Estimating the benefit of a second bone anchored hearing implant in unilaterally implanted users with a testband

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Accepted - 03 November 2015

Running head: Benefit of a 2nd bone anchored implant

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source: https://doi.org/10.7892/boris.76283 | downloaded: 20.9.2024

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Abstract

Conclusion: Using a second bone anchored hearing implant (BAHI) mounted on a testband in unilaterally implanted BAHI users to test its the potential advantage preoperatively underestimates the advantage of two BAHIs placed on two implants.

Objectives: To investigate how well speech understaning with a second BAHI mounted on a testband approaches the benefit of bilaterally implanted BAHIs.

Method: Prospective study with 16 BAHI users. Eight were implanted unilaterally (group A) and eight were implanted bilaterally (group B). Aided speech understanding was measured. Speech was presented from the front and noise came either from the left, right, or from the front in two conditions for group A (with 1 BAHI, and with 2 BAHIs, where the second device was mounted on a testband) and in 3 conditions for group B (same two conditions as group A, and in addition with both BAHIs mounted on implants).

Results: Speech understanding in noise improved with the additional device for noise from the side of the first BAHI (+0.7 to +2.1dB) and decreased for noise from the other side (-1.8 dB to -3.9dB). Improvements were highest (+2.1dB, p=0.016) and disadvantages were smallest (-1.8dB, p=0.047) with both BAHIs mounted on implants. Testbands yielded smaller advantages and higher disadvantages of the additional BAHI (average difference -0.9dB).

Key Words: Bone anchored hearing aids, Baha, bilateral fitting, binaural benefit, speech in noise, testband

Introduction

A bone anchored hearing implants system (BAHI) consists of a retroauricularly implanted titanium fixture, a skin-penetrating abutment, and an externally worn speech processor, which can be adjusted and removed by the user [1]. BAHIs are widely used for the treatment of conductive or mixed hearing loss [2,3] and, more recently, also to overcome the acoustic head shadow effect in single-sided deafness [4-6]. They are used successfully in adults and in children [7-10].

In patients with a bilateral conductive or mixed hearing loss, BAHIs are often used bilaterally. Benefits of a bilateral fitting with BAHIs include improved speech understanding in noise and improved sound localisation. This has been shown repeatedly [11,12] and it is not a primary aim of this investigation to reproduce these results. One advantage of BAHIs is that they can be tested preoperatively in the patient's own environment using either a softband or a testband. Such trials are recommended by several authors [6,13].

At our centre, such preoperative trials with test bands are also routinely performed for unilateral BAHI users, who wish to evaluate the subjective benefit of a second BAHI. During these trials, we have observed repeatedly a lower benefit of the additional BAHI when compared to the situation later on, when the second BAHI was properly implanted. This may be due to the fact that sound transmission to the skull is different even for the same sound processor, depending on whether it is mounted on a testband or snapped to an abutment on a bone anchored implant [14,15]. Furthermore, as sound is transmitted with a relatively small attenuation from the implant to the contralateral inner ear and new feedback paths are created by a second BAHI, the fittings of both sound processors need to be adjusted during these trials and then, one more time, after the implantation of the second BAHI. This investigation has two aims. The first aim is to see, (i) how much unilaterally implanted BAHI users, who are potential be candidates for a second BAHI, benefit from a second sound processor on a testband in terms of speech understanding in noise. The second and probably more important aim is establish, (ii) whether speech understanding in noise improves, if this additional BAHI is placed on an implant rather than a testband.

Materials and Methods

Ethics and consent

The study was approved by the local ethical committee (application 184/13). All participants gave their informed consent prior to their inclusion. All procedures were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983.

Study population

16 adult BAHIs users participated in this investigation. All were German speaking and between 27 and 76 (mean 65.0 years) old. Seven were female, nine male. All subjects had a bilateral, mixed or conductive hearing loss and were regular BAHI users for at least 1 year at the time of the investigation. Eight subjects were unilaterally implanted with a BAHI (group A) and eight subjects were bilaterally implanted (group B). Data from experiments with both groups (A and B) were used to answer the above research question (i) and data from group B to answer research question (ii). All 16 subjects qualified for bilateral BAHIs, but only the subjects from group B actually decided to have two implants, whereas all subjects from group A declined. We believe that this approach of investigating two groups is more useful than a more straightforward comparison between preoperative results with a test band and postoperative results with a second BAHI, for two reasons: it allows the inclusion of subjects who decided against a second BAHI and it minimizes potential bias due to training, if the measurements with test bands are not performed systematically before any the measurements with two implanted BAHIs.

Although the unaided hearing thresholds of the two groups are similar (figure 1), we refrain from direct comparisons between the results of the two groups, as they differ in at least three features: their decision regarding a second implant, their average age (71.7 years for group A and 58.3 years for group B), and their speech understanding in quiet at low presentation levels (figure 2).

Study protocol

After otoscopy and inspection of the implant site, pure tone audiometry was performed in all subjects. Figure 1 shows the average bone conduction (BC) and air conduction (AC) thresholds of the two groups.

For group A, all of the measurements listed below were performed in 2 different conditions: with one BAHI on the implant (termed "1 BAHI") and with one BAHA on their implant and a second BAHI placed on the contralateral side with a testband (condition termed "1 BAHI + 1 Testband"). For group B, additional measurements were performed in a third condition with 2 BAHIs mounted on 2 implants, termed "2 BAHIs". For these bilaterally implanted subjects, in conditions "1 BAHI" and "1 BAHI + 1 Testband" the BAHI mounted on the implant was always on the side of the better

AC hearing thresholds (Figure 1). For group B and condition "1 BAHI and 1 Testband" the disc of the test band was placed close to the abutment but not touching it.

Baha 4 ® sound processors (Cochlear Bone Anchored Hearing Solutions, Mölnlycke, Sweden) were used for all experiments. None of the subjects was a regular user of this specific model. There were two reasons for using this new speech processor rather than the types already used by the subjects for some time. Firstly, we wanted to test the subjects in their best aided condition. Limited preliminary tests with six subjects showed that even immediately after the first fitting speech understanding in noise was better with the Baha 4 than with their own, older device. Secondly, we wanted to reduce the number of uncontrolled factors by using the same device for all subjects, rather the than the multitude of devices (Compact, Divino, BP100, BP110, Intenso, Ponto, Ponto pro) used by them.

The Speech processors were fitted using the Cochlear Baha fitting Software Version 4.0 SR1 for each subject and for each of the 2 or 3 aided conditions separately. BC-direct thresholds [16] through the sound processor and feedback limits were measured first, then the sound processors were fitted following the guidelines of the manufacturer. Settings for abutment / test band and for unilateral / bilateral fittings were set according the test condition in order to compensate bilateral summation across the skull and/or the additional skin attenuation when using a test band. Wind noise reduction was deactivated, the multi-microphone system was set to omnidirectional, but position compensation was activated. No fine adjustments were performed and for each fitting only a minimal adaption time of 15 minutes was given before testing started.

For all subjects and for each of the above conditions, speech understanding was measured in quiet and in noise. All measurements took place in sound proof chamber sized 6.0 x 4.1 x 2.2 m³ with an average reverberation time of 0.17 s. Subjects were seated and signal were presented through speakers (Control 1 pro, JBL Professional, Northridge CA, USA) at head level at a distance of 1 m from the subjects.

Speech understanding in quiet was measured using German monosyllabic words from the Freiburg test [17]. Two lists of 20 words each was presented at levels of 50, 65, and 80 dB SPL. Test words were always presented from the front.

For speech understanding in noise, a German adaptive matrix test (OLSA, [18]) was used. The test set consists of 40 lists with 30 sentences and speech babble noise with the same long-term frequency spectrum as the test sentences. This noise was presented at a fixed level of 65 dB SPL, and the test sentence level was adapted according to the algorithm proposed by the authors of the test to estimate the signal-to-noise ratio (SNR) for 50% word understanding in noise . Two training lists were presented to each subject before the actual testing started.

For all subjects and in all test conditions, speech understanding in noise was measured in three different spatial settings. Noise was presented either (1) from the front, (2) from the side of the testband or (3) from the side contralateral to the testband. The target sentences were always presented from the front.

The order of the test conditions, the order of the tests within each test condition, and the test list numbers were systematically varied between subjects in order to reduce effects of differences between lists, training or fatigue.

Statistical analysis

Statistical analysis was performed by a certified statistician (M.K.) using the Instat 3.10 software package (GraphPad, Inc., La Jolla, CA, USA). The non-parametric , two-sided Wilcoxon rank-signed test (for differences from 0) and the two-sided Wilcoxon matched pairs test (for comparisons between test conditions within a group) were used.

Results

Figure 1 shows the pure tone audiograms of the subjects. All subjects had a bilateral mixed or conductive hearing loss. The unilateral BAHI users of group A were all implanted in the ear with the poorer AC thresholds.

Figure 2 shows the aided speech understanding in quiet for both groups and 3 levels from 50 to 80 dB. Group A (unilaterally implanted subjects) performs, on average, worse at the lowest presentation levels (50 dB) than group B. Figure 2 shows also that for speech understanding in quiet and sound presentation from the front, the differences between the three conditions tested (1 BAHI, 1 BAHI + 1 Testband, 2 BAHIs) are small and not statistically significant for any group and at any presentation level.

Figure 3 shows the results for speech understanding in noise for the unilaterally implanted group A. The values shown are SNR improvements in dB, when a second BAHI on a test band is added. There is virtually no difference between 1 or 2 BAHIs for speech and noise coming from the front. However, if noise arrives from the side of the original BAHI, the second speech processor BAHI mounted on the test band on the less noisy side is helpful. The gain of +1.2 dB is statistically significant (p=0.039). If noise comes from the side of the testband, the effect of the second speech

processor is detrimental. The average loss in SNR of -3.9 dB is statistically significant (p=0.0078) and considerably larger than the gain in the contralateral spatial setting.

Figure 4 shows the results for the bilaterally implanted group B. The values shown are gains in SNR for the bilateral BAHI fittings when compared to the unilateral BAHI fitting (baseline). Similar to the results found for group A, there is no significant benefit from the second speech processor, if speech and noise arrive from the front (average gain -0.8 to +0.2 dB, p=0.69 to 0.94). If noise comes from the side contralateral to the testband, there is a small (+0.7 dB) and statistically not significant (p=0.38) benefit if the additional speech processor if is mounted on a testband, and substantially larger (+2.1 dB) and statistically significant (p=0.016) if it is placed properly on the implant. Similar to group A, there is a detrimental effect of the additional sound processor, if noise arrives from its side. The drawback is statistically significant (p=0.0078 to 0.047) and greater if the second speech processor is placed on a testband (-2.2 dB) than when it is mounted on the implant (-1.8 dB).

For group B, speech understanding in noise is always better if the additional speech processor is mounted on the implant than when it is placed on a test band. These differences are not statistically significant for any of the three spatial settings separately (p=0.38 to 0.94). Averaged over the three spatial settings (noise from the front, from the left and from the right) the SNR advantage of having the second BAHI mounted on the implant is +0.9 dB. Whereas there is an SNR advantage for the additional BAHI on the implant when averaged over all 3 spatial settings, there is an average disadvantage of -0.7 dB for an additional, second speech processor placed on a test band.

Discussion

The test results for speech understanding in quiet show basically the same speech understanding for 1 or for 2 BAHIs, no matter whether they are mounted on implants or on testbands. The prescription built into the fitting software by the manufacturer was used without modification. The built in correction reduces the gain in both devices in order to compensate for the additive effect of two devices driving both ears to a certain extent, even though the perceived level at the contralateral will, on average, be smaller than at the ipsilateral inner ear. Our results (figure 2) suggest that the extent of this compensation is chosen reasonably. Nevertheless, one could argue that a certain gain, mimicking the summation effect of normal bilateral hearing, might be useful.

For speech understanding in noise there is (1) almost no effect of an additional, second BAHI for noise from the front, (2) a benefit for noise from the side of the contralateral to the testband and (3) a detrimental effect for noise from the side of the testband, as expected. These findings hold for both study groups.

Our first research question was, (i) how much unilaterally implanted BAHI users, who might be potentially candidates for a 2nd BAHI, benefit from a 2nd processor on a test band in terms of speech understanding in noise. Figures 2 and 3 show that there is indeed a statistically significant benefit of +0.7 to +1.2 dB in SNR for both groups in a favourable spatial setting. Unfortunately, in an unfavourable spatial setting, the loss is also significant and generally even greater than the benefit (-2.2 to -3.9 dB). It is thus comprehensible that some candidates for a second BAHI may be disappointed after a trial. As in group A the implant was on the side of the poorer ear, and in group B it was on the side of the better ear, we believe that hearing asymmetry and the choice of the side of the first implant do not have an important effect.

It is well known that the performance of a bone conduction sound processors placed on a test band is, on average, poorer than the performance of the same processor placed on an implant (e.g. [14]). Nevertheless, in unilateral users there is usually a considerable advantage of having a device at least on a testband, rather than not using it at all. In our results, however, we encounter a different and new phenomenon: averaged over three spatially settings in noise, our subjects are, on average, worse off using an additional sound processor on a test band than not using a second device at all. This is a new and, to our knowledge, hitherto unreported finding.

The second research question was to establish, (ii) whether speech understanding in noise improves, if the second speech processor is placed on a properly implanted titanium fixture rather than a test band. As shown in figure 3, there is indeed an improvement in terms of speech understanding in noise. This advantage can be seen for noise arriving from any of the 3 directions tested and amounts, on average, to +0.9 dB SNR. The average benefit in the favourable spatial setting (+2.1 dB) is only then greater than the detrimental effect in an unfavourable setting (-1.8 dB), when both BAHIs are placed on implants. This may explain some of the general satisfaction of group B with their BAHIs in everyday life.

This investigation was not designed to find the reasons for the difference between the two different methods of attachment. However, it is well established that there is a considerable additional skin attenuation is with the test band, especially at frequencies above 2 kHz [14,15], which are important for speech understanding in noise. While a part of this attenuation may be compensated for by appropriate sound processor fitting [14], the highest possible output level at the inner ear and consequently the dynamic range will be smaller than with the implant. Generally, the gains in SNR are modest. There are probably several reasons for this. Firstly, bilateral BAHIs influence the contralateral ear more than bilaterally worn conventional hearing aids. Secondly, in our experiments no fine tuning of the fitting and no significant acclimatization time were provided. It is possible that these measures would further improve speech understanding with 2 BAHIs.

Note also that the benefit of two BAHIs in everyday life is not limited to improvements in speech understanding in noise, but encompasses also the alleviation of the head shadow effect if a speaker is standing at the wrong side of the BAHI user and improved sound localization [11,12], which were not investigated here.

Currently there is no other simple method to estimate the effect of a second BAHI than to test it on a test band or a soft band. However, when counselling these patients it should be kept in mind that at least in terms of speech understanding in quiet, the benefit of a second BAHI after implantation may be expected to be larger than during the test phase using a test band.

Conflicts of interest

This research was supported by Cochlear Bone Anchored Hearing Solutions (CBAS), Mölnlycke, Sweden. Co-author Mark Flynn is employed by CBAS.

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Figure Legends:

Figure 1: Pure tone thresholds of the two study groups. Broken lines denote average bone conduction thresholds, continuous lines denote average air conduction thresholds, error bars show ranges.

Figure 2: Aided speech understanding for German monosyllabic words for group A (top) and for group B (bottom). Symbols show mean values, error bars show standard errors of the mean. Speech was presented at 50, 65 and 80 dB SPL, respectively. Symbols for the same presentation levels are shifted by 1 dB with for better visibility.

Figure 3: Group A: Improvement of speech understanding in noise with a second speech processor, when compared to the situation with 1 BAHI. Higher values show better speech understanding with 2 devices. Symbols show individual results, horizontal lines denote means. Mean values and significance levels for each column are given at the bottom of the graph.

Figure 4: Group B: Improvement of speech understanding in noise in dB with a second speech processor, mounted either on a testband (filled symbols) or on an implant (empty symbols), when compared to the situation with 1 BAHI. Symbols show individual results, horizontal lines denote means. Mean values and significance levels (* = p<0.05, N.S.= not significant) for each column are given at the bottom of the graph.





Figure 2















Direction of Noise Incidence