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Assessment of Hearing Aid Benefit Using Patient-Reported Outcomes and Audiologic Measures

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Keywords
Abbreviated Profile of Hearing Aid Benefit (APHAB) · Hearing aid benefit · Audiologic measures · Patient-reported outcome measure

Abstract

Purpose: To determine the contributions to hearing aid benefit of patient-reported outcomes and audiologic measures. ***Methods:*** Independent review was conducted on audiologic and patient-reported outcomes of hearing aid benefit collected in the course of a middle ear implant FDA clinical trial. Unaided and aided data were extracted from the preoperative profiles of 95 experienced hearing aid users, and the relationships between a patient-reported outcome and audiologic measures were assessed. The following data were extracted: unaided and aided pure-tone or warble-tone thresholds (PTA), word recognition in quiet (NU-6), Speech Perception in Noise (low-/high-context SPIN), and patient-reported benefit (Abbreviated Profile of Hearing Aid Benefit, APHAB). Hearing aid benefit was defined as the difference in thresholds or scores between unaided and aided conditions, as measured in the sound field. Correlations were computed among audiologic measures and global APHAB and subscale scores of hearing aid benefit. ***Results:*** Significant improvements in all audiologic measures and APHAB scores were observed comparing unaided to aided listening (all $p < 0.001$). However, correlations between audiologic and patient-reported measures of aided performance or hearing aid benefit were low-to-weak or absent. No significant correlations were found between aided audiologic measures (PTA, NU-6, SPIN) and any aided APHAB scores (all $p > 0.0125$), and significant relationships for hearing aid benefit were absent with only few exceptions. Hearing aid benefit defined by global APHAB using NU-6 and SPIN scores showed significant but weak positive correlations ($r = 0.37$, $p < 0.001$; $r = 0.28$, $p = 0.005$, respectively) and ease of communication APHAB subscale scores ($r = 0.32$, $p < 0.001$; $r = 0.33$, $p = 0.001$, respectively). ***Conclusion:*** Hearing aid benefit assessed with audiologic measures were poor predictors of patient-reported benefit. Thus, patient-reported outcomes may provide a unique assessment of patient-perceived benefit from hearing aids, which can be used to direct hearing aid programming, training, or recommendations of alternative hearing services.

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Introduction

Approximately 38 million individuals in the United States over the age of 12 years have some form of hearing loss [Goman and Lin, 2016; Huddle et al., 2017]. The majority of individuals have mild to moderate hearing loss, which is typically treated by amplification with hearing aids, which can result in significant improvement in quality of life [Humes and Krull, 2012; Goman and Lin, 2016]. New hearing aid technologies and complex fitting algorithms have become available over the past several years, but with limited evidence to guide the selection and fitting of specific hearing aid features. Hearing aid fitting is typically determined by pure-tone thresholds, with the fitting verified by other audiologic measures, such as speech recognition scores and real-ear probe-microphone measures [Carhart, 1946; Dillon et al., 1997]. Some audiologists may also use patient-reported outcome measures (PROMs) of hearing aid benefit and quality of life to supplement audiologic measures, such as the Abbreviated Profile of Hearing Aid Benefit (APHAB), Clinically Oriented Scale of Improvement (COSI), Speech Spatial and Qualities of Hearing Scale (SSQ), and International Outcomes Inventory-Hearing Aids (IOI-HA) [Cox and Alexander, 1992; Dillon et al., 1997; Cox et al., 2000; Gatehouse, 2001; Killion and Gudmundsen, 2005; Mendel, 2007]. However, the relationship between audiologic measures used for hearing aid fitting and PROMs that assess hearing aid benefit remains uncertain, which limits the ability of providers to assess the appropriateness of the fit and predict hearing aid use and satisfaction.

Research in this area is lacking and, at times, inconsistent [Cox et al., 2000; Humes and Krull, 2012]. A review of the literature indicates that audiologic measures tend to poorly correlate with PROMs evaluating hearing aid benefit [Kapteyn, 1977; Parving, 1991; Cox et al., 2000; Humes, 2003; Killion and Gudmundsen, 2005; Chang et al., 2016]. However, many of these studies have small sample sizes – often fewer than 30 subjects [Cox and Alexander, 1992; Cox et al., 2000; Mendel, 2007] and report results from non-validated, study-specific instruments that are not commonly used in clinical or research settings [Kapteyn, 1977; Parving, 1991; Killion and Gudmundsen, 2005]. Those reporting results from validated PROMs with reasonable sample sizes examined only the relationship of PROMs with unaided audiologic measures and not hearing aid benefit, which the current study aims to address [Humes, 2003; Humes et al., 2003; Chang et al., 2016].

The APHAB is one of the most commonly used PROMs to evaluate hearing aid benefit and is often cited for its ease of delivery and interpretation [Cox and Alexander, 1995; Löhler et al., 2017]. Despite widespread use, little is known regarding its relationship to hearing aid benefit as indicated by audiologic measures [Cox et al., 2000; Cox et al., 2003; Killion and Gudmundsen, 2005; Löhler et al., 2017]. Cox et al. [2003] demonstrated a moderate correlation of unaided APHAB scores with pure-tone average (PTA) and unaided speech recognition (Northwestern University Auditory Test Number 6; NU-6) testing in quiet and in noise; however, the audiologic outcomes were measured with headphones and subjects were not tested under aided conditions. As such, the relationship of aided audiologic measures with aided APHAB scores is unknown, as is the relationship between hearing aid benefit assessed with audiologic measures and PROMs.

The purpose of this study is to assess the relationship between patient self-report of aided performance and hearing aid benefit, as measured by the APHAB, and audiologic measures, including pure-tone and warble-tone thresholds, speech recognition scores using the NU-6, and the Speech Perception in Noise test (SPIN) [Tillman and Carhart, 1966]. This information may demonstrate the relative value of each type of measure as a component in a hearing aid evaluation battery and aid in interpreting results to maximize hearing aid benefit.

Materials and Methods

Data

Data for this study were collected by Ototronix (Houston, TX, USA) as part of a multicenter phase III Food and Drug Administration (FDA) clinical trial for the Soundtec Direct Drive Hearing System (now Maxum Hearing Implant). A Material Transfer Agreement was signed between our institution and Ototronix before de-identified data were shared with the authors. Raw data for individual subjects were provided without prior statistical manipulation. Ototronix personnel did not participate in the planning, execution, or composition of this project and did not review the manuscript.

Subjects

The study sample included 95 subjects (34.7% female; median age: 67 years; age range: 21–80 years) with mild to moderate hearing loss who were experienced users of traditional hearing aids electing to pursue evaluation for middle ear implantation due to dissatisfaction with their hearing aids. These subjects were previously described in McRackan et al. [2016 and 2018a]. Data on the effects of middle ear implantations were not collected or assessed. Rather, this study took advantage of preoperative audiologic and quality of life data from a large sample of experienced hearing aid users, measured without and with hearing aids. The clinical trial inclusion and exclusion criteria were as follows. Subjects were required to be native English speakers with a minimum 2-year history of stable hearing loss. They were required to have bilateral symmetrical sensorineural hearing

Table 1. Conditions under which outcomes were measured

Outcome measure	Earphone	Unaided	Aided
Pure-tone thresholds	×		
Warble-tone thresholds		×	×
NU-6	×	×	×
SPIN		×	×
APHAB		×	×

NU-6, Northwestern University Auditory Test No. 6; SPIN, Speech Perception in Noise test; APHAB, Abbreviated Profile of Hearing Aid Benefit.

loss with <15 dB difference in PTA (average of 1,000, 2,000, and 4,000 Hz) between ears, and <10 dB difference between air and bone conduction thresholds. Frequencies for calculating this PTA were part of the clinical trial protocol and were not used in analysis for the current study. Preoperative, bilateral pure-tone thresholds were required to fall within the following ranges: 0–50 dB HL at 250 Hz, 0–60 dB HL at 500 Hz, 10–70 dB HL at 1,000 Hz, 35–75 dB HL at 2,000 Hz, 50–75 dB HL at 3,000 Hz, 50–80 dB HL at 4,000 Hz, 40–100 dB HL at 6,000 Hz; PTA was required to range from 35 to 70 dB HL. Word recognition scores measured under earphones in quiet using 50-word lists from the NU-6 were required to be >60% in both ears. As determined by the clinical trial protocol, the poorer hearing ear was selected as the test ear.

Prior to data collection, subjects were required to have worn properly fitted hearing aids, defined according to NAL-R targets [Byrne and Dillon, 1986] for a minimum of 6 months. Hearing aids that had not been fitted using NAL-R targets were refitted by clinical trial audiologists and subjects were required to use their hearing aids with their new settings for a minimum of 45 days before enrollment. Patients utilized their hearing aids for an average of 7.2 years prior to data collection, ranging from 6 months to 30 years. Subjects with conductive or retrocochlear pathology were excluded from the study.

Audiologic Measures (Thresholds and Speech-Recognition Scores)

Pure-tone or warble-tone thresholds, NU-6 word-recognition scores, and SPIN scores were the primary audiologic outcome measures. Conditions under which each were tested are presented in Table 1. Thresholds from 250 to 6,000 Hz were measured under three conditions: pure tones with either supra-aural or insert earphones, warble tones unaided in the sound field, and warble tones with hearing aids in the sound field. These conditions will be referred to as earphone, unaided, and aided thresholds, respectively. For statistical analysis, PTAs (500, 1,000, and 2,000 Hz) were calculated for each subject and in each condition. Hearing aid benefit was defined as the reduction in PTA with hearing aid use. This was calculated as unaided PTA in sound field minus aided PTA in sound field, so improvements in threshold with hearing aid use yield positive values.

Word recognition scores using the NU-6 was also measured under the same three conditions: supra-aural or insert earphones with words presented at 40 dB above speech recognition threshold (earphone), unaided in the sound field with words presented at 63 dB SPL (unaided), and with hearing aids in the sound field at 63 dB SPL (aided). Sentence recognition using the SPIN was measured under unaided and aided conditions. The SPIN is composed of 8 lists of 50 sentences each with multitalker babble presented at a +8 dB signal-to-noise ratio. Listeners are instructed to repeat the last word of each sentence. Half of the sentences are high-context sentences in which the final word was predictable from the earlier part of the sentence, and half of the sentences were low-context sentences in which the final word cannot be determined from the earlier part of the sentence. Hearing aid benefit was defined as improvement in scores with hearing aid use. This was calculated as aided scores in the sound field subtracted by unaided scores in the sound field. As with PTA, improvements in scores with hearing aid use yield positive values.

All sound field testing was performed in sound-attenuated booths that met ANSI standards for sound attenuation, with subjects sitting 1 m from the loudspeaker and speech (and babble, if present) delivered at 0 degrees azimuth. The non-test ear was occluded with a foam plug during testing.

Patient-Reported Outcome Measure (APHAB)

The APHAB [Cox and Alexander, 1995] is a self-report questionnaire in which individuals rate their frequency of problems in various situations, which are scored in 4 subscales: ease of communication in quiet (EC), in background noise (BN), and in situations of reverberation such as gymnasiums or classrooms (RV). Subjects also rate the frequency with which they experience negative reactions or aversion to environmental sounds (AV) [Humes, 2003]. Global scores are calculated as the average of the EC, BN, and RV subscale scores. Higher scores reflect greater frequency of problems. As part of the FDA clinical trial, subjects provided responses to the APHAB that reflected their frequency of problems without and with hearing aids (unaided and aided). Hearing aid benefit as indicated by APHAB was calculated as unaided scores minus aided scores, so improvement with hearing aids yields positive values [Cox and Alexander, 1995].

Statistical Analyses

All analyses were performed with SPSS 25.0 (IBM Corp., Armonk, NY, USA). All continuous variables were tested for normal distribution as determined by the Kolmogorov-Smirnov test. Nominal variables were summarized by frequency, percentage, and/or range. Continuous variables were summarized by mean (standard deviation) where appropriate. PTAs and NU-6 scores in earphone, unaided, and aided conditions were analyzed with a one-way ANOVA or Kruskal-Wallis test, with Dunn-Bonferroni post hoc testing employed as necessary for pairwise assessment of continuous variables. Unaided and aided SPIN, APHAB global and APHAB subscale scores were compared using repeated samples t test for repeated measures in the same subject. Pearson's correlations were used to test for the presence of significant associations among APHAB and audiologic measures. During correlational analysis, aided APHAB global and subscores and APHAB hearing aid benefit were analyzed independently against aided thresholds, NU-6 scores, SPIN scores, and each estimate of hearing aid benefit.

A p value <0.05 was used to determine statistical significance in non-correlational analyses. For Pearson correlation testing against multiple independent variables, p values underwent Bonferroni correction by a factor of 4, with significance defined as $p < 0.0125$. The strength of correlations was defined as follows: very weak = 0.00–0.19; weak = 0.20–0.39; moderate = 0.40–0.59; strong = 0.60–0.79; very strong; 0.80–1.00 [Löhler et al., 2017].

Table 2. Comparison of audiologic and patient-reported outcome measures

	Earphone	Unaided	Aided	*p* value
PTA, dB HL	40.9 (8.8)	40.9 (10.6)	25.4 (6.7)	<0.001* 0.309 earphone vs. unaided <0.001 earphone vs. aided <0.001 unaided vs. aided
NU-6, %	81.5 (10.7)	42.8 (28.9)	77.4 (16.5)	<0.001* <0.001 earphone vs. unaided 0.427 earphone vs. aided <0.001 unaided vs. aided
SPIN, %				
Low context	n/a	3.76 (4.2)	9.96 (5.4)	<0.001
High context	n/a	11.97 (9.1)	21.4 (4.4)	<0.001
APHAB				
Ease of communication	n/a	60.7 (21.7)	26.1 (14.3)	<0.001
Background noise	n/a	73.8 (15.1)	40.0 (15.5)	<0.001
Reverberation	n/a	73.1 (14.9)	36.1 (15.6)	<0.001
Aversiveness	n/a	21.1 (18.4)	47.0 (26.4)	<0.001
Global	n/a	69.2 (14.4)	34.0 (12.5)	<0.001

Values are presented as mean (SD). PTA, pure-tone average; NU-6, Northwestern University Auditory Test No. 6; SPIN, Speech Perception in Noise test; APHAB, Abbreviated Profile of Hearing Aid Benefit. * ANOVA of earphone, unaided, and aided conditions; subsequent pairwise analysis is done post hoc.

Results

Audiologic Measures: Thresholds and Speech Recognition Scores

Audiologic measures are summarized in Table 2. As expected, subjects' mean PTAs were higher in the earphone and unaided conditions as compared to the aided condition ($p < 0.001$ for both). Earphone and unaided PTAs were not significantly different ($p = 0.309$). Scores on the NU-6 were better in the aided and earphone conditions as compared to the unaided condition ($p < 0.001$ for both). NU-6 scores in the earphone and aided conditions were not significantly different ($p = 0.427$). Similarly, scores were higher for both low- and high-context SPIN in the aided condition as compared to the unaided condition ($p < 0.001$ for both). Significant decreases in thresholds and significant improvements in scores between aided and unaided conditions reflect significant hearing aid benefit.

Patient-Reported Outcome Measure (APHAB)

APHAB subscale and global scores under unaided and aided conditions are reported in Table 2. Significant reductions in reported frequency of problems (hearing aid benefit) in ease of communication, background noise, reverberation subscales, and global APHAB scores were observed in the aided condition as compared to the unaided condition ($p < 0.001$). In contrast, significant increases in reported frequency of negative reactions or aversions to environmental sounds were observed in the aided condition as compared to the unaided condition ($p < 0.001$). Length of hearing aid usage was not significantly associated with improvement in global APHAB scores ($r = 0.002$, $p = 0.978$) or any APHAB subset score ($p > 0.1$ for all).

The aided values shown in this patient population correspond to previously identified normative APHAB scores for modern, wide dynamic range compression hearing aids. The 50th percentile APHAB scores for modern hearing aids are EC = 23, BN = 40, RV = 37, AV = 38, and global = 33 [Johnson et al., 2010]. The scores for the current study's patient population fall at the 50th to 65th percentile scores globally and in each category.

Correlations among Audiologic and Patient-Reported Outcome Measures

Correlations among aided audiologic measures (PTA, NU-6, SPIN) and aided APHAB subscale and global

Table 3. Pearson correlations among aided APHAB (subscale and global scores) and aided audiologic measures (PTA, NU-6, SPIN)

Aided measures		PTA	NU-6	Low-context SPIN	High-context SPIN
APHAB: ease of communication	*r* (95% CI)	–0.07 (–0.26 to 0.13)	0.06 (–0.14 to 0.26)	0.15 (–0.07 to 0.32)	0.05 (–0.15 to 0.24)
	sig. (2-tailed)	0.525	0.572	0.154	0.649
APHAB: reverberation	*r* (95% CI)	–0.05 (–0.25 to 0.14)	–0.19 (–0.37 to 0.01)	–0.09 (–0.29 to 0.10)	–0.03 (–0.22 to 0.17)
	sig. (2-tailed)	0.612	0.071	0.383	0.808
APHAB: background noise	*r* (95% CI)	–0.07 (0.26 to 0.13)	–0.03 (–0.23 to 0.17)	–0.02 (–0.22 to 0.18)	0.05 (–0.15 to 0.25)
	sig. (2-tailed)	0.478	0.742	0.869	0.610
APHAB: aversiveness	*r* (95% CI)	–0.08 (–0.27 to 0.12)	0.13 (–0.06 to 0.33)	0.09 (–0.10 to 0.29)	0.21 (0.02 to 0.39)
	sig. (2-tailed)	0.472	0.198	0.399	0.039
APHAB: global	*r* (95% CI)	–0.08 (–0.27 to 0.12)	–0.07 (–0.27 to 0.12)	0.01 (–0.18 to 0.22)	0.03 (–0.16 to 0.23)
	sig. (2-tailed)	0.455	0.503	0.912	0.777

p value <0.0125 is significant. None of these associations were statistically significant. PTA, pure-tone average; NU-6, Northwestern University Auditory Test No. 6; SPIN, Speech Perception in Noise test; APHAB, Abbreviated Profile of Hearing Aid Benefit.

Table 4. Pearson correlations among hearing aid benefit (improvement in measure with hearing aid use) as indicated by APHAB (global and subscale) and audiologic measures (PTA, NU-6, SPIN)

Measures of hearing aid benefit		PTA	NU-6	Low-context SPIN	High-context SPIN
APHAB: ease of communication	*r* (95% CI)	0.16 (–0.04 to 0.33)	**0.32** **(0.13 to 0.49)**	0.15 (–0.05 to 0.33)	**0.33** **(0.14 to 0.49)**
	sig. (2-tailed)	0.133	**0.002**	0.155	**0.001**
APHAB: reverberation	*r* (95% CI)	**0.26** **(0.44 to 0.07)**	**0.33** **(0.13 to 0.49)**	0.02 (–0.17 to 0.22)	0.23 (0.03 to 0.41)
	sig. (2-tailed)	**0.011**	**0.001**	0.814	0.027
APHAB: background noise	*r* (95% CI)	0.02 (–0.20 to 0.21)	0.16 (–0.04 to 0.34)	0.13 (–0.07 to 0.31)	0.05 (–0.14 to 0.25)
	sig. (2-tailed)	0.864	0.123	0.209	0.607
APHAB: aversiveness	*r* (95% CI)	–0.08 (–0.25 to 0.14)	–0.08 (–0.27 to 0.12)	–0.01 (–0.21 to 0.19)	–0.09 (–0.27 to 0.12)
	sig. (2-tailed)	0.864	0.123	0.209	0.607
APHAB: global	*r* (95% CI)	0.20 (0.39 to 0.01)	**0.37** **(0.18 to 0.52)**	0.13 (–0.05 to 0.33)	**0.28** **(0.09 to 0.46)**
	sig. (2-tailed)	0.051	**<0.001**	0.205	**0.005**

p value <0.0125 is significant. Bold text shows significant associations. PTA, pure-tone average; NU-6, Northwestern University Auditory Test No. 6; SPIN, Speech Perception in Noise test; APHAB, Abbreviated Profile of Hearing Aid Benefit.

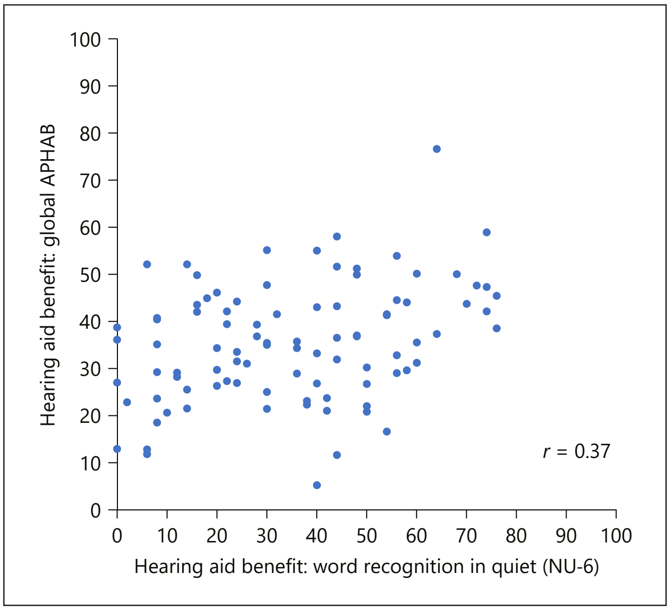

Fig. 1. Hearing aid benefit as indicated by global APHAB score plotted against hearing aid benefit as indicated by word recognition score in quiet (NU-6).

scores showed no significant relationships (Table 3). Correlations among audiologic and patient-reported measures of hearing aid benefit showed several weak correlations (Table 4). Hearing aid benefit as indicated by NU-6 and high-context SPIN scores showed weak positive correlations with global APHAB benefit ($r = 0.37$, $p < 0.001$ and $r = 0.28$, $p = 0.005$, respectively) and ease of communication APHAB benefit ($r = 0.32$, $p = 0.002$ and $r = 0.33$, $p = 0.001$, respectively). Hearing aid benefit as indicated by APHAB RV subscores showed a weak positive correlation with benefit as indicated by PTA and with benefit as indicated by NU-6 scores ($r = 0.26$, $p = 0.011$ and $r = 0.33$, $p = 0.001$, respectively). Figure 1 shows global APHAB benefit plotted against benefit as determined by NU-6 and is the strongest association observed between patient-reported and audiologic measures of hearing aid benefit ($r = 0.37$). Benefit as indicated by the APHAB BN and AV subscale scores were not significantly associated with any audiologic measures of hearing aid benefit.

Discussion

In this study, we showed that audiologic measures and PROMs of aided performance were not significantly correlated, but some weak correlations were observed among audiologic and self-report measures of hearing aid benefit. Specifically, hearing aid benefit as indicated by NU-6 and high-context SPIN scores correlated weakly and positively with benefit as indicated by global and ease of communication APHAB scores, whereas PTA and NU-6 benefit correlated weakly and positively with benefit assessed by the APHAB reverberation subscale. No single audiologic measure of hearing aid benefit predicted patient self-report of hearing aid benefit as measured with the APHAB. Therefore, given that the APHAB appears to provide unique information about hearing aid benefit that is not provided by audiologic outcomes, administering PROMs such as the APHAB should be considered when evaluating benefit for hearing aid users.

Evidence of the strength of relationship between audiologic measures and PROMs under aided conditions is limited. Many studies have small sample sizes [Cox and Alexander, 1992; Cox et al., 2000; Mendel, 2007] and/or used experimental and non-standardized audiologic measures and non-validated PROMs [Kapteyn, 1977; Parving, 1991; Killion and Gudmundsen, 2005]. Those studies with large sample sizes and validated PROMs include primarily unaided measures [Humes, 2003; Humes et al., 2003; Chang et al., 2016]. However, these studies show similar outcomes to the current study with absent to low correlations between PROMs and unaided audiologic measures [Kapteyn, 1977; Parving, 1991; Killion and Gudmundsen, 2005; Humes and Krull, 2012]. In a multiple regression analysis, Chang et al. [2016] reported a significant but small negative association of unaided word recognition score and PROMs at 1 month but a weak positive correlation at 3 months ($\beta = -0.68$ and 1.01, respectively). Humes [2003] and Humes et al. [2003] showed no correlation in a similar sample as well as in a large meta-analysis. In addition, absent to low correlations between patient self-report and speech recognition have been reported in cochlear implant users [Brendel et al., 2014; McRackan et al., 2016; Ramakers et al., 2017; McRackan et al., 2018a; McRackan et al., 2018b; Moberly et al., 2018]. Together, these data support the added value of PROMs as an independent measure of patient-perceived benefit from hearing interventions.

The most likely explanation for the low to absent correlations seen in the current study is that hearing aid users' real-world listening environments are more varied than can be predicted by simple audiologic measures. By extension, the benefit users achieve from their hearing aids in these environments is difficult to predict from benefit estimated from audiologic measures, including speech recognition in noise (in this case, SPIN). For example, no significant correlations were seen between aided performance or benefit as indicated by audiologic measures and by the APHAB background noise subscale, which asks about communication ability in specific listening situations (i.e., in the grocery store, in a crowd). Likewise, the aversiveness subscale asks about patients' perceptions of particular environments (i.e., construction work, traffic) being too loud. Although there is value in optimizing hearing aid benefit as indicated by audiologic measures, low to absent correlations suggest that this benefit may not necessarily translate to self-perceived hearing aid benefit. Patient-perceived benefit is important as it is one of the most accurate predictors of hearing aid acquisition and consistent use [Fischer et al., 2011; McCormack and Fortnum, 2013] with an odds ratio of hearing aid acquisition 2–3 times greater than audiologic evidence of hearing loss or communication difficulties [Fischer et al., 2011]. Of patients who are candidates for hearing aids, only 1 in 5 acquire them [Fischer et al., 2011; Chien and Lin, 2012; McCormack and Fortnum, 2013]. Moreover, patients wait an average of 8.9 years to acquire hearing aids after becoming hearing aid candidates [Simpson et al., 2019] and, of those patients who acquire hearing aids, up to 24% do not routinely wear them [Chien and Lin, 2012; McCormack and Fortnum, 2013]. Similar to data on acquisition, a systematic review of the literature found that the most commonly cited reasons for inconsistent hearing aid use were related to perceived benefit and general quality of life issues, such as hearing aid ease of use, in contrast to audiologic evidence of benefit [McCormack and Fortnum, 2013].

Hearing aid success is often defined as consistent and proper use of hearing aids [Fischer et al., 2011; Chien and Lin, 2012; McCormack and Fortnum, 2013; Gallagher and Woodside, 2018]. Given the link between patient-perceived benefit and hearing aid acquisition and use, PROMs may help guide patients toward successful hearing rehabilitation. PROMs may also help providers direct changes in hearing aid use to maximize perceived benefit and examine non-audiologic factors that are commonly cited as leading to increased success with hearing aids. These include increased family support, access to counselling, hearing aid comfort, ease of hearing aid use, and a favorable cost-benefit ratio of the hearing aid device [McCormack and Fortnum, 2013; Gallagher and Woodside, 2018]. These factors are more difficult to predict using audiologic measures of hearing aid benefit alone. PROMs may also be used to advise patients about alternate means of rehabilitation such as a middle ear or cochlear implants.

The large, multicenter sample size is a major strength of the current study. The rigorous nature of the prospective FDA trial that provided these data is additional strength. Specifically, all hearing aids were optimally fit (met NAL-R targets for at least 4 weeks prior to enrollment) and subjects included in this study were experienced hearing aid users (minimum of 6 months of hearing aid use). In addition, audiologic data included earphone, unaided, and aided conditions, speech recognition in quiet and babble, along with a validated PROM (APHAB), which supported the comprehensive analyses performed in the current study.

One limitation of the current study is that participants in the FDA clinical trial were recruited for evaluation for middle ear implantation on the presumption of dissatisfaction with their current hearing aids. A potential limitation is that such patients may rate their patient-reported hearing aid benefit relatively low given their dissatisfaction, or may have poor audiologic outcomes with their hearing aids as a cause of such dissatisfaction. Nevertheless, hearing aid benefit as indicated by audiologic measures was robust and consistent with estimates reported in the literature [Humes and Krull, 2012; Goman and Lin, 2016]. Similarly, the aided APHAB scores and APHAB benefit scores fall well within the population norm as defined by Johnson et al. [2010] for modern hearing aids, as reported in the Results section.

A second limitation of this study is the absence of certain subject demographics, which may contribute to hearing aid use and benefit. Studies have linked consistent use of hearing aids with perceived cost-benefit ratio, social pressure/encouragement, comfort, and ease of hearing aid use rather than specific audiologic outcomes [McCormack and Fortnum, 2013; Gallagher and Woodside, 2018]. As such, subject demographics, such as income, education, comfort with technology, and perceived social support, may play a role in determining self-perceived hearing aid benefit or may modify the relationship between audiologic measures and these outcomes. Future studies should consider the contribution of these factors to audiologic outcomes and PROMs related to hearing aid benefit. These analyses could help identify patterns of audiologic and demographic factors that correlate with the patient-perceived benefit and help further individualize hearing aid selection and fitting and selection of other hearing services and technologies.

Conclusions

Hearing aid benefit assessed with audiologic outcomes shows absent to low correlation with patient self-report assessments of hearing aid benefit. As such, PROMs provide a unique view of patients' perceived benefit from the use of hearing aids, independent of audiologic measures. This is notable because perceived benefit rather than audiologic benefit is a strong independent predictor of hearing aid acquisition and consistent use. Thus, results of the current study support the use of PROMs as supplements to audiologic measures of hearing aid outcomes to help direct recommendations for continued hearing aid use or alternative hearing services or technologies.

Acknowledgement

Data for this study were collected by Ototronix (Houston, TX, USA) as part of a multicenter phase III Food and Drug Administration (FDA) clinical trial for the Soundtec Direct Drive Hearing System (now Maxum Hearing Implant). A Material Transfer Agreement was signed between our institution and Ototronix before de-identified data were shared with the authors.

Statement of Ethics

All data analyzed in this manuscript were de-identified before data access, handling, or analysis. Due to the de-identified nature of the source data, the current study was exempted from review by the Institutional Review Board of the Medical University of South Carolina.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

James R. Dornhoffer, MD: participated in the analysis and interpretation of data; participated in the development and revision of the research manuscript. Ted A. Meyer, MD, PhD: participated in the analysis and interpretation of data; participated in the development and revision of the research manuscript. Judy R. Dubno, PhD: participated in the analysis and interpretation of data; participated in the development and revision of the research manuscript. Theodore R. McRackan, MD, MSCR: participated in the analysis and interpretation of data; participated in the development and revision of the research manuscript.

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