Preliminary observations on outcomes with a self-fitted hearing aid

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The President's Council of Advisors on Science and Technology (PCAST) report<sup>1</sup> that was submitted to the US Government last October has sparked much debate about the future provision of hearing health care in the US<sup>2-7</sup>. The primary aim of the report's recommendations is to make hearing technology more accessible and affordable for a growing number of Americans living with hearing loss. To achieve this, the report suggests that direct-to-consumer sale of hearing aids, which can lower the cost of devices, be approved; and that the cost of hearing services be made more affordable and transparent by introducing an unbundled pricing structure for hearing health care. The latter strategy would ensure that hearing-impaired people who choose to buy a cheaper device on the direct-to-consumer market are not denied access to diagnostic and counselling services. Similar recommendations are largely corroborated in a recent report released by the Committee on Accessible and Affordable Hearing Health Care for Adults<sup>8</sup>.

The two reports endorse a growing range of products, currently only accessible online, that provide the user with optional access to software applications for independently fine-tuning a preprogrammed hearing aid or self-managing the entire fitting process (self-fitting hearing aids). While such products have been accessible for a few years now<sup>9</sup>, there is limited information available about their potential benefit and performance relative to conventional hearing aids that have been dispensed by a hearing health professional. Not surprisingly, one of the major concerns expressed by hearing health practitioners surrounds this lack of evidence. Preliminary data suggest that selfadjustable hearing apps for smartphones provide outcomes comparable to those obtained with basic hearing aids, and therefore may serve well as an introduction to amplification for people with milder hearing loss<sup>10</sup>. Through a series of studies done over the past six years at our laboratory, we have gained important knowledge on management of the self-fitting process<sup>11-14</sup> and the efficacy and reliability of performing hearing aid fine-tuning in the field<sup>15</sup>. While these studies largely support the feasibility of self-fitting and self-adjustable devices, they also identified a number of improvements - both to the self-fitting processes within the device and the ways in which users are guided to interact with the device - that are anticipated to improve overall outcomes<sup>9</sup>. Ultimately, however, we need to examine how the benefit, satisfaction, and performance capabilities of selfadjustable and self-fitting hearing aids compare with professionally fitted hearing aids.

We recently conducted a study to examine how well both experienced and inexperienced hearing aid users can manage the self-directed fitting process associated with a prototype of the Companion, a commercially available self-fitting hearing aid from SoundWorldSolutions<sup>17</sup>. As part of this study, experienced hearing aid users who had completed all steps of the self-fitting procedure accurately according to a set of instructions, and had achieved fine-tuned settings that were considered by the experimenter to be safe to wear in everyday life took part in a six-week field trial. A range of subjective and objective outcomes were measured at the end of the trial. The outcome measures were also performed on the participants' own hearing aids, and the order in which the two device types were tested was counterbalanced across the group.

In total, 11 participants met the criteria for inclusion in the field trial. Unfortunately, the ear hook disconnected from the body of four participants' hearing aids (a fault that has since been rectified by the manufacturer), one participant accidentally submerged his devices in water, and one participant withdrew from the trial after reporting physical discomfort while wearing the test devices. As a result, only five participants were able to complete the field trial and provide outcome measures with both their own hearing aids and the test devices. These data have never been published before and due to the small sample size do not present strong evidence, but they are summarized in this paper to illustrate what may be expected from self-fitted hearing aids currently sold through the direct-to-consumer channel.

## Method

The five participants who completed the field trial were all males who ranged in age from 72 to 79 years. They all had symmetrical sloping hearing loss with a mean pure-tone average (PTA) of 47.1 dB HL (range = 36 to 61 dB HL), and had worn hearing aids for an average of 9.5 years (range = 4 to 38 years). These five participants all entered the study as bilateral users of advanced technology; wearing receiver-in-canal (RIC) behind-the-ear (BTE) hearing aids from – in alphabetical order – Blamey & Saunders, GN ReSound, Rexton, and Sivantos.

The test hearing aid was also a RIC BTE instrument that featured 16-channel compression, noise reduction, feedback cancellation, and a directional microphone. Self-fitting of the test devices took place in a large sound-treated room. To guide the participants through the procedure, they were provided with a set of written, illustrated instructions that had been collaboratively produced by the experimenter and the device manufacturer. If possible, the participants brought a family member or friend along who could assist with the self-fitting process when needed. No one else was present in the test room during self-fitting, but participants were monitored by the experimenter from outside the room via headphones and a webcam.

To fit the hearing aids, the participants had to select appropriate instant-fit domes from a range of three sizes and adjust the aids' retractable tubes to a length that allowed the devices to sit comfortably over the pinna. The aids were then wirelessly paired via Bluetooth with a Samsung Galaxy tablet. Participants then accessed SoundWorldSolutions' CS Customizer app to perform a self-directed pure tone hearing test and fine-tuning adjustments. The controls on the fine-tuning screen, which was laid out like a graphic equalizer, enabled participants to make adjustments to overall gain as well as gain in the low-, mid-, and high-frequency bands within a range of ±12 dB. Since participants did not have access to the self-fitting app during the field trial, no further permanent adjustments could be made to their settings after the self-fitting session; however, they were able to adjust overall gain to their preferred levels while in the field by using the hearing aids' onboard controls.

Outcome measures collected with the test devices and the participants' own devices included the signal-to-noise ratio (SNR) at which 50% speech intelligibility was achieved when listening to speech in noise (SRT50), loudness perception of wideband speech, and perceived benefit and satisfaction.

SRT50 was measured with an automated version of the Beautifully Efficient Speech Test (BEST<sup>16</sup>). The noise level was fixed at 55 dB SPL, while the speech level varied adaptively throughout the test from a starting level of 65 dB SPL. Speech was presented to the participant from a loudspeaker at 0° azimuth, while uncorrelated 8-talker babble was presented from four loudspeakers positioned at  $\pm$ 45° and  $\pm$ 135°. The test continued until a minimum of 16 sentences were presented and a test-retest standard error of 0.8 dB was reached, or a maximum of 32 sentences were administered<sup>17</sup>.

The BEST lists were scored morphemically. Three lists were presented and the results averaged to yield a single robust SRT50 score.

Loudness perception of wideband speech was measured by presenting single sentences spoken by a male talker at increasing levels, beginning at 45 dB SPL and ascending in 3 dB steps to a maximum presentation level of 75 dB SPL. Participants were asked to rate the loudness of each presentation using a seven-point categorical loudness scale<sup>18</sup> until Level 6 ("Loud, but Ok") was reached. Three runs of the test were performed. Results of the first run were discarded as practice, and the median categorical loudness rating for each presentation level from the last two runs were then calculated to obtain the loudness growth function.

Self-reported benefit, satisfaction, participation restriction, and perceived performance were probed through three questionnaires: the International Outcome Inventory for Hearing Aids (IOI-HA<sup>19</sup>), the Abbreviated Profile of Hearing Aid Benefit (APHAB<sup>20</sup>), and the short form of the Speech, Spatial and Qualities of Hearing Scale (SSQ12<sup>21</sup>). On all questionnaires higher ratings were associated with greater benefit and satisfaction, and less participation restriction.

## Results

Figure 1 compares the average 2 cc coupler gain of the walk-in-the-door responses in the test device with that obtained for the participants' own devices. According to a repeated-measures analysis of variance (ANOVA), preferred gain levels in the test device were significantly higher than the use gain levels in the participants' own devices at 250 (p = 0.002), 500 (p = 0.01), and 6000 Hz (p = 0.0002). Across the individuals, the root-mean-square (rms) difference between the responses, calculated across ears and audiometric frequencies from 250 to 6000 Hz, varied from 6.9 to 16.9 dB (or from 6.4 to 13.5 dB when excluding 6000 Hz).

Figure 2 shows the mean of three independent measures of SRT50 obtained for each participant with each device and the group mean. Lower values here mean better performance. Four of the five participants performed slightly better with their own devices, with the largest individual difference in SRT50 being 1.5 dB (participant 2). However, according to a t-test for dependent samples, the mean difference of 0.7 dB across participants did not reach significance (p = 0.06).

Figure 3 shows the relationship between the loudness ratings assigned to each device at each SPL for each participant. Points falling above the unity line indicate that the test device was rated louder than own device at the same SPL. On average, across participants, the test devices were rated slightly louder than their own devices by 0.2 rating points. According to a Wilcoxon matched-pairs test, this differences in loudness categorization between the two device conditions was significant (p = 0.01).

Figure 4 shows the global scores on the three self-report inventories that were obtained by each participant and the group mean. Higher scores here mean better performance. Only one participant (participant 3) consistently rated performance better with his own devices. The other participants rated the performance of the test device greater than that for their own devices on at least one inventory. On average, the global scores were highest for the participants' own devices by 6.3%, 5.2%, and 3% rating points for the IOI-HA, APHAB, and SSQ12, respectively, but according to t-tests for dependent variables, none of these differences reached significance (p > 0.37).

## Discussion

Internet shopping is a booming business. There seems to be no limit to the kinds of goods and services that can be obtained online, and hearing aids are no exception. Previously published

investigations into online hearing products have primarily focused on the process necessary to obtain the devices<sup>22-24</sup> or their electroacoustic performance<sup>25-27</sup>. In this study, we compared the benefit, performance, and satisfaction outcomes obtained with a pair of commercially available self-fitting hearing aids – which offer standard hearing aid features but retail online for a significantly lower price – with those provided by audiologist-fitted hearing aids dispensed in the traditional face-to-face setting.

Five experienced hearing aid users set up the self-fitting hearing aids for their own use and wore them for six weeks in the field. Relative to the setting of their own aids, higher gain settings were measured for a 65 dB SPL input in the test hearing aids across the lowest and highest frequencies. We don't know to what extent these settings were the result of leakage during threshold testing, the proprietary prescription that translates the measured threshold levels to the baseline hearing aid setting, or the fine-tuning performed immediately after self-fitting. However, given that several studies have demonstrated that hearing aid users during self-adjustments generally make little change to the baseline response shape<sup>28-29</sup>, a combination of the first two suggestions seems the most likely explanation. The extra gain resulted in the participants rating the test aids slightly, but significantly, louder than their own aids when listening to speech in quiet. However, based on group data, there was no significant effect of hearing aid type on a range of commonly used outcome measures. The somewhat flatter gain/frequency response selected in the test device may, however, have caused some upward spread of masking that affected speech-in-noise performance. While not reaching significance, the difference in SRT50 values approached significance, and we note that those participants producing the greatest difference in SRT50 values, presented the greatest rms difference between the coupler responses obtained for the two devices. The consistently lower benefit score reported for the test devices by participant 3 may be explained by his dissatisfaction with the ear tips. At the time of fitting, he was disappointed that he was unable to transfer the open domes on his own hearing aids to the test devices and reported a belief that the closed domes of the test devices were inferior. Despite this issue, the participant voluntarily persevered with the study, but we cannot exclude the possibility that his perception of the ear tips colored his view of his overall benefit, satisfaction, and performance with the test aids. Particularly as this participant compared the smallest difference in gain between devices and produced the same SRT50 values with both devices.

While limited, these data suggest that for those who can manage the self-fitting process, self-fitting aids may provide satisfactory benefit and performance. A more extensive crossover study is clearly needed before a firm conclusion can be drawn on this matter. We also note that only people who performed the self-fitting process in an acceptable way and achieved an audiologist-approved outcome were invited to complete the field trial. That is, our preliminary conclusion regarding the efficacy of self-fitting hearing aids is predicated on the assumption that instructions were accurately followed when the initial setup procedure was performed. Making the self-fitting process simple, intuitive, and accessible to a wide range of hearing aid candidates is definitely a challenge<sup>9</sup>, but we anticipate that the optimal implementation of the automated processes in the device, complemented by suitable instructional and support materials, will serve to reduce barriers to access and ensure satisfactory outcomes in the future. In the future, it may also be possible to screen hearing aid candidates for the ability to self-fit.

## Summary

Online-available hearing products are becoming increasingly sophisticated in terms of the features and self-directed processes they have to offer. Both the capability of these devices and the clinical infrastructure to support their use are likely to further evolve over the coming years. While there is still scope for improvement – whether it be in terms of safety, efficacy, accessibility, or affordability – our preliminary data demonstrates that at least one currently available self-fitting product is capable of providing benefit and satisfaction comparable to those measured with professionally dispensed hearing aids.

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Figure 1. The mean 2 cc coupler gain of the field trial participants' (N = 5) preferred use gain in the test devices and their own hearing aids as measured at the end of each trial period. Error bars represent the 95% confidence intervals.



Figure 2: The mean SRT50 values measured for each of five participants with own devices and test devices, together with the grand means. Error bars represent the standard deviation



Figure 3: For each participant, the relationship between loudness ratings assigned each device at each input level until the maximum rating of 6 was reached for either device. The black dotted line shows unity.





