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First European Multicenter Results With a New Transcutaneous Bone Conduction Hearing Implant System: Short-Term Safety and Efficacy

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Objective: To investigate safety and efficacy of a new transcutaneous bone conduction hearing implant, over a 3-month follow-up period.
Study Design: Prospective, single-subject repeated-measures design in which each subject serves as his/her own control.
Setting: Departments of Otolaryngology at 4 hospitals in Germany and Austria.
Patients: Subjects were 12 German-speaking adults who suffered from conductive or mixed hearing loss. The upper bone conduction threshold limit was set to 45 dB HL at frequencies between 500 Hz and 4 kHz.
Intervention: Implantation of a transcutaneous bone conduction hearing implant.
Main Outcome Measures: Subjects' speech perception (word recognition scores and $SRT_{50\%}$) and audiometric thresholds (air conduction, bone conduction and sound field at frequencies 500 Hz to 8 kHz) were assessed preoperatively, 1 month postoperatively and 3 months postoperatively. The subjects were monitored for adverse events and given a questionnaire to assess their satisfaction levels.
Results: Speech perception as measured by word recognition scores and $SRT_{50\%}$ improved on average about 78.8% and 25 dB HL, respectively, 3 months after implantation. Aided thresholds also improved postoperatively at all tested frequencies and continued to improve from 1 to 3 months postoperatively. Air conduction and bone conduction thresholds showed no significant changes, confirming that subjects' residual unaided hearing was not deteriorated by the treatment. Only minor adverse events were reported and resolved by the end of the study.
Conclusion: The new transcutaneous bone conduction implant was demonstrated to be safe and effective in adults up to 3 months of device use. **Key Words:** Bonebridge—Bone conduction—Conductive hearing loss—Hearing implant—Mixed hearing loss—Transcutaneous.
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Bone conduction hearing aids and bone-anchored hearing aids (BAHA) have a long tradition in the treatment of conductive or mixed hearing loss (1–3), particularly in patients who would receive little benefit from a conventional hearing aid because of the conductive component in the middle ear (4). Conventional bone conduction hearing aids (e.g., pocket and spectacle hearing systems) provide a useful level of hearing for patients, at the cost of some discomfort from the constant pressure that must be applied externally to the head to provide good signal transmission (5). Higher frequency sounds tend to be attenuated by transmission through the skin, and unpleasant levels of feedback can occur. To circumvent these problems and provide a more consistent level of hearing assistance, BAHA systems have been developed (and continually refined) since the 1970s (6,7). A fixture screw is implanted into the mastoid bone and remains there long term. The sound processor is connected to an abutment that is attached percutaneously to the implanted fixture (7,8). Audiologic outcomes with BAHA have been favorable; patients gain the ability to understand speech and communicate in spite of background noise with great success and high subjective satisfaction rates (8–13).

Some disadvantages of percutaneous devices remain, in the form of high infection rates (30%–37%) and fixture losses (17.5%–26%) (14–16). Skin overgrowth can lead

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to the re-enclosure of the abutment (17,18). The skin around the abutment requires regular maintenance and a good level of hygiene. Fixture losses are more frequent in children because of osseointegration issues or trauma to the head (14,19,20). Such issues result in escalating treatment costs, inconvenience to the patient, temporary inability to wear the hearing aid, and revision surgery in a large number of cases (26%–42%) (14–16). They can be a persistent concern during the lifetime of the implant (17,21). Some centers implant 2 fixtures in children, a primary and a ''sleeper'' implant to be used when the primary fixture is lost (20).

Users of an earlier transcutaneous device for treatment of conductive hearing loss enjoyed a remarkably low rate of complications (22,23), although audiologic outcomes were superseded by the BAHA system (24). Several years on, demand still exists for an effective bone conduction system that avoids the problems associated with percutaneous abutments (25). The purpose of this study is to establish the safety and efficacy of a recently developed transcutaneous bone conduction implant system with separate external and implanted components, for the treatment of conductive and mixed hearing losses with an up to moderate inner ear impairment. Here, we present the first data of a study in which the device was implanted and evaluated in human subjects, with a 3-month follow-up period.

MATERIALS AND METHODS

Device Description

The Bonebridge (Vibrant MED-EL, Innsbruck, Austria) consists of an external audio processor (AP, Amadé Model BB; Fig. 1A) and an internal bone conduction implant (BCI; Fig. 1B). The BCI surgical kit provided with the implant includes 2 connectable templates, one for the transducer (T-sizer), and one for the coil (C-sizer) (Fig. 1C–1D) to allow optimal positioning of the BCI, cortical screws, and a 1.5-mm drill. The externally worn AP is attached to the patient's head, behind the ear, and is kept in position over the implant by magnetic force. The magnet comes in different strengths to accommodate the individual needs of the patients and can easily be changed during fitting of the device. The audio processor includes 2 microphones to pick up sound from the environment, a sound processing circuitry to modify the output signal to the patient's specific requirements, and a digital compression processor making use of wide dynamic range compression. The device is powered by a single standard 675 battery. The implanted part of the Bonebridge consists of the internal receiver coil, a magnet, a demodulator, and the Bone Conduction Floating Mass Transducer (BC-FMT). The transition between the demodulator and the BC-FMT can bend to ± 90 degrees in the horizontal plane and -30 degrees in the vertical plane to accommodate individual skull anatomies. The sound signal and the energy to drive the BC-FMT are transferred transcutaneously via an inductive link to the internal coil, processed by the demodulator and then relayed to the BC-FMT. The BC-FMT transduces the signal into mechanical vibrations, which are conducted to the mastoid bone via the cortical fixation screws. For signal transmission, osseointegration of the cortical screws was expected not to be crucial. Typically reported osseointegration times in the mastoid bone are 6 to 8 weeks (26,27). As torques or forces with the magnetic audio processor attachment were expected to be lower than with the snap coupling of BAHA systems, subjects were activated after 4 weeks. Nevertheless, an integrating process between screws and mastoid bone will take place during the healing process. The transmitted vibrations stimulate the auditory system and are interpreted by the patient as sound (28). In this way, it is possible to bypass damaged parts of the outer and/or middle ear.

Preclinical performance testing was carried out on a device similar to a skull simulator as described in (29).This device features a suspended mass of 50 g, rigidly coupled to the Bonebridge implant and to an accelerometer. Design goals were based on direct bone conduction thresholds (30). Magnetic resonance imaging (MRI) with up to 1.5 Tesla can be carried

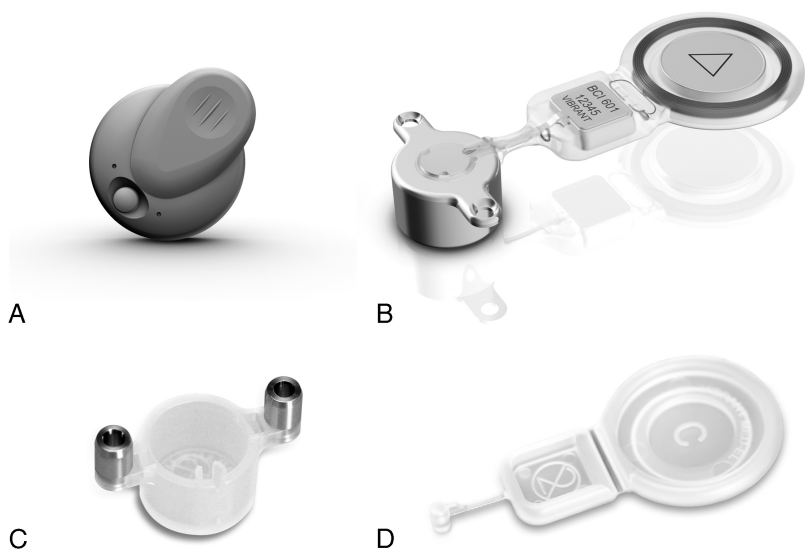

FIG. 1. *A*, Bonebridge audio processor (AP). *B*, Bonebridge bone conduction implant (BCI). *C*, T-sizer. *D*, C-sizer.

TABLE 1. *Demographic data and medical parameter disease factors of the 12 study participants*

Demographics				Disease factors and medical history						
Subject no.	Age at surgery	Sex	Study site	Implanted ear	No. previous ear surgeries	Duration of HL (yr)	Type of HL	Etiology	PTA_4 BC implanted ear (dB HL)	PTA_4 AC implanted ear (dB HL)
1	69	M	Berlin	R	2	60	CHL	Cholesteatoma	5	45
2	69	F	Berlin	R	4	60	CHL	Cholesteatoma	19	46
3	44	F	Berlin	R	2	9	Mixed	Otosclerosis	35	50
4	28	M	Hannover	R	2	15	CHL	COM	6	30
5	65	F	Hannover	R	1	2	CHL	Glomus tumor	6	66
6	65	F	Hannover	L	1	1	Mixed	Chronic mastoiditis	14	53
7	63	F	Hannover	L	3	22	Mixed	COM	18	67
8	35	M	Würzburg	R	5	35	CHL	Cholesteatoma	8	49
9	20	F	Innsbruck	L	2	20	CHL	Atresia auris	11	73
10	19	F	Innsbruck	R	2	19	Mixed	Cholesteatoma	21	61
11	28	F	Innsbruck	R	0	28	Mixed	Atresia auris	25	93
12	27	F	Innsbruck	R	1	27	CHL	Atresia auris	15	73

out with a Bonebridge implant, provided the AP is not worn. An artifact around the implant will be visible on the images. Interactions of the Bonebridge implant with MRI scanners were studied using standardized methods and found to comply with MRI up to 1.5 Tesla (31–34).

Study Design

The study was a prospective, single-subject repeated-measures design, in which each subject served as his/her own control. Performance on audiometric tests preoperatively was compared with the aided 3 month postoperative condition using the Bonebridge. This type of design has been applied frequently to the evaluation of implantable hearing devices in multicenter clinical trials (35–37). It minimizes the effect of variability inherent to the population to the evaluation of treatment outcomes. Standardized evaluation methods were used to assure the reliability of the data across different investigational centers.

Subjects

Twelve German-speaking adults for whom an improvement of hearing either by otologic surgeries or by conventional hearing aid fitting was not possible or not successful were enrolled at four otorhinolaryngology departments in Austria (University Clinic Innsbruck) and Germany (Unfallkrankenhaus Berlin, Hannover Medical School and University Clinic Würzburg). The mean age of the 9 men and the 3 women was 44 years (range, 19–69 yr). Subject demographics and medical factors are provided in Table 1. To qualify for enrollment, patients were required to be 18 years of age or older with conductive or mixed hearing loss, as indicated by audiometric testing. Upper bone conduction threshold limits were set to 45 dB HL at frequencies 500 through 4,000 Hz (Fig. 2). Fluentness in German, a stable inner ear function without episodic hearing fluctuation, absence of severe-to-profound hearing impairment in the nonimplanted ear and no previous use of an active middle ear hearing implant or BAHA in either ear were obligatory.

Criteria that specifically excluded a subject from participating in the investigation involved chronic or nonrevisable vestibular or balance disorders, abnormally progressive hearing loss, chronic headache, evidence of conditions that would prevent good speech recognition potential and evidence that the hearing loss was of retrocochlear or central origin. In addition, patients with nonresponsive ear infections that could impair success with a bone conduction device, skin or scalp conditions that may preclude attachment or interfere with the usage of the audio processor, skull size or abnormalities that would preclude appropriate placement of the Bonebridge implant as determined by CT scan, and the inability to undergo general or local anesthesia were not qualified to participate. Informed consent was obtained from all patients, and the study was approved by the respective national competent authorities in Austria and Germany and by the local ethics committees in the respective investigational centers.

Surgical Technique

CT imaging was used to verify suitability of implant placement, focusing on adequate space in the mastoid bone (sinodural angle), adequate bone thickness in the retromastoid area in cases with open or obliterated radical cavities. Optimal positioning of the BC-FMT and the fixation screws were planned, whereas thickness and consistency of the bone, the position of the sigmoid sinus and dura mater were taken into consideration.

The BCI outline was marked on the skin of the surgical field using the connectable templates, followed by injection of a

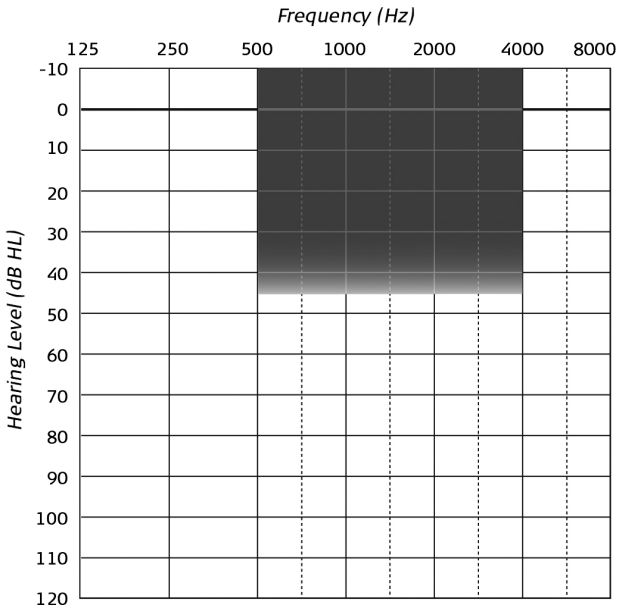

FIG. 2. Indication range for the Bonebridge (maximum tolerable bone conduction threshold at each individual frequency, courtesy of Vibrant MED-EL).

vasoconstrictive agent in most cases, before the postauricular incision and preparation of the surgical field. Skin flap thickness was measured because it should not exceed 7 mm above the receiving coil to assure optimal signal transmission and magnetic attraction of the AP. Again, implant position was checked and marked on the skull using the templates. The 8.7-mm deep recess for the BC-FMT was drilled sinodural in 7 cases, retromastoidal in 4 cases, and retrosigmoidal in 1 case. The dimension of the recess was constantly controlled using the T-sizer. The 2 holes for the fixation screws were drilled using the T-sizer as a drill guide, using the supplied 1.5-mm drill. The BCI was bent at the transition according to required final position; the coil and the demodulator were placed into an elevated periostal pouch, and the BC-FMT was placed into the recess. Tightening of the screws was performed using a torque wrench. In most cases, fixation of the BC-FMT with the two 6-mm-long cortical screws provided was sufficient. In some cases, slightly broader screws were used. These so-called emergency or back-up screws are part of the implant kit and come with every implant. They are intended to be used in cases where over tightening of the regular screws has taken place. As the back-up screws have a slightly broader diameter (2.4 mm compared with 2.0 mm for the regular screws), they provide a snug fit in the predrilled hole. After another verification that the receiver coil and therefore the external AP was in the desired position, the wound was closed, and the patient underwent standard postoperative care. All surgeries were performed under general anesthesia and took 45 to 60 minutes.

Device Fitting

First fitting of the audio processor took place 4 weeks after implantation and was additionally applied at the 2- and 3-month postoperative evaluation interval as needed. The audio processor is programmed using the software Connexx 6.4.3 and Symfit 6.0 using a programming cable and the HI-Pro Box type 1072 (GN Otometrics A/S, Taastrup, Denmark). To calculate the target gains, bone conduction thresholds of the implanted ear were entered into the fitting software. Fitting procedure took approximately 30 minutes.

Data Collection and Statistics

Audiometric testing was carried out in an audiometric sound-attenuated room, using calibrated signals and equipment. Subjects were tested unaided preoperatively and 1 and 3 months postimplantation in the aided condition with the Bonebridge. Speech perception in quiet was tested using the Freiburger Monosyllable Test (word recognition score presented at 65 dB SPL [38]) and the German Oldenburger Satztest (OLSA, speech reception threshold for 50% word intelligibility in sentences [39]).

Soundfield thresholds (warble tones) were tested at 500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz, and 8 kHz with the subject sitting 1 meter in front of (0-degree azimuth) and level with the loudspeaker. The contralateral ear was plugged and covered, and narrow-band masking noise was applied if necessary. Audiometric pure tone thresholds were determined for air conduction at 500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz, and 8 kHz, signals were delivered to the subjects under headphones. Bone conduction thresholds were determined at 500 Hz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz using a calibrated bone conduction vibrator.

Repeated-measure analysis of variance (ANOVA) was performed for all speech tests. The specific hypotheses for effectiveness were as follows: i) that the word recognition score would improve through the treatment, ii) that the $SRT_{50\%}$ would decrease as a result of the treatment, and iii) that postimplantation aided sound field thresholds would improve when compared with those obtained unaided preoperatively. The specific hypothesis for safety was that residual hearing, as measured by bone conduction thresholds (pure tones), would not decrease significantly in subjects as a result of the treatment. As device installation takes place apart from inner or middle ear structures, there was expected to be little or no risk to residual hearing in these patients. A decrease of 5 dB or less at a particular frequency would be within test-retest reliability and would not be considered clinically significant (40).

Subjective device satisfaction was tested by means of the Hearing Device Satisfaction Scale (HDSS) questionnaire. This self-assessment questionnaire was repeatedly used in other studies on implantable hearing devices and evaluates the user's general satisfaction with the hearing device (35,41). The answer categories were transformed into a percentage score from 100% (very satisfied) to 0% (not satisfied) based on the answers given.

Statistical analyses were performed using IBM SPSS Statistics 19 (IBM, Armonik, NY, USA). One-way repeated-measure ANOVAs with time as factor were performed (significance was accepted at $p \leq 0.05$) and followed by post hoc pairwise comparisons to examine significant differences between the single test intervals. For each ANOVA, Mauchly's test of sphericity was applied. If sphericity could not be assumed, a Greenhouse-Geisser correction was used as part to the ANOVA. P-values of the pairwise comparisons were adjusted with the Holm-Sidak method. Box-Whisker Plots represent the whole data set. Whiskers extend to the maximum value within 1.5 times the interquartile range (IQR) above the third quartile or the minimum value within 1.5 times the IQR below the first quartile. Values outside this range are considered to be outliers, depicted as individual dots. Tukey box-whisker plots were generated using GraphPad Prism 5 (http://www.graphpad.com).

RESULTS

Mean unaided word recognition scores (Fig. 3) averaged 14.2% (SD, ±18.1) preoperatively, compared with 82.9% (SD, ±12.5) 1 month postimplantation and 92.9% (SD, ±6.9) 3 months postimplantation. Repeated-measure ANOVA indicated a significant change with respect to time ($F_{2,\ 22} = 195.07$, $p < 0.001$). Post hoc pairwise comparisons confirmed that scores improved significantly between preoperative testing and 1 month after implantation ($p < 0.001$), between preoperative testing and 3 months after implantation, and from 1 to 3 months ($p = 0.010$).

Before implantation, the mean OLSA $SRT_{50\%}$ thresholds (Fig. 4) averaged 61.9 dB (SD, ±8.6), compared with 42.0 dB (SD, ±8.9) 1 month and 36.6 dB (SD, ±8.8) 3 months postimplantation. Repeated-measure ANOVA indicated a significant change over time ($F_{2,\ 20} = 41.282$, $p < 0.001$). Post hoc pairwise comparisons indicated significant improvements from preoperative to 1 month testing ($p < 0.001$), preoperative to 3-month testing ($p < 0.001$), and between 1- and 3-month testing ($p = 0.035$).

Audiometric thresholds for air conduction (Fig. 5) and bone conduction (Fig. 6) showed no significant change with respect to time, at the 5% significance level, for any of the tested frequencies. Conversely, sound field testing

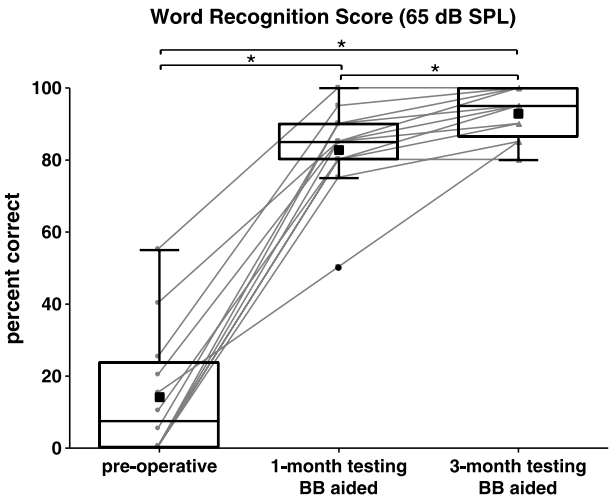

FIG. 3. Word recognition scores in quiet (Freiburger monosyllables) for the implanted ear: preoperative, 1-month postoperative and 3-months postoperative. Both postoperative scores are significantly improved from preoperative scores ($p < 0.001$) and from each other ($p = 0.010$), n = 12, BB = Bonebridge.

(Fig. 7) showed a significant improvement over time at the 5% significance level for warble tones at all tested frequencies and at the 0.1% significance level for frequencies from 500 Hz to 6 kHz. F-statistics and *p*-values obtained from repeated-measure ANOVAs for the 3 different audiometric tests at 7 frequencies are presented in Table 2.

Subjective hearing device satisfaction ranged from 49% to 99% with a mean of 79% (Fig. 8).

A total of 4 adverse events occurred after implantation, all of which were minor. One patient reported transient tinnitus shortly after recovering from the implantation, which resolved without any intervention 1 day after surgery. Another patient reported headache and vertigo after discharge from the hospital, which was resolved after medical treatment without any further action required. A third patient presented with a seroma at the implant site, which was punctured and treated with local antibiotics. The fourth subject presented with a minor skin infection

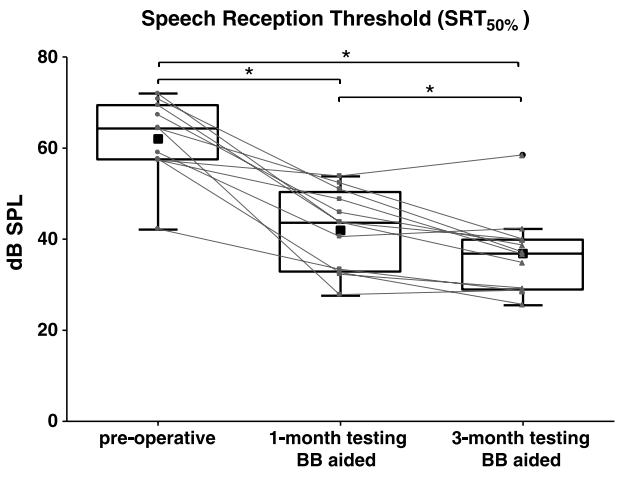

FIG. 4. Speech reception threshold ($SRT_{50\%}$) in quiet for the implanted ear: preoperative, 1-month postoperative and 3-month postoperative. Both postoperative scores are significantly improved from preoperative scores ($p < 0.001$) and from each other ($p = 0.035$), n = 12 BB = Bonebridge.

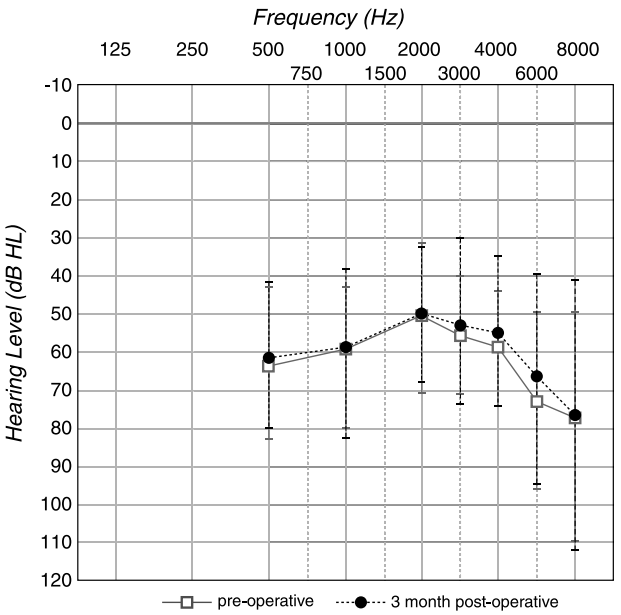

FIG. 5. Mean air conduction thresholds for the implanted ear: preoperative unaided testing compared with 3-month postoperative tests. Error bars represent T 1 SD (n = 12).

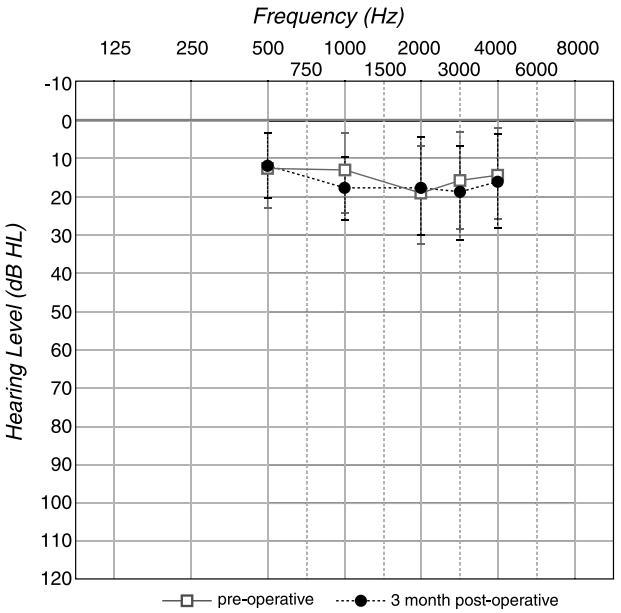

FIG. 6. Mean bone conduction thresholds for the implanted ear: preoperative unaided testing compared with 3-month postoperative tests. Error bars represent T 1 SD (n = 12).

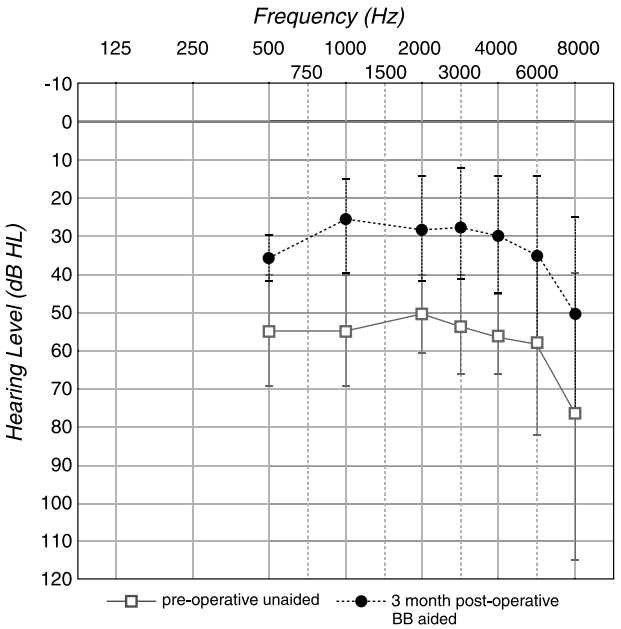

FIG. 7. Mean soundfield thresholds (warble tones) for the implanted ear: preoperative unaided testing compared with 3-month postoperative aided tests. Error bars represent ± 1 SD (n = 12), BB = Bonebridge.

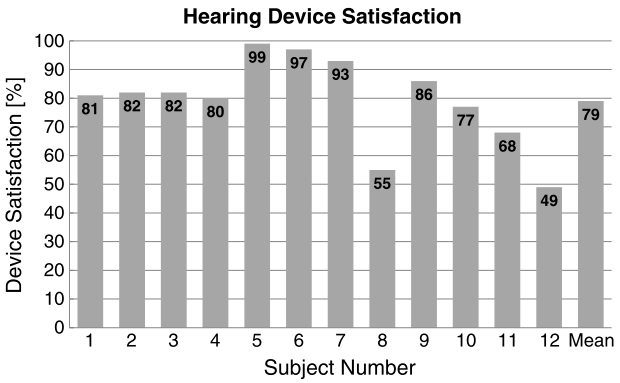

FIG. 8. Hearing Device Satisfaction Scale (HDSS): individual and mean scores across all subjects (n = 12).

at the implant site and was also treated with local antibiotics. None of these complications required surgery, and all of them resolved completely before the end of each patient's study participation.

DISCUSSION

These results indicate the effectiveness of the Bonebridge, the first transcutaneous bone conduction implant system. Subjects' word recognition scores increased to a level comparable with and in excess of studies carried out with other successful implanted hearing devices (8,35). Improvements to subjects' speech recognition thresholds, from 61.9 dB preoperatively to 36.6 dB after 3 months, was also comparable to published results from bone conduction and BAHA studies (8,12). Subjects' word recognition and speech recognition results improved from 1 to 3 months postimplantation, suggesting that during this period of acclimatization, auditory comprehension with the device continued to improve.

The secondary hypothesis that audiometric sound field thresholds will improve upon treatment can also be confirmed. Mean aided sound field thresholds (warble tones) improved after treatment by more than 20 dB across all tested frequencies.

Mean air conduction and bone conduction thresholds did not change by more than 5 dB at any tested frequency. This confirms that, as expected, the treatment did not degrade the subjects' residual unaided hearing capabilities; as with BAHA systems, implantation of the BCI should not at all affect the inner ear. This, together with the lack of major complications, indicates a good level of safety.

During surgery, care must be taken to avoid damaging the dura mater or the sigmoid sinus when drilling the recess for the BC-FMT or when drilling the fixation holes. Damage to the dura would increase the risk of infection, potentially subjecting the patient to the risk of further complications. The status of the mastoid (open or obliterated radical cavities, subtotal petrosectomy, normal outer ear canal) did not influence the usability of the device, nor did it increase the complication rate. Preoperative CT scanning is highly recommended to help determine the optimal placement of the implant with regard to bone thickness, bone consistency, and the location of critical structures like the dura or the sigmoid sinus. The reported adverse events were minor and were resolved by the end of the study.

For comparison, complications immediately after implantation of BAHA systems are rare (42), although somewhat dependent on surgical technique, adverse reactions, and complications tend to accumulate months or

TABLE 2. *F statistics and p values from analysis of variance of audiometric tests (preoperative, 1-month postoperative and 3-month postoperative; n = 12)*

	500 Hz		1 kHz		2 kHz		3 kHz		4 kHz		6 kHz		8 kHz	
	$F_{(2,22)}$	p	$F_{(2,22)}$	p	$F_{(2,22)}$	p	$F_{(2,22)}$	p	$F_{(2,22)}$	p	$F_{(2,22)}$	p	$F_{(2,22)}$	p
Air conduction (Fig. 5)	0.394	0.68	0.555	0.58	0.681	0.52	0.723	0.50	1.00	0.38	0.726	0.50	0.032	0.97
Bone conduction (Fig. 6)	0.919	0.41	1.00	0.38	1.16	0.33	1.61	0.22	1.46	0.25	—	—	—	—
Soundfield (Fig. 7)	14.7	<0.001	48.1	<0.001	24.3	<0.001	64.8	<0.001	61.8	<0.001	28.7	<0.001	5.00	0.036

years after implantation (16,43,44). This might partly be due to the percutaneous nature of the BAHA, with all the drawbacks and problems of a skin penetrating abutment and partly due to the requirement of the implant to achieve osseointegration. Experience with other transcutaneous hearing implants such as cochlear implants and middle ear implants suggests that recipients of a transcutaneous bone conduction implant system will experience fewer such problems (35,45) as the implant is secured to the skull via screws and is covered by intact skin. The performance of the Bonebridge is not dependent on osseointegration of the screws. Long-term studies among a larger subject pool are planned to make an empirical safety comparison with other systems, as well as to assess the long-term performance and stability of the system.

The maximum output force level (OFL dB related to 1 μN, subsequently abbreviated dB μN) reachable with the system at full-on gain setting is typically around 114 dB μN at 1 kHz. In the present study, the rms mean output force level at 1 kHz across study subjects for input levels of 65 dB SPL is 89.9 dB μN (range, 83–99 dB μN). Consequently, the system provides an additional gain reserve. It could be used for patients with poorer bone conduction thresholds than the ones evaluated within the present cohort. Additionally, the audio processor makes use of wide dynamic range compression. The mean compression ratio across all study subjects and over all frequencies is 1:1.48, with a mean compression knee point set to 42.2 dB SPL. The fitting software allows compression ratios up to 1:4, showing that higher compression ratios can be applied to subjects with a more narrow dynamic range.

For this study, the system was activated 4 weeks after implantation but because osseointegration is not required, earlier activation might be possible, depending on the status of the skin flap. No staged procedure is required with this device, which allows for earlier fitting of the external part. In other respects, the results of this short term trial clearly demonstrate comparable audiologic advantages of this transcutaneous bone conduction system as other bone-anchored hearing devices with the potential of less complications and a generally high level of patient satisfaction.

CONCLUSION

In summary, good aided benefit in terms of word recognition scores, speech reception thresholds, aided soundfield thresholds, and high subjective device satisfaction was shown. A thorough radiologic and surgical planning by means of a CT scan is beneficial to find the optimal implant placement. Further studies will be needed to confirm these promising initial results. They should compare this new treatment option to already established surgical procedures as well as other devices for hearing restoration. Fewer medical findings as in percutaneous bone-anchored solutions can be expected from this device because of a transcutaneous signal transmission. Furthermore, long-term follow-up studies are needed. This first active transcutaneous bone conduction implant opens another treatment alternative for patients with mixed and conductive hearing losses.

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