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A comparison study of audiological outcome and compliance of bone conduction implantable hearing implants

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Abstract

Purpose The present study aimed to evaluate and compare the outcome of different bone conduction hearing implants (BCHIs) in subjects with mixed hearing loss (MHL) and single-sided deafness (SSD) in terms of audiometric results and compliance.

Methods Twenty-one subjects with MHL and 18 subjects with SSD undergoing implantation of Baha connect, Baha attract, or Bonebridge were enrolled. Functional gain, effective gain, and usage rate of BCHIs were retrospectively reviewed.

Results As for MHL, the functional gain of three devices was not significantly different ($p=0.477$), while the effective gain of Bonebridge was higher (−8.8 [−15.0, −3.5] dB) than that of Baha connect (−20.0 [−26.3, −11.3] dB, $p=0.037$), especially at 0.5 kHz ($p=0.010$) and 1 kHz ($p=0.014$). In SSD subjects, the effective gain of Bonebridge was significantly higher than that of Baha attract (−11.3 [−15.0, −7.5] vs −21.3 [−21.3, −16.3] dB, $p=0.012$), while the functional gain of Bonebridge and Baha attract was not different. The constant usage rate of BCHIs tends to be higher in MHL subjects [17/21 (82%)] than that in SSD subjects [10/18 (56%)]. In SSD subjects, the constant user group showed higher functional gain than the non-constant user group, with a significant difference at 3 kHz (35.0 [33.8, 45.0] vs 17.5 [10.0, 27.5] dB, $p=0.006$).

Conclusion Bonebridge shows a higher effective gain than Baha connect in the MHL group and Baha attract in the SSD group. The usage rate of BCHIs is lower in SSD than that in MHL. In SSD subjects, the constant user group tended to show higher functional gain than the non-constant user group. Irrespective of the device type, the tendency of higher functional gain of BCHIs, especially at mid frequencies, may potentially lead to yield good compliance in SSD, mandating a meticulous fitting strategy ensuring a sufficient mid-frequency functional gain in SSD.

Keywords Bone conduction hearing implant · Bone-anchored hearing aids · Functional gain · Compliance · Bonebridge · Baha

Introduction

According to the degree and type of hearing loss, various auditory rehabilitation methods could be utilized, i.e., conventional hearing aids, bone conduction hearing implants (BCHIs), middle ear implant, and cochlear implant. Among them, BCHIs is a well-established treatment option for patients with conductive or mixed hearing loss (MHL), which could not be corrected with middle ear surgery, canaloplasty, or conventional hearing aids [1]. In addition, BCHIs is also applied in patients with single-sided deafness (SSD), utilizing a bone conduction sound transmission to the contralateral side with normal hearing [2].

Since the first introduction of bone-anchored hearing aid (Baha) into clinical practice in the 1970s [3], various kinds of BCHIs were developed and launched commercially. According

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to the vibration pathway to the skull, they can be classified as direct-drive or skin-drive devices [4]. Direct-drive devices transfer the vibration to the skull with direct contact, whereas skin-drive devices transfer the vibration stimuli through the skin. Direct-drive devices can be subdivided into two variations: percutaneous (Baha connect, Cochlear, Australia; Ponto, Oticon Medical, Sweden) and active transcutaneous devices (Bonebridge, MED-EL, Austria). The sound processor of percutaneous direct-drive devices is located externally, and directly connected to the skull via abutment. Skin-drive devices, including Baha attract (Cochlear, Australia) and Sophono (Medtronic, USA), do not have a direct connection to the bone, and vibration stimuli are transmitted through the skin to an implanted magnet.

Although percutaneous BCHIs showed a higher aided gain—of about 10 dB—than skin-drive BCHIs [5, 6], complications, such as soft tissue overgrowth and skin infection, were reported in percutaneous BCHIs [7, 8]. Therefore, skin-drive BCHIs were preferred due to its benefits related to postoperative care, cost, and cosmesis [9, 10]. To overcome the attenuation of the vibration of external stimulator in skin-drive BCHIs, an active transcutaneous device, with an internally implanted floating mass transducer, which is commercially available, could be used [11]. Audiometric results of active transcutaneous device was reported to be equivalent to that of percutaneous BCHIs (functional gain of Bonebridge vs Baha connect with BP 100, 27.5 dB vs 26.3 dB) [12], with a low rate of complication [13].

While compliance with percutaneous BCHIs was reported to be 80% in bilateral conductive or mixed hearing loss [14], the BCHIs rejection rate was higher in SSD patients than in patients with bilateral MHL, and it ranged from 32.0 to 69.6% [15, 16]. The main reasons for the lower usage rate of BCHIs in SSD patients were subjective, with limited benefits from the device.

Although several studies addressed the effectiveness and usefulness of BCHIs, to the best of the authors knowledge, a comprehensive audiological comparison between the various kinds of BCHIs was limited so far. Moreover, to the best of the authors knowledge, the audiological outcomes with respect to the usage rate of BCHIs, which is obviously a reflection of subjective satisfaction, have not been reported to date in the literature. Therefore, this study aimed to compare the audiological outcomes and the usage rate of different BCHIs in patients with MHL and SSD, and this study attempted to find audiological factors that were related with the compliance of BCHIs.

Materials and methods

Participants

BCHI implantees undergoing an operation from March 2013 through November 2017 were retrospectively recruited; 21 patients (5 males, 16 females) with bilateral MHL and 18 patients (5 males, 13 females) with SSD were enrolled. The median age at operation was 58.0 [54.5, 68.0] years in the MHL group and 58.0 [43.0, 60.8] years in the SSD group. In the MHL group, all participants were exclusively the ones who previously underwent tympanomastoidectomy due to chronic otitis media at the implanted side prior to BCHI, and whose hearing outcomes were not sufficiently satisfactory, with air–bone gap of 25 dB or larger postoperatively. In the SSD group, all patients had severe to profound sensorineural hearing loss at the implanted site, and the hearing level at opposite site was within 30 dB HL. All of the candidates went through a rigorous headband trial of Baha BP110 or test device for Bonebridge (Apollon; BHM-Tech, Austria) to minimize the postoperative non-use rate. One experienced surgeon (the corresponding author) performed all surgeries with routine procedure, in accordance with the manufacturer's recommendation. Implanted bone conduction devices were Baha connect (Cochlear, Australia), Baha attract (Cochlear, Australia), or Bonebridge (MED-EL, Innsbruck, Austria). There were no perioperative complications. Applied sound processors were BP110 for Baha connect/attract and Amadé BB for Bonebridge. The fitting of the devices was performed in accordance with the manufacturers' guidelines. The implant processors were programmed using the Connexx 6.5 (Siemens, Erlangen, Germany) and the Symfit 7.0 software (Vibrant MED-EL, Innsbruck, Austria) for Amadé BB, and the Baha Fitting Software 4.0 (Cochlear Bone Anchored Solutions AG, Mölnlycke, Sweden) for Baha BP110. The initial activation of the sound processor was performed 4–6 weeks after implantation. The fitting procedure was as follows: First, to apply the appropriate prescription and to obtain a good first-fit outcome, the required information, including patient's audiogram, were entered. A feedback analysis was performed, and the individual feedback margins for the sound processor were measured. For fine tuning, gain and/or output per band was adjusted until the patient was satisfied or extreme settings had been reached. The maximum output level was set close to the maximum. On the program settings, directionality of the microphone and the level of feedback reduction and noise reduction were chosen. After this initial fitting, the patient tested the settings by walking around the hospital; afterward, if necessary, the settings were further adjusted. An audiological evaluation took place when the patient

and the audiologist were satisfied with the results or when the settings were set at the maximum. In this study, a program for universal use with omnidirectional microphone mode was used for all audiological tests.

All participants were followed-up for 3–12 months after surgery, and postoperative audiological results, presence of complication, usage time of BCHIs, and cause of poor compliance were evaluated. The daily average time of BCHIs use was assessed using data logging. Participants who used BCHIs for at least 2 h per day were classified into the constant user group, and others were assigned to the non-constant user group, as previously described [17]. All data generated or analyzed during this study are included in this published article and its supplementary information file.

Audiological evaluation

Pure tone audiometry and speech audiometry were performed preoperatively and postoperatively. The bone conduction (BC) threshold, air conduction (AC) threshold, and aided threshold level were measured at frequencies of 250, 500, 1000, 2000, 3000, and 4000 Hz. The pure tone average was calculated across the conversational frequencies of 0.5, 1, 2, and 4 kHz, if not stated otherwise. The speech discrimination score was evaluated with monosyllabic phonetically balanced words (KS-MWL-A) to be presented at the level of 30 dB above speech recognition threshold. The examiner presented 50 words, and the intensity of examiner's voice was balanced at 0 dB on a volume unit meter. The percentage of words repeated correctly by the patient was recorded. Free-field audiometry was performed in an adapted, soundproofed room, with the signal presented from a loudspeaker placed at the height of the subject's ears, at a distance of 1 m and angle of 45° or −45°. The aided hearing thresholds with BCHIs were determined using warble tones over the range 500–4000 Hz at octave intervals. The functional gain was calculated as a difference between the mean AC thresholds and aided thresholds for 500, 1000, 2000, and 4000 Hz. When the hearing level of non-implanted site was better than the implanted site, such as patients with SSD, the aided thresholds were evaluated with non-test ear blocked. The blocking of the non-test ear was performed with earmold impression for hearing aid and covered with an earmuff, and the attenuation of the non-test ear blocking was about 40 dB SPL [18]. To evaluate the effectiveness of BCHIs as "devices directing to the cochlea," the effective gains were evaluated as the difference between the mean BC thresholds at the side with better BC level and the mean aided levels in the MHL group and between the BC thresholds at the opposite site and aided level in the SSD group for 500, 1000, 2000, and 4000 Hz [19, 20]. Preoperative audiological evaluation was performed within 1 month before the surgery. Postoperative BC threshold, AC threshold, and aided level with BCHIs were evaluated at around 12 months after surgery.

Statistical analysis

All results are presented as median [lower quartile, upper quartile]. Statistical analyses were performed using the SPSS software (ver. 18.0; SPSS, Chicago, IL). p values < 0.05 were considered to indicate statistical significance. Comparisons of audiological outcome between the devices were performed with non-parametric test because of limited number of subjects. In the MHL group, the functional gain and effective gain were compared among Baha connect, Baha attract, and Bonebridge using Kruskal–Wallis test with Tukey test using ranks as post hoc test. When comparing the aided hearing thresholds, functional gain, and effective gain in participants with SSD, the Mann–Whitney U test was used.

Results

Compliance and complications of BCHIs

The constant usage rate of BCHIs appeared to be different between the MHL group (81%) and SSD group (56%), although the difference was not statistically significant (Fisher exact test, $p = 0.162$). Specifically, among the 21 patients with MHL, 17 patients used BCHIs constantly (81%), whereas 4 patients did not use BCHIs (19%) (Table 1). The four non-constant users did not use the device due to postoperative complication: granulation at the abutment site of Baha connect ($n = 2$, 12%) and wound infection ($n = 2$, 12%). In contrast, the usage rate of BCHIs in the SSD group was only 56% ($n = 10/18$). A total of 8 patients refused to use BCHIs constantly, and the cause of non-constant use was "limited benefit" ($n = 6$, 75%), loss of the external device ($n = 1$, 13%), and pain/noise ($n = 1$, 13%). Moreover, the usage rate of BCHIs showed a difference again, depending on the devices. About 60% of those in the SSD group, who underwent implantation of Bonebridge, used the device constantly ($n = 9/15$), whereas the usage rate of Baha attract in the SSD group was limited to only 33% ($n = 1/3$).

Audiological outcome of BCHIs in mixed hearing loss

Among the 21 participants with MHL, the averaged BC threshold was 35.0 [23.8, 45.7] dB HL at the implanted side and 22.5 [17.5, 35.0] dB HL at the opposite side. The averaged AC thresholds were 71.3 [58.8, 83.8] dB HL at the implanted side and 53.8 [42.5, 72.5] dB HL at the opposite side. All participants showed significant improvement

Table 1 Compliance and complication of bone conduction hearing implants

	Constant user *N* (%)	Non-constant user *N* (%)	Complication (*N*)	Cause of non-use (*N*)
Mixed hearing loss				
Baha connect ($N = 7$)	5 (71%)	2 (29%)	Granulation (3) Extrusion (1)	Granulation/limited benefit (1) Removal d/t granulation (1)
Baha attract ($N = 4$)	3 (75%)	1 (25%)	Wound infection (1)	Wound infection (1)
Bonebridge ($N = 10$)	9 (90%)	1 (10%)	Wound infection (1)	Removal d/t wound infection (1)
Total ($N = 21$)	17 (81%)	4 (19%)		
Single sided deafness				
Baha attract ($N = 3$)	1 (33%)	2 (67%)		Pain and noise (1) Limited benefit (1)
Bonebridge ($N = 15$)	9 (60%)	6 (40%)		Lost (1) Limited benefit (5)
Total ($N = 18$)	10 (56%)	8 (44%)		

N number, *HL* hearing loss

of the hearing level with BCHIs, and the average aided level was 37.5 [33.1, 45.0] dB HL. The functional gains, which indicated the difference between the AC thresholds and aided level, was 35.0 [22.3, 43.2] dB, and the effective gain, which indicated the difference between BC thresholds and aided level, was -15.0 [− 17.5, − 6.3] dB. For patients with MHL, the functional gain and effective gain of each device were compared with each other. The average effective gain of Bonebridge ($n = 10$, − 8.8 [− 15.0, − 3.5] dB) was significantly higher than that of Baha connect with BP110 ($n = 7$, − 20.0 [− 26.3, − 11.3] dB, $p = 0.037$), and the difference between the two devices was the most prominent at 0.5 kHz (− 20.0 [− 26.3, − 8.8] vs. − 40.0 [− 40.0, − 25.0] dB, $p = 0.010$) and 1 kHz (− 7.5 [− 10.0, − 3.8] vs − 15.0 [− 30.0, − 10.0] dB. $p = 0.014$) (Online resource 1 and Fig. 1a). The difference of average effective gain between Bonebridge ($n = 10$, − 8.8 [− 15.0, − 3.5] dB) and Baha attract with BP110 ($n = 4$, − 16.3 [− 17.5, − 10.4] dB) was not significant ($p = 0.234$). The average functional gains of Baha connect ($n = 7$), Baha attract ($n = 4$), and Bonebridge ($n = 10$) were 38.8 [20.0, 45.0], 21.9 [14.1, 38.2], and 36.9 [22.5, 48.8] dB, respectively, and the differences among the devices were not significant at all frequencies (all $p > 0.05$, Online resource 1 and Fig. 1b).

Audiological outcome of BCHIs in single-sided deafness

In the SSD group, the average BC threshold was 85.6 [68.4, 98.8] dB HL at the operation side and 18.1 [10.3, 20.6] dB

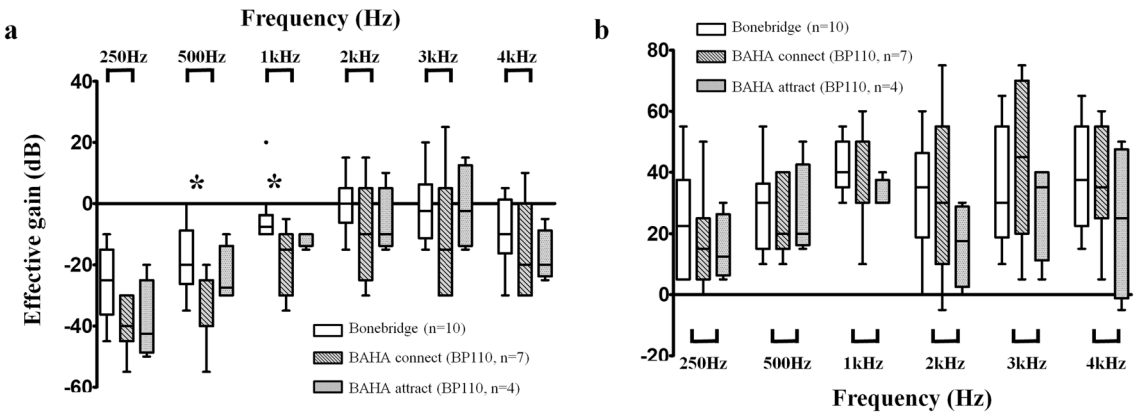

Fig. 1 Comparison of functional gain and effective gain according to devices in participants with mixed hearing loss. **a** Bonebridge shows higher effective gain in patients with mixed hearing loss than Baha connect and Baha attract, and the difference between Bonebridge and Baha connect was significant at 0.5 and 1 kHz (*). **b** The functional gains of bone conduction hearing implants are not significantly different between Baha connect, Baha attract, and Bonebridge. The box-and-whisker plots show the median (central line), interquartile range (box), and extreme values (whisker)

HL at the opposite side. To evaluate the hearing level with BCHIs in the SSD group, the unaided level (M level) and the aided level were evaluated, in the free-field with the opposite ear blocked. The average aided level was 28.1 [22.2, 33.8] dB HL, and the average effective gain, which indicated BC thresholds at the opposite side minus the aided level, was − 13.2 [− 16.3, − 9.4] dB. The average effective gain of Bonebridge was significantly higher than that of Baha attract (− 11.3 [− 15.0, − 7.5] vs. − 21.3 [− 21.3, − 16.3] dB, respectively) ($p = 0.012$), and the difference between the two devices was mostly prominent at 3 kHz (− 10.0 [− 15.0, 0.0] vs − 25.0 [− 30.0, − 20.0] dB, $p = 0.016$) (Online resource 2 and Fig. 2a). The averaged M-level was 48.1 [39.7, 60.6] dB HL, and the averaged functional gain, which indicated M-level minus aided level, was 21.3 [15.0, 28.8] dB. The averaged functional gains of Bonebridge ($n = 10$) and Baha attract ($n = 3$) were 21.3 [15.0, 28.8] and 18.8 [15.0, 28.8] dB, respectively, and the differences of the functional gains between two devices were not significant at all frequencies (all $p > 0.05$, Online resource 2 and Fig. 2b).

Compliance and related factors in SSD

To evaluate the audiological factors influencing the usage rate of BCHIs, the effective gain and functional gain of the constant user group ($n = 10$) with those of the non-constant user group ($n = 8$) within the SSD were compared. The effective gain was not significantly different between the constant user and non-constant user groups at all frequencies (all $p > 0.05$, Online resource 3 and Fig. 3a). In contrast, the functional gain was higher in the constant user group than that in the non-constant user group (user group vs non-user group; average, 22.5 [21.0, 28.8] dB vs 15.0 [11.6, 27.2] dB, $p = 0.068$), and the difference was significant at a frequency of 3 kHz frequencies (user group vs non-user group; 35.0 [33.8, 45.0] vs 17.5 [10.0, 27.5] dB at 3 kHz, $p = 0.004$) (Online resource 3 and Fig. 3b).

Discussion

A comparative study among the different BCHIs is important due to the recent development and utilization of various different types of BCHIs. For successful auditory rehabilitation, proper selection of devices, with consideration of patients' hearing level/type, characteristics, and personal needs, is mandatory. In this study, the authors performed a comparative evaluation of the audiological outcome and tried to relate it to the compliance of the various types of BCHIs. Among the types of BCHIs evaluated in this study, Bonebridge showed a higher effective gain by 12 dB than Baha connect (BP110) in this cohort of MHL patients and by 7.7 dB than Baha attract (BP110) in SSD patients. Compliance of BCHIs in the SSD group was relatively poorer than that in the MHL group, and most of the patients with poor compliance complained of limited audiological benefits from BCHIs. In comparative analyses between the constant and non-constant users among SSD patients, constant users showed higher functional gain from BCHIs than did non-constant users. Therefore, preoperative counseling with patients regarding the potential risks of low subjective benefit and postoperative management for appropriate functional gain by checking it in a free-field setting with blockage of the non-implanted ear might be important for the successful rehabilitation using BCHIs in SSD patients.

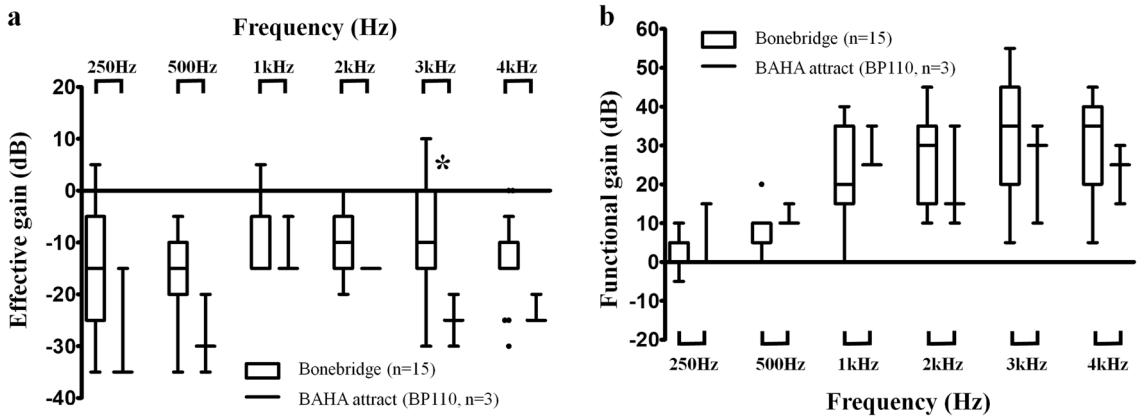

Fig. 2 Comparison of audiological outcome of Bonebridge and Baha attract in participants with single-sided deafness. **a** The effective gain (aided level—opposite BC thresholds) of Bonebridge was higher than that of Baha attract at all frequencies in patients with single-sided deafness, and the difference between the two devices was mostly prominent at 3 kHz (*). **b** In patients with single-sided deafness, the functional gain (unaided level—aided level) of Bonebridge and Baha attract does not show any obvious difference. Error bars depict standard deviation. The box-and-whisker plots as per Fig. 1

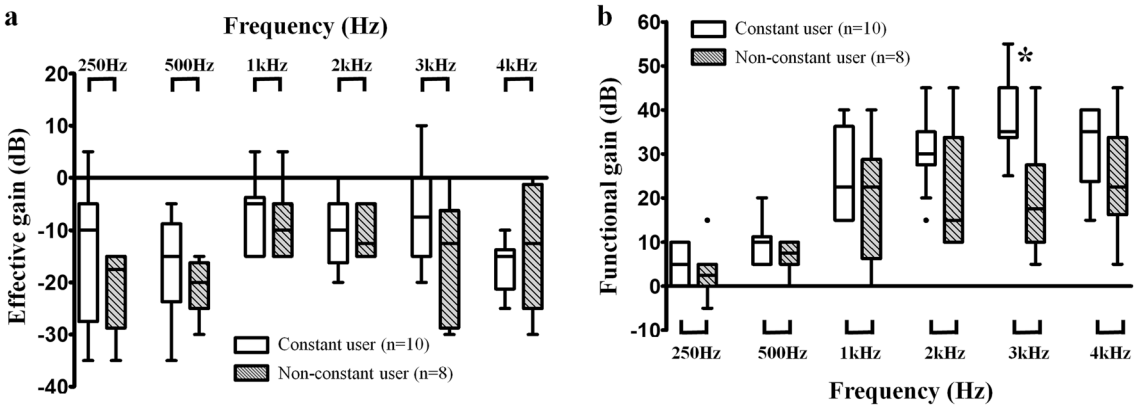

Fig. 3 Comparison of functional gain and effective gain between constant user and non-constant user groups in participants with single-sided deafness. **a** Effective gains (aided level—opposite BC thresholds) are not significantly different between the user and non-user groups in participants with single-sided deafness. **b** However, the functional gains (unaided level–aided level) are higher in user group than those in non-user group, and the difference between two groups was significant at 3 kHz (*). The box-and-whisker plots as per Fig. 1

Audiological outcome of BCHIs

The average functional gain of percutaneous BCHIs was reported to be 30–35 dB [5, 18] with about 10 dB higher gain than transcutaneous BCHI [6], due to the direct transfer of vibration to skull escaping from skin attenuation in transcutaneous BCHIs. In a recent systemic review, the functional gain of transcutaneous BCHIs, such as Sophono or Baha attract, was reported to be 28.4 dB among those with MHL [21]. In addition, the maximum power output of transcutaneous BCHIs was 5–15 dB lower than percutaneous BCHIs due to the dampening of sound by skin and subcutaneous tissues [22]. The lower maximum power outcome would result in poor coverage of speech sound and narrow dynamic range [22]. In contrast, a comparative study between percutaneous and transcutaneous BCHIs reported that the functional gains of the two different types of devices were not significantly different [5]. Specifically, Iseri et al. reported that the average gains were 32.9 dB in percutaneous BCHIs and 31.0 dB in transcutaneous BCHIs [5]. Furthermore, the functional gain of Bonebridge, active transcutaneous BCHIs, ranged from 24 to 37 dB [13, 23–25] and showed a comparable outcome with percutaneous BCHIs [12, 18]. These discrepancies of audiological outcome of BCHIs between the studies might be attributed to the fact that the functional gain is an inadequate parameter for evaluating the outcome of BCHIs. The BCHIs compensate for conductive hearing loss, and they were least affected by the degree of air–bone gap and AC thresholds. The difference in the degree of air–bone gap may have outpowered the difference in the true gain, especially in those with MHL. In accordance with this, the average functional gains of Baha connect, Baha attract, and Bonebridge were 38.8 [20.0, 45.0], 21.9 [14.1, 38.2], and 36.9 [22.5, 48.8] dB, respectively, and the difference of the functional gains among those with MHL between the devices was also not significant in this study (Fig. 1b).

Therefore, an improvement of hearing with BCHIs should be evaluated with consideration of BC hearing level at the side of better BC thresholds in MHL and SSD patients irrespective of air–bone gap. This gain, which is the difference between the BC thresholds and aided thresholds, has been referred to as the effective gain or bone conduction gain [19, 20, 26]. Indeed, it turned out that among MHL patients, the average effective gain of Bonebridge was higher (− 8.8 [− 15.0, − 3.5] dB) than those of Baha connect (− 20.0 [− 26.3, − 11.3] dB) and Baha attract (− 16.3 [− 17.5, − 10.4] dB) (Fig. 1a). Therefore, the effective gain was a better and adequate parameter in evaluating the effectiveness of BCHIs, and Bonebridge showed a better outcome than transcutaneous BCHIs. From a pure audiological perspective, Bonebridge has greater strengths when compared with Baha attract. Although Baha attract may be inferior with respect to audiological improvement, it could be useful when postoperative complications, such as skin reaction, infection, soft tissue overgrowth, develop from using Baha connect, requiring conversion to the attract system [10, 27]. Interestingly, Baha connect, which was powerful transcutaneous BCHI having high maximum power output, showed also lower effective gain than Bonebridge [22]. Although maximum power output of Baha connect with BP 110 was reported to be higher over 10 dB than that of Bonebridge, sufficient gain with Baha connect could not be applied due to feedback. Feedback is more likely to occur in percutaneous BCHIs than that in active transcutaneous BCHIs, because the microphone and vibrator were co-located in the same external device. The vibration of the sound processor and oscillation of the skull may create an acoustic signal that travel back to the

microphone [28]. This issue of feedback from the BP110 sound processor has previously been reported; the authors of that study suggested the possibility of reducing a gain to control feedback [29]. Alternatively, recently developed and updated sound processors, such as Baha® 5 Sound Processors, containing active feedback cancellation system could be considered to minimize and manage the issue of feedback [28]. In addition, Baha® 5 Power or SuperPower sound processors having a higher maximum power output would be another option to overcome the limited effective gain of Baha connect with BP 110 [30].

Binaural hearing provides the benefit of the summation, head shadow, and squelch effect. Patients with SSD suffer mainly from impairment of speech recognition in noise and sound localization. Several treatment options for SSD have been introduced, and BCHIs were reported as one of the effective treatment options for SSD. BCHIs showed a significant improvement of speech discrimination in noise circumstances [31]. If the speech sound was presented to the implanted side, BCHIs reduce the head shadow effect of speech sound by direct transfer to the cochlea at the opposite side [32–34]. However, the ability of sound localization was not improved with BCHIs because binaural hearing, which allows the detection of interaural time/intensity difference and the localization of sound, could not be completely restored with BCHIs [2, 33, 35, 36]. In the literature, to the best of the authors knowledge, there has not been any comparative study evaluating the difference between the various types of BCHIs in SSD; therefore, the audiological outcome and compliance of Baha attract and Bonebridge were evaluated. The functional gains of BCHIs were not significantly different between the three types of BCHIs in patients with SSD (Fig. 2b). Although the average functional gain of Bonebridge ($n = 15$) and Baha attract ($n = 3$) was not significantly different from each other, the average effective gain of Bonebridge was significantly higher than that of Baha attract (− 11.3 [− 15.0, − 7.5] vs. − 21.3 [− 21.3, − 16.3] dB, respectively) ($p = 0.005$) (Fig. 2a). This may imply that the effective gain may be more adequate for evaluating the intrinsic efficacy of BCHIs. The difference of the effective gain between the two groups ranged from 4.7 to 16.7 dB, which was mostly prominent and significant at 3 kHz (Fig. 2a). Therefore, Bonebridge showed better performance than Baha attract in patients with SSD. The recently released Baha® 5 SuperPower Attract system showed higher maximum power output and better preference over previous sound processors [30]. Therefore, change to updated processor having high maximum power output and advance feedback cancellation system could be a solution for limited effective gain and low usage rate of Baha attract with BP 110 in patients with SSD.

Compliance of BCHIs

The constant usage rate of BCHIs was higher in patients with MHL (81%) than those with SSD (56%). Moreover, in the MHL group, non-use was mainly attributed to the development of postoperative complications, such as granulation and wound infection (Table 1). In the MHL group, Bonebridge showed a higher constant usage rate (90%) than Baha connect (71%), and the difference between two devices might result from low complication rate of transcutaneous BCHIs. In contrast, the compliance of BCHIs in the SSD group was relatively poor, and patients refused to use the BCHIs due to the limited subjective benefits (Table 1). Therefore, clinicians should keep in mind the possibility of low compliance of BCHIs in SSD patients before performing the surgery and evaluate the related factors preoperatively to predict compliance of BCHIs.

The constant usage rate (60%, 9/15) of Bonebridge for SSD seemed to be higher than that of Baha attract (33.3%, 1/3); however, there was no statistical significance due to the low number of enrolled patients (Fisher exact test, $p = 0.558$). In detail, six patients with SSD in the Bonebridge group decided to stop wearing BCHIs due to limited subjective benefit ($n = 5/15$, 33%) and loss of speech processor ($n = 1/15$, 17%). One patient with Baha attract also complained of limited subjective benefit from the device ($n = 1/3$, 33%). Another patient had severe pain and noise/feedback from using Baha attract ($n = 1/3$, 33%). Transcutaneous BCHIs transfer the vibration stimuli directly onto the skin, which could contribute to skin irritation and pain. Additionally, feedback is more likely to occur in passive transcutaneous BCHIs than that in active transcutaneous BCHIs [28], and it makes the possibility of reducing low tone gain to control feedback [29]. Therefore, Bonebridge might be a preferred option for SSD patients with respect to minimizing the complication of Baha, such as pain and noise/feedback (Table 1).

Indeed, Pennings et al. reported that among SSD patients with an initially favorable response in the clinic with Baha headband, 32% decided not to proceed with surgery after about two weeks of use at home [37]. Furthermore, only 40% underwent implantation of Baha. The authors of this article proposed the importance of an extended preoperative trial of bone conduction devices, and the intensive preoperative counseling makes realistic expectation for BCHIs and higher compliance after surgery [37]. At the same time, the limited output inherent from headbands could account for relatively lower proportion of subjects who decided to undergo Baha implantation. Conversely, Schrøder et al. reported that 95% of patients with SSD used Baha after surgery, and 81% used it more than 8 h a day [38]. Furthermore, 90% considered Baha as a moderate to significant aids. The

discrepancy of higher usage rate of Baha connect from their study and 60% of constant usage rate of Bonebridge in this study might be attributed to the difference between the percutaneous and transcutaneous devices. Therefore, a BCHI device with higher maximal output, higher effective gain, and better feedback cancellation ability should be considered for patients with SSD. Additionally, careful counseling of SSD patients regarding the potential risks of non-usage and providing patients with sufficient experience the bone conduction test devices should be considered prior to the operation. In the current study, the constant usage rate of Bonebridge seems to be higher than Baha attract for SSD patients. Better effective gain have been shown from Bonebridge than from Baha attract, especially at 3 kHz. Therefore, the authors tried to see whether audiological parameters, i.e., better effective gain from Bonebridge, resulted in better constant usage rate of BCHI in SSD patients. For this purpose, several audiological outcomes were compared between the constant user group and non-constant user group among SSD subjects. The constant user group showed a higher functional gain than the non-constant user group, and the difference was mostly prominent and significant at 3 kHz frequencies (user group vs non-user group; 35.0 [33.8, 45.0] vs 17.5 [10.0, 27.5] dB at 3 kHz, $p = 0.004$) (Online resource 3 and Fig. 3b). Most important benefit from BCHIs is to overcome the head shadow effect. If the functional gain of BCHIs is not sufficient, i.e., the functional improvement of the BCHIs not exceeding the loss due to the head shadow effect, patients may think that BCHIs are not sufficiently effective. The interaural intensity difference was prominent at mid to high frequencies and was reported as 5 dB at 1 kHz and 10 dB at 5 kHz when the sound was presented with 90 degrees azimuth [39]. Another study reported that the head shadow effect was about 10 dB at 2 and 3 kHz, and 15 dB at 3 kHz [34]. In this cohort, the constant user showed higher functional gain than the non-constant user at 2 (30.0 [27.5, 35.0] vs 15.0 [10.0, 33.8] dB), 3 (35.0 [33.8, 45.0] vs 17.5 [10.0, 27.5] dB), and 4 kHz (35.0 [23.8, 40.0] vs 22.5 [16.3, 33.8] dB), and these higher levels of functional improvement in subjects with SSD would enable to overwhelm the head shadow effect in mid frequencies, probably leading to a higher usage rate among SSD subjects. Since the majority in the SSD group was users of Bonebridge, the higher effective gain observed from Bonebridge compared with Baha attract among SSD subjects was not recapitulated in a comparison between the constant user group and the non-user group. These data suggest that the effective gain observed among SSD patients in this cohort could be rather intrinsic to the device; the functional gain may better reflect the subjective benefit in SSD subjects, irrespective of the type of BCHIs.

Study limitations

This study had several limitations. Firstly, the number of subjects was not large enough to draw any convincing conclusion due to relative short experience of these devices in the author's institute. In this reason, the statistical results about the difference of effective or functional gain between the devices might have weak reliability. In the future, the authors hope to include more patients and show more reliable results. A prospective cohort study design may also be possible. Secondly, they only used daily average usage time using data logging as a measurement of compliance. The use of a comprehensive and well-controlled questionnaire survey including items about compliance of hearing aids, such as International Outcome Inventory—Hearing Aids (IOI-HA) [40] or Abbreviated Profile of Hearing Aid Benefit (APHAB) [41], would make their next study much better off.

Conclusion

This study suggests that Bonebridge might be preferred due to higher complication rate of Baha connect and lower effective gain of Baha connect with BP110 in MHL patients and Baha attract with BP110 in SSD patients. The compliance of BCHIs is relatively poor in subjects with SSD compared with MHL, and extensive counseling and trial of test devices should be considered before surgery regarding the potential risks of low subjective benefit. Irrespective of the type of BCHIs used by subjects with SSD, higher functional gain especially at mid frequencies might lead to subjective satisfaction, and thereby good compliance. Therefore, an evaluation of the functional gain of BCHIs in free-field and meticulous fitting targeting a sufficient mid-frequency functional gain would be beneficial for higher usage rate of BCHIs in SSD subjects.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to disclose.

Research involving human participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board of our institute for research involving human subjects (No. B-1904/532-106) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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