The Prediction of Speech Recognition in Noise With a Semi-Implantable Bone Conduction Hearing System by External Bone Conduction Stimulation With Headband: A Prospective Study

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Abstract

Semi-implantable transcutaneous bone conduction devices are treatment options for conductive and mixed hearing loss (CHL/MHL). For counseling of patients, realistic simulation of the functional result is desirable. This study compared speech recognition in noise with a semi-implantable transcutaneous bone conduction device to external stimulation with a bone conduction device fixed by a headband. Eight German-language adult patients were enrolled after a semi-implantable transcutaneous bone conduction device (Bonebridge, Med-El) was implanted and fitted. Patients received a bone conduction device for external stimulation (Baha BP110, Cochlear) fixed by a headband for comparison. The main outcome measure was speech recognition in noise (Oldenburg Sentence Test). Pure-tone audiometry was performed and subjective benefit was assessed using the Glasgow Benefit Inventory and Abbreviated Profile of Hearing Aid Benefit questionnaires. Unaided, patients showed a mean signal-to-noise ratio threshold of 4.6 ± 4.2 dB S/N for speech recognition. The aided results were -3.3 ± 7.2 dB S/N by external bone conduction stimulation and -1.2 ± 4.0 dB S/N by the semi-implantable bone conduction device. The difference between the two devices was not statistically significant, while the difference was significant between unaided and aided situation for both devices. Both questionnaires for subjective benefit favored the semi-implantable device over external stimulation. We conclude that it is possible to simulate the result of speech recognition in noise with a semi-implantable transcutaneous bone conduction device by external stimulation. This should be part of preoperative counseling of patients with CHL/MHL before implantation of a bone conduction device.

Conductive and mixed hearing loss (CHL/MHL) are types of hearing impairment often caused by chronic inflammatory middle ear disease. Primarily, chronic inflammation is to be treated surgically. The second step is the reconstruction of sound transmission for air conduction. In case of residual CHL or MHL, acoustic hearing aids may be applied for amplification (Verhaert, Desloovere, & Wouters, 2013). However, there is a sizeable number of patients who still do not achieve a satisfying audiological result by those measures. Bone conduction hearing devices are important options in those cases. Bone conduction hearing relies on sound

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waves transmitted as vibration via the skull and thereby stimulating the cochlea. Further indications for bone conduction devices are recurrent otitis externa, aural aplasia, and malformation as well as single-sided deafness.

The principle of bone conduction has been applied for centuries. Today, bone conduction devices are a growing and dynamic field (Edmiston, Aggarwal, & Green, 2015; Reinfeldt, Hakansson, Taghavi, & Eeg-Olofsson, 2015). Modern external devices can be included in glasses or rely on transmission via the teeth (Miller, 2010). Beyond that, surgical options exist. The first percutaneous bone conduction device with an abutment applying the principle of osseointegration was described more than three decades ago (Tjellstrom & Granstrom, 1994; Tjellstrom, Lindstrom, Hallen, Albrektsson, & Branemark, 1981) and the Bone-anchored hearing aid (Baha) percutaneous device on an osseointegrated post is currently the most widely distributed bone conduction device so far (Snik et al., 2005). Two devices are commercially available at present, Baha (Cochlear Bone Anchored Solutions, Mölnlycke, Sweden; (Bento, Kiesewetter, Ikari, & Brito, 2012; Boleas-Aguirre, Bulnes Plano, de Erenchun Lasa, & Ibanez Beroiz, 2012; Dun, Faber, de Wolf, Cremers, & Hol, 2011; Lustig et al., 2001) and Ponto (Oticon, Smørum, Denmark; Westerkull, 2011). However, certain drawbacks are inherent to the principle of a percutaneous device. The osseointegrated percutaneous post applied for Baha is a cosmetic issue for many patients (Hakansson, 2011). The overall complication rate of Baha implantation is given as up to 23.9% (Dun et al., 2012; Hobson et al., 2010) and a percutaneous abutment requires continuous care. Those issues have stimulated research into new options for bone conduction implants.

Recently, two new principles have emerged for bone conduction devices and have been labeled as active and passive transcutaneous (Edmiston et al., 2015; Reinfeldt et al., 2015). Passive transcutaneous bone conduction is an advancement of the percutaneous device and relies on an osseointegrated post that is covered by intact skin. External vibration is applied and acts transcutaneously. The actuator and the audio processor are located in the same external housing and are held on the intact skin by magnetic force. A new system is available and marketed as Baha Attract (Cochlear Bone Anchored Solutions, Mölnlycke, Sweden; Briggs et al., 2015; Iseri et al., 2015). Another, independently developed device (Sophono Alpha; Medtronic, Dublin, Ireland) employs a likewise principle with a flat implantable magnet (Mulla, Agada, & Reilly, 2012; Siegert, 2011). Active transcutaneous bone conduction depends on the actuator being implanted into the skull and covered by intact skin. Energy and information are transmitted transcutaneously via induction. As the audioprocessor as well as power supply are external yet necessary components of these devices, they are called semi-implantable. One device, Bonebridge (MED-EL, Innsbruck, Austria), is commercially available since 2012 (Ihler, Volbers, Blum, Matthias, & Canis, 2014; G. Sprinzl et al., 2013; G. M. Sprinzl & Wolf-Magele, 2015; Zernotti & Sarasty, 2015). Another similar device was developed independently and is currently being tested in clinical studies (Reinfeldt, Hakansson, Taghavi, Fredén Jansson, & Eeg-Olofsson, 2015; Taghavi et al., 2015).

The indication for implantation of a bone conduction device has to take audiological and otological aspects into account and usually requires proven failure of acoustic hearing aids (Gavilan et al., 2015). An important aspect for patient counseling is the prediction of hearing outcome. A trial with external stimulation by a bone conduction device for the simulation of the functional result after implantation is generally recommended before implant surgery (Gavilan et al., 2015). Usually, for that purpose, headbands are applied to press an external bone conduction actuator to the temporal bone. A headband for the most widely applied bone conduction device was initially developed for the use in young children (Verhagen, Hol, Coppens-Schellekens, Snik, & Cremers, 2008).

An important aspect for the comparability of an external and an implanted source of stimulation is the dampening effect inherent to external stimulation. Those effects are frequency specific and depend on the position of stimulation (Reinfeldt, Hakansson, Taghavi, & Eeg-Olofsson, 2014; Stenfelt, 2012). It has been shown that dampening of headband devices is an issue in the range from 1 to 4 kHz when compared with an implanted percutaneous bone conduction device on an osseointegrated post (Zarowski, Verstraeten, Somers, Riff, & Offeciers, 2011). The attenuation of sound transmission by skin dampening prohibits drawing conclusions when devices are compared by different routes of stimulation. Because of dampening effects by skin and subcutaneous tissue, a device will usually not show the optimal performance when compared with the use in the implanted situation, but results by external stimulation may serve as approximation of the results after implantation (Zarowski et al., 2011).

To date, there has been no prospective study to assess the comparability of external stimulation with a semi-implantable transcutaneous bone conduction device. Therefore, in this study, we compared the intra-individual results of speech recognition in noise with external stimulation by a bone conduction device fixed with a headband to the results with an active semi-implantable transcutaneous bone conduction device.

Materials and Methods

Institutional Review Board Approval

The present study was approved on July 19, 2012 by the institutional review board of the University Medical Center Göttingen (Ethikkommission der Universitätsmedizin Göttingen), reference number 6/7/12.

Devices

All patients were implanted with a semi-implantable bone conduction device (Bonebridge, MED-EL GmbH, 6020 Innsbruck, Austria). The device is CE certified since April 4, 2012 (No. I7120351383010).

For noninvasive bone conduction hearing by external stimulation, the processor of the Bone-anchored hearing device Baha BP110 (Cochlear Bone Anchored Solutions AB, 435 33 Mölnlycke, Sweden) was applied with the dedicated headband, an adjustable elastic band (Baha softband). The device is CE certified since April 2, 2000 (No. 41313419).

Study Protocol

Patients who were native speakers of German and with CHL or MHL were included in this prospective crossover study after implantation and fitting of the semi-implantable bone conduction device. Indications for implantation were otological and audiological and included failure with acoustic hearing aids, chronic conditions of the outer ear precluding acoustic hearing aids (e.g., otitis externa), difficult middle ear conditions (e.g., after multiple surgical procedures), middle ear conditions potentially necessitating repeated middle ear surgery and thus precluding active middle-ear implants (e.g., recurrent cholesteatoma), or patient preference.

After implantation of the semi-implantable bone conduction device, 6 weeks of wound healing were observed. Thereafter, the audio processor Amadé (Model BB) was individually fitted. After 3 months of usage, all patients implanted at the study center from November 2012 to November 2014 were invited to participate and all eight patients agreed to take part. Audiological measurements for the study took place unaided and aided by the implanted bone conduction device at the time of inclusion.

Thereafter, the implant was deactivated and a bone conduction device (Cochlear Baha 3 Power, BP110) was applied with the dedicated headband for external transcutaneous bone conduction stimulation. The site of external stimulation was 3 to 5 cm dorsally of the ear canal at the height of the upper edge of the pinna. This device was also individually fitted and actively worn for 1 week. After that, audiological measurements were performed again. Questionnaires were completed by the patients after wearing each of the devices.

Primary Outcome Measure—Speech Recognition Testing

The primary outcome measure was the signal-to-noise ratio threshold for speech recognition assessed by a commonly used German language adaptive sentence test, presented in a sound field at a fixed noise level of 65 dB SPL, compliant with DIN EN ISO 8253–3:2012–08 (Oldenburg Sentence Test, Oldenburger Satztest; HörTech gGmbH, 26129 Oldenburg, Germany). In brief, this test is composed from a fixed syntactic structure with five words and is semantically unpredictable due to randomly assigned words from word lists. The test was performed in an anechoic chamber by professional staff with the loudspeakers for signal and noise in front of the patient at a fixed distance of 1 m. The contralateral ear was plugged and muffled during measurements.

Before each assessment by the Oldenburg Sentence Test, a cycle of 20 measurements was conducted and discarded to reduce the influence of possible learning effects. Consequently, 30 consecutive measurements of randomly generated single sentences took place to determine speech recognition. Noise was presented at a fixed level of 65 dB SPL, while the speech material was presented at an adaptive level that changed depending on the number of correct words in the previous measurement. The level of speech that enables correct identification of 50% of the words represented the result of this speech test. This level is given as the signal-to-noise ratio threshold (dB S/N).

The test has been validated in normal-hearing individuals, who achieved an average value of -7.11 dB S/N across studies (Brand & Kollmeier, 2002; Kollmeier et al., 2015; Wagener, Kühnel, & Kollmeier, 1999). The Oldenburg Sentence Test is currently viewed as the most realistic speech test in noise in German language.

Audiological Testing

Pure-tone audiometry was performed as described in previous studies in an anechoic chamber by professional staff (Ihler, Kohler, et al., 2014; Ihler, Volbers, et al., 2014). Thresholds were measured at 0.5, 1.0, 2.0, 3.0, 4.0, and 6.0 kHz with pure tones over headphones. Aided air conduction was measured with warble tones in a sound field with the loudspeaker standing in front while the contralateral ear was plugged.

Summary data of audiometric tests are reported in this study according to current guidelines (Guidelines for the results of conductive hearing loss—AAO-HNS,

1995; Gurgel, Jackler, Dobie, & Popelka, 2012), with divergences stated. Pure-tone average (PTA4) was calculated as mean value of thresholds at 0.5, 1.0, 2.0, and 3.0 kHz. Average air–bone gap (ABG) was calculated as PTA4 for air conduction minus PTA4 for bone conduction for each ear. Average functional gain was calculated by subtracting aided air conduction PTA4 from unaided air conduction PTA4.

Surgical Procedure

The implantation of the semi-implantable bone conduction device was performed as described previously by Ihler, Volbers, et al. (2014). The anatomical situation was evaluated preoperatively by computed tomography.

Placement of the transducer is mostly planned in the mastoid in patients with regular anatomy where sufficient bone is present to take up the respective diameter of the transducer. When placement in the mastoid was not possible, for example, due to a preexisting tympanomastoid cavity, a retrosigmoidal approach provided an alternative. Intraoperative navigation was applied when the need arose (Canis, Ihler, Blum, & Matthias, 2013).

Questionnaires

Quality of life was assessed by the Glasgow Benefit Inventory (GBI) after 1 week with each device. In brief, the questionnaire compares the change of subjective health status after a conservative or surgical intervention (Robinson, Gatehouse, & Browning, 1996) on a scale from $+100$ (maximal improvement) to -100 (maximal worsening). The GBI assesses a total quality of life score as well as three subdomains reporting general, social, and physical benefit.

For the assessment of subjective hearing aid performance, the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire was applied (Cox & Alexander, 1995). The results were calculated as intended by the developers. In brief, for the calculation of the global scale, the results of the subscales Ease of Communication (EC), Background Noise (BN), and Reverberation (RV) were averaged. Benefit was assessed by subtracting the result with the semi-implantable device from the result by external stimulation for each subscale individually, including Aversiveness of Sounds (AV). Overall benefit was calculated by subtraction of the results for the global scale of the devices. Improvement of the semi-implantable device over external stimulation was calculated by dividing overall benefit by the result in the global scale for external stimulation and multiplication of the result by 100%. As a critical difference to judge a difference in the score as significant, in the subscales, 26 was applied for EC, 28 for RV, 27 for BN, and 31 for AV, while 10% was applied for benefit

scores (Cox & Alexander, 1995). In this questionnaire, lower values indicate a higher grade of satisfaction, except AV, where lower value may be indication of poorer detection thresholds. Both questionnaires were administered in the German language and self-completed by the patients during visits in the course of the study. All patients completed both questionnaires.

Statistical Analysis

To test for statistically significant differences in the results of the Oldenburg Sentence Test, a one-way repeated measures analysis of variance (ANOVA) was used to make pairwise comparisons. A correction for multiple testing was performed by the Holm–Sidak method. The power of the test was 95.4% with a desired power of $>80\%$.

The Pearson Product Moment Correlation was employed to identify a correlation between the result in the Oldenburg Sentence Test aided with external bone conduction stimulation and with the implant. In all statistical tests, a p value of $<.05$ was considered to be statistically significant.

Results

Patients' Characteristics

Eight German-speaking adults with CHL or MHL were included in the study. The mean age at implantation was 38.8 ± 13.3 years (range 20.8–54.9 years). The underlying cause for hearing impairment was cholesteatoma in five patients, chronic suppurative otitis media in two patients, and middle ear malformation in one patient. Those conditions lead to an average of 3.8 ± 1.2 (range 1–5) middle ear procedures before the bone conduction device was considered. Four patients had a tympanomastoid cavity.

Three patients were previous users of an active middle-ear implant on the respective side that had to be removed due to recurrent middle ear infections. The semi-implantable device was positioned in a retrosigmoidal position in all eight patients. The distribution of ipsilateral and contralateral hearing loss is given in Table 1.

Primary Outcome Measure

The results in the Oldenburg Sentence Test for speech recognition in noise showed a statistically significant difference in the comparison of the three situations, unaided, external bone conduction stimulation and semi-implantable bone conduction device ($p = .002$, $F = 10.495$; RM ANOVA). In paired comparisons, the difference between the devices was statistically not significant ($p = .239$; Holm–Sidak), while the difference

Table 1. Hearing Loss by Number of Patients in Ipsilateral (Implanted) and Contralateral Ears.

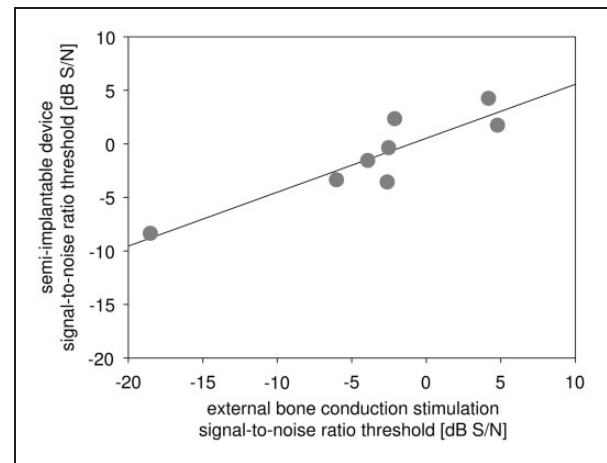|		Implanted ear					
		Conductive hearing loss	Mixed hearing loss	Total	AC-PTA4 [dB HL]	BC-PTA4 [dB HL]	ABG [dB]
Contralateral ear	Normal hearing	4	2	6	9.6 ± 5.6	6.5 ± 5.3	3.2 ± 0.7
	Mixed hearing loss	1	0	1	42.0	22.3	19.8
	Profoundly deaf	1	0	1	n.a.	n.a.	n.a.
	Total	6	2	8			
	AC-PTA4 [dB HL]	50.9 ± 13.4	60.4 ± 7.4				
	BC-PTA4 [dB HL]	16.3 ± 4.9	30.6 ± 3.4				
	ABG [dB]	34.6 ± 11.9	29.8 ± 4.0				

Note. ABG = air-bone gap; AC = air conduction; BC = bone conduction; n.a. = not applicable; PTA4 = pure-tone average of the frequencies 0.5, 1.0, 2.0, and 3.0 kHz; mean values $\pm$ standard deviation.
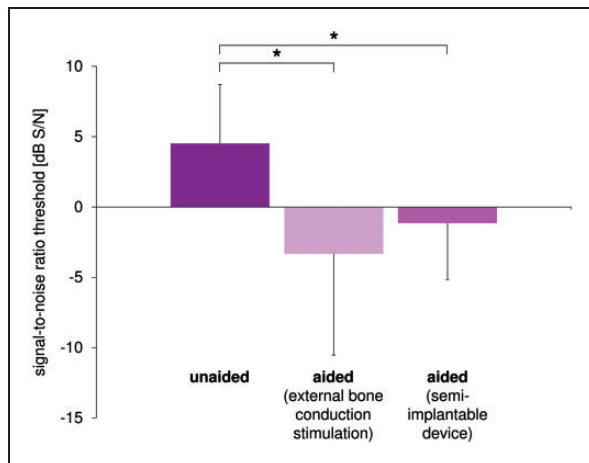
Figure 1. Speech recognition (German language Oldenburg Sentence Test) in eight patients unaided and after 1 week aided with external bone conduction stimulation or a semi-implantable transcutaneous bone conduction device. *$p < .05$ (RM ANOVA, Holm–Sidak); mean values $\pm$ standard deviation.
Note. RM ANOVA = repeated measures analysis of variance.

Figure 2. Scattergram of individual results of speech recognition (German language Oldenburg Sentence Test) in eight patients after 1 week aided with external bone conduction stimulation (abscissa) or a semi-implantable transcutaneous bone conduction device (ordinate). Plotted line signifies a linear regression.

between the aided and unaided conditions was statistically significant for external bone conduction stimulation ($p = .002$; Holm–Sidak) as well as for the semi-implantable bone conduction device ($p = .013$; Holm–Sidak). Unaided, the patients showed a mean signal-to-noise ratio threshold of 4.6 ± 4.2 dB S/N (range -2.0–11.2 dB S/N) in the Oldenburg Sentence Test. Aided by external bone conduction stimulation, the performance improved to -3.3 ± 7.2 dB S/N (range -18.5 to 4.8). Aided by the semi-implantable bone conduction device, the mean result in the sentence test was -1.2 ± 4.0 dB S/N (range -8.4 to 4.2). A graphical depiction of the results is given in Figure 1.

The result with the semi-implantable device is predictable from the result with external stimulation.

A significant positive correlation was identified between the result in the Oldenburg Sentence Test for speech recognition with the two different devices (Pearson Product Moment Correlation, Correlation Coefficient 0.902, $p < .01$; Figure 2).
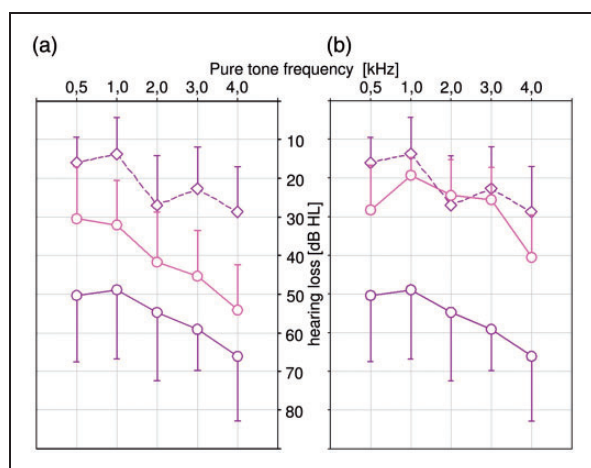
Audiometric Results

Assessed by pure-tone audiometry, patients had an unaided air-conduction PTA4 (AC-PTA4) of 53.3 ± 13.8 dB HL. Average bone conduction PTA4 (BC-PTA4) was 19.9 ± 5.3 dB HL. With external bone conduction stimulation, the air conduction threshold could be improved to 37.4 ± 11.3 dB HL (Figure 3(a)). With the application of the semi-implantable bone

conduction device, an AC-PTA4 of 24.4 ± 6.1 dB HL could be achieved (Figure 3(b)).

The ABG could be reduced to within 10 to 20 dB in six patients by external stimulation. By the implanted bone conduction device, the ABG was reduced to 10 to 20 dB in one patient, 5 to 10 dB in two patients, and 0 to 5 dB in four patients. One patient achieved overclosure of the ABG with the implant.

In average values, an initial ABG of 33.4 ± 3.3 dB in the unaided situation could be reduced to 17.6 ± 3.3 dB by external stimulation and 4.5 ± 5.3 dB by the semi-

implantable device. Overclosure was achieved at 2.0 kHz by the semi-implantable device with -2.5 ± 8.7 dB. In higher frequencies, there tended to remain a wider ABG in the aided situation with 25.4 ± 7.8 dB and 11.8 ± 9.7 dB at 4 kHz as well as 33.6 ± 9.6 dB and 14.4 ± 13.8 dB at 6 kHz for external stimulation and the semi-implantable device, respectively.

For functional gain, external bone conduction stimulation achieved 15.8 ± 2.7 dB while the semi-implantable device was able to provide 28.9 ± 4.2 dB. Aided by external stimulation, functional gain was relatively uniform in the frequencies assessed. In contrast, the semi-implantable device showed a relatively strong performance especially in higher frequencies. The highest value of functional gain of 34.0 ± 10.5 dB was found at 6 kHz, the highest frequency assessed. Table 2 provides an overview of pure-tone audiometric results.

Figure 3. Pure-tone audiometry in eight patients unaided and aided.
Legend: Violet continuous line (circles)—unaided air conduction; violet broken line (diamonds)—bone conduction; pink continuous line (circles)—aided air conduction. (a) After 1 week aided by external bone conduction stimulation; (b) after 1 week aided by semi-implantable transcutaneous bone conduction device. Mean values ± standard deviation.

Quality of Life and Subjective Hearing Aid Benefit

Quality of life was assessed by the GBI. The total score for the application of external stimulation was -6.9 ± 25.9. Five of the eight patients (62.5%) reported a negative total score. Also, the general and the physical subdomain of the GBI were negative on average, while the social subdomain yielded a positive value. The percentage of negative results for individual patients was 62.5%, 12.5%, and 12.5% for the general, social, and physical subdomain, respectively.

The total score with the GBI after the use of the semi-implantable bone conduction device was 38.5 ± 16.5 and was positive in all patients. All subdomains were positive on average. Negative results in individual patients were noted in two cases in the physical subdomain (25.0%) and in one case in the general subdomain (12.5%), while the social subdomain yielded positive results in all

Table 2. Average Values of Pure-Tone Audiometry.

Measure	Unaided	Aided (external bone conduction stimulation)	Aided (semi-implantable device)
Air conduction PTA4 (dB HL)	53.3 ± 13.8	37.4 ± 11.3	24.4 ± 6.1
Bone conduction PTA4 (dB HL)	19.9 ± 5.3	n.a.	n.a.
Air-bone gap 0.5–3.0 kHz (dB)	33.4 ± 3.3	17.6 ± 3.3	4.5 ± 5.3
Functional gain at 0.5 kHz (dB)	n.a.	19.9 ± 16.0	22.1 ± 14.7
Functional gain at 1.0 kHz (dB)	n.a.	16.8 ± 11.3	29.6 ± 14.3
Functional gain at 2.0 kHz (dB)	n.a.	13.0 ± 7.8	30.3 ± 11.0
Functional gain at 3.0 kHz (dB)	n.a.	13.8 ± 9.5	33.5 ± 6.7
Functional gain at 4.0 kHz (dB)	n.a.	12.0 ± 9.1	25.6 ± 15.5
Functional gain at 6.0 kHz (dB)	n.a.	14.8 ± 10.9	34.0 ± 10.5
Average functional gain 0.5–3.0 kHz (dB)	n.a.	15.8 ± 2.7	28.9 ± 4.2

Note. n.a. = not applicable; PTA4 = pure-tone average of the frequencies 0.5, 1.0, 2.0, and 3.0 kHz; mean values ± standard deviation.

patients. Taken together, patients viewed quality of life more favorably with the semi-implantable device over external bone conduction stimulation.

Subjective hearing aid performance was measured by the APHAB questionnaire. In the global scale, calculated from the subdomains EC, BN, and RV, external stimulation resulted in a score of 28.2 ± 27.8, while the semi-implantable device achieved 15.2 ± 14.9. The results in all subdomains of APHAB and on the global scale were higher with external stimulation, thereby signifying lower satisfaction with external stimulation. EC and BN differences were above the respective critical difference for a significant improvement.

The average benefit of the semi-implantable device over external stimulation was 28.3 ± 28.9 for EC, 22.7 ± 25.4 for RV, 27.4 ± 24.7 for BN, and 6.5 ± 18.3 for AV. Thereby, EC, RV, and BN differences showed significant values favoring the implant. Negative individual values for benefit were only noted in the AV subscale in four of the eight patients (50%). Overall benefit of the semi-implantable device over external stimulation was 12.9 ± 24.9. All individual patients reported positive overall benefit. This corresponded to an improvement in hearing performance of $45.6\% \pm 24.3\%$ (range 25.8%–94.5%) with the semi-implantable device over external stimulation. Summarized, subjective hearing performance was estimated to be superior with the semi-implantable device compared with external stimulation. An overview of the results of subjective outcome assessment by the patients is given in Table 3.

Discussion

Randomized controlled trials are difficult to realize for surgical interventions, particularly from an ethical point of view (Niemansburg, van Delden, Dhert, & Bredenoord, 2015; Wartolowska et al., 2014). For the present aim to quantify and compare effects on speech recognition in noise of external bone conduction stimulation with a semi-implantable device, a blinded approach was deemed unethical, as it would involve randomizing a surgical intervention for the treatment of hearing loss.

The sequential design chosen for the present study allowed us to achieve the aim of the study without a similar ethical dilemma. The study included only patients who were scheduled to be implanted with a hearing device regardless of inclusion into the study. Comparable protocols have been employed before to compare a transcutaneous bone conduction device (Leterme et al., 2015) or an active middle-ear implant (Boeheim, Pok, Schloegel, & Filzmoser, 2010; Sziklai & Szilvassy, 2011; Truy, Philibert, Vesson, Labassi, & Collet, 2008; Uziel, Mondain, Hagen, Dejean, & Doucet, 2003) to acoustic hearing aids. Also, passive (Briggs et al., 2015) and active transcutaneous devices (Reinfeldt, Hakansson, Taghavi, Fredén Jansson, et al., 2015) have been studied in comparison to external stimulation via headband.

The conclusion drawn from the data presented here is that external bone conduction stimulation and the implanted bone conduction device were both able to improve speech recognition in noise significantly. Comparatively, the application of the devices did not result in significantly different values, thereby suggesting that external bone conduction stimulation can provide a good approximation of the result with the implanted device.

A major obstacle in comparing the results of speech audiometry between different studies is the lack of uniformity in test paradigms in quiet and noise in different health care systems and languages. In the German language, for example, there are two competing speech tests with the more widely applied Freiburg Monosyllabic Test being the older one with severe drawbacks (Hahlbrock, 1953; Kollmeier et al., 2011). The choice

Table 3. Subjective Outcome Assessment.

Questionnaire	Subdomain/subscale	Aided with external bone conduction stimulation	Aided with semi-implantable device
GBI	General	-12.5 ± 43.7	54.7 ± 27.4
	Social	6.3 ± 31.1	6.3 ± 16.5
	Physical	-2.1 ± 21.1	4.2 ± 28.6
	Total	-6.9 ± 25.9	38.5 ± 16.5
APHAB	EC	36.7 ± 29.9	8.5 ± 5.7
	BN	48.1 ± 26.4	20.8 ± 22.0
	RV	40.9 ± 28.1	18.2 ± 18.0
	AV	43.0 ± 29.8	36.6 ± 25.1

Note. APHAB = Abbreviated Profile of Hearing Aid Benefit; GBI = Glasgow Benefit Inventory; EC = Ease of Communication; BN = Background Noise; RV = Reverberation; AV = Aversiveness of Sounds.

of the adaptive Oldenburg Sentence Test in noise as primary outcome measure is due to the fact that this test is currently seen as the most realistic speech recognition test for the assessment of hearing rehabilitation in German language (Kollmeier et al., 2011).

A comparable study (Reinfeldt, Hakansson, Taghavi, Fredén Jansson, et al., 2015) investigated a newly introduced transcutaneous bone conduction device compared to external bone conduction stimulation carried out before implantation. The reported signal-to-noise ratio threshold of an adaptive Swedish language sentence test showed no significant difference between the implant and external stimulation, comparable to the result reported here. Another study with retrospective design applying external stimulation before surgery for a transcutaneous bone conduction implant showed a correlation between the performance with both stimulation modes in PTA4, word recognition score at 65 dB HL and subjective assessment of sound quality (Monini et al., 2015).

For a transcutaneous bone conduction device, the signal-to-noise ratio threshold with adaptive sentence tests was also compared with external bone conduction stimulation by application of a headband. In this study, a signal-to-noise ratio threshold of -4.9 ± 5.1 dB was shown by the implanted device, significantly different both from the unaided situation and the previously applied external stimulation with a headband (Briggs et al., 2015). With significant improvement also over external stimulation, this contrasts the result in the present study. Possible explanations for this could be more skin dampening than in the setup reported here or actually greater gain achieved by that implant.

The results in pure tone audiometry presented here are comparable to other reports of bone conduction devices. Two previous studies so far published comparable results in functional gain of an externally worn bone conduction device as trial for a later implant. Those results of 14.3 dB to 26.9 dB (Monini et al., 2015; Reinfeldt, Hakansson, Taghavi, Fredén Jansson, et al., 2015) were comparable to 15.8 ± 2.7 dB observed here for external stimulation with a headband.

In clinical trials with other types of transcutaneous implants, average functional gain compared to unaided hearing was 18.4 dB to 42.3 dB (Barbara, Perotti, Gioia, Volpini, & Monini, 2013; Bianchin, Bonali, Russo, & Tribi, 2015; Briggs et al., 2015; Busch, Giere, Lenarz, & Maier, 2015; Centric & Chennupati, 2014; Escorihuela-Garcia, Llopez-Carratala, Pitarch-Ribas, Latorre-Monteagudo, & Marco-Algarra, 2014; Hassepass et al., 2015; Hol, Nelissen, Agterberg, Cremers, & Snik, 2013; Ihler, Volbers, et al., 2014; Iseri et al., 2015; Lustig et al., 2001; Magliulo, Turchetta, Iannella, Valperga di Masino, & de Vincentiis, 2015; Manrique, Sanhueza, Manrique, & de Abajo, 2014; Monini et al., 2015; Rahne et al., 2015; Reinfeldt,

Hakansson, Taghavi, Fredén Jansson, et al., 2015; Riss et al., 2014; Siegert & Kanderske, 2013). So, 28.9 ± 4.2 dB achieved with the implant here fits well within the published range, while systems on an osseointegrated post tend to achieve higher values.

External stimulation resulted in reduced quality of life estimates, as measured by the GBI in total of -6.9 ± 25.9. The active transcutaneous bone conduction implant was associated with an increase in quality of life, with 38.5 ± 16.5 in total. A positive total score of 32.4 to 47.7 was reported with the same transcutaneous device (Bianchin et al., 2015; Ihler, Volbers, et al., 2014), while with an active percutaneous bone conduction implant on an osseointegrated post, the mean score on the total GBI scale was 42.7 (Iseri et al., 2015). With a passive transcutaneous bone conduction implant, the positive mean total score on the GBI was 19.2 ± 13.8 to 40.5 (Iseri et al., 2015; Leterme et al., 2015). Taken together, the increase in quality of life in the present study is comparable to results reported before.

The results in the APHAB questionnaire showed a significant improvement with the implant over external stimulation in the overall benefit and in several subscales. Comparison to results from the literature is hindered as there are a wide variety of approaches of assessing subjective hearing aid benefit in different studies.

Generally, by the APHAB, an improvement of subjective hearing assessment is reported for the global as well as the RV and BN subscales compared with the unaided situation (Briggs et al., 2015). The percutaneous bone conduction device on an osseointegrated post achieved a global score of 42 to 45 (Boleas-Aguirre et al., 2012; Desmet, Wouters, De Bodt, & Van de Heyning, 2014). In conclusion, the increased subjective benefit by the implant that was seen in the present study is consistent with results from the literature. The observation that patients might have seen external stimulation more negative might be inherent to the study design. Patients had already been implanted by the transcutaneous device and therefore would certainly associate specific experiences with that device in this nonblindable setting. Another issue is a possible inconvenience of the headband. From the view of the patient, however, it seems reasonable to assume that a good subjective benefit with external stimulation will most likely be even better with the implant.

In all patients in the present study, the implant was placed retrosigmoidal. This could be a factor for increased attenuation due to the distance from the site of stimulation being greater than from the mastoidal implantation site. Previous studies showed increasing attenuation effect with increasing distance from the cochlea (Reinfeldt et al., 2014; Stenfelt, 2012). Here, the audiological results did not show a specific problem with attenuation compared to external stimulation.

In another study, two of the four patients (50%) received a retrosigmoidal implant as well (Barbara et al., 2013). Considering the high rate of tympanomastoideal cavities (four of the eight, 50.0%) and of patients who were previous users of an active middle-ear implant (three of the eight, 37.5%) in the present study, the bone conduction implant evaluated here might be better suited for difficult middle ears than an active middle-ear implant, while attenuation effects should be systematically addressed in further studies.

As the main finding of the present prospective cross-over study, we suggest the application of external bone conduction stimulation as a routine step for the preoperative assessment and counseling of patients for hearing implants like the active transcutaneous bone conduction device evaluated here. This approach has been already suggested earlier for the widely used active percutaneous bone conduction implant on an osseointegrated post (Verstraeten, Zarowski, Somers, Riff, & Offeciers, 2009; Zarowski et al., 2011) and for an active middle-ear implant (Monini, Filippi, Atturo, & Barbara, 2013). Only one study so far reported on the consequences of a trial period before a hearing implant. Of 18 patients who tried an external bone conduction device for 7 days in a prospective study, 13 patients (72.2%) opted for implantation of the device (Leterme et al., 2015). This means that a considerable share of five patients (27.7%) did not opt for the implant after the experience of external stimulation.

Conclusion

The application of external bone conduction stimulation could be a valuable tool for the realistic prediction of speech recognition in noise with a commercially available semi-implantable bone conduction hearing system. Subjective benefit with the semi-implantable device reliably exceeds external stimulation. Patients should be counseled regarding the different applications of the devices.

Author Contributions

F. I. designed the experiments, collected and analyzed data, and wrote the paper; J. B. designed and performed experiments and provided critical revision; M. U. B., B. G. W., and C. W. performed experiments, collected and analyzed data, and provided critical revision; M. C. designed the experiments, analyzed data, and provided critical revision. All authors discussed the results and implications and commented on the manuscript at all stages.

Authors' Note

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