Validation of a Novel Combination Hearing Aid and Tinnitus Therapy Device

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Objectives: Most patients with tinnitus also have hearing loss. Hearing aids have been well-documented to provide amelioration for both hearing and tinnitus problems. Some hearing aids have built-in noise/sound generators that are intended to provide added benefit to patients with tinnitus. It has not been proven, however, whether these "combination instruments" are more effective for tinnitus management than hearing aids alone. The purpose of this study was to collect initial data addressing this question.

Design: Thirty individuals meeting study requirements (bothersome tinnitus, hearing aid candidate, and no use of hearing aids for the previous 12 months) were enrolled. All participants initially completed the primary outcome questionnaire (Tinnitus Functional Index [TFI]) and then returned to be fitted with combination instruments. The hearing aid portion of the devices was adjusted to optimize hearing ability. Participants were then randomized to either the experimental group (n = 15) or the control group (n = 15). The experimental group had the noise feature of the instruments activated and adjusted to achieve optimal relief from tinnitus. The control group did not have the noise portion activated. Following the hearing aid fitting, all study participants also received brief tinnitus counseling. Participants returned 1 to 2 weeks later for a follow-up appointment to confirm proper fit of the instruments and to make any necessary programming adjustments. Additionally, they returned 3 months after the fitting to complete the TFI, which also concluded their participation in the study.

Results: Both groups revealed significant improvement, as indicated by reductions in mean TFI index scores. Differences between groups at 3 months were not statistically significant. However, the experimental group showed a mean reduction in the TFI score that was 6.4 points greater than that for the control group. The difference approached significance (p = 0.09), suggesting that a larger group of participants may have resulted in a significant difference between groups. This possibility is tempered by the fact that effect sizes, which control for variation, were very similar between groups.

Conclusions: Results of this study suggest that the use of hearing aids alone or hearing aids plus the use of sound generators both provide significant benefit with respect to alleviating effects of tinnitus. A larger controlled clinical trial is needed to obtain more definitive results regarding the two configurations of hearing aids.

Key words: Acoustic stimulation, Hearing, Outcomes research, Randomized controlled trial, Tinnitus.

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INTRODUCTION

Anything that can cause hearing loss can also trigger the onset of tinnitus (Coles 1995; Dobie 2004). People experiencing tinnitus typically have peripheral auditory damage, such as that caused by exposure to loud noise (Axelsson & Barrenas 1992; Penner & Bilger 1995). A direct correlation exists between degree of hearing loss and prevalence of tinnitus, such that the odds of having tinnitus increase as hearing loss increases (Coles 2000). Based on multiple studies, the prevalence of tinnitus among adults in the United States is estimated at 10% to 15% (Hoffman & Reed 2004). Further, tinnitus is the most common of all the service-connected disabilities for military Veterans (Department of Veterans Affairs, Veterans Benefits Administration, 2012). For a variety of personal, social, environmental, and situational reasons (that are not well-understood), about 20% of those who experience tinnitus report their tinnitus to adversely affect their daily lives to the degree that clinical intervention would be warranted (Jastreboff & Hazell 1998; Davis & Refaie 2000). Numerous clinical studies have reported positive outcomes from various interventions for tinnitus; however, because there is no consensus on how to measure the outcomes of tinnitus treatment, statistical evidence supporting the effectiveness of these treatments remains inconclusive (Meikle et al. 2008; Kamalski et al. 2010).

The use of hearing aids has long been a mainstay of tinnitus treatment provided by audiologists (Saltzman & Ersner 1947; Surr et al. 1985; Melin et al. 1987). Even for patients who are marginal hearing aid candidates, high-frequency amplification (i.e., primary gain at 3000–4000 Hz) may be readily accepted and beneficial. The majority of audiologists do not possess specialized tinnitus expertise, but they are aware that hearing aids often have beneficial effects for patients with tinnitus.

This approach to tinnitus treatment was previously reported on by Surr et al. (1985), who found the prevalence of tinnitus to be 62% in a group of new hearing aid users. Among these individuals, half obtained either "partial or total" relief through hearing aid use alone. In a follow-up study, Surr et al. (1999) administered the Tinnitus Handicap Inventory (Newman et al. 1996) to new hearing aid users before and 6 weeks after the hearing aid fitting. A statistically significant reduction in mean Tinnitus Handicap Inventory scores was seen at 6 weeks. These and numerous other studies are important in showing that hearing aids can provide tinnitus relief as an independent outcome, even when treatment is for a different purpose (Shekhawat et al. 2013).

It has been estimated that up to 90% of patients with tinnitus may benefit from amplification (Johnson 1998; Schechter et al. 2002). The benefit may be due to reduced stress associated with hearing loss (which often accompanies tinnitus) and/or the result of the amplification from ambient sounds masking the tinnitus or making it less noticeable. There are different philosophies concerning the use of amplification for tinnitus patients and thus no clear agreement as to when a patient would benefit from amplification. Some clinics specializing in the treatment of tinnitus have reported that only 20 to 30% of their patients

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are fitted with amplification (Gold et al. 1996; Jastreboff et al. 1996), whereas Wedel et al. (1998) reported that their clinic dispensed amplification to 60% of the tinnitus patients.

Since 1976, externally generated sound has been used as a clinical technique to provide tinnitus masking (Vernon 1976). This approach employs wearable ear-level devices to provide masking sound to patients, including noise generators ("tinnitus maskers"), hearing aids, and combination instruments (amplification and noise generator combined) (Vernon 1992). Although hearing aids have been reported to provide masking relief for about 12% of tinnitus clinic patients, broadband noise was used for most of these patients (Vernon 1988). The types of noise stimuli currently used in combination devices vary across the industry and include stimuli that are broadband, band-shapeable, amplitude adjustable, amplitude and frequency modulated, and fractal.

Some explanation is necessary regarding the clinical objective of masking noise as treatment for tinnitus. Early reports by the founder of this method (J. Vernon) described the purpose of masking as making the tinnitus inaudible, that is, to achieve "complete masking" (Vernon 1976, 1977). The tinnitus-replacing masking sound obviously had to be more "acceptable" than the tinnitus. With the advent of combination instruments, Vernon noted "masking that is *incomplete* can be nevertheless acceptable" (Vernon 1982) (p. 17). He later noted that masking noise sometimes produced "only a partial reduction in the tinnitus: it is still perceivable but in a suppressed form" (Vernon 1988) (p. 101). Vernon further reported that when masking was suggested for patients, combination instruments were recommended 67% of the time (and tinnitus maskers 21%). Thus, in the 1980s, the preferred "masking" treatment involved the use of combination instruments, and complete masking was not necessary when using those devices (although complete masking was advocated when using tinnitus maskers).

With respect to tinnitus, the term "masking" refers to a particular form of treatment, which has undergone changes in definition as just described. The potential confusion caused by the term "masking" might suggest the need for different terminology, such as "sound-based relief" to refer to the use of sound to provide a sense of relief from tinnitus, regardless of whether the tinnitus is completely or partially masked.

Hearing aids are an important component of treatment with tinnitus masking (Vernon 1988) and tinnitus retraining therapy (Jastreboff & Hazell 1998). For these methods, hearing aids are usually incorporated into a combination instrument, although hearing aids without an added noise feature are also used. The primary purpose of either the combination instruments or the hearing aids is to mitigate the tinnitus, with improved audibility considered a secondary benefit. While the masking method uses sound to achieve "immediate relief," that objective is irrelevant to tinnitus retraining therapy, which uses sound enrichment to promote long-term habituation to tinnitus.

Until the present decade, combination instruments had limited amplification features relative to full-featured hearing aids. That tradeoff is no longer a concern with the introduction of new combination instruments from most of the major hearing aid manufacturers. These combination instruments do not sacrifice hearing aid features, so patients can be fitted with these devices as state-of-the-art hearing aids.

While the market has produced a number of good options for combination hearing aid and tinnitus therapy devices, research has not been conducted to evaluate whether these instruments provide greater benefit to patients than the use of hearing aids alone. The present study was conducted to address this question. More specifically, a small randomized controlled study was completed to compare the use of combination instruments for tinnitus management with and without the use of broadband noise produced from the instruments.

MATERIALS AND METHODS

The study was conducted at the National Center for Rehabilitative Auditory Research (NCRAR) located at the Portland (Oregon) Veterans Affairs Medical Center and was approved by the Portland (Oregon) Veterans Affairs Medical Center Institutional Review Board.

Outcome Measures

Outcome measures were completed by participants at baseline (preintervention) and at 3 months (postintervention). Outcomes for the tinnitus intervention were based on the Tinnitus Functional Index (TFI) (Meikle et al. 2012). The TFI has been validated for scaling the negative impact of tinnitus and for measuring changes in tinnitus impact (*responsiveness*) as a result of an intervention. The TFI includes 25 questions, each with a response scale of 0 to 10 (two items are 0 to 100, which are recoded to 0–10 for scoring). Completing the TFI provides an index score from 0 to 100, with higher numbers reflecting a greater problem with tinnitus. The developers of the TFI determined that a score of at least 25 (out of a total possible 100 points) indicates, on average, a significant problem with tinnitus, with possible need for intervention. In addition, a 13-point reduction in the TFI index score was considered a reasonable criterion for meaningful reduction in outcome scores.

Participants completed the TFI at baseline, that is, before undergoing any testing, being fitted with hearing aids, or receiving counseling. Outcomes were assessed at the final visit. In our previous studies, participants have commonly expressed confusion when completing outcome questionnaires with respect to whether their responses should reflect how they feel while wearing the devices or while *not* wearing the devices. For this reason, at the final visit participants completed the TFI twice to indicate their responses with respect to when they were (1) using their hearing aids ("*with* hearing aids") and (2) not using their hearing aids ("*without* hearing aids"). They were carefully instructed to differentiate between these conditions when answering each question. Consequently, three TFI index scores were obtained for each participant—one at baseline and two following the intervention.

Outcome measures were also obtained to assess benefit from the devices on hearing ability. For this purpose, the Hearing Handicap Inventory for the Elderly (HHIE) was used (Ventry & Weinstein 1982). The HHIE is a 25-item, psychometrically valid instrument containing 12 items that measure the effect of hearing loss on social/situational functioning and 13 items that measure the emotional impact of hearing loss. As for the TFI, each participant completed the HHIE twice at the 3-month visit to indicate their responses with respect to when they were (1) using their hearing aids (*with* hearing aids) and (2) not using their hearing aids (*without* hearing aids).

Weinstein et al. (1986) evaluated the test–retest reliability of the HHIE to determine minimum change in the score that would indicate a change in perceived hearing handicap. They studied two groups of participants—one that completed the HHIE using paper-and-pencil at home (received by mail) and one that responded to the questions interview-style (face-to-face). Test–retest reliability was good for both conditions, but relatively better for interview-style administration of the HHIE. Based on these results, the authors concluded that, for a change score to indicate a true change (95% confidence) in perceived handicap, the difference should be 36 points for paper-and-pencil administration and 19 points when administered interview-style. For the present study, participants completed the HHIE in the presence of an audiologist, who was available to explain any items that seemed unclear. Administration of the HHIE was therefore considered more like the face-to-face condition, and we used the 19-point criterion to indicate significant change.

Recruitment and Screening

Candidates were recruited from two sources: previous research participants at the NCRAR who provided written permission to be contacted for future research projects and advertisements placed in the local newspaper.

All interested candidates initially contacted a member of the research team who performed screening over the telephone to first determine if they met the following criteria: (1) at least 18 years of age; (2) English-speaking; (3) perceived hearing difficulties; (4) no hearing aid experience within the previous 12 months; and (5) no mental, emotional, or health conditions that would prevent participating in the study. If they met these initial criteria, they were screened to determine if they had "clinically significant" tinnitus based on responses to Section A of the Tinnitus and Hearing Survey (Henry et al. 2010a, 2012). Section A includes four statements that address problems related to tinnitus that would not be confused with a hearing problem. To prequalify, a minimum total score of 4 was required for section A; if the score was 4 to 6, then at least one of the items required a score of at least 3. None of the callers had difficulty talking on the telephone, and those who passed the screening were invited to the NCRAR for the Visit 1 evaluation.

Visit 1 Evaluation

During Visit 1, candidates first signed an informed consent form and then completed three questionnaires: TFI, HHIE, and a general tinnitus survey. The general tinnitus survey obtained demographic information and descriptions of various aspects of tinnitus. An index score on the TFI of at least 25 (out of a maximum score of 100) was required for candidates to qualify for study inclusion. The Mini Mental State Exam (MMSE) (Bleecker et al. 1988) was also administered. The MMSE is an 11-item test to screen for cognitive impairment and was used to ensure that participants had sufficient cognitive functioning to participate in the study protocol. Candidates who had a minimum TFI index score of 25 and passed the MMSE then underwent standard audiologic testing.

Before audiologic testing, a clinical case history was conducted to obtain information about current and past hearing and tinnitus issues, any ear-related problems, and current health status. In addition, candidates were asked, "On a scale from 0 to 10, how motivated are you to try hearing aids?" and "On a scale from 0 to 10, how motivated are you to find relief from tinnitus?" In response, their mean levels of motivation were 9.4 to try hearing aids and 9.7 to find relief from tinnitus. Otoscopy, immittance testing, and pure tone and speech audiometry were then conducted. Ear canals and tympanic membranes were visually inspected for abnormalities, such as cerumen blockage or perforation. Immittance audiometry was used to examine middle ear function and to rule out conductive or retrocochlear pathology. Air-conduction and bone-conduction thresholds were measured using the American Speech-Language-Hearing Association-recommended procedure (ASHA 1978). Pure-tone thresholds were used to define degree and type of hearing impairment. Speech reception thresholds were obtained using a recorded disc presentation of spondaic words as a way to verify pure-tone thresholds. Word recognition testing was also conducted using the recorded Central Institute for the Deaf Auditory Test W-22 word list.

To qualify for a hearing aid assessment, candidates needed to have a symmetrical [defined as a difference between left and right ear four-frequency (0.5, 1, 2, 4 kHz) pure-tone averages of 15 dB or less] sensorineural hearing loss within the mild to moderately severe range (four-frequency pure-tone average 25–70 dB HL). Candidates were excluded if they had (1) active external ear disease or conductive component to hearing loss (i.e., abnormal tympanometry and/or air-bone gaps exceeding 10 dB at two consecutive frequencies); (2) diagnosis of retrocochlear pathology, Meniere's Disease, endolymphatic hydrops, or perilymphatic fistula; or (3) presence of medical contraindications to a hearing aid fitting, including sudden onset hearing loss, fluctuating hearing sensitivity, ear pain, and vertigo. Qualified candidates then received a hearing aid assessment to determine if the use of hearing aids was indicated to remediate hearing loss.

Thirty qualifying candidates were enrolled as study participants and scheduled for a hearing aid fitting (Visit 2). Participants were randomized to either the hearing-aid-plus-noise (experimental) or the hearing-aid-only (control) group. Participants were not monetarily reimbursed for their participation; however, they were allowed to keep the combination instruments they used during the study.

Visit 2 Device Fitting

Within 2 weeks of Visit 1, participants returned to be fitted binaurally with a pair of commercially available receiver-in-the-canal combination instruments, that is, hearing aids that include a shapeable sound-generating feature. Twenty eight of the 30 participants were fit using manufacturer-provided ear-domes. Because of their hearing loss configurations, two individuals required custom acrylic earmolds, which were provided by the hearing aid company. Using the NAL-NL2 formula (Keidser et al. 2012), real-ear measures, in addition to patient feedback, were used to verify and adjust the amplification settings. There were no specific deviation points from the NAL-NL2 criteria (at which a person would be ineligible based on preferred fit). The instruments had data-logging capability, that is, the number of hours the devices were used per day was logged for later retrieval by the audiologist.

Tinnitus counseling occurred immediately following the fitting and adjustment of the instruments. Both groups received the same scripted counseling that described how sound can be

used to make tinnitus less of a problem. The counseling followed pp. 31–64 in the flip-chart counseling book *Progressive Tinnitus Management: Counseling Guide* (Henry et al. 2010b).

For the experimental group, the noise generators were activated following the counseling and adjusted according to the participants' individual preferences to achieve "immediate relief from tinnitus." More specifically, the amplitude- and frequency-modulated noise stimulus was fine-tuned across 16 channels to each individual user in the effort to optimize relief from tinnitus. The default settings were based on an algorithm that used data from the audiogram. The participant could select slow, medium, or fast modulation rates or no modulation. While the software allowed participants to manipulate the settings across the 16 channels, this feature was not employed as part of this study.

Visit 3 Follow-Up

One to 3 weeks after the fitting, participants returned for a follow-up appointment. The research audiologist checked the performance of the instruments, retrieved the data-logging information, and provided any necessary instructions to participants to ensure they were using the devices properly. If needed, adjustments were made to the gain settings of the hearing aids. For the participants using noise from the instruments (experimental group), the audiologist assisted in adjusting the noise according to individual preferences.

Visit 4 Final Appointment

Three to 4 months after the fitting appointment, participants returned for their final visit. They completed the TFI and HHIE and answered a series of open-ended questions (Exit Interview) to determine their subjective impressions of using the instruments. The Exit Interview questions asked about general impressions of the hearing aids, if they helped their tinnitus, when they were/were not helpful, and other comments. A final hearing aid check was completed at this time, and data-logging information was retrieved. Once data collection was complete, participants had the option of changing the sound-generator settings on their combination instruments. At this time, individuals in the control group were allowed to activate the sound-generating noise, if they desired to do so.

Data Analysis

Data from this study were provided to the NCRAR data manager who developed and maintained a database. The data manager performed double entry of the data to check for and remediate any errors. All analyses were overseen by the NCRAR biostatistician.

To verify treatment groups were similar across demographic variables, chi square analysis was performed. Independent *t* tests were conducted to compare pure-tone thresholds across groups.

Data were first analyzed for the two groups combined ($N = 30$). Mean TFI and HHIE scores were calculated for the three conditions: baseline, 3 months *with* hearing aids, and 3 months *without* hearing aids. Paired *t* tests were used to compare outcomes between baseline and 3 months *with* hearing aids and between baseline and 3 months *without* hearing aids.

Data were then analyzed for the two groups separately: experimental and control. For each group, mean TFI and HHIE scores were calculated for the three conditions: baseline, 3 months *with* hearing aids, and 3 months *without* hearing aids. A Bonferroni correction was used for multiple comparisons ($p = 0.05/12 = 0.004$). Repeated measures analysis of variance (ANOVA) was conducted to compare outcomes between groups for all interactions.

The Exit Interview provided feedback from participants regarding the hearing aids and their potential benefit. A comprehensive analysis of these qualitative responses is beyond the scope of this article. The responses are, however, summarized in the Results.

RESULTS

In response to the Visit 1 questions about motivation, the mean level of motivation to try hearing aids was 9.3 for the experimental group and 9.4 for the control group. The mean level of motivation to find relief from tinnitus was 9.3 for the experimental group and 9.8 for the control group.

Demographics and Descriptive Data

Table 1 shows the breakdown of demographic characteristics for the overall group and separately for the experimental and control groups. Mean age for the overall group ($N = 30$) was 67 years with 67% male and 90% Caucasian. For the overall group, 67% were retired, 23% were employed full or part time, and 10% were unemployed because of health or other reasons. The majority were married (57%), 76% had completed some college, and 93% reported their health to be good to excellent. Of those who were Veterans (43%), 15% had received a service-connected disability award for hearing loss and tinnitus.

Twenty-two participants reported their tinnitus to be "always" present and 27 had experienced their tinnitus for 3 or more years. Forty percent of the overall group reported a "big" to "very big" problem with their tinnitus, 57% reported a "moderate" problem, and 3% reported a "slight" problem. A chi square analysis revealed no significant differences ($p > 0.05$) between the two groups within each of the characteristics shown in Table 1.

Figure 1 shows the mean hearing thresholds for the experimental and control groups for right (Fig. 1A) and left (Fig. 1B) ears. Independent *t* tests indicated no significant differences ($p > 0.05$) between the two groups in regards to hearing sensitivity.

Data Logging

Data logging information was obtained at Visits 3 and 4. Table 2 shows the average number of hours per day participants had been using their devices at these two time points. At Visit 3, they were using their devices on an average of 8.7 and 8.8 hr/day (right and left ears, respectively). At Visit 4, they had used their devices on an average of 7.0 and 6.9 hr/day (right and left ears, respectively). Differences in device usage between experimental and control groups were not significant at either of the visits ($p > 0.05$).

Outcome Measures

Tinnitus Functional Index • For the overall sample ($N = 30$), the initial TFI mean index score was 58.3. At 3 months, the mean TFI score *with* hearing aids was 22.2 and *without* hear-

TABLE 1. Demographic characteristics of participants

Demographic Characteristic	Overall Group (*N* = 30)	Control (*n* = 15)	Experimental (*n* = 15)
Age	67.2 (SD 9.2)	67.9 (SD 11.0)	66.5 (SD 7.4)
Ethnicity			
Non-Caucasian	10%	13%	7%
Caucasian	90%	87%	93%
Gender			
Male	67%	80%	53%
Female	33%	20%	47%
Employment			
Full-time	13%	20%	7%
Part-time	10%	7%	13%
Retired	67%	60%	73%
Unemployed	10%	13%	7%
Marital status			
Living with spouse	57%	47%	67%
Married, separated	3%	0%	7%
Widowed	20%	27%	13%
Divorced	17%	20%	13%
Never married	3%	6%	0%
Education			
Completed high school	17%	13%	20%
Post high school/vocational	7%	7%	7%
Some college	30%	33%	26%
Completed college	46%	47%	47%
Health status			
Excellent	13%	7%	20%
Very good	33%	20%	47%
Good	47%	60%	33%
Fair	3%	7%	0%
Poor	3%	7%	0%
Veteran			
No	57%	40%	73%
Yes	43%	60%	27%
Tinnitus present			
Some of the time	17%	13%	20%
Most of the time	10%	13%	7%
Always	73%	74%	73%
Tinnitus duration, years			
<1	3%	0%	7%
1–2	7%	7%	7%
3–5	3%	0%	7%
6–10	10%	13%	7%
11–20	27%	27%	26%
>20	40%	46%	33%
Unsure	10%	7%	13%
Tinnitus problem			
Slight problem	3%	0%	7%
Moderate problem	57%	53%	60%
Big problem	33%	33%	33%
Very big problem	7%	14%	0%

ing aids was 44.8. Paired *t* tests showed the mean 3-month reductions on the TFI of 36.1 points (*with* hearing aids) and 13.5 points (*without* hearing aids) as both significant ($p < 0.0001$).

Table 3 displays the means and standard deviations for each of the three conditions (baseline, 3 months *with* hearing aids, and 3 months *without* hearing aids) and effect sizes for improvement from baseline to 3 months. For the control group, the mean baseline TFI index score was 60.5. At 3 months, the mean score was 27.6 (*with* hearing aids) and 44.3 (*without* hearing aids). The mean 3-month reductions on the TFI of 32.9 points (*with* hearing aids) and 16.2 points (*without* hearing aids) were both significant ($p < 0.0001$ and $p = 0.002$, respectively). Effect sizes for the control group were 2.1 (*with* hearing aids) and 1.1 (*without* hearing aids).

For the experimental group, the mean baseline TFI index score was 56.1 (Table 3). Three months following the hearing aid fitting, the mean score was 16.8 (*with* hearing aids) and 45.3 (*without* hearing aids). The mean 3-month reduction on the TFI of 39.3 points (*with* hearing aids) was significant ($p <$

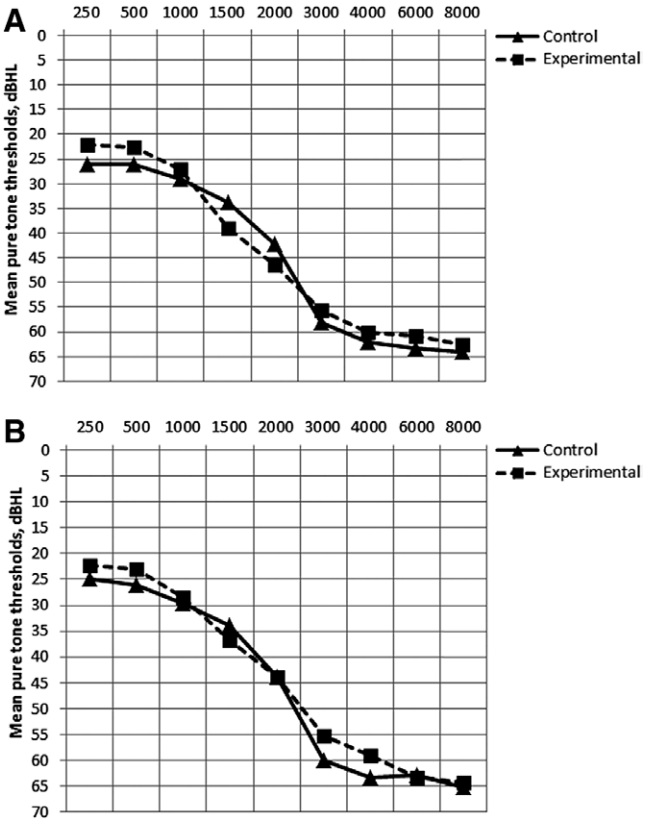

Fig. 1. Mean pure-tone thresholds by experimental and control groups. A, Right ears. B, Left ears.

0.0001) but the 3-month reduction of 10.8 points (*without* hearing aids on) was not significant using the Bonferroni correction ($p = 0.034$). Effect sizes for the experimental group were 2.2 (*with* hearing aids) and 0.6 (*without* hearing aids).

Repeated measures ANOVA revealed a significant main effect between baseline and 3-month mean scores for the TFI *with* hearing aids [$F(1,28) = 66$, $p < 0.0001$] and *without* hearing aids [$F(1,28) = 18.8$, $p < 0.0001$], but no significant interaction between the groups, both *with* and *without* hearing aids. The differences between the two 3-month conditions (*with* hearing aids versus *without* hearing aids) were significant for both the control group (difference = 28.5; $p < 0.0001$) and the experimental group (difference = 16.6; $p < 0.0001$), meaning that, for both groups, answering the TFI questions with respect to when they were wearing hearing aids (*with* hearing aids) resulted in significantly better TFI scores than when they were not wearing hearing aids (*without* hearing aids).

Between-group differences for change in TFI score from baseline to 3-month follow-up are summarized in Table 4, which shows (1) the range of individual changes (negative change reflects improvement in TFI score; positive change reflects worsening of TFI score) and (2) the number (and percentage) of participants showing improvement in TFI scores that would be considered a meaningful reduction (≥13-point reduction) in outcome scores according to the developers of the TFI (Meikle et al. 2012). Table 4 shows that for the *with* hearing aids condition, 13 of 15 (87%) of the control participants and 13 of 15 (87%) of the experimental participants showed at least a 13-point improvement in their TFI scores. For the *without* hearing aids condition, 8 of 15 (53%) of the control participants and 6 of 15 (40%) of the experimental participants had at least a 13-point improvement in their TFI scores.

Individual differences for the TFI are further displayed in Figure 2, which shows Box-and-Whisker plots for each group in the two conditions (Fig. 2A—*with* hearing aids; Fig. 2B—*without* hearing aids). In Figure 2A (*with* hearing aids), the median difference score appears greater for the experimental group. However, application of nonparametric tests, Mann–Whitney *U* and Median tests, revealed no statistical differences between the two groups. Similarly, in Figure 2B (*without* hearing aids), differences that appear between groups did not turn out to be significantly different using the nonparametric tests.

Hearing Handicap Inventory for Elderly • For the overall group of participants, the initial mean HHIE index score was 52.6. At 3 months, the mean HHIE score was 23.6 (*with* hearing aids) and 47.5 (*without* hearing aids). Paired *t* tests showed the mean 3-month reduction on the HHIE of 29 points (*with* hearing aids) as significantly different ($p < 0.0001$). The mean 3-month reduction of 5.1 points (*without* hearing aids) was not significantly different ($p > 0.05$).

In Table 5, the HHIE means and standard deviations for each of the three conditions (baseline, 3 months *with* hearing aids, and 3 months *without* hearing aids) and effect sizes for improvement from baseline to 3 months are shown. For the control group, the mean baseline HHIE index score was 55.3. At 3 months, the mean score was 26.9 (*with* hearing aids) and 47.5 (*without* hearing aids). The mean 3-month reduction on the HHIE of 28.4 points (*with* hearing aids) was significant ($p < 0.0001$) but the mean 3-month reduction of 7.8 points (*without* hearing aids) was not significant using the Bonferroni correction ($p = 0.04$). Effect sizes for the control group were 1.8 (*with* hearing aids) and 0.5 (*without* hearing aids).

For the experimental group, the mean baseline HHIE index score was 49.3 (Table 5). Three months following the hearing aid fitting, the mean score was 20 (*with* hearing aids) and 47.5 (*without* hearing aids). The mean 3-month reduction on the HHIE (*with* hearing aids) of 29.3 points was significant at $p = 0.001$. The mean 3-month reduction on the HHIE (*without* hearing aids) of 1.8 points was not significant after the Bonferroni correction ($p = 0.04$). Effect sizes for the experimental group were 1.8 (*with* hearing aids) and 0.1 (*without* hearing aids).

TABLE 2. Average number of hours per day the ear-level devices were used by participants, based on data-logging from the devices

	Visit 3			Visit 4		
Ear	Control (n = 15)	Experimental (n = 15)	Combined (N = 30)	Control (n = 15)	Experimental (n = 15)	Combined (N = 30)
Right	8.5	9.0	8.7	6.9	7.0	7.0
Left	8.7	8.9	8.8	6.9	6.9	6.9

TABLE 3. Means, SDs, and effect sizes for TFI at baseline and 3-month follow-up for experimental and control groups

	TFI Mean (SD) Index Score			TFI Effect Size	
Group	Baseline	3 mo *With* Hearing Aids	3 mo *Without* Hearing Aids	3 mo *With* Hearing Aids	3 mo *Without* Hearing Aids
Control (*n* = 15)	60.5 (15.3)	27.6 (16.1)*	44.3 (14.6)†	2.1	1.1
Experimental (*n* = 15)	56.1 (16.5)	16.8 (19.8)*	45.3 (18.8)‡	2.2	0.6

These data were retrieved at Visits 3 and 4.
**Significantly different from baseline (p < 0.0001).*
†Significantly different from baseline (p = 0.002).
‡Not significantly different from baseline after Bonferroni correction (p = 0.034).
TFI, Tinnitus Functional Index.

Repeated measures ANOVA revealed a significant main effect between baseline and 3-month mean HHIE scores *with* hearing aids ($F(1,7) = 50$, $p < 0.0001$) but no significant differences in HHIE scores *with* hearing aids between the treatment groups. There was no overall difference from baseline to 3 months or between groups for the HHIE *without* hearing aids. The differences between the two 3-month conditions (*with* hearing aids versus *without* hearing aids) were significant for both the control group (difference = 20.6; $p = 0.001$) and the experimental group (difference = 25.7; $p = 0.004$), meaning that, for both groups, answering the HHIE questions with respect to when they were wearing hearing aids (*with* hearing aids) resulted in significantly better HHIE scores than when they were not wearing hearing aids (*without* hearing aids).

Individual differences for change in HHIE score from baseline to 3-month follow-up are summarized in Table 6, which shows (1) the range of individual changes (negative change reflects improvement in HHIE score; positive change reflects worsening of HHIE score) and (2) the number (and percentage) of participants showing an improvement of ≥19 points in the HHIE score that would be considered significant change (Weinstein et al. 1986). Table 6 shows that for the *with* hearing aids condition, 9 of 15 (60%) of the control participants and 10 of 15 (67%) of the experimental participants showed at least a 19-point improvement in their HHIE scores. For the *without* hearing aids condition, 3 of 15 (20%) of the control participants and 1 of 15 (7%) of the experimental participants had at least a 19-point improvement in their HHIE scores.

Figure 3 displays Box-and-Whisker plots for the HHIE differences for each group in the two conditions (Fig 3A—*with* hearing aids; Fig. 3B—*without* hearing aids). As for the TFI (Fig. 2), nonparametric testing showed no significant differences between the two groups in either condition.

Exit Interview

When asked about general impressions of the hearing aids, responses were mostly positive: of the 41 comments from the control group, 29 (71%) were positive, nine (22%) were negative, and three (7%) were mixed (positive and negative). Of the 33 comments from the experimental group, 25 (76%) were positive, four (12%) were negative, and four (12%) were mixed. When asked if the hearing aids were helpful, 15 responses were obtained from each group. From the control group, seven (47%) said yes, six (40%) said no, and two (13%) had a mixed response. From the experimental group, nine (60%) said yes, five (33%) said no, and one (7%) had a mixed response. When asked *when* the hearing aids were helpful, the control group provided 34 responses and the experimental group provided 33 responses. When asked when the hearing aids were *not* helpful, both the control and the experimental groups gave 14 responses. When asked if there were "other" comments, the control participants provided eight positive and two negative comments, while the experimental participants provided five positive and six negative comments.

DISCUSSION

For this study, both groups (control and experimental) revealed significant improvement based on reductions in mean TFI index scores. These results suggest that the use of hearing aids alone or hearing aids plus the use of sound generators both provide significant benefit with respect to alleviating effects of tinnitus.

Differences in mean TFI scores between the two groups at 3 months were not statistically significant. However, it should be noted that the experimental group (hearing aids plus use of sound generators) showed a mean reduction in the TFI score that was 6.4 points greater than the control group (hearing aids alone) (in the *with* hearing aids condition, see Table 3 and Fig. 2A). This difference approached statistical significance ($p = 0.09$), possibly suggesting that a larger group of participants may have resulted in a significant difference between groups. However, effect sizes (Table 3) indicate that after controlling for variation, the difference between groups was similar. It thus remains unknown whether use of hearing aids plus a sound

TABLE 4. Individual differences in TFI scores between baseline and 3 months

	Control (*n* = 15)		Experimental (*n* = 15)	
3-Month Condition	Range of Change	Number (%) Improved by ≥13 Points	Range of Change	Number (%) Improved by ≥13 Points
With hearing aids	–5 to –83	13 (87%)	+15 to –82	13 (87%)
Without hearing aids	+7 to –51	8 (53%)	+19 to –46	6 (40%)

For Range of Change, negative change reflects improvement in TFI score; positive change reflects worsening of TFI score. Number (%) Improved by ≥13 Points refers to the number of participants showing improvement in TFI scores from baseline to 3 months meeting criteria for "meaningful reduction" (Meikle et al. 2012).
TFI, Tinnitus Functional Index.

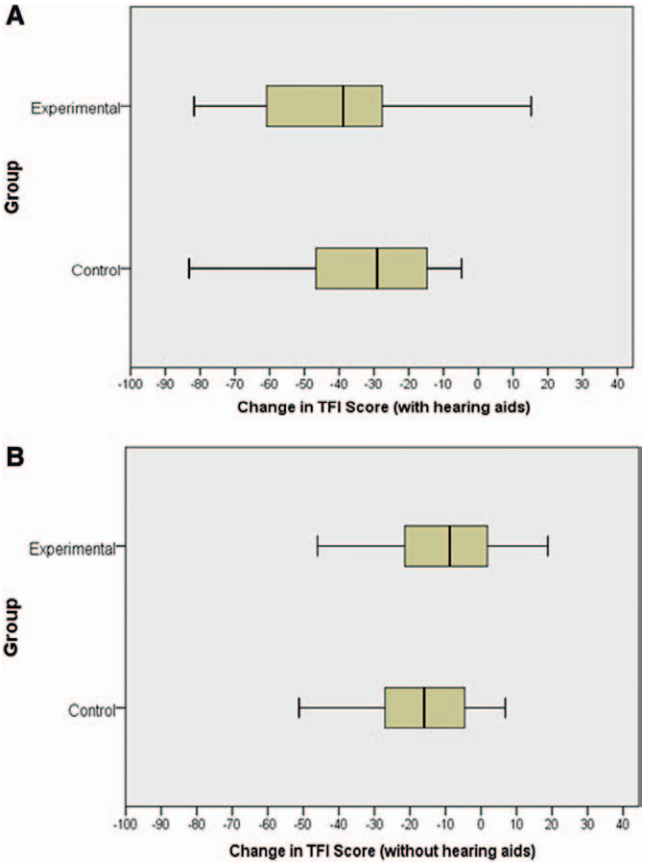

Fig. 2. Individual changes in Tinnitus Functional Index score from baseline to 3 months using Box-and-Whisker plots (Box = median, 25th, and 75th percentiles; Whisker = minimum, maximum values). A, *With* hearing aids. B, *Without* hearing aids. A color version is available online.

generator provides greater benefit than hearing aids alone. A larger study is needed to answer this question more definitively.

The HHIE data suggest that hearing benefit was not compromised by the addition of the noise stimulus as there was no significant difference in the amount of reduction in self-perceived hearing handicap between the participants in the hearing aid alone (control) and the hearing aid plus noise (experimental) groups. Overall, participants' impressions regarding use of the hearing aids were positive based on responses to the Exit Interview questions. The distribution of positive and negative responses was similar between groups.

As reviewed in the Introduction, numerous studies have been conducted to evaluate the use of hearing aids for providing relief from tinnitus. Recently, Shekhawat et al. (2013) conducted a "scoping review" to more fully evaluate the effectiveness of hearing aids in tinnitus management. These authors concluded, "Although the quality of evidence for hearing aids' effect on tinnitus is not strong, the weight of evidence (17 research studies for, 1 against) suggests merit in using hearing aids for tinnitus management" (p. 747). They also noted the overall low quality of these studies and the need for "randomized control trials" for this purpose.

To the authors' knowledge, the present study is the first randomized controlled trial to evaluate the relative efficacies of hearing aids versus combination instruments for tinnitus management. All variables for both groups were the same except for the use of broadband noise in the experimental group. That is, all participants (1) had to meet the same inclusion criteria; (2) expressed a high level of motivation to try the devices; (3) had an equal chance of being placed in the experimental group or the control group; (4) received the same make and model of combination instruments using the same hearing aid fitting procedures; (5) received the same counseling to address reactions to tinnitus; (6) attended appointments on the same schedule; and (7) completed the same outcome instruments on the same schedule. For the experimental group only, the internal noise generator from the hearing aids was activated and adjusted to the point that participants indicated "maximum relief" from tinnitus. As part of the consenting process, all participants were made aware that they would be randomized into one of two groups and that they may or may not utilize the noise generator from their hearing aids. Some (but not all) of the control participants were cognizant of this fact during the fitting process. While the audiologist did not remind them of it, she also did not deny anything if they asked questions.

Data-logging information revealed no significant difference in daily hours using the devices between experimental and control groups. Both groups revealed a reduction in device use between Visits 3 and 4. At Visit 3 (approximately 2 weeks after fitting), participants used their devices on average 8.7 and 8.8 hr (right and left ears, respectively) per day. At Visit 4 (3–4 months after fitting), device use averaged 7.0 and 6.9 hr (right and left ears, respectively) per day. This average reduction in usage amounted to about 20% over a 3-month period, which would not be considered unusual based on our collective clinical experience with new hearing aid users. The literature addressing this issue is, however, equivocal. Only one study to date has reported data-logging information from both hearing aids in individuals receiving a binaural fitting (Laplante-Lévesque et al. 2014). In that study, participants averaged 10.5 hr of daily hearing aid use over a 14-day period. This high level of use was explained by the authors as partially due to this

TABLE 5. Means, SDs, and effect sizes for HHIE at baseline and 3-month follow-up for experimental and control groups

	HHIE Mean (SD) Index Score			HHIE Effect Size	
Group	Baseline	3 mo *With* Hearing Aids	3 mo *Without* Hearing Aids	3 mo *With* Hearing Aids	3 mo *Without* Hearing Aids
Control (n = 15)	55.3 (13.9)	26.9 (17.9)*	47.5 (19.0)†	1.8	0.5
Experimental (n = 15)	49.3 (13.5)	20.0 (18.7)‡	47.5 (18.0)§	1.8	0.1

*Significantly different from baseline ($p < 0.0001$).
†Not significantly different from baseline ($p = 0.62$).
‡Significantly different from baseline ($p = 0.001$).
§Not significantly different from baseline after Bonferroni correction ($p = 0.04$).
HHIE, Hearing Handicap Inventory for the Elderly.

TABLE 6. Individual differences in HHIE scores between baseline and 3 months

	Control (n = 15)		Experimental (n = 15)	
3-Month Condition	Range of Change	Number (%) Improved by ≥19 Points	Range of Change	Number (%) Improved by ≥19 Points
With hearing aids	–2 to –62	9 (60%)	+30 to –80	10 (67%)
Without hearing aids	+20 to –30	3 (20%)	+28 to –24	1 (7%)

For Range of Change, negative change reflects improvement in HHIE score; positive change reflects worsening of HHIE score. Number (%) Improved by ≥19 Points refers to the number of participants showing improvement in HHIE scores from baseline to 3 months meeting criteria for "true change in perceived handicap" (Weinstein et al. 1986).
HHIE, Hearing Handicap Inventory for the Elderly.

being a research study that included only participants who had no impediments to hearing aid use. Follow-up data were not reported. In another study, Humes et al. (2002) used self-report measures of hearing aid usage in elderly participants. These authors found that many participants decreased their usage, especially during the first 6 months, in spite of their being instructed at each visit to increase usage. Mulrow et al. (1992) reported gradual reduction in hearing aid use at 4, 8, and 12 months after fitting. Finally, in an unpublished study, Bock and Abrams (2013, Reference Note 1) reported that hearing aid use dropped about 15% for a control group over about a 3-month period. Combined, these studies suggest that hearing aid usage decreases during the first few months for some new hearing aid users, although the question certainly warrants further study

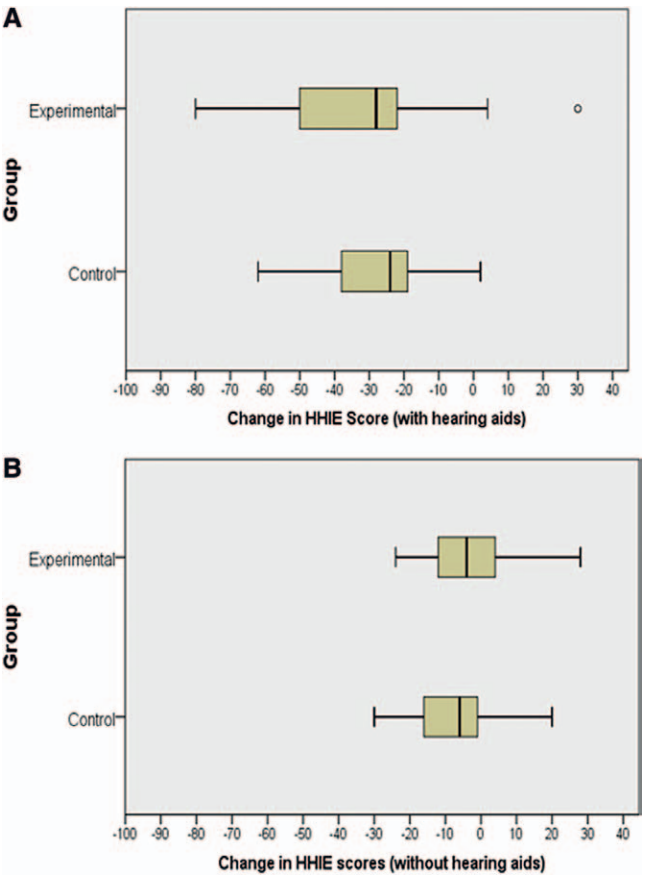

Fig. 3. Individual changes in Hearing Handicap Inventory for the Elderly score from baseline to 3 months using Box-and-Whisker plots (Box = median, 25th, and 75th percentiles; Whisker = minimum, maximum values). A, *With* hearing aids. B, *Without* hearing aids. A color version is available online.

to reach more definitive conclusions, particularly among individuals wearing devices for tinnitus management purposes.

The evaluation of ear-level devices for tinnitus management presents a problem that is somewhat unique to this population. Patients with chronic tinnitus experience their tinnitus continually, while the devices are worn only during the day. This would be different than, for example, a patient with chronic pain who takes medications to relieve the pain throughout the day and night. The situation for the tinnitus patient might be more analogous to the pain patient who uses a transcutaneous electrical nerve stimulation unit for only certain periods to achieve pain relief. With hearing aids, however, the situation is even more complex—hearing aids are used to improve hearing ability, with the *secondary* benefit of providing relief from tinnitus. When the hearing aids are removed, presumably because they are not needed for hearing purposes, the tinnitus is still experienced (and possibly more prominently). It would seem likely that patients with bothersome tinnitus would wear their hearing aids more than if they did not experience bothersome tinnitus. However, patients almost universally remove their hearing aids before going to bed, and it is often reported that "trouble sleeping" is the most common complaint of people with bothersome tinnitus (Tyler & Baker 1983; Meikle & Taylor-Walsh 1984; Jakes et al. 1985; Erlandsson 2000).

Because of these concerns, it was determined for this study to evaluate outcomes in two conditions: while wearing the hearing aids (*with* hearing aids) and while not wearing the hearing aids (*without* hearing aids). It might be noted that J. Vernon made the recommendation many years ago that ear-level devices should be evaluated for their efficacy in tinnitus management with respect to their efficacy *while being worn* (personal communication). The present study achieved that objective as well as also evaluating efficacy while the devices were *not being worn*. Thus, two different outcomes were achieved for all participants. The differences between these two conditions were statistically significant for both groups (Table 3). Significant differences were also observed between mean index scores for the HHIE *with* hearing aids versus *without* hearing aids (Table 5). Thus, results from this study indicate that the use of hearing aids or combination instruments has greater effectiveness for both tinnitus management and reducing hearing handicap when the devices are being worn versus not being worn. This might be an expected result; however, we are not aware of any previous study that has obtained outcome data for each of these conditions separately.

Limitations of This Study

This was a small-scale study designed to obtain initial data that would lead to a larger, more comprehensive trial. Limitations of the study include (1) as already mentioned, a larger *N* might

have resulted in detection of a significant difference in outcomes between groups, although the high variability would suggest that a much larger *N* might be needed; (2) a waitlist control group was not included, which would have been desirable to compare outcomes to a no-treatment group; it should be noted, however, that we previously completed a tinnitus-intervention study with a 1-year no-treatment group of 91 participants, which showed that, at 1, 6, and 12 months, the no-treatment group did not change with respect to the severity of their tinnitus (Henry et al. 2007); this group could be considered an "historical control group," although for the present study a no-treatment control group was not included because this was a preliminary study with very limited resources; (3) The study did not screen for hyperacusis, that is, reduced tolerance to sound that is often reported by patients with tinnitus; although this is not thought to have affected the study, future studies should ensure that participants do not have a significant hyperacusis problem; and (4) the sound stimuli available to participants for providing relief from tinnitus were limited to the shapeable noise that was delivered from the instruments. With respect to this last point, devices from different manufacturers offer different sound-therapy options, including fractal tones and streamed sounds from separate wearable devices. While it is not feasible to compare all sounds between all devices, future studies should evaluate as many different types of sounds as possible to look for trends in patient preferences.

CONCLUSIONS

This study was conducted to evaluate the use of combination instruments relative to hearing aids for tinnitus management. Results revealed that both devices provided significant benefit, although differences between groups were not significant. Indeed, 26 of the 30 participants (86.7%) reported meaningful reduction in their tinnitus. These results are consistent with the preponderance of studies that have investigated the use of hearing aids for tinnitus management (Shekhawat et al. 2013). What remains unanswered is the degree of benefit provided by noise generators that are combined with hearing aids. It is possible that the noise stimulus has some beneficial effects that were not captured by the measures used in this study. It should be recalled that, for the purposes of this study, the noise stimulus parameters were based on each participant's audiogram as determined by the manufacturer's algorithm. It is possible that participants may have experienced additional perceived benefit if they could adjust the parameters themselves. A larger randomized controlled trial is needed to more definitely address these questions.

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The authors declare no other conflict of interest.

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