Study Title: Coupler-Based Hearing-Aid Fitting Approach for Experienced Users

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Principal Investigator: Sherri L. Smith, Au.D., Ph.D.

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The purpose of this study is to evaluate procedures designed to greatly improve the efficiency of hearing-aid delivery to experienced hearing-aid wearers. Specifically, the fitting accuracy and patient experience for two approaches that would not require additional direct patient contact will be compared to the current standard-of-care (SoC) approach in which *in situ* real-ear aided responses (REARs) measures are obtained. The proposed approaches use derived REAR hearing-aid fittings based on either (1) average-corrected or (2) individually-measured real-ear to coupler differences (RECDs) for fitting and verification of *replacement* amplification. The primary research aims are to determine:

1. if the *in situ* REARs differ from the derived REARs in the experimental groups and if the derived REARs in the experimental groups differ from the *in situ* REARs in the SoC group,
2. if fittings based on measured versus average-corrected RECD values differ in the experimental groups, and
3. if the subjective hearing-aid outcomes differ among the groups.

RESEARCH DESIGN AND METHODS

Design. A mixed model, repeated measure design will be used in the current study.

Participants. There will be three groups of participants. One group will serve as the active-control group and will receive the standard-of care 30-min appointment (SoC group). One experimental group will have the average-corrected (for venting) RECD (Exp-AVGc Group) incorporated during the RECD-based verification and the other experimental group will have the measured (with custom earmold) RECD (Exp-M Group) incorporated during verification. The two experimental groups will be mailed their replacement hearing aids *after* they are programmed and verified with RECD-based fittings. The participants will be randomly assigned to each group.

Inclusion Criteria: Participants will be included in the study if the following criteria are met:

- experienced BTE hearing-aid users who are obtaining replacement VA-issued BTE hearing aids coupled to a custom earmold that is simply an upgrade in model (e.g., 2010 Phonak Exeila 211 Art BTE upgrading to a 2014 Phonak Bolero Q90 BTE) with the same style earmold
- no more than a moderate sensorineural hearing loss (defined as < 60 dB HL pure-tone average at 500, 1000, and 2000 Hz AU)
- ability to read and write in English as determined by reading a few sentences from the consent document aloud so that self-report measures can be completed

Exclusion Criteria: Participants will be excluded if any of the following criteria are true:

- outer or middle ear pathology as determined by otoscopy, immittance, and/or audiometric testing (e.g., conductive or mixed losses)
- lack of phone or non-use of the phone as the participants will be required to conduct a telephone interview after they obtain their replacement hearing aids
- unwilling or unable to be mailed hearing aids
- co-morbid condition that would preclude their participation as determined by a chart review (e.g., dementia, visual impairment/legal blindeness, substance abuse, etc.)

Materials/Tests:

In addition to RECD and REAR measures, this study will include measures of speech-in-noise abilities and hearing-aid outcomes. These measures are described below:

Client-Oriented Scale of Improvement (COSI; Dillon, James, & Ginis, 1997). The listener nominates up to five listening goals on the COSI. After hearing-aid use, the listener assesses two outcomes for each goal. One outcome is the “degree of change” relative to the patient’s unaided experience. Responses are recorded on a categorical scale from ‘worse’ to ‘much better.’ The second outcome is the final satisfactory “aided” ability for each goal as measured on a categorical scale from hardy ever (10%) to almost always (95%). The percentage of ‘better’ and ‘much better’ responses and the average of the final ability will be calculated across goals. (Session 1—goals established and Session 3—outcomes established—See Procedure Section below) (5 minutes).

Device Oriented Subjective Outcome (DOSO) Scale (Cox, Alexander, & Xu, 2009). The questionnaire is comprised of 28 items making up the following six subscales related to listening performance with hearing aids: (1) speech cues, (2) listening effort, (3) pleasantness,(4) quietness, (5) convenience, and (6) use. Responses from 'not at all' (1 point) to tremendously (7 points) are recorded for each item. Higher scores represent better device-oriented subjective outcome. This is a post-only measure (Session 3) (10 minutes).

Satisfaction with Amplification in Daily Life (SADL) (Cox and Alexander, 1999). The SADL questionnaire has 15 items that examine self-reported hearing-aid satisfaction. The following four subscales are included: (1) positive effect, (2) negative features, (3) personal image, and (4) service and cost. For the current study, item 14 on the service and cost subscale was not used as the Veterans were not charged for the cost of their bilateral hearing aids. The SADL uses a 7-item response scale in 1-unit steps, 1 (poorest) to 7 (highest) for each item, which are averaged for each subscale and total scale score. (Session 3) (5 minutes).

Words-In-Noise (WIN) test uses the NU-6 materials in a six-talker multi-talker babble. The words are presented at 7 signal-to-noise ratios (S/N), 24-dB to 0-dB S/N, in 4-dB decrements. The noise level remains constant and the level of the words varies. Listeners with pure-tone averages ≤25-dB HL will be presented with noise levels at 70-dB SPL and the words will vary from 94- to 70-dB SPL. Listeners with pure-tone averages 25.1- to 40-dB HL will be presented with noise levels at 80-dB SPL and the words will vary from 104- to 80-dB SPL. Listeners with pure-tone averages between 40.1- and 60-dB HL will be presented with noise levels at 90-dB SPL and the words will vary from 114- to 90-dB SPL (following Wilson, 2003; Wilson, Abrams, & Pillon, 2003; Wilson & Burks, 2005). The 50% point on the WIN will be calculated for each ear using the Spearman-Kärber equation (Finney, 1952) in addition to the percent correct performance at each signal-to-noise ratio. (Session 1) (5 minutes).

Procedures.

Session 1 (Baseline, Pre-Fitting). All testing will be completed separately in each ear for all groups. Otoscopy will be performed and cerumen management completed as needed. The standard audiometric evaluation including air- and bone-conduction pure-tone audiometry; word-recognition in quiet (NU-6 words) and in noise (WIN) will be completed. Tympanometry and aural acoustic reflexes also will be measured. The COSI will be completed to obtain the listening goals of the participant and to facilitate programming needs of the replacement hearing aids (e.g., whether or not manual programs are needed/desired). In addition, an intake form (**Appendix 2**) will be completed for all groups to determine other device options and function (e.g., volume control options such as yes/no or unlinked/linked; removal filament or not; earmold style from previous order form; and tubing length; etc.). If care or use questions arise based on responses on the intake form, then they will be answered during this session. The replacement hearing aids and earmolds will be ordered using the earmold scans on file with the manufacturer provided that the current earmolds from the old hearing aid are a good fit. If not, then ear impressions will be made for replacement earmolds.

For the experimental groups, the tubing length of the current earmolds will be measured carefully so that the replacement earmold tubing can be cut to the same length at the RECD-fitting (Session 2-below). For the Exp-AVGc group, the current earmold vent size will be measured if the actual size is not available on the previous order form. That way, the average RECD values can be corrected for the vent size of the earmold at the RECD-fitting (Session 2).

For the Exp-M group only, RECD values will be obtained separately for each ear with the patient's current earmolds after they have been cleaned and tubing changed as needed. Using the current earmold as opposed to the foam insert will allow venting and tubing characteristics to be incorporated in the RECD-fitting. The RECD measurement protocol will follow the standard clinical protocol and will use the Verifit 2 system. The test box reference microphone will be calibrated. The RECD transducer will be placed on the BTE coupler and the coupler response will be obtained. The probe tube will be inserted 25-27 mm from the antitragal notch in order to ensure placement

within approximately 2-5 mm from the eardrum. The participant's current earmold (lubricated to ensure a good seal) will be placed in the ear canal and care will be taken not move the probe tube during earmold insertion. The RECD transducer will be coupled to the earmold tubing and the real-ear response will be obtained. The difference between the coupler and real-ear responses is the measured RECD.

Session 2: The Intervention 'Visit'.

SoC Group Fitting. This group will receive the SoC, 30-minute face-to-face fitting appointment 4-6 weeks after Session 1, the average wait time for a fitting appointment. The right and left hearing aids will be programmed separately to the National Acoustics Laboratory Non-Linear 2 (NAL-NL2) prescription. The REAR of the hearing aids will be verified to the 50-, 65-, and 75-dB SPL prescriptive targets generated by the Verfit 2 system using the speechmap stimulus. The criterion for an appropriate fitting would be ± 3 dB between the output and the prescriptive target from 250 Hz to the frequency in which the unaided threshold crossed the 65-dB SPL target. The Real Ear Saturation Response (RESR) will be measured using an 85-dB swept pure-tone to ensure that the maximum output of the hearing aids does not exceed the predicted uncomfortable loudness levels of the participant. The programming options will be optimized based on the information obtained on the intake form (**Appendix 2**). The participant will be provided with the manufacturer brochure, programming report from the manufacturer software, and the VA Hearing Aid Booklet. Consistent with current SoC, no orientation will be provided.

Experimental Group Fittings. The participants in the experimental groups will not be present during the fitting. The hearing aids will be fitted in a manner similar to the SoC fitting except the average-corrected (for vent size) RECD (Exp-AVGc Group) or measured RECD from Session 1 (Exp-M group) will be inputted into the Verfit 2 to generate the prescriptive targets and the derived REARs will be obtained following the standard clinical procedure. In short, the tubing of the *replacement* earmold will be cut to length and coupled to each hearing aid. The earmold will be attached to the HA-1 coupler with putty ensuring that the eartip is flush against the opening of coupler and the vent sealed, as is standard with this procedure. The hearing aids will be programmed and the derived REARs will be obtained and verified against the prescription. After programming and verification, the hearing aids will be mailed to the patient along with the manufacturer brochure, programming report from the manufacturer software, and the VA Hearing Aid Booklet within one business day of their receipt from the manufacturer. It is estimated that these experimental fittings will take 15 minutes, or half the time of the SoC fittings. A signature will be required to accept the delivery and the delivery will be tracked.

Two-Day Follow-Up Phone Call. All participants will receive a 2-day follow-up phone call after the hearing-aid fitting. The experimental groups will be phoned after delivery of the hearing aid is confirmed with the delivery receipt. A telephone script (**Appendix 2**) will be used to ask questions about the physical comfort of the device, sound quality, and any other hearing-aid problems or questions.

Session 3 (One-Month Post-Fitting). One month after the hearing-aid fitting, all groups will return to complete subjective outcome measures. The measures will be presented in random order. The COSI outcomes will be measured to determine if the hearing aids are meeting the patient-nominated goals. The SADL will be completed and the *Service and Cost* subscale will be of great interest due to the service-related items that may differentiate between groups. The DOSO will be used as it assesses hearing-aid outcomes in six domains. An exit survey (**Appendix 2**) also will be administered to gain insight into the perceptions related to service delivery, access, and convenience. In addition, *in situ* REARs will be obtained from all groups using the current programming from the replacement aids. These *in situ* REARs will allow within and between group comparisons regarding the hearing-aid function and determine the accuracy of the experimental fittings relative to the SoC fittings. The repeat *in situ* REAR measurements in the SoC group (i.e., Sessions 2 and 3) will serve to assess the inherent variability with *in situ* REAR measurements and

will facilitate interpretation of REAR data when comparing the accuracy of the *in situ* and derived REARs in the experimental groups.

Attrition. In our experience (Smith and Ricketts) with a multi-session (4 sessions over 6 months), hearing-aid clinical trial, we had a low local attrition rate of 8.7%. The primary reasons for withdrawal were due to personal reasons which included illness, moving out of state, and transportation issues during inclement weather (i.e., snow). Thus, we considered a conservative estimate of 15% attrition for the proposed multi-session study.

Sample Size. Based on an expectation that REAR measurements should be within 2 dB on average across frequency, and an SD of 2, then 18 participants are needed for each group (total N = 54) assuming a power of at least $\beta = .80$ and $p = .05$. Considering 15% attrition, then 9 additional subjects will be needed (N = 63) resulting in 21 participants per group. Participants will be recruited from the Mountain Home VA audiology clinics. Last year, our clinic served 7,481 Veterans during 16,278 patient visits and dispensed 7,134 hearing aids. Also, based on the national average, it is estimated that ~50% of VA hearing aids dispensed are replacement hearing aids for experienced users. Thus, we anticipate no difficulty in recruiting the target sample at Mountain Home.

Data Analysis.
Specific Aim 1 and 2. A mixed-model analysis of variance (ANOVA) will be conducted. This analysis will examine differences (in dB SPL) for REAR (actual vs derived using average vs measured RECD) across frequency and ears within and between the groups. This analysis will determine (1) if the *in situ* REARs differ from the derived REARs in the experimental groups and if the derived REARs in the experimental groups differ from the *in situ* REARs in the SoC group (2) if coupler-derived REARs using average-corrected or measured RECDs differ; and (3) if the average-corrected RECD differs from the measured RECD.

Specific Aim 3. A multivariate ANOVA will be conducted to examine group differences among the outcome measure subscales. A logistic regression also will be conducted to examine if the proportion of responses differ among the groups on the specific telephone and exit survey items of interest.