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OTOLOGY

A multicenter study on objective and subjective benefits with a transcutaneous bone-anchored hearing aid device: first Nordic results

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Abstract Examination of objective as well as subjective outcomes with a new transcutaneous bone-anchored hearing aid device. The study was designed as a prospective multicenter consecutive case-series study involving tertiary referral centers at two Danish University Hospitals. A total of 23 patients were implanted. Three were lost to follow-up. Patients had single-sided deafness, conductive or mixed hearing loss. Intervention: Rehabilitative. Aided and unaided sound field hearing was evaluated objectively using (1) pure warble tone thresholds, (2) pure-tone average (PTA4), (3) speech discrimination score (SDS) in quiet, and (4) speech reception threshold 50% at 70 dB SPL noise level (SRT50%). Subjective benefit was evaluated by three validated questionnaires: (1) the IOI-HA, (2) the SSQ-12, and (3) a questionnaire evaluating both the frequency and the duration of hearing aid usage. The mean aided PTA4 was lowered by 14.7 dB. SDS was increased by 37.5% at 50 dB SPL, SRT50% in noise improved 1.4 dB. Aided thresholds improved insignificantly at frequencies above 2 kHz. 52.9% of the patients used their device every day, and 76.5% used the device at least 5 days a week. Mean IOI-HA score was 3.4, corresponding to a good benefit. In SSQ-12, "quality of hearing" scored especially high. Patients with a conductive and/or mixed hearing loss benefitted the most. This device demonstrates a significant subjective hearing benefit 8 month post surgery. In patients with conductive and/or mixed hearing losses, patient satisfaction and frequency of use were high. Objective gain measures showed less promising results especially in patients with single-sided deafness (SSD) compared to other bone conduction devices.

Keywords Bone-anchored hearing device · BAHA attract · Transcutaneous · Bone-anchored hearing aid · Hearing loss · Bone conduction

Introduction

The principle of bone conduction with transmission of sound through the cranial bone is well known and well described. In 1977, Kjellström et al. were the first to make use of a percutaneous bone conduction hearing aid by combining osseo integrated titanium implants with a bone conducting hearing aid [1]. Bone conduction hearing systems bypass any outer- and/or middle ear pathologies by converting airborne sound waves into mechanical vibrations. These vibrations are transmitted through the skull into the inner ear bilaterally. Therefore, BC devices serve as a treatment option for patients with a conductive or a mixed hearing loss (con/mix HL), along with patients not eligible for a conventional hearing aid. Patients with single-sided deafness (SSD) may benefit from a BC device as well. Sound waves intercepted on the deaf side will be transmitted as mechanical vibrations to the contralateral cochlea, thereby repealing the head shadow effect [2, 3]. Today, more than 120,000 implantations have carried out

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worldwide making bone-anchored hearing devices, the most widely used means of implantable hearing aids second only to cochlear implantation [4]. The bone-anchored hearing aids (BAHA) attached to a percutaneous titanium temporal bone implant have been used for decades [4]. There has been a continuous improvement and development of both the nature of the implant, the method of surgery, and the auditory processors. Major per- and postoperative complications are reported as rare [5]. Still, minor complications such as adverse skin reactions, skin overgrowth, implant loss, and discomfort remain a problem with the traditional percutaneous devices [5–9].

A whole new generation of bone-anchored hearing aids has been developed. They differ from existing models by being transcutaneous, rather than percutaneous, and the external processor is held in place on the skin by magnetic forces between an internal and external magnet. There are several different options with both passive and active devices.

This bone-anchored system consists of five different components: an implant, an *internal* magnet, an *external* magnet, a soft pad, and an external sound processor. The relative large contact area between the two magnets should result in lower skin pressures when wanting to achieve the necessary retention force [10]. The primary objective of this study was to examine both objective and subjective audiological outcomes with this new transcutaneous bone-anchored hearing aid device. Important surgical parameters were also included as part of this study.

Methods

Study design and outcome measurements

This prospective multicenter clinical investigation included patients from two different University Hospitals in Denmark. Selection of candidates included thorough audiological evaluation as well as a preoperative test period, where the sound processor was worn by the patient on a soft band. Patients with a conductive or mixed hearing loss must show bone conduction thresholds with a PTA_4 of 45 dB HL or better at the frequencies 500 Hz and 1, 2, and 3 kHz. For patients with single-sided sensorineural deafness, air conduction thresholds must be $\leq PTA_4$ of 20 dB HL at frequencies 500 Hz and 1, 2, and 3 kHz on the contralateral ear.

The patients included in this study were all parts of a controlled-market release surgical setup. They all followed the same surgical follow-up scheme. Peri- and postoperative complications were registered at regular visits. All patients were scheduled for fitting 4–6 week post surgery and all patients were fitted with the same sound processor. A total of 23 patients were included and they all met the standard criteria for a bone conduction hearing aid device stated in the introduction. Seven months after fitting of the sound processors, patients underwent a thorough audiological evaluation along with fulfillment of three validated questionnaires.

At follow-up, sound field audiometry was performed in a soundproof box, unaided and aided. Warble tone thresholds at eight different frequencies were determined. A pure-tone average at four frequencies (PTA_4) was calculated from values at 500 Hz and 1, 2, and 3 kHz. The speech discrimination score in quiet (SDS) was determined at 50, 65, and 80 dB sound pressure level (SPL) with a monosyllable word list (Dantale). Speech reception threshold ($SRT_{50\%}$) was tested with the Danish Hagerman sentences (Dantale II) [11] at a noise level of 70 dB SPL. The $SRT_{50\%}$ was determined as the SPL, where 50% of the words were recognized. To avoid comb filter effect, the speech signal was presented directly in front of the patient with non-correlated speech-shaped noise being applied from loudspeakers placed in all four corners (positioned at 45°, 135°, 225°, and 315° angles around the patient). The patient was placed in the middle of the setup.

When sound field audiometry was carried out in subjects with bilateral hearing, the non-test ear was masked. Masking noise was presented through an earphone placed on the non-test ear, and a signal presentation level minus 10 dB was used as the masking level. For testing with warble tones, the standard audiometer narrow band masking was used. For speech audiometry, the standard audiometer pink noise was used. When the same tests were carried out in subjects with single-sided deafness (SSD), no masking was used. In those patients, a noise excluding headset was placed on the non-test ear. Patients wearing other hearing aids were tested without these.

Three questionnaires were applied to evaluate subjective benefit: the International Outcome Inventory for Hearing Aids (IOI-HA), which is designed to evaluate the effectiveness of hearing aid treatment [12, 13]. The Speech, Spatial, and Qualities of Hearing Scale 12 (SSQ12), which through 12 questions describing everyday situations, evaluates the patients ability to hear speech and localize sound, as well as the quality of sound inputs [14] and finally a questionnaire developed at the Audiological Department at Copenhagen University Hospital for patients with bone-anchored hearing aids, questioning frequency, and duration of device usage were used [15].

Subjects

The 23 patients were found eligible for a bone conduction device. Eligibility assessment included both audiological testing and also a trial period of minimum 14 days. During the trial period, the device was worn on a soft band. At the

final follow-up, three patients were lost to follow-up. Patients were implanted unilaterally from October 2013 to February 2014 (see Table 1 for population characteristics).

Surgical technique

All surgical procedures, except one, were performed in general anesthesia. A semi-circular incision was made behind the auricle. The implant was inserted as the standard procedure prescribes. If the dura was exposed after 3 mm drilling, a 3 mm implant was inserted. Otherwise, a 4 mm implant was used. The internal magnet was attached to the implant and the wound was closed completely. Mean duration time of surgery was 36.8 min (SEM ±2.69, range 19–65) (Table 1).

Statistical analysis

GraphPad Prism 6 and stata 13 was used for statistical analysis and graphing. Significance was defined as p values at or below 0.05. Differences between the aided and unaided situations for warble tone thresholds, PTA_4, and speech tests (SDS and SRT) were tested using paired t test with bootstrap to account for non-normality. Results from patients with con/mix HL were compared with the results of patients with SSD, using paneled linear regression with bootstrap resampling to account for non-normality.

Table 1 Population characteristics

Patients, numbers	
Lost to follow-up	3
Total (after exclusion)	20
Age at surgery, years	
Mean (range)	47.6 (8–72)
Sex, number (%)	
Male	8 (40)
Female	12 (60)
Type of hearing loss	
SSD	13
Conductive	6
Mixed	1
Surgical time, min (range)	37 (19–65)
Tissue reduction	
Yes	4
No	16
Implant size	
3 mm	2
4 mm	18
Side of implantation	
Left	16
Right	4

Results

Operative and postoperative complications

No major surgical complications occurred neither per- nor postoperatively. One patient was extremely hard to anesthetize with local anesthetics and this particular surgical procedure lasted approximately 1 h. As a consequence, all subsequent surgical procedures were done in general anesthesia. One patient was initially very hard to fit with the processor because of difficulties with the magnet attachments. The patients' subcutaneous tissue thickness was 6 mm peroperatively and the patient did not have any skin reduction done. He later underwent revision surgery with subcutaneous skin reduction, and after that, he performed well with his processor in place.

Skin evaluation at the half-year follow-up

Intact and otherwise normal skin was found over the implant in all patients at the final study follow-up. Figure 1 shows two patients with and without the processor at the time of follow-up.

Audiological results at follow-up

Warble tone thresholds

Mean sound field warble tone thresholds were lowered by device use at all frequencies tested, overall and for all patient subgroups, with the largest gain in the low and mid frequencies (Fig. 2a). Gain values between 3 and 8 kHz were insignificant. The con/mix HL group showed the

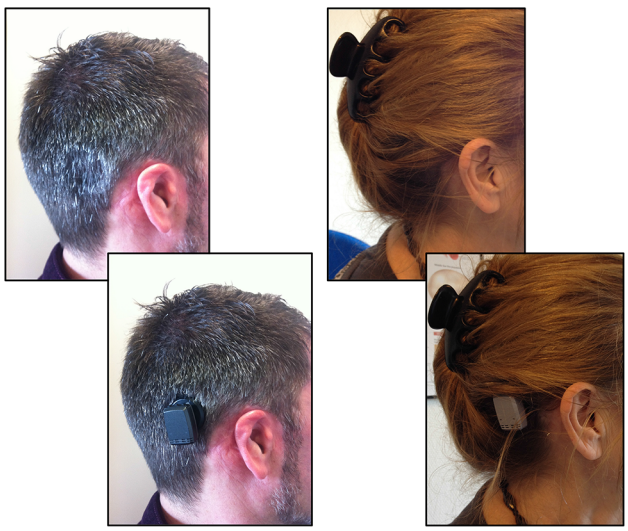

Fig. 1 Two patients with and without the bone-anchored hearing aid at follow-up 8 months after surgery

same pattern but with greater gain at the low and mid frequencies (Fig. 2b). For the SSD group, improvements were small at the extremities of the frequency scale and largest between 1 and 2 kHz (Fig. 2c).

Overall, the PTA_4 improved by 14.8 dB (SEM ±1.6), from 50.6 dB (SEM ± 2.5) to 35.9 dB (SEM ± 2.0) ($p < 0.01$) (Fig. 3). The PTA_4 for the group with con/mix HL improved by 19.8 dB (SEM ± 3.0), from 61.1 dB (SEM ± 3.5) to 41.3 dB (SEM ± 3.4) ($p < 0.01$) (Fig. 3). The improvement for the SSD group was 11.1 dB (SEM ± 1.6), from 46.1 dB (SEM ± 2.6) to 35.0 dB (SEM ± 2.4), which was also significant ($p < 0.01$) (Fig. 3).

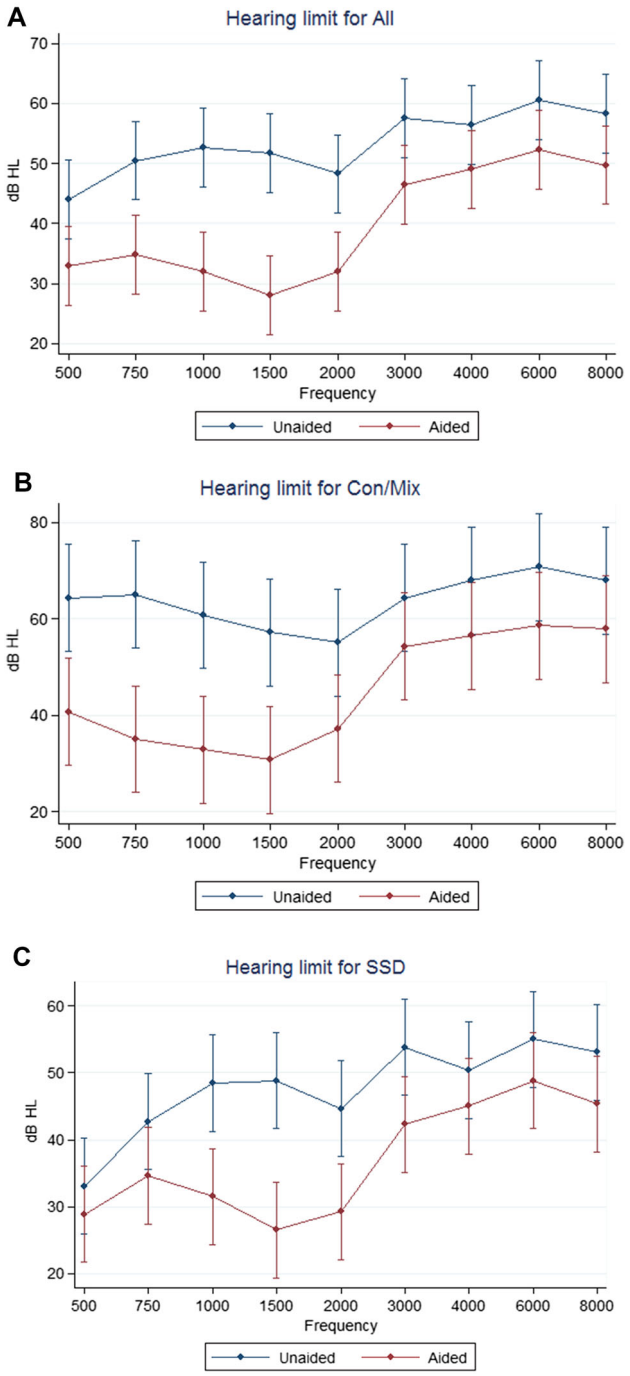

Fig. 2 **a–c** Mean Warble Tone sound field thresholds at the time of follow-up. **a** Hearing limits for all patients. **b** Patients with con/mix HL. **c** Patients with SSD. *Error bars* standard error of mean (SEM)

Speech discrimination score

SDS at 50 dB SPL and 65 dB SPL showed a significant improvement by device use for the whole group of patients ($p < 0.01$) (Fig. 4a). No significance was found at 80 dB SPL (p value 0.17). The mean increase in SDS at 50 dB SPL was 37.5% (SEM ± 6.4), from 42.6% (SEM ± 7.1) unaided to 80.1% (SEM ± 4.5) aided. At 65 dB SPL, the increase was 13.4% (SEM ± 4.2), from 78.9% (SEM ± 5.0) to 92.3% (SEM ± 2.1), and at 80 dB SPL, the increase was 3.2% (SEM ± 2.4), from 90.2% (SEM ± 3.5) to 93.3% (SEM ± 1.9).

For the con/mix HL group, SDS improved 55.3% (SEM ± 10.0) at 50 dB SPL ($p < 0.01$), 29.4% (SEM ± 7.4) at 65 dB SPL ($p < 0.01$), and 3.1% (SEM ± 2.4) at 80 dB SPL ($p = 0.19$) (Fig. 4b). For the SSD group, a significant improvement of 27.9% (SEM ± 6.8) was found at 50 dB SPL ($p = <0.01$) and insignificant improvement of 4.7% (SEM ± 2.8) at 65 dB SPL ($p = 0.09$) and 3.2% (SEM ± 3.3) at 80 dB SPL ($p = 0.34$) (Fig. 4c).

Speech reception thresholds in noise

For all patients, the mean $SRT_{50\%}$ at 70 dB noise level was lowered by 1.4 dB (SEM ± 0.7, $p = 0.053$) from an unaided threshold of 72.7 dB (SEM ± 1.1) to an aided of 71.3 dB (SEM ± 0.8).

For the patients with con/mix HL, the $SRT_{50\%}$ was lowered by 1.9 dB (SEM ± 0.98) ($p = 0.051$), from

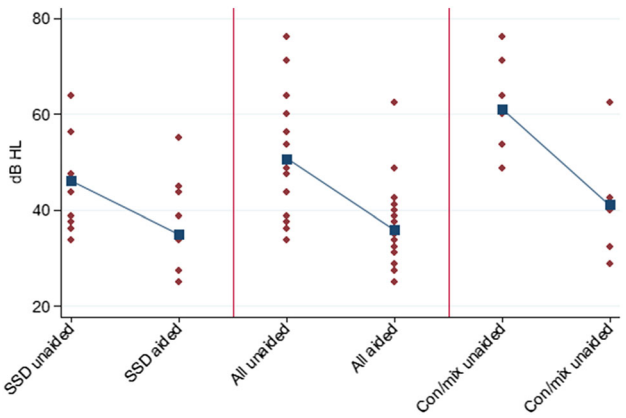

Fig. 3 Scatter plots of pure-tone averages (PTA_4) at frequencies 0.5, 1, 2, and 3 kHz. *Blue squares* represent mean values

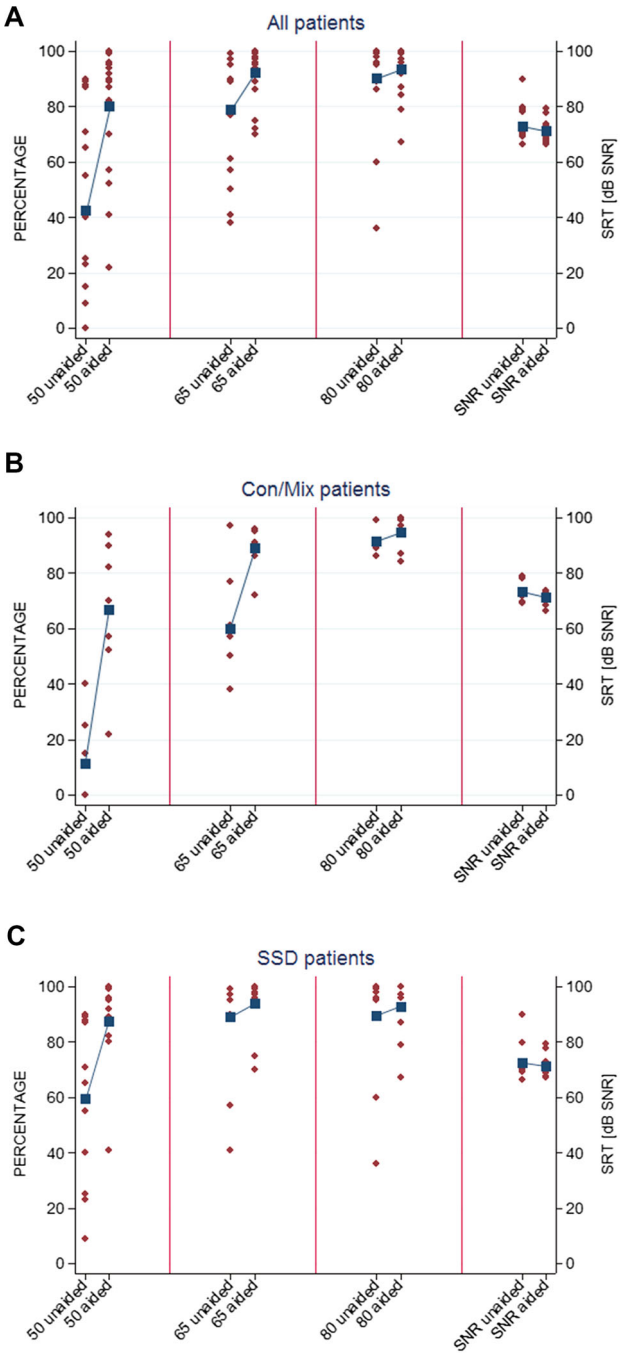

Fig. 4 **a–c** Scatter plots of speech discrimination score (SDS) in quiet at 50, 65, and 80 dB SPL. Please note that $SRT_{50\%}$ at 70 dB is also included on the far right with SNR changes shown in dB. *Blue squares* represent mean values. **a** SDS and $SRT_{50\%}$ all patients. **b** SDS and $SRT_{50\%}$ con/mix HL group. **c** SDS and $SRT_{50\%}$ SSD group

73.2 dB (SEM ± 1.4) to 71.3 dB (SEM ± 1.0). For the patients with SSD, the $SRT_{50\%}$ showed no significant lowering. The $SRT_{50\%}$ only showed a change of 1.1 dB (SEM ± 0.93) from 72.4 dB (SEM ± 1.6) and aided mean 71.3 dB (SEM ± 0.97) ($p = 0.246$).

Questionnaire results at follow-up

Three patients were non-users. The non-users were all left-sided SSD patients with a mean age of 41 (range 20–64 years). Two female and one male patient made up the group of non-users. The non-users were BAHA recipients from both centers involved in the study. They all had at least one complaint that was related to their non-usage. One patient complained about headache when using the BAHA; one patient reported that the processor fell off too easily when doing sports and also during dressing and undressing. Two patients complained about the size of the processor. On average, the patients used their processor 4.8 days a week (SEM ± 0.59). If we exclude the three SSD non-users, the average use for the whole group of patients is 5.6 days a week (SEM ± 0.43). Patients with con/mix HL use their processor 6.1 days a week (SEM ± 0.54) and SSD patients use their processor an average of 4.1 days a week (SEM ± 0.74) and 5.3 (SEM ± 0.58) days a week if you leave out the three non-users. If you leave out the three non-users, 52.9% of the patients used their device every day, and 76.5% used the device at least 5 days a week. 11.8% used the device ≥5 h a day, 52.9% used the device ≥4 h a day, and 88.2% used the device ≥3 h a day. There were significant differences in use between con/mix HL and SSD patients ($p = 0.037$).

Subjective hearing outcome measured on a scale from 1 to 5 in the IOI-HA was 3.4 (SEM ± 0.21). Patients with con/mix HL scored significantly higher at 3.9 (SEM ± 0.25), compared to the SSD patients, who scored 2.9 (SEM ± 0.26) ($p = 0.01$).

The overall SSQ12 score was 5.2 (SEM ± 0.37). For the con/mix HL group, the overall SSQ score was 6.3 (±0.76) and for the SSD group 4.5 (SEM ± 0.28). The "Hearing speech" component was scored 5.0 (±0.39), the "Sound localization" 4.0 (±0.67), and the "Quality of hearing" 6.1 (±0.40). A significant difference was found in favor of the subgroup con/mix in the "Hearing speech" component 6.5 (±0.65) versus 4.2 (±0.34) in the SSD group. In the "Sound localization" group, no significant difference was found 5.6 (±1.2) versus 3.1 (±0.63) (Fig. 5).

Discussion

To our knowledge, this is the first Nordic audiological evaluation of patients implanted with this device. This investigation evaluated the clinical performance of a magnetic bone conduction implant in 20 patients with either conductive, mixed, or SSD hearing losses. This study demonstrates a significant subjective hearing benefit when evaluated on average 8 months post operatively. In contrast

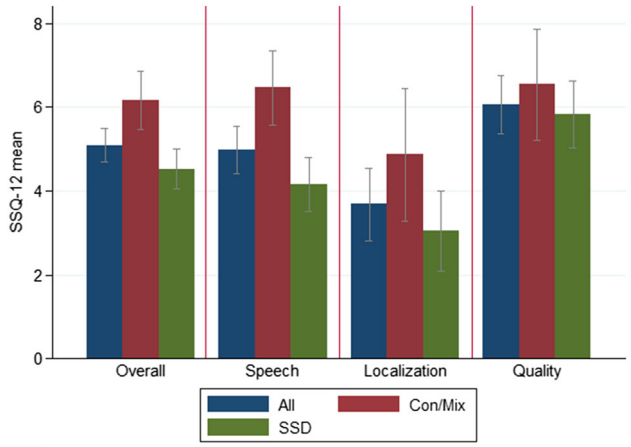

Fig. 5 Mean speech, spatial, and qualities of hearing scale (SSQ12) scores with *error bars*. *Error bars* represent 95% confidence intervals

to another similar study [16], the concomitant objective measurements do not all support significant improvements in hearing performance. In general, the frequency of use as well as the patient satisfaction was high. However, SSD patients as a group did not benefit as much from this device, as did the con/mix group. No major per- or post-operative complications occurred.

Subjective outcome with the device

Most patients use their device on a daily basis for several hours. The extent of use must be a reasonable measure of subjective outcome, as patients with no or little benefit would discontinue using their device. In average, patients with con/mix HL used their device two more days than the SSD group did. Among the 13 SSD patients, three discontinued use and seven patients used their device less than 4 h a day. When comparing to another transcutaneous device, patients in this study used their device to a less extent. Other studies have found usage to be 5–12 h on a daily basis [16, 17]. More than 50% of the patients use their device every day and three out of four of patients use their device 5 days a week. Most patients are still either employed or go to school 5 days a week and this might explain the trend of 5 day usage.

The three non-users were all SSD patients. They all had complaints about their device. The complaints were both related to cosmetics, pain, and also to difficulties with the processor falling off too easily. Unfortunately, the length of the SSD condition was not registered for these patients. The user group in general was very satisfied with the device; especially in regard to sound quality, general hearing improvement, and also hearing in noise.

A general trend is seen when you compare the two different groups of patients. All three questionnaires show that patients with a conductive or mixed hearing loss have a better subjective outcome than SSD patients do. One reason for this, of course, is that patients with a fully or partially functional ipsilateral cochlea will receive more intense sound stimuli because of less attenuation. Furthermore, if localization of sound is of great importance to the individual patient, SSD patients will per se have a less degree of satisfaction, as one cochlea cannot provide that information to the patient.

A recent study with another transcutaneous device showed similar results with subjective parameters from the same three questionnaires. There were minor differences, primarily time of usage in favor of patients with the other device, but overall scores in both studies are quite similar [18].

The IOI-HA defines scores of one or two on one item or a total score of 20 or less (mean item score $\leq$2.9) as non-beneficial outcome. At the other end of the scale, a total score of 33 or more (mean item score $\geq$4.7) are in the top 10% [12, 19]. In this study, we have seven patients in the non-beneficial group. Three of these are the non-users. If we leave out these three patients, we have a total of four non-beneficial users and two of these have average of exactly 2.9. We can, therefore, conclude that the subjective outcome is good for the majority of patients in this study. The highest mean score was 4.4. Again, SSD patients had the lowest ranking. One could also speculate that perhaps, the duration of the SSD condition before fitted with a hearing aid has an impact on the patient satisfaction. Unfortunately, we did not collect data from this population in regard to the length of the SSD condition.

In the abbreviated questionnaire, SSQ-12, the patients were asked questions on everyday life situations. Hearing aid benefit was evaluated on a scale from zero to ten, with ten being the utmost benefit and zero being no benefit [14]. A score of five indicates ability to do or experience the situation described half of the time. The highest score was achieved in the category "quality of hearing" but also "hearing speech" achieved a score of five and above (Fig. 5). Sound localization was not improved, which is consistent with the literature on other bone-anchored hearing devices [2, 20].

Objective benefit with the device

Threshold audiometry showed that the test device provides a significant functional gain at all frequencies. The improvement is largest in the important speech frequency range up to and including 3000 Hz. As expected, the performance drops gradually above 3000 Hz because of the soft-tissue attenuation, which is known to mainly affect the high frequencies [20, 21]. When aided with the device, free field audiometry improved in all patients despite type of hearing loss, but was only significant in the low and mid

frequencies. Warble tone thresholds were lowered throughout the full spectrum of frequencies tested. Similar results have been found in other studies [22–24]. One study showed significant improvements with the same device in all frequencies including the high-frequency range up until 6 kHz in the aided condition [16]. The largest gain in this study was seen in the mid frequencies. For the SSD group, however, improvement was minimal at the extremities of the frequency spectrum. Speech discrimination scores improved considerably with the device, especially at the lower intensities. Again, the con/mix subgroup had the most pronounced improvement. At the higher intensities, SSD patients had no or very little improvement. Hearing in noise was not improved significantly overall and neither for any of the subgroups.

Figure 2a–c displays poor aided hearing thresholds at all frequencies, especially at 3 kHz and above. Figure 2b shows mean aided thresholds to be more than 40 dB in the higher frequencies. Similar studies with percutaneous BAHA have shown aided thresholds to be between 15 and 20 dB [25]. When looking at Fig. 2c, one must conclude that the noise excluding headset only dampens the sounds approximately 50 dB and not to the intended level of deafness. Aided thresholds are poor and do not compensate for the head shadow effect that one would expect to be approximately 10 dB at 1 and 2 kHz increasing to 20–25 dB at 4 kHz. So far, only three other rather similar studies evaluating both objective and subjective parameters have been published on this device [16, 26, 27]. A comparison of data is not easy. Both methods used to evaluate especially audiological data differ quite a lot and the populations evaluated are also rather incomparable hearingwise. Our reported PTA_4 gain of approximately 15 dB seems to be comparable and equivalent to former results published. Recently, there has been a review of the literature on this device. A total of ten articles with 89 cases conclude that both functional and audiological results have proven satisfactory with a low complication rate. In this review, only two studies were prospective studies, and with this device, there is still missing a multi-center randomized controlled trial from the literature. In these ten studies, a number of both subjective and objective measures are taking into account thereby making comparisons difficult between studies [28].

The SDS was improved significantly overall at both 50 dB SPL and 65 dB SPL. SDS at 80 dB was insignificantly improved. Again, favorable scores were seen in the con/mix subgroup as the SSD subgroup only has a significant improvement at 50 dB SPL.

In general, but especially when looking at SSD patients, a lack of benefit was demonstrated when looking at speech reception in noise. The lack of benefit in noise was not surprising when considering the test setup. The speech signal was presented in front of the test person and noise was presented from the sides of the person. Patients with SSD will preferable benefit from the device by an elimination of the head shadow effect. To measure this effect properly, noise must be applied towards the hearing ear, while the speech signal is presented to the implanted deaf ear. In all other test setups—as well as everyday situations—the aided to unaided advantage is negligible.

A comparison between the results of this study and those of previous studies of percutaneous devices will undoubtedly include potential biases due to different study designs and variations among patients included. However, Hakansson et al. [29] did a comparable sound field threshold testing on 122 patients with percutaneous devices. These patients, all with con/mix HL, had a bone conducting profile similar to the con/mix HL group in this study. A comparison of the data shows that the gain and aided thresholds are quite similar between the two studies. We did also, in this article, include the latest recommendations of reporting hearing assessment, as we included standardized scattergrams (Fig. 6a, b). These scattergrams, relating average pure-tone thresholds to word recognition scores, act as a new minimal standard of reporting hearing results in clinical trials. They were endorsed by the Hearing Committee of the American Academy of Otolaryngology Head and Neck Surgery in 2012 but are still not widely implemented [30]. Hopefully, these scattergrams should facilitate easier future comparisons between different studies evaluating hearing assessments as no other golden standards of reporting hearing benefit currently exist. When looking at the scattergrams of this study, one should notice that post-treatment (evaluation with the processor in place) all patients but one showed improved PTA_4 as well as improvement in Word Recognition Scores.

Due to logistic issues, patients underwent follow-up at quite different time intervals at the two centers involved in this study. Theoretically, this might have affected the outcome, as one center evaluated their patients on average 5 month post-op and the other center evaluated their patients after an average of 13 months. We will expect, though, that the tissue surrounding the abutment will be completely healed at both times of evaluation and that measurements, therefore, are comparable.

Conclusion

This study on the first 23 Nordic patients implanted with this device demonstrates a significant subjective hearing benefit when evaluated 8 month post-implant. Objective measurements showed less promising results than other bone conduction devices, especially when evaluating SSD patients. No significant benefit was shown in the higher

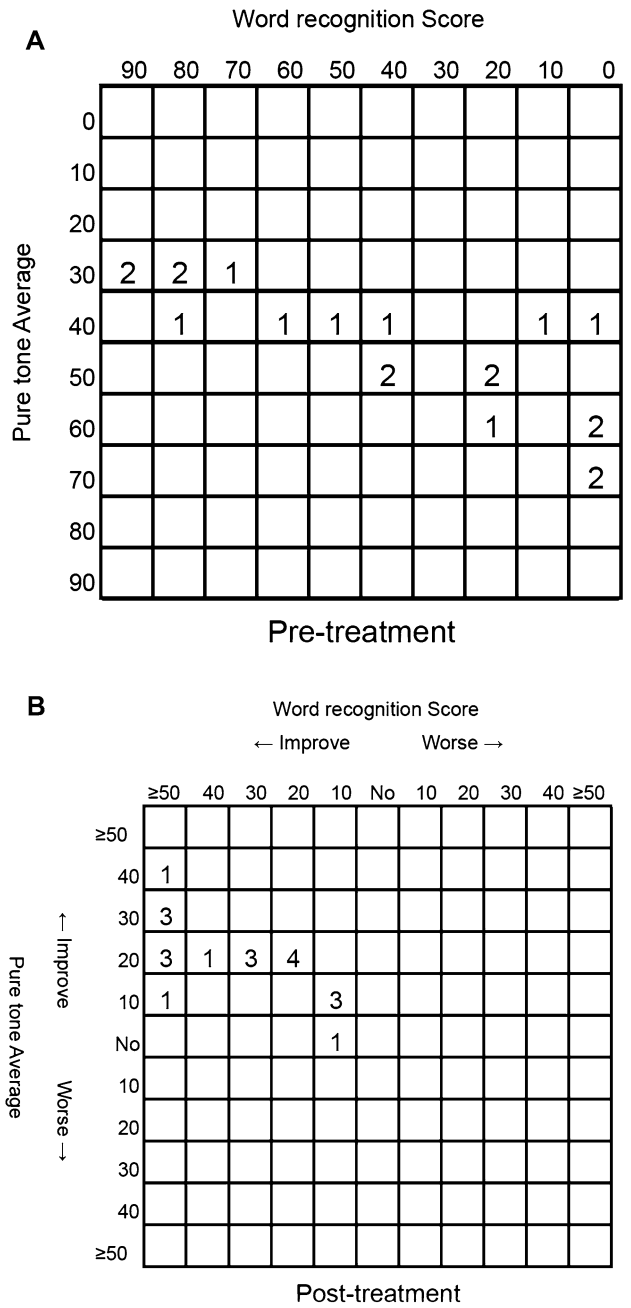

Fig. 6 Standardized scattergrams. **a** Pre-treatment, **b** Changes pre-/-post-treatment. Sound field pure-tone averages (dB HL) and word recognition scores with SDS at 50 dB SPL are included

frequencies. No major complications occurred. In general, the patient satisfaction was high and the frequency of use was also quite high. The device was shown to be safe and effective, because it provides good hearing performance in patients with both conductive and mixed hearing losses. Patients reported good wearing comfort and minimal soft-tissue complications were observed. This device needs further evaluation in patients with SSD before it can be recommended for this subpopulation.

Compliance with ethical standards

Conflict of interest No organization has sponsored this research. The Danish distributor of Cochlear products, Danaflex, has granted funding for the transportation of nine patients from one region of the country to another region to have the audiological testing done at the Audiological Department at Copenhagen University Hospital. The funding has been equal to the cost of a return train ticket from one part of the country to the other. The audiological testing could only take place at one facility due to the extent of advanced equipment required. A total amount of approximately 1500 USD was granted for this purpose.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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