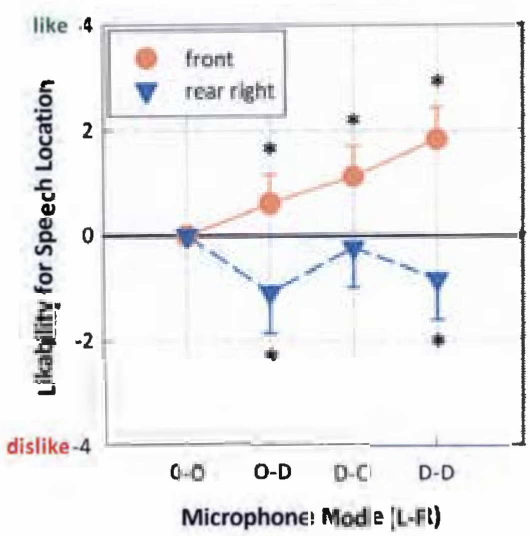

Figure 2: Likability of various microphone modes for speech located in front or in the rear right. Higher likability reflects greater preference. O-O is the reference mode. Asterisks (*) indicate a statistically significant (p<0.05) difference from the O-O mode. Error bars show the 95% confidence interval. O=omnidirectional, D=directional.

The scenarios evaluated in both of these studies are similar to the hypothetical (but realistic) one mentioned previously – a hearing aid wearing parent in the driver's seat engaged in conversation with a child in the back seat of a car (as shown in Figure 1).

To evaluate the implications of these findings, let us first consider synchronized processing in systems where both hearing aids are forced into the same mode. If the right device was forced into the directional mode because that was the mode selected by the left device (closer to the noise), audibility of the speech signal would be severely impaired. Although speech audibility would be unaffected if the left device was forced into the omnidirectional mode by the right device (closer to the speech), interference from the noise may require the hearing aid wearer to expend more effort in listening (Mackersie & Cones, 2011). Increased listening effort can cause stress, taking cognitive resources away from the task of driving, and possibly leading to increased fatigue over time. Thus, neither outcome of synchronized signal processing is desirable.

The goal of collaborative signal processing is to optimize the overall outcome based on the information available at each ear. Sometimes, this means that asymmetric signal processing will yield the best outcome. In the car, for example, the right device may remain omnidirectional because the directional mode degrades the signal-to-noise ratio (SNR); the left device, finding no SNR advantage in either mode, could favor the directional mode in the interest of maintaining comfort. This asymmetric configuration yields maximum speech audibility with minimum listening effort. This power of collaborative signal processing is harnessed in Binaural Spatial Mapping.

Design of Binaural Spatial Mapping

Binaural Spatial Mapping is Starkey's wireless ear-to-ear communication protocol. It continuously analyzes the acoustic environment surrounding the hearing aid wearer and applies the appropriate signal processing strategy for InVision Directionality, AudioScapes and Voice iQ. Binaural Spatial Mapping can only be achieved with inputs from two hearing aids with wireless features.

The design of the algorithm is based on two guiding principles: 1) preserve audibility whenever speech is present and 2) maintain comfort if speech is absent and/or overall input levels are high.

Speech, the primary vehicle for communication, is arguably the single most important sound for hearing aid wearers. As such, the significance of preserving it cannot be overstated. Hearing aids must rely on a relatively degraded input – mixed in with noise and reverberation – at the microphone of the device to determine the presence of speech in the environment. When both devices are constantly scanning the environment and sharing information, it effectively improves the detection of speech at the far ear by as much as five dB. The practical implication is, that with Binaural Spatial Mapping, speech audibility can be preserved at SNRs that are too poor for a single hearing aid to detect the presence of speech.

Speech audibility is preserved in two ways. First, InVision Directionality selects the microphone mode (omnidirectional or directional) that yields the higher (i.e., better) SNR at each ear. And, second, fast-acting Voice iQ reduces background noise without adversely impacting the speech signal (Pisa, Burk, & Galster, 2010).

Noise is generally considered undesirable and the hearing aid wearer, like anyone else, wants to listen to it as little as possible. Enhanced speech detection, made possible by Binaural Spatial Mapping, allows a conservative approach to maintaining comfort in the presence of background noise. In other words, inadvertent loss of the speech signal at low SNRs is minimized. If only noise is present in the environment, the hearing aids go into the directional mode and apply noise reduction to maintain comfort.

According to Pearsons, Bennett and Fidell (1977), inputs exceeding ~80 dBSPL are typically comprised of noise. However, if a speech signal is detected in such environments, Binaural Spatial Mapping attempts to strike a balance between preserving speech audibility and maintaining loudness comfort. This is achieved through collaborative decision-making – i.e., the device with the better SNR preserves speech audibility while the other device maintains comfort. Thus, Binaural Spatial Mapping may intentionally cause the left and right devices of a bilateral pair to be in different signal processing states under such conditions. Identical states in both devices are not automatically forced.

Finally, an incidental benefit of Binaural Spatial Mapping is that auditory disturbances arising from signal processing algorithms are reduced. Switching and/or adaptation in independently functioning hearing aids can occur with a noticeable time delay that many hearing aid wearers find distracting. Collaborative decision-making causes any switching and/or adaptation to occur in both devices simultaneously, thereby minimizing the distraction caused by this behavior.

Validation

Galster and Burk (2011) described a large-scale study of 47 patients at various clinics throughout the United States. The study examined various aspects of IRIS™ Technology in Starkey's Wi Series™ hearing aids, with Binaural Spatial Mapping. IRIS Technology is Starkey's wireless communication protocol, which uses the 900 MHz band within the Industrial and Scientific Medical Spectrum. It is the only wireless hearing aid system that allows wireless ear-to-ear communication, wireless programming and wireless media streaming without any relay devices.
Of particular relevance to the present discussion are patient reports on two standardized questionnaires that target real-world hearing experiences.

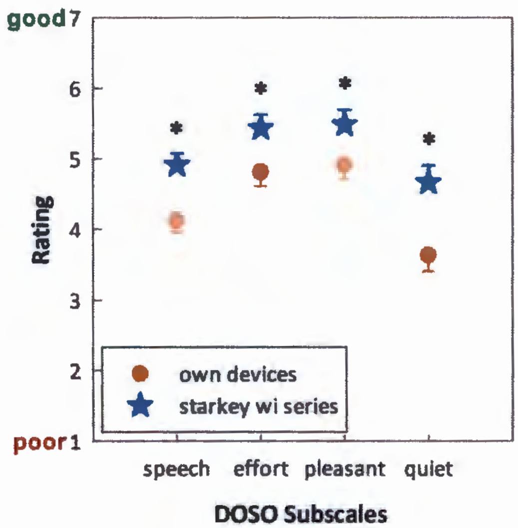

Figure 3: Patient ratings on the Device-Oriented Subjective Outcome (DOSO) scale. Higher ratings reflect better outcomes. Error bars show the 95% confidence interval. Asterisks (*) indicate a statistically significant (p<0.05) difference in rating between own devices and Starkey's Wi Series (with Binaural Spatial Mapping). Speech=speech cues, Effort=listening effort, Pleasant=pleasantness, Quiet=quietness.

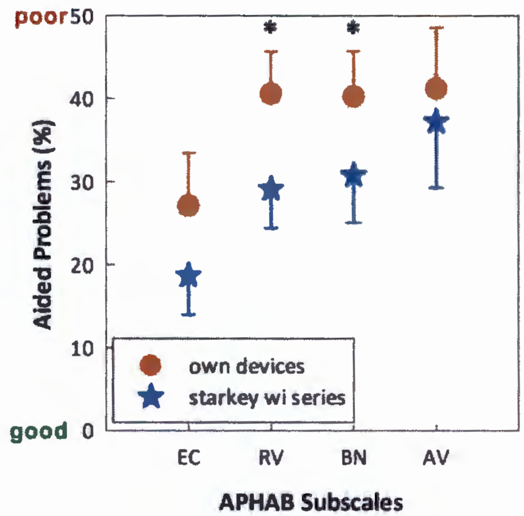

Figure 4: Patient ratings on the Abbreviated Profile of Hearing Aid Benefit (APHAB). Lower rates of aided problems reflect better outcomes. Error bars show the 95% confidence interval. Asterisks (*) indicate a statistically significant (p<0.05) difference in rating between own devices and Starkey's Wi Series (with Binaural Spatial Mapping). EC=ease of communication, RV=reverberation, BN=background noise, AV=aversiveness.

The Device-Oriented Subjective Outcome (DOSO) scale (Cox, et al., 2009) asks respondents to rate: 1) their ability to hear speech cues [speech], 2) amount of listening effort expended in noisy situations [effort], 3) pleasantness of amplified sound [pleasant], 4) quietness of the hearing aids [quiet], 5) convenience of manipulating the devices and 6) daily use of hearing aids. The first four subscales are directly (speech cues and listening effort) or indirectly (pleasantness and quietness) related to Binaural Spatial Mapping. As shown in Figure 3, study participants indicated significantly better performance – i.e., higher ratings – with Starkey's Wi Series hearing aids compared to their own devices on the relevant subscales of the DOSO scale.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995) is a self-assessment inventory where respondents report the amount of problems experienced in: 1) communicating under relatively favorable conditions [EC – ease of communication], 2) communicating in reverberant rooms [RV], 3) communicating in noisy environments [BN] and 4) unpleasantness of environmental sounds [AV – aversiveness]. As shown in Figure 4, compared to their own devices, study participants indicated significantly better performance – i.e., fewer problems – with Starkey's Wi Series hearing aids in reverberant and noisy listening situations. There was also a non-significant trend toward reduction of problems in favorable conditions with Starkey's Wi Series.

Figure 5: Schematic illustration of collaborative decision-making in Starkey's Binaural Spatial Mapping.

Summary

Binaural Spatial Mapping, illustrated in Figure 5, is Starkey's wireless ear-to-ear communication protocol. It applies the combined speed and power of multiple dual-core platforms to achieve parallel processing benefits. This new protocol queries, analyzes and maps the acoustic space surrounding the hearing aid wearer, applying the appropriate signal processing strategy for InVision Directionality, AudioScapes and Voice iQ. Binaural Spatial Mapping can only be achieved with inputs from two Wi Series hearing aids.

Binaural Spatial Mapping's collaborative decision-making allows speech audibility to be preserved, while simultaneously maintaining loudness comfort. This yields demonstrated, real-world benefits to hearing aid wearers.

Acknowledgements

The author thanks Matt Burk, Ph.D., Elizabeth Galster, Au.D., Ivo Merks, Ph.D., and Justyn Pisa, Ph.D., for their work in developing and evaluating Binaural Spatial Mapping. Thanks are also due to Sara Burdak, Au.D., Burk and Jason Galster, Ph.D., for helpful suggestions on early versions of this paper.

References

Banerjee S. (2010). *Laboratory Evaluation of Directional Preference: Effects of Speech & Noise Location, Stimulus Type & Response Criterion.* Paper presented at the International Hearing Aid Research Conference.

Banerjee S. (2011). Hearing aids in the real world: Typical automatic behavior of expansion, directionality and noise management. Journal of the American Academy of Audiology, 22(1), 34-48.

Beutelmann R & Brand T. (2006). Prediction of speech intelligibility in spatial noise and reverberation for normal-hearing and hearing-impaired listeners. *Journal of the Acoustical Society of America, 120*(1), 331-342.

Cherry EC. (1953). Some experiments on the recognition of speech with one and with two ears. *Journal of the Acoustical Society of America, 25,* 975-979.

Cox RM & Alexander GC. (1995). The Abbreviated Profile of Hearing Aid Benefit (APHAB). *Ear and Hearing, 16,* 176-186.

Cox RM, Alexander GC & Xu J. (2009). *Development of the Device-Oriented Subjective Outcome Scale (DOSO).* Paper presented at the American Auditory Society.

Galster E & Burk M. (2011). *Wi Series: Optimizing the Wireless Experience.* Eden Prairie, MN: Starkey Laboratories, Inc.

Hornsby BWY & Ricketts TA. (2007). Effects of noise source configuration on directional benefit using symmetric and asymmetric directional hearing aid fittings. *Ear and Hearing, 28*(2), 177-186.

Kochkin S. (2007). Increasing hearing aid adoption through multiple environment listening utility. *Hearing Journal, 60*(11), 28-31.

Kochkin S. (2010). MarkeTrak VIII: Consumer satisfaction with hearing aids is slowly increasing. *Hearing Journal, 63*(1), 19-32.

Mackersie C & Cones H. (2011). Subjective and psychological indexes of listening effort in a competing-talker task. *Journal of the American Academy of Audiology, 22*(2), 113-122.

Noble W & Gatehouse S. (2006). Effects of bilateral versus unilateral hearing aid fitting on abilities measured by *Speech, Spatial and Qualities of Hearing Scale (SSQ). International Journal of Audiology, 45*(2), 172-181.

Pearsons KS, Bennett RL & Fidell S. (1977). *Speech Levels in Various Environments (Report No. EPA-600/1-77-025).* Washington, D.C.: United States Environment Protection Agency.

Pisa J, Burk M & Galster E. (2010). Evidence-based design of a noise-management algorithm. *Hearing Journal, 63*(4), 42-48.

Wagener KC, Hansen M & Ludvigsen C. (2008). Recording and classification of the acoustic environment of hearing aid users. *Journal of the American Academy of Audiology, 19,* 348-370.

A global hearing technology
company headquartered in
Eden Prairie, Minnesota, U.S.A.

Starkey Laboratories, Inc.
6700 Washington Avenue South
Eden Prairie, MN 55344-3476
800.328.8602

StarkeyPro.com

Comparison of Wireless and Acoustic Hearing Aid-Based Telephone Listening Strategies

Erin M. Picou and Todd A. Ricketts

Objective: The purpose of this study was to examine speech recognition through hearing aids for seven telephone listening conditions.

Design: Speech recognition scores were measured for 20 participants in six wireless routing transmission conditions and one acoustic telephone condition. In the wireless conditions, the speech signal was delivered to both ears simultaneously (bilateral speech) or to one ear (unilateral speech). The effect of changing the noise level in the nontest ear during unilateral conditions was also examined. Participants were fitted with hearing aids using both nonoccluding and occluding dome ear tips. Participants were seated in a room with background noise present and speech was transmitted to the participants without additional noise.

Results: There was no effect of changing the noise level in the nontest ear and no difference between unilateral wireless routing and acoustic telephone listening. For wireless transmission, bilateral presentation resulted in significantly better speech recognition than unilateral presentation. Bilateral wireless conditions allowed for significantly better recognition than the acoustic telephone condition for participants fitted with occluding ear tips only.

Conclusion: Routing the signal to both hearing aids resulted in significantly better speech recognition than unilateral signal routing. Wireless signal routing was shown to be beneficial compared with acoustic telephone listening and in some conditions resulted in the best performance of all of the listening conditions evaluated. However, this advantage was only evident when the signal was routed to both ears and when hearing aid wearers were fitted with occluding domes. Therefore, it is expected that the benefits of this new wireless streaming technology over existing telephone coupling methods will be most evident clinically in hearing aid wearers who require more limited venting than is typically used in open canal fittings.

(Ear & Hearing 2011;32;209–220)

INTRODUCTION

Telephone usage is prominent in almost every household in the United States and continues to be one of the most widely used pieces of technology for people in all age groups (Mormer & Mack 2003). Telephone use is important for communication purposes and for safety reasons. Unfortunately, many people with hearing loss report difficulty listening over the telephone (Palmer 2001), and hearing aids may not provide satisfactory benefit when using the telephone. Kochkin (2000) reported that one reason patients buy but do not use hearing aids is because they perceive that hearing aids do not work with the telephone. Furthermore, in a large scale survey investigating customer satisfaction with hearing aids, Kochkin (2002) reported that as few as four of 10 people who use hearing aids are satisfied with hearing aid performance on the telephone. In 2005, one of five survey respondents reported dissatisfaction when using the telephone with a hearing aid (Kochkin 2005). Some of the dissatisfaction may be due to difficulty using the telephone. In a test of hearing aid skills, more than 75% of experienced users were not able to perform the necessary actions for appropriate telephone use with their hearing aids (Desjardins & Doherty 2009). In addition, problems with feedback and reduced speech recognition in background noise are expected to contribute to dissatisfaction with telephone use in hearing aid wearers (Smith 1974; Goldberg 1975).

There are at least three factors contributing to difficulties understanding speech over the telephone; they include absence of visual cues, problems or difficulties associated with telephone coupling, and background noise. Although technological advances have made videoconferencing possible, the average consumer may not regularly use this technology as a primary means of telecommunication. So, it is likely that the lack of visual cues problem will persist. Regarding telephone coupling, telephone listening with a hearing aid using simple acoustic coupling is difficult because feedback often occurs when the telephone receiver gets close to the hearing aid. Although advances in feedback reduction algorithms for use in hearing aids have decreased the likelihood of bothersome feedback, it remains problematic, particularly for listeners who require significant gain (Latzel et al. 2001; Palmer 2001; Chung 2004).

As an alternative to acoustic telephone coupling, inductive telecoil technology has advanced through the years as a wireless signal transmission strategy to provide adequate telephone signal level at the listener's ear by amplifying the electromagnetic leakage from a telephone handset (Smith 1974; Yanz 2005). Because the hearing aid microphone is turned off, the telecoil may substantially enhance the signal-to-noise ratio (SNR) for the ear listening to the telephone. Although telecoils have been shown to provide some benefits relative to acoustic coupling (Cashman et al. 1982; Sorri et al. 2003), the benefit of induction loop or telecoil usage does not always yield superior speech recognition performance (Vargo et al. 1970; Tannahill 1983; Holmes 1985).

One of the reasons for the variable reports of benefit is that the potential SNR improvement depends on the amount of venting in the fitting. Venting will allow background noise to leak into the ear canal, with larger vents allowing more background noise (Dillon 1985). This reduction in SNR will be particularly problematic for listeners with less hearing loss, because the limited gain provided to the telephone signal will result in a signal that is closer in level to the background noise leaking in through the vent. Furthermore, the strength of the telephone signal arriving at the listener's ear is sensitive to the position of the telephone receiver relative to the telecoil. That is, traditionally, the magnetic source must be positioned very near the telecoil for effective operation, and some amount of user positioning is often needed to optimize the signal delivery level (Tannahill 1983; Compton 1994; Yanz & Preves 2003). A

Vanderbilt University Medical Center, Department of Hearing and Speech Science, Dan Maddox Hearing Aid Research Laboratory, Vanderbilt Bill Wilkerson Center, Nashville, Tennessee.

0196/0202/11/3202-0209/0 • Ear & Hearing • Copyright © 2011 by Lippincott Williams & Wilkins • Printed in the U.S.A.

further limitation of the telecoil is that it is susceptible to competing electromagnetic noise from cellular telephones, power lines, and fluorescent lights (Vargo et al. 1970; Yanz & Preves 2003). Thus, although the telecoil has the potential to improve telephone listening for hearing aid users, the technology continues to have practical limitations, particularly while listening to digital cellular telephones.

At the time of this writing, most major hearing aid manufacturers have introduced, or are planning on introducing, wireless signal routing to alleviate some communication difficulties over the telephone. Currently, at least three hearing aid manufacturers have introduced such a strategy. Generally, wireless strategies use transmitters that accept signal input from cell phones or other auxiliary sources. With this technology, cell phone signals are transmitted using a commercially available wireless technology, such as Bluetooth®, to an intermediary device called a transmitter. The transmitter, typically housed within the hearing aid remote control, routes the incoming signal to the hearing aid(s) using a proprietary wireless interface. Alternatively, the intermediary device receiving the commercial wireless transmissions may be a small "boot" that is directly connected to the base of behind-the-ear style hearing aids. Another recent alternative is to couple a wireless transmitter directly to the telephone or other audio source which then allows for wireless transmission directly to the hearing aid using a manufacturer-specific wireless transmission scheme. Although an intermediary transmitter is currently necessary due to the size and power constraints of hearing aids, direct wireless transmission using common, commercially available wireless protocols is certainly expected in the future.

As with telecoils, new wireless transmission systems may be beneficial for telephone listening because they offer individualized amplification based on the amount of gain in the hearing aid and because they may offer improved SNR because the hearing aid microphone can be disabled during use. Although potentially suffering from the same SNR constraints related to venting, these newer wireless transmission schemes have at least three potential advantages over traditional wireless transmission using a telecoil. First, they do not suffer from many of the same positioning constraints, and the transmitting telephone position relative to the hearing aid is only limited by the distance constraints of the wireless protocols being used. Second, the newer wireless technology is compatible with digital cellular phones, in addition to many other devices (e.g., television and music players). This compatibility allows for improved convenience because listeners are able to easily switch between multiple audio devices. A final potential advantage to the newer wireless transmission schemes is that they are capable of delivering the signal wirelessly to one or both hearing aid(s). Although there has been some investigation into theoretical advantages of binaural signal sharing by enhancing interaural level and phase differences (Richards et al. 2006), we are aware of no studies that have examined the potential effect of unilateral and bilateral wireless speech signal delivery for telephone listening.

With wireless signal routing, several general strategies may be implemented to alleviate the speech recognition difficulty experienced with telephone use that arises from listening in noisy environments. One strategy for telephone listening is to alter the input to the non-telephone ear. Two unilateral routing strategies include removing the hearing aid in the non-telephone ear and plugging that ear (unilateral signal, contralateral ear plugged; $U_{plugged}$) and turning off the hearing aid not receiving the telephone signal (unilateral signal, contralateral hearing aid unamplified; U_{unamp}). These two strategies are in contrast to the typical listening situation wherein the speech signal is presented to one ear and the contralateral hearing aid remains turned on, amplifying the environmental noise (unilateral signal, contralateral hearing aid amplified; U_{amp}). With the advent of wireless streaming technology, a new strategy is to send an identical speech signal to both hearing aids, diotic wireless speech transmission (bilateral signal; B).

Unilateral Signal, Contralateral Ear Plugged ($U_{plugged}$) and Unilateral Signal, Contralateral Hearing Aid Off (U_{unamp})

Licklider (1948) demonstrated the potential to improve speech recognition by removing a contralateral noise source presented over headphones in participants with normal hearing. He presented monosyllabic words to one or both ears and presented white noise (90 dB) to one or both ears. When the speech signal was only in one ear, Licklider reported a benefit of approximately 6% from turning off the noise to the ear with no speech signal. Therefore, it is possible that patients can improve their speech recognition over the telephone by plugging the non-telephone ear if they are in a noisy environment. Because Licklider tested participants with normal hearing, the degree to which people with hearing loss can benefit from eliminating background noise from the ear not receiving speech signal is unclear.

Despite the potential for benefit resulting from plugging the contralateral ear, removing the hearing aid from the ear not receiving the telephone signal may be awkward and is likely to contribute to the perception that hearing aids are not useful (Palmer 2001). Therefore, assuming that the noise in the contralateral ear is audible, turning off the non-telephone ear hearing aid is likely a preferable alternative to removing the non-telephone ear hearing aid and plugging the ear.

Bilateral Signal

Wireless streaming technology allows for the unique solution of bilateral signal delivery such that an identical speech signal can be delivered to both ears simultaneously. Although this technology allows for an identical signal to be transmitted to both ears, it is not a truly diotic listening situation, particularly in cases of an open canal (OC) fitting. Specifically, substantial background noise enters the ear canal through the vent, while the hearing aid amplifies the speech signal based on the amount of programmed gain. The level of environmental noise entering the ear canal will be highest when large vents are used. Because OC hearing aids are nonoccluding, they have a similar effect to a hearing aid with a very large vent (Dillon 1991). Patients who are candidates for OC instruments typically have only a high-frequency hearing loss; hence, OC hearing aids are designed to amplify only high frequencies. For these patients, the low-frequency background noise may be easily audible because it will not be attenuated by the OC fitting and hearing thresholds are typically near normal at those frequencies. Therefore, for people with sloping mild-to-moderate hearing loss, the high-frequency speech signal is amplified above the level of the noise and is essentially diotic while the low-frequency signal contains both the binaurally audible noise from the environment and the low-level diotic speech. Consequently, for any specific listener, the actual SNR at each frequency will vary as a function of the level of the noise leaking into the ear canal, which will in part be determined by the vent configuration and the magnitude of real ear gain applied to the wireless signal.

It is expected that wireless bilateral signal routing is likely to allow speech recognition improvement for listeners with hearing loss compared with unilateral routing, given previously identified benefits of binaural listening. Specifically, binaural signal presentation in the presence of uncorrelated noise yields better thresholds and speech recognition scores than unilateral signal presentation. For listeners with normal hearing, previous research suggests a 4 dB binaural advantage in threshold for detection of low-frequency signals in the presence of broadband uncorrelated noise (Green 1976; Moore 1998). Although the benefit is smaller for listeners with hearing loss, they also benefit from binaural signal delivery in the presence of an uncorrelated noise (Quaranta & Cervellera 1974; Hall et al. 1984). Listeners also derive speech recognition benefit from binaural speech presentation in the presence of uncorrelated noise, although the benefit may be smaller than the benefit for pure-tone signals (Levitt & Rabiner 1967).

In addition to improved detection and speech recognition in the presence of low-frequency correlated noise, there may be further binaural benefits in the high frequencies. Because the high-frequency noise is low level relative to the speech signal, a benefit may result from binaural summation applied to the speech signal. Binaural summation has been investigated for speech recognition tasks in diotic listening conditions and has been found to lead to improved detection and discrimination of speech for people with normal hearing (Plomp & Mimpen 1981; Davis et al. 1990; Moore 1998). For example, Davis et al. (1990) reported that listeners showed a diotic listening performance improvement of 9 points when their monaural speech recognition scores were 70% on a sentence identification task for listeners with normal hearing. Binaural summation for speech signals has been demonstrated to be similar for people with hearing loss, provided the signals are at sufficient sensation levels (Hall & Harvey 1985; Moore 1998). Therefore, wireless bilateral signal routing is likely to allow speech recognition improvement for listeners with hearing loss.

Further evidence suggesting possible benefits of bilateral signal delivery comes from the investigation into the advantage of bilateral fittings. Research investigating the efficacy of bilateral versus unilateral hearing aid fittings has generally been mixed. Although researchers seem to consistently demonstrate an advantage for two hearing aids in quiet environments (Byrne 1981; Schreurs & Olsen 1985), the results are less consistent for bilateral hearing aid advantage in noise (Nabelek & Mason 1981; Schreurs & Olsen 1985; Festen & Plomp 1986; Moore et al. 1992). For example, Festen and Plomp (1986) found that the addition of a second hearing aid improved speech recognition thresholds only if study participants had significant hearing loss or if there was little background noise. In contrast, when the background noise level was high relative to participants' hearing thresholds, the addition of a second hearing aid did not improve scores. Despite the mixed results regarding bilateral hearing aid advantage, it is expected that bilateral wireless signal presentation in a noisy room will enhance speech recognition for signals presented over the telephone because wireless transmission results in a diotic speech signal in the presence of low-frequency correlated room noise. Relative to a monaural signal, binaural detection and speech recognition are improved in the presence of low-frequency correlated noise (Licklider 1948; Levitt & Rabiner 1967). In addition, diotic summation in the high frequencies may improve speech recognition (Davis et al. 1990). In contrast, bilateral hearing aid fittings have limited benefits in some everyday listening environments because a true binaural speech signal is not available.

Environmental Monitoring

When using wireless speech transmission methods for telephone conversations, it may be desirable to maintain an auditory connection to the surrounding world (e.g., to monitor oncoming traffic, pedestrians, or stray dogs). One potential solution to maintain auditory connection to the external environment would be to activate an external microphone while receiving the signal from the transmitter. Activating an external microphone is a strategy that has been used with limited success for FM plus hearing aid combination systems primarily because the SNR is reduced by amplifying potentially unwanted signals from the environment. Indeed, activating the hearing aid microphone has been shown to significantly reduce the speech recognition advantage that FM systems provide (Hawkins 1984; Boothroyd & Iglehart 1998). Therefore, it is expected that activating a hearing aid's external microphone will negatively affect speech recognition performance when using wireless routing from telephones.

The purpose of this study was to examine the speech recognition performance across multiple telephone listening conditions including unilateral and bilateral wireless transmission, in addition to acoustic telephone coupling (all using occluding and nonoccluding dome ear tips). Within these conditions, there were several effects of primary scientific and clinical interest. These included the effect of altering the noise level in the nontest ear, the effect of bilateral speech routing, and the effect of activating the external microphone. In addition, it was of considerable clinical interest to investigate possible differences in speech recognition between wireless speech transmission and acoustic telephone coupling. Because these effects may depend on background noise level and degree of venting, speech recognition was investigated in two background noise levels and with occluding and nonoccluding dome ear tips.

PATIENTS AND METHODS

Participants

Participants were native English-speaking adults (14 men and 6 women) aged 47 to 84 years ($\bar{x}$ = 67.15, σ = 9.55). For each participant, hearing was evaluated within 6 months of study enrollment. Participants exhibited no evidence of middle ear pathology (as indicated by air-bone gaps <10 dB and normal tympanogram) or asymmetrical hearing loss (<15 dB interaural difference at any frequency between 500 and 3000 Hz). See Figure 1 for average audiometric data.

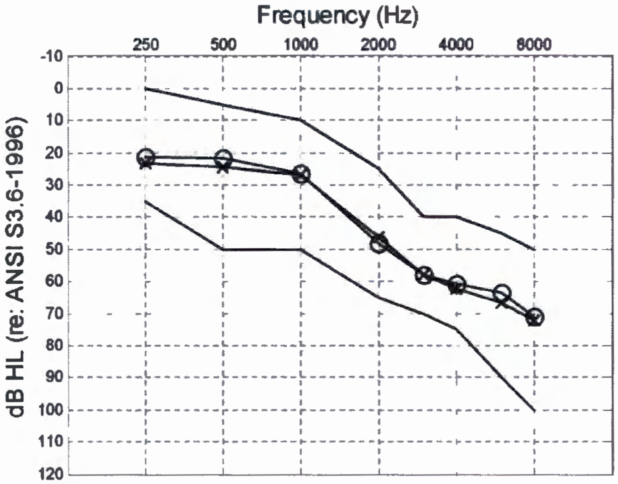

Fig. 1. Average hearing thresholds of study participants (x = left ear, 0 = right ear). Solid lines represent the maximum and minimum thresholds of all participants.

Hearing Aid Fitting

All participants were fitted bilaterally with Siemens Pure 700 receiver-in-the-canal hearing aids with the accompanying Siemens Tek Connect. The Tek Connect is both a remote control and a wireless transmitter. It can be synchronized to a Bluetooth® device or programmed to accept an auxiliary input. The signal from the Tek Connect can then be transmitted wirelessly to the hearing aid(s). For all fittings, standard, noncustom ear tips with thin tubing (0.95 mm) available from the manufacturer were used. Given the expected effects of venting on SNR as described earlier, nonoccluding and occluding dome ear tips were used to explore the effect of venting on speech recognition performance. Half of the participants were tested with nonoccluding domes and the other half were tested with occluding domes.

During the hearing aid fitting, digital noise reduction, speech enhancement, and wind management were disabled. Digital feedback suppression was activated for all conditions to limit feedback, which was of particular concern when using the nonoccluding ear tips and during the acoustic telephone conditions. All participants were fitted using the National Acoustic Laboratory-Non-Linear 1 (NAL-NL1; Byrne et al. 2001) prescriptive method. With the hearing aid input set to omnidirectional, real ear verification using an Audioscan Verefit indicated that all targets were matched within +5 and −10 dB for frequencies 250 to 6000 Hz for all participants (Fig. 2). Five programs with an identical NAL-NL1 fit but differing by signal routing were generated for each listener. Signal routing included acoustic (omni-directional microphone), Tek Connect with external microphone muted (both unilateral and bilateral routing), or Tek Connect with external microphone activated but attenuated by 6 dB (both unilateral and bilateral routing). Attenuation of the external microphone when activated was completed in accordance with the American Speech-Language-Hearing Association (ASHA) recommendations for external microphones when using FM systems (ASHA 2002). For these hearing aids, there are multiple settings encompassing 6 dB cut to a 6 dB boost for the Tek Connect as an input. For all Tek Connect conditions, the hearing aid was programmed for the maximum Tek level (6 dB boost).

Hearing Aid Conditions

The seven experimental hearing aid conditions for this study varied based on the configuration of the nontest ear and on the telephone signal routing configuration. There were three unilateral conditions wherein the speech signal was delivered wirelessly only to the test ear using the Tek Connect. In the $U_{plugged}$ condition, the nontest ear was plugged with an Aearo Company E.A.R. foam plug. In the U_{unamp} condition, the hearing aid in the nontest ear remained in place but turned off. In the U_{amp} condition, the hearing aid in the nontest ear was turned on, allowing for amplification of environmental background noise.

In addition, there was a bilateral speech condition (B) wherein an identical speech signal was delivered simultaneously to both ears. Also, to determine whether the test conditions were superior to simple acoustic coupling, an acoustic telephone condition (Phone) was included. During the Phone condition, participants were instructed to hold the telephone

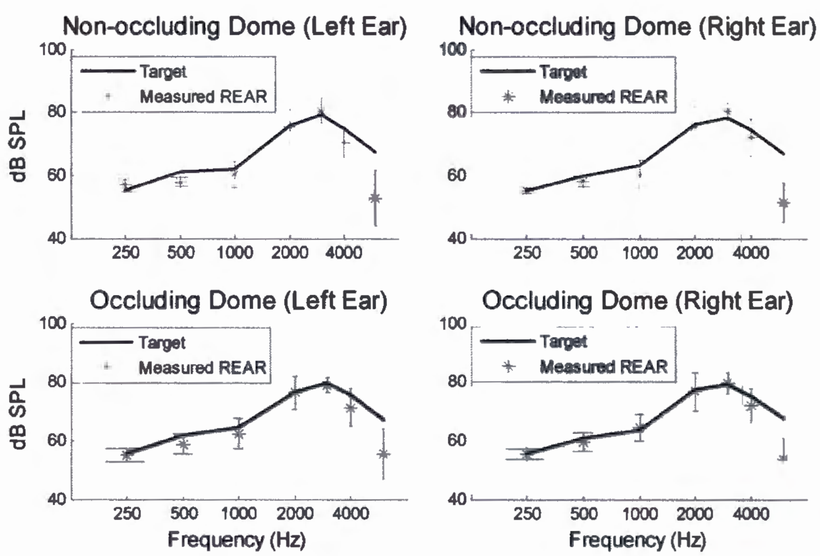

Fig. 2. Average NAL-NL1 (Byrne et al. 2001) prescribed target and match to target used during study testing. Solid lines indicate the average prescribed target and asterisks indicate average match to targets. Bars represent ± 1SD.

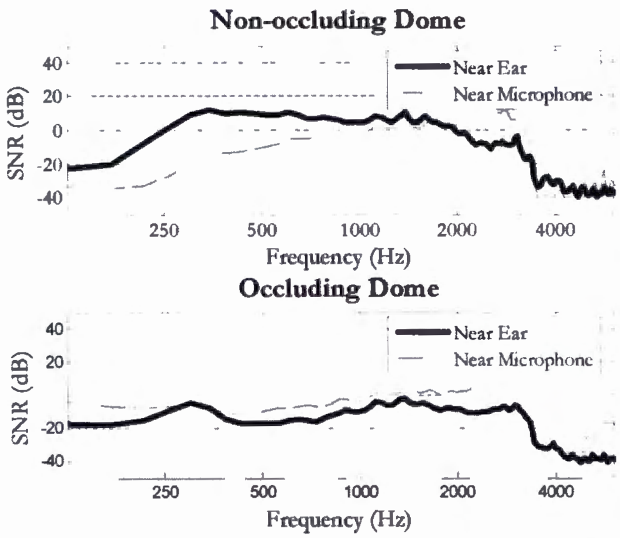

Fig. 3. Signal-to-noise ratio (SNR) of the test signals as measured with average gain used for testing with an IEC 711 artificial ear simulator mounted on a K.E.M.A.R. Solid lines indicate telephone receiver placed tightly against the pinna, whereas dashed lines indicate telephone receiver near the hearing aid microphone.

where it was easiest to hear the signal. Participants were reminded at the beginning of testing that they might hear best if the telephone receiver was placed behind the ear near the hearing aid microphone and were encouraged to try all positions before testing started. After instruction, participants typically pushed the telephone receiver against the pinna, rather than placing the telephone receiver near the hearing aid microphone.

Although this placement may seem counterintuitive, for participants fitted with nonoccluding domes, placing the telephone receiver near the ear canal results in a better SNR than placing it near the microphone. For those fitted with occluding domes, the placement of the telephone receiver changes the SNR less significantly. Figure 3 displays the SNR for two positions of the telephone receiver as measured in an IEC 711 artificial ear simulator mounted on a K.E.M.A.R. Steady state noises with the same long-term average spectral shape and level as the signals were used for testing. Clearly, for those fitted with nonoccluding domes, placing the receiver near the ear canal provides the most beneficial SNR. Conversely, for those fitted with occluding domes, there would be a slight advantage in placing the receiver near the hearing aid microphone. However, it is speculated that this listening advantage might not have been large enough to encourage participants to deviate from the more typical telephone placement.

Two final conditions ($U_{amp,em-6}$ and B_{em-6}) were included to evaluate the effect of activating the external microphone. These conditions were similar to the U_{amp} and B conditions, except the hearing aids' external omni-directional microphone(s) was (were) activated. This allowed speech signal mixed with noise from the listener's environment to be presented to the test ear.

In summary, speech recognition in seven listening conditions was evaluated. These listening conditions included bilateral routing (speech to both hearing aids), typical unilateral routing (unilateral signal, contralateral hearing aid amplified; U_{amp}), and acoustic phone coupling (Phone). In addition, two other unilateral conditions were examined: nontest ear plugged ($U_{plugged}$) and hearing aid turned off in the nontest ear (U_{unamp}). Last, two further conditions were included to investigate the effect of activating the external microphone. These were identical to U_{amp} and B, except the external microphone was activated and attenuated by 6 dB. These conditions were designated $U_{amp,em-6}$ and B_{em-6}. See Table 1 for a summary description of the seven conditions.

Noise Conditions

In each of the seven hearing aid conditions, the speech signal was transmitted without additional noise. However, all test conditions included background noise present in the listener's environment. Each of the seven hearing aid conditions was tested in two background noise levels, yielding 14 conditions. A noise level of 55 dBA was used because it is representative of the average levels commonly found in department stores, general office environments, and hospitals (Pearsons et al. 1977). A level of 65 dBA was used to assess telephone listening in environments with higher levels of background noise. Pilot data demonstrated that this level is representative of restaurants, airport terminals, and shopping malls during nonpeak hours.

Stimuli

Speech Stimuli • Because it was of interest to determine the speech recognition ability of participants in various hearing aid conditions using highly contextual materials, the Connected Speech Test (CST) was chosen to be used as speech stimuli. The CST contains 24 passage pairs derived from a children's encyclopedia. Each passage contains 10 sentences on a topic, and the passage pairs are approximately equally intelligible. Key words were scored to derive a percent correct speech recognition score (Cox et al. 1987, 1988). One passage pair was used for each hearing aid configuration and noise level combination (total of 14). The presentation level of the speech was measured to be 65 dBA in an IEC 711 artificial ear simulator with 0 dB insertion gain programmed on a K.E.M.A.R.

During testing, recorded speech stimuli were played from one channel of a DVD player (Pioneer DV-563A) and routed to an audiometer (Madsen Electronics Orbiter 922) for level control. From the audiometer, speech stimuli were routed through a multi I/O processor (System 3 Tucker-Davis Technologies RX8) that allowed for linear gain in eight frequency bands and for filtering of speech signals, all controlled by a custom computer program. After processing, speech signals were routed to either the Tek Connect via auxillary input for the wireless routing conditions or to a telephone handset for the acoustic telephone condition.

The I/O processor was used to filter the speech signals and to apply frequency-specific gain. All speech signals were bandpass filtered (300 to 3400 Hz; 800th order FIR filters) to simulate telephone transmission signals. Pilot data confirmed that telephone transmission signal is bandpassed at approximately 300 to 3400 Hz. In addition to filtering, the multi I/O processor was used to apply frequency-specific gain to the wireless speech signals. Frequency-specific gain was necessary because preliminary measures revealed that when the hearing aid input was changed from omni-directional to wireless transmitter, the frequency response of the hearing aid changed

TABLE 1. General descriptions of the hearing aid conditions under evaluation

Name	Condition	Speech Signal	Background Noise	Purpose
$U_{plugged}$	Wireless speech signal to one ear, contralateral hearing aid removed, E.A.R. plug inserted	Delivered to one test ear via hearing aid	Arrives at test ear via hearing aid vent Attenuated at nontest ear by E.A.R. plug	Is plugging the ear with no speech signal helpful?
U_{unamp}	Wireless speech signal to one ear, contralateral hearing aid turned off	Delivered to one test ear via hearing aid	Arrives at test ear and nontest ear via hearing aid vents	Is turning off the contralateral hearing aid helpful?
$U_{amp,em-6}$	Wireless speech signal to one ear, contralateral hearing aid turned on	Delivered to one test ear via hearing aid, external microphone is activated	Arrives at test ear via hearing aid vent Amplified by hearing aid in nontest ear	Typical configuration
U_{amp}	Wireless speech signal to one ear, contralateral hearing aid turned on	Delivered to one test ear via hearing aid, external microphone muted	Arrives at test ear via hearing aid vent Amplified by hearing aid in nontest ear	Typical configuration
B_{em-6}	Wireless signal sent to both ears simultaneously	Delivered to both ears via shared signal, external microphone activated	Arrives at both ears via hearing aid vents	Is a binaural speech signal helpful?
B	Wireless signal sent to both ears simultaneously	Delivered to both ears via shared signal, external microphone muted	Arrives at both ears via hearing aid vents	Is a binaural speech signal helpful?
Phone	Speech signal delivered via telephone handset to the test ear only	Delivered to one ear from telephone	Arrives at test ear via hearing aid vent Amplified by hearing aid in nontest ear	Is the standard listening condition different than wireless speech transmission?

slightly. To ensure that these spectral differences did not contribute to differences between conditions, a frequency-specific gain correction was applied to all speech signals transmitted wirelessly. Gain was applied in each of the eight frequency bands using the computer-controlled multi I/O processor until the difference between the response of the omni-directional microphone and wireless transmitter was ±2 dB. The resultant gain values were noted and used for all testing when the speech signal was delivered wirelessly to the hearing aids.

Noise Stimuli • During testing, four uncorrelated wave files were used as background noise. Each file was played using Adobe Audition (v1.5) and routed using a multichannel soundcard (Echo Layla) to four loudspeakers placed a distance of 1 m at equal eccentricities around the participant (45°, 135°, 225°, and 315°), which delivered uncorrelated speech-shaped babble. The spectral shapes of the noise files were then matched to the long-term average spectrum of the CST. However, during testing, the speech heard by participants was shaped by the amount of gain in the hearing aid and by the bandpass filter. The amount of noise in an individual's ear canal also depended on the type of dome (i.e., nonoccluding or occluding). In addition, when the external microphone was activated, gain was applied by the hearing aid to the noise in the environment. Consequently, the SNR used for testing varied by frequency, hearing aid testing condition, and by participants' individually prescribed hearing aid gain.

Figures 4 and 5 display the average SNRs present during the study for background levels of 55 and 65 dB, respectively. To measure SNRs, the study hearing aids were programmed in an IEC 711 artificial ear simulator and GRAS microphone amplifier (PowerModule Type 12AA) mounted within a K.E.M.A.R.

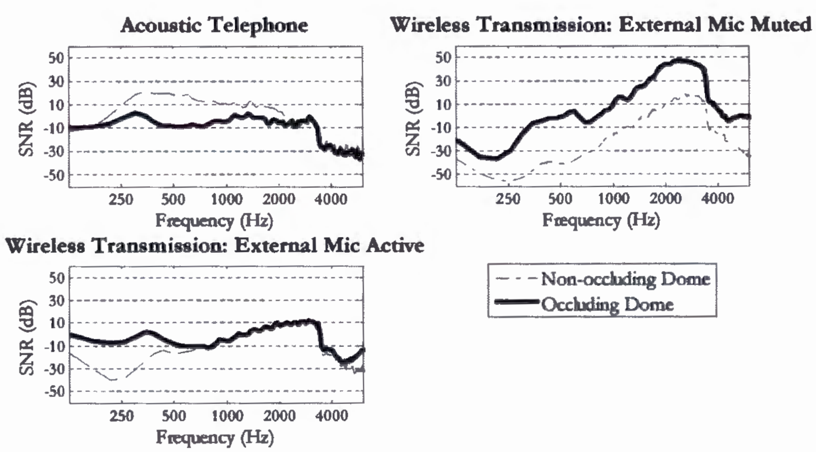

Fig. 4. Signal-to-noise ratio (SNR) of the test ear used during testing. Each panel displays the SNR for a speech delivery type (telephone, wireless transmission with external microphone muted, and wireless transmission with external microphone activated). SNR for participants tested with occluding domes are represented by solid lines and those fitted with nonoccluding domes are represented by dashed lines. Background noise level was 55 dB SPL.

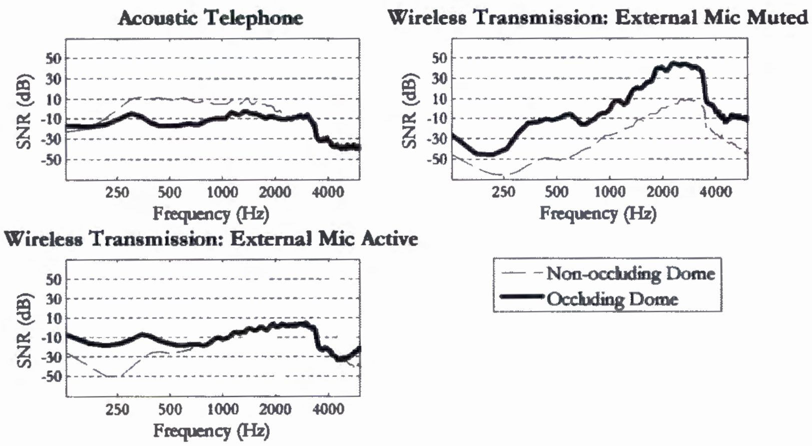

Fig. 5. Signal-to-noise ratio (SNR) of the test ear used during testing. Each panel displays the SNR for a speech delivery type (telephone, wireless transmission with external microphone muted, and wireless transmission with external microphone activated). SNR for participants tested with occluding domes are represented by solid lines and those fitted with nonoccluding domes are represented by dashed lines. Background noise level was 65 dB SPL.

to match the NAL-NL1 targets for the average hearing loss of the study participants. Steady state noises with the same long-term average spectral shape and level of the speech and noise levels used during testing were played independently for each of the inputs (acoustic telephone, wireless input with external microphone muted, and wireless input with external microphone activated) with the K.E.M.A.R. in the position participants were seated during testing. The microphone amplifiers delivered line input to an A/D converter (Echo Layla) connected to a laptop (Dell PC). The files were recorded into sound editing software (Adobe Audition v1.5). For each recording, a 1024-point Fast Fourier Transfer was calculated. Thus, the spectral information in each of the conditions served the basis of the SNR calculation.

Procedures

Participants completed speech recognition testing in 14 conditions (i.e., seven hearing aid configurations in two levels of background noise). Participants were counterbalanced for dome type (occluding or nonoccluding) and for test ear in the unilateral and acoustic phone conditions (right or left). Consequently, five participants were tested in the right ear with occluding domes; five were tested in the left ear with occluding domes; five were tested in the right ear with nonoccluding domes; and five were tested in the left ear with nonoccluding domes. All participants were tested with speech presented to both ears in the bilateral condition. To avoid effects of learning and fatigue, the order of conditions was counterbalanced within a given noise configuration.

Test Environment

Speech recognition scores were collected in a double-walled, sound-attenuating room (4 × 4.3 × 2.7 m). Participants were seated in the center of the room that was surrounded by loudspeakers delivering the background noise. The remaining equipment used for testing was outside the test environment.

Data Analysis

The speech recognition scores from each passage pair on the CST were transformed into rationalized arcsine units (rau) according to Studebaker (1985). A mixed-model overall analysis of variance (ANOVA) was completed with three between subject factors (test ear, dome type, and noise level) and one within subject factor (hearing aid condition). Given the potential effects of interest (altering the noise level in the nontest ear, unilateral versus bilateral wireless routing, activating the external microphone, and wireless routing versus acoustic telephone coupling), five a priori planned comparisons were completed as follow-up analyses to address five specific questions. For the follow-up comparisons, mixed-model ANOVAs were used, as was a Bonferroni adjustment to control for family-wise error rate. The standard significance level of $p < 0.05$ was divided by the number of comparisons (five), as suggested Dunn (1961). Therefore, a significance level of $p < 0.01$ was used for the five follow-up comparisons. Significant main effects or interactions in the planned comparisons were further analyzed using Tukey's HSD post hoc comparisons to evaluate all possible comparisons. For these additional follow-up analyses, the same significance level of $p < 0.01$ was maintained.

RESULTS

Figure 6 shows the average speech recognition performance in rau for the unilateral (U_{amp}), bilateral wireless (B), and acoustic phone conditions in both noise levels. Figure 7 shows the average speech recognition performance in rau for the conditions with external microphone active and muted for both noise levels. An overall ANOVA revealed a main effect of hearing aid condition ($F_{6,96} = 23.05$, $p < 0.001$) and noise level ($F_{1,16} = 450.95$, $p < 0.001$). There were significant interactions between hearing aid condition and dome type ($F_{6,96} = 3.98, p < 0.01$) and between hearing aid condition and noise level ($F_{6,96} = 10.73$, $p < 0.001$). There were no main effects of test ear or dome type. There were no other significant interactions. The significant effects were further investigated using five planned comparisons. For all planned comparisons, there were significant main effects of noise level ($p < 0.01$), but there were no significant main effects of dome type or test ear. There were no interactions except where noted.

There was no main effect of hearing condition when the performances in unilateral wireless transmission conditions were compared with each other, suggesting that alterations to the noise level in the nontest ear did not significantly influence speech recognition performance. See Table 2 for average scores (rau) in the unilateral conditions. There was also no

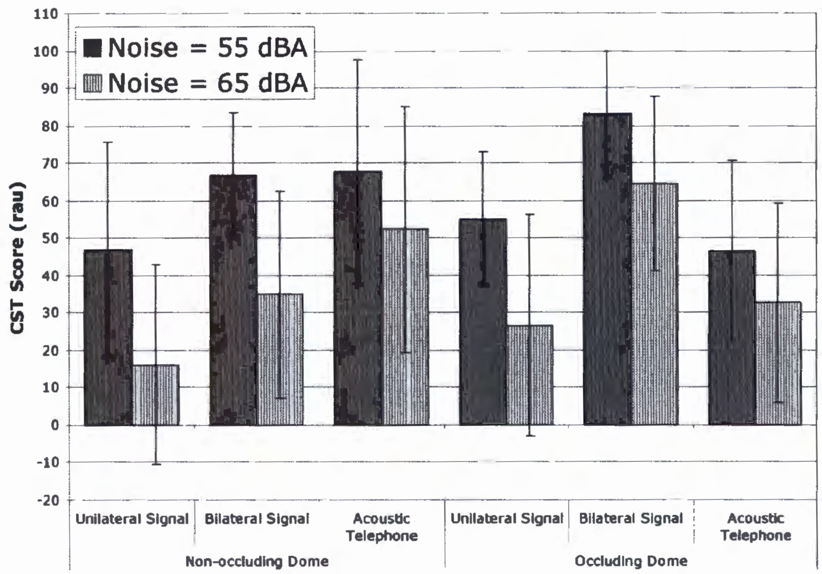

Fig. 6. Average speech recognition performance (rau) for the unilateral and bilateral wireless speech transmission conditions, in addition to the acoustic telephone condition. Error bars represent ± 1SD. Dark bars indicate conditions with background noise levels of 55 dB, whereas lighter bars represent conditions with 65 dB background noise.

significant difference between unilateral wireless routing and acoustic telephone routing. These results indicate that, regardless of dome type, the unilateral wireless transmission conditions were not different from each other and were not different from the acoustic telephone condition.

Further follow-up analysis revealed a significant benefit to bilateral compared with unilateral wireless speech transmission ($F_{1,16} = 67.45$, $p < 0.001$). Furthermore, when examining the difference between acoustic telephone and bilateral routing, there was no significant main effect of routing. However, there was a significant interaction between hearing aid condition (telephone or bilateral routing) and dome type ($F_{1,16} = 17.01$, $p < 0.001$). Follow-up Tukey's HSD post hoc comparisons revealed that bilateral wireless routing was significantly better than acoustic phone for those participants fitted with occluding domes ($p < 0.01$). Those fitted with nonoccluding domes did not demonstrate the same degree of benefit of bilateral listening (e.g., no significant difference in performance).

Last, the effect of activating the external microphone was investigated. There was a significant main effect of activating the external microphone (active, muted; $F_{1,16} = 74.14$, $p < 0.001$), in addition to a main effect of hearing aid condition (unilateral, bilateral; $F_{1,16} = 107.81$, $p < 0.001$). Furthermore, there was a significant interaction between microphone activation and noise level ($F_{1,16} = 17.07$, $p < 0.001$), indicating that activating the external microphone had a detrimental effect, which was larger for the higher background noise level relative to the lower noise level (see Fig. 7). The results also suggest that, although overall performance was impaired by activating the external microphone, the benefit of wirelessly routing the speech signal to both hearing aids instead of unilateral routing was preserved.

DISCUSSION

This study investigated speech recognition for listeners with sensorineural hearing loss using hearing aids and either wireless transmission or acoustic telephone. Listeners were seated in a noisy room and a speech signal was transmitted that included no noise. Two background noise levels were used to

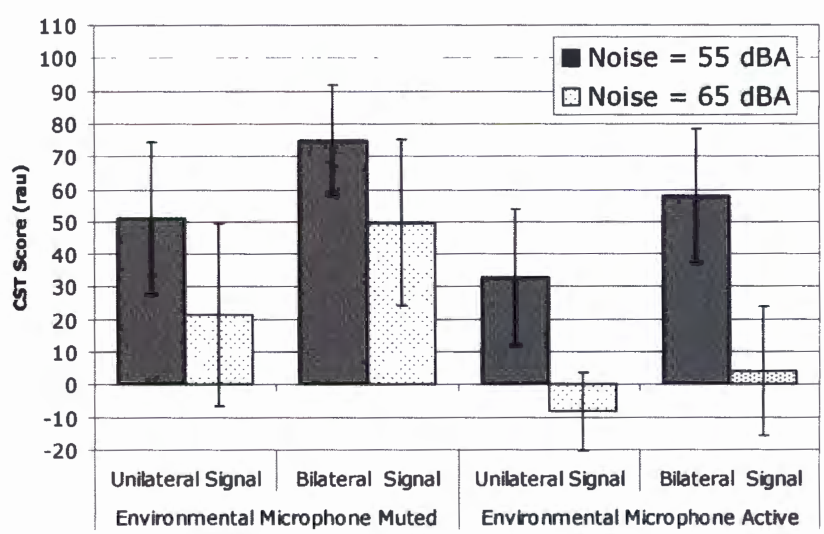

Fig. 7. Average speech recognition performance (rau) for the unilateral and bilateral wireless speech transmission conditions. External microphone is either muted or active but attenuated 6 dB. Error bars represent ± 1SD. Dark bars indicate conditions with background noise levels of 55 dB, whereas lighter bars represent conditions with 65 dB background noise.

TABLE 2. Average score (rau) in the unilateral hearing aid conditions

Condition	55 dB Background Noise	65 dB Background Noise
$U_{plugged}$	54.06	28.07
U_{unamp}	51.87	26.11
U_{amp}	51.01	20.74

represent typical background noise levels (55 and 65 dB SPL). Although speech recognition performance was always worse in the higher noise level, the pattern of results was generally the same for both noise conditions. In brief, the unilateral wireless speech transmission conditions ($U_{plugged}$, U_{unamp}, and U_{amp}) were not different from each other. However, bilateral wireless transmission was significantly better than the unilateral wireless speech transmission conditions. Also, results were generally independent of dome type (occluding or nonoccluding), although there were some significant differences between dome types when the acoustic telephone condition was considered. Therefore, the results will be discussed generally for both noise conditions and both dome types, except where indicated by significant statistical interactions.

Unilateral Conditions

Speech recognition performance was not different in any of the hearing aid configurations with unilateral wireless speech transmission. Plugging the nontest ear or turning off the nontest hearing aid did not improve speech recognition performance. These results were consistent with masking level difference data for pure tones. Typically, prior research has shown no benefit of signal detection in noise when listening to a tone in noise in one ear, compared with a condition with a tone in one ear and uncorrelated noise in both ears (for a review see Green 1976; Moore 1998). Such a scenario would be analogous to the difference between $U_{plugged}$ and U_{amp} in this study. Indeed, the same null effect has been reported for speech recognition as well. Holmes et al. (1983) tested speech recognition of monosyllable words transmitted over the telephone and found no benefit of plugging the nontest ear if listeners with normal hearing were seated in a room with white noise or a multitalker babble. Because plugging the contralateral ear does not seem to affect speech recognition performance, it is unclear why clinical patients report doing so. However, it is possible that there is some other benefit to this technique that was not evaluated in the current study, such as a reduction in listening effort.

It was also of clinical interest to determine whether unilateral wireless transmission was different from standard acoustic telephone listening. Although providing individualized amplification has been shown to improve phoneme recognition for speech transmitted over the telephone and listeners seated in a quiet room (Mackersie et al. 2009), these results suggest no difference between individualized amplification (wireless transmission) and standard acoustic telephone transmission. However, this study tested speech recognition of sentences for listeners seated in a noisy room, so the effect of background noise must be considered. Figure 3 reveals that the average SNR is essentially flat from approximately 300 to 3400 Hz, whereas the average SNR for unilateral wireless transmission has a substantial peak around 1500 to 3400 Hz. In the acoustic telephone condition, participants were instructed to hold the telephone receiver at a position that was comfortable and they could understand the speech the best. These instructions resulted in each participant pressing the telephone against the pinna, blocking the background noise. This difference in average SNR meant that the SNR is positive for a substantially larger frequency region for the acoustic telephone transmission than the unilateral wireless transmission. Having a more favorable SNR is important in the lower and middle frequency regions and is necessary to attain better speech recognition. Indeed, a frequency importance function for the CST published by Sherbecoe and Studebaker (2002) indicates the CST has 75.5% of important information that is between 315 and 3150 Hz but only 37.22% between 1600 and 3150 Hz. Because of the discrepancy in SNR shape, unilateral wireless transmission has less important information (38.3%) for portions of the signal with a positive SNR. Therefore, although the speech signal is amplified based on each individual's hearing loss, the potential benefits seem to be negated by the presence of the background noise. Although telecoils were not tested in this study, the results are expected to be similar using telecoil and wireless signal transmission because both are susceptible to the effects of venting and both provide individualized amplification of the telephone signal. Furthermore, for listeners with mild-to-moderate hearing loss, telecoil and acoustic telephone performance has been reported to be similar (Cashman et al. 1982). However, future studies are warranted to further investigate the differences between acoustic telephone, telecoil, and wireless transmission conditions, especially for listeners with more significant hearing loss.

Bilateral Conditions

Although investigators have generally reported mixed results for bilateral versus unilateral hearing aid fittings in noisy environments (Nabelek & Mason 1981; Schreurs & Olsen 1985; Festen & Plomp 1986; Moore et al. 1992), these results indicated a significant benefit of bilateral speech transmission compared with unilateral wireless speech transmission for all noise configurations. These results are consistent with several lines of evidence that suggest listening with two ears typically yields better results than listening with only one ear. The benefit is often attributed to binaural summation (or binaural redundancy) and binaural squelch.

Previous work suggests that the amount of binaural summation depends on the stimuli and the threshold measurement procedure but ranges from 3 to 10 dB for 500 and 4000 Hz pure tones and speech-shaped noise (Hirsh 1948; Byrne 1981; Hawkins et al. 1987). For speech stimuli, Davis et al. (1990) reported that listeners showed a diotic listening performance improvement of 9 points when their monaural speech recognition scores were 70% on a sentence identification task for listeners with normal hearing. Because the degree of binaural summation is likely similar for listeners with normal hearing and with hearing loss (Plomp & Mimpen 1981; Hawkins et al. 1987; Davis et al. 1990; Moore 1998), similar results may be expected in this study. Although the speech signal in this study was not truly diotic due to the presence of background noise, in the higher frequencies, the speech signal was clearly dominant (see Figs. 3 and 4). Thus, the high frequency portion of the signal was essentially diotic, and benefits from summation could be expected. However, on average, participants benefited 20 rau points from a bilateral speech signal compared with a unilateral speech signal. Thus, binaural summation likely is not the only explanation to the bilateral advantage.

Binaural squelch, an additional possible explanation for the bilateral improvement, is related to binaural summation but accounts for the effect of the background noise. According to Zurek (1992), binaural squelch occurs when the interaural differences of the speech are different from the interaural differences of the background noise. The binaural auditory system is able to use the differences between the interaural relationships to "squelch" the background noise, allowing speech recognition to improve relative to a monotic listening situation and relative to true diotic presentation (Koenig 1950).

This advantage may be due in part to the "cross-over" effect reported by Byrne and Dermody (1974). They suggested that if a patient has better hearing at some frequencies in one ear, and better hearing at different frequencies in the other ear, fitting two hearing aids allows for better overall hearing at the combination of those frequencies than fitting either ear with a single hearing aid. Similarly, if the SNR is better at some frequencies in one ear and better at other frequencies in the opposite ear, listeners will likely perform better listening bilaterally than monaurally. Although the traditional evaluations of binaural squelch compare performance when speech and noise are placed on opposite sides of the head, the mechanisms underlying binaural squelch probably contribute to better speech recognition for the wireless diotic condition compared with wireless monotic speech transmission conditions.

Although bilateral wireless routing allowed for significantly better performance compared with unilateral conditions, it was also of considerable clinical and practical interest to determine whether bilateral wireless speech transmission was superior to the traditional acoustic telephone listening scenario. Results indicated that the efficacy of bilateral wireless speech transmission compared with acoustic telephone speech transmission was dependent on the degree to which the hearing aid was occluding. When the hearing aids were coupled to the ear with occluding domes, wireless bilateral speech transmission resulted in significantly better speech recognition compared with acoustic telephone listening for both background noise levels in the listener's environment (55 and 65 dBA). Conversely, participants who were tested with nonoccluding domes did not perform better with bilateral speech condition than with traditional acoustic telephone coupling. As discussed previously, this interaction between hearing aid condition and dome type was driven by poorer performance of individuals tested with occluding domes while listening on the telephone. The occluding domes attenuate the signal from the acoustic telephone, impairing performance in the acoustic telephone condition (see Figs. 4 and 5).

One caveat to the study findings was that all participants in the study had similar hearing loss configurations. People with more severe hearing loss might be expected to benefit more from wireless technology relative to an acoustic telephone for several reasons. First, more hearing loss often requires less venting to achieve sufficient gain. The results of this study indicated that occluding domes with minimal venting impaired performance with an acoustic telephone, allowing for benefit from modern wireless streaming. Second, in the acoustic telephone condition, participants in this study pressed the telephone receiver tightly against the pinna. This resulted in the hearing aid amplifying only noise, while the speech signal reached the ear canal unamplified. Because participants were instructed to place the telephone receiver where they could hear optimally, it is unlikely changing the position of the receiver would improve performance in the acoustic telephone condition. Placing the telephone receiver near the hearing aid microphone would significantly reduce the differences between nonoccluding and occluding domes. However, instead of improving performance for those fitted with occluding domes, performance for people fitted with nonoccluding domes would be impaired because the SNR is worse when the telephone is placed near the hearing aid microphone instead of against the ear (see Fig. 3). Thus, holding the receiver against the pinna may have been the best strategy for the participants in this study. If people with greater hearing loss used a similar strategy, performance in the acoustic telephone condition would be predicted to be worse, resulting more benefit from the wireless streaming. Last, the level of the transmitted speech signal depends on the amount of gain in the hearing aid. People with more hearing loss will require more hearing aid gain and thus will likely experience a more positive SNR for wireless streaming conditions. Therefore, future studies are needed to investigate the effect of degree and configuration of hearing loss on the efficacy of the modern wireless transmission for telephone use.

External Microphone

In noisy environments similar to those simulated in the laboratory for this study, activating the external microphone negatively affected performance. This finding is consistent with the findings of Holmes et al. (1983) who reported that deactivating the side-tone feedback feature of a telephone handset improved speech recognition for listeners with normal hearing listening to a telephone in a noisy room. The side-tone feedback feature amplifies signal near the telephone receiver including the talker's voice and background noise and routes the signal to the earpiece. By enabling the feature, more background noise is introduced into the signal of interest and speech recognition performance suffers.

The finding that activating the external microphone negatively affects performance is also consistent with research that investigated FM system use wherein activating the external microphone limited performance. For example, Hawkins (1984) reported that, for children with mild-to-moderate hearing loss, the 15 dB SNR benefit of using an FM system over use of a hearing aid was reduced when the external microphone was activated. Indeed, for FM fittings, ASHA recommends attenuating the external microphone by 10 dB for use in classrooms (ASHA 2002). For this study, when the external microphone was activated, it was attenuated 6 dB relative to the wireless signal. It is possible that attenuating the external microphone more would have yielded better speech recognition scores.

SUMMARY AND CONCLUSIONS

- Regardless of noise configuration, there was no benefit of plugging the nontest ear or muting the nontest hearing aid if the speech signal was delivered to one ear only. For unilateral scenarios, it appears there is no benefit to muting the contralateral hearing aid.

- There were significant objective benefits observed for bilateral wireless speech transmission compared with unilateral wireless speech transmission regardless of background noise level.
- Activating the external microphone decreased speech recognition performance relative to muting the external microphone. Regardless of the noise configuration, it is unclear to which extent activating the external microphone allowed for environmental monitoring, as the ability to monitor the environment was not tested. Furthermore, the nonoccluding aspects of some hearing aids may allow for sufficient environmental monitoring, provided the listener has sufficient hearing. Future studies are warranted to investigate the ability of participants to monitor their environment with the external microphone activated and muted.
- Wireless signal streaming was shown to be beneficial compared with acoustic telephone listening and in some conditions resulted in the best performance of all of the listening conditions evaluated. However, this advantage was only evident when the signal was routed to both ears and when hearing aid wearers were fitted with occluding domes.
- The findings from this study are explainable by examining the SNRs that result from listening telephone in a noisy room. Other technologies that create similar SNRs will likely yield similar results. Therefore, while the results of this study are specific to the wireless streaming system used for testing (Siemens Pure 700 receiver-in-the-canal hearing aids paired with a Tek Connect transmitter), similar findings may be expected with wireless systems from other manufacturers that operate similarly.

ACKNOWLEDGMENTS

The authors thank Drs. Benjamin W.Y. Hornsby, Daniel Ashmead, and Gene Bratt for their helpful suggestions throughout the design and implementation of this experiment. The authors also thank Tasha Cantelmo, Jeremy Federman, Elise Neukom, and Lisa Sykes for their assistance with the project.

This work was supported in part by Siemens Hearing, Inc.

Address for correspondence: Erin M. Picou, AuD, Vanderbilt University Medical Center, 1215 21st Ave South Room 8310, Nashville, TN 37232-8242. E-mail: erin.picou@vanderbilt.edu.

Received December 8, 2009; accepted July 29, 2010.

REFERENCES

American Speech-Language-Hearing Association (ASHA). (2002). Guidelines for fitting and monitoring FM systems [Guidelines]. Retrieved October 11, 2009, from www.asha.org/policy.

Boothroyd, A., & Iglehart, F. (1998). Experiments with classroom FM amplification. *Ear Hear*, *19*, 202–217.

Byrne, D. (1981). Clinical issues and options in binaural hearing aid fitting. *Ear Hear*, *2*, 187–193.

Byrne, D., & Dermody, P. (1974). An incidental advantage of binaural hearing aid fittings the "cross-over" effect. *Br J Audiol*, *8*, 109–112.

Byrne, D., Dillon, H., Ching, T., et al. (2001). NAL-NL1 procedure for fitting nonlinear hearing aids: Characteristics and comparisons with other procedures. *J Am Acad Audiol*, *12*, 37–51.

Cashman, M. Z., Rossman, R. N., Abel, S. M. (1982). A comparison of three modes of hearing aid-telephone coupling. *J Otolaryngol*, *11*, 239–247.

Chung, K. (2004). Challenges and recent developments in hearing aids. Part II. Feedback and occlusion effect reduction strategies, laser shell manufacturing processes, and other signal processing technologies. *Trends Amplif*, *8*, 125–164.

Compton, C. (1994). Providing effective telecoil performance with in-the-ear hearing instruments. *Hear J*, *47*, 23–26.

Cox, R. M., Alexander, G. C., Gilmore, C. (1987). Development of the Connected Speech Test (CST). *Ear Hear*, *8(5 suppl)*, 119S–126S.

Cox, R. M., Alexander, G. C., Gilmore, C., et al. (1988). Use of the Connected Speech Test (CST) with hearing-impaired listeners. *Ear Hear*, *9*, 198–207.

Davis, A., Haggard, M., Bell, I. (1990). Magnitude of diotic summation in speech-in-noise tasks: Performance region and appropriate baseline. *Br J Audiol*, *24*, 11–16.

Desjardins, J. L., & Doherty, K. A. (2009). Do experienced hearing aid users know how to use their hearing aids correctly? *Am J Audiol*, *18*, 69–76.

Dillon, H. (1985). Earmolds and high frequency response modification. *Hear Instrum*, *36*, 8–12.

Dillon, H. (1991). Allowing for real ear venting effects when selecting the coupler gain of hearing aids. *Ear Hear*, *12(6)*, 406–416.

Dunn, O. J. (1961). Multiple comparisons among means. *J Am Stat Assoc*, *56*, 52–64.

Festen, J. M., & Plomp, R. (1986). Speech-reception threshold in noise with one and two hearing aids. *J Acoust Soc Am*, *79*, 465–471.

Goldberg, H. (1975). Telephone amplifying pick-up devices. *Hear Instrum*, *26*, 19–20.

Green, D. M. (1976). *An Introduction to Hearing*. Hillsdale, NJ: Lawrence Erlbaum Associates.

Hall, J. W., & Harvey, A. D. (1985). Diotic loudness summation in normal and impaired hearing. *J Speech Hear Res*, *28*, 445–448.

Hall, J. W., Tyler, R. S., Fernandes, M. A. (1984). Factors influencing the masking level difference in cochlear hearing-impaired and normal-hearing listeners. *J Speech Hear Res*, *27*, 145–154.

Hawkins, D. B. (1984). Comparisons of speech recognition in noise by mildly-to-moderately hearing-impaired children using hearing aids and FM systems. *J Speech Hear Disord*, *49*, 409–418.

Hawkins, D. B., Prosek, R. A., Walden, B. E., et al. (1987). Binaural loudness summation in the hearing impaired. *J Speech Hear Res*, *30*, 37–43.

Hirsh, I. J. (1948). Binaural summation; a century of investigation. *Psychol Bull*, *45*, 193–206.

Holmes, A. E. (1985). Acoustic vs. magnetic coupling for telephone listening of hearing-impaired subjects. *Volta Rev*, *87*, 215–222.

Holmes, A. E., Frank, T., Stoker, R. G. (1983). Telephone listening ability in a noisy background. *Ear Hear*, *4*, 88–90.

Kochkin, S. (2000). MarkeTrak V: "Why my hearing aids are in the drawer": The consumers' perspective. *Hear J*, *53*, 34–42.

Kochkin, S. (2002). MarkeTrak VI: 10-year customer satisfaction trends in the US hearing instrument market. *Hear Rev*, *9*, 14–25.

Kochkin, S. (2005). MarkeTrak VII: Customer satisfaction with hearing aids in the digital age. *Hear J*, *58*, 30–39.

Koenig, W. (1950). Subjective effects in binaural hearing. *J Acoust Soc Am*, *22*, 61–62.

Latzel, M., Gebhart, T. M., Kiessling, J. (2001). Benefit of a digital feedback suppression system for acoustical telephone communication. *Scand Audiol Suppl*, *52*, 69–72.

Levitt, H., & Rabiner, L. R. (1967). Binaural release from masking for speech and gain in intelligibility. *J Acoust Soc Am*, *42*, 601–608.

Licklider, J. C. R. (1948). The influence of interaural phase relations upon the masking of speech by white noise. *J Acoust Soc Am*, *20*, 150–159.

Mackersie, C. L., Qi, Y., Boothroyd, A., et al. (2009). Evaluation of cellular phone technology with digital hearing aid features: Effects of encoding and individualized amplification. *J Am Acad Audiol*, *20*, 109–118.

Moore, B. C. J. (1998). *Cochlear Hearing Loss*. London: Whurr Publishers.

Moore, B. C., Johnson, J. S., Clark, T. M., et al. (1992). Evaluation of a dual-channel full dynamic range compression system for people with sensorineural hearing loss. *Ear Hear*, *13*, 349–370.

Mormer, E., & Mack, A. (2003). Telephone across the lifespan: An issue for all. *Semin Hear*, *24*, 1–16.

Nabelek, A. K., & Mason, D. (1981). Effect of noise and reverberation on binaural and monaural word identification by subjects with various audiograms. *J Speech Hear Res*, *24*, 375–383.
Palmer, C. V. (2001). Ring, ring! Is anybody there? Telephone solutions for hearing aid users. *Hear J*, *54*, 10.
Pearsons, K. S., Bennett, R., Fidell, S. (1977). *Speech Levels in Various Noise Environments*. Washington, DC: US Environmental Protection Agency.
Plomp, R., & Mimpen, A. M. (1981). Effect of the orientation of the speaker's head and the azimuth of a noise source on the speech reception threshold for sentences. *Acoustica*, *48*, 325–328.
Quaranta, A., & Cervellera, G. (1974). Masking level difference in normal and pathological ears. *Audiology*, *13*, 428–431.
Richards, V. M., Moore, B. C., Launer, S. (2006). Potential benefits of across-aid communication for bilaterally aided people: Listening in a car. *Int J Audiol*, *45*, 182–189.
Schreurs, K. K., & Olsen, W. O. (1985). Comparison of monaural and binaural hearing aid use on a trial period basis. *Ear Hear*, *6*, 198–202.
Sherbecoe, R. L., & Studebaker, G. A. (2002). Audibility-index functions for the Connected Speech Test. *Ear Hear*, *23*, 385–398.
Smith, G. M. (1974). The telephone adapter and other telephone aids for the hard of hearing. *Volta Rev*, *76*, 474–484.
Sorri, M., Piiparinen, P., Huttunen, K., et al. (2003). Hearing aid users benefit from induction loop when using digital cellular phones. *Ear Hear*, *24*, 119–132.
Studebaker, G. A. (1985). A "rationalized" arcsine transform. *J Speech Hear Res*, *28*, 455–462.
Tannahill, J. C. (1983). Performance characteristics for hearing aid microphone versus telephone and telephone/telecoil reception modes. *J Speech Hear Res*, *26*, 195–201.
Vargo, S. W., Taylor, G., Tannahill, J. C., et al. (1970). The intelligibility of speech by hearing aids on inductance loop and microphone modes of signal reception. *J Speech Hear Res*, *13*, 87–91.
Yanz, J. L. (2005). A new solution for telephone/hearing aid issues. *Hear J 58*, 41, 42, 44, 48.
Yanz, J. L., & Preves, D. (2003). Telecoils: Principles, pitfalls, fixes, and the future. *Semin Hear*, *24*, 29–41.
Zurek, P. M. (1992). Binaural advantages and directional effects in speech intelligibility. In G. A. Studebaker & I. Hochberg (Eds). *Acoustical Factors Affecting Hearing-Aid Performance* (pp. 255–276). Boston, MA: Allyn & Bacon.

A new method for wireless connectivity in hearing aids

By Jason A. Galster

In this era of wireless connectivity, the way we use technology to interact and communicate with each other has changed our perception of the world around us. Happily, hearing aids are no longer an exception, as these devices have become more than just sophisticated signal processors designed to amplify speech. For many patients with hearing loss, a hearing aid is not only a personal communication device, but also a gateway to media connectivity and greater convenience in communication.

Today's digital wireless protocols allow for wireless communication between hearing aids and from hearing aids to numerous forms of media devices. Some of these offerings use frequencies that allow for far-field signal transmission, while others focus on near-field communication. A wide array of frequencies is available for wireless data and audio transmission; the transmission and reception of these signals is performed by small radios embedded in the hearing aids and remote devices.

This article will focus on the wireless communication ability of currently available hearing aids, which, at the time of this publication, function in one of three different frequency bands: 3- to 15-MHz near-field magnetic induction; 2.4-GHz industrial scientific medical band; and 900-MHz industrial scientific medical band.

NEAR-FIELD MAGNETIC INDUCTION

The most common approach to wireless communication in hearing aids is near-field magnetic induction (NFMI). Wireless communication through NFMI uses technology similar to a traditional telecoil. The range of frequencies used in hearing aids for NFMI data transmission typically falls between 3 and 15 MHz.

The benefits of NFMI technology lie in a few different areas. First, the hardware used in NFMI data transmission is well established, making it accessible for all hearing instrument manufacturers. Second, NFMI operates within a frequency band that easily propagates through and around the human head and body. This ease of propagation allows for ear-to-ear communication between hearing aids, providing the convenience of synchronized adjustments to memory or volume, as well as the benefits of binaural signal processing between hearing aids.

The fundamental drawback to the use of NFMI is limited transmission range. Its use of magnetic signal transmission, similar to a telecoil, results in a wireless signal that degrades quickly. Specifically, the magnetic signal degrades approximately proportionally to the inverse of the transmission distance *cubed*, whereas with far-field or long-distance transmission methods (e.g., 900-Mhz and 2.4-GHz), signals degrade at a rate proportional to the inverse of the distance *squared*. This relationship is illustrated in Figure 1. For this reason, most modern hearing aids using NFMI have a transmission range that falls within 1 meter of the hearing aids.

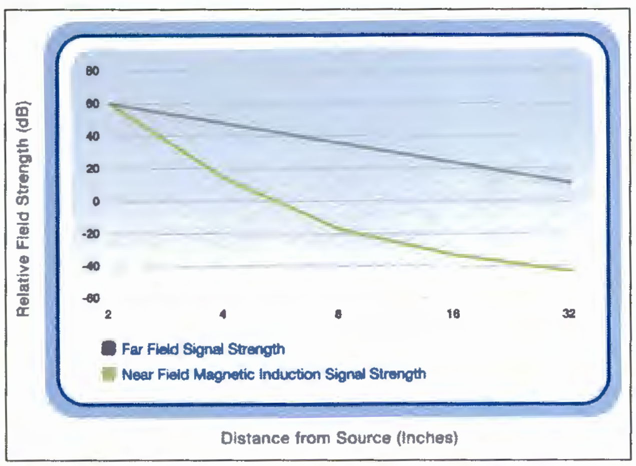

Figure 1. *Illustration of relative field strength as a function of distance for near-field magnetic induction and far-field transmission methods.*

The range of NFMI wireless transmission has been the impetus for the development of intermediate relay accessories that facilitate wireless communication over longer distances. The relay device remains close to the hearing aids, translating the short-range NFMI signal from the hearing aids to a longer-range transmission method, such as Bluetooth.

This type of hybrid wireless transmission must combat delay in the transmission of audio information. These delays result from the audio data compression and transcoding of standardized wireless protocols, such as Bluetooth, to each manufacturer's proprietary NFMI signal. In the case of audio/video media, delayed audio may result in a "lip sync" effect, or a lack of synchrony between the video and the streamed audio. The International Telecommunication Union suggests that audio/video transmission delays should not exceed -40 milliseconds (audio delayed) and +20 milliseconds (audio advanced).[1]

Listeners' tolerance for delay within an audio stream is even smaller when the amplified audio stream and the airborne, direct audio path are combined, leading to a perceived echo during audio streaming. Small delays in streamed audio may be especially detrimental for patients who enjoy listening to music through open-canal hearing aids. Patients with normal-to-mild, low-frequency thresholds may want to enjoy music through their stereo speakers while simultaneously listening to streamed, amplified audio through their hearing aids. In the case of well vented or open-canal hearing aids, a delay of even 5 milliseconds may degrade sound quality, as the direct, unamplified audio path arrives sooner than the amplified audio.[2]

2.4-GHz INDUSTRIAL SCIENTIFIC MEDICAL (ISM) BAND

Many wireless technologies operate at or near 2.4 GHz. Some of these technologies include Bluetooth, Wi-Fi, wireless telephones, and wireless video game controllers. In 2001, the Federal Communications Commission (FCC) opened the 2.4-GHz band to public use. This resulted in an influx of products that use this band. A 2010 joint publication from the European Hearing Instrument Manufacturer's Association (EHIMA) and the Hearing Industries Association (HIA) reports the number of FCC product grants (i.e., product approvals) submitted annually since 2001.[3] In 2009, the number of product approvals for 2.4-GHz wireless systems was approximately 100 times that for products in all other ISM frequency bands.

Considering the widespread use of the 2.4-GHz band for audio transmission, it seems intuitive to use this frequency band for wireless data transmission in hearing aids. The high-frequency nature of the 2.4-GHz band allows signals to propagate easily through air, experiencing much less degradation of signal strength than with NFMI. For this reason, wireless hearing aid communication in this band allows for long-distance audio streaming, as well as wireless programming.

However, the high-frequency nature of the 2.4-GHz signal also results in a short wavelength that does not propagate well through and around the human head and body. Therefore, while the 2.4-GHz band has the benefit of increased transmission distance compared to NFMI, it may not allow a pair of bilateral hearing aids to communicate for the purposes of ear-to-ear processing without high-power consumption or the use of an intermediate relay device.

900-MHz INDUSTRIAL SCIENTIFIC MEDICAL BAND

The 900-MHz ISM band is a third frequency band used with medical devices for wireless data transmission. This band is now being used for communication between hearing aids. The 900-MHz transmission characteristics allow for long-distance wireless programming, audio streaming, and ear-to-ear binaural processing, without an intermediate relay device.

A 900-MHz signal will propagate through and around the body with less signal degradation than is encountered with a 2.4-GHz signal, making it the only stand-alone option currently available for both far-field wireless transmission and reliable ear-to-ear communication.

These combined benefits relate, in part, to the wavelength of the transmission signal. The calculated wavelength of a signal transmitted at 900 MHz is 0.33 meters; this falls between that of a 2.4-GHz signal and of NFMI, yet is still greater than the width of the human head. This allows for reliable signal propagation through and around the head, which is difficult with the higher 2.4-GHz signal using typical hearing aid power levels, and does so without need for an intermediate relay device positioned within 1 meter of the hearing aids.

Table 1 summarizes the capabilities of currently available wireless technologies.

IRIS—FOR LONG-DISTANCE WIRELESS TRANSMISSION

The 900-MHz implementation of wireless hearing aids features a wireless technology developed by Starkey Laboratories, called Iris. The term calls to mind the eye and connotes the ability to transmit and receive data across a long distance.

Table 1. *A comparison of wireless capabilities for transmission within the 3- to 15-MHz, 2.4-GHz, and 90- MHz spectra.*

	Far-field Wireless Transmission	No Intermediate Device	Bilateral Signal Processing
NFMI	✗	✗	✓
2.4 GHz	✓	✓	✗
900 MHz	✓	✓	✓

The Iris wireless system is designed to offer long-distance audio streaming, wireless programming, and binaural signal processing, without need for an intermediate relay. For wireless audio streaming, a wireless media device, SURFLink Media, connects to the patient's television or other media source and streams stereo audio directly to the hearing aids—up to 20 feet away. When a hearing aid enters the range of the media device, it can be programmed to detect that streaming device automatically and accept the new audio input.

For instance, if a patient returned home from work, her hearing aids could immediately begin streaming audio from the television when she entered the front door; or the option to manually initiate audio streaming is also available. An unlimited number of hearing aids can access a single SURFLink media device, without the need for pairing. If used in a group living environment, everyone wearing hearing aids with the Iris wireless technology can access the television's audio by simply walking into the same room as the television. Disconnecting from the audio stream is as easy as leaving the room or tapping the memory button on the hearing aid.

Adaptive Frequency Agility

Any robust wireless technology must be designed to avoid interference from nearby electronics. Iris uses a system called Adaptive Frequency Agility for avoiding signal interference, maintaining signal quality, and allowing for wireless communication without need for "pairing" routines.

Adaptive Frequency Agility uses a "look ahead" approach to data transmission. The hearing aid constantly monitors wireless data channels around the 900-MHz frequency band, searching for the optimal frequency channel. If an adjacent frequency channel can offer improved signal quality, the system will transition to the optimum channel. Not only does this maintain a high-quality media stream, but it also allows for multiple wireless programmers and SURFlink media devices to work in the same office or household.

Enabling the instrument to select among multiple frequency channels around the 900-MHz ISM band dramatically reduces the probability of degraded communication. For example, if the probability for interference on a single channel is 1% and the probability for interference on a second channel is 1%, the probability for interference on both channels simultaneously is 0.01%. Such conditional probabilities across independent channels result in an overall likelihood of interference that is strikingly small.

APPEAL TO PATIENTS AND PROFESSIONALS

In focus groups and personal communication, hearing care providers have requested wireless systems that do not need intermediate relay devices for media streaming and remote programming. They have also asked for systems that do not require pairing for media connectivity.

Meanwhile, professionals say their patients express delight in the convenience of synchronizing memory and volume adjustments, and they appreciate the hearing benefits that binaural signal processing can provide.

There are many options for wireless connectivity in modern hearing aids. Each of these offers a unique set of benefits that will change quickly as technology advances.

Acknowledgments

Thanks go to Dave Fieves, Jeff Solum, Yoshi Kasahara, Justyn Pisa, and Renata Solum for their contributions.

Jason A. Galster, PhD, is Director of Audiology Communications at Starkey Laboratories, Inc. Readers may contact Dr. Galster at jason_galster@starkey.com.

REFERENCES

1. EHIMA/HIA TR 101 V2.2 (2010-03-04) Draft. *Electromagnetic compatibility and radio spectrum matters (ERM); Hearing instrument RF interference analysis.*
2. International Telecommunication Union: Document 11A/47-E, 13, October 1993.
3. Stone MA, Moore BCJ, Meisenbacher K, Derleth RP: Tolerable hearing aid delays. V. Estimation of limits for open canal fittings. *Ear Hear* 2008;29(4): 601-617.

Trends in Amplification
14(1) 3–11
© The Author(s) 2010
Reprints and permission: http://www.sagepub.com/journalsPermissions.nav
DOI: 10.1177/1084713810364396
http://tia.sagepub.com
SAGE

Improvements in Speech Understanding With Wireless Binaural Broadband Digital Hearing Instruments in Adults With Sensorineural Hearing Loss

Brian M. Kreisman, PhD,[1] Annette G. Mazevski, AuD,[2] Donald J. Schum, PhD, and Ravichandran Sockalingam, PhD[4]

Abstract

This investigation examined whether speech intelligibility in noise can be improved using a new, binaural broadband hearing instrument system. Participants were 36 adults with symmetrical, sensorineural hearing loss (18 experienced hearing instrument users and 18 without prior experience). Participants were fit binaurally in a planned comparison, randomized crossover design study with binaural broadband hearing instruments and advanced digital hearing instruments. Following an adjustment period with each device, participants underwent two speech-in-noise tests: the QuickSIN and the Hearing in Noise Test (HINT). Results suggested significantly better performance on the QuickSIN and the HINT measures with the binaural broadband hearing instruments, when compared with the advanced digital hearing instruments and unaided, across and within all noise conditions.

Keywords

hearing aid technology, speech perception, speech in noise, focused contrasts

Introduction

As a field, audiology has long focused on improving audibility as the primary method for correcting hearing loss. While hearing aids provide audibility to enable users to hear better, being able to understand speech is the main reason why hearing aids are used. Several studies have reported speech perception as the single most important aspect of hearing that attributes to hearing aid success (Meister, Lausberg, Kiessling, Walger, & von Wedel, 2002; Meister, Lausberg, Walger, & von Wedel, 2001; Walden & Walden, 2004). With this consideration in mind, hearing aid developers have directed much of their efforts on improving speech intelligibility in noise.

A noisy environment is invariably more challenging for most hearing aid users. In a survey of 3,000 hearing instrument owners by Kochkin (2005), it was found that only 59% of hearing aid users were satisfied with the overall performance of their instruments. Primary reasons for declines in use included difficulties communicating in noisy or difficult listening situations. Naturalness and clarity of sound were reported to be the strongest attributes for successful use of amplification. Walden and Walden (2004) investigated factors contributing to successful amplification use and concluded that variable signal-to-noise ratios (SNRs) within particular environments could determine an individual's successfulness with his or her amplification. Specifically, they found that individuals with hearing loss who could understand speech at lower SNRs are more likely to be successful with hearing aids than individuals that needed higher SNRs. Therefore, bilateral digital technology that promotes noise reduction and enhances the intended speech may encourage successful interactions in situations where communicating can be difficult for an individual with hearing loss.

With the advent of new technologies such as wireless communication between instruments and extended bandwidth, the focus on speech perception has been extended to understanding speech in complex listening environments. Day-to-day listening situations can include following conversation between multiple speakers and listening to a speaker in the presence of competing speakers. In these

[1]Towson University, Towson, MD, USA
[2]Gallaudet University, Washington, DC, USA
[3]Oticon Inc., Somerset, NJ, USA
[4]Oticon A/S, Smørum, Denmark

Corresponding Author:
Brian M. Kreisman, Department of Audiology, Speech-Language Pathology & Deaf Studies Towson University, 8000 York Road, Towson, MD 21252, USA
Email: bkreisman@towson.edu

environments, the SNR is not the only key to speech understanding. Spatial characteristics of sound, such as time differences (sound reaching one ear prior to the other) and level differences (sound louder in the ear that is closer to the sound), also play an integral role in helping the listener navigate through the complex listening world against a backdrop of competing speakers. These characteristics influence how successful an individual will be with localizing speech information.

Hearing instruments in which compression parameters can be differentially adjusted between ears via the wireless link to maintain the interaural differences are available commercially today. With ear to ear synchronization of gain and directionality becoming more common in advanced digital technologies, it could be possible for psychoacoustic cues such as interaural level differences (ILDs) that are vital for source localization to be preserved. Schum and Bruun Hansen (2007) provided a demonstration of the effectiveness of coordinated compression (Spatial Sound) with recordings of white noise presented at 90° azimuth made in KEMAR ear canals. With no hearing aids on KEMAR, the ILD was 8 dB between the near ear and far ear. With Epoqs programmed to a flat 50 dB hearing loss (HL) and a closed microMold, the ILD was 6.5 dB with Spatial Sound on, but only 2.5 dB with Spatial Sound off (Schum & Bruun Hansen, 2007). However, the questions remain as to whether extended bandwidth and/or wirelessly linking the right and left instruments results in better speech intelligibility in the presence of competing speech or speech-spectrum noise.

The purpose of the present investigation was to examine the first of these two questions. Specifically, the present study compared the speech in noise performance of an extended bandwidth (10kHz) wireless binaural broadband instrument (Epoq XW) with an advanced nonwireless instrument with a lower bandwidth (8kHz; Syncro) in both experienced and first-time users of amplification.

Methods

Participants

A total of 36 individuals (22 men, 14 women), aged 39 to 79 years (mean 64.5 years), volunteered for the study. All participants (18 new and 18 experienced hearing instrument users) had symmetrical sensorineural hearing loss, were fluent speakers of English, had sufficient literacy to read and comprehend the language of the test instruments used in this study, and were motivated to try two digital behind the ear (BTE) hearing instruments from Oticon A/S, Denmark. Sensorineural hearing loss could not be worse than 75 dB HL at 250 Hz and 500 Hz, and no worse than 80 dB HL at any other frequency, up to 8 kHz. The hearing loss had to be symmetrical (average of 500Hz, 1kHz, 2kHz, and 4 kHz) and no greater than 10 dB at any frequency. Participants were excluded from the study if any cognitive deficits and/or auditory processing disorders were present, as well as chronic middle ear pathology.

Materials

QuickSIN. The QuickSIN (Etymotic Research, 2001) measures a listener's SNR loss when given six sentences to repeat in the presence of background babble. A list of six sentences with five key words per sentence, spoken by a female talker, is presented in four-talker babble noise. The sentences are presented at prerecorded SNRs that decrease in 5-dB steps from 25 dB SNR (very easy) to 0 dB SNR (extremely difficult). SNR loss is calculated as 25.5 – total correct key words (Etymotic Research, 2001). SNR loss reflects an individual's receptive speech understanding in noise. Participants completed two lists of the QuickSIN with speech presented at 65 dBA at 0° azimuth in two conditions of uncorrelated speech babble created from tracks extracted from the QuickSIN CD (Etymotic Research, 2001). The first condition was speech babble presented at ±135° azimuths, and the second condition was speech babble presented at "four corners," that is, ±45° and ±135° azimuth.

Hearing in Noise Test. The Hearing in Noise Test (HINT; Nilsson, Soli, & Sullivan, 1994) was developed to provide a reliable and efficient measure of speech reception thresholds for sentences in quiet and in noise. HINT materials consist of 25 equivalent 10-sentence lists. Twenty HINT sentences, spoken by a male talker, were presented from the commercially available HINT CD, version 2.0 (Maico Diagnostics, 2004a), via an adaptive procedure for each condition. Specifically, the adaptive procedure increased the presentation level of the first sentence in 4-dB steps until the sentence was repeated correctly then used 4-dB adaptive steps for sentences 2 to 4 and 2-dB steps for sentences 5 to 20. The presentation levels of the last 16 sentences and the calculated presentation level that the next sentence would have been presented based on the participant's response to sentence 20, were averaged to calculate the receptive threshold for sentences (RTS; Maico Diagnostics, 2004b). A lower RTS indicates better performance. The speech stimuli were presented at 0° azimuth. Noise competition consisted of uncorrelated continuous HINT noise presented at 65 dB A. The noise was convolved in a similar method as that reported by Valente, Mispagel, Tchorz, and Fabry (2006). Specifically (a) List 1 from the HINT CD was imported into Adobe Audition 1.5, (b) the noise track was isolated by removing the speech track, (c) the quiet segments between the noise presentations were removed, and (d) the resulting noise was duplicated several times. Three noise conditions with continuous uncorrelated HINT noise were presented: ±135° azimuths; "four corners," that is, ±45° and ±135° azimuths; and "eight speakers," that is, 45° angles from 0° to 315° azimuths.

Procedure

Audiometric testing. Prior to participation in this investigation, participants underwent a complete audiological evaluation administered in a double-walled Industrial Acoustics Company, Inc. (IAC) sound-treated room using a GSI-61 clinical audiometer and E.A.R. 3-A earphones. Tympanometry, acoustic reflexes, and acoustic decay were screened using the Madsen Otoflex 100. Participants who qualified for the study had to sign an institutional review board–approved informed consent document. After the consent document was signed, earmold impressions were made for individuals that were to be fit with custom micromolds/earmolds based on audiometric thresholds.

Hearing instrument fittings. All patients were fit randomly with a set of Epoq XW RITEs (with ear to ear synchronization and 10-kHz bandwidth) or Syncro V2 BTEs (with no ear to ear synchronization and 8-kHz bandwidth). After a period of adaptation (2 weeks for experienced users and 4 weeks for new users) and testing with the first instruments, the participants were then switched to the other hearing instruments. For the participants whose pure tone average (PTA) at 250 Hz, 500 Hz, and 1 kHz was less than 30 dB HL, the appropriate sized open dome was used. For participants whose PTA was greater than 30 dB HL, custom micromolds were supplied by Oticon for the Epoq, and standard skeleton earmolds with a 3.0-mm vent for the Syncro, based on ear impressions. The hearing instruments were fit to prescribed settings, as per Genie, Oticon's proprietary software. New users were fit initially with Adaptation Manager Step 1 to allow for acclimatization and then gradually increased to Adaptation Manager Step 3 over the first 2 weeks of the 4-week adaptation period. Experienced users were fit with Adaptation Manager Step 3 and were allowed 2 weeks of use prior to testing. All environmentally adaptive circuitry was active, as per the default fitting. It should be noted that the fitting algorithm (voice aligned compression [VAC]) was also the same for both the Syncro and the Epoq, which enabled similar frequency responses for both models, except for bandwidth, once the hearing instruments were on Adaptation Manager Step 3. The time delay in the digital signal processing platform used in both products is set (approximately 5 ms). This time delay is not affected by any setting in the hearing instruments except whether the device is in directionality in the low frequencies. One reason that the wireless binaural broadband instruments (Epoq) coordinate the mode shifts in directionality is to try to have the devices in the same directional mode as much as possible. Microphone location was controlled for inasmuch as both the Syncro and Epoq are over-the-ear devices. Hearing instrument fittings were verified via real-ear measurements with an Audioscan Verifit.

Testing procedures. All stimuli were imported into and presented via Pro Tools LE v.7.3 software on an Apple Macbook laptop, with a firewire connection to a Digidesign Digi002 rack. The Digidesign Digi002 rack routed eight balanced-line cables through an opening in the IAC double-walled sound-treated booth to eight KRK Rokit 5 Powered loudspeakers. Within the sound-treated test booth, the eight loudspeakers were arranged symmetrically in the horizontal plane at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° azimuths. All loudspeakers were positioned at a height of 3.5-feet, approximating the ear level of an average seated participant. Prior to testing, the stimuli were calibrated using the IE35 system on a Dell Axim X51v personal digital assistant. An Ivie Model IE2P Type I microphone was mounted on a microphone stand in the center of the speaker array, at the level of the loudspeakers.

Participants were seated in the center of the sound-treated booth, with the center of the head 2.5-feet from each loudspeaker. Participant head movements were monitored to ensure that the participant was facing 0° azimuth by visual inspection. Tests, noise conditions, and hearing instruments were randomized and counterbalanced to reduce order effects. The hearing aid cases were unmarked and the aids were given pseudonyms to blind participants to the hearing aids. The participants were blinded to the noise conditions.

The course of the study lasted approximately 2 months for each participant, during which the participant had four to five sessions, each lasting between 1 and 2 hours. Breaks were given to the participants as needed per session. For each test, participants were tested with the Epoq, Syncro, and without hearing instruments (unaided).

Follow-up. After testing, the participants were allowed to keep their preferred set of hearing aids and instructed on care and use. Participants were informed that they may be asked to participate in further testing, but that their participation would be voluntary.

Results

Means and standard deviations for new and experienced users' audiometric data are shown in Figures 1 and 2, respectively.

Verification of Hearing Aids

Coupler measures were completed by electro-acoustics of Oticon A/S for the Syncro and Epoq hearing aids to confirm the extended bandwidth of the Epoq devices. Both 2-cc coupler and 711-coupler recordings were made to compare the gain-frequency response of both hearing aids. It should be noted that the impedance of the 711-coupler more closely resembles the response of the average adult ear than the 2-cc coupler, which is commonly used clinically to assess the output of the hearing aid (Kuk & Baekgaard, 2009). Specifically, the 711-coupler recordings demonstrate a broader frequency range and greater amplitude in the high frequencies than the 2-cc coupler recordings. Results are shown in Figures 3 and 4.

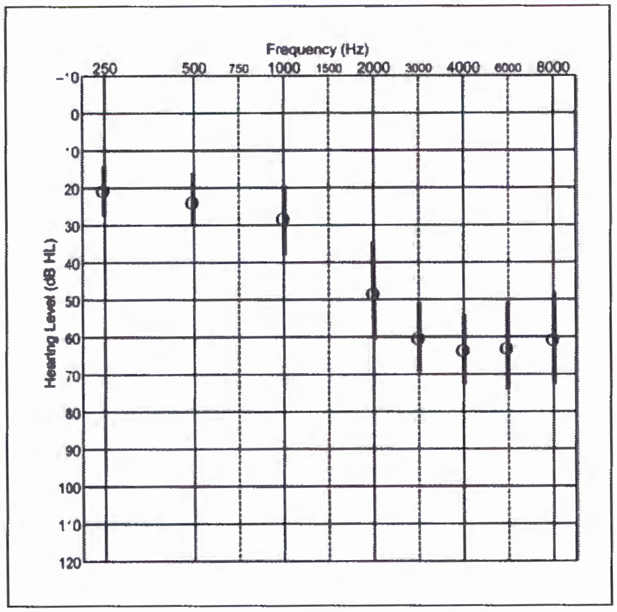

Figure 1. Audiometric data for new hearing aid users
Circles represent mean thresholds. Lines represent one standard deviation.

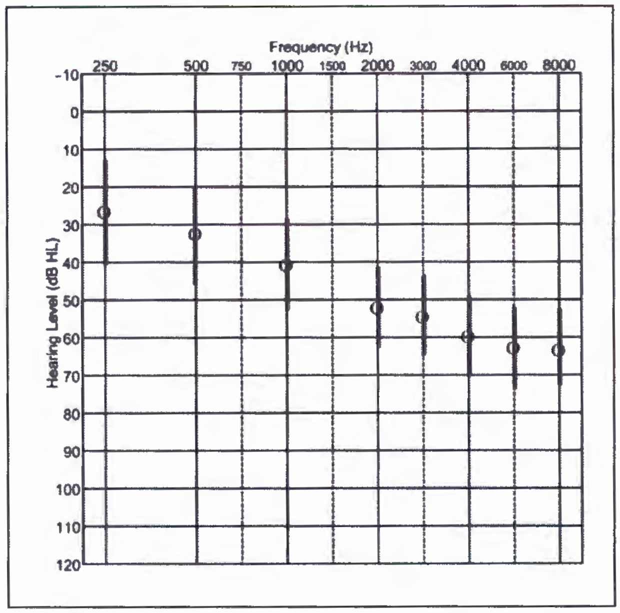

Figure 2. Audiometric data for experienced hearing aid users
Circles represent mean thresholds. Lines represent one standard deviation.

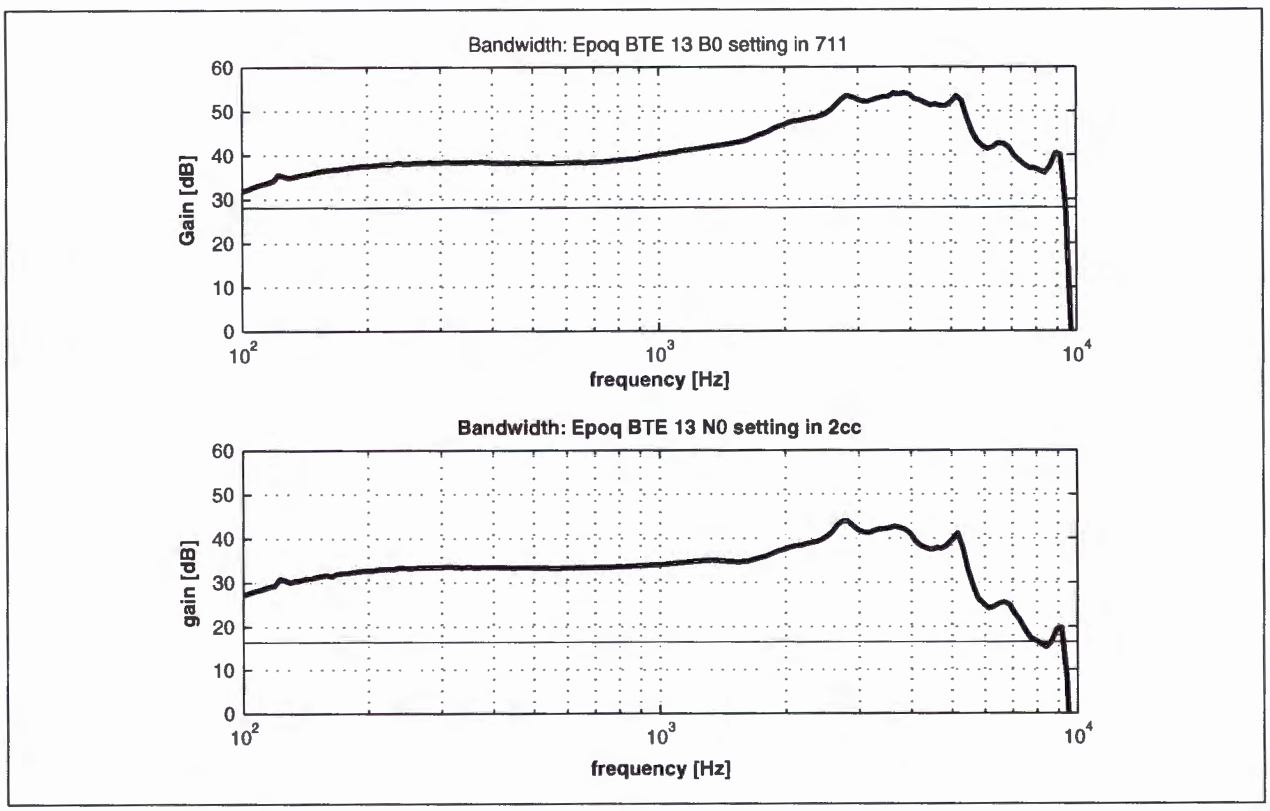

Figure 3. Coupler recordings for the Epoq XW
The upper curve is the 711-coupler measurement, based on Deutsche Norm (DIN 45.605; German standard), based on IEC 60188.0. The lower curve is the 2-cc coupler measurement based on ANSI 3.22 and IEC 60188-7. Note that by virtue of its larger volume, the 711-coupler recordings have less damping in the high frequencies and thus are better suited for demonstrating extended bandwidth.

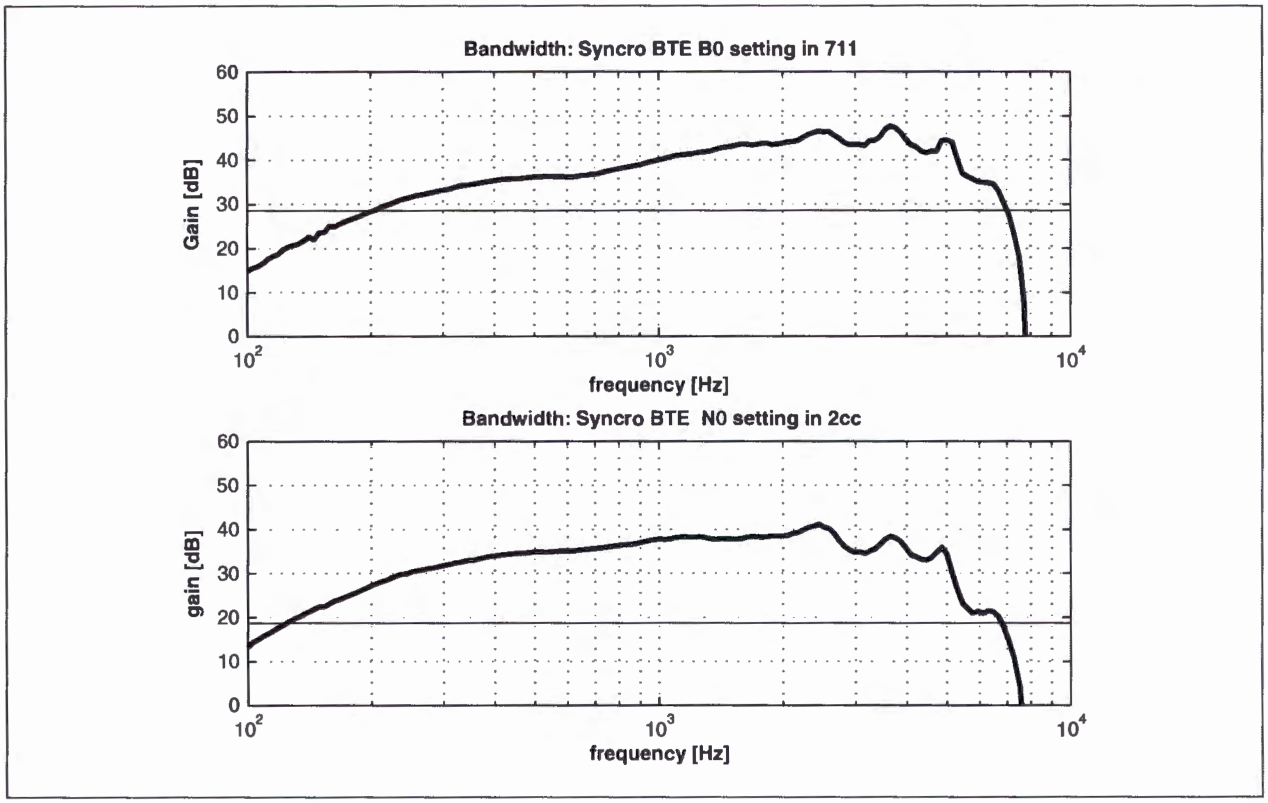

Figure 4. Coupler recordings for the Syncro V2
The upper curve is the 711-coupler measurement, based on Deutsche Norm (DIN 45.605; German standard), based on IEC 60188.0. The lower curve is the 2-cc coupler measurement based on ANSI 3.22 and IEC 60188-7.

Speech Perception Results

Comparisons for each test were made via repeated-measures analysis of variance (ANOVA). A focused contrast was then computed to test the specific prediction that the speech perception scores would improve from unaided, to Syncro, to Epoq. Focused contrasts are a more powerful technique to compare independent variables with no underlying continuity than the more traditional post hoc analyses, can be used in repeated-measures contexts, and have been used in other fields, such as psychology, for many years (Furr & Rosenthal, 2003). For a complete discussion on focused contrasts, the reader is referred to Rosenthal and Rosnow (1985).

QuickSIN

Comparisons of each noise condition between unaided, Syncro, and Epoq were made via 2 × 3 repeated-measures ANOVA. A significant main effect for aid was observed for the QuickSIN scores for both noise conditions, suggesting that at least one of the scores were different than the other scores, $F(2, 70) = 15.10$, $p < .001$. The focused contrast between aid conditions was significant, $F = 41.82$, $p < .001$, suggesting that the QuickSIN scores were progressively better between the unaided ($M = 1.38$), Syncro ($M = 0.29$), and Epoq ($M = -0.79$) conditions. There was an increase in SNR loss (i.e., worse performance) between the ±135° azimuth noise condition ($M = -0.29$) and the four corners noise condition, that is, ±45° and ±135° azimuths ($M = 0.87$) and this difference was significant, $F(1, 35) = 26.26$, $p < .001$. There were no significant trends in the aid × angle interaction. Repeated-measures ANOVAs compared results for each noise condition to further analyze these differences. For ±135° azimuth noise condition, results suggested a significant difference for at least one of the aid three conditions, $F(2, 70) = 17.79$, $p < .001$. The focused contrast between aid conditions was significant, $F = 45.03$, $p < .001$, suggesting that the QuickSIN scores were progressively better (i.e., less SNR loss) between the unaided ($M = 1.08$), Syncro ($M = -0.38$), and Epoq ($M = -1.57$) conditions. For the four corners noise condition, results suggested a significant difference for at least one of the three aid conditions, $F(2, 70) = 5.26$, $p = .007$. The focused contrast between aid conditions was significant, $F = 14.12$, $p < .001$, suggesting that the QuickSIN scores were progressively better between the unaided ($M = 1.68$), Syncro ($M = 0.94$), and Epoq ($M = -0.01$)

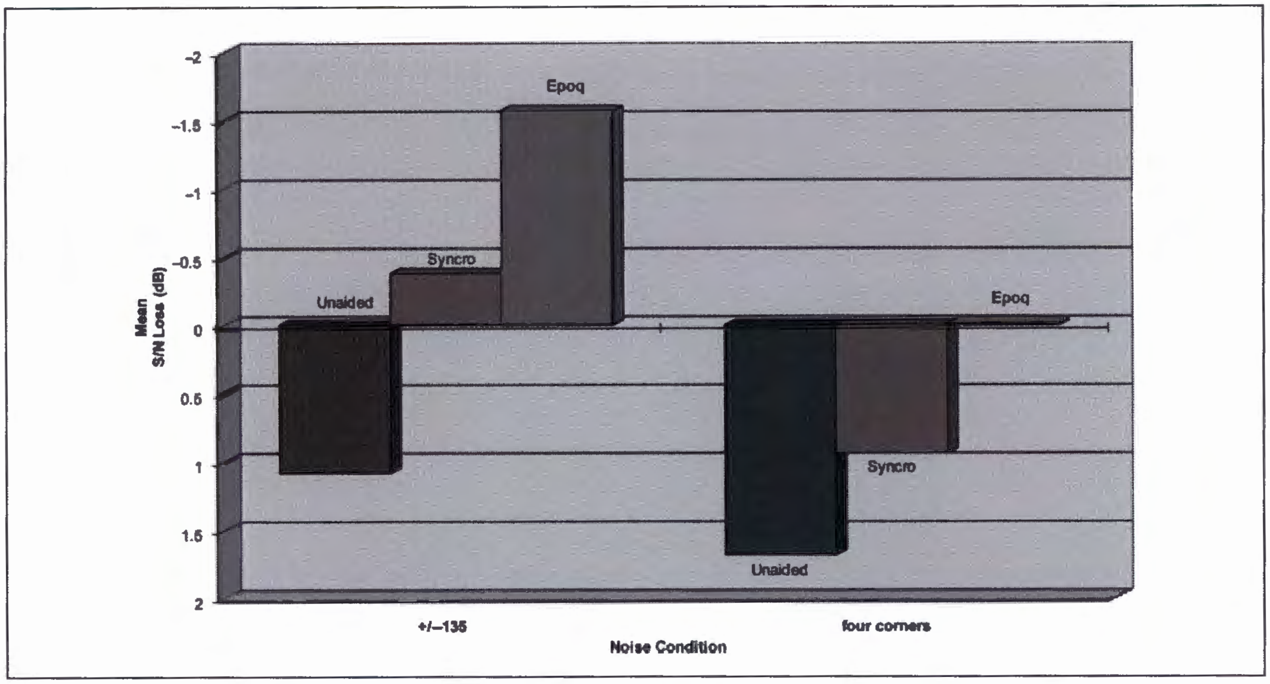

Figure 5. QuickSIN results for unaided, Syncro, and Epoq XW
Recall that the smaller signal-to-noise ratio (SNR) loss indicates better performance.

conditions. Results are shown in Figure 5. Recall that a smaller SNR loss indicates better performance on the QuickSIN.

Hearing in Noise Test

Comparisons of each noise condition between unaided, Syncro, and Epoq were made via 3 × 3 repeated-measures ANOVA. A significant main effect for aid was observed for the HINT scores across all noise conditions, suggesting that at least one of the scores were different than the other scores, $F(2, 70) = 12.66, p < .001$. The focused contrast between aid conditions was significant, $F = 19.86, p < .001$, suggesting that the HINT scores were progressively better (i.e., lower RTS) between the unaided ($M = 63.33$), Syncro ($M = 62.70$), and Epoq ($M = 61.88$) conditions. There was an increase in RTS (i.e., worse performance) between the three noise conditions: ±135° azimuths ($M = 62.04$), four corners ($M = 62.91$), and eight speakers ($M = 62.96$), and this difference was significant, $F(2, 70) = 15.95, p < .001$). There were no significant trends in the aid × angle interaction. Repeated-measures ANOVAs compared results for each noise condition to further analyze these differences. For ±135° azimuths noise condition, results suggested a significant difference for at least one of the three aid conditions, $F(2, 70) = 13.29, p < .001$. The focused contrast between aid conditions was significant, $F = 30.66, p < .001$, suggesting that the HINT scores were progressively better (i.e., lower RTS) between the unaided ($M = 63.03$), Syncro ($M = 62.12$), and Epoq ($M = 60.98$) conditions. For the four corners noise condition, results suggested a significant difference for at least one of the three conditions, $F(2, 70) = 7.80, p = .001$. The focused contrast between aid conditions was significant, $F = 17.88, p < .001$, suggesting that the HINT scores were progressively better between the unaided ($M = 63.49$), Syncro ($M = 63.01$), and Epoq ($M = 62.24$) conditions. For the eight speakers noise condition, results suggested a significant difference for at least one of the three conditions, $F(2, 70) = 4.41, p = .016$. The focused contrast between aid conditions was significant, $F = 9.95, p = .003$, suggesting that the HINT scores were progressively better between the unaided ($M = 63.48$), Syncro ($M = 62.98$), and Epoq ($M = 62.41$) conditions. Figure 6 displays results for each noise condition. Recall that a lower RTS indicates better performance on the HINT.

Discussion

The major finding for this study is that speech perception in noise via the Epoq XW was better than either Syncro or unaided. Statistically significant differences were found for every noise condition for both the QuickSIN and HINT. These tests feature a female talker with a background of uncorrelated multitalker babble and a male talker with uncorrelated speech noise, respectively.

The HINT and QuickSIN data are consistent with previous research in terms of the relative differences between the two tests. For example, Wilson, McArdle, and Smith (2007)

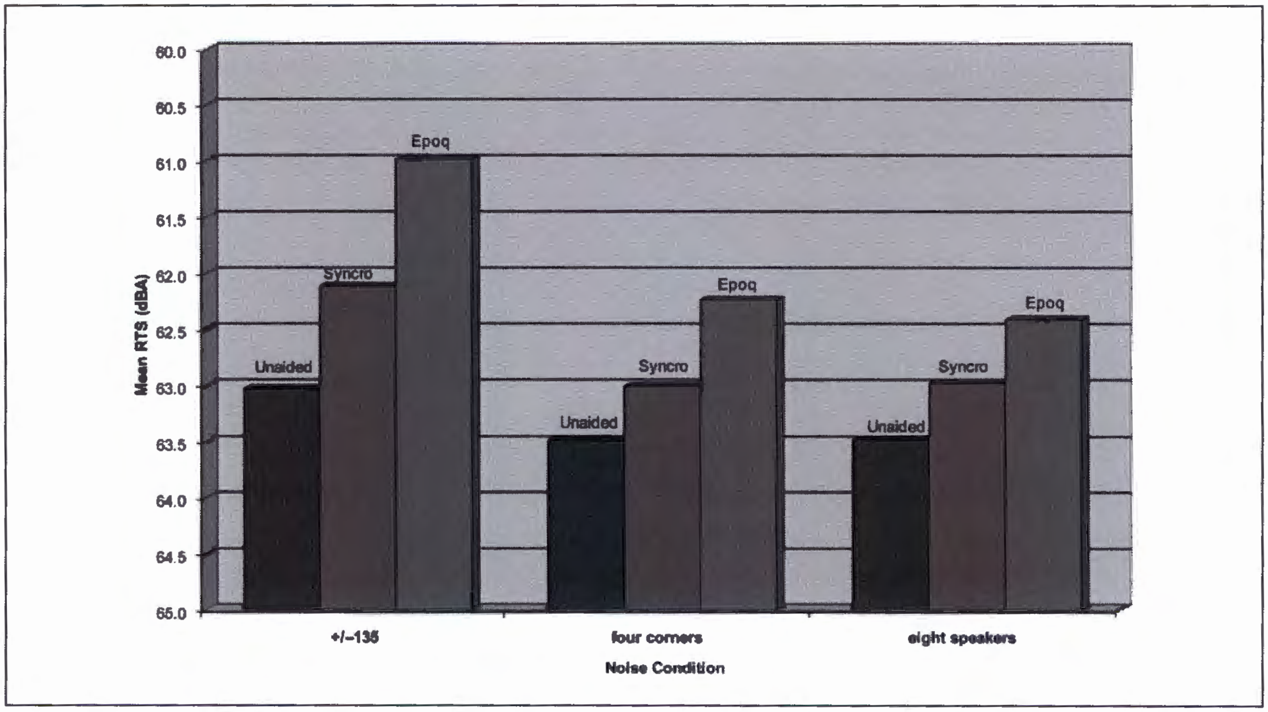

Figure 6. Hearing in Noise Test (HINT) results for unaided, Syncro, and Epoq XW
Recall that a lower receptive threshold for sentences (RTS) indicates better performance.

compared HINT to QuickSIN sentences in male adults with hearing loss by administering the tests as suggested by each test developer. Their results demonstrated a 3.1 to 3.5 difference between the HINT and QuickSIN scores, with the HINT scores having a lower SNR (i.e., better performance). In the present study, the differences in unaided SNR between the HINT and the QuickSIN are 3.03 dB and 3.19 dB for the ±135° azimuth and four corners noise conditions, respectively. The participants in the present study included both men and women, and had better hearing thresholds than the participants in the Wilson et al. (2007) study. In addition, the present study used different noise conditions than those prescribed by the test developers, and used by Wilson et al., including uncorrelated noise from multiple speakers. These differences may account for the better overall test performance of participants in the present investigation when compared with the participants in the Wilson et al. study.

Our understanding of the role of amplification in affecting speech understanding over the past two decades has been influenced heavily by the concepts of the Articulation Index (AI; Fletcher & Galt, 1950; Kryter, 1962), the Speech Transmission Index (STI; Houtgast & Steeneken, 1973; Steeneken & Houtgast, 1980), and the Speech Intelligibility Index (SII; ANSI S3.5-1997; American National Standards Institute, 1997). Although primarily designed to predict performance of speech communication systems and synthesized speech, these formulae are also applied in an attempt to predict or model the perception and recognition of speech sounds. It should be stated that none of these indexes were originally designed to predict binaural speech perception or speech perception for individuals with hearing loss. This has not prevented much attention to the idea of applying the AI (Allen, 2005; Killion, 2002; Rankovic, 2002; Souza, Yueh, Sarubbi, & Loovis, 2000; Vickers, Moore, & Baer, 2001) and the SII (Kates & Arehart, 2005; Kringlebotn, 1999; Rhebergen, Versfeld, & Dreschler, 2006) to predict speech understanding in individuals with hearing loss.

Speech understanding is assumed to be predicted by the amount of speech information that is above auditory threshold and the effective masking of the background noise. Although AI-based predictions do not account completely for patient-to-patient differences in absolute speech-in-noise performance, they have been accurate in accounting for relative differences between treatment conditions. In other words, the more speech that is made audible, the better the patient will typically perform.

The importance weightings from the AI and SII approaches indicate that speech information only extends up to 6 kHz. These weightings would suggest that speech understanding should not be affected by extending the bandwidth of a hearing aid beyond 6 kHz. However, more recent acoustical analyses have demonstrated that there is significant speech energy above 6 kHz and that extension of the bandwidth of amplification will result in improved speech understanding performance (Boothroyd & Medwetsky, 1992; Kortekaas & Stelmachowicz, 2000; Lindley, 2009; Stelmachowicz, Lewis, Choi, & Hoover, 2007). Furthermore, speech energy above 8 kHz has been demonstrated to improved localization (Best, Carlile, Craig, & van Schaik, 2005), which is the underlying skill necessary to organize the listening environment.

If the AI and SII approaches accounted for all aspects of speech understanding in noise, then there would not be an expected difference in performance between Syncro and Epoq XW. Although Syncro represented state-of-the-art technology when released in 2004, the continued improvements in hearing aid technology are reflected in the superior performance in noise by Epoq XW in this investigation. The improvements are likely some combination of the improved bandwidth, preservation of interaural intensity differences and a generalized improvement in the digital platform that underlies the Epoq XW product. It should be noted that although the coordinated compression is a major difference between the Syncro and the Epoq, the objective tests in this study were not designed to evaluate this difference.

Speech understanding in complex listening environments, especially in the presence of competing talkers, is more complicated than just a matter of audibility. The binaural auditory system will use subtle monaural high-frequency cues as well as ear-to-ear differences in intensity and time of arrival to organize the sources of sound in the environment. As hearing aid technology continues to evolve, protection or even enhancement of these "newer" sources of information will be more in focus. These are the sort of dimensions that may well allow for continued improvements in performance.

The results of this study clearly demonstrated an improvement of speech understanding in noise on both the QuickSIN and the HINT for the Epoq over the Syncro. However, it should be noted that the reasons for such improvement are less clear, in part due to the limitations in the study design. Based on the study design, it can be assumed that the coordinated processing features had minimal effect on speech perception. Recall that the participants were in a diffuse noise field during the four corners and eight speakers conditions, with the speech stimuli arriving from the front. The level and spectral characteristics of the noise, therefore, would be about the same for both ears. Furthermore, these results may be difficult to explain due to the difference in bandwidth of the devices, specifically because the validated, commercially available materials used as speech stimuli and noise competition do not exceed the bandwidth of speech. It is possible that the improvement in speech understanding was primarily because of the differences in the digital signal processing between the two products. Further research is needed to determine how the different technologies may contribute to the improvement in speech understanding with the Epoq. In addition, as hearing aid technology continues to improve, a need for validated materials has emerged as an area of future research.

Regardless of the actual reason(s) for the differences between the Epoq and the Syncro in this study, it should be noted that these are commercial products and the nature of the hearing aid market is that technologies are bundled. The basic clinical question is whether there is evidence that a new product is better on key performance measures (such as speech understanding in noise) than the older product. These results clearly demonstrated improved speech understanding in noise with the Epoq. Although this study is limited in determining the precise underlying technologies that contributed to this improvement, it does reflect the decision-making approach in the clinic.

Authors' Note

Portions of this article were presented orally at AudiologyNOW! 2009, Dallas, TX, in April 2009.

Acknowledgments

The authors thank Melanie King and John Govern, PhD, of Towson University for assistance in data collection and statistical analysis, respectively. The authors also thank Yang Liu of Oticon A/S for providing the coupler measures displayed in Figures 3 and 4. In addition, the authors thank the anonymous reviewers for their valuable comments and suggestions on earlier versions of this manuscript.

Declaration of Conflicting Interests

The authors declared no conflicts of interest with respect to the research and/or publication of this article. The data were collected and analyzed by the first and second authors, who have no affiliation with the sponsoring agency.

Funding

The authors disclosed receipt of the following financial support for the research and/or authorship of this article:
Oticon A/S

References

Allen, J. B. (2005). Consonant recognition and the articulation index. *Journal of the Acoustical Society of America, 117*, 2212-2223.

American National Standards Institute. (1997). *ANSI S3.5-1997, American national standard methods for calculation of the speech intelligibility index*. New York: Author.

Best, V., Carlile, S., Craig, J., & van Schaik, A. (2005). The role of high frequencies in speech localization. *Journal of the Acoustical Society of America, 118*, 353-363.

Boothroyd, A., & Medwetsky, L. (1992). Spectral distribution of /s/ and the frequency response of hearing aids. *Ear and Hearing, 13*, 150-157.

Etymotic Research. (2001). QuickSIN: Speech-in-Noise Test (Version 1.3) [Audio CD]. Elk Grove Village, IL: Author.

Fletcher, H., & Galt, R. H. (1950). The perception of speech and its relation to telephony. *Journal of the Acoustical Society of America, 22*, 89-151.

Furr, R. M., & Rosenthal, R. (2003). Repeated-measures contrasts for "multiple-pattern" hypotheses. *Psychological Methods, 8*, 275-293.

Houtgast, T., & Steeneken, H.J.M. (1973). The modulation transfer function in room acoustics as a predictor of speech intelligibility. *Acustica, 28*, 66-73

Kates, J. M., & Arehart, K. H. (2005). Coherence and the speech intelligibility index. *Journal of the Acoustical Society of America, 117*, 2224-2237.

Killion, M. C. (2002). New thinking on hearing in noise: A generalized articulation index. *Seminars in Hearing, 23*, 57-75.

Kortekaas, R., & Stelmachowicz, P. (2000). Bandwidth effects on children's perception of the inflectional morpheme /s/: Acoustical measurements, auditory detection, and clarity rating. *Journal of Speech, Language, and Hearing Research, 43*, 645-660.

Kochkin S. (2005). Customer satisfaction with hearing aids in the digital age. *Hearing Journal, 58*(9), 30-37.

Kringlebotn, M. (1999). A graphical method for calculating the speech intelligibility index and measuring hearing disability from audiograms. *Scandanavian Audiology, 28*, 151-160.

Kryter, K. D. (1962). Methods for the calculation and use of the articulation index. *Journal of the Acoustical Society of America, 34*, 1689-1697.

Kuk, F., & Baekgaard, L. (2009). Considerations in fitting hearing aids with extended bandwidths. *Hearing Review, 16*(11), 32-38.

Meister, H., Lausberg, I., Kiessling, J., Walger, M., & von Wedel, H. (2002). Determining the importance of fundamental hearing aid attributes. *Otology & Neurotology, 23*, 457-462.

Meister, H., Lausberg, I., Walger, M., & von Wedel, H. (2001). Using conjoint analysis to examine the importance of hearing aid attributes. *Ear and Hearing, 22*, 142-150.

Lindley, G. (2009). The impact of an extended bandwidth and binaural compression in pediatric fittings. *The Hearing Journal*, in press.

Maico Diagnostics. (2004a). Hearing in Noise Test (Version 2.0) [Audio CD]. Eden Prairie, MN: Author.

Maico Diagnostics. (2004b). Operating Instructions HINT Audio CD 2.0. Eden Prairie, MN: Author.

Nilsson, M., Soli, S. D., & Sullivan, J. (1994). Development of the Hearing in Noise Test for the measurement of speech reception thresholds in quiet and in noise. *Journal of the Acoustical Society of America, 95*, 1085-1099.

Rankovic, C. M. (2002). Articulation index predictions for hearing-impaired listeners with and without cochlear dead regions. *Journal of the Acoustical Society of America, 111*, 2545-2548.

Rhebergen, K. S., Versfeld, N. J., & Dreschler, W. A. (2006). Extended speech intelligibility index for the prediction of the speech reception threshold in fluctuating noise. *Journal of the Acoustical Society of America, 120*, 3988-3997.

Rosenthal, R., & Rosnow, R. L. (1985). *Contrast analysis: Focused comparisons in the analysis of variance*. Cambridge, UK: Cambridge University Press.

Schum, D. J., & Bruun Hansen, L. (2007). New technology and spatial resolution. *Audiology Online*. Retrieved February 9, 2010, from http://www.audiologyonline.com/articles/article_detail.asp?wc=1&article_id=1854

Souza, P. E., Yueh, B., Sarubbi, M., & Loovis, C. F. (2000). Fitting hearing aids with the articulation index: Impact on hearing aid effectiveness. *Journal of Rehabilitation Research and Development, 37*, 473-481.

Stelmachowicz, P. G., Lewis, D. E., Choi, S., & Hoover, B. (2007). Effect of stimulus bandwidth on auditory skills in normal-hearing and hearing-impaired children. *Ear and Hearing, 28*, 483-494.

Steeneken, H.J.M. & Houtgast, T. (1980). A physical method for measuring speech transmission quality. *Journal of the Acoustical Society of America, 67*, 318-326.

Valente, M., Mispagel, K. M., Tchorz, J., & Fabry, D. (2006). Effect of type of noise and loudspeaker array on the performance of omnidirectional and directional microphones. *Journal of the American Academy of Audiology, 17*, 398-412.

Vickers, D. A., Moore, B. C. J., & Baer, T. (2001). Effects of low-pass filtering on the intelligibility of speech in quiet for people with and without dead regions at high frequencies. *Journal of the Acoustical Society of America, 110*, 1164-1175.

Walden, T. C., & Walden, B. E. (2004). Predicting success with hearing aids in everyday living. *Journal of the American Academy of Audiology, 15*, 342-352.

Wilson, R. H., McArdle, R. A., & Smith, S. L. (2007). An evaluation of the BKB-SIN, HINT, QuickSIN, and WIN materials on listeners with normal hearing and listeners with hearing loss. *Journal of Speech, Language, and Hearing Research, 50*, 844-856.

Wireless technology designed to provide true binaural amplification

By Thomas A. Powers and Pamela Burton

Over the past decade, we have witnessed dramatic changes in hearing instrument technology. Multi-channel digital instruments, once reserved for "special fittings," are now considered routine entry-level products. Adaptive feedback reduction is no longer novel, but an expected feature for many products. Enhanced technology has allowed us to combine different types of digital noise-reduction algorithms in the same instrument, and some directional hearing instruments now employ as many as three microphones and offer automatic switching and adaptive polar patterns. Yet, as new products emerge, hearing care professionals and consumers expect ever more and better new features.

This paper describes the fourth-generation digital hearing instrument from Siemens Hearing Instruments, Acuris™ with e2e wireless™. Available in a complete range of models, this product includes technology that is new to the hearing industry. Before describing the new e2e wireless technology, we'll review the advances that have been made in core technology for this product.

> "...enhanced technology has allowed us to combine different types of digital noise-reduction algorithms in the same instrument..."

ADVANCES IN CORE TECHNOLOGY

There are five general areas of Acuris's core technology that may significantly impact patient benefit and satisfaction: multi-channel dynamic range compensation, digital speech and noise management, high-speed digital feedback cancellation, multi-dimensional directional optimization, and precision environmental classification.

Dynamic range compensation

It is widely recognized that multi-channel wide dynamic range compression (WDRC) is useful for maximizing audibility and intelligibility. Acuris uses 16 independent channels of frequency shaping and AGCi, with adjustable kneepoints *and* ratios to accommodate a wide variety of hearing losses. To facilitate programming, four handles control the 16 channels. As recent research has suggested that different individuals may benefit from different compression release times,[1,2] this product provides a choice of short or long compression time constants.

While adjusting the WDRC parameters is the primary focus of most fittings, the importance of multi-channel AGCo cannot be overlooked. The use of a 16-channel AGCo system means that the output for louder sounds is not unnecessarily "capped" in channels where the knee point has not been reached, as it would be in a single-channel system. This results in expanded headroom and increases the utilization of the patient's residual dynamic range while maintaining the output below the patient's loudness discomfort levels.[3]

Finally, it should be noted that Acuris employs low-level, channel-specific expansion with adaptive kneepoints so as to minimize the annoyance of soft sounds without reducing gain for important soft speech signals.

Speech and noise management

Digital noise reduction, often using a modulation detection strategy, has been implemented successfully in hearing instruments for several years (for a review see Powers et al.[4]). A generally accepted benefit of digital noise reduction is that it provides the user with "listening comfort" or "relaxed listening." It is assumed that when listeners are relaxed they will be more focused and alert, which increases the likelihood that improved intelligibility also will follow. However, in two studies addressing the listener comfort issue, the implementation of digital noise reduction did not increase listener comfort.[5,6] In contrast, in a separate study, when a noise-reduction strategy similar to that employed in the Acuris was used, subjects expressed a significant preference for the "noise reduction on" setting.[7] Research has also shown that when digital noise reduction is applied, the annoyance from noise is no worse for hearing aid wearers than for persons with normal hearing.[8]

In Acuris, speech and noise management operates independently in 16 channels. First, when the dominant signal in a given channel is found to be noise, gain in that channel is reduced. Simultaneously, an adaptive sound-processing algorithm is used for the digital speech enhancement in 16 channels. This second algorithm dynamically adjusts based upon the frequency of noise detected within the signal. The amount of noise filtered out is optimized to preserve frequencies contributing to the desired speech signal. In addition, the software has the flexibility to allow precise customization of the speech and noise management in each program.

Digital feedback cancellation

The new Siemens instrument uses a high-speed phase-cancellation system to address feedback (Figure 1). This system employs extremely fast adaptation to changes in the feedback path, with maximum energy efficiency (less than 50 uA current consumption). A detector specifically designed to analyze feedback allows the system to determine the source of feedback (internal or external) and avoids inappropriate cancellation of environmental tonal signals, such as microwave beeps, music, etc. The feedback-cancellation design does not require any initialization procedure with the instrument in the ear in order to pre-set a cancellation filter, as some systems do. The cancellation is adaptive and does not affect the gain or frequency response of the hearing instrument, thereby maintaining sound quality and intelligibility.

Directional optimization

The basic directional features of Acuris are based in large part on the adaptive directional technology of Siemens's third-generation product, Triano.[9] Independent research on this instrument showed encouraging findings, both for the fixed polar pattern and for the adaptive directional options.[10–12] In general, researchers found that the directional technology allowed for improved speech intelligibility in background noise for a variety of listening conditions.

The directional optimization system in this new instrument has been expanded and has several different aspects. First, there is automatic transition between omnidirectional and directional modes. In order to enable the directional mode, the incoming signal must first be classified as "noise" *and* it must be at a high enough input level to trigger the transition. The level at which transitions occur varies depending on the type of noise, its frequency composition and bandwidth, or, speaking more generally, the power and spectrum of the noise environment. For the Acuris P BTE (TriMic™), automatic transition between microphone modes (omnidirectional, TwinMic™, and TriMic) is accomplished with level-dependent directivity to ensure that as environmental noise levels increase, the number of microphones increases to meet the requirements of the situation.

A second component of the directional-microphone system is adaptive directionality. In Acuris, this technology has been enhanced so that it not only adaptively modifies the polar null to the most dominant noise source, but it also simultaneously applies multiple (up to four) polar nulls to address different noises that occur at the same time within different frequency areas. Figure 2 provides an example of the polar pattern for two simultaneous noise sources. This feature is designed to ensure maximum improvement of the signal-to-noise ratio (SNR) and thereby optimize speech intelligibility and comfort for the patient in challenging and dynamic listening environments.

Finally, real-time microphone matching is employed across the entire frequency spectrum, with on-going phase and amplitude matching being done at four separate calibration points. Directional-microphone systems that match at only one frequency or in a narrow frequency range are more likely to need frequent servicing by the manufacturer because of reduced directivity. Real-time microphone matching is intended to ensure optimal directional performance and the long- term stability of the directional-microphone system.

Environmental classification

The environmental classification system is the governing intelligence in Acuris. It employs new algorithms for accurate and comprehensive classification of the external environment. Speech, speech in noise, stationary noise, fluctuating noise, and music are all classified via ongoing analysis and continuous alignment of the signal processing. Many features of the instrument's core technology are affected by the environmental classification system, including noise reduction, speech enhancement, adaptive multi-channel directional microphone, feedback cancellation, and wind noise reduction. Accurate classification permits dynamically adaptive sound processing for the wearer's changing listening situation.

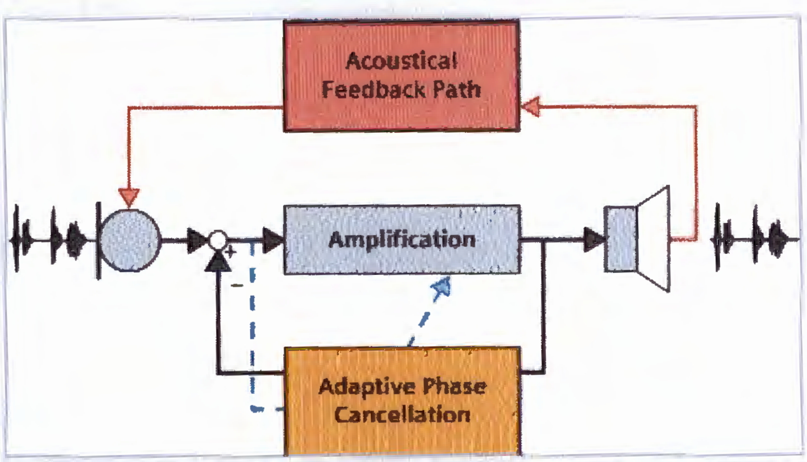

Figure 1. *This high-speed adaptive phase cancellation system is used in all Acuris models. The system differentiates feedback from the hearing aid from tonal signals of external origin.*

e2e WIRELESS TECHNOLOGY

As noted earlier, the core technology in this new product contains enhanced DSP. In addition, Acuris contains e2e wireless synchronization, which is designed to allow all of the benefits of the technology to be harmonized in two hearing instruments so they work together as one system. The input obtained from both instruments is shared, and common decisions regarding sound processing parameters are based on this combined information.

The e2e wireless technology uses electromagnetic transmission to communicate between instruments and also with

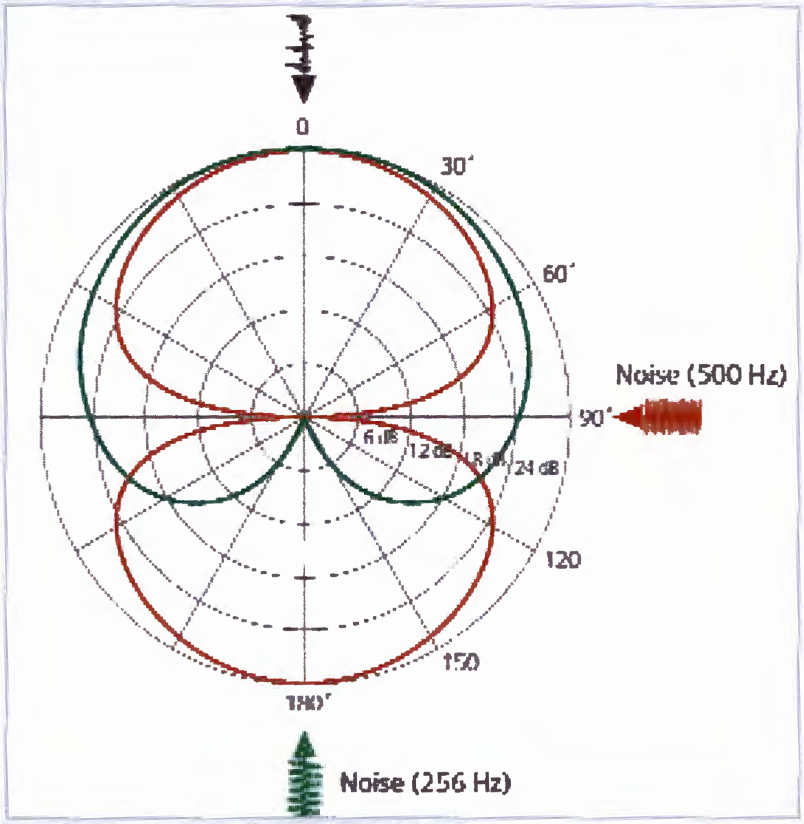

Figure 2. *A multi-channel adaptive directional-microphone polar plot for two simultaneous noise sources in different frequency ranges. Acuris will produce frequency-specific polar plots for up to four different inputs.*

an optional ePocket™ remote control. The modulation occurs via frequency shift keying (FSK) technology, with a typical current consumption of 120 uA. The transmission frequency shifts between 115 kHz and 120 kHz and transmission between instruments is enabled at distances up to 25–30 cm.

This new wireless technology allows communication and synchronization of selected core DSP features. It is based on the concept of one integrated auditory system and simplifies the fitting and wearing of two hearing instruments.

The advantages of this technology to the patient fall into four general categories: maintaining binaural signal processing, optimizing the accuracy of signal classification, expanding options on smaller custom instruments, and ease of use.

Binaural versus bilateral

Binaural hearing offers many benefits. These include improved SNR, auditory localization, loudness summation, reduction of head shadow effect, and improved sound quality.[13] Patients who wear two independent hearing instruments gain a bilateral advantage. However, they do not necessarily enjoy the benefits of binaural hearing.[14] That is, it's possible to have a *bilateral* fitting with minimal *binaural* benefits. e2e wireless ensures that both instruments are analyzing, interpreting, and reacting together as a single system, thus enabling patients to take full advantage of potential binaural hearing benefits.

A primary benefit of binaural hearing is improved localization. However, because localization of sound is determined through interaural time and intensity cues and is optimized during the fitting process, it can be easily compromised by mismatched volume settings. As shown by Hornsby and Ricketts,[15] some hearing aid wearers who start out with "balanced" gain may have a significant mismatch when they attempt to re-balance gain following independent right and left volume control adjustments for different listening conditions. While we know that persons with hearing loss can adapt to altered interaural intensity cues,[16] we also can assume that this adaptation is facilitated when the loudness differences (if any) between ears remain constant.

With e2e wireless, when the wearer touches the gain control, gain changes equally in both instruments. As a result, the volume settings between ears continue to be matched after the fitting to ensure appropriate loudness balance within the system. If the loudness was imperfectly matched at the time of the fitting, the mismatch will remain constant, which will facilitate adaptation. Correct localization for speech signals can enhance speech understanding. For example, in small groups, the hearing aid wearer is better able to follow conversations that switch rapidly from one talker to another.

A second area where we believe the consistent gain matching will be beneficial relates to the binaural squelch effect, sometimes referred to as the binaural masking level difference or the binaural intelligibility level difference.[17] Related to the squelch effect is binaural redundancy, which also can provide an improvement in the SNR.[18] Recently, Ricketts has shown that bilateral hearing instruments provide an advantage of 2.5 to 3.0 dB for listening in background noise over a unilateral fitting, which demonstrates that hearing-impaired persons also experience binaural squelch benefits.[19] This improvement was found with both omnidirectional and directional microphone settings. There is evidence to show, however, that for persons with hearing loss, the binaural masking level difference is reduced when asymmetry is present.[20] Since e2e wireless helps maintain loudness symmetry, it should also help maximize the patient's binaural squelch and redundancy.

A final point regarding loudness symmetry relates to binaural loudness summation. In general, we consider binaural summation to be about 3 dB at or near threshold and 6 to 10 dB at supra-threshold levels.[21,22] The practical advantage of binaural summation is that less gain for each individual hearing aid is necessary, which means that more headroom is available and feedback problems are reduced. Again, since e2e wireless helps maintain loudness symmetry, it should optimize binaural loudness summation.

Although the issue of symmetry often is overlooked in hearing instrument

"...e2e wireless synchronization is designed to allow all of the benefits of the technology to be harmonized in two hearing instruments so they work together as one system..."

fittings, Gatehouse and Noble recently examined this issue using the Speech Spatial and Qualities of Hearing scale (SSQ).[23,24] They found that asymmetry contributes to the experience of disability, especially in the area of spatial hearing: direction, distance, and movement. They also report that asymmetry is linked to reduced naturalness and clarity of sound and an increase in the effort needed in conversation.

Optimizing signal classification

A second general patient benefit of the e2e wireless system is that it permits synchronized digital signal processing. This begins with the environmental classification system, which uses a composite of information from both instruments and integrates the analysis to form a complete picture of the current listening environment. The signal processing is optimized bilaterally and simultaneously according to a common decision reached by the hearing system from the shared information. A binaural classification matrix is designed so that speech signals are always prioritized. With regard to speech and noise management, these systems are simultaneously harmonized in both instruments based on the information that the classification system obtained.

With independent hearing instruments, speech and noise management settings may differ or the same settings can be achieved at different times. With e2e wireless, this is impossible, since both hearing instruments reach the same settings at exactly the same time. The same is true for directional technology, as the system ensures that the automatic directional-microphone systems transition between omnidirectional and directional modes simultaneously, without need for manual intervention by the wearer. The binaural directional-microphone activation eliminates the risk that speech intelligibility is not maximized, as can occur with mixed microphone settings between ears. For example, Hornsby and Ricketts have shown that for a bilateral fitting, if only one of the instruments is set to directional microphone, the SNR advantage is approximately 40% less than if both hearing aids are set to directional.[25]

Ease of use

The e2e wireless technology enables communication and synchronization of wearer-operated controls between instruments, such as the volume control and push-button for changing programs or memories. When the patient changes the program button or volume control on one side, the changes are simultaneously made on the opposite side. The synchronized user controls make it easier for patients to make program and volume changes to their hearing instruments and improve usability by providing new control configurations when desired or necessary. For patients with reduced dexterity or limited range of arm and/or hand motion, the synchronized controls offer significant benefit in locating, differentiating, and manipulating controls with one hand. Even patients with normal dexterity may prefer e2e wireless because it allows them to make changes more discreetly and precisely.

We recently completed a four-site field study of e2e wireless. One goal was to examine user acceptance of the volume and program changes. The 42 subjects were experienced hearing instrument wearers who did not have specific problems adjusting the volume or changing programs on their current instruments. Significantly, all but 16% of the subjects stated that it was important to them to minimize effort when adjusting their hearing instruments. When asked if the bilateral control of hearing instruments using one volume control or button was useful, very few subjects disagreed, and 42% to 46% said they "Strongly Agree."

Expanded options

In Acuris, both controls (volume and program) for each hearing aid can be placed on one hearing aid or there can be one control on each aid (push-button on one, volume control on the other). Patients can operate their instruments more discreetly, because they no longer have to reach up to both hearing instruments to make adjustments. Also, the number of adjustments to volume control may be minimized because patients no longer have to make numerous changes to both sides to "get balanced." Patients who need or want a combined volume and program control can still use smaller custom instruments, since the same hearing aid does not have to accommodate two controls.

REMOTE CONTROL

The latest Siemens hearing instrument is available with ePocket, an optional remote control. ePocket, the first bi-directional hearing aid remote control, gives the wearer binaural control of volume and program selection, and also provides read-out functionality so patients may review the volume setting, memory location, and battery status for both instruments.

SAFETY

As with any communication system, e2e wireless has been tested to ensure safety and efficacy. Based on the guidelines from the International Commission on Non-Ionizing Radiation Protection (ICNIRP), Acuris and ePocket were tested and found to be completely safe. ICNIRP is an independent advisory body that works closely with the World Health Organization.

Specific absorption rate (SAR) measurements were also conducted for Acuris prior to patient testing. SAR is a measurement of exposure to electromagnetic fields. The guidelines for SAR are set by ICNIRP. These measurements indicated that the new hearing aid had SAR values at least 478 million times lower than the U.S. safety limit. In comparison, mobile phones have SAR values 3.2 times below the U.S. safety limit.

SUMMARY

Hearing care professionals and consumers expect a fourth-generation digital product to include new features that have a real potential to improve patient benefit and satisfaction. We believe that Acuris with e2e technology will meet this expectation. The enhancements to the core technology build on clinically proven past success. And the e2e wireless not only improves ease of use, but its synchronized decision making and digital signal processing alterations have the potential to improve the patient's overall listening comfort and speech understanding in a variety of listening situations. (HJ)

Thomas A. Powers, PhD, is Chief Research Officer, and **Pamela Burton**, MA, is Director, Product Management, both at Siemens Hearing Instruments, Piscataway, NJ. Correspondence to the authors at Tpowers@siemens.com and Pburton@siemens.com, respectively.

REFERENCES

1. Gatehouse S: Benefits from hearing aids in relation to the interaction between the user and the environment. *Int J Audiol* 2003;July;42,Suppl 1:S77-85.
2. Behrens T, Sundewall E, Naylor G: Relations between cognitive function, compression time constants, and speech perception in different background noise types. Paper presented at the International Hearing Aid Research Conference, Lake Tahoe, CA, August 2004.
3. Powers T, Burton P: Combining 4-channel WDRC with 4-channel AGCo: A new solution to an old problem. Paper presented at the American Academy of Audiology Association Annual Convention, Chicago, March 2000.
4. Powers T, Holube I, Wesselkamp M: The use of digital features to combat background noise. *Hear Rev* 1999; 6(3, Supplement):36-39.
5. Walden BE, Surr RK, Cord MT, et al.: Comparison of benefits provided by different hearing aid technologies. *JAAA* 2000;11(10):540-560.
6. Alcantara JI, Moore BC, Kuhnel V, Launer S: Evaluation of the noise reduction system in a commercial digital hearing aid. *Int J Audiol* 2003;42(1):34-42.
7. Ricketts TA, Hornsby BWY: Sound quality measures for speech in noise through a commercial hearing aid implementing digital noise reduction. *JAAA* 2005 (in press).
8. Palmer C, Bentler R, Mueller H, Powers T: Hearing aids and the perception of annoying and aversive sounds. Paper presented at the International Hearing Aid Research Conference, Lake Tahoe, CA, August 2004.
9. Powers T, Hammaker V: Three-microphone instrument is designed to extend benefits of directionality. *Hear J* 2002;55(10):38-45.
10. Bentler R, Palmer C, Dittberner A: Hearing in noise: Comparison of listeners with normal and (aided) impaired hearing. *JAAA* 2003;15(3):216-225.
11. Powers T, Hammaker V: Providing adaptive directional technology works: A review of studies. *Hear Rev* 2004;11(4):46-50.
12. Ricketts TA, Hornsby BWY, Johnson EE: Adaptive directional benefit in the near field: Competing sound angle and level effects. *Sem Hear* 2005 (in press).
13. Mueller HG, Hall JW: *Audiologists' Desk Reference*, Vol. II. San Diego: Singular Publishing, 1998.
14. Noble W, Byrne D: Audirory localization under conditions of unilateral fitting of different hearing aid systems. *Brit J Audiol* 1991;25(4):237-250.
15. Hornsby B, Ricketts T: Hearing aid user volume control adjustments: Bilateral consistency and effects on speech understanding. Unpublished manuscript, 2004.
16. Byrne D, Dirks D: Effect of acclimatization and deprivation on non-speech auditory abilities. *Ear Hear* 1996;17:29S-37S.
17. Zurek P: Binaural advantages and directional effects in speech intelligibility. In Studebaker GA, Hochberg I, eds., *Acoustical Factors Affecting Hearing Aid Performance*. Boston: Allyn and Bacon, 1993: 255-276.
18. Bronkhorst A, Plomp R: The effect of head-induced interaural time and level differences on speech intelligibility in noise. *J Acoust Soc Am* 1988;83(4):1508-1516.
19. Ricketts T: The impact of head angle on monaural and binaural performance with directional and omnidirectional hearing aids. *Ear Hear* 2000;21(4): 318-328.
20. Jerger J, Brown D, Smith S: Effect of peripheral hearing loss on the MLD. Arch Otolaryngol 1984;110: 290-296.
21. Dillon H. *Hearing Aids*. 2001. Sydney: Boomerang Press, 2001.
22. Bentler R, Nelson J: Effect of spectral shaping and content on loudness discomfort. *JAAA* 2001;12(9): 462-470.
23. Gatehouse S, Noble W: The speech, spatial and qualities of hearing scale (SSQ). *Int J Audiol* 2004;43(2):85-99.
24. Noble W, Gatehouse S: Interaural asymmetry of hearing loss, speech, spatial and qualities of hearing scale (SSQ) disabilities, and handicapd *Int J Audiol* 2004;43(2):100-114.
25. Hornsby B, Ricketts T: Benefits of bilateral use of directional hearing aids. Unpublished manuscript, 2004.