

Safety and efficacy of the Bonebridge bone conduction implant: a comparative study

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ABSTRACT

Objective: We prospectively evaluated safety and clinical efficacy of an active bone conduction implant, named Bonebridge, in patients with conductive hearing loss (CHL). Performance was compared with the preoperative aided condition.

Methods: Nine Dutch-speaking patients were implanted with Bonebridge in a single tertiary referral center and were followed up for 4 years and 11 months (mean). Six patients had CHL, one had mixed hearing loss (MHL), and two had single-sided deafness. Preoperatively, patients were fitted with a conventional air conduction hearing aid (HA) and/or a bone-anchored HA processor worn on a headband. Intra- and postoperative complication rates were assessed for all patients. Five patients with CHL/MHL participated in an extensive audiological evaluation, including regular measurements of hearing thresholds (air and bone conduction), speech reception in quiet (consonant vowel consonant or CVC words) and noise (sentences), and subjective satisfaction (Abbreviated Profile of Hearing Aid Benefit questionnaire and the Speech, Spatial and Qualities of Hearing Scale).

Results: Patients' residual hearing was not deteriorated by the implantation, and no adverse events were reported. For CHL and MHL cases (n=5), the median functional gain was 20 dB at activation and remained stable thereafter. After 3 months, the median word recognition score in quiet at 40 dB A was 80%. The median speech reception threshold in noise was 4.8 dB signal to noise ratio 1 year postoperatively. Comparison with preoperative scores with a bone conduction device on a headband revealed no significant differences. Questionnaires demonstrated subjective satisfaction. Stable performance was observed along the entire follow-up period.

Conclusion: Bonebridge can be considered a safe and effective treatment option for patients with CHL.

Keywords: Bone conduction, conductive hearing loss, hearing aids

Introduction

Otologic surgery and conventional hearing aids (HAs) are the primary treatment options in the management of hearing rehabilitation for conductive hearing loss (CHL) (1, 2). However, if surgery is contraindicated or rejected or if conventional HAs are not suitable owing to either audiological issues or local anatomical conditions, a bone conduction implant (BCI) can be a valid alternative (1, 3-6). On the basis of maximum power output, BCIs have been reported to be ideally indicated in pure CHL or mild mixed hearing loss (MHL) (1). Besides their application in CHL, BCIs are a treatment option for patients with single-sided deafness (SSD) (3-6).

A BCI, percutaneous or transcutaneous and passive or active, stimulates the inner ear through the bone conduction (BC) pathway. This implies that pathological parts of the external and middle ear are bypassed and that the ventilation of these spaces is main-

tained. However, energy-wise, the BC pathway is less efficient than the air conduction (AC) pathway, and the use of a BC transducer requires a static force to press it to the skull. The most commonly used type of BCIs is a so-called bone-anchored HA (BAHA) with a percutaneous connection (Baha® Connect – Cochlear Ltd, Sydney, Australia – or Ponto® – Oticon A/S, Copenhagen, Denmark). This device consists of an externally worn sound processor that is percutaneously connected to a bone-anchored implant via an abutment. Numerous studies on the application of a BAHA for CHL, MHL, and SSD reported favorable audiological outcomes in terms of functional gain, speech reception in quiet and noise, and subjective satisfaction (7, 8). However, the skin-penetrating abutment and the requirement of osseointegration of the implant are associated with some well-known complications and with a lack of cosmetic acceptance. In a meta-analysis by Kiringoda et al., the following type and incidence of complications of BAHA were identified in a very large series of patients (n=2134): skin reactions (16-

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Table 1. Characteristics of subjects

Subject	Sex	Age at implantation (yrs;mos)	Implanted ear	Indication	Etiology	Previous surgery implanted ear	Hearing loss or previous surgery contralateral ear	Speech processor
1	F	32;9	Right	CHL Failed tympanoplasty	Tympanosclerosis	TP (2014)	No	Amadé
2	F	14;8	Right	CHL	Acquired Stenosis EAC	MP (2014) TT	No	Amadé
3	F	23;0	Right	CHL	Secreting chronic otitis media	TT (1996,1998)	CHL TT (1996, 1998)	Amadé
4	M	13;2	Left	CHL	Secreting chronic otitis media	TT	CHL CAT (2011)	Amadé
5	M	59;3	Left	MHL	Tympanosclerosis	TT	No	Samba
6	M	43;2	Right	CHL	Aural atresia with middle ear malformation	No	No	Amadé
7	F	23;11	Left	CHL Failed Tympanoplasty	Ossicular chain disruption	TP (2005) Revision TP (2006,2007)	No	Amadé
8	M	49;4	Right	SSD	Skull base trauma	No	No	Amadé
9	M	48;11	Left	SSD	Meniere's disease	Intratympanic gentamycin (2013)	No	Amadé

F: female; M: male; CHL: conductive hearing loss; MHL: mixed hearing loss; SSD: single sided deafness; EAC: external auditory canal; TP: tympanoplasty; MP: meatoplasty; TT: tympanostomy tube; CAT: combined approach tympanoplasty

38%), implant infection (1-50%), skin overgrowth (10-29%), and failure of osseointegration (0-18%) (9).

To avoid the classical drawbacks of BAHAs, transcutaneous BCIs preserving the skin's integrity have been developed. The Bonebridge system (MED-EL, Innsbruck, Austria) was the first active transcutaneous BCI. As the transmitted signal is electromagnetic instead of mechanic and as the implant transduces this signal into mechanical vibrations, Bonebridge is a BCI that uses an active implant and overcomes signal attenuation. Moreover, a systematic review by Sprinzl et al. (6) showed that Bonebridge's transcutaneous design tends to have lower complication rates than percutaneous systems. An alternative system with transcutaneous magnet forces is called the Baha® Attract (Cochlear, Mölnlycke, Sweden).

The present study had two main goals: 1) to evaluate the safety of Bonebridge surgical implantation with respect to residual hearing and complication rate and 2) to determine its clinical efficacy in terms of gain, speech reception in quiet and in noise, and patient-reported measures in subjects with CHL.

Main Points:

- Bonebridge leads to an improvement in functional and effective hearing for patients with conductive hearing loss.
- Good results with Bonebridge are maintained five years after implantation.
- The Bonebridge implant is a safe treatment for conductive hearing loss.
- There is good subject satisfaction with Bonebridge.

Methods

Subjects and study design

This prospective study was performed at a tertiary referral center, the University Hospitals of Leuven (Belgium). Nine patients were implanted with Bonebridge between June 2013 and December 2015. Table 1 provides an overview of the subjects' characteristics. The study population consisted of five men and four women. Their mean age at implantation was 34.3 (range: 13.2-59.3) years. The surgical technique for implantation of Bonebridge has been described comprehensively in previous reports (10, 11). The implant was activated 4-6 weeks after implantation. At each follow-up visit, adjustments to the sound processor were performed with the Medel Symfit 7.0 fitting software, according to the individual needs of patients. At the time of writing, patients had a mean follow-up period of 4 years and 11 months (range: 3 years to 5 years 7 months). Intra- and postoperative complication rates were assessed for all nine patients. Five of them, all with CHL (n=4) or mildly mixed hearing loss (MHL) (n=1), participated in an extensive audiological evaluation.

All procedures were in accordance with the ethical standards of the Medical Ethics Committee of UZ Leuven (S53530) and with the 1964 Helsinki declaration and its later amendments. Written informed consent was obtained from each patient prior to device implantation.

Device description

Bonebridge is a semi-implantable hearing system. The device consists of an external part, a sound processor, and an implantable part, the bone conduction implant.

For CHL, Bonebridge obtained CE (Conformity with Europe) mark for adults and children aged 5 years and older.

Currently, there are two sound processors for Bonebridge on the market: the Amadé and SAMBA processors. SAMBA is the latest generation speech processor and provides advanced signal processing, such as directionality and noise suppression. Only one patient (no.5) already used the SAMBA processor.

Audiometric thresholds

Unaided pure tone AC and BC thresholds were measured preoperatively and at the time of activation of Bonebridge. Thresholds with a BC device (BAHA processor) on a softband were also recorded preoperatively. Bonebridge-aided thresholds were measured at the time of activation and at 3, 6, 12, and 24 months after activation. Pure tones with octave frequencies from 0.25 to 4 kHz were presented through insert phones, TDH-39 headphones or a bone conductor for the unaided measurements. Aided measurements were obtained for the same frequencies with warble tones presented in a sound field through a speaker positioned at 0° azimuth. The non-implant ear was blocked with a BILSOM 303S or MAX earplug and a PELTOR Optime III earcap. The pure tone average (PTA) was calculated by averaging the thresholds at 0.5, 1, 2, and 4 kHz. Functional gain was calculated by subtracting the Bonebridge-aided thresholds (PTA) from the preoperative unaided AC thresholds (PTA). The effective gain was calculated by subtracting the Bonebridge-aided thresholds from the unaided BC thresholds (12, 13).

Speech reception tests

Speech reception in quiet was assessed using a standardized Dutch monosyllabic word list (NVA) (14). NVA words were presented in quiet at 40, 50, 65 and 80 dB A.

The Leuven Intelligibility Sentence Test (LIST) sentences (15) were used to measure speech reception in noise, with speech and noise both coming from the front. The speech reception threshold (SRT), determined as the signal-to-noise ratio that

yielded 50% correct speech recognition, was determined using a one-down, one-up adaptive method. The noise level was fixed at 65 dB A. Speech level started at 55 dB A and was varied with a step size of 2 dB (16). Per condition, two lists of 10 LIST sentences were assessed, and the average SRT in noise for each condition was determined.

Speech reception tests in quiet were performed preoperatively unaided and with BAHA on a softband and postoperatively in the Bonebridge-aided condition at 1, 3, 6, 12, and 24 months after activation. Speech perception in noise was measured at 6, 12, and 24 months after activation. Results are compared with preoperative aided results with BAHA or HA. The contralateral ear was again plugged and muffled.

Patient-reported outcome measures

In this study, subjective benefit analysis was determined through the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire (17) and the Speech, Spatial and Qualities of Hearing Scale (SSQ) (18).

Both questionnaires were administered preoperatively and at 6, 12, and 24 months after device activation. Validated Dutch versions of APHAB and SSQ were used.

Statistical analysis was performed using IBM Statistical Package for the Statistical Package for Social Sciences version 23.0 software (IBM Corp.; Armonk, NY, USA). To examine within-subject differences between the single test intervals, the data were compared using the Wilcoxon signed rank test with a significance level of 5%.

Results

Bonebridge implantation was successful in all nine patients. With a mean follow-up time of 4 years and 11 months (range, 3 years to 5 years 7 months), no major adverse events related to the procedure or the device, including skin reactions and revision surgery, were reported in any of the cases.

Audiometric Results

Pure tone and sound field thresholds

Figure 1 provides the median unaided and aided thresholds for five patients with CHL or MHL with respect to their preoperative and postoperative conditions. The median preoperative unaided PTA for BC was 13.8 dB HL (minimum: 1.3 dB HL, maximum: 35 dB HL) at the implant side. All thresholds were compliant with the manufacturer's recommendations to be better than or equal to 45 dB HL at every frequency (except for patient no. 5, who had a threshold of more than 70 dB HL at 4 kHz).

The median postoperative Bonebridge-aided PTA at the time of activation was 23.8 dB HL (minimum: 1.3 dB HL, maximum: 35 dB HL). The median preoperative unaided PTA for AC was 43.8 dB HL (minimum: 40 dB HL, maximum: 83.8 dB HL). The median functional gain, defined as the improvement in PTA with Bonebridge, was 20.0 dB (minimum: 16.3 dB, maximum: 52.5 dB) at the time of activation. After 12 and 24 months of Bonebridge use, the median functional gain was 22.5 dB (minimum: 21.3 dB, maximum: 53.8 dB) and 22.5 dB (minimum: 20.0 dB, maximum: 53.8 dB), respectively. The slight improvement in functional gain across time was not significant (activation vs 24 months: $p=0.066$).

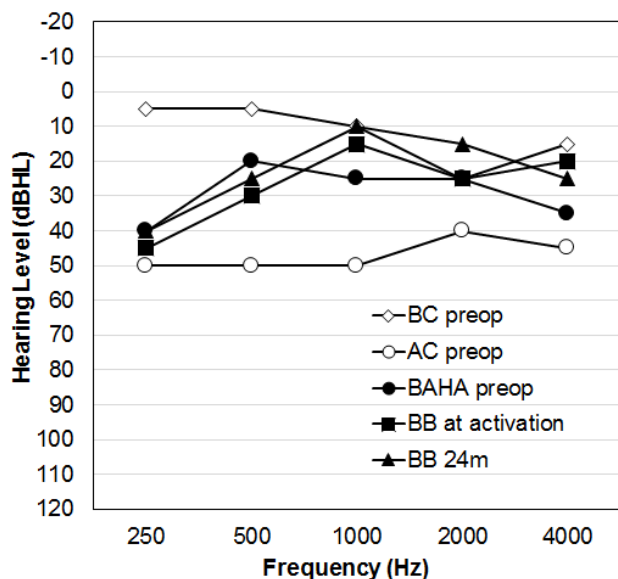


Figure 1. Median detection thresholds: preoperative unaided, preoperative BAHA-aided, and Bonebridge (BB)-aided conditions at the time of activation and 24 months after activation

With a median of 17.5 dB (minimum: 15 dB, maximum: 56.3 dB), the functional gain obtained with the BAHA processor on a headband preoperatively was similar to that obtained with Bonebridge at activation ($p=0.461$).

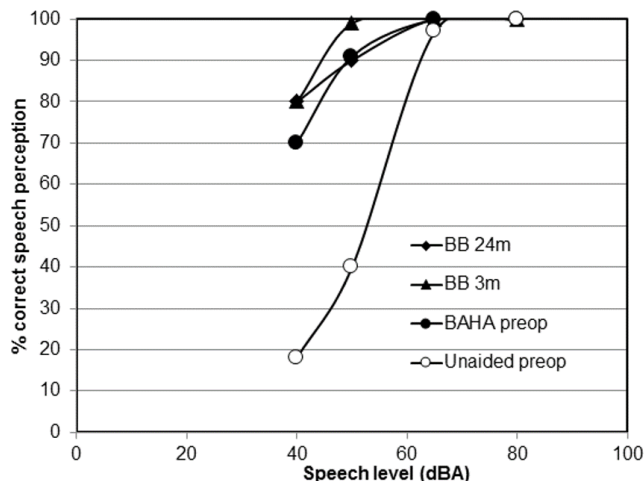


Figure 2. Median word recognition scores in quiet for presentation levels of 40, 50, 65, and 80 dB A: preoperative unaided, preoperative BAHA-aided, and Bonebridge (BB)-aided conditions at 3 and 24 months after activation

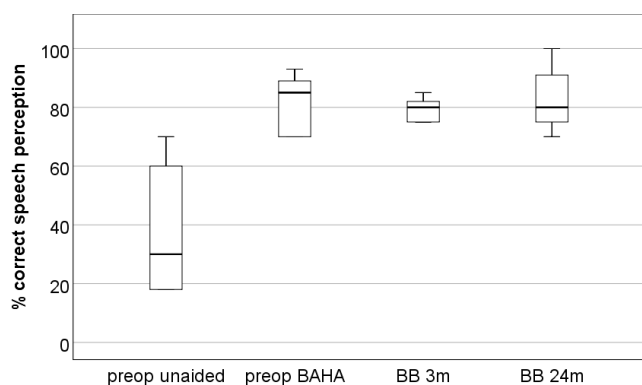


Figure 3. Box plots of word recognition scores in quiet at 40 dB A: preoperative unaided, preoperative BAHA-aided, and Bonebridge (BB)-aided conditions at 3 and 24 months after activation

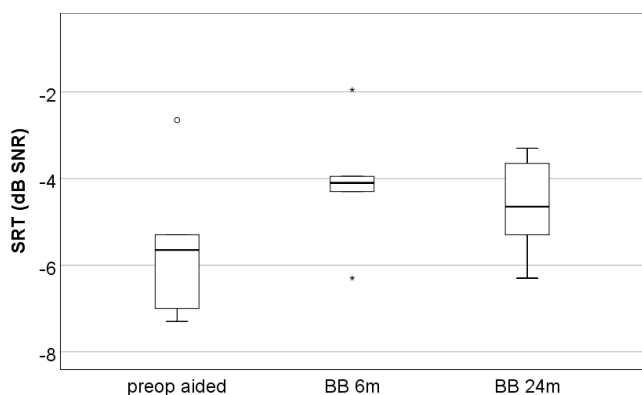


Figure 4. Box plots of the speech reception thresholds (SRT) in noise (in dB signal-to-noise ratio): preoperatively with BAHA or conventional HA and Bonebridge (BB)-aided conditions at 6 and 24 months after activation

The median effective gain of Bonebridge, defined as the difference between the unaided BC thresholds and the Bonebridge-aided AC thresholds, was -10 dB (minimum: -18.8 dB, maximum: 3.8 dB) at the time of activation. This gain improved slightly to -7.5 dB after 24 months. The improvement was not significant ($p=0.066$).

To determine the safety of the surgical procedure, the mean pre- and postoperative unaided PTAs for BC were compared. Median PTAs for BC were 13.8, 10.0, and 10.0 dB HL preoperatively, at the time of activation of Bonebridge, and 24 months post activation, respectively. Postoperative BC thresholds differed with less than 5 dB from preoperative values, for nearly all subjects and frequencies. Only for one subject (no.4), BC thresholds at 1 and 2 kHz were 10 dB worse at 24 months post activation compared with preoperative thresholds.

Speech reception in quiet

Figure 2 provides median word recognition scores (WRSs) in quiet for the NVA words for the group of five listeners, measured preoperatively unaided and with BAHA on a headband, and with Bonebridge at 3 and 24 months post activation. The WRSs for a speech level of 40 dB A are presented in more detail in Figure 3.

Three months after the activation of Bonebridge, WRSs in quiet improved by 62% (minimum: 52%, maximum: 75%; $p=0.043$), 59% (minimum: 16%, maximum: 90%; $p=0.043$), 3% (minimum: 0%, maximum: 100%; $p=0.109$), and 0% (minimum: 0%, maximum: 100%; $p=0.180$) at 40, 50, 65, and 80 dB A, respectively, compared with those in the preoperative unaided condition. In fact, already after 1 month post-activation speech reception scores were high and showed stable performance levels; these results are not presented in the figure because of few missing data. When comparing WRSs obtained 3 and 24 months after activation, no significant differences were found (40 dB HL: $p=0.465$; 50 dB HL: $p=0.068$; 65 dB HL: $p=0.317$; and 80 dB HL: $p=1.000$). Scores were similar for the Bonebridge condition at 3 months and the preoperative BAHA-aided condition with median differences of 6% (minimum: -9%, maximum: 20%; $p=0.225$), 3% (minimum: -4%, maximum: 20%; $p=0.345$), 0% (minimum: -2%, maximum: 15%; $p=0.285$), and 0% (minimum: 0%, maximum: 5%; $p=0.317$) at 40, 50, 65, and 80 dB A, respectively.

Speech reception in noise

SRTs in noise are shown in Figure 4. Median SRTs were -5.7, -4.1, and -4.7 dB for the preoperative aided condition, Bonebridge-aided condition at 6 months after activation, and Bonebridge-aided condition at 24 months after activation. Differences were not significant (Bonebridge-aided at 6 months versus preoperative aided: $p=0.225$; Bonebridge-aided at 24 months versus that at 6 months: $p=0.498$).

Subject satisfaction

Questionnaire data were obtained in four of five patients (all except patient no. 3). Figures 5 and 6 provide the distribution of APHAB and SSQ scores for the preoperative (i.e. BAHA on headband) and postoperative Bonebridge-aided conditions at 6, 12, and 24 months after activation.

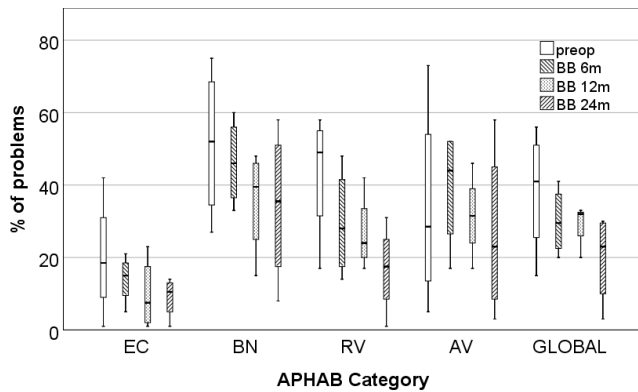


Figure 5. Distribution of patients' (n=4) Abbreviated Profile of Hearing Aid Benefit (APHAB) scores and global scores for four subscales (ease of communication [EC], background noise [BN], reverberation [RV], and aversiveness [AV]): preoperative BAHA-aided and Bonebridge (BB)-aided conditions at 6, 12, and 24 months after activation. The lower and upper bounds of each boxplot denote the first and third quartile, respectively. The horizontal line within each boxplot represents the median

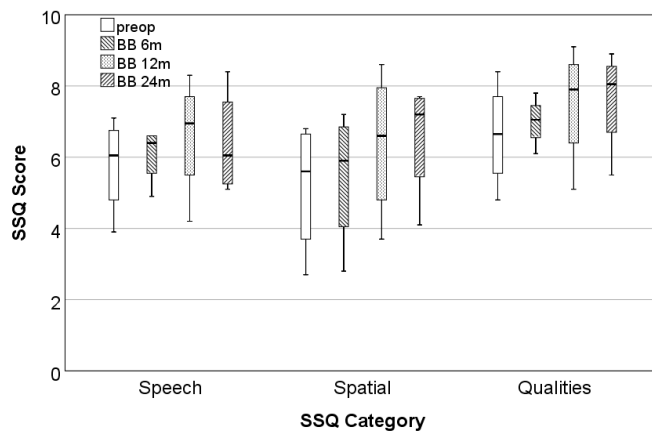


Figure 6. Distribution of the patients' (n=4) subscale scores of the Speech, Spatial and Qualities of Hearing Scale (SSQ): preoperative BAHA-aided, Bonebridge (BB)-aided at 6 months after activation, BB-aided at 12 months after activation, and BB-aided conditions at 24 months after activation. The lower and upper bounds of each boxplot denote the first and third quartile, respectively. The horizontal line within each boxplot represents the median

APHAB

After 24 months of Bonebridge use, median APHAB scores improved by 8%, 17%, 22%, 6%, and 18% for the ease of communication subscale, background noise subscale, reverberation subscale, aversiveness subscale, and global score, respectively. The improvement compared with that with preoperative BAHA-aided condition was not significant (global score, sign test: $p=0.125$). SSQ in addition, for SSQ, a slight improvement was observed for the three subscales but without statistical significance (speech: median difference=0.8, $p=0.273$; spatial: median difference=0.55; $p=0.285$; qualities: median difference=0.7; $p=0.273$).

Discussion

Safety

Unaided pure tone thresholds for BC were stable after Bonebridge implantation. Thresholds did not change significantly at any test-

ed frequency, confirming the safety of the implant procedure regarding residual sensorineural hearing. In our study, no surgical complications or device-related adverse events, including skin reactions and revision surgery, were recorded. Overlooking 12 published studies with a total of 117 patients, Sprinzl et al. (6) calculated that the rate of minor adverse events and revision surgeries after Bonebridge implantation was 5% and 0.85%, respectively. In summary, Bonebridge can be considered a safe treatment and offers a lower complication rate than percutaneous BAHA.

Gain

For the five patients with CHL or MHL in this analysis, a median functional gain of 20 dB was observed with Bonebridge at the time of activation. This result is comparable to that in previous studies on Bonebridge in patients with CHL or MHL (3, 4, 19-24). Overall, in these studies, a total of 74 subjects were included, and the mean functional gain ranged from 24 dB to 37 dB. It should be noted that different definitions of functional gain have been used as mentioned by Snik et al. (13).

The negative effective gain in the present study might indicate that Bonebridge did not give sufficient amplification, something to take into account in future interventions. However, note that the negative gain applied especially to the lower frequencies (as can be derived from Figure 1). This low amplification was mostly related to subjective preferences and not to limits of the device. At 4 kHz, Bonebridge performed better than BAHA.

Speech reception

The WRS in quiet at 40 and 50 dB A showed a statistically significant improvement 1 month after activation compared with that in the preoperative unaided condition. No significant difference was noted between the Bonebridge-aided condition and the preoperative BAHA-aided condition. Shortly after activation, significantly better speech reception in quiet was obtained with Bonebridge compared with that in the preoperative unaided condition, at 40 and 50 dB A. Aided scores were comparable to those in previous studies (3, 22, 23, 25).

In this study, speech reception in noise was also similar for the Bonebridge-aided condition and the preoperative BAHA/HA-aided condition.

Patient-reported outcome measures

The scores of SSQ and APHAB, comparing the patients' satisfaction with the Bonebridge-aided condition to the BAHA-aided condition, showed a slight but non-significant improvement for the global score and all subscale scores. Previous studies also compared scores between unaided and Bonebridge-aided conditions and saw improvements on most subscales (26, 27) with no difference between BAHA and Bonebridge (27). This shows that preoperative testing with a bone stimulation HA on a soft-band or something alike is a good predictor of the outcome.

Long-term results

No significant change was noted between the results after 24 months of Bonebridge use and initial results for functional gain or speech reception. These results concur with results after 18 months in a previous study by Sprinzl et al. (24), demonstrating stable treatment success. Baumgartner et al. did notice a significantly higher benefit for speech reception in quiet at 24 months compared with the benefit at 6 months (28). In the

present study, safety of Bonebridge was demonstrated for up to more than 5 years of device use.

This study demonstrated the safety of Bonebridge with no change in residual hearing and the absence of device-related adverse events. Efficacy was shown in terms of functional and effective gain, improvement of speech reception in quiet and in noise, and good subject satisfaction, in patients with CHL, also in the long term. Taking into account that for Bonebridge, performance was similar and complication rates were lower than for BAHA on a headband, the former can be considered a valuable treatment option for these patients.

Ethics Committee Approval: All procedures were in accordance with the ethical standards of the Medical Ethics Committee of UZ Leuven (S53530).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – K.D.V., N.V.; Design – K.D.V., N.V.; Supervision – N.V., C.D.; Resources – N.V.; Materials – K.D.V., L.V.D.; Data Collection and/or Processing – K.D.V., L.V.D., N.V.; Analysis and/or Interpretation – K.D.V., L.V.D.; Literature Search – K.D.V., L.V.D.; Writing Manuscript – L.V.D.; Critical Review – K.D.V., N.V., C.D.

Conflict of Interest: The authors have no conflicts of interest to declare.

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