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The Bonebridge in Adults with Mixed and Conductive Hearing Loss: Audiological and Quality of Life Outcomes

Piotr H. Skarżyński[a–c] Anna Ratuszniak[d] Bartłomiej Król[d] Magdalena Kozieł[e] Kamila Osińska[d] Katarzyna B. Cywka[d] Anna Sztabnicka[d] Henryk Skarżyński[d]

[a]Heart Failure and Cardiac Rehabilitation Department, Second Faculty of the Medical University of Warsaw, Warsaw, Poland; [b]Institute of Sensory Organs, Kajetany, Poland; [c]Department of Teleaudiology and Screening, World Hearing Center, Institute of Physiology and Pathology of Hearing, Kajetany, Poland; [d]Otorhinolaryngosurgery Clinic, World Hearing Center, Institute of Physiology and Pathology of Hearing, Kajetany, Poland; [e]Clinical Studies, Institute of Sensory Organs, Kajetany, Poland

Keywords
Bonebridge · Implantation · Quality of life · Benefits · Bone conduction

Abstract
Background: Considering that hearing loss has a significant impact on social functioning, everyday activity and a person's emotional state, one of the most important goals of hearing rehabilitation with bone conduction devices is improvement in a patient's quality of life. ***Objectives:*** To measure self-assessed quality of life in patients implanted with the Bonebridge, a bone conduction device. ***Method:*** Prospective, observational, longitudinal study with one treatment group. Twenty-one patients with mixed or conductive hearing loss were included, and each individual served as its own control. The Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to measure patient-reported quality of life before intervention and at 3 and 6 months after activation of the device. At the same time frames, pure-tone audiometry and speech understanding in quiet and in noise were tested. ***Results:*** Hearing-specific quality of life increased significantly after intervention and remained stable up to 6 months. Both word recognition in quiet and speech reception threshold in noise were significantly better after 6 months compared to before surgery. Outcomes of aided speech understanding were independent of initial bone conduction thresholds and equally high (word recognition score >75%) across the device's indication range. ***Conclusions:*** The Bonebridge provides not only significant audiological benefit in both speech understanding in quiet and in noise, but also increases self-perceived quality of life in patients suffering from mixed and conductive hearing loss. Together with a very low rate and minor nature of adverse events, it is the state-of-the-art solution for hearing rehabilitation in patients with mixed or conductive hearing loss up to a bone conduction threshold of 45 dB HL.

Introduction

The causes of conductive or mixed hearing loss are manifold, include various pathologies (congenital atresia, chronic otitis media, cholesteatoma, otosclerosis) and are often associated with complex surgical histories. Differ-

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E-Mail karger@karger.com
www.karger.com/aud

Piotr H. Skarżyński
Institute of Sensory Organs
Mokra 1 Street
PL–05-830 Kajetany (Poland)
E-Mail p.skarzynski@inz.waw.pl

ent options for hearing rehabilitation exist for these patients [Gavilan et al., 2015; Ratuszniak et al., 2017], including traditional hearing aids, surgical rehabilitation (e.g., ossiculoplasty), bone conduction implants (BCIs) and middle-ear implants [Olszewski et al., 2017]. While traditional hearing aids provide insufficient amplification to many of these patients [Braun et al., 2014; Alzahrani et al., 2015], the audiological benefit of surgical hearing restoration has been shown to be limited compared to BCIs in some conditions (e.g., in atresia patients) [Nadaraja et al., 2013]. Also, surgical hearing restoration can be associated with a relatively high risk of revision surgeries [Gardner et al., 2004; Govil et al., 2017]. Conversely, both BCIs and middle-ear implants are excellent treatment options, and it is up to the surgeon to balance pros and cons for each patient individually.

Recent years have seen a dynamic development in the field of implantable bone conduction (BC) hearing implants as manufacturers developed transcutaneous devices in an attempt to overcome the elevated incidence of dermatological complications known from classical, percutaneous bone-anchored hearing implants [Wazen et al., 2011]. The latest technological solution – active BC devices – is represented on the market by only one device, the Bonebridge (MED-El, Innsbruck, Austria), which has been introduced in 2012. This semi-implantable system consists of two components: an active, implantable part (BCI) and an externally worn audioprocessor. Sound is transmitted from the audioprocessor to the BCI, where it is converted into mechanical vibration that is directly applied to the skull bone via the bone conduction floating-mass transducer (BC-FMT). Like in other devices, the audioprocessor is held in place by magnetic force. However, since the active (vibrating) part is implanted, less force is needed to hold the audioprocessor in place. Due to the active design, damping caused by skin and soft tissues, as known from other transcutaneous devices, is eliminated. Additional features differentiating this implant from other implantable solutions are: method of fixation of the subcutaneous vibrating transducer (with two dedicated screws) and size of the implanted part (size of the BC-FMT: diameter 15.8 mm, height 8.7 mm). The system can be used in patients with conductive or mixed hearing loss, whose BC thresholds are not higher than 45 dB HL for 500, 1,000, 2,000 and 3,000 Hz in the ear to be implanted, or, in cases of single-sided deafness, in the ear with a severe to profound hearing loss and contralateral normal hearing [Sprinzl et al., 2013; Riss et al., 2014]. Other inclusion criteria are: age above 5 years (since 2014), stable BC thresholds and realistic expectations. Due to the size of the vibrating transducer, another important factor is that the anatomy of the mastoid allows a safe placement of the BCI. For this reason, the surgical procedure for implantation of this device is considered more difficult compared to other solutions, especially in the case of patients with extensive bone loss due to previous surgeries in the mastoid area. In these patients it is recommended to perform a CT scan before making a decision about surgery [Weiss et al., 2017a].

The introduction of a new treatment solution is an occasion to pose questions about the effectiveness of compensating conductive and mixed hearing loss, long-term clinical effects of the device use and safety of use. Although audiological results of the Bonebridge that have been published by other authors from different centres indicate that it is a safe and highly efficient solution [Sprinzl et al., 2013; Ihler et al., 2014; Laske et al., 2015; Rahne et al., 2015; Baumgartner et al., 2016; Schmerber et al., 2017; Weiss et al., 2017b; Bravo-Torres et al., 2018], these were mainly based on small patient groups. One aim of this study is thus to assess the effectiveness of the Bonebridge system in a larger patient group with conductive or mixed hearing loss and complex patient histories.

Considering that hearing loss has a significant impact on social functioning, everyday activity and the patient's emotional state, one of the most important goals of this medical intervention is improvement in a patient's quality of life. A second aim of this study is thus the assessment of pre- versus postintervention benefits in hearing-related quality of life (QoL).

Materials and Methods

Study Design

This study was designed as prospective follow-up study with each patient's pre-operative unaided outcomes serving as control. The study protocol was approved by the Institutional Review Board of the Institute of Physiology and Pathology of Hearing (IFPS:/KB/05/2014) and conformed with the Declaration of Helsinki. Between July 2014 and August 2016, 25 patients were included.

Surgery

For all patients, CT scans were carried out in order to evaluate optimal positioning of the BC-FMT in the mastoid bone. All surgeries were conducted under general anaesthesia following standard procedures suggested by the manufacturer of the device. After confirmation by CT scans, the Bonebridge implant was placed in the sinodural angle in all cases (Fig. 1). In patients after the radical operation, the cavities were obliterated with the bioactive glass

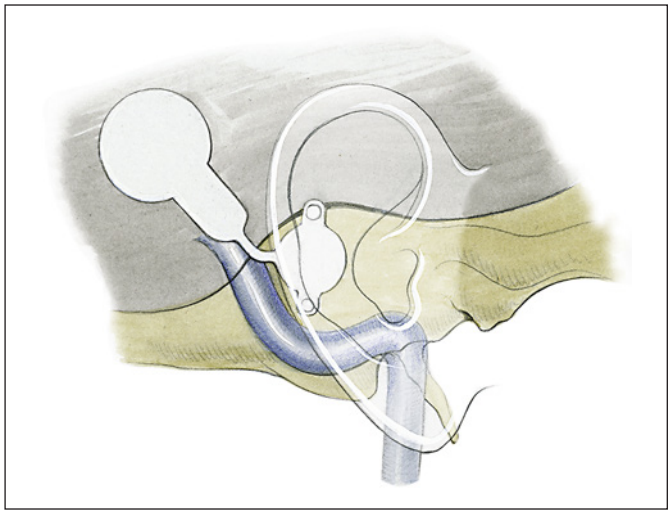

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Fig. 1. The sinodural positioning of the BC-FMT. Copyright by MED-El.

(BonAlive) before implantation of the Bonebridge system. Whenever needed, spacers (BCI lifts; available in 1, 2, 3 or 4 mm height from the manufacturer) were positioned under the transducer wings to allow for lower drilling depth.

Audiometric Testing

Audiometric tests were performed with an Otometrics Madsen Itera II diagnostic audiometer before implantation of the Bonebridge as well as 3 and 6 months after first fitting of the device. At each time interval, air conduction and BC thresholds, sound field thresholds, word recognition score (WRS) and speech reception thresholds in noise were measured – with the exception that speech reception threshold in noise was not measured at the 3-month interval. All tests were performed in an anechoic chamber. Sound field thresholds were measured using warble tones presented from a loudspeaker that was situated 1 m in front of the subject. The WRS was assessed with the Demenko & Pruszewicz Polish Monosyllabic Word Test at 50, 60 and 70 dB SPL presented via a loudspeaker. The contralateral ear was double-blocked with an earplug and over-earphone or masked with noise if necessary. Speech reception thresholds in noise were assessed using the Polish Matrix Sentence Test with signal and noise presented from the front (S0N0). The noise level was fixed at 65 dB SPL.

QoL Questionnaire

Patient-reported outcomes were collected using the Abbreviated Profile of Hearing Aid Benefit (APHAB; hearing-specific QoL by Cox and Alexander [1995]) The APHAB is the most widely used hearing-specific questionnaire and was chosen for comparability with other studies. The unit reported is the amount of problems in percent. Thus, lower values indicate better outcomes. A global score and 4 subscores can be calculated for ease of communication, background noise, reverberation and aversiveness to sound.

Statistical Analyses

The Friedman test was used to test for significance of overall effects among blocks of paired data. Whenever missing data were present, a generalized version of the Friedman test, the Skillings-Mack test [Chatfield and Mander, 2009], was used. The Wilcoxon signed-rank test and the Holm p value adjustment were used for pairwise comparisons. The α-level was set to 0.05. All statistical tests were performed in *R* v3.4.1 statistical computing environment [R Core Team, 2015] via the graphical user interface *RStudio* v1.0.136. All plots were built using the *ggplot2* package [Wickham, 2009].

Results

Patient Demographics

Between 2014 and 2016, 25 consecutive patients were included in this prospective study. Three patients were lost to follow-up, and 1 patient was excluded due to inconsistent outcomes. Different measuring stations were used in the latter case and that may have biased measurements at the pre-operative time frame. The final population included 21 patients (21 ears). Demographic information is summarized in Table 1. Age at implantation ranged from 18 to 58 years with a mean of 40.29 years (SD = 13.64). There were 8 patients with conductive and 13 patients with mixed hearing loss. In 8 patients, the hearing loss was bilateral, but all patients were unilaterally implanted in this study. The causes of hearing loss in these patients include chronic otitis media, cholesteatoma, otosclerosis or congenital malformations of the middle or outer ear.

Surgical Outcomes and Adverse Events

CT scans favoured the placement of the BC-FMT in the sinodural position in all patients. No adverse events were observed during surgeries. In 1 case, sclerotic and extremely hard mastoid bone was observed. BCI lifts were used in 8 patients (3 × 1 mm, 4 × 2 mm, 1 × 3 mm lift size; Table 1), and in 1 case, self-tapping screws were used. In 1 case the dura was exposed, and a small bone plate was placed between dura and implant to prevent direct pressure from the BC-FMT. Besides 1 case of slight swelling, no further complications were noted in the immediate postoperative period.

No major adverse events occurred up to the 6-month follow-up. In total, 8 patients experienced minor adverse events: patient 2 had pain at the audioprocessor site at 3 months of follow-up. Following change of magnet strength, the pain was gone at 6 months of follow-up. Patient 3 had a feeling of numbness and tingling at the implant site 1 month after surgery. These symptoms were decreasing after 3 months without any treatment and were absent at the 6-month follow-up. Patient 6 had pain

Table 1. Patient demographics

Patient	Age at implantation, years	Sex	Implant side	HL type	HL side	Cause of HL	BCI lift type	Previous surgery (implanted side)
1	55	F	Right	MHL	Bilateral	Bilateral COM; cholesteatoma left	No	3 × tympanoplasty
2	41	F	Left	MHL	Left	Microtia/atresia	No	Plastic surgery of the pinna
3	45	F	Right	MHL	Right	Congenital defect outer and middle ear	No	No
4	18	M	Right	CHL	Right	Congenital defect outer ear	No	4 × plastic surgery of the pinna (surgery divided into 4 stages)
5	56	F	Right	MHL	Bilateral	Otosclerosis	No	Stapedotomy, revision with removal of adhesions from middle ear
6	56	M	Right	MHL	Bilateral	COM	No	Myringoplasty
7	22	M	Right	MHL	Bilateral	Congenital defect outer and middle ear	No	Reconstructing the auditory canal + myringo-ossiculoplasty
8	55	M	Left	MHL	Bilateral	COM	No	Myringoplasty, ossiculoplasty
9	58	F	Right	MHL	Bilateral	COM	3 mm	Myringo-ossiculoplasty
10	56	F	Left	CHL	Left	COM; cholesteatoma	2 mm	2 × myringo-ossiculoplasty
11	41	M	Left	MHL	Bilateral	COM; cholesteatoma	2 mm	Radical mastoidectomy
12	56	M	Left	MHL	Bilateral	COM	2 mm	Radical mastoidectomy
13	18	M	Right	MHL	Right	Congenital defect outer and middle ear	No	Plastic surgery of the pinna
14	37	F	Left	MHL	Left	COM; cholesteatoma	No	2 × cholesteatoma removal, ossiculoplasty
15	36	F	Right	CHL	Right	COM; cholesteatoma	No	Ossiculoplasty
16	29	F	Left	CHL	Left	COM	1 mm	Tympanoplasty with ossiculoplasty
17	32	M	Left	CHL	Left	Atresia	2 mm	Plastic surgery of the ear canal
18	30	F	Right	CHL	Right	Congenital defect outer ear	1 mm	No
19	18	M	Right	CHL	Right	Congenital defect outer ear	No	No
20	41	F	Left	MHL	Left	COM	No	Tympanotomy + myringoplasty
21	46	M	Left	CHL	Left	COM	1 mm	Radical mastoidectomy

HL, hearing loss; BCI, bone conduction implant; F, female; M, male; CHL, conductive hearing loss; MHL, mixed hearing loss; COM, chronic otitis media.

at the implant site and discharge from the ear. The symptoms were not resolved at the 6-month follow-up, and the patient was referred to a hospital where he was treated for otitis media with corticosteroid ointment and local antibiotics. Patient 7 had discharge from the implanted ear 1 month after surgery, but this resolved without treatment and was no longer present at the 3-month follow-up. Patient 9 reported mild dizziness when moving at 3 months of follow-up, but this resolved without treatment. The patient was referred to consultation for suspected problems with blood pressure, and subsequently hypertension treatment was applied. Patient 13 had slight swelling during the healing process, but this resolved before the 1-month follow-up without any special treatment. Patient 18 had discharge from the implanted ear at the 3-month follow-up, which was resolved at 6 months. Pa-

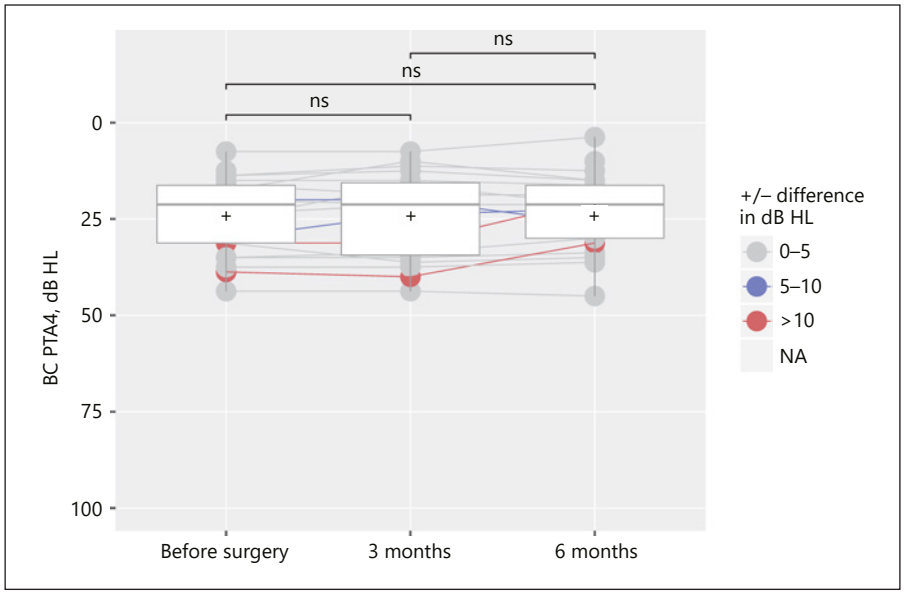

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Fig. 2. Bone conduction (BC) threshold stability over 6 months of follow-up. Paired samples are connected by lines. Mean and median are given as crosses and horizontal lines, respectively. Boxes give 25 and 75% quartiles. Whiskers denote minimum/maximum values but do not include outliers, which are defined as values deviating more than ±1.5 times the interquartile range from the respective quartiles. PTA4, pure tone average (0.5, 1, 2 and 4 kHz); ns, not significant; NA, not available.

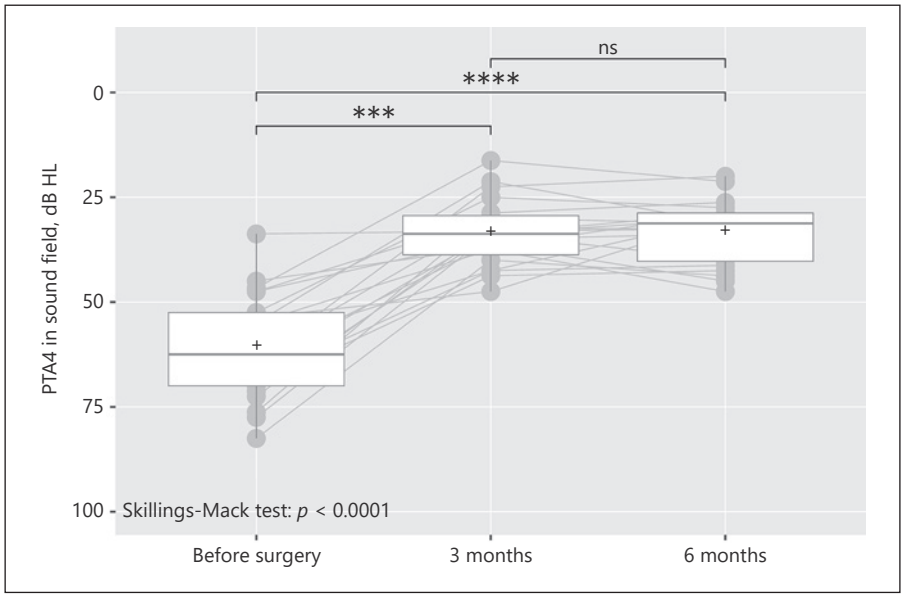

Fig. 3. PTA4 of sound field thresholds (warble tones) over 6 months of follow-up. Paired samples are connected by lines. Mean and median are given as crosses and horizontal lines, respectively. Boxes give 25 and 75% quartiles. Whiskers denote minimum/maximum values but do not include outliers, which are defined as values deviating more than ±1.5 times the interquartile range from the respective quartiles. PTA4, pure tone average (0.5, 1, 2 and 4 kHz); ns, not significant; *** $p \leq 0.001$; **** $p \leq 0.0001$.

tient 19 had problems accepting the device immediately after surgery. However, acceptance was good during the further follow-up period.

Audiometry and Speech Tests

BC thresholds varied between 3.75 and 45 dB HL (median: 21.25 dB HL) but remained stable (i.e., had a threshold shift of less than ±10 dB HL) throughout the study period in almost all subjects (Fig. 2; Skillings-Mack test: $p_{overall} = 0.455$). In the 2 subjects where shifts of >10 dB HL occurred, thresholds shifted to lower values (and thus better hearing). Average hearing thresholds in sound field decreased from 60.55 dB HL (SD: 12.55 dB HL; median: 62.5 dB HL) to 33.75 dB HL (SD: 8.23 dB HL; median: 29.38 dB HL) after 3 months (Fig. 3). After 6 months the mean threshold was 33.19 dB HL (SD: 7.71 dB HL; median: 31.25 dB HL). At both time frames, mean thresholds were significantly lower than before the intervention (Wilcoxon signed-rank test: pre vs. 3 months: $p_{adj} < 0.001$; pre vs. 6 months: $p_{adj} < 0.0001$) and did not change significantly between 3 and 6 months of follow-up ($p_{adj} = 0.831$). The mean functional gain after 6 months com-

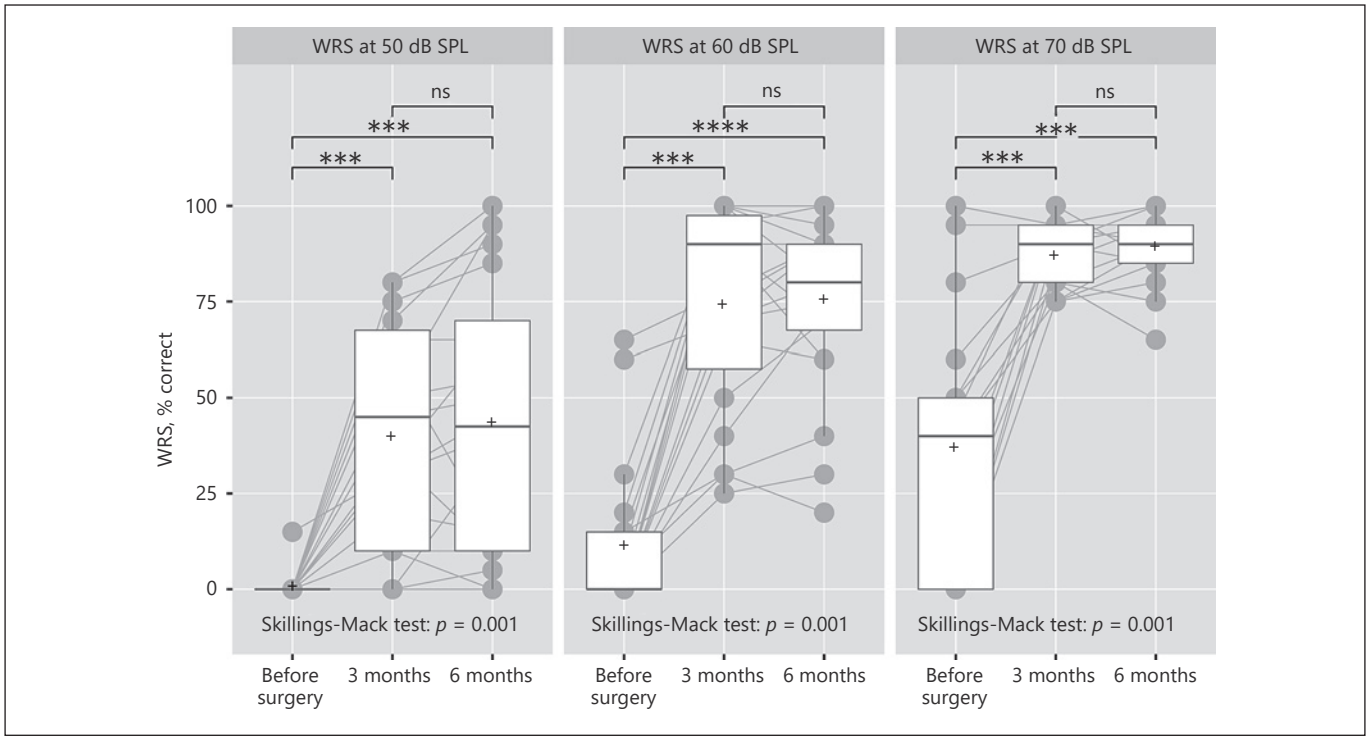

Fig. 4. Word recognition scores (WRS) over time at different sound pressure levels. Paired samples are connected by lines. Mean and median are given as crosses and horizontal lines, respectively. Boxes give 25 and 75% quartiles. Whiskers denote minimum/maximum values but do not include outliers, which are defined as values deviating more than ±1.5 times the interquartile range from the respective quartiles. ns, not significant; *** $p \leq 0.001$; **** $p \leq 0.0001$.

pared to before surgery was 28.02 dB HL (SD = 12.77). In all 3 level settings (50, 60, 70 dB), WRS increased significantly from 0, 43 and 62% before surgery to 40, 74 and 87% after 3 months and 43, 75 and 89% after 6 months of follow-up, respectively. As indicated in Figure 4, this corresponds to a statistically significant increase compared to before intervention. There was no significant correlation of aided WRS (at 6 months of follow-up) with pre-operative BC thresholds (Fig. 5), indicating that the success of hearing rehabilitation with the Bonebridge is independent of a sensorineural hearing loss component at least up to 45 dB HL. Speech reception thresholds in noise decreased significantly from 11.54 dB SNR (signal-to-noise ratio; SD: 8.24 dB SNR; median: 12.8 dB SNR) before surgery to 0.28 dB SNR (SD: 7.12 dB SNR; median: –1.1 dB SNR) at 6 months of follow-up (Fig. 6; Wilcoxon signed-rank test; $p_{adj} < 0.001$). Detailed summary statistics for speech tests are given in the upper part of Table 2.

Patient-Reported Outcomes

The APHAB questionnaire showed an increase in QoL after implantation of the Bonebridge. Global scores decreased significantly from 48.5% (SD: 16.9%; median: 48.6%) before surgery to 32% (SD: 17%; median: 33.6%) after 3 months and 29.6% (SD: 17.7%; median: 27.7%) after 6 months of follow-up, respectively (Fig. 7a; Wilcoxon signed-rank test; pre vs. 3 months: $p_{adj} < 0.01$; pre vs. 6 months: $p_{adj} < 0.01$). There was no significant change between 3 and 6 months of follow-up (3 vs. 6 months: $p_{adj} < 0.36$). Likewise, ease of communication, background noise and reverberation subscores decreased in the same way, indicating congruent improvement in these categories. No significant change was observed in the aversiveness subscore. More detailed summary statistics for APHAB scores are given in the lower part of Table 2.

Discussion/Conclusions

In general, results from this study confirm the effectiveness of the Bonebridge. The most important outcome is a very good audiological benefit (WRS at 70 dB SPL >75%) up to pre-operative BC of 45 dB (Fig. 5). This corroborates the effectiveness of the device over its full

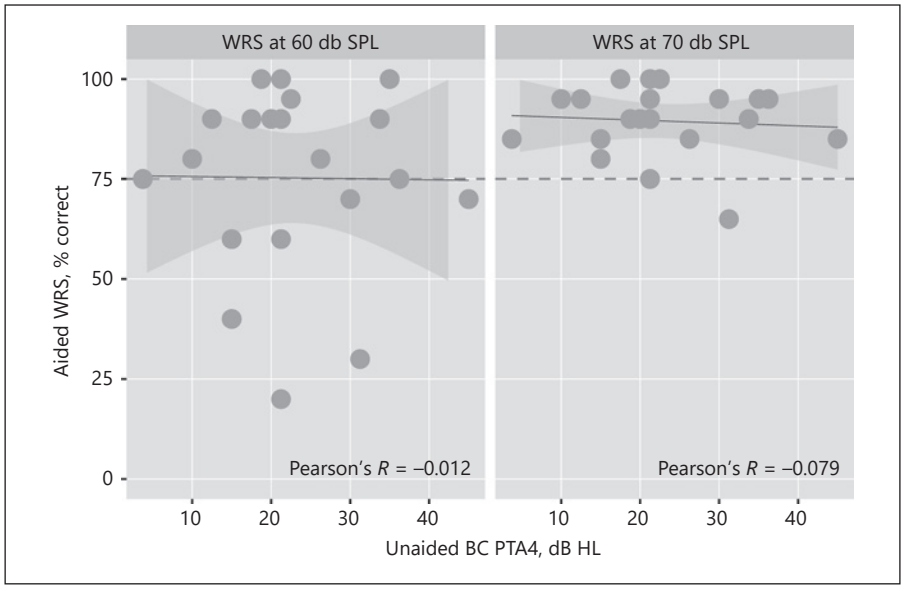

Fig. 5. Correlation of aided word recognition scores (WRS at 60 and 70 dB SPL) and pre-operative BC thresholds. The dashed line indicates 75% word recognition. PTA4, pure tone average (0.5, 1, 2 and 4 kHz).

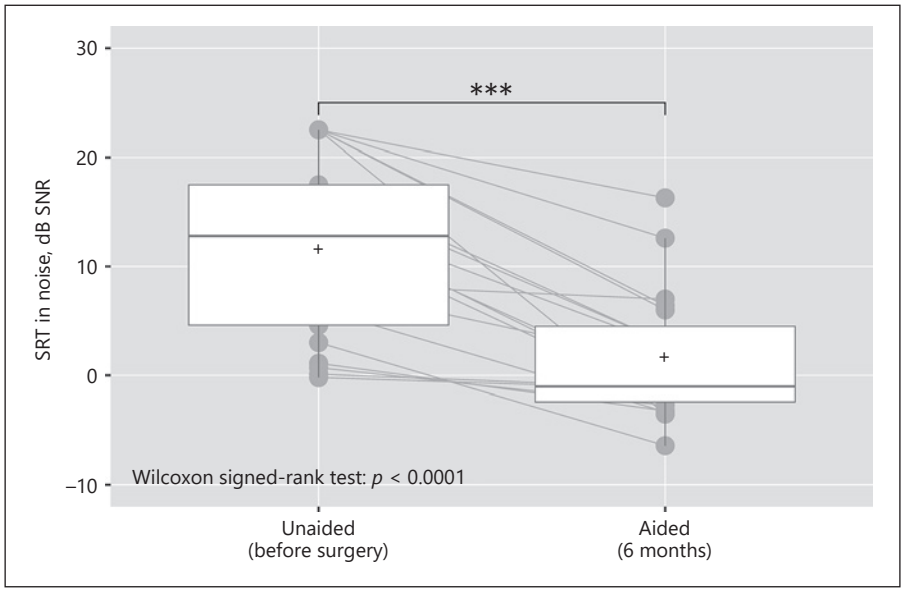

Fig. 6. Speech reception thresholds (SRT) in noise (S0N0) before surgery and after 6 months of follow-up. Paired samples are connected by lines. Mean and median are given as crosses and horizontal lines, respectively. Boxes give 25 and 75% quartiles. Whiskers denote minimum/maximum values but do not include outliers, which are defined as values deviating more than ±1.5 times the interquartile range from the respective quartiles. SNR, signal-to-noise ratio. *** $p \leq 0.001$.

indication range. Mean functional gain in the study population was 28.02 dB HL, and this corresponds to results of many other studies where functional gain was reported from 24 dB up to 37 dB [Sprinzl et al., 2013; Rahne et al., 2015; Sprinzl and Wolf-Magele, 2016; Weiss et al., 2017b]. Furthermore, it is confirmed that there is no hearing deterioration in audiometric hearing results associated with this intervention.

From a surgical point of view, implants were positioned in the sinodural angle in all patients to reduce the risk of inference with the sigmoid sinus and dura mater. Some authors claim that under specific conditions, a retrosigmoidal approach is better, e.g., when the available area between sigmoid sinus and posterior wall of external meatus is too small due to radical cavities [Sprinzl and Wolf-Magele, 2016]. From personal experience and restricted available literature data [Lassaletta et al., 2016; Salcher et al., 2017] there is no evidence of negative side effects associated with dura or sinus compression. However, we followed the manufacturer's recommendation to avoid compression. Whenever drilling depth is an issue (as determined by CT scan) lifts can be used to safely position the BC-FMT in the mastoid bone. There are 4 sizes available (1, 2, 3 and 4 mm). When 3- or 4-mm lifts are used, screws

Table 2. Summary statistics of speech test results and quality of life outcomes at each time frame

	Time frame	Unit	Mean	SD	Min.	Max.
Speech test						
WRS50	Pre-operative	%	0.02	0.06	0.00	0.25
WRS50	3 months FU	%	0.40	0.31	0.00	0.80
WRS50	6 months FU	%	0.42	0.36	0.00	1.00
WRS60	Pre-operative	%	0.45	0.38	0.00	1.00
WRS60	3 months FU	%	0.74	0.27	0.25	1.00
WRS60	6 months FU	%	0.72	0.26	0.15	1.00
WRS70	Pre-operative	%	0.64	0.36	0.00	1.00
WRS70	3 months FU	%	0.87	0.09	0.75	1.00
WRS70	6 months FU	%	0.88	0.11	0.55	1.00
SRT in noise	Pre-operative	dB SNR	11.36	8.09	–0.20	22.50
SRT in noise	6 months FU	dB SNR	0.41	6.98	–14.10	16.30
APHAB score						
Global	Pre-operative	%	48.84	16.64	17.00	84.22
Global	3 months FU	%	32.03	17.06	3.44	69.11
Global	6 months FU	%	29.68	17.24	7.83	73.72
EC	Pre-operative	%	42.44	23.00	6.50	82.83
EC	3 months FU	%	25.50	19.42	1.00	66.05
EC	6 months FU	%	22.55	16.79	4.67	63.67
BN	Pre-operative	%	53.64	21.47	12.83	89.00
BN	3 months FU	%	39.05	20.52	4.67	80.83
BN	6 months FU	%	35.27	21.18	8.33	84.83
RV	Pre-operative	%	49.48	17.35	17.17	89.00
RV	3 months FU	%	31.54	17.35	2.83	62.33
RV	6 months FU	%	31.07	17.46	8.67	72.67
AV	Pre-operative	%	29.52	22.62	1.00	89.00
AV	3 months FU	%	34.59	24.85	1.00	89.00
AV	6 months FU	%	34.93	23.15	4.67	88.83

WRS50/60/70, word recognition score at 50/60/70 dB SPL; FU, follow-up; SRT, speech reception threshold; SNR, signal-to-noise ratio; APHAB, Abbreviated Profile of Hearing Aid Benefit; EC, ease of communication; BN, background noise; RV, reverberation; AV, aversiveness to sound.

of adequate length (8 and 10 mm, respectively) are included within the implant kit. Thirty-eight percent of patients implanted in this study group received BCI lifts, and there was no complication related to that after 6 months. Neither skin infections nor skin or bone overgrowth were observed. With other devices, the rates of these complications vary from 17.5 to 37% [Granström et al., 2001; Lloyd et al., 2007; McDermott et al., 2009; Kraai et al., 2011; Van Rompaey et al., 2011]. The discharge of fluid observed in 3 patients was not related to the intervention but rather due to chronic ($n = 1$) or acute ($n = 2$) otitis media.

Regarding patient-reported outcomes, APHAB proved to be a very good tool for the assessment of hearing-related QoL in Bonebridge patients, as reported previously for other BCIs and middle-ear implants [Monini et al., 2017; Bosman et al., 2018]. The benefits in patient satisfaction are in line with hearing benefits as measured by functional gain, WRS and signal-to-noise ratio. Similar positive correlations have been reported in other studies on BCIs, hearing aids and cochlear implants [Ambert-Dahan et al., 2018; Giannantonio et al., 2018]. We want to emphasize the need for long-term observations and comparative designs in future studies on QoL associated with implantable hearing solutions.

Patient-reported outcomes should be considered when selecting among treatment options with equal audiological benefit. The Bonebridge provides significant audiological benefit for patients suffering from mixed and conductive hearing loss in both speech understanding in quiet and in noise. Together with a very low rate and minor nature of adverse events, it is an excellent solution for hearing rehabilitation in patients with mixed or

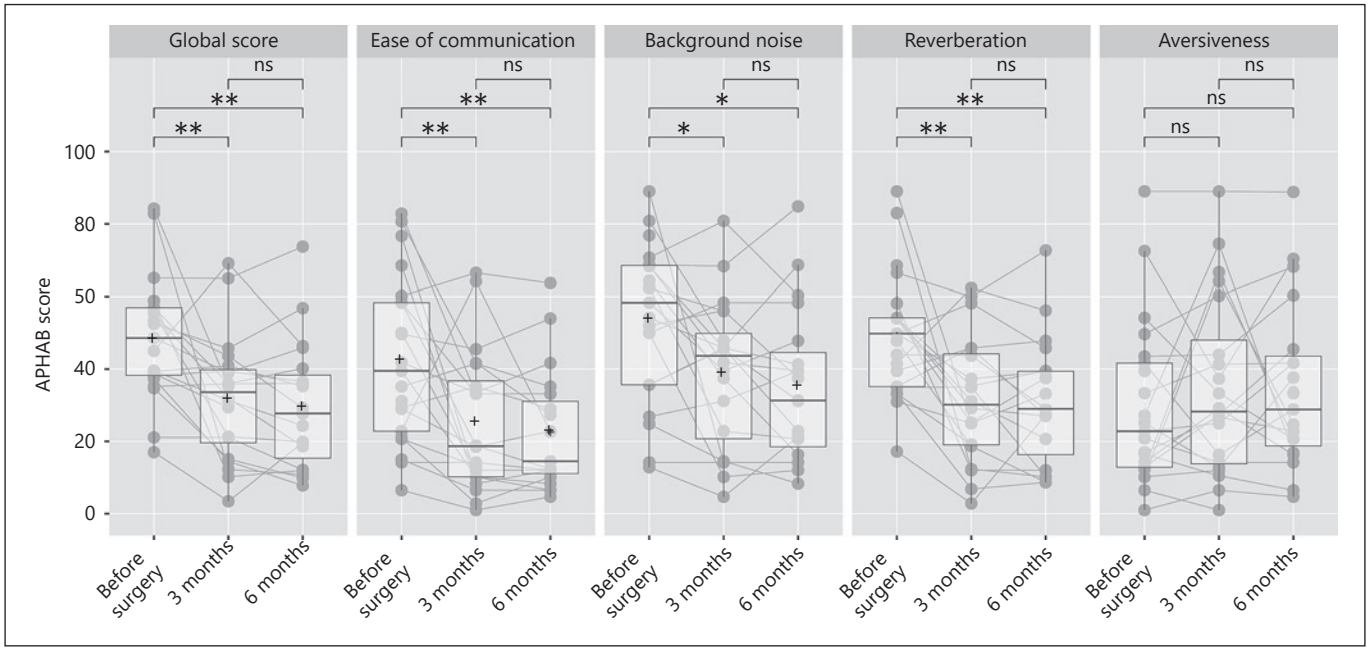

Fig. 7. QoL outcomes for the APHAB global score and four subscores. Mean and median are given as crosses and horizontal lines, respectively. Boxes give 25 and 75% quartiles. Whiskers denote minimum/maximum values but do not include outliers, which are defined as values deviating more than ±1.5 times the interquartile range from the respective quartiles. ns, not significant; * $p \leq 0.05$; ** $p \leq 0.01$.

conductive hearing loss up to a BC threshold of 45 dB HL. Future studies should investigate the long-term effect of this device on the patient's QoL.

Statement of Ethics

Subjects have given their written informed consent. The study protocol has been approved by the research institute's committee on human research.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

P.H.S. and H.S. performed surgeries; P.H.S. and M.K. planned the study; P.H.S., B.K., K.O., K.C., A.S. and A.R. conducted the study; P.H.S., A.R. and M.K. wrote the main manuscript; all authors discussed the results and implications and commented on the manuscript at all stages.

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