

Original Study

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Multicenter Results with an Active Transcutaneous Bone Conduction Implant in Patients with Single-sided Deafness

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Objective: To evaluate the audiological and subjective benefit from hearing rehabilitation with an active bone conduction implant in subjects with single-sided sensorineural deafness (SSD).

Study Design: Prospective, multicenter, single-subject repeated measures.

Setting: Tertiary referral center, five clinics in Germany and Switzerland.

Patients: Seventeen subjects aged 18 years and older with severe to profound unilateral sensorineural hearing loss and contralateral normal hearing were followed up for 24 months.

Intervention: Active bone conduction implant.

Main Outcome Measures: Speech understanding in noise was assessed in three situations: with signal from front, deaf, or normal hearing side (with noise from front in all set-ups). Subjective benefit was evaluated using the Speech, Spatial, and Qualities of Hearing (SSQ-B) and Bern Benefit in Single-Sided Deafness (BBSS) questionnaire.

Results: When the signal was coming from the deaf side the mean improvement of the speech reception threshold in noise ranged from 1.5 up to 2.2 dB with the device and was statistically and clinically significant at all tested timepoints. No significant difference between the aided and unaided situation was found when signal and noise were coming from the front. With the signal from the normal hearing side no clinically significant difference, that is, greater than 1 dB between the aided and unaided situation was found. The SSQ-B and BBSS questionnaire showed an overall improvement with no significant difference between time points.

Conclusions: The study demonstrates long-term efficacy and benefit of the device in adults with SSD. Patients reported substantial and persistent subjective benefit from the active bone conduction implant. **Key Words:** Bone conduction—Implant—Single sided deafness.

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INTRODUCTION

Single-sided Deafness (SSD) is characterized by severe to profound hearing loss in one ear and normal hearing in the other ear. Etiologies of congenital or acquired SSD vary considerably and are often unknown. Possible causes include idiopathic sudden sensorineural hearing loss (SNHL), viral or bacterial inner ear

infections, acoustic neuromas, physical trauma to the ear or head, and unilateral Menière's disease.

Although some SSD patients report few hearing problems in their daily lives, many suffer in various listening situations and seek treatment. Individuals with SSD report good comprehension in quiet environments. However, SSD patients often have poor sound localization abilities (1,2) as well as difficulties with speech

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recognition in noise and other challenging listening situations due to the loss of binaural processing (3).

Patients with SSD have different hearing rehabilitation options ranging from cochlear implants, contralateral routing of signals (CROS) hearing aids to bone conduction (BC) devices. In patients with a functioning cochlear nerve, cochlear implants may restore binaural hearing but require surgical access to the inner ear and long-term rehabilitation. In conventional CROS devices, sound is recorded through a microphone on the deaf side and transmitted to a hearing aid worn on the better ear to overcome the acoustic head shadow effect. CROS devices require no surgery and are thus the least invasive option, although the patient will have to wear a device at each ear (4,5).

BC devices employ the same principle as CROS devices by transmitting sound from the ear with SSD to the better ear, using BC. Device options include BC sound processors held in place via Softband (6), an adhesive adapter (7,8), an implanted magnet (9), a percutaneous abutment (i.e., bone-anchored hearing aids, BAHA) and an active transcutaneous bone conduction implant system (tBCI). Up-to-date, the largest number of studies on BC solutions in SSD have been published on BAHA, with significant improvements in speech perception and quality of life noted (10–15). Fewer studies have been published on the tBCI in SSD patients, but initial results (16–19), including a temporal bone study comparing the tBCI to the BAHA (20), have shown similar outcomes for both devices. The tBCI implantation is more complex and requires more space in the temporal bone than BAHA, but the advantage is that the skin is intact after postoperative healing. Some SSD users require support only in certain hearing situations; thus, the tBCI is completely invisible when not in use. For all BC devices a trial period with a non-implantable BC device and intensive counseling is essential to assess preoperatively if the SSD candidate would benefit from such a treatment option. A systematic review concluded that after a trial period 32 to 70% of SSD patients would decline BAHA implantation (21). Others reported that the subjectively perceived benefit was less than expected or decreased with time (22,23), suggesting that SSD patients are a challenging cohort.

The tBCI is intended to treat patients with either conductive or mixed hearing loss (C/MHL) or SSD. Previous studies have shown long-term benefit from the tBCI in patients with C/MHL (24). The number of tBCI users with SSD is still limited. The aim of this prospective study was to evaluate the long-term audiological and subjective benefit in 17 SSD patients implanted with the tBCI followed-up for up to 24 months.

MATERIALS AND METHODS

Device Description

The BONEBRIDGE system (MED-EL, Innsbruck, Austria) tBCI is composed of an external audio processor (AP) and an active BC implant under the intact skin (25). Surgical implantation is performed under general or local anesthesia as

described previously (25–27). If the AP is removed, the active tBCI is MRI-conditional up to 1.5 T, allowing postoperative control of pathologies only detectable in MRI (e.g., vestibular schwannoma). An adapted imaging protocol was recently introduced that enables diagnostically useful MRIs in tBCI patients by reducing the artefact around the implant site (28).

Study Design

We used a prospective, single-subject repeated-measures design in which each subject serves as his/her own control. The study was approved by the local institutional review boards: cantonal ethics commission (EC) Zurich ECNo. 2012_0240, cantonal EC Bern ECNo. 148/12, EC Northwest- and central Switzerland ECNo. 12062, EC LMU Munich ECNo. 276-12, EC University Lübeck ECNo. 13-154. All subjects signed the informed consent form upon study inclusion.

Subjects

Seventeen subjects from five centers in Germany and Switzerland were enrolled. The inclusion criteria were: 1) unilateral severe-to-profound SNHL in one ear and 2) contralateral normal hearing. All patients were given the choice between CROS hearing aids, percutaneous BCI, transcutaneous passive BCI, transcutaneous active BCI, or cochlear implant (CI). However, at the time of the study, the CI was not reimbursed in one of the countries. Preoperatively, all patients underwent a two-week trial of a commercially available BCI on a headband. Mean duration of hearing loss was 12 years (range 3–44 years). All patients reported difficulties communicating in their professional and social lives. All surgeries were performed under general anesthesia. One of these 17 subjects (ID6) suffered from moderate-to-severe unilateral SNHL (AC PTA4 = 57.5 dB HL), and was excluded from the analysis. Patient demographics are found in Table 1. Subjects were followed for 24 months except for subject ID7 who decided not to participate further after baseline testing and subject ID16 who moved away after the 12-month evaluation. Three subjects were lost to follow-up: subjects ID12 and ID15 participated until the 18-month evaluation; subject ID9 until the 12-month evaluation. Adverse events were reported according to ISO 14155:2011.

Audiometric Testing

Speech understanding in noise was tested using the OLSA (German Oldenburg Sentence Test, (29)) at a fixed noise level of 65 dB SPL at baseline (within 3 months after surgery), the 6-month, 12-month, 18-month, and 24-month evaluations. The signal level was adapted until the speech reception threshold (SRT) for 50% correct recognition was determined and the signal-to-noise ratio (SNR) calculated. The tBCI-aided and unaided conditions were tested with noise always from the front (0° azimuth) and speech presented frontally (Scenario 1, S0° azimuth), at the contralateral side (Scenario 2, 270° azimuth) or at the implanted ear (Scenario 3, 90° azimuth) (see Fig. 1).

Subjective Benefit

Subjective benefit was determined at the 6, 12, and 24-month evaluations using two questionnaires. The “Speech, Spatial, and Qualities of Hearing” (SSQ) questionnaire measures self-reported auditory disability across a variety of domains that reflect the patient’s everyday hearing perception (30). This study used the benefit version of the questionnaire (SSQ-B). The “Bern Benefit in Single-Sided Deafness” (BBSS) (31) comprises 10 questions to assess SSD patients’ benefit with a CROS or BC device. Answers on both questionnaires range

TABLE 1. Baseline demographics and etiology

Subject ID	Gender	Age in Years	Implanted Side	Contralateral AC PTA4 (dB HL)	Etiology
1	M	46	R	8.75	Otitis Media
2	F	56	R	18.75	Sudden Hearing Loss
3	M	56	L	15	Sudden Hearing Loss
4	F	62	R	20	Barotrauma
5	F	18	L	18.75	Unknown
6	F	48	R	13.75	Menière's Disease
7	F	22	R	3.75	Meningitis
8	F	48	L	25	Unknown
9	M	32	L	5	Congenital
10	M	35	R	1.25	Congenital
11	M	28	R	12.5	Congenital
12	M	46	R	12.5	Congenital
13	M	23	R	0	Mumps
14	F	45	L	5	Unknown
15	F	33	L	N/A	Hypoxia during birth
16	F	24	R	9	Acoustic shock
17	M	58	R	11.5	Cholesteatoma

Air conduction (AC) PTA4 (four frequency pure tone average) was calculated across 0.5, 1, 2, and 3 kHz.

F indicates female; L, left; M, male; N/A not available; R, right.

from -5 to $+5$, where -5 indicates “much worse” with the device than without and $+5$ “much better.” The midpoint of the scale (0) indicates that the ability or experience is “unchanged.”

Statistical Analysis

Data were tested for normal distribution with the Kolmogorov–Smirnov and Shapiro–Wilk tests. Normally distributed datasets were analyzed with the paired-sample t test; the non-normally distributed datasets with the Wilcoxon signed-rank test. A p -value of ≤ 0.05 was considered statistically significant. For pairwise comparisons the p -value was adjusted with the Bonferroni correction method.

Pairwise comparisons between the single test intervals were made with the paired-sample t test for the SSQ-B questionnaire

and with the Wilcoxon signed-rank test for the BBSS questionnaire. The SSQ-B subscale total scores were calculated as the average of all items within a subscale. The Total BBSS score is the average of all 10 items. Missing values were treated as missing values. Only subjects with missing values on ≤ 3 questions were included in the calculation of the total score.

RESULTS

Speech Understanding in Noise

In scenario 1 with signal and noise from front ($S0^\circ N0^\circ$), no statistically significant difference was found between the aided and the unaided test conditions at any time points (Fig. 2A). In scenario 2, with signal to the normal-hearing ear and noise from front ($S270^\circ N0^\circ$)

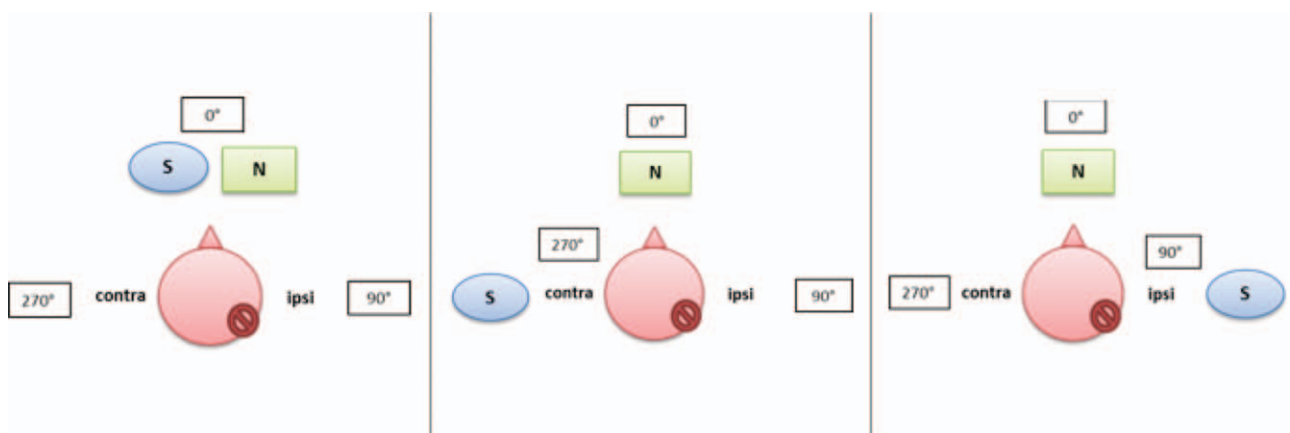


FIG. 1. Test scenarios for speech understanding in noise. Test scenario 1 (left). $S0^\circ N0^\circ$: Both, Signal and noise presented frontally (0° azimuth). Test scenario 2 (middle). $S270^\circ N0^\circ$: Signal presented contralateral to the SSD side (270° azimuth) and noise presented frontally (0° azimuth). Test scenario 3 (right). $S90^\circ N0^\circ$: Signal presented at the implanted side (90° azimuth) and noise presented frontally (0° azimuth). Contra indicates contralateral: normal hearing side/ear; ipsi, ipsilateral: SSD affected/implanted side; S, Signal; N, Noise.

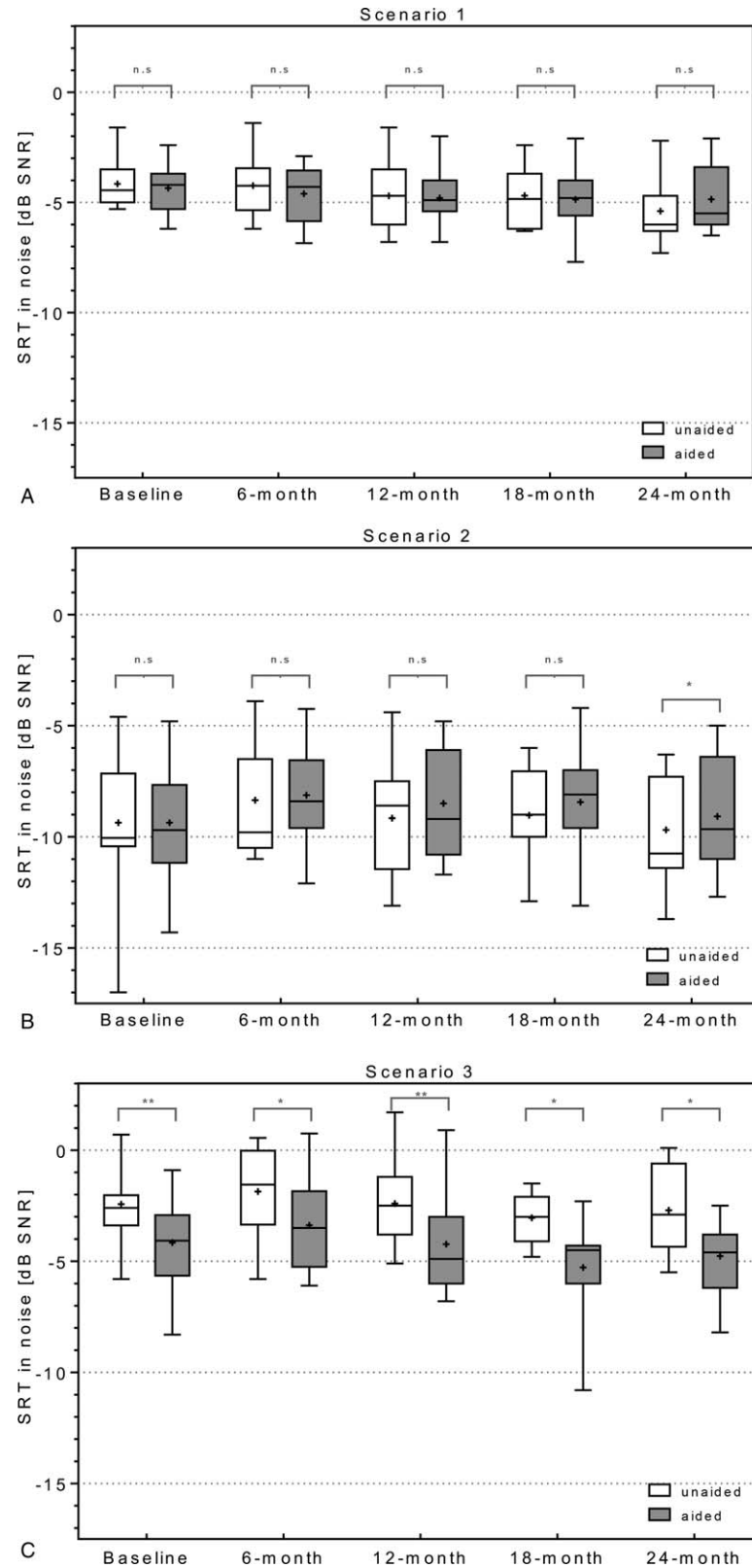


FIG. 2. Speech understanding in noise. OLSA at a fixed noise level of 65 dB SPL from front and speech adapted level from front (A, Scenario 1, S0°N0°), from the normal hearing side (B, Scenario 2, S270°N0°) and from the SSD side (C, Scenario 3 S90°N0°). Box Plots: median = horizontal lines; + = mean; whiskers = min.–max. values; n.s. = nonsignificance; * = significance ($p \leq 0.01$); ** = significance ($p \leq 0.001$).

(Fig. 2B), no statistically significant difference was found at baseline, the 6-month, 12-month, and 18-month evaluations ($p = 0.393$ at baseline; $p = 0.807$ at 6-month; $p = 0.109$ at 12-month; $p = 0.139$ 18-month). However, at the 24-month evaluation, a statistically significant increase in the SRT in noise of 0.6 dB was found when comparing the aided to unaided conditions ($p = 0.008$). In Scenario 3 ($S90^\circ N0^\circ$) with speech at the implanted side and noise from the front, tBCI-aided SRT in noise improved in all subjects compared to the unaided situation, with a mean improvement of 1.7 dB at baseline, 1.5 dB at 6-month, 1.8 dB at 12-month, 2.2 dB at 18-month, and 2.1 dB at 24-month (Fig. 2C, $p = 0.001$ baseline; $p = 0.011$ 6-month evaluation; $p = 0.001$ 12-month evaluation; $p = 0.003$ 18-month evaluation; $p = 0.004$ 24-month evaluation). Detailed descriptive statistics are provided in Supplement 1, <http://links.lww.com/MAO/B381>.

Subjective Benefit

All subscales of the SSQ-B questionnaire showed overall improvement. The speech hearing subscale scores were 1.85 ± 0.83 at the 6-month, 1.63 ± 0.65 at the 12-month and 1.57 ± 0.93 at the 24-month evaluations. The spatial hearing subscale scores were 0.78 ± 1.14 , 0.96 ± 1.32 , and 1.22 ± 1.30 , while the quality scale scores were 1.13 ± 0.88 , 1.22 ± 1.09 , and 1.12 ± 1.47 at these timepoints (Fig. 3). No statistical significance was found between the different timepoints. The speech section of the SSQ-B yielded the most positive scores,

while results were closer to 0 for the spatial section. Detailed results for the SSQ-B individual subscales can be found in Supplement 2, <http://links.lww.com/MAO/B381> (speech), Supplement 3, <http://links.lww.com/MAO/B381> (spatial) and Supplement 4, <http://links.lww.com/MAO/B381> (qualities). Out of 16 subjects who completed the questionnaire, 13 scored positively, one scored (ID12) 0 (i.e., no difference) and two subjects (ID5, ID6) scored negatively on the speech domain at their latest evaluation. On the spatial domain, 10 scored positively, 2 scored 0 (ID5, ID12), and 4 subjects (ID4, ID6, ID11, and ID15) scored negatively at their latest evaluation. On the qualities domain, 12 scored positively and four (ID4, ID6, ID11, and ID12) negatively.

BBSS questionnaire results showed an overall improvement with the tBCI at all timepoints (Fig. 4). The patients reported an average device-aided benefit of 2.2 ± 0.9 at the 6-month, 1.7 ± 0.9 at the 12-month and 1.7 ± 1.7 at the 24-month evaluations compared to unaided. Subject ID5's average benefit was negative at the 24-month evaluation but was 3 at baseline. The subjects rated their hearing with the tBCI slightly more positively at the 6-month evaluation compared to the 12- and 24-month timepoints, though this was not statistically significant (Wilcoxon signed-rank test: $p = 0.158$ and $p = 0.173$). The average benefit was positive for all items on the BBSS. Across all timepoints the highest benefit was reported for overall hearing (question 10), participation in a group conversation (question 8), holding a conversation while driving a car (question 6) and

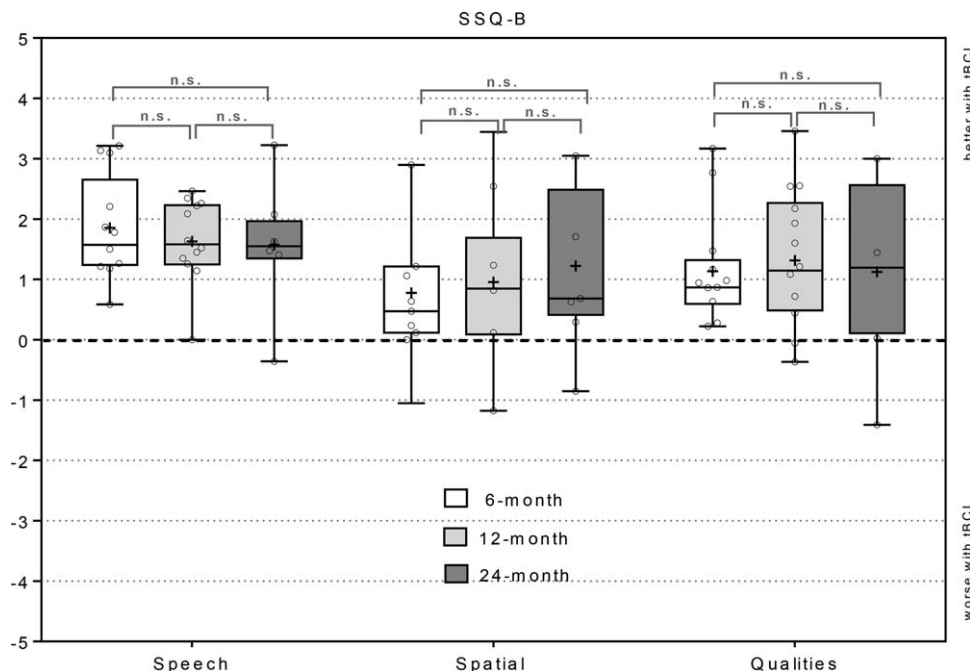


FIG. 3. Subjective benefit based on the SSQ-B questionnaire. The score for the subdomains Speech, Spatial and Qualities was calculated as the average of all items within a subdomain. Positive scores indicate a better hearing perception with the device, negative scores indicate a worse hearing perception with the device. Only subjects with missing values on ≤ 3 questions were included in the calculation of the total score. Box Plots: median = horizontal lines; + = mean; whiskers = min.-max. values; circles = individual scores; n.s. = no significance.

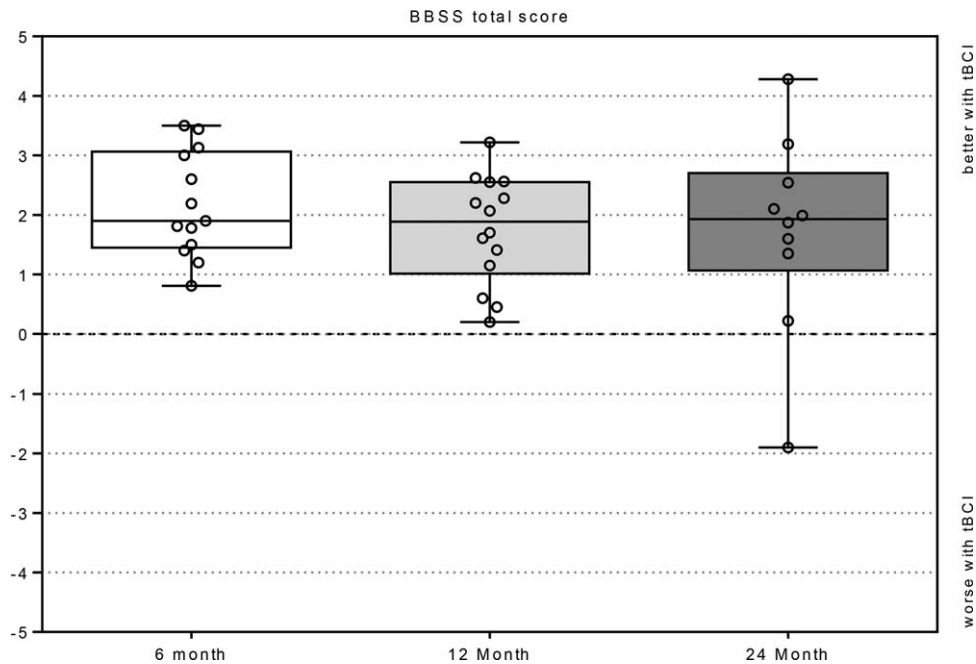


FIG. 4. BBSS Total Score. The BBSS total score is the average of all 10 items. Box Plots: median = horizontal lines; + = mean; whiskers = min.–max. values; circles = individual scores; n.s. = no significance.

conversation in a quiet environment (question 1). Questions concerning tBCI-aided hearing in noise and background sound (question 5) showed the lowest benefit, as well as hearing indoors, such as churches or entrance halls (question 7). Average daily wearing time was 10.1/11.3/8.4 hours at the 6-, 12-, and 24-month assessments. BBSS questionnaire individual question results are found in Supplement 5, <http://links.lww.com/MAO/B381>.

Adverse Events

Out of 10 adverse events reported during the study, 4 were deemed procedure- or device-related. One patient experienced retroauricular wound healing problems that were locally treated with medication. One patient had local swelling and pain after implantation that resolved without treatment. Another patient experienced occasional local swelling without pain at the implant site in the evening that resolved in the morning. One patient reports headache once per month. Two nonrelated serious adverse events required hospitalization due to an inguinal hernia and acute cholecystitis.

DISCUSSION

This study assessed hearing performance in challenging real-life listening situations and subjective benefit in SSD adult subjects using a tBCI. They were followed for up to 24 months after surgery. Subjective benefit was demonstrated in two questionnaires reporting on everyday listening situations with and without the tBCI.

Speech Understanding in Noise

Three different scenarios were employed to test speech intelligibility in noise in real-world listening situations.

For test scenario 1 ($S0^\circ N0^\circ$), in which both the signal and noise originate from the front of the user, no significant improvement in speech intelligibility was observed in the aided compared to the unaided condition. In this test scenario, there is no spatial separation between signal and noise and both sound and speech are processed by the normal hearing ear without obstruction/attenuation by the head. Similarly, no improvement was found for the percutaneous BAHA device in this test condition (32,33). As expected, the user appears to gain no benefit from the tBCI in this listening situation, but no significant deterioration in speech intelligibility was observed at any timepoint investigated.

In test scenario 2, with speech presented to the normal hearing side, SSD patients typically have fewer difficulties understanding speech in noise. However, this is also the most unfavorable test situation for the device under investigation, as it mainly amplifies noise. Previous publications have shown that if speech is presented to the normal hearing side, decreased speech understanding is observed in the aided condition with conventional and BC-CROS devices (34). In our study, no statistically or clinically significant difference was found between the aided and unaided conditions at baseline, the 6-month, 12-month, or 18-month evaluations. At the 24-month evaluation, we found a statistically significant difference in test scenario 2. The mean speech reception threshold in noise was 0.6 dB better in the unaided compared to the aided situation. However, this difference was within the 1-dB test–retest variability of the speech in noise test, thus it was considered not clinically significant (35). In the most recent individual data, three subjects experienced a deterioration of more than 1 dB in this test set-up: ID4 (1.3 dB), ID10 (1.1 dB), and ID11 (1.75 dB). ID1,

ID13, and ID14 experienced difficulties with the device at baseline in this scenario, but not at the later evaluations. In a previous study with speech presented from the front and noise at the SSD side, no significant difference was found between the unaided and tBCI aided condition (36).

The most complicated real-world hearing situation for unaided SSD individuals occurs in scenario 3 ($S90^{\circ}N0^{\circ}$), when the signal is presented to the deaf ear and noise to the front. In this scenario, the head shadow is present, as the head obstructs the signal which is therefore attenuated at the normal hearing ear and may not be separated from the noise. Device benefit would be most visible in this condition. Indeed, the greatest decrease in SRT in noise and thus the greatest speech understanding improvement was observed in test scenario 3. The primary endpoint for all subjects was reached and a clinically as well as statistically significant improvement was observed between the tBCI-aided and unaided conditions at all timepoints. At the latest individual-subject evaluation, 13 of 17 subjects showed clinically significant improvement of at least 1 dB in this scenario. Subjects ID6 (0.4 dB decrease), ID13 (0.4 dB decrease), and ID15 (0.8 dB decrease) did not reach this at the last evaluation although they showed an improvement of 2.2, 2.1, and 5 dB at baseline. Subject ID16 showed an improvement of 1, 1.2, and 0.9 dB at the 12-, 18-, and 24-month evaluations. The results for test scenario 3 are in accordance with results reported by Laske (16) in a prospective cohort study on adults implanted with the tBCI and by Linstrom (1) and Bosman (2003) (37) on SSD subjects using a BAHA. The large decrease in SNR for test scenario 3 shows that the tBCI can reduce the head shadow effect in this difficult listening situation for SSD patients.

Although our study involved patients with sensorineural SSD (both congenital and acquired), a recent study explored the possibility that the tBCI might also benefit patients with unilateral conductive hearing loss (UHL) as well. Vyskocil et al. (38) tested sound source localization in five congenital UHL patients with tBCI, with all patients showing improvement over the unaided condition; however, more examinations with a larger number of patients and/or longer follow-up are necessary to draw any conclusions. Similar studies in congenital UHL patients using a BAHA (39,40) showed very little sound localization benefit with the device. Fan et al. investigated sound localization abilities in 32 atresia patients implanted with the tBCI in this study, with and without an additional adhesive bone conduction device on the contralateral ear, interestingly finding a statistically significant improvement in the bilateral condition (41).

Subjective Benefit

In addition to the significant improvement in speech understanding in noise in scenario 3, an increase in subjective benefit was documented on the SSQ-B and BBSS questionnaires at the 6-month, 12-month, and 24-month evaluations. The subjective benefit from the tBCI

was most prominent in the “Speech” subscale of the SSQ-B, compared to the “Spatial” and “Quality” subscales. The “Speech” subscale contains six questions that are mostly related to hearing situations that are challenging for SSD patients, for example, background noise, conversations taking place without eye contact, environments with an echo, interference of voices with the same/different pitch and following conversations with many people talking (see questions 5 to 9 and 11 in supplement 2, <http://links.lww.com/MAO/B381>). The tBCI users benefited the most from their device in these situations.

Although it is not expected that treatment with the tBCI restores binaural hearing, patients in our study reported having better lateralization after receiving their devices. They particularly reported an improved ability to locate a speaker to the right or the left (see question 3 in supplement 3, <http://links.lww.com/MAO/B381>). This question scored highest on average on the SSQ-B “spatial” subscale.

Since speech understanding can be exhausting over the course of the day for the hearing impaired, it is important to point out that the subjects also experienced a benefit with the tBCI in the “Qualities” subscale of the SSQ-B for hearing situations associated to concentration and attention (see questions 14–17 in Supplement 4, <http://links.lww.com/MAO/B381>). However, the subjects did not experience a benefit regarding the naturalness of other voices, everyday sounds or their own voice (see questions 10–12 in Supplement 4, <http://links.lww.com/MAO/B381>).

The total BBSS score of 2.2 at 6, 1.7 at 12 and 1.7 at 24 months postimplantation demonstrate that the subjects in this study benefited from the device. The decrease in the subjectively perceived benefit over time in the BBSS score was not significant. Such a decrease over time has been previously noted in SSD subjects receiving another BC device (15). BBSS outcomes for conversations in groups or cars and overall hearing (see Supplement 5, <http://links.lww.com/MAO/B381>) further indicate that the SSD subjects treated with the tBCI benefit in situations where the head shadow effect plays a role.

To assess whether there are different outcomes after tBCI treatment in subjects suffering from congenital SSD (ID9, ID10, ID11, and ID12), a comparison to cases with acquired SSD was done. Due to the limited number of subjects no statistical analysis was performed. Another limitation of this comparison is that all congenital SSD patients were enrolled in the same study center. In scenario 2, two (ID10 and ID11) of the four congenital SSD cases experienced a clinically significant worsening of speech understanding in noise with the tBCI switched on, whereas this was only the case for one of the remaining 14 subjects. In scenario 3 all of them experienced a clinically significant improvement of 1 to 2.4 dB for speech understanding in noise. Three of the four subjects also reported a subjective benefit from the device in the BBSS and the speech domain of the SSQ-B, but not subject ID12. None of the congenital

SSD patients reported an improvement greater than 1 in the spatial hearing or hearing quality domain.

Safety

Safety of the device was confirmed by a lack of revision surgeries, serious device-related adverse events or serious device deficiencies up to 2 years postoperatively. Also, no explantation was reported. Changes in bone and air conduction thresholds are not associated with tBCI implantation (18,42). Clinical experience with the tBCI in subjects with conductive and mixed hearing losses has confirmed that the implantation procedure involves risks comparable to other implantable BC hearing implants, but avoids the most frequent postoperative complications observed with BAHA, namely those associated with the percutaneous abutment (19,43–48). Up-to-date, all reported complications with the tBCI have been comparable to those of other BC hearing implants.

Although this is the first study following up SSD patients implanted with the tBCI for up to 24 months, some limitations should be noted: Only 17 patients were enrolled with only 11 completing the 24-month assessment. The effect of treatment on spatial hearing was not assessed with an objective test, only within a questionnaire. Evaluation of the subjective measurement instruments would have benefitted from an untreated control group.

CONCLUSION

This study demonstrates the long-term benefit from the tBCI in adults with SSD. The device alleviates the head shadow effect in difficult listening situations in noise when speech is lateralized to the hearing-impaired ear. Complications were considerably lower than those found with other, especially percutaneous, bone-anchored hearing aids. The patients reported a substantial persistent subjective benefit for up to 2 years of device usage.

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