

Comparison of Personal Sound Amplification Products to Professionally-Fitted Hearing Aids

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ABSTRACT

Objectives: To our knowledge this study, conducted in 2007, was the first of its kind. The purpose was to compare a self-fitted personal sound amplification product (PSAP) with professionally-fitted hearing aids in terms of real-ear aided gain, audibility, and speech understanding in background noise. A second objective was to quantify subjects' reactions to the PSAP used in this study.

Design: The study sample was comprised of thirty-two adults self-referred for a hearing evaluation. All subjects were first-time hearing aid users. Subjects were provided with 1 or 2 PSAP devices based on the examining audiologist's decision to provide unilateral or bilateral hearing aids. Each subject received a routine diagnostic hearing evaluation using standard clinical protocols. Aided gain, audibility and speech recognition in noise were measured with the PSAP device and the hearing aids. Subjects completed a questionnaire regarding their use of, and satisfaction with, the PSAP.

Results: Average aided gain was not significantly different between the PSAP and the prescribed hearing aids. While significant differences between the 2 device types were noted at specific frequencies, the average audibility at 50 dB HL in the sound field was similar (70% for the prescribed aid, 68% for the PSAP, and 57% unaided). Speech recognition in background noise (QuickSIN) tested at 70 dB HL input was good with both devices: an average of 2.9 dB SNR for the hearing aids and 3.8 dB SNR for the PSAP. (Normal-hearing subjects typically require 2 dB SNR.) Slightly more than half of the subjects reported overall satisfaction with the PSAP and 34% reported they would be "very likely" to continue wearing the PSAP if they had not received hearing aids. The remaining subjects reported issues with fit and comfort with

extended use, and dissatisfaction with the PSAP cosmetics and occlusion effect in some cases. On average, the subjects reported using the PSAP between 4 and 8 hours throughout the 3-6 week trial.

Conclusions: The PSAP provided almost the same performance as the hearing aids on measures of aided gain and intelligibility in noise. A post-facto analysis indicates that the PSAP device used in this study meets the new ANSI/CTA 2051 Standard: *Personal Sound Amplification Performance Criteria*.

Key Words: hearing aids; PSAP; sound amplifier; aided gain; audibility; SNR; comfort

Abbreviations: AASC = Army Audiology and Speech Center; SNR = signal-to-noise ratio; QSA= Quiet Sound Amplifier; QSIN = Quick Speech-in-Noise Test; PSAP = Personal Sound Amplification Product; PI = Principal Investigator; HAE = Hearing Aid Evaluation; IRB = Institutional Review Board; NU-6 = Northwestern University List 6; REAG = real-ear aided gain; RIC = Receiver in the canal. PCAST = President's Council of Advisors on Science and Technology; NASEM = National Academies of Science, Engineering and Medicine; CTA = Consumer Technology Association; TILL = treble increases at low levels.

INTRODUCTION

A fundamental assumption in the professional fitting of hearing aids is that the gain-frequency response of the instrument needs to be customized to the person's hearing loss. Various prescriptive formulae are used to derive amplification targets based on audiometric measures specific to the person (Byrne & Dillon 1986; Killion 1994; Cox 1995; Seewald et al. 1996), and real-ear measures are performed to determine how closely these targets have been achieved (Swan & Gatehouse 1995; Aazh & Moore 2007; Mueller et al. 1992.; Polonenko et al. 2010).

Despite the tacit assumption that a close approximation to prescriptive gain targets is important to hearing aid benefit and success, some evidence suggests that such precision may not be essential. Several investigators (Humes 1986; Sullivan et al. 1988; Humes & Hackett 1990) have observed that insignificant differences in speech recognition are obtained among different prescriptive formulae. In a study comparing custom versus fixed-format hearing aids, Walden et al. (2002) questioned the necessity of precise matching of hearing aid output to target prescriptions, noting that, "... as long as comparable spectral regions are made sufficiently audible and uncomfortable loudness is avoided, there may be a relatively broad range of frequency-gain responses that will suffice." Most dramatic was Dirks' (1982) finding with ski-slope loss subjects: A uniform frequency response and rising frequency response gave nearly identical scores for speech in noise for speech levels from 80 dB to 95 dB SPL.

The concept that precise fitting of the gain/frequency response to individual hearing losses may not be necessary for many persons has its historical roots in the Harvard Report (Davis et al. 1947), which concluded that a flat or a 6-dB/octave rising frequency response was adequate for most hearing losses. Simply increasing the volume to a comfortable listening range is adequate for good intelligibility for a large number of persons with impaired hearing; therefore, it can be speculated that a well-designed PSAP device can provide benefit for those who have so far declined to seek professional intervention.

The 2015 report of the President's Council of Advisors on Science and Technology (PCAST) and the 2016 recommendations from the National Academies of Science Engineering and Medicine (NASEM) urged: a) increasing opportunities for consumer choice; b) opening up the market for innovative hearing technologies; and c) implementing innovative models of hearing health care, all for the purpose of improving access, quality, and affordability of hearing care.

Both PCAST and NASEM recommended the implementation of an over-the-counter device category for wearable hearing devices. In December 2016, the Food and Drug Administration (FDA) issued a guidance document stating that, effective immediately, neither medical evaluation nor a signed waiver is required for persons 18 and over prior to purchasing a hearing aid. In the same guidance, FDA announced its commitment to consider creating a category of over-the-counter (OTC) hearing aids. That announcement followed FDA's 2009 guidance in which it established a category of personal sound amplifier products (PSAPs) but restricted their use to persons with normal hearing.

MATERIALS AND METHODS

Subjects

Thirty-two first-time hearing aid users participated in the study. Subjects were 39-84 years of age ($M = 63.1$, $SD = 13.0$) and included 29 males and 3 females. All were self-referred.

Initial Hearing Evaluation

Each subject received a routine diagnostic hearing evaluation, using standard clinical protocols administered by one of several licensed audiologists prior to enrollment in the study. Pure-tone air- and bone- conduction testing and standard immittance measures were performed. All subjects had sensorineural hearing loss, with the exception of 1 subject who had a conductive hearing loss in 1 ear. Supra-threshold word-recognition (NU-6) testing in quiet was evaluated in all but 2 of the subjects. All audiometric testing was conducted in sound-attenuating test suites using standard audiometric equipment: GSI61 audiometer with EARtone 3A insert earphones or Telephonics TDH-50 supra-earphones and a RadioEar B71 bone conduction transducer. Based on the results of the initial hearing evaluation, appropriate custom-fit or mini/standard BTE hearing aids were ordered for the subject by the examining audiologist. The hearing aids were digital, multi-band/channel/memory, wide dynamic range compression circuits representing a variety of hearing aid manufacturers. The style of hearing aid was based on the diagnostic test results and each subject's style preference. The preponderance of miniBTE/RIC fittings in this study (see Figure 3) reflected general practice patterns for all hearing aids prescribed in the clinic.

Following the initial hearing evaluation, subjects were invited to participate in the study by the Principal Investigator (PI). Subjects were provided with a volunteer agreement describing the study and questions were answered by the PI prior to enrollment. Non-active-duty subjects were paid for their participation in accordance with local IRB guidelines.

Experimental PSAP Device

The PSAP device shown in Figure 1 was supplied with four eartips: 1 standard triple-flange, 1 large triple-flange, 1 single flange eartip and 1 foam eartip. Subjects chose an eartip and inserted it on the end of the PSAP. The depth of insertion into the canal varied across subjects and was typically based on a balance between retention and comfort. Note: The PSAP used in this study had the same microphone, receiver, and circuit used in the "BEAN[®]" device (Etymotic 2013),

whose 2 cc coupler response curves are essentially identical to those shown in Fig. 2.

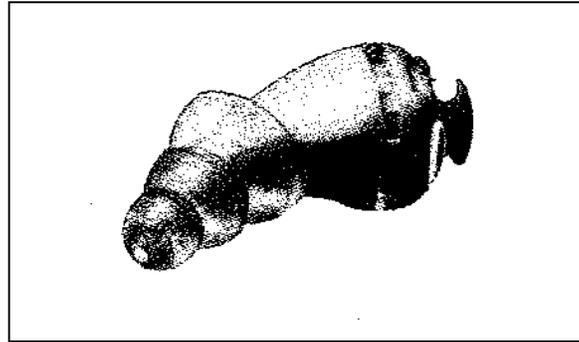


Figure 1. Photograph of PSAP device used in the study.

The PSAP had 2 user-selectable gain settings. Figure 2A shows the 2 cc coupler gain response for 3 input levels for the low-gain (left panel) and the high-gain (right panel) settings.

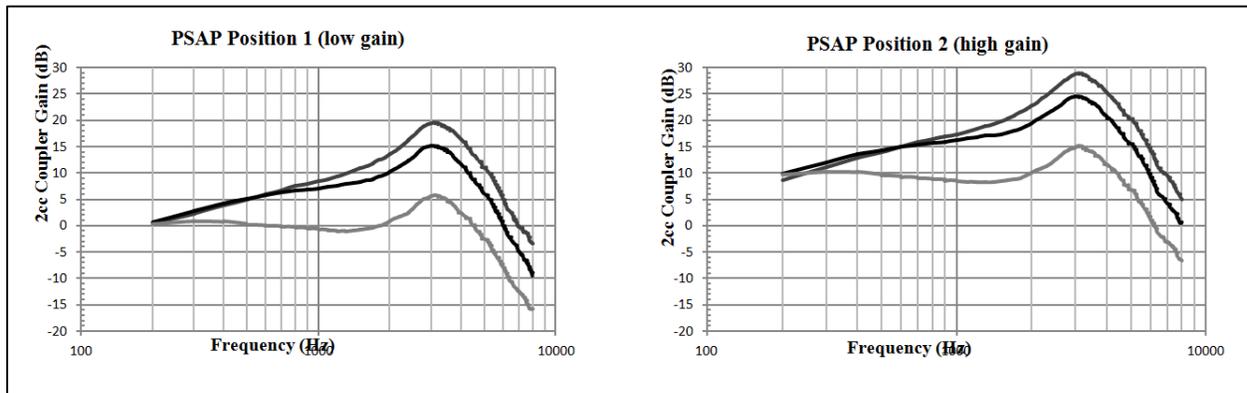


Figure 2A. PSAP 2 cc coupler gain response for inputs of 50 dB SPL (highest curve), 65 dB SPL (middle), and 80 dB SPL (lowest curve) for position 1 (LO gain) and position 2 (HI gain) conditions.

The estimated insertion gain for 2 input levels is shown in Figure 2B.

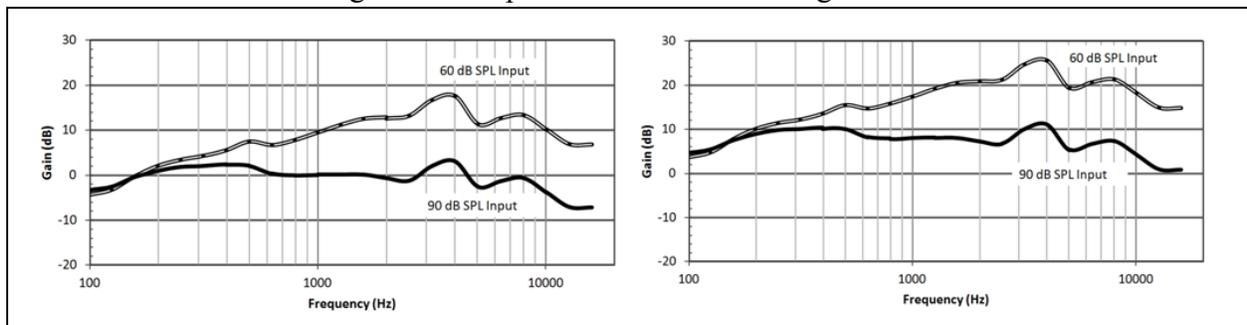


Figure 2B. Estimated PSAP insertion gain (KEMAR) for 60 and 90 dB SPL for position 1 (LO gain) and position 2 (HI gain) conditions.

PSAP Trial Period

Subjects were given 1 or 2 PSAP devices based on the determination of unilateral or bilateral amplification. The PSAP device used in this study (See Figure 1) was a lightweight (2.2 gm) instrument with a 16-kHz bandwidth, single-channel wide-dynamic-range-compression circuitry and level-dependent TILL frequency response. The PSAP devices were used for a 3-6 week period between the initial hearing evaluation and the next appointment when subjects received professionally prescribed hearing aids. Subjects were asked to use the PSAP for a minimum of 4 hours per day and longer if they so desired.

As much as possible, an attempt was made to simulate the circumstances that a consumer might encounter if s/he purchased a PSAP in a retail store or via the Internet. User instructions were provided in written form, and subjects were instructed to review the materials on their own. No verbal instructions were provided. Subjects were referred to the printed instructions for answers to any specific questions.

Hearing Aid Fitting and Evaluation

Following the 3-6 week trial use with the PSAP, subjects returned to the clinic for the follow-up fitting/evaluation of their prescribed hearing aids. Standard fitting procedures were employed, including verification of the fitting using real-ear methods (Audioscan Verifit version 3.4; ANSI S3.22, 2003) and any other measures deemed appropriate by the audiologist. The prescriptive method used during fitting and verification was at the discretion of the audiologist. Of the 32 subjects, 27 were fitted bilaterally and 5 were fitted unilaterally, resulting in a total of 59 hearing aid fittings. The hearing aid fittings consisted of: 38 mini/micro-BTE instruments, 4 RIC (receiver-in-the-canal) instruments, 2 standard BTE (behind-the-ear) instruments and 15 custom (7 completely-in-the-canal and 8 canal) devices. Figure 3 shows the distribution of hearing aid styles.

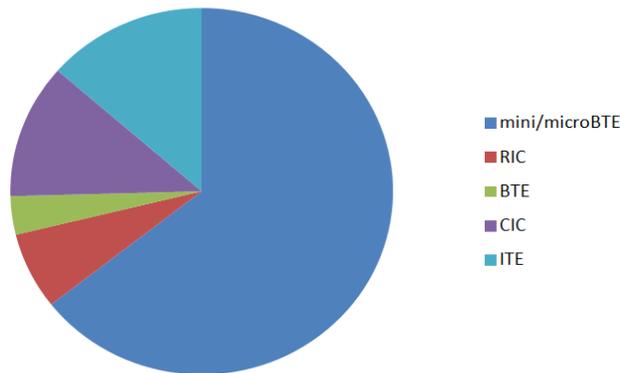


Figure 3. Hearing aid style distribution for bilateral and unilateral prescriptions.

Outcome Measures

Once the hearing aid fitting/evaluation was completed by the audiologist, subjects were referred to the PI for testing with the PSAP and with the professionally-fitted hearing aids. Real-ear aided gain, audibility, and speech recognition in noise were measured with the PSAP devices

and with the hearing aids. Subjects also completed a questionnaire regarding their use of, and satisfaction with, the PSAP devices.

Aided Gain. Real-ear aided gain (REAG) for a 65 dB SPL input signal (pink noise) was measured for both types of device. Subjects were positioned within 20 inches of the monitor/loudspeakers of the Verifit and the real-ear measures were completed on each ear independently. The prescribed hearing aids were set to the ‘automatic’ or baseline algorithm and all basic and advanced hearing aid features were maintained for the real-ear measures. For the PSAP, the gain setting (low or high) was selected based on the gain setting used most frequently during the 3-6 week trial.

Nineteen of the 32 subjects reported wearing the PSAP in the mild-gain position all of the time. Only 2 subjects reported selecting the high-gain position most of the time. Ten additional subjects reported using both gain settings at least part of the time, but tended to rely more on the mild-gain setting. For those subjects, the mild-gain setting was used to obtain REAG measures. One subject wore the PSAP in the high-gain position on the right ear and in the low-gain position in the left ear. REAG measures were obtained accordingly.

Although the majority of subjects chose to use the PSAP in the low-gain setting, for some, this decision was motivated more by the presence of feedback in the high-gain setting than an actual preference for the lower gain.

Audibility. Unaided audibility was estimated using the Mueller and Killion (1990) count-the-dots articulation index (AI) method. That is, the (unaided) audiometric thresholds were applied to the AI template and the audible ‘dots’ were counted to quantify residual audibility. For the aided condition, the measured real-ear insertion gain value at each test frequency was subtracted from the unaided thresholds and the AI then calculated from the count-the-dots template.

Speech Recognition in Background Noise. Following real-ear measures, the QuickSIN Test (2001) was administered at 70 dB HL in sound field with speech and noise presented through the same loudspeaker. Subjects were seated in a chair positioned at 0-degree azimuth and 1 meter from the center of a wall-mounted loudspeaker. The order of testing of the PSAP and prescribed hearing aids was randomized across the subjects. For those subjects who were fitted unilaterally, the unaided ear was unoccluded for testing. Hence, the aided QuickSIN score for these subjects was based on the aided ear in combination with the unoccluded unaided ear.

Questionnaire. Each subject completed a written questionnaire designed to assess their evaluation of the PSAP in everyday listening (see Appendix). The questionnaire included ratings of the clarity of the PSAP user instructions, ease of use of the device, comfort, occlusion, feedback, improved hearing in various everyday listening situations, and overall benefit and satisfaction.

RESULTS

The mean audiogram for the 32 subjects is shown in Figure 4. Only the 59 ears that were fitted with hearing devices are depicted; that is, the non-aided ear of the 5 subjects fitted unilaterally was not included. As evident in Figure 4, a rather broad range of individual hearing losses was represented in this group, especially in the higher frequencies.

NU-6 word-recognition in quiet averaged 91.1% (SD: 13.9 range: 44-100 in the right ear and 91.8% (SD: 12.6, range: 52-100) in the left ear, presented supra threshold. The average unaided QuickSIN score was 4.03 dB SNR (SD: 2.9 dB, range: 0.5-10.5 dB) across the 32 subjects.

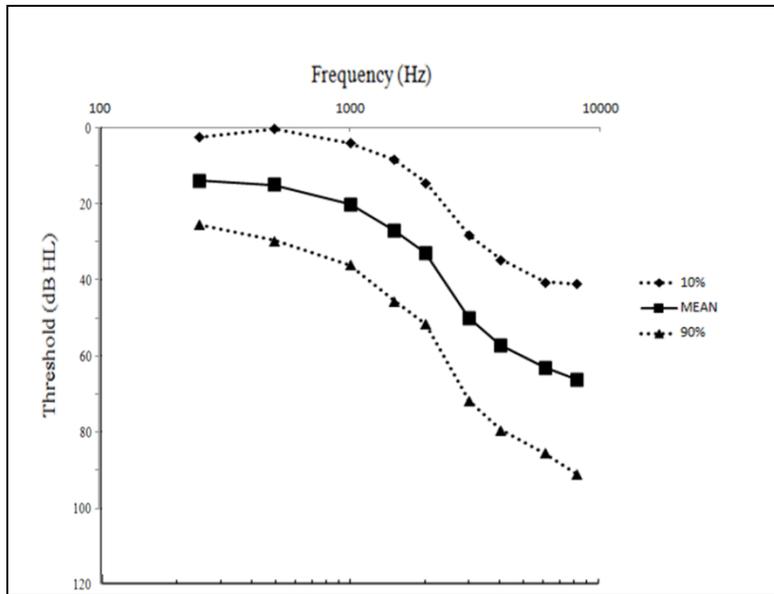


Figure 4. Mean audiogram for the 32 subjects (29 right ears; 30 left ears). The 10- and 90-percentile curves were estimated from 1.28 times the standard deviations at each frequency.

Aided Gain

Figure 5 shows the average real-ear aided gain (65 dB SPL input) for the PSAP and the prescribed hearing aids. Aided gain data for the PSAP and hearing aids were subjected to a 2-factor repeated measures analysis of variance. The main effect for the 2 device types (PSAP, HA) was not significant ($F = .027$; $p = 0.61$), indicating that neither device type, on average, provided greater aided gain than the other. The 2-factor interaction was significant ($F = 12.97$; $p < 0.001$) indicating that significant differences in aided gain existed between the PSAP and hearing aids depending upon frequency. Separate t-tests were performed between the 2 device types at each of the 7 test frequencies. Significantly greater aided gain ($p < 0.001$) was provided by the PSAP at 500 Hz and 1000 Hz, and by the hearing aids at 3000 Hz ($p < 0.001$), 4000 Hz ($p = 0.01$), and 6000 Hz ($p = 0.01$). Although average aided gain for the PSAP and hearing aids was relatively similar (Figure 5), there were substantial individual differences across the 59 ears.

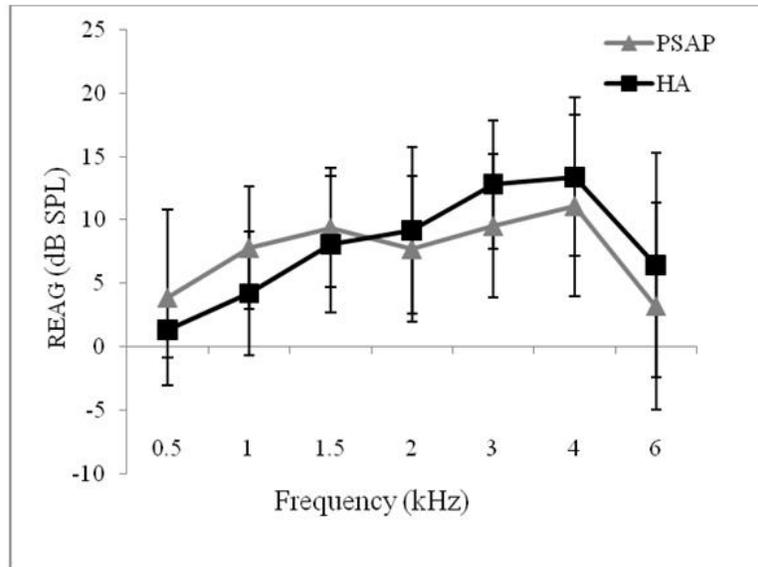


Figure 5. REAG group average for PSAP and Hearing Aid (HA) by test frequency.

Audibility Index (AI)

Table 1 shows the mean count-the-dots AI for the unaided condition and for each device type. These data were also subjected to a single-factor, repeated measures analysis of variance. Pairwise comparisons revealed that aided audibility was significantly better than unaided audibility, both for the PSAP ($p < 0.001$) and for the prescribed hearing aids ($p < 0.001$).

The 2.2 point difference in AI between the hearing aids and the PSAP was statistically significant ($p < 0.05$), but from a practical standpoint this AI difference typically corresponds to a difference of less than 1 word on a 50-word NU-6 list (estimated from Figure 3 in Killion & Mueller, 2010).

Table 1. Mean and range for the unaided and aided AI for the 59 ears. The corresponding standard deviations are shown in parentheses beside each mean value.

	Unaided	PSAP	HA
Audibility Index (AI)	55.6 (18.7)	67.9 (18.1)	70.1 (16.4)
Range	12-87	28-93	26-93

Individual variability in audibility provided by the 2 device types is illustrated in Figure 6. Shown is a scatter plot of the PSAP AI versus the hearing aid AI for each of the 59 ears. Although a wide range of audibility estimates was observed across the 59 ears, generally similar audibility ($r = 0.94$) was provided by the two devices.

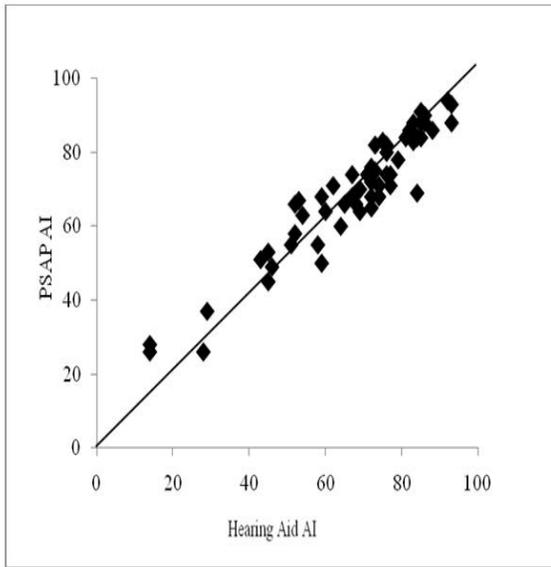


Figure 6. Scatter plot of Audibility Index (AI) for PSAP and Hearing Aid.

Speech Recognition in Noise

Results of QuickSIN testing, conducted at the recommended 70 dB HL (85 dB SPL, typical of a social gathering) are summarized in Table 2. Shown are the mean QuickSIN scores across the 32 subjects for the unaided condition and for each device type.

Table 2. Mean and range for the unaided and aided QuickSIN for the 32 subjects. The corresponding standard deviations are shown in parentheses beside each mean value.

	Unaided	PSAP	HA
QuickSIN (SNR)	4.03 (2.9)	3.75 (2.4)	2.92 (3.0)
Range (dB)	0.5-10.5	-1.5-9.5	-4.5-10.5

A single-factor, repeated measures analysis of variance revealed a significant difference among the 3 listening conditions ($F = 4.42$; $p = 0.016$). Pairwise comparisons revealed that, on average, the prescribed hearing aids provided significantly better speech recognition in noise than unaided ($p = 0.05$) and the PSAP ($p = 0.05$). From a practical standpoint, the 0.8 dB better SNR average for the hearing aids corresponds to slightly less than 1 word out of the 30 key words in sentences in the QuickSIN test. (The QuickSIN scoring corresponds to 1 dB difference in SNR for each word repeated correctly.)

Individual QuickSIN data for the 2 device types are shown in Figure 7. As with the audibility estimates, a range of QuickSIN scores was observed across the 32 subjects and the SNR between the PSAP and the hearing aids was correlated ($r = 0.78$). The diagonal line is drawn to represent the 0.8 dB better hearing aid scores.

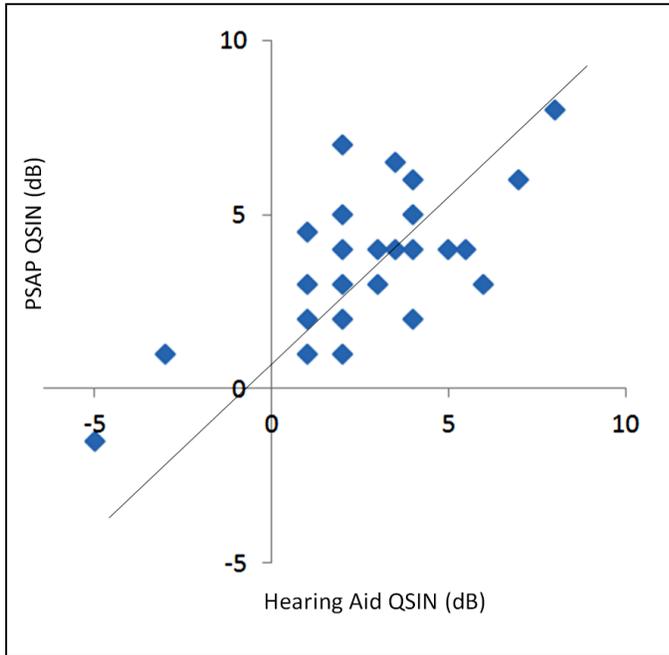


Figure 7. Scatter plot of QuickSIN scores for PSAP and HA for recommended 70 dB HL presentation level. The diagonal line represents the average 0.8 dB better scores for the hearing aid.

Questionnaire Results

A common concern regarding the use of a PSAP for the self-treatment of hearing loss is that consumers will not use the amplification device appropriately without professional assistance. The questionnaire used in this study was designed to evaluate the extent of this potential problem. Results are summarized in Table 3.

Table 3 shows results for questions 1-8 and 13. Questions 9, 14, and 15 are addressed in the text. Note: For questions with a 5 point range, 3 is neutral. With a 4-point range, 2.5 is neutral. With a 3 point range, 2 is neutral.

Table 3. PSAP questionnaire results (Questions 9, 14, and 15 are addressed in the text).

Question	Mean Rating (SD)	Mode	Range
<i>Instructions (Scale: 1 = Very clear; 2 = fairly clear; 3 = unclear)</i>			
1.a.) Selecting the eartip size	1.5(.6)	2	1 - 3
1.b.) Attaching the eartip	1.3(.5)	1	1 - 3
1.c.) Inserting the battery	1.0(.2)	1	1 - 3
1.d.) Inserting the QSA	1.8(.8)	2	1 - 3
1.e.) Switching the volume	1.3(.6)	1	1 - 3
<i>Hours of Use (Scale: 1 = less than 1 hour; 5 = more than 12 hours)</i>			
<i>Note that the rating numbers are not hours. On average, subjects reported using the PSAP between 4 and 8 hours throughout the 3-6 week trial</i>			
2) Hours/day (initial use)	2.3(.9)	2	1 - 5
3) Hours/day (end of trial)	2.3(1.0)	2	1 - 5
<i>Comfort (Scale: 1 = very comfortable; 4 = immediately uncomfortable)</i>			
4) Comfort (initial use)	2.5(1.0)	1	1 - 4
5) Comfort (end of trial)	2.3(1.0)	2	1 - 4
<i>Retention/Feedback/Occlusion (Scale: 1 = never had the problem; 5 = constantly had this problem)</i>			
6) Loose in the canal	2.1(1.2)	1	1 - 5
7) Squealing	3.1(1.0)	3	1 - 5
8) Stopped up feeling	3.4(1.3)	3	1 - 5
<i>Hearing Ability (Scale: 1 = much better; 4 = worse)</i>			
10.a) One-on-One (quiet)	1.5(.6)	1	1 - 4
10.b.) One-on-One (noise)	1.8(.9)	1	1 - 4
10.c.) Groups	1.9(.9)	1	1 - 4
10.d.) In a car	2.2(1.1)	1	1 - 4
10.e.) Television/Radio	1.5(.7)	1	1 - 4
10.f.) Environmental	1.5(.8)	1	1 - 4
<i>Appearance/Overall Rating (Scale: 1 – very satisfied; 5 = very dissatisfied)</i>			
12) Appearance	3.2(1.3)	3	1 - 5
13) Overall	2.8(1.3)	2	1 - 5

The first question concerned the ability of a consumer to assemble and insert the PSAP in the ear based on the user instructions. For most subjects, selecting the eartip size, attaching it to the device, inserting the battery, inserting the device into the ear canal, and switching between the 2 volume settings did not represent a problem.

Questions 2 and 3 provided an estimate of the number of hours per day that subjects wore the PSAP. On average, subjects reported using the PSAP between 4 and 8 hours throughout the 3-6 week trial.

Questions 4 and 5 evaluated comfort. The average result was slightly better than neutral by the end of the trial, although the results suggest that many subjects experienced comfort issues with the PSAP throughout the trial period. Questions 6 through 8 addressed issues related to the fit of the PSAP in ear canal. The PSAP was pre-packaged with a standard triple-flange eartip installed; however, the subject could change to a larger triple-flange eartip, a single-flange eartip,

or a foam eartip. The user instructions guided the subject in the eartip selection. Nearly 75% of the subjects reported that they tried the various eartips and 85% reported using the standard triple-flange eartip. In general, subjects rarely had problems with the PSAP coming loose in the canal, although occasional problems with feedback were reported. Occlusion and a hollow-voice sound were reported by more than half the subjects, regardless of eartip used.

Question 9 asked the subjects to report the amount of time they spent in each gain position. Approximately 90% of the subjects selected the lower gain setting for the majority of the trial period.

Question 10 evaluated the benefit in a variety of listening situations compared to unaided listening. On average, subjects reported their hearing ability to be ‘a little better’ or ‘much better’ in one-on-one and group conversations, as well as listening to television, radio, and non-speech environmental sounds. Listening in a car was rated slightly poorer with the average response resulting in little benefit.

Question 11 addressed loudness discomfort at the end of the trial period, in order to assess loudness acclimatization. The mean response indicated that loudness was ‘usually comfortable’ to ‘often too soft’, indicating that the loudness experienced from the (predominantly) lower gain setting was not obtrusive.

Questions 12 evaluated satisfaction with the appearance of the PSAP. The average rating was nearly neutral (3 on a 5 point scale), but the STDEV of 1.3 suggests that 16% of the subjects were somewhat or very dissatisfied with the appearance.

Question 13 evaluated overall satisfaction. Slightly more than half of the subjects reported that they were satisfied with the PSAP overall.

Question 14 asked subjects how likely they would be to continue wearing the PSAP, and how much they would be willing to pay for the PSAP. Thirty-four percent of the subjects reported that they would be ‘very likely’ to continue wearing the PSAP(s) if they had not been fitted with hearing aids, and 44% reported that it would be ‘very unlikely’ to do so.

Question 15 asked what the subjects would be willing to pay for a single PSAP. The average was \$100.

DISCUSSION

Many developments over the past several years increase the likelihood that consumers will consider purchasing personal sound amplifiers for their hearing loss. In 2016 FDA indicated that the agency is willing to consider the development of an over-the-counter hearing aid category.

This study evaluated the efficacy of a 2007 prototype Quiet Sound Amplifier[®] PSAP device as a potential treatment for hearing loss for first-time hearing aid candidates. Subjects were given access to these devices as though they had been purchased in a retail store or via the Internet. Specifically, subjects were given the packaged devices and told that user instructions were contained in the box.

Although the study PSAP provided only 2 gain settings, the average aided gain provided was generally comparable to that provided by the professionally prescribed hearing aids. In general, the statistically significant differences were modest from a clinical perspective. On the other hand, in many cases success and satisfaction with professionally-fitted hearing aids are strongly related to individual attention and management provided by the professional during and following the treatment process (Wong et al, 2009; Humes et al, 2001). Further, Wong et al, 2009, found that when service, hearing aid performance and limited problems with the hearing aids were better than expected, subjects experienced better overall satisfaction.

Only 13% of the subjects rated the PSAP as ‘very comfortable’ initially and toward the end of

the trial period (3-6 weeks). The remainder of the subjects rated the comfort in the ear canal as comfortable for an hour or more. In some cases, it later became uncomfortable. A few rated the PSAP as ‘immediately uncomfortable.’ Almost half (49%) reported using the PSAP for 4 or more hours per day.

Comments on the questionnaire clearly indicated that reduced use was specifically related to comfort for extended use (more than 1 hour). The same conclusion has been reported with traditional hearing aids, where comfort and fit are decisive and significant predictors of overall success in the use of amplification for the treatment of hearing loss (Walden et al, 2002; Johnson, 2007; Hickson et al, 2010; Kochkin et al, 2010).

The results of this study suggest that the acoustic performance of a PSAP can be comparable to that of professionally-fitted hearing aids when tested with normal 65 dB SPL speech. Note that only 1 prototype PSAP was evaluated in this study.

CONCLUSION

The findings of this study are consistent with several recent studies of PSAP devices with hearing-impaired subjects (Xu et al., 2015; Mamo et al., 2016; Smith et al., 2016). Indeed, most recently, Humes et al. (2017) conducted the first-ever randomized placebo-controlled double blind study using a) hearing aids chosen through audiology best practices, b) hearing aids equivalent to over-the-counter devices, and c) a placebo device. They concluded that both a) and b) devices were efficacious in older adults, and that the *OTC delivery model yielded only slightly poorer outcomes than the audiology-best-practices model.* (italics ours)

The PSAP used in this study provided almost the same performance as the professionally-fitted hearing aids on measures of aided gain and intelligibility in noise. Slightly more than half of the subjects reported overall satisfaction with the PSAP and 34% reported they would be “very likely” to continue wearing the PSAP. The remaining subjects reported issues with fit and comfort with extended use.

In summary, data from the 2007 study reported here confirm that a high-quality PSAP can provide benefit in audibility and judged hearing ability comparable to many professionally-fitted hearing aids.

ACKNOWLEDGEMENTS

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Appendix A.

Quiet Sound Amplifier[®] QUESTIONNAIRE

We would like for you to answer some questions regarding the Quiet Sound Amplifier[®] hearing aid that you have been wearing for the past 2 weeks.

1. Recall that you were asked to fit yourself with the Quiet Sound Amplifier[®] rather than have your audiologist fit it to you. Do you believe that the printed information that was provided to you gave you clear instructions regarding:

a. selecting the eartip size

_____ very clear

_____ fairly clear

_____ unclear

b. attaching the eartip to the hearing aid:

____ very clear

____ fairly clear

____ unclear

c. inserting the battery into the hearing aid

____ very clear

____ fairly clear

____ unclear

d. inserting the hearing aid into your ear

____ very clear

____ fairly clear

____ unclear

e. switching between the two volume settings

____ very clear

____ fairly clear

____ unclear

2. How many hours per day did you wear the Quiet Sound Amplifier[®] for the first few days?

____ less than 1 hour

____ 1-4 hours

____ 4-8 hours

____ 8-12 hours

____ more than 12 hours

3. How many hours per day did you wear the Quiet Sound Amplifier[®] toward the end of the 2 weeks?

less than 1 hour

1-4 hours

4-8 hours

8-12 hours

more than 12 hours

4. How comfortable was the Quiet Sound Amplifier[®] during the first few days that you wore it?

very comfortable

comfortable for an hour or more, but later became uncomfortable

uncomfortable within 1 hour

immediately uncomfortable

5. How comfortable was the Quiet Sound Amplifier[®] during the last few days that you wore it?

very comfortable

comfortable for an hour or more, but later became uncomfortable

uncomfortable within 1 hour

immediately uncomfortable

6. Did you have problems with the Quiet Sound Amplifier[®] coming loose in your ear and/or falling out?

never had this problem

rarely had this problem

occasionally had this problem

___ frequently had this problem

___ constantly had this problem

7. Did you have problems with “squealing” sounds while you were wearing the Quiet Sound Amplifier®?

___ never had this problem

___ rarely had this problem

___ occasionally had this problem

___ frequently had this problem

___ constantly had this problem

8. Did your own voice sound hollow and/or did your ears feel stopped up while wearing the Quiet Sound Amplifier®?

___ never had this problem

___ rarely had this problem

___ occasionally had this problem

___ frequently had this problem

___ constantly had this problem

9. While wearing the Quiet Sound Amplifier®, what percentage of the time did you use each volume setting? (the 2 percentages should total 100%)

Volume setting #1 _____%

Volume setting #2 _____%

100 %

10. How would you describe your ability to hear/understand with the Quiet Sound Amplifier® in each of the following listening situations?

a. One-on-one conversations in relatively quiet listening environments

___ much better

___ a little better

___ about the same

___ worse

b. One-on-one conversations when background noise and other distractions are present

___ much better

___ a little better

___ about the same

___ worse

c. Group conversations

___ much better

___ a little better

___ about the same

___ worse

d. Inside a car

___ much better

___ a little better

___ about the same

___ worse

e. Listening to the television or radio

___ much better

___ a little better

___ about the same

___ worse

f. Non-speech environmental sounds (e.g., birds, footsteps, warning sounds, wind, bells, clocks, motors, etc.)

___ much better

___ a little better

___ about the same

___ worse

11. During the last few days that you used the Quiet Sound Amplifier[®], how comfortable was the loudness of sound through the hearing aid?

___ always comfortably loud

___ usually comfortably loud

___ often too soft

___ often too loud

___ usually too soft

___ usually too loud

12. How satisfied were you with the appearance of the Quiet Sound Amplifier[®] in your ear?

___ very satisfied

___ generally satisfied

___ somewhat dissatisfied

___ generally dissatisfied

___ very dissatisfied

13. Overall, how satisfied were you with the Quiet Sound Amplifier[®]?

___ very satisfied

- generally satisfied
- somewhat dissatisfied
- generally dissatisfied
- very dissatisfied

14. If you were not being fitted with your own hearing aids, how likely would you be to continue wearing the Quiet Sound Amplifier[®]?

- very likely
- somewhat likely
- somewhat unlikely
- very unlikely

15. If you had to purchase the Quiet Sound Amplifier[®] and you could expect it to last 2-4 years, how much would you be willing to pay for one?

- more than \$500
- \$300-\$500
- \$150-\$300
- \$100-\$150
- \$50-\$100
- less than \$50
- I would not purchase one at any price

16. Please provide any comments about the Quiet Sound Amplifier[®] that would help us to assess your performance with and attitudes toward this hearing aid.