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Titel
Fördelar med högre ”Maximal Force Output” i benförankrade hörapparatsystem: en crossover-studie

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Sammanfattning
Syfte: Att undersöka hur högre ”Maximal Force Output” (MFO) i ljudprocessorn för benförankrade hörapparatsystem påverkar den upplevda nyttan och ljudupplevelsen samt den uppmätta hörselförmågan hos personer med kombinerad hörselnedsättning, sett i förhållande till en mindre ljudprocessor med lägre MFO.
Material och metod: Studiedesign: Prospektiv, randomiserad crossover-studie (ABA). Nitton erfarna användare av benförankrat hörapparatsystem med kombinerad hörselnedsättning inkluderades i studien. Två ljudprocessorer med olika design och MFO utvärderades i studien, apparat A: Oticon Medical Ponto 3 och apparat B: Oticon Medical Ponto 3 Super Power. Utfallsmått var taluppfattning i brus med olika signal/brus förhållanden, förstärkta hörtrösklar och frågeformulär.
Resultat: Taluppfattningstest visade signifikant bättre resultat med apparat B. Dessutom visade SSQ12-C på signifikant större upplevd nytta med apparat B vid lokalisering, avstånd och rörelse av ljudkällan. Efter studiens avslut valde elva utav nitton deltagare (58%) att fortsätta med apparat A. De vanligaste anledningarna var ljudprocessorns storlek och en mer behaglig ljudupplevelse.
Konklusion: Högre MFO i ljudprocessorn för benförankrat hörapparatsystem förbättrar taluppfattningen i krävande ljudmiljöer för personer med kombinerad hörselnedsättning. Dessutom upplevs högre MFO vara fördelaktigt för att ta emot spatial information. Ljudprocessorns storlek och design är viktiga faktorer för många användare vid val av ljudprocessor.

Nyckelord: Benförankrat hörapparatsystem, maximal force output, kombinerad hörselnedsättning

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Title
Benefit of higher maximum force output in bone anchored hearing systems: A crossover study

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Abstract
Objective: To investigate how higher maximum force output (MFO) in Bone Anchored Hearing Systems affects the perceived benefit, subjective experience of sounds as well as hearing outcomes in subjects with mixed hearing loss, seen in relation to a smaller sound processor with lower MFO.
Material and method: Prospective, randomized cross-over study (ABA). Nineteen experienced users of bone anchored hearing system and with a mixed hearing loss were included in the study. Two sound processors with different design and MFO were evaluated in the study, device A: Oticon Medical Ponto 3 and device B: Oticon Medical Ponto 3 Super Power. Outcome measurements were speech recognition in noise at different signal to noise ratios, aided thresholds, and questionnaires.
Results: Speech intelligibility test showed significant improvement using device B. Moreover, SSQ12-C showed a significant larger perceived benefit with device B concerning localization, distance and movement of the sound source. At the end of the study, eleven out of nineteen participants (58%) chose to keep device A for further use, main reasons were size of the sound processor and a more comfortable sound experience.
Conclusion: Higher MFO in bone anchored hearing sound processors allows improvement of speech intelligibility in sound demanding environments. Additionally, higher MFO is perceived as beneficial to receive spatial information. However, when choosing in-between two sound processors design and size of the device play an important role for many users.

Keywords: Bone anchored hearing systems, maximum force output, mixed hearing loss

Manuscript

Benefit of higher maximum force output in bone anchored hearing systems: A crossover study

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Conflict of interest
Marianne Philipsson and Tove Rosenbom are employees of Oticon Medical AB, Askim, Sweden.

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Introduction

A bone anchored hearing system (BAHS) is a rehabilitation option to treat hearing loss through bone conduction. Bone conducted devices can be categorized according to how the vibrations are transferred: direct-drive, skin-drive or in-the-mouth (e.g. Soundbite Hearing System). Skin-drive systems can be divided into conventional headband/softband or passive transcutaneous, for example through an implanted magnet. The direct-drive systems can be active transcutaneous through an implanted transducer or percutaneous (Reinfeldt, Håkansson, Taghavi, & Eeg-Olofsson, 2015). This study has evaluated the percutaneous direct-drive device and the term “BAHS” will refer to this type of device throughout this paper. A percutaneous direct-drive BAHS consists of a titanium fixture implanted into the skull bone, an abutment penetrating the skin and a sound processor attached to the abutment. The sound processor picks up the sound and converts it to mechanical vibrations. The vibrations are then transmitted to the abutment and the implant, through the skull bone and further to the inner ear (Hakansson, Tjellstrom, Rosenhall, & Carlsson, 1985). The pathway for bone conducted sound energy bypasses the outer and middle ear and can therefore be beneficial in both conductive and mixed hearing loss. The main audiological indications for BAHS are accordingly conductive hearing loss, mixed hearing loss and also single sided deafness (SSD). BAHS can also be used when conventional hearing aids are contraindicated due to e.g. chronic ear infections or atresia (de Wolf, Hendrix, Cremers, & Snik, 2011; Snik et al., 2005; Zwartenkot, Snik, Mylanus, & Mulder, 2014).

Previous studies have demonstrated good benefit with BAHS for people with conductive hearing loss, mixed hearing loss or SSD (Gardell, Andresen, Faber, & Wanscher, 2015; van Wieringen, De Voecht, Bosman, & Wouters, 2011). Despite good results, BAHS uptake rate is rather low. The most common reasons for rejecting BAHS are cosmetics, anxiety for surgery or perceived limited benefit (Siau, Dhillon, Siau, & Green, 2016; Zawawi, Kabbach, Lallemand, & Daniel, 2014). The perceived limited benefit may be due to low maximal force output (MFO) in BAHS sound processors. MFO is the maximal level of force that the sound processor can transmit to the inner ear without distortion and to date all BAHS available in the market have a low MFO mainly due to technical limitations (van Barneveld, Kok, Noten, Bosman, & Snik, 2018; Zwartenkot et al., 2014). When the MFO is reached, signal processing in modern BAHS sound processor controls and attenuates the level in that frequency band to avoid physical saturation. However, saturations artefacts can be produced when the output signal is close to the MFO. The input level at which these artefacts will occur depends partly on the MFO in the device but also on how much gain that is prescribed. For patients with mixed hearing loss the input level that will be affected can be already at normal speech levels (Zwartenkot et al., 2014).

There are currently several manufactures producing different types and models of BAHS sound processors. Size, design and MFO differ in different models. Generally, sound processors with a larger size and a larger vibrator provide a higher MFO. However, all available BAHS sound processors have due an MFO that is below the listener's loudness discomfort level with the consequence that only part of the dynamic range of hearing can be reproduced. A sound processor with lower MFO saturates at lower input levels compared to a sound processor with higher MFO (van Barneveld et al., 2018; Zwartenkot et al., 2014). Accordingly, higher MFO in BAHS sound processors can provide a larger dynamic range of hearing and should give higher fidelity of sounds. The drawback of higher MFO is in general that loud sounds could elicit discomfort. A BAHS sound processors should not produce sounds that is perceived as uncomfortably loud since the level of MFO is well below the listener's loudness discomfort level (Bosman, Kruyt, Mylanus, Hol, & Snik, 2018a, 2018b; Zwartenkot et al., 2014). Some research has been done on how the higher MFO is perceived by the users of BAHS. One study that compared an older device with lower MFO with a newer device with higher MFO concluded that higher MFO was perceived as more beneficial for receiving spatial information and was preferred when listening to speech in large groups and listening to music (Bosman et al., 2018a). In addition, higher MFO in BAHS has been proved to reduce listening effort when measured with pupillometry and to improve speech recognition in noisy environments (Bianchi et al., 2019).

Theoretically, most BAHS users should benefit from the larger dynamic hearing range provided by higher MFO in the device. However, it is also known that cosmetics also can affect the patient's choice of device and many users prefer smaller and more cosmetically appealing devices (Siau et al., 2016; Tyler, Witt, & Dunn, 2004). Some research has been done to investigate how higher MFO affect the user's experiences and performance, but the effect has not yet fully been investigated. In addition, patients' benefits with a higher MFO in relation to the patients' experiences of the cosmetics of a BAHS have never been investigated. To be able to support audiologist and patients in the important decision on treatment options, research with clinical focus and where benefits with higher MFO and subjective parameters are included, is needed. Therefore, the main aim of this study was to evaluate how BAHS users benefits from a device with higher MFO as seen in relation to a smaller device with lower MFO. The primary objective was to investigate if a BAHS sound processor with higher MFO can provide a larger perceived benefit in the daily life and better experience of the sound compared to a BAHS with lower MFO in subjects with mixed hearing loss. The secondary objective was to examine which sound processor was preferred when both appearance and hearing experience were considered. The tertiary objective was to examine how hearing outcomes in terms of speech intelligibility and aided thresholds were affected considering MFO in different sound processors. The hypothesis was that the sound processor with higher MFO should provide a more comfortable and natural sound experience, particularly at louder sound levels and that it should be preferred by most participants.

Materials and methods

Participants

Clinical data were collected from the databases available at Hearing Organization, Region Västra Götaland, Sweden. Fifty-two patients were initially invited to participate and were given written information about the study before they decided to participate. The response rate was 48% (n=25). Of these, four patients did not meet the audiological criteria (see below) for inclusion. In addition, two other participants chose to stop participation during the trial, due to handling problems, leaving in total 19 participants in the study.

Participants were included based on following criteria:

- Unilateral implanted with BAHS.
- Mixed hearing loss: Pure tone average (PTA 0.5, 1, 2 and 3 kHz) unmasked bone conduction (BC) thresholds between 20-40 dB Hearing Level (HL) and an air-bone gap larger than 10 dB.
- Experience of using BAHS for more than one year.
- Age $\geq$18 years
- Signed consent form
- Swedish as native language or sufficient knowledge in spoken Swedish

Moreover, participants were excluded if they were judged to be unable to perform the tests and/or fulfil the questionnaires, had sign of infections around the abutment or previously had used Oticon Medical Ponto 3, Ponto 3 Power or Ponto 3 Superpower sound processors.

Procedures

The study was performed with a randomised crossover design (ABA) (Byiers, Reichle, & Symons, 2012). A test-design with four different sessions was used and each participant served as its own control. The intervention included three trial periods using two different sound processors and participants were randomised into two trial groups at the first visit. Group 1 evaluated the sound processors in the order: A, B, A and group 2 in reverse order i.e. B, A, B. Each trial period was approximately two weeks.

At the first visit, further information about the study was given and informed consent for participation was obtained. Moreover, unaided standard pure tone audiometry and unaided sound field measurements were performed. Participants were then fitted with one of the two sound processors. Thereafter, the device was evaluated in their daily life over a period of approximately two weeks. At the second visit, the other sound processor was fitted and evaluated for two weeks. During the second trial period, participants were asked to fill in a questionnaire (SSQ12). At the third visit, participants were again fitted with the sound processor they tried initially. They were asked to fill in the questionnaire (SSQ12) again. At the final visit, aided sound field measurements were performed with both sound processors. Furthermore, participants were asked to fill in two more questionnaires (SSQ12-C and preference). A flowchart of the whole procedure is presented in figure 1.

Intervention

Two different sound processors from Oticon Medical AB were used; device A: Ponto 3 and device B: Ponto 3 Superpower. Device B has 11 dB higher peak MFO at an input level of 90 dB SPL compared to device A. The size of the two devices differs, device B is 3 mm higher than device A, device B takes a size 675 battery, while device A takes a size 13 battery. In addition, device B is 3 grams heavier than device A.

The sound processors were programmed using the software Genie 2016.1 distributed by Oticon Medical AB, and the programming process followed the manufacturer’s directions. First, a feedback measurement was performed. Next, BC in-situ thresholds were obtained and based on the measured thresholds the gain was calculated according to the prescription formula NAL-NL1. The volume control remained activated during the trials. Automatic functions, such as noise reduction and directional settings, were not changed from the standard settings during the test periods. Finally, if needed the gain was finetuned to a level that was preferred by the participant. Five participants needed adjustments of the first fit and the same adjustments were done in both sound processors to assure the same gain settings in both devices. Four participants required increase in gain with 1-8 dB. One participant (#19) could not accept the gain level of the first fit and it was fine-tuned by -12 dB to reach an acceptable level.

Audiological measurements

Pure tone audiometry was conducted with a calibrated audiometer (Astera, Madsen) equipped with earphones TDH-39 and bone conductor B-71. The measurements were performed in a soundproof room, according to a standardized method complying with the ISO-standard 8253-1.

Sound field thresholds were obtained by using the same audiometer and soundproof room described above. Warble-tones were presented from a loudspeaker (Canton Plus XL) placed 1 meter in front of the participant. To avoid impact of the opposite ear during the measurements, it was blocked using an earplug (Cirrus Healthcare Products) in the ear canal and an earmuff (Optime III, Peltor) placed over the pinna. The earplug was placed as deep as possible in the ear canal to decrease the effect of occlusion (Stenfelt & Reinfeldt, 2007). The directional setting in the sound processor was during the measurements in omni directional mode and the noise reduction and digital feedback cancellation were switched off not to interfere or affect the measurements.

Swedish hearing in noise test (HINT) (Hallgren, Larsby, & Arlinger, 2006) was performed with a passive method and using the same equipment described above. Speech and a constant noise were presented simultaneously at 0 degrees azimuth. The noise was fixed at a level of 75 dB SPL (Sound Pressure Level) and speech was presented by a female speaker at four levels, 78-, 75-, 72- and, 70 dB SPL, resulting in a signal to noise ratio (SNR) of +3, 0, -3 and -5 dB. Before each set of tests, a practice list was presented. Two lists, containing 10 sentences each, were used for each level. The order of the lists was randomised, and no list was used twice for the same participant. Correctly repeated words were compiled, and percentage of correct answers was calculated.

Questionnaires

A range of hearing disabilities connected to each participant and across several domains were evaluated using a Swedish version of the 12-items questionnaire Speech Spatial and Quality of hearing scale (SSQ12) (Gatehouse & Noble, 2004; Noble, Jensen, Naylor, Bhullar, & Akeroyd, 2013). The questionnaire is specialised to target how speech is perceived in competition with additional sounds and the effect of distance, direction and movement of the sound source. Participants rated each question related to their experience in daily life by using a visual analogue scale. The scale is from 0 (not at all) to 10 (perfectly). The higher score the better is the experienced benefit of the intervention, in this case specific sound processor. The questions can be divided in three subscales; speech, spatial and quality. In addition, the comparative version of SSQ i.e. SSQ12-C were used. SSQ12-C consists of the same questions as SSQ12, but the rating is from -5 to +5 where 0 in the middle means no difference, -5 indicate strong preference for one of the sound processors and +5 indicate strong preference for the other one.

A comparison between the two sound processors was also made using a self-designed questionnaire. It covered aspects such as speech understanding, in quiet and noise, listening to music, own voice, sound quality, sound comfort, listening effort, and cosmetic. The categorical rating was “much better”, “better” or “no difference”.

Statistical analysis

Each participant served as its own control. Statistical analyses were performed using IBM SPSS statistics version 25. The non-parametric test Wilcoxon signed rank test was used to analyse the outcomes of all tests except for the preference questionnaire. For comparison at preference, the Sign test was used. All significance tests were two-sided and conducted at the 5% significance level.

Ethical considerations

The study was approved by the Regional Ethical review board in Gothenburg, Sweden, references number 1002-17.

Results

In total, 19 BAHS users participated in the study. Demographic data is presented in table 1. Distribution of unmasked bone conduction (BC) thresholds and the medians of unaided pure tone threshold for air conduction (AC) and BC for the implanted side are displayed in figure 2. Pure tone averages (PTA 0.5, 1, 2 and 3 kHz) for each participant are shown in table 2. Median PTA for the fitted side was 62.5 dB HL for AC and 31.3 dB HL for BC (unmasked). On the opposite ear the median PTA AC was 41.3 dB HL and median PTA BC (masked) was 35 dB HL. The BC in-situ measurement had a median PTA of 28.8 dB HL for device A and 27.5 dB HL for device B. According to datalogging usage of device A were between 3 to 20 hours/day (mean 10,6 h, median 11 h) and usage hours were similar for device B, between 3 to 24 hours/day (mean 10,1 h, median 11 h).

Aided thresholds

Results for sound field measurements of aided thresholds are shown in figure 3. The gain in the devices was calculated from BC in-situ measurements and resulted in approximately the same gain settings for both devices. Consequently, Wilcoxon signed rank test with Bonferroni corrections for multiple comparisons showed no significant differences between the aided thresholds for device A and device B at any frequency. Accordingly, no significant differences were showed in effective gain neither (difference between BC in-situ thresholds and aided thresholds). The distribution of the results for effective gain are displayed in figure 4. The median effective gain showed a remaining air-bone gap of 5 to 10 dB in most frequencies and up to 35 dB at 250 Hz.

Hearing in noise test

Figure 5 shows the results for speech intelligibility in noise. There were significant improvements at all four levels and with both sound processors compared with unaided results (p <0.001). Comparing the two devices, device B showed better results at all four levels, significant better result at 78 dB SPL (p=0.014) and 75 dB SPL (p=0.002).

Questionnaires

The results for SSQ12-C are shown in figure 6. Device B was rated significantly higher than device A at question 6 (localization) (p=0.016) and at question 7 (distance and movement) (p=0.043). The results divided in three subscales: speech, spatial and quality, showed no significant differences between the two devices in any domain. Results from questionnaire SSQ12 were not significant different for device A compared with device B at any question or domain. (data not shown).

Device preferences are presented in figure 7. There was a slight preference for device A at the questions concerning loud noise, own voice, sound comfort and listening effort. Device B was preferred in speech in quiet, speech in large groups and when listening to TV/radio or music. These differences were though not significant. However, rating of the devices' appearance was significant different, device A was preferred of 58% (n=11) of the participants and no subjects preferred device B (p<0.001).

After completed the study, eleven participants (58%) chose device A for further use and eight participants (42%) chose device B. Main reasons for keeping device A were the size of the sound processor (n=6), more comfortable sound experience (n=6) and some thought it was easier to handle (n=2). Device B was mainly chosen because of the fuller and richer sound (n=3), the better sound quality (n=3) and better speech perception (n=3).

Discussion

The objective of this study was to investigate the subjective and objective performance of two BAHS sound processors which only differ in size/design and MFO. The fact to be consider here is having partly a small enough sound processor willing to be worn by patients but also powerful enough to vibrate the skull and reproduce as much as possible of the dynamic range of hearing.

Real-life experiences evaluated with SSQ12-C questionnaire showed large variations between individuals in perceived benefit and sound experience with the two devices. No significant differences could be found between the two devices except for two of the questions concerning spatial abilities. At these questions, device B with higher MFO was perceived as more beneficial. Sound localization in the horizontal plane relies mainly on binaural acoustic differences in sound level and phase. Asymmetric hearing loss can negatively affect localization of sounds since the differences in time and phase between the two ears are changed. With a unilateral BAHS the ability to use interaural time and level differences might be limited due to the low transcranial attenuation. Even so, better sound localization ability has been demonstrated with BAHS compared to unaided results in patients with conductive losses (Agterberg et al., 2011; Agterberg, Snik, Hol, Van Wanrooij, & Van Opstal, 2012). Since the two sound processors used in this study only differ in MFO, weight and size, results indicate that the perceived improved ability to receive spatial information may be due to the higher MFO in device B. In a prior study that evaluated higher MFO in BAHS, the results on SSQ showed better performance at all three domains (Speech, Spatial and Quality) with the newer sound processor with higher MFO. The better result on the spatial factor was attributable to the MFO differences in the two devices that was compared (Bosman et al., 2018a). Furthermore, the varying results between individuals at the questionnaires in this study may be explained by the degree of hearing loss in the opposite ear which varied from mild to profound hearing loss (PTA AC: 21,25->110 dB HL). Another aspect that might have affected our results is bimodal fitting i.e. subject with conventional hearing aid at the non-implanted side. Bilateral hearing has shown in general to improve speech recognition in quiet and in noise and to improve sound localization compared with unilateral use of hearing device alone (Bosman, Snik, van der Pouw, Mylanus, & Cremers, 2001; Zeitooni, Maki-Torkko, & Stenfelt, 2016). In this study nine participants were fitted bimodal. The participants that was unaided on the opposite ear seemed to rate device B higher at the questionnaires compared to those fitted bimodal. These tendencies could be explained by the fact that participants fitted bimodal perhaps rely more on the conventional hearing aid and are not dependent on the BAHS to the same extend compared to unilateral fitted subjects. It is however unclear to what degree bimodal fitting has affect our results related to real life experience among our study subjects.

It was hypothesized that listeners would experience a more comfortable and natural sound experience and a larger perceived benefit as a consequence of higher MFO, and that most participants should prefer the sound processor with higher MFO despite the larger size. This hypothesis was valid in some subjects (e.g. 1, 5, 8, 9, 11, 16, 18 and 19). These subjects rated device B higher on questionnaires and performed better with device B at HINT, and at the end they chose to keep device B for further use. Some other subjects (e.g. 2, 3, 12 and 13) chose to keep device A despite better performance and higher ratings on questionnaires with device B, size and a more comfortable sound experience were the most common reasons for their choice. One interesting subject is number 14, performance with device B on HINT was considerably better compared to device A but the questionnaires showed a preference for device A and at the end of the study device A was chosen. One potential explanation may be that this subject in his daily life might not be exposed to the noisy environments reproduced in the laboratory set-up. In total, 58% of participants (n=11) choose the smaller sound processor with lower MFO (device A) for further use. This result can be interpreted as visual characteristics such as the size and weight can be more important in device selection in relation to the sound processing technologies aspects, such as higher MFO. However, device B was preferred when listening to speech in large groups and listening to music. These sound environments have high dynamics and higher MFO are supposed to be most beneficial in these types of environments. The findings are congruent with the result by Bosman et al. (2018a) that also concluded a preference for the device with higher MFO in these sound environments. Furthermore, previous studies have showed that higher MFO in BAHS do not elicit discomfort when listening to loud sounds since the MFO still is below the uncomfortable level (Bosman et al., 2018a, 2018b). Conversely, in this study a small preference for device A was found at questions concerning the own voice or loud sounds. It may be explained by the fact that participants in this study are more accustomed to a diminished aided dynamic range due to the usage of a sound processor with relatively low MFO. The relatively short follow-up and probation periods might explain this finding.

Results from speech recognition in noise test showed significant better performance with device B for two of the tested SNR conditions. Four different stimuli levels with both positive and negative SNR were used in the test setup. The stimuli levels used in this study were louder than normal conversation level. Prior studies had showed that higher MFO is perceived to be most beneficial in noisier environments and the effect of higher MFO is supposed to be greatest at louder stimulus levels (Bosman et al., 2018a, 2018b). However, in daily life hearing aid users spend most of their time in environments with positive SNR and as much as half of their time in relatively quiet environments (Smeds, Wolters, & Rung, 2015). Although, hearing speech in a noisy environment is of high importance for many people with hearing loss (Wolters, Smeds, Schmidt, Christensen, & Norup, 2016). The HINT setup cannot be comparable to all real-life experience, but it can be an indication that higher MFO can be beneficial for perception of loud speech in a noisy environment, for instance in a restaurant environment or at a party. Moreover, the results are consistent with a previous study that also concluded that higher MFO improved speech recognition in noise (Bianchi et al., 2019).

A strength with this study is the cross-over design, using this methodology both devices used in the study are new for the patient. Furthermore, differences between the two devices are only the level of MFO, weight and size. The ABA-design was chosen based on prior experience from the manufacture, indicating that when patients shift from a sound processor with higher MFO to one with lower MFO, greater differences are experienced compared to the reverse order. With this design all participants had opportunity to shift both from and to a Super Power device. A further extension of this design is the ABAB setup. This setup provides additional opportunity to participants with the reimplantation of both interventions. It is however unclear to what degree different setup might change our results. A limitation with this study is the lack of blinding. It was not possible to blind the participant during the trials due to the different size of the sound processors. The size of the sound processor was also a part of the research question. Blinding researcher during the sound-field measurements could have been possible but was not done of practical reasons.

All participants in this study have a hearing loss that is within the fitting range of device A according to the guidelines from the manufacture (PTA 0,5, 1, 2 and 3kHz BC threshold $\leq$45 dB HL). The PTA limit for inclusion was set to 40 dB HL to confirm that the gain prescription in both sound processors would be similar. Due to miscalculation one participant with a BC PTA of 41,3 dB HL was included in the study. The PTA is higher than the limit for inclusion but still in the fitting range of device A and the gain was not affected. Nevertheless, all sound processors for BAHS has an MFO that diminish the aided dynamic range of hearing. According to van Barneveld et al. (2018) the smallest acceptable remaining dynamic range of hearing is 35 dB. With this criterion, patients with a sensorineural hearing loss at the level of >30-35 dB HL should not be fitted with a standard sound processor as device A. Some of the participants in this study had a larger sensorineural loss. However, no connection was found between the degree of hearing loss and device selection at the end of the study.

In summary, the results from this study have showed that patients with mild mixed hearing loss benefits more from higher MFO in the BAHS sound processor. The only disadvantage with higher MFO is that it entails a larger sound processor. Consequently, all users of BAHS with mild mixed hearing loss should be recommended a Super Power device. The result from this study can serve as support for audiologists and patients in the decision on treatment options and in the counselling of the patient group.

In future studies evaluating the effect of higher MFO in bone conducted devices, it would be of interest to evaluate different indications such as single sided deafness and conductive hearing losses. The methodology could also be developed with longer trials, speech intelligibility tests at other levels of speech/SNR and perhaps using other outcome measurements.

Conclusion

Higher MFO in BAHS sound processors allow improvement of speech intelligibility in sound demanding environments in subjects with mixed hearing loss. In addition, higher MFO are perceived as beneficial to receive spatial information. However, as we could see in this study the design and size of the BAHS sound processors will play an important role when choosing in-between two sound processors for many users and for some users cosmetic factors will be more important than higher MFO.

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Appendix

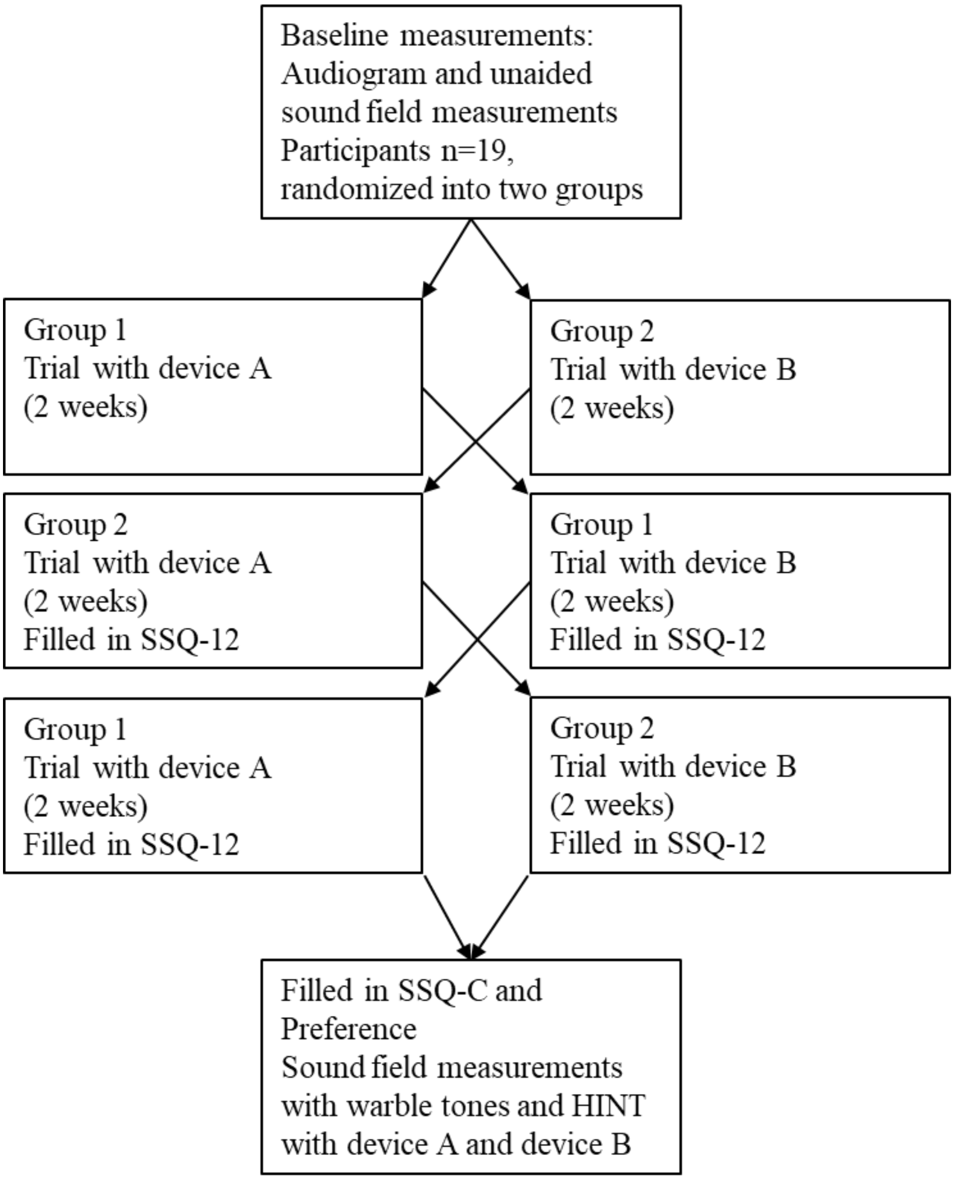

Figure 1. Flowchart of the procedure. Group A n=9 subjects, group B n=10 subjects.

Table 1. Demographic data of the study group

Participant	Age	Gender	Reason for hearing loss	Implanted side	Prior device	Device opposite ear
1	73	Male	Mastoidectomy	Right	OM Ponto Pro P	Phonak Ambra H20
2	65	Female	Otosclerosis	Right	OM Ponto Pro	Unaided
3	55	Male	Mastoidectomy	Left	OM Ponto Pro	Unaided
4	61	Female	Mastoidectomy	Left	OM Ponto Plus P	Signia Pure 7 mi
5	71	Male	Mastoidectomy	Left	OM Ponto Plus	Unaided
6	64	Female	Mastoidectomy	Left	OM Ponto Plus	Unaided
7	67	Female	Mastoidectomy	Right	OM Ponto Pro P	Unaided
8	76	Male	Mastoidectomy	Left	OM Ponto Plus P	Unaided
9	70	Male	Mastoidectomy	Left	OM Ponto Pro P	Phonak Audéo V90
10	72	Female	Mastoidectomy	Left	OM Ponto Pro	Unaided
11	69	Male	Mastoidectomy	Left	Cochlear Baha 5	Unaided
12	63	Male	Mastoidectomy	Right	OM Ponto Pro P	Unaided
13	69	Female	Mastoidectomy	Left	OM Ponto Plus	Unaided
14	72	Male	Mastoidectomy	Left	Cochlear Baha 5	Phonak Bolero V90M
15	68	Female	Chronic otitis	Right	OM Ponto Plus	Oticon H330 minirite
16	67	Male	Mastoidectomy	Left	Cochlear Baha 5	Phonak Audéo V90
17	72	Male	Chronic otitis	Left	OM Ponto Plus P	Oticon Alta 2 Pro
18	68	Male	Otosclerosis	Right	Cochlear Intenso	Phonak Ambra microP
19	46	Female	Atresia	Left	OM Ponto Plus	Siemens Motion SX
Total	**Mean (SD): 66,74 (6,97) Median (min-max): 68 (46-76)**	**11 men 8 women**	**15 mastoidectomy, 2 otosclerosis, 1 chronic otitis, 1 atresia**	**6 right 13 left**	**15 Oticon Medical 4 Cochlear**	**9 bimodal 10 unaided**

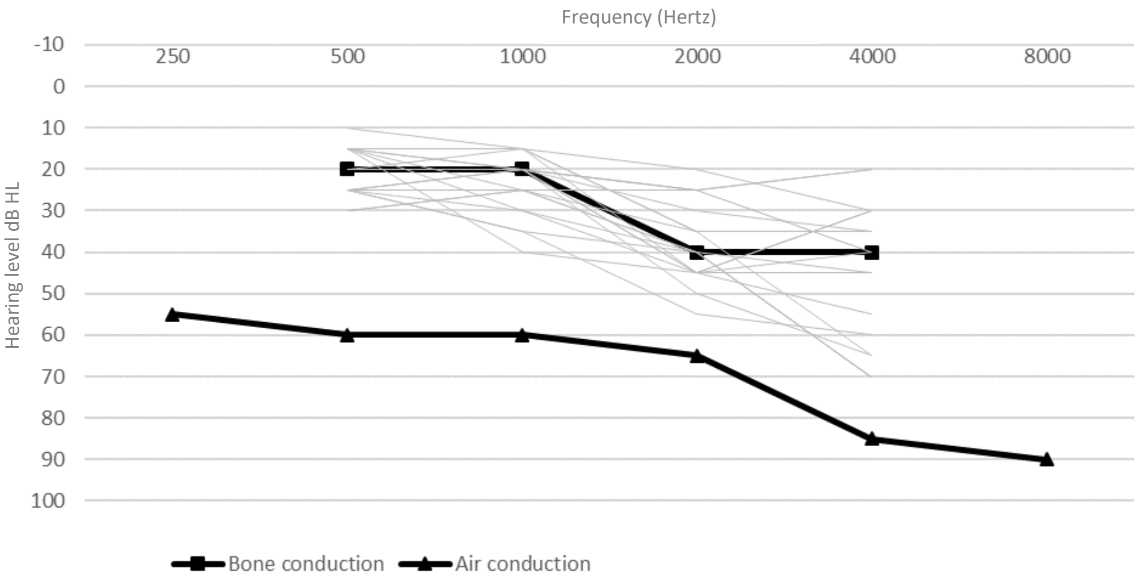

Figure 2. Bone conduction (BC) thresholds on the implanted side (measured with pure tone audiometry) of the nineteen participants included in the study displayed in grey. Median scores of unaided hearing thresholds for air and bone conduction on the implanted side depicted by the black curves.

Table 2. Pure tone average (PTA) for each participant

Participant	PTA air (0.5, 1, 2, 3kHz) (dB HL)		PTA bone (0.5, 1, 2, 3 kHz) (dB HL)			PTA (0.5, 1, 2, 3 kHz) Bone in-situ (dB HL)	
	Fitted ear	Opposite ear	Fitted ear (unmasked)	Fitted ear (masked)	Opposite ear (masked)	Device A	Device B
1	58.8	50.0	21.3	22.5	30.0	13.8	11.3
2	60.0	>110	33.8	-	>70	28.8	28.8
3	61.3	21.3	21.3	30.0	23.8*	18.8	17.5
4	87.5	52.5	31.3	43.8	35.0	31.3	30.0
5	78.8	27.5	28.8	35.0	26.3*	26.3	25.0
6	41.3	35.0	21.3	22.5	22.5	13.8	13.8
7	68.8	23.8	25.0	32.5	26.3*	22.5	27.5
8	75.0	40.0	38.8	52.5	33.8*	31.3	25.0
9	73.8	43.8	40.0	46.3	38.8*	37.5	33.8
10	43.8	20.0	23.8	31.3	25.0*	16.3	21.3
11	55.0	61.3	30.0	31.3	37.5	22.5	25.0
12	63.8	>110	31.3	-	>70	32.5	31.3
13	55.0	36.3	33.8	37.5	31.3*	28.8	30.0
14	62.5	36.3	33.8	40.0	38.8*	26.3	27.5
15	62.5	52.5	30.0	31.3	38.8	35.0	28.8
16	77.5	41.3	41.3	45.0	37.5*	37.5	37.5
17	58.8	62.5	36.3	38.8	43.8	33.8	33.8
18	85.0	56.3	38.8	45.0	45.0	45.0	41.3
19	97.5	22.5	28.8	36.3	23.8*	25.0	23.8
Total: **Mean (SD)** **Median** **(min-max)**	 **66.7 (14.5)** **62.5** **(41.3-97.5)**	 **47.5 (25.7)** **41.3** **(20->110)**	 **31.0 (6.4)** **31.3** **(21.3-41.3)**	 **36.5 (8.3)** **36.3** **(22.5–52.5)**	 **36.7 (13.6)** **35** **(22.5–70)**	 **27.7 (8.5)** **28.8** **(13.8–45)**	 **27.0 (7.5)** **27.5** **(11.3–41.3)**

** not masked due to overmasking or not applicable because of sensorineural hearing loss*

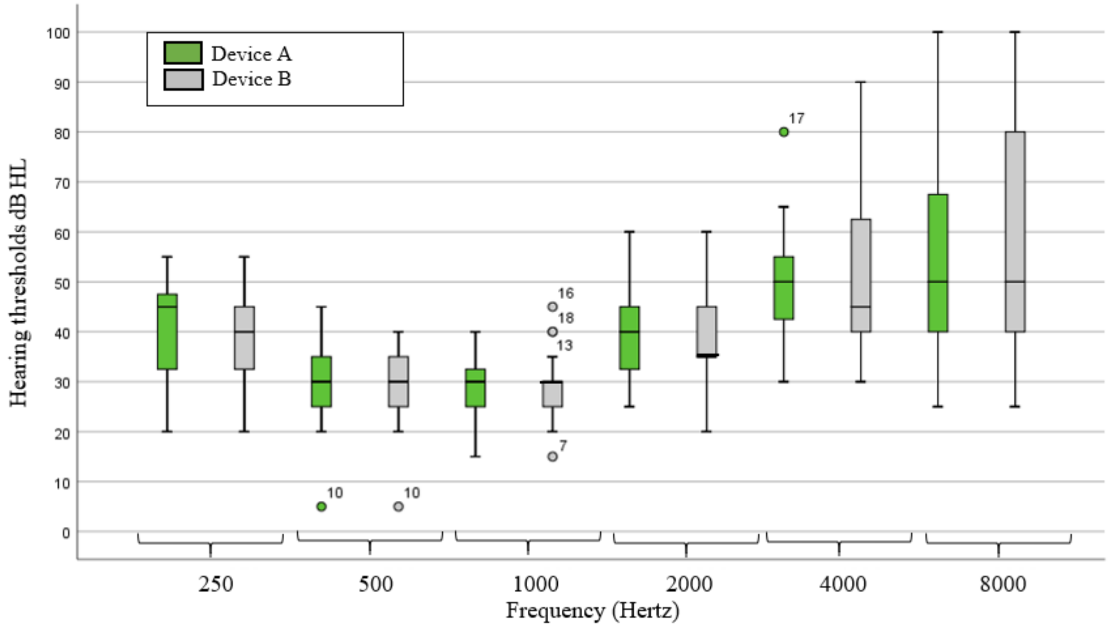

Figure 3. Results for aided sound field thresholds measured with warble tones for device A and device B. The whiskers display minimum and maximum values, excluding outliers. Outliers are depicted by a circle and the boxes range from the first to the third quartile. There were no significant differences between the two devices at any frequency.

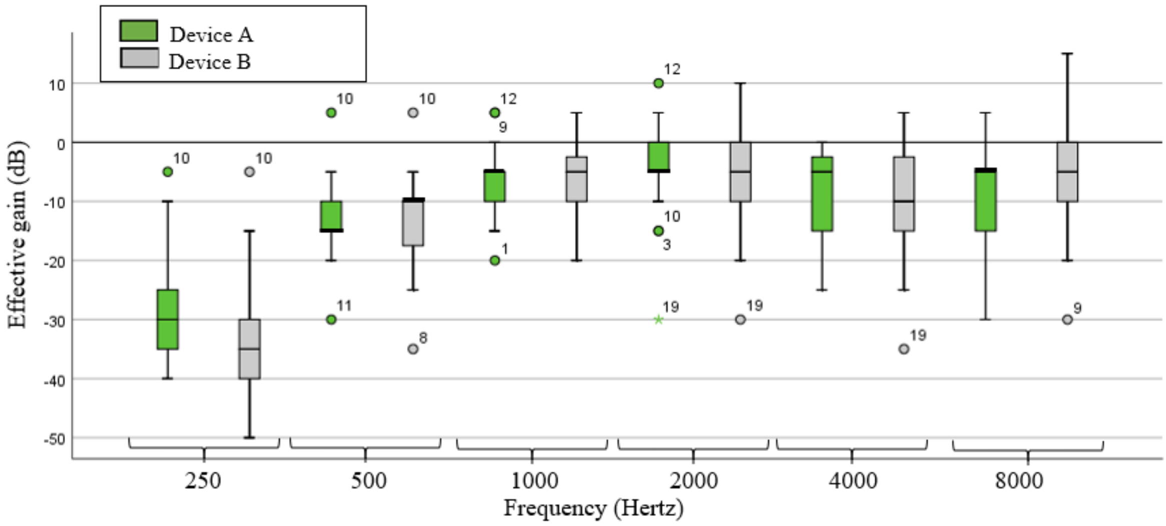

Figure 4. Effective gain (differences between bone in-situ and aided thresholds) displayed in the figure for each device expressed in dB. The whiskers show minimum and maximum values, excluding outliers. Outliers are depicted by a circle and extreme outliers are shown with an asterisk. The boxes range from the first to the third quartile. There were no significant differences between devices at any frequency.

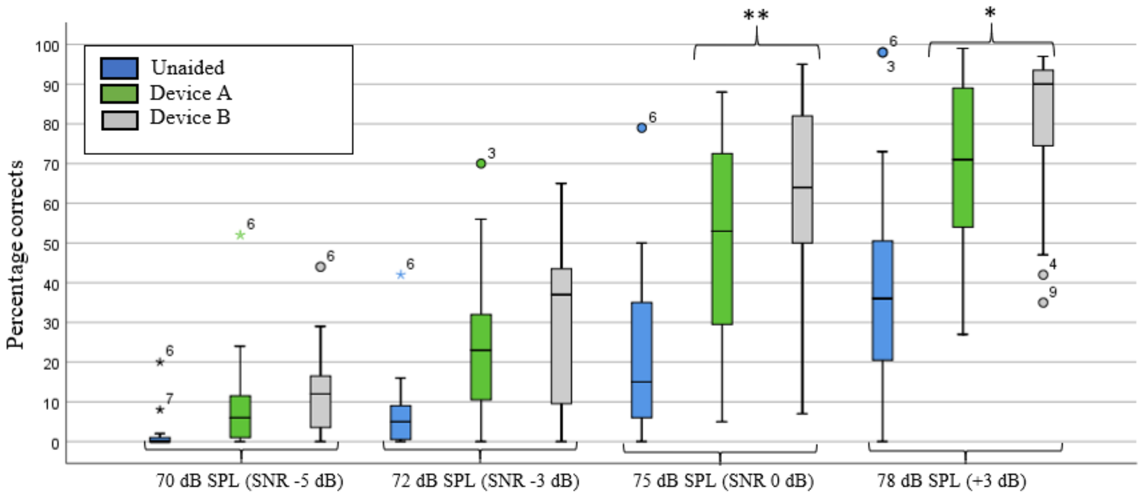

Figure 5. Hearing in noise test (HINT) results for unaided, device A and device B expressed in percentage correct repeated words. The whiskers show minimum and maximum values excluding outliers. Outliers are depicted by a circle and extreme outliers are shown with an asterisk. The boxes range from the first to the third quartile. The test resulted in significant better results for device B compared to device A at level 75 dB SPL (p=0.002) and 78 dB SPL (p=0.014).

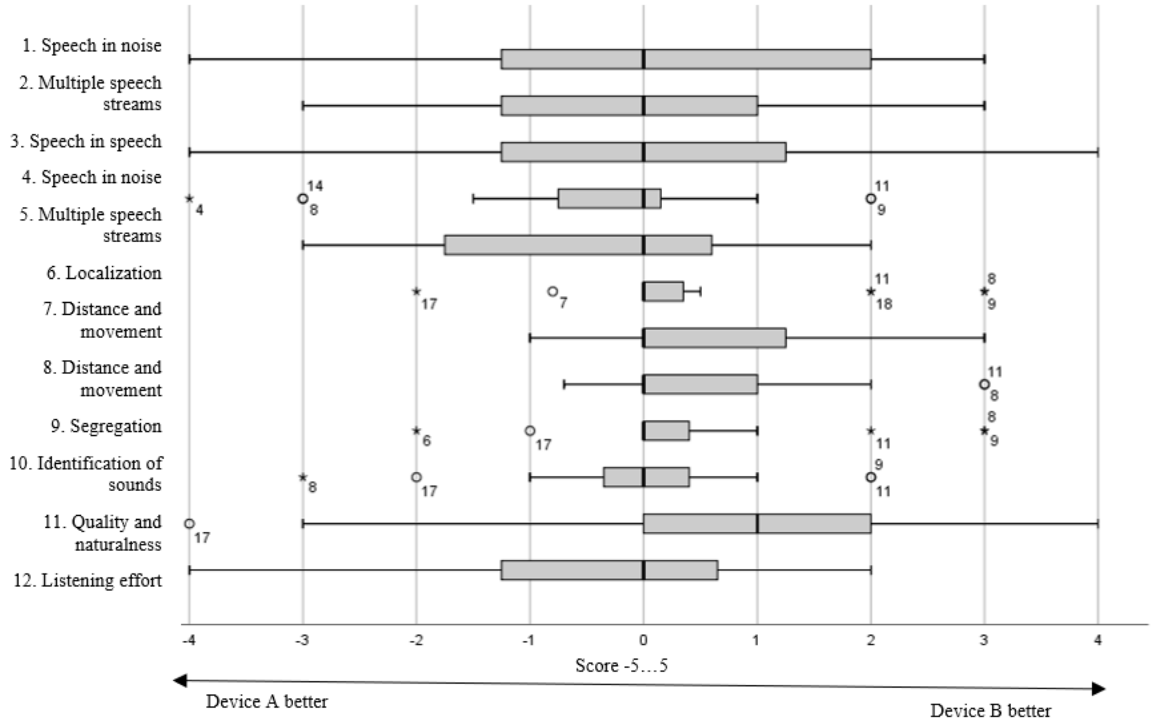

Figure 6. Results for the comparative version of Speech, of hearing scale (SSQ12-C). The whiskers show minimum and maximum values, excluding outliers. Outliers are depicted by a circle and extreme outliers are shown with an asterisk. The boxes range from the first to the third quartile. There was significant better result for device B compared to device A at question 6 localization (p=0.016) and question 7 distance and movement (p=0.043). There were no significant differences at the other questions.

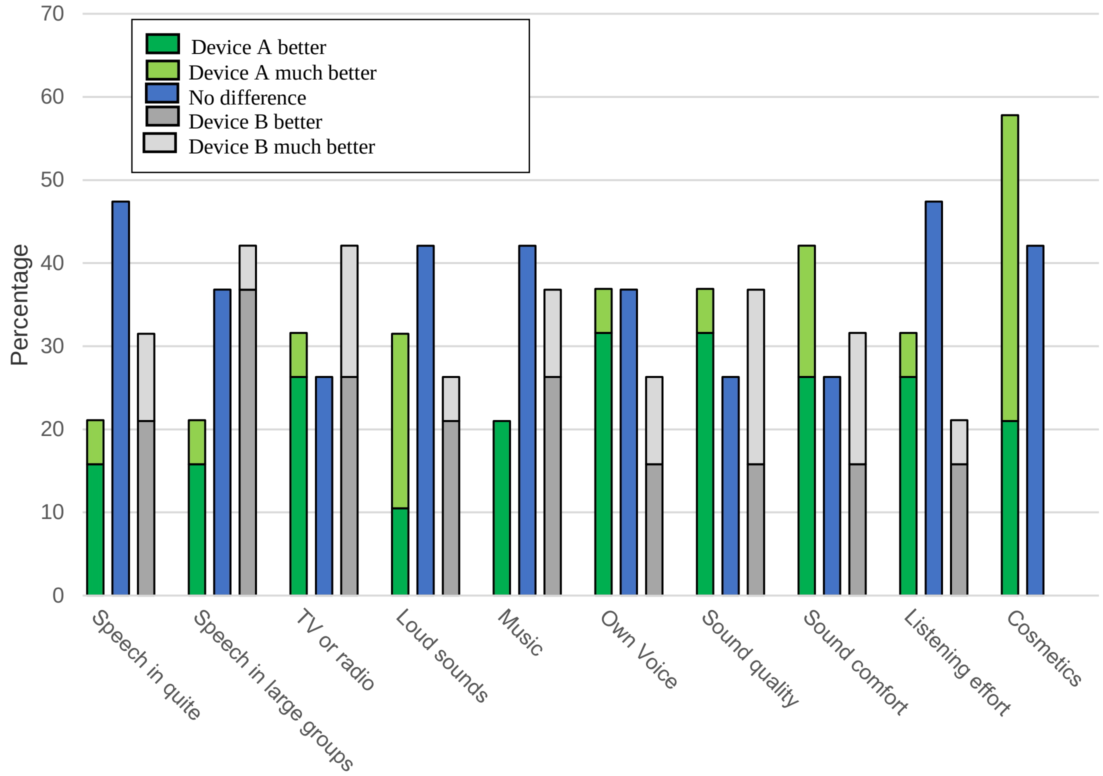

Figure 7. Device preference for ten categories, presented in how many percentages of the subjects that preferred respectively device in each category. Differences between the two devices were not significant at any question except the question concerning cosmetics (p<0.001).

SSQ12

Instructions

The following questions inquire about aspects of your ability and experience hearing and listening in different situations. For each question, put a mark, such as a cross (x), anywhere on the scale shown against each question that runs from 0 through to 10. Putting a mark at 10 means that you would be perfectly able to do or experience what is described in the question. Putting a mark at 0 means you would be quite unable to do or experience what is described. As an example, question 1 asks about having a conversation with someone while the TV is on at the same time. If you are well able to do this then put a mark up toward the right-hand end of the scale. If you could follow about half the conversation in this situation put the mark around the mid-point, and so on.

1. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow what the person you're talking to says?	Not at all — Perfectly 0 1 2 3 4 5 6 7 8 9 10
2. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying?	Not at all — Perfectly 0 1 2 3 4 5 6 7 8 9 10
3. You are in conversation with one person in a room where there are many other people talking. Can you follow what the person you are talking to is saying?	Not at all — Perfectly 0 1 2 3 4 5 6 7 8 9 10
4. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation?	Not at all — Perfectly 0 1 2 3 4 5 6 7 8 9 10

5. You are with a group and the conversation switches from one person to another. Can you easily follow the conversation without missing the start of what each new speaker is saying?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
6. You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
7. Can you tell how far away a bus or a truck is, from the sound?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
8. Can you tell from the sound whether a bus or truck is coming towards you or going away?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
9. When you hear more than one sound at a time, do you have the impression that it seems like a single jumbled sound?	Jumbled … Not jumbled 0 1 2 3 4 5 6 7 8 9 10
10. When you listen to music, can you make out which instruments are playing?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
11. Do everyday sounds that you can hear easily seem clear to you (not blurred)?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10
12. Do you have to concentrate very much when listening to someone or something?	Not at all … Perfectly 0 1 2 3 4 5 6 7 8 9 10 Min … Max

SSQ12-C

1. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow what the person you're talking to says?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
2. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
3. You are in conversation with one person in a room where there are many other people talking. Can you follow what the person you are talking to is saying?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
4. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
5. You are with a group and the conversation switches from one person to another. Can you easily follow the conversation without missing the start of what each new speaker is saying?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
6. You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look?	A much better No difference B much better -5 -4 -3 -2 -1 0 1 2 3 4 5

7. Can you tell how far away a bus or a truck is, from the sound?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
8. Can you tell from the sound whether a bus or truck is coming towards you or going away?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
9. When you hear more than one sound at a time, do you have the impression that it seems like a single jumbled sound?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
10. When you listen to music, can you make out which instruments are playing?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
11. Do everyday sounds that you can hear easily seem clear to you (not blurred)?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5
12. Do you have to concentrate very much when listening to someone or something?	A much better / No difference / B much better -5 -4 -3 -2 -1 0 1 2 3 4 5

Preference

1. Hear conversation in quiet environments

A much better A better No difference B better B much better

2. Hear conversations in large groups, for instance at a party

A much better A better No difference B better B much better

3. Listening on TV or radio

A much better A better No difference B better B much better

4. Loud sounds or noise

A much better A better No difference B better B much better

5. Listening to music

A much better A better No difference B better B much better

6. Own voice

A much better A better No difference B better B much better

7. Sound quality

A much better A better No difference B better B much better

8. Sound comfort

A much better A better No difference B better B much better

9. Listening effort

A much better A better No difference B better B much better

10. Device appearance

A much better | A better | No difference | B better | B much better

11. Which device do you want to use in daily life, considering hearing ability, sound experience and appearance?

Device A | Device B

The main reasons for your choice

1.____

____

2.____

____

3.____

____