



# Audiological effectiveness of Bonebridge implantation for bilateral congenital malformation of the external and middle ear

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## Abstract

**Purpose** To evaluate the audiological effectiveness of Bonebridge implantation in patients with bilateral congenital malformation of the external and middle ear.

**Methods** Twenty-eight cases [17 boys and 11 girls; median age, 12 years (range 8–36 years)] had unilateral Bonebridge implantation. Audiological tests were performed preoperatively and postoperatively, and included the pure-tone audiometry test, speech discrimination score (SDS), and evaluation of the unaided and aided hearing thresholds in sound fields. For the group of patients aged > 12 years, Mandarin Speech Test Materials were used to determine the SDS. For the other cases, the Mandarin Lexical Neighborhood Test was used. The daily life efficacy was assessed using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire postoperatively. The *t* and *t'* tests were used in the statistical analyses.

**Results** The hearing threshold with the Bonebridge improved by 25–35 dB HL, compared to that of the unaided condition. The SDS of patients aged > 12 years improved by about 50%; the SDS also improved by 10–20% in the three patients aged < 12 years. According to the APHAB, the mean Bonebridge scores of ease of communication, background noise, and reverberation decreased by  $60.3 \pm 15.7$ ,  $50.2 \pm 11.1$ , and  $59.4 \pm 7.8$ , respectively, compared to the preoperative scores, and the Bonebridge score of aversiveness was higher ( $69.8 \pm 10.8$ ) than the unaided score.

**Conclusions** The audiological effectiveness of the Bonebridge was significant and noticeable in bilateral congenital malformation of the external and middle ear. The Bonebridge can be an alternative and effective solution for those patients to improve hearing.

**Keywords** Bilateral · Congenital malformation · External and middle ear · Bone-conduction hearing aids · Transcutaneous bone-conduction implant · Bonebridge

## Introduction

Congenital malformation of the external and middle ear is relatively common in clinical settings, and the average incidence of ear malformations in China is between 3.06 in 10,000 live births in China [1]. Approximately 10% of the patients suffer from bilateral malformation [2]. Different degrees of aural deformity, atresia, or stenosis of the

external ear canal (EAC) and middle ear deformity are the main clinical presentations. Auricular reconstruction to achieve better esthetic appearance can be achieved when the condition reaches an operative condition. Conductive hearing loss is mainly the clinical manifestation with an air–bone-conduction gap (ABG) up to 60 dB HL or so because of atresia or stenosis of the EAC and middle ear deformity [3]. Most patients with bilateral congenital malformation of the EAC and middle ear have slurred speech, developmental retardation, and even personality defects, and they face substantial social obstacles in daily life. The need for hearing improvement is even more urgent, and surgical hearing improvement should be considered first. EAC reconstruction and tympanoplasty, the earliest hearing reconstruction methods, are difficult to perform in high-risk patients, and they are associated with a high postoperative complication

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rate and poor long-term auditory effectiveness [3–6], especially in patients with severe malformation. Facial paralysis, stenosis, and even re-atresia of the EAC and infection of the reconstructed aural anatomy occur because of severe malformation and other reasons. In addition, the bone-anchored hearing aid can cause skin irritation, infection around the abutment, and a whistling sound. As a new technique, the Bonebridge (BB, Med-EL, Innsbruck, Austria) has been used in the clinical setting in China since March 2016, and it has provided an effective option for such patients, although it has only been introduced for a short period and its clinical application is still in its infancy. This study evaluated the audiological effectiveness of the BB in 28 patients after implantation to provide data to support the clinical application of BB implantation in patients with congenital malformation of the external and middle ear.

## Materials and methods

### Study patients

From March 2016 to April 2018, 28 patients with bilateral congenital malformation of the external and middle ear underwent unilateral BB implantation (implant model: Bone-Conduction Implant [BCI] 601, Med-EL) in Beijing Tongren Hospital.

The patients were selected according to the following criteria:

- All patients had to be older than 6 years of age.
- Auricular reconstruction if needed had been done or was completed until the final stage.
- Subjective hearing tests and pure-tone audiometry (PTA) were performed. The hearing thresholds had to accord with the manufacturer's suggested criteria, i.e., that bone-conduction hearing thresholds better than 45 dB HL of frequencies 500–4000 Hz and ABG more than 30 dB HL for conductive and mixed hearing loss.
- The bone-conduction thresholds from the last 12 months were stable before the surgery.
- The inner ear had no malformation and no central auditory-processing disorders were present (preoperative cerebral MRI was performed in all cases).
- Through the annotations and 3D visualization observed in the BB FastView software, the BC-FMT, a part of the implant, could be simulatively placed on the mastoid process.
- Patients were required to have realistic and rational expectations of the benefits and limitations of the Bonebridge.
- The operation side was selected in the following circumstances:
  - By comparison of hearing loss of two ears, the worse one was selected.
  - By compassion of the Jahrsdoerfer scores, the less one was selected. If the one could not be carried on according to the preoperative simulation, the other one was selected.
  - If one side was stenosis and the other atresia, the atresia side was selected.
  - If there were no significant differences in temporal bone structure and hearing loss in both ears, the patient chose the operative side voluntarily.

Due to the effect of social experience, the level of education and other factors based on age, and the understanding and logic of the vocabulary in the speech test materials differs. Thus, appropriate speech audiometry materials were selected to ensure the reliability of the results. The 28 patients were divided into two age groups based on age:  $\leq 12$ -year-old group (3 patients) and  $> 12$ -year-old group (25 patients). All patients were assessed using audiological tests, including the pure-tone audiometry (PTA), unaided and aided hearing thresholds in sound fields, and speech test.

### Preoperative assessment

Audiological assessment: PTA (0.25, 0.5, 1, 2, and 4 kHz) was conducted using the GSI-61 audiometer. For patients aged  $\leq 12$  years, the Mandarin Lexical Neighborhood Test (MLNT) [6], including monosyllabic (MLNT-M) and disyllabic words (MLNT-D), was used to assess the unaided speech discrimination score (SDS). For patients aged  $> 12$  years, the Mandarin Speech Test Materials (MSTMs) [7] were used to assess the unaided SDS of monosyllabic and disyllabic words under the 65-dB SPL and 80-dB SPL sound fields.

Radiographic evaluation: all the patients underwent temporal bone thin-layer computed tomography (CT) to assess the thicknesses of the mastoid process and temporal bone cortex. According to the Jahrsdoerfer grading scale [5], 20 patients with the osseous atresia of the EAC had Jahrsdoerfer scores  $< 6$ , meaning that canaloplasty of the EAC and tympanoplasty were not suitable [8]. 4 of left patients, who had Jahrsdoerfer scores of 7, had got hearing reconstruction before. The remaining 4 patients had a milder deformity of both auricles without osseous atresia of the EAC, and they did not have any request about their esthetic appearance.

The bone-conduction-floating mass transducer (BC-FMT) of the BB implant can be simulated using three-dimensional (3D) reconstruction with the BB FastView software, which imports the Digital Imaging and Communications in Medicine format of the CT scan, and then the

reconstruction is used to avoid oppressing two important structures, the sigmoid sinus and dura mater.

## Surgical procedure

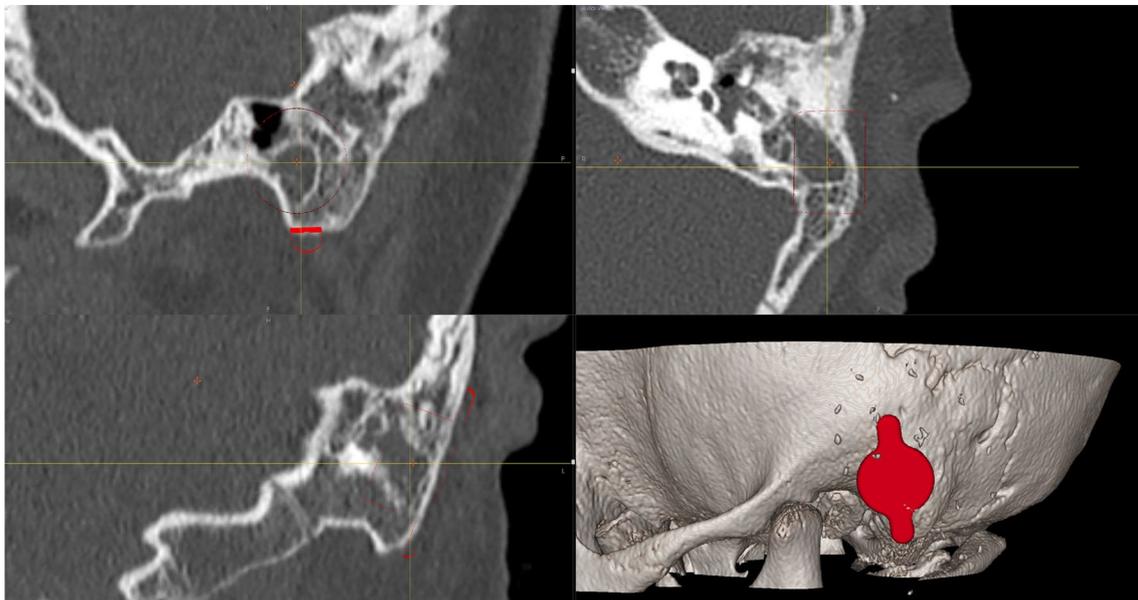
Based on the preoperative audiological assessment and radiographic evaluation, the ear that had worse hearing or the ear in which the BC-FMT could be placed in the mastoid cavity was selected. All 28 patients underwent implantation under general anesthesia. The implantation location of the BC-FMT was marked behind the ear according to the 3D reconstruction (Fig. 1). The coil was situated at the posterior superior auricle, at a 45° angle with the posterior wall of the EAC and 4–5 cm away from the auricle. A C-shaped postauricular incision about 5 cm long was made. In patients who underwent complete auricle reconstruction, the incision was made along the depression of the reconstructed auricle. The mastoid process was grinded gradually using the cutting burr to form a round bone bed with a diameter of 15.7 mm and depth of 8.7 mm or less, which was measured by a mold of the BC-FMT (named the T-Sizer). After the bone bed was prepared, two holes for the screws were drilled. Then the BC-FMT was placed into the bone bed and fixed with two cortical screws. The coil of the implant was placed under the skin flap according to the marker.

## Postoperative assessment

The external audio processor (model: Amadé BB, Med-EL) was first fitted 7–10 days postoperatively. The follow-up hearing evaluations were performed 12 months after the first fitting. After the fitting, the hearing by bone conduction (BC) (0.25, 0.5, 1, 2, and 4 kHz) was tested to determine if there was an increase of the hearing threshold by BC, i.e., the occurrence of sensorineural hearing loss. The BB-aided hearing threshold (0.25, 0.5, 1, 2, and 4 kHz) in the sound fields was tested later. For patients aged  $\leq 12$  years, the MLNT [9], including the MLNT-M and MLNT-D, was used again to assess the SDS under unaided and aided conditions. For patients aged  $> 12$  years, the MSTM [10] was used again to assess the SDS of monosyllabic and disyllabic words under the 65-dB SPL and 80-dB SPL sound fields.

The audiological effectiveness after BB implantation was analyzed by comparing preoperative unaided hearing thresholds with aided hearing thresholds in sound fields and by analyzing the differences in the SDS under these two conditions.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a structured questionnaire that includes 24 items grouped into 4 domains: ease of communication (EC), background noise (BN), reverberation voice (RV), and aversiveness. Each question has 7 different responses: 99% = always, 87% = almost, 75% = generally, 50% = half the time, 25% = occasionally, 12% = seldom, and 1% = never [11, 12]. The APHAB was used to evaluate auditory and quality



**Fig. 1** The bone-conduction implant coil is placed on the cranial surface under the skin flap, and the bone-conduction-floating mass transducer (BC-FMT) is fixed with cortical screws through the BB Fast-

View software preoperatively (the connection between the BC-FMT and the demodulator can be twisted as needed)

of daily life development, stability of hearing benefits at baseline (0 months), 6, 12, and 24 months postoperatively in all the cases.

**Statistical analysis**

We used the *t* and *t'* tests to analyze the data. The statistical analysis was conducted using the SPSS 17.0 software package (IBM Corp., Armonk, NY, USA).

**Results**

This study included 17 boys and 11 girls aged 8–36 years (median age, 12 years); and their implantations showed in Table 1. Among them, 4 patients had a milder deformity of both auricles without osseous atresia of the EAC, and they did not have any request about their esthetic appearance; the remaining 24 patients underwent postoperative bilateral total auricle reconstruction for osseous atresia of the EAC. In addition, 24 patients experienced regular use of softband bone-anchored hearing devices preoperatively except that 4 patients who did not achieve stable aural benefit from EAC reconstruction in the long term.

**Pure-tone audiometry results and BC threshold**

The PTA and BC threshold were evaluated in 28 patients postoperatively, and the results are shown in Table 2. For the 3 patients aged ≤ 12 years, their preoperative and postoperative mean unaided BC thresholds were 8 dB HL and 9 dB HL, respectively, with an average of 8.5 dB HL. For

the group of 25 patients aged > 12 years, the preoperative mean unaided BC threshold was 7.17 ± 5.34 dB HL, and the postoperative unaided BC threshold was 7.08 ± 4.94 dB HL (0.25, 0.5, 1, 2, and 4 kHz). There were no statistically significant differences in the preoperative and postoperative unaided BC thresholds between the age groups (*P* > 0.05). However, a significant change trend of the AC thresholds was found preoperatively and postoperatively in all patients, include preoperative hearing aided by softband bone-anchored hearing devices (Fig. 2).

The preoperative and postoperative mean BC and AC thresholds were tested. There were no significant differences between preoperative and postoperative mean BC and AC of the one-surgery ears (Table 3).

**Speech discrimination score**

Under 70-dB SPL sound fields, the SDS of the group of patients < 12 years increased by 10–20% with the aid of the BB (Table 4). For the group of patients > 12 years of age, the SDSs of monosyllabic and disyllabic words tested under the 65-dB SPL and 80-dB SPL sound fields improved to 56.79 ± 5.31% and 65.43 ± 8.46%, respectively, as shown in Table 5. There were statistically significant differences in

**Table 1** Distribution of patients with unilateral BB implantation

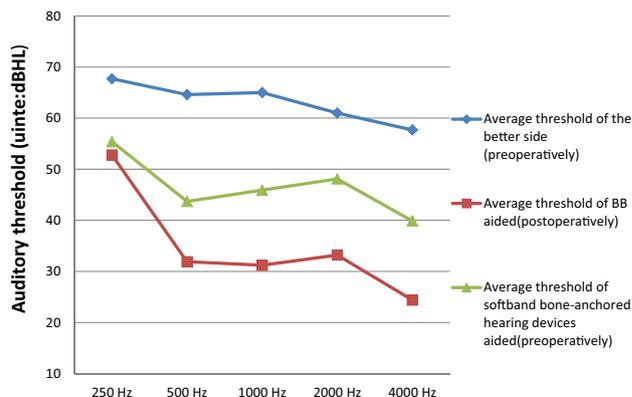
Age group	Operative side		Sex ( <i>n</i> )		Median age (years)
	Left	Right	Male	Female	
≤ 12 years	1	2	2	1	8
> 12 years	11	14	15	10	13
Total	12	16	17	11	12

BB Bonebridge

**Table 2** Comparison of preoperative and postoperative bone-conduction mean thresholds of surgery ears between the age groups

Age group	Preoperatively		Postoperatively	
	Bone conduction (dB HL)	Unaided ear conduction (dB HL)	Bone conduction (dB HL)	BB-aided auditory threshold (dB HL)
≤ 12 years	8.5	61.5	8.5	38
> 12 years	7.17 ± 5.34	62.01 ± 6.53	7.08 ± 4.94	34.17 ± 5.34
<i>P</i> value of the <i>t'</i> test	> 0.05	> 0.05	> 0.05	> 0.05

BB Bonebridge



**Fig. 2** Comparison of the change in the auditory threshold at five different frequencies in preoperative and postoperative hearing of patients include preoperatively aided by softband bone-anchored hearing devices

**Table 3** Comparison of preoperative and postoperative PTA mean thresholds of non-surgery ears between the age groups

Age group	Preoperatively		Postoperatively	
	Bone conduction (dB HL)	Air conduction (dB HL)	Bone conduction (dB HL)	Air conduction (dB HL)
≤ 12 years	9	60	8.5	60.5
> 12 years	7.20 ± 5.23	62.22 ± 6.67	7.76 ± 5.01	61.87 ± 7.03
<i>P</i> value of the <i>t</i> ' test	> 0.05	> 0.05	> 0.05	> 0.05

**Table 4** Comparison of the postoperative mean SDS (%) according to the MLNT results in the ≤ 12-year-old group

	Monosyllabic		Disyllabic	
	Easy words	Difficult words	Easy words	Difficult words
Unaided	20	10	75	75
BB-aided	35	20	95	85

The sound field strength is 70 dB SPL

*BB* Bonebridge, *MLNT* Mandarin lexical neighborhood test, *SDS* speech discrimination score

the SDSs with and without the aid of the BB in both age groups (*P* < 0.05).

**Questionnaire survey**

According to the APHAB questionnaire, the mean BB-aided scores of EC, BN, and RV were decreased by 60.3 ± 15.7, 50.2 ± 11.1, and 59.4 ± 7.8, respectively, compared to the unaided scores (Fig. 3). The subjective evaluation showed the same trend of the auditory thresholds and speech audiometry materials (Fig. 3). However, the BB-aided score of aversiveness (69.8 ± 10.8) was higher than the unaided score. A comparison of the preoperative and postoperative average BB-aided scores of EC, BN, RV and AVE is shown in Fig. 4.

**Stability and complication**

The APHAB questionnaire of the 28 patients were followed up via telephone during the 6–24 months. The mean follow-up duration was 12 months. In addition, they returned to the hospital and complete auditory tests at 12 months

**Table 5** Comparison of the postoperative mean SDS (%) according to the MLNT results in the > 12-year-old group

	65-dB SPL sound field		80-dB SPL sound field	
	Monosyllabic	Disyllabic	Monosyllabic	Disyllabic
Unaided	10.2 ± 6.98	25.87 ± 5.64	28.2 ± 9.31	39.52 ± 10.87
BB-aided	56.79 ± 5.31	65.43 ± 8.46	69.99 ± 9.57	89.54 ± 9.82
<i>P</i> value of the <i>t</i> ' test	< 0.05	< 0.05	< 0.05	< 0.05

*BB* Bonebridge, *MLNT* Mandarin lexical neighborhood test, *SDS* speech discrimination score

postoperatively. None of the patients experienced flap necrosis, infection around the operative area, hearing deterioration, or implant rejection. All the patients were satisfied with the audiological efficacy after implantation.

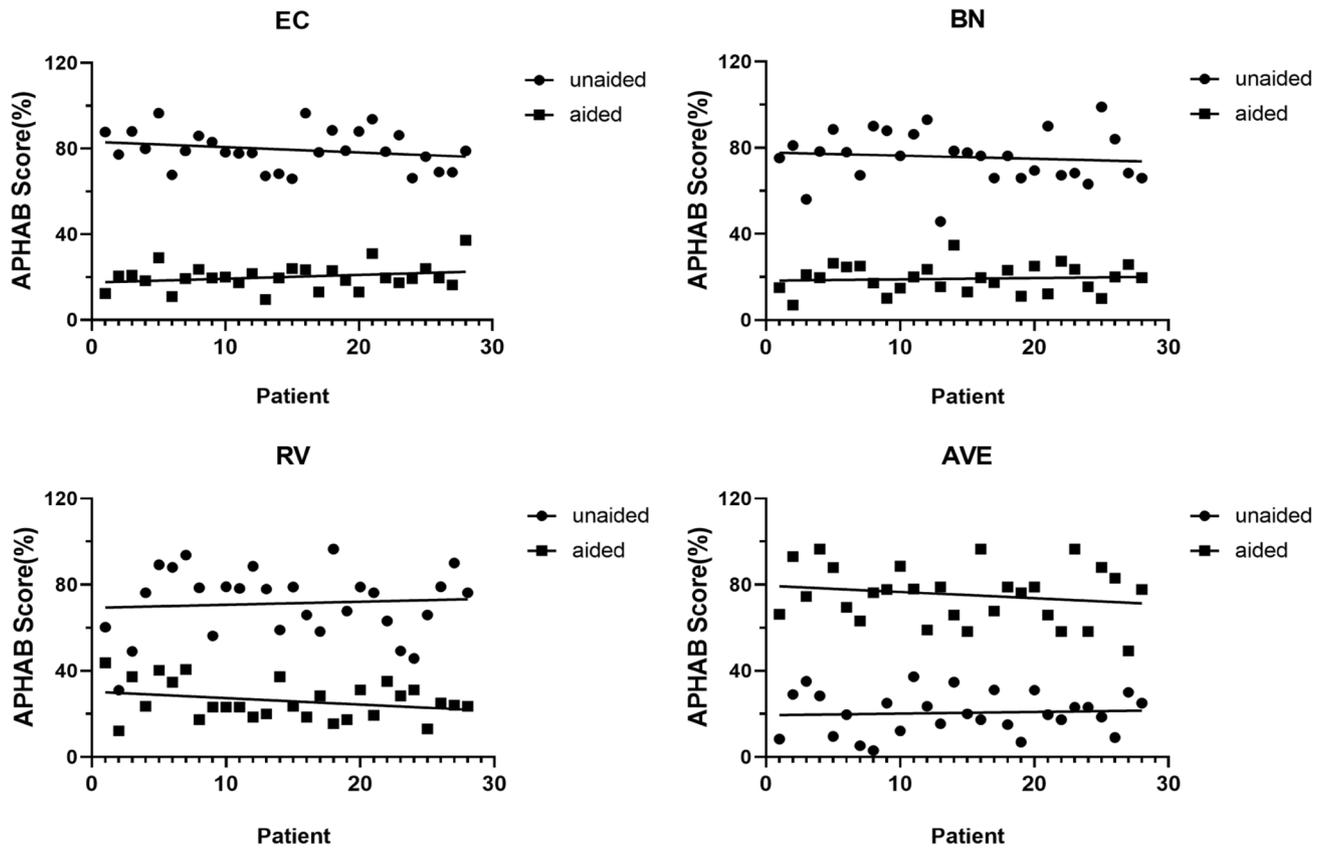
**Discussion**

Indications and audiological features of bilateral congenital malformation of the external and middle ear.

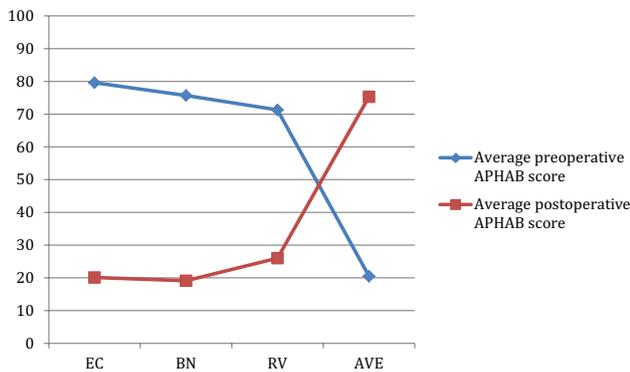
The BB is indicated for (1) conductive or mixed hearing loss with BC thresholds ≤ 45 dB HL; and (2) single-sided deafness with BC thresholds of the normal ear ≤ 20 dB HL. The audiological features of bilateral congenital malformation of the external and middle ear are almost conductive with the normal BC threshold. Usually, the ABG can be up to 60 dB or so [3]. These features indicate the suitability of the BB.

**Postoperative complication**

Congenital external/middle ear malformation is often combined with abnormalities in the middle ear structures [13], especially in the ossicle abnormalities, facial nerve aberrance and vestibular window morphology, which are usually negative factors of the auditory outcome of tympanoplasty. The Jahrsdoerfer grading scale, a widely accepted method for grading cases of aural atresia, can be used to estimate the feasibility of EAC reconstruction universally. Patients with aural atresia with a score > 7 usually can experience stable hearing improvement from EAC reconstruction and tympanoplasty in the long term. Overall, more cases with a score ≥ 7 are reported to get hearing close to practical level (< 30 dB), compared to only 45% of cases with a score ≤ 6 after EAC tympanoplasty [3]. Even under strict indication



**Fig. 3** Total preoperative and postoperative APHAB scores of the 28 patients. *APHAB* abbreviated profile of hearing aid benefit, *EC* ease of communication, *BN* background noise, *RV* reverberation voice, *AVE* aversiveness



**Fig. 4** Difference in the average APHAB scores between preoperatively and postoperatively. *APHAB* abbreviated profile of hearing aid benefit, *EC* ease of communication, *BN* background noise, *RV* reverberation voice, *AVE* aversiveness

selection and surgery, the rates of restenosis and unstable hearing in the long term are reported, respectively, at about 18.5–60.0% and 32–52.2% [14–16]. The traditional hearing reconstruction method is so difficult to perform. Even though under sophisticated surgical technology, possible

postoperative complications are not avoided completely. Especially for patients with a Jahrsdoerfer score < 6, meaning a poor development of temporal bone, bone-conduction implant is a more reasonable choice for improving hearing by surgery [3].

The BB is an active transcutaneous BC hearing aid, which keeps the skin intact and facilitates effective transmission of the vibrant. The surgical approach of BB implantation just reaches the surface of the mastoid process, avoiding facial paralysis. For severe malformation of the temporal bone, the sigmoid sinus and dura mater can be compressed by the BC-FMT, which could likely cause headaches. The magnetic attraction between the audio processor and coil is not strong to prevent inflammation of the skin flap and hair loss. For patients with total auricle reconstruction, the low risk of complications may guarantee the effects of the reconstructed auricle and the audiological effectiveness of the BB implantation. In the long-term follow-up of the present study, none of the 28 patients had skin flap inflammation, infection, rejection, implant loss, adverse skin reactions, skin overgrowth, or other complications, suggesting that the safety and stability of BB implantation are consistent with those reported by Sprinzl et al. [17].

## Audiological effectiveness

According to Table 2, there were basically no changes of the BC threshold between preoperatively and postoperatively in either group, which indicated that BB implantation did not cause sensorineural deafness or hearing deterioration. The auditory thresholds improved to 25–35 dB after BB implantation. The results were very close to those reported by Sprinzl et al. and Tsang et al. [17–19]. Specifically, the auditory average thresholds were 50–55 dB at 0.25 kHz and 10–35 dB at 0.5–4 kHz. These findings suggest that the BB results in significant audiological gain in the speech frequency from 0.5 to 4 kHz, but barely works in the low frequencies. In the low-frequency zone, sound energy tends to be attenuated during transmission, and since acoustic signals are not easily captured by microphones of the external audio processor, the gain is less appreciable. This study tried to fit the internal processing mode of the Amadé to increase the gain at a low frequency, and we found that the amplitude of fitting was too large, causing sensation of ear fullness, serious low-frequency acoustics distortion, etc. In addition, the low gain in the low-frequency zone may be somewhat associated with the inertness of the BC-FMT of current sizes.

As shown in Tables 4 and 5, the BB-aided SDS was significantly superior to that of the unaided condition. This result was similar to that observed by Sprinzl et al. [17]. However, the improvement of SDS in the  $\leq 12$ -year-old group was not as significant as that in the  $> 12$ -year-old group. Older patients had better comprehension and logical capability for the speech test materials, which may explain this finding. In addition, using the existing speech test materials, we could not thoroughly distinguish the differences at the different levels of hearing conditions. Therefore, further research in audiology is required to develop more suitable speech test materials for such patients.

The audiological gain of the BB has been recognized by many scholars [20–24]. During the follow-up, most adult patients reported that their recognition of low and fine sounds was significantly enhanced. The parents of younger patients reported that they had smooth and clear communication with their children, and the patients who had slurred speech became more articulate 3–5 months after implantation. In particular, the 4 patients who received total auricle reconstruction stated that their hearing was better than before the initial activation 12 months later. In view of reduction in the skin swelling and skin flap thickness, the magnetic attraction between the external audio processor (Amadé) and the implant (BCI 601) became strong, and as a result, the sound signals and energy could be more passed on during transmission with less acoustic energy, further improving hearing. Thus, the patients had a better auditory experience.

From Fig. 2, the hearing thresholds of postoperative BB implantation were lower than those aided by softband bone-anchored hearing devices, about 10–15 dB in speech frequencies. The trend was consistent with the patients' response that the sound aided the BB louder and clearer than softband bone-anchored hearing devices preoperatively. There were no skin wounds, skin pressure feeling and noisy echoes and the patients got better user experience by the BB implantation.

In addition, there were no differences between preoperative and postoperative hearing, the non-surgery ear of the same patient, by PTA (Table 3). It indicated that the non-surgery ear did not affect sound field hearing and SDS evaluation of the surgery ear.

## Daily life efficacy

According to the APHAB questionnaire, the mean BB scores of EC, BN, and RV each decreased compared to those of the unaided scores. The subjective evaluation showed the same trend of the auditory thresholds and speech audiometry. However, the BB score of aversiveness was higher than the unaided score (Fig. 4). These findings indicated that the BB can amplify and transmit the noise signal synchronously, while delivering the target sound signal into the inner ear. However, it decreased the patients' aversion and rejection to the increased noise signal. This result may be related to the difference between the low-frequency and speech frequency gain. The trend of less gain of low frequency is shown in Fig. 2, which contrasts with that of speech frequency. The former may lead to the ear fullness, fuzzy hearing, and even a headache. However, unilateral implantation still cannot compensate for bilateral aural hearing, and the patient does not have the benefit of controlling bilateral noise reduction postoperatively. Once the sound exceeded the normal speech sound, the patients felt overwhelmed and uncomfortable from the noise, and some even developed a headache. These factors decreased the patients' auditory experience and affected their satisfaction with the BB.

## Conclusions

This study, conducted in 28 patients suffering from bilateral congenital malformation of the external and middle ear showed the safety of the Bonebridge at the 12-month follow-up with very good and stable hearing benefits. Bonebridge has been shown to significantly reduce audiometric thresholds and improve speech discrimination, especially in a noisy environment. The long-term stability and safety of the BB, as a new BC device, should be evaluated through more data and a longer follow-up are required. However, the BB can be an alternative option for congenital malformations of

the external and middle ear based on its noticeable audiological effectiveness, especially for patients with bilateral conductive hearing loss.

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### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** The institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study design was approved by the Institutional Ethics Committee at Beijing Tongren Hospital.

**Informed consent** All study participants provided informed consent.

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