

Are open-fit hearing aids a possible alternative to bone-anchored hearing devices in patients with mild to severe hearing loss? A preliminary trial

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Abstract

Open-fit hearing aids (OFHAs) may be of benefit for some individuals with chronic outer and middle ear conditions for which bone-anchored hearing devices (BAHDs) are normally recommended. The purpose of this study was to compare performance between OFHAs and BAHDs. A Starkey Destiny 800 OFHA was fit on eight adult BAHD users and speech perception measures in quiet and in background noise were compared under two different test conditions: i) BAHD only and ii) OFHA only. Equivalent outcome measure performance between these two conditions suggests that the OFHA was able to provide sufficient amplification for mild to moderate degrees of hearing loss (pure-tone averages (PTAs) less than 47 dB HL). The improved speech perception performances and increased loudness ratings observed for several of the participants with moderately-severe to severe degrees of hearing loss (PTAs of 47 dB HL or greater) in the BAHD only condition suggest that the OFHA did not provide sufficient amplification for these individuals. Therefore, OFHAs may be a successful alternative to the BAHD for individuals with no more than a moderate conductive hearing loss who are unable or unwilling to undergo implant surgery

or unable to wear conventional hearing aids due to allergies, irritation, or chronic infection associated with the ear being blocked with a shell or earmold.

Introduction

Most individuals with hearing loss can benefit from conventional air-conduction hearing aids (HAs), which are traditionally placed partially or completely in the ear canal.¹ For some types of hearing losses, however, conventional HAs may not provide maximal benefit or are impossible to fit.² For example, individuals with a chronic conductive hearing loss in combination with aural abnormalities are particularly difficult to fit with conventional HAs. Some individuals are not able to wear conventional HAs due to allergies to hearing aid shells or earmolds, chronically draining ears, irritation or infection. Middle ear infections, or otitis media, that fail to respond to treatment often result in persistent and unpleasant discharge. In some instances, infections can be successfully managed in conventional HA patients. However, most consistently recur as the conventional HA obstructs the canal, resulting in excessive humidity and lack of drainage, which may provoke and aggravate the infection, possibly leading to otorrhea and long-term cochlear damage.^{3,4} Many individuals also suffer from recurrent external ear canal problems, or otitis externa, such as discomfort, itching and moisture, that results from wearing an earmold.⁵ For these patients, a bone-anchored hearing device (BAHD) can be used instead.

The BAHD system bypasses the conductive mechanisms of the external auditory canal and middle ear and stimulates the functioning hair cells of the cochlea directly.⁶ The BAHD system provides beneficial outcomes for those persons with a conductive or mixed hearing impairment caused by a chronic infection of the middle or outer ear by significantly reducing ear discharge and irritation.⁷ The BAHD can also offer some relief of the occlusion effect, which is a discomfort involving a hollow or echoing sound that some individuals experience with conventional HA use, especially with their own voice.^{5,8} However, this system also requires a short surgery where a titanium fixture is implanted to osseointegrate into the mastoid bone of the skull. Some individuals may not have access to this specialized surgery or follow-up care because of distance or financial constraints. Existing health conditions or co-morbidities may also prevent or exclude some candidates from undergoing surgery.

In recent years, hearing aid manufacturers have developed air-conduction hearing aids that utilize an open-fitting approach. Open-fit behind-the-ear hearing aids deliver amplified sound via a thin tube that fits in the ear leaving the ear canal minimally occluded. Although open-fit hearing aids (OFHAs) have not been developed for individuals with chronic outer and middle ear conditions, they may be of some

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benefit to those patients who would normally be candidates for BAHDs. This may be of particular importance when considering patients in regions where the specialty BAHD device and/or surgical services are not available or beyond a candidate's financial means.

Several studies have investigated the benefits of OFHAs compared to conventional HAs. The results reveal advantages for problems related to occlusion, voice quality, wearer comfort, sound localization, telephone usability, size, clearness and natural sound quality.^{9,10} However, to date no studies have compared the performance of OFHAs to the BAHD. As OFHAs minimally occlude the ear canal, it may be possible to fit them on some patients who would normally be BAHD candidates due to conductive problems and pathologies related to the outer ear. While in many cases there may be medical indications for choosing a BAHD over an OFHA, this preliminary investigation was designed to determine if there were audiological performance differences in a group of existing BAHD users. Specifically, we were interested in the following research question: Are OFHAs a viable audiological alternative for individuals with mild to severe hearing loss who are unable or unwilling to undergo BAHD implant surgery or unable to wear conventional HAs due to allergies, irritation, or chronic infection associated with the ear being blocked with a shell or earmold?

Materials and Methods

Participants

Eight adults, three males and five females, fitted with BAHDs participated in the study. Length of time since initial BAHD fitting varied

from two months to four and a half years, with an average BAHD usage time of 2.4 years. Participants were between the ages of 37-61 with a mean age of 49 years. Attempts were made to recruit BAHD users with external ear conditions, such as irritation or allergies, that prevented them from wearing an occluding mold, but who still required amplification due to a conductive loss. Individuals participating also possessed an external ear structure, including pinna and canal, on which it was physically feasible to fit an OFHA. Participants exhibited mild to severe conductive or mixed hearing losses, with PTAs at 0.5, 1, 2, 3 and 4 kHz of 36-77 dB HL air conduction and 17-51 dB HL bone conduction thresholds in the BAHD ear. All participants were native speakers of English. No compensation was provided and all subjects provided informed consent. Subjects were recruited through the Nova Scotia Hearing and Speech Centre, Dickson Building Site. This study underwent research ethics review at Dalhousie University. Participant characteristics and audiometric information are displayed in Tables 1-3 and Figure 1.

Procedure

Participants first underwent otoscopy and a hearing assessment where thresholds at 0.25, 0.5, 1, 2, 3 and 4 kHz were measured for both air and bone conduction, and 6 and 8 kHz for air conduction only. All audiometric testing was conducted in a double-walled IAC sound-attenuated booth. Initial attempts to program the OFHA, a Starkey Destiny 800 model, were guided by NAL-NL1. However, due to hearing loss severity, NAL-NL1 fitting targets were not met for five participants even with the OFHA set to maximum possible gain. Since no prescriptive rationale existed for BAHD (and the devices under test had little to no adjustability), and the OFHA could not reach NAL-NL1, the best statement we can make about the settings of the two technologies is that

Table 1. Participant characteristics.

Participant	Age (years)	Years of BAHD use	BAHD processor model*	AC PTA BAHD ear (dB HL) ^o	BC PTA BAHD ear (dB HL) ^o	AC PTA non-BAHD ear (dB HL) ^o
1	53	2	Divino	36	8	22
2	56	4	Compact	42	20	40
3	49	4.5	Compact	46	29	26
4	39	0.5	Compact	46	4	21
5	47	0.2	Divino	47	34	9
6	37	4.5	Compact	51	11	51
7	50	2	Divino	70	19	12
8	61	1.5	Divino	77	43	41
Average	49.0	2.4		48.0	21.0	27.8

*All Cochlear™ Baha® models; ^oPTA, pure tone average at 0.5, 1, 2, 3 and 4 kHz. BAHD, bone-anchored hearing device.

Table 2. Pure tone air conduction thresholds of ear with bone-anchored hearing device (dB HL).

Participant	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
1	40	40	40	35	35	30	40	45
2	40	40	45	35	40	50	60	65
3	40	50	55	50	40	35	25	20
4	35	35	45	55	50	45	35	45
5	50	40	25	30	60	80	90	95
6	60	60	60	55	45	35	35	45
7	80	75	75	60	65	75	65	90
8	70	80	65	75	80	85	95	-
Average	48.3	45.0	43.3	46.7	51.7	53.3	53.3	61.7

they were as good an approximation as could be achieved with the devices available for this study. The OFHA was fit on the same side or ear on which the BAHD was worn. The OFHA model used, the Starkey Destiny 800, was a behind-the-ear open-fit design with a receiver located within the body of the aid opposed to in the canal. Receiver-in-the-canal (RIC) OFHAs are becoming increasingly popular, with power receivers allowing for increased maximum gain, particularly in the high frequencies.¹¹ An RIC OFHA was not utilized in this study as it was postulated that a large number of participants would have moist or draining ears, which may lead to damage of the in-canal receiver, making it a less viable option.

Immediately following these unaided, baseline audiograms and OFHA fittings, three speech perception measures in quiet and in background noise were compared under two different test conditions: i) the BAHD only and ii) the OFHA only. The order of the test conditions was randomized between participants. In the BAHD only condition, participants were asked to set the volume of the device to their most comfortable listening level.

The first of the speech perception tests was the QuickSIN, also known as the Quick Speech-in-Noise Test, which quantifies an individual's signal to noise ratio loss (SNR loss).¹² The QuickSIN administration involves presenting six pre-recorded sentences, each containing five key words. Each of the six phrases is presented at differing signal-to-noise ratios (SNR), decreasing in 5 dB steps from 25. The test uses four-talker babble as noise, with one male and three females, to be rep-

resentative of real-world environments such as social gatherings. One point is given for each key word in each sentence that is correctly repeated. The number of key words correctly identified from the list of six sentences is then totaled and used to calculate the SNR loss. SNR loss is defined as the dB increase in signal-to-noise ratio required by a person with hearing loss to understand speech in noise, compared to someone with normal hearing. A score less than 2 dB SNR loss is considered normal (participant able to hear normal or near normal in noise).¹³

Three lists of six sentences each were presented in each of the testing conditions (*i.e.*, the BAHD only and the OFHA only) and the SNR loss scores averaged. The literature accompanying the QuickSIN Version 1.3 assessment states that a 95% confidence level is more common for reporting research results to reduce risk of error; whereas, an 80% confidence level is adequate for clinic testing as the results are used in context with other factors.¹² Therefore, using an 80% confidence interval and considering the number of lists (3) administered for each condition, a critical difference of 1.8 dB is appropriate to evaluate the experimental results. It is important to improve reliability, especially when comparing multiple test conditions, by averaging the SNR loss scores of several QuickSIN lists. The QuickSIN was administered to the participants via soundfield and the speech sound level set at 70 dB HL, so as to be perceived as loud, but not uncomfortable.

The second speech perception measure included word recognition scores (WRS) using the Northwestern University Auditory Test No. 6,

Table 3. Air-bone gap of ear with bone-anchored hearing device (dB HL).

Participant	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	A-B gap PTA BAHD ear (dB HL)*
1	40	35	35	30	25	15	28
2	35	30	25	20	10	25	22
3	30	20	30	10	15	10	17
4	30	35	45	45	45	40	42
5	25	5	15	10	15	20	13
6	60	50	45	40	35	30	40
7	75	70	55	40	50	40	51
8	60	40	35	30	35	30	34
Average	44.4	35.6	35.6	28.1	28.8	26.3	30.9

*PTA, pure tone average at 0.5, 1, 2, 3 and 4 kHz. BAHD, bone-anchored hearing device.

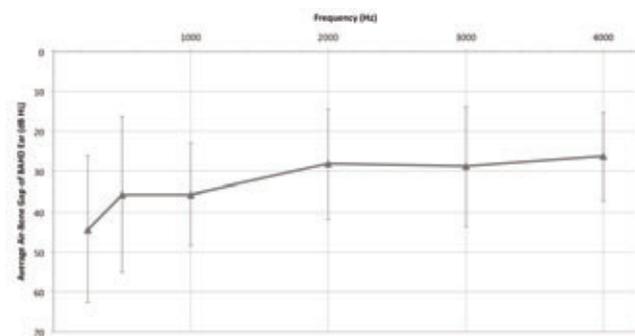


Figure 1. Average air-bone gap of the bone-anchored hearing device (BAHD) ear by frequency for all participants. Errors bars represent +/- one standard deviation.

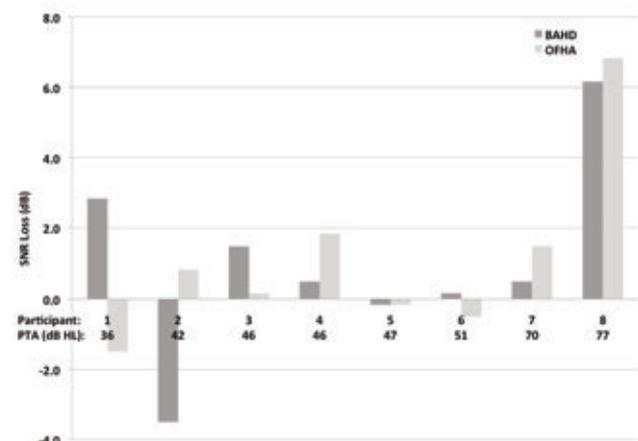


Figure 2. QuickSIN results for each participant for the open-fit hearing aid (OFHA) and bone-anchored hearing device (BAHD) conditions. A score below 2 dB SNR loss is considered normal (able to hear normal or near normal in noise).

or the NU-6. Lists of fifty pre-recorded monosyllabic words were administered at 50 dB HL in multitalker noise with a SNR of +5 in soundfield and the percentage of words correctly repeated was calculated.

Critical difference ranges for NU-6 speech recognition measures were based on a binomial distribution probabilistic model adapted from Thornton and Raffin.¹³ Sensitivity is proportional to the number of trials or test items administered, with performance variability highest in the middle range scores and lowest at the extreme ranges of scores. Test scores reflected the percentage of stimuli correctly perceived. All scores were plotted on the Speech Recognition Interpretation (SPRINT) chart for 50-word NU-6 lists to determine if the results were significantly different at a 95% confidence level.¹⁴ Lastly, a Contour Test was performed to document loudness judgment of real speech.¹⁵ Normal loudness perception is an important consideration when evaluating the effectiveness of hearing aid and BAHD fittings.¹⁵ The goal is to obtain functions that correspond roughly to the loudness ranges of normal hearing listeners. That is, after amplification, soft sounds should be audible, average sound should be comfortable and loud sounds should be loud, but not uncomfortable.¹⁵ The Loudness Contour Test was used to quantify and compare the loudness growth function for amplified sounds. An Auditec of St. Louis' recording of Male Discourse was presented via soundfield to the participants at intensity levels of 30, 50, and 70 dB HL, with the level changed only after the participant had rated it. The participant was asked to give a loudness judgment for each presentation level using the following categories of loudness: 1. very soft; 2. soft; 3. comfortable, but slightly soft; 4. comfortable; 5. comfortable, but slightly loud; 6. loud, but OK; 7. uncomfortably loud and 8. extremely uncomfortable.

When a standardized method is consistently applied to contour loudness scaling, the reliability can be similar to that of clinical threshold testing.¹⁶ And although test-retest reliability varies with gender, sequencing effects, loudness categories, stimuli type, and increment size, individual differences for hearing impaired listeners generally remain less than 10 dB for all categories.^{16,17} For this study, a conservative difference rating of 2 was used to determine if there was a critical loudness difference between the OFHA and BAHD.^{18,19}

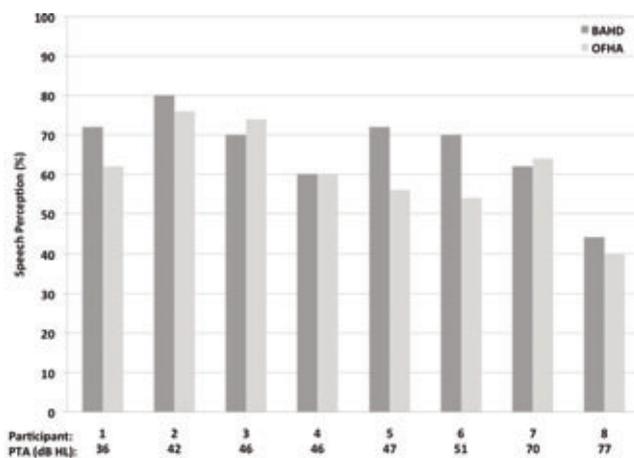


Figure 3. NU-6 speech perception results for each participant for the open-fit hearing aid (OFHA) and bone-anchored hearing device (BAHD) conditions.

Results

For the QuickSIN, a critical difference of 1.8 dB SNR was used to determine if one test condition was clinically different from the others.¹² As shown in Figure 2,¹² only Participants 1 and 2 had different QuickSIN results between test conditions. Participant 1 performed better with the OFHA than with the BAHD whereas Participant 2 performed better with the BAHD. The rest of the participants showed similar performance with each condition.

For the NU-6 speech recognition measures, a critical difference of 16% was used to determine if a performance was clinically different from the others.¹⁴ As shown in Figure 3, only Participants 5 and 6 had different NU-6 results between test conditions, both considerably better with the BAHD than the OFHA alone. The rest of the participants showed similar performance in word recognition ability between the two test conditions. For the Contour Test, a critical difference of 2 was used to determine if a loudness rating was clinically different from the other test conditions. As shown in Figure 4, at 30 dB HL presentation levels, Participant 8 considered the BAHD alone to be louder than the OFHA condition. At 50 dB HL, Participants 6, 7 and 8 perceived the BAHD to be considerably louder than the OFHA. This is detailed in Figure 5. At 70 dB HL presentation levels, Participant 6 found the OFHA alone to be quieter than the BAHD condition. This is shown in Figure 6. The rest of the participants showed similar ratings with each condition at the three levels.

Discussion

The purpose of this study was to determine if OFHAs were a viable solution for those patients who have mild to severe conductive hearing losses and who are not able to wear conventional hearing aids or easily obtain a BAHD.

The QuickSIN results, for the most part, indicated few differences between test conditions. Participant 1 performed better with the OFHA,

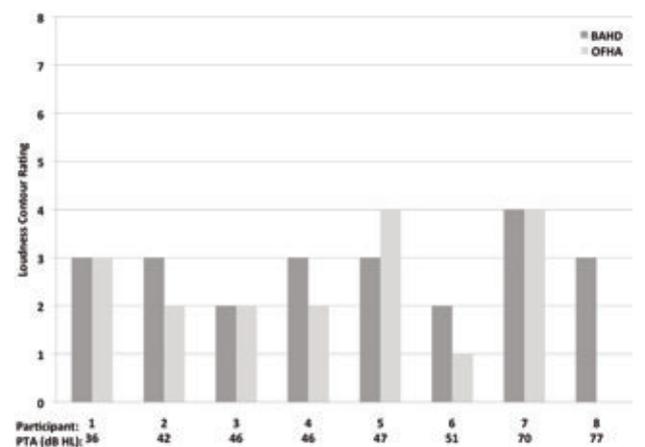


Figure 4. Loudness contour test results at 30 dB HL for each participant for the open-fit hearing aid (OFHA) and bone-anchored hearing device (BAHD) conditions. Ratings defined as 1. very soft; 2. soft; 3. comfortable, but slightly soft; 4. comfortable; 5. comfortable, but slightly loud; 6. loud, but OK; 7. uncomfortably loud and 8. extremely uncomfortable.

but only had a mild conductive hearing loss with an air conduction PTA of 36 dB HL and an average air-bone gap or conductive loss of 28 dB HL. The fitting range of the hearing aid was likely better suited to this loss and provided adequate performance for this individual. Participant 2 had a moderate hearing loss with an air conduction PTA of 42 dB HL and an average air-bone gap of 22 dB HL; therefore, the OFHA should have provided adequate gain for equivalent speech recognition results between devices. The notably improved performance observed for the BAHD condition may be due to sound quality bias and/or amplification experience.²⁰ Measured objective benefits may have changed if available resources permitted participants a period of adjustment or acclimatization with the newly fitted OFHAs. The rest of the participants showed similar performance with each device.

The NU-6 results suggest that the OFHA offered little or no benefit for participants with losses of moderately-severe degrees or greater. Participants 5 and 6, with pure tone air conduction and air-bone gap averages of 47, 13 and 51, 40 dB HL respectively, performed considerably better with the BAHD than the OFHA. Participant 5 had a very small air-bone gap and within-normal-limit air conduction thresholds in the non-BAHD ear. The better or dominant ear may have contributed to improved performance measures. Participant 6 had a large air-bone gap of 40 dB in the BAHD ear and an air conduction PTA of 51 dB HL on the non-BAHD side. The BAHD was likely able to provide better access to the speech signal given the severity of the bilateral, conductive loss. In addition, the critical difference range of 16% from Thornton and Raffin¹³ is likely narrower as their model was based on wordlists in quiet, not a +5 SNR as was utilized in this study. More participants may have significant performance differences between conditions than what was noted with a 16% range.

Loudness Contour Test results showed a tendency for the BAHD condition to be perceived considerably louder for several of the participants with moderately-severe to severe losses. This was particularly evident for presentation levels of 50 dB HL. This finding is not surprising considering the gain limitations of the OFHA and the large average air-bone gap of 34-51 dB HL of participants 6, 7 and 8. Feedback difficulties were encountered reaching NAL-NLI targets for these individuals, resulting in a volume reduction, meaning less of the speech signal may have been audible than would be prescribed. The BAHD did not have to

accommodate this additional conductive loss as it bypasses the outer and middle ear. These results may also be explained by differences in the frequency response of each device. For example, the BAHD devices used in this investigation best amplify low to mid frequency sounds due to the mechanical resonant peak of the transducer.

The above speech perception and loudness results suggest that the Starkey Destiny 800 was able to provide reasonably similar audiological outcomes for some individuals with mild to moderate degrees of hearing loss (PTAs less than 47 dB HL). Participants 1, 2, 3 and 4 showed similar performances with the BAHD or OFHA for most measures. That said, several participants demonstrated clinically higher speech perception performances and increased loudness ratings in the BAHD test condition. Indeed, because of their degree of hearing loss and the OFHA gain limitation before feedback, most of these individuals did not receive the full amount of gain prescribed by NAL-NLI.

While these preliminary results with an OFHA may be encouraging, there are several areas to consider for future studies in this area. First, the frequency responses of the BAHD and OFHA were not matched according to any prescribed rationale. The OFHAs were fitted to NAL-NLI; but, at the time of this study, there was no prescriptive rationale available for setting the BAHD devices and matching for audibility. Related to that, the BAHD devices used in this investigation were non-programmable, which limited the investigators' ability to adjust the frequency responses of the devices. Therefore, it is quite likely that audibility differences existed in each of the patients between devices, which may in fact be the predominant reason for any observed differences in performance between conditions. As the degree of conductive loss (size of the air-bone gap) increased beyond the limits of the output capabilities of the OFHA, the relative performance with the BAHD should improve since the BAHD operates independently from the size of the air-bone gap. A future study where the audibility could be measured and controlled for may shed more light on a potential cut-off between size of air-bone gap and the performance differences between OFHAs and BAHDs.

This study was designed to simply address the audiological feasibility of using an OFHA instead of a BAHD for some patients. It is important to emphasize that there may be medical contraindications that preclude the use of a conventional HA even if the air-bone gap is fairly

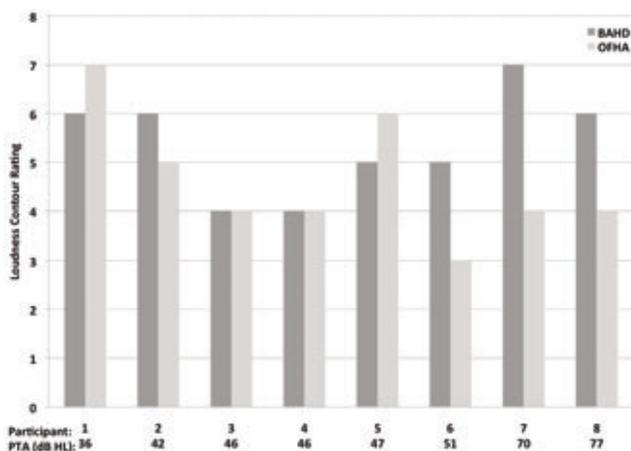


Figure 5. Loudness contour test results at 50 dB HL for each participant for the open-fit hearing aid (OFHA) and bone-anchored hearing device (BAHD) conditions. Ratings defined as 1. very soft; 2. soft; 3. comfortable, but slightly soft; 4. comfortable; 5. comfortable, but slightly loud; 6. loud, but OK; 7. uncomfortably loud and 8. extremely uncomfortable.

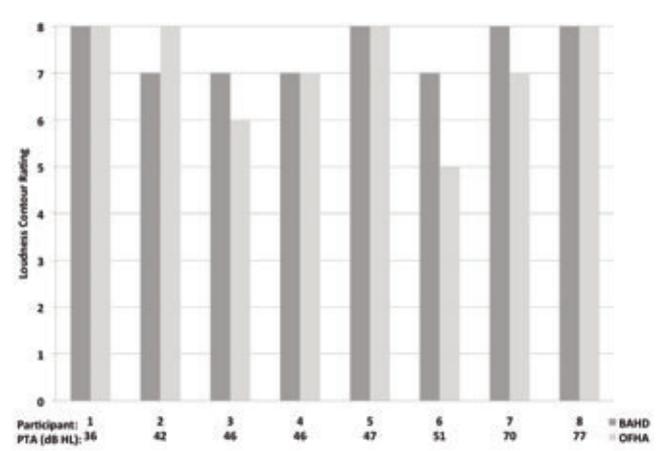


Figure 6. Loudness contour test results at 70 dB HL for each participant for the open-fit hearing aid (OFHA) and bone-anchored hearing device (BAHD) conditions. Ratings defined as 1. very soft; 2. soft; 3. comfortable, but slightly soft; 4. comfortable; 5. comfortable, but slightly loud; 6. loud, but OK; 7. uncomfortably loud and 8. extremely uncomfortable.

small. A future study should address the long-term medical complications that may arise for individuals with a history of ear disease using OFHAs.

However, this preliminary investigation does suggest that at least in this small group of subjects, if surgery or the BAHD was unappealing, unavailable, too expensive, financially prohibitive etc., it may be audiology feasible to consider an OFHA for some patients. Some individuals may be able to avoid waiting lists and the possible complications that accompany surgery (tissue maintenance, visits to specialty centers that may be a long distance from their home, etc.), while still receiving the benefits of amplification. More work is needed to sort out the cut-off between size of the air-bone gap and the medical contraindications for this technology. In addition, future work should attempt to better control for, or at least account for, audibility differences between technologies for a given hearing loss.

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