

A review of surgical and audiological outcomes of bonebridge at tertiary centres in Malaysia

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ABSTRACT

Objectives: To investigate the surgical and audiological outcome of Bonebridge (BB) at tertiary centres in Malaysia. **Study Design:** Prospective, intra-subject repeated measurements of which each subject is his/her own control, from year 2012 to 2016 at two tertiary referral centres.

Methods: Twenty patients with hearing loss who fulfilled criteria for BB and showed good response to bone conduction hearing aid trial were included. Implantations of BB were carried out under general anaesthesia with pre-operative computed tomography (CT) planning. Complications were monitored up to six months postoperatively. Subjects' audiometric thresholds for air conduction, bone conduction and sound field at frequencies of 250Hz to 8kHz were assessed preoperatively and at six months postoperatively. Subjects' satisfaction was evaluated at 6 months post operatively with Hearing Device Satisfaction Scale (HDSS) questionnaire.

Results: There was no major complication reported. Mean aided sound field thresholds showed significant improvement for more than 30dB from 500 to 4000kHz ($p < 0.05$). There was no significant change in mean unaided air conduction and bone conduction thresholds pre and post operatively from 500 to 4000kHz, with a difference of less than 5dB ($p > 0.05$). All the patients were very satisfied (>80%) with the implant, attributing to the promising functional outcome and acceptable cosmetic appearance.

Conclusions: BB implantation surgery is safe and is effective in restoring hearing deficits among patients aged five and above with conductive or mixed hearing loss and single-sided hearing loss.

KEY WORDS:

Bone conduction implant; Bonebridge; Conductive hearing loss; Single-sided sensorineural deafness; Surgical outcome; Audiological outcome

INTRODUCTION

Bone conduction implant (BCI) has been widely adopted as a rehabilitation option for patients with conductive or mixed hearing loss for more than three decades.¹ A recent systematic review by Kim showed that BCI is effective in improving speech discrimination in noise and quality of life in patients

with single-sided hearing, though there was no significant improvement in sound localization.²

Bonebridge (BB, Med-El) is a new active transcutaneous BCI which was launched onto European Union (EU) market in September 2012 and was subsequently approved by Communauté Européenne (CE) for implantation in children aged five years and above.³ As compared to percutaneous BCI, BB's transcutaneous technology enables the avoidance of several complications including skin reaction, growth of skin over the abutment, implant extrusion and wound infection.⁴

Bonebridge consists of an external part (audio processor) and an internal implanted part (bone conduction implant). The audio processor (AP) consists of microphone and a digital signal processor which is powered by a standard hearing aid battery. The internal part includes a demodulator that processes the signal, a receiver coil and an active, electromagnetic bone conduction-floating mass transducer (BC-FMT) which transforms the electrical signal into mechanical vibrations that stimulate the inner ear directly.

Bonebridge is indicated in adults and children aged five years and above with³:

1. conductive or mixed hearing loss, who can still benefit from sound amplification. The pure tone average bone conduction (BC) threshold (measured at 0.5, 1, 2, 3 and 4 kHz) should be better than or equal to 45 dB HL.
2. single-sided sensorineural deafness. The pure tone average air conduction (AC) threshold in the contralateral ear (measured at 0.5, 1, 2, 3 and 4 kHz) should be equal to or better than 20 dB HL.

The first BB implantation in Malaysia was in year 2012. To date, there are no reported series of BB in Malaysia. This study aims to investigate the surgical and audiological outcomes of BB at tertiary referral centres in Malaysia.

MATERIALS AND METHODS

Study Design

This study was conducted in two tertiary centres in Malaysia from January 2012 to December 2016, using a prospective, intra-subject repeated measures design of which each subject is his/her own control.

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Subjects

Twenty subjects aged 7 to 67 were enrolled into this study. Subject demographics and medical history were shown in Table I.

The patients were selected according to the following criteria:

- Fulfilled criteria for BB as described above
- Benefit from trial of bone conduction hearing aid

Surgical Technique

The surgical technique has been extensively described elsewhere⁵. The BB implantation surgery was carried out under general anaesthesia. Preoperatively, a high resolution CT scan of temporal bone was performed to determine the optimum location for BC-FMT and screws, by analysing the thickness and consistency of the temporal bone, the sigmoid sinus and the dura. The ideal implantation site is the sinodural angle which has the least interference with sigmoid sinus and dura. Alternatively, BC-FMT can be placed at retrosigmoid or above the temporal line in cases of underpneumatised mastoid or prior mastoidectomy.

Device Fitting

The first fitting of sound processor was attempted once the wound healed at about two to three weeks after implantation. The target gain was tested using bone conduction thresholds of the implanted ear.

Data Collection and Statistics

Subjects were monitored for any operative complications up to six months post implantation.

Subjects were evaluated preoperatively (unaided) and at six months postoperatively. Audiometric pure-tone thresholds for air conduction (with headphones) and bone conduction (with bone-conduction vibrator) were measured at 250kHz to 8kHz. Sound field tests were conducted via loudspeaker placed one meter in front of the subject at 250kHz to 8kHz, with the contralateral ear masked with earmuffs.

The statistics were analysed with Statistical Programme for Social Science (SPSS) statistical software version 22. Paired sample t tests were used to analyse the difference between (i) mean air audiometric threshold, (ii) mean bone audiometric threshold, (iii) mean sound field threshold; preoperative unaided and 6-month postoperative.

Subjects' satisfaction was assessed at six months post-operatively with Hearing Device Satisfaction Scale (HDSS) questionnaires. The score ranged from 0% (not satisfied) to 100% (very satisfied).

RESULTS

Twenty patients aged 7 to 67 were included in the study. There were 12 (60%) males and eight (40%) females. Thirteen (65%) of them had conductive hearing loss, three (15%) with mixed hearing loss and four (20%) with single-sided hearing loss. The aetiologies of hearing loss include canal atresia (60%), idiopathic (15%), post mastoidectomy (10%), post lateral temporal bone dissection (10%) and cerebellopontine angle tumour (5%).

The placement of BC-FMT was at sinodural angle in ten (50%) cases, retrosigmoid region in seven (35%) patients and presigmoid region in three (15%) patients.

There was no major complication reported. Two (10%) patients had mild surgical site infection and recovered within a week with local and oral antibiotics treatment.

Sound field testing showed significant changes preoperative and six month postoperative ($P<0.05$) for 500 to 4000Hz, with a functional gain ranged from 11 to 36dB, a mean score of 27dB (Figure 1, 2). Mean audiometric thresholds for BC and AC showed no significant changes preoperative and six month postoperative ($P>0.05$) for 500 to 4000 Hz (Figure 3A, 3B).

Subject device satisfaction ranged from 80 to 98%, with a mean score of 90.45% (Figure 4).

DISCUSSION

Bone Conduction Implant is a rehabilitative option for patients with conductive and mixed hearing loss due to chronic ear condition or with external or middle ear malformations which are not treatable by surgery or conventional air conductive hearing aids; and single-sided hearing loss patients.⁶ Percutaneous BCI, e.g. bone anchored hearing aid (BAHA) which gives a favourable audiological outcome has been the primary choice of rehabilitation for many years until the introduction of transcutaneous BCI. Percutaneous BCI surgery works based on osseointegration of titanium implant into the temporal bone, which shall complete at about three weeks post-surgery.⁷ However, this process may take a longer duration in children or patients with poor bone quality; and can even result in implant loss in the event of failure of osseointegration.^{8,9} In contrast, BB can be activated as soon as the surgical wound healed; therefore fitting of speech processor can be carried out at around two weeks post implantation.¹⁰

The usual complications post percutaneous BCI surgery were local inflammation and infection at the implant site and failure of osseointegration.¹¹ A local study by Asma et al reported a postoperative complication rate of 33.3% among 33 patients post BAHA implantation, of which 10 (30.3%) of them had different degree of skin reaction at implant site and one (3.0%) of them had failure of osteointegration.¹¹

Bonebridge is a relatively new transcutaneous BCI which has gained popularity with the favourable hearing outcome and yet without the skin care issues.⁶ Bonebridge does not require osseointegration as in percutaneous osseointegrated BCI, therefore there are fewer complications and early activation can be done.¹² BAHA Besides, this transcutaneous technology allows patients to participate in activities such as swimming without risk of skin infection.¹²

Our study showed that BB surgery is safe in terms of surgical techniques and surgical complications, with no intraoperative or postoperative major complication recorded. Both systematic reviews by Sprinzel GM and Zernotti reported no major complications for BB surgery.^{3,4} Zernotti

Table I: Demographic data and medical parameter

Subject Number	Age	Sex	Implanted ear	Type of hearing loss	Aetiology of hearing loss	PTA4 BC Pre-Implanted Ear (dB HL)	PTA4 AC Pre-Implanted Ear (dB HL)	PTA4 HL Post-Implanted Ear (dB HL)
1	22	M	L	MIXED	Cholesteatoma	55	115	30
2	11	F	L	CHL	B Canal Atresia	11	66	28
3	38	M	L	SSD	Idiopathic	70	120	11
4	22	M	L	CHL	B Canal Atresia	20	82	23
5	27	M	L	CHL	B Canal Atresia	10	65	27
6	19	M	L	CHL	B Canal Atresia	13	61	30
7	59	F	L	MIXED	Temporal Bone SCC	46	88	20
8	18	F	R	CHL	Cholesteatoma	18	58	31
9	17	F	R	CHL	R canal Atresia	15	67	30
10	42	F	L	SSD	L Acoustic Neuroma	72	110	25
11	22	M	L	CHL	B Canal Atresia	20	82	23
12	19	M	L	CHL	B Canal Atresia	8	75	23
13	15	M	L	CHL	L Canal Atresia	12	82	21
14	57	F	L	CHL	Cholesteatoma	25	108	30
15	51	M	R	SSD	Idiopathic	78	113	28
16	67	M	L	MIXED	Temporal Bone SCC	28	74	36
17	19	M	R	CHL	B canal Atresia	13	61	30
18	11	F	R	CHL	Right Canal Atresia	18	46	30
19	7	F	L	CHL	B Canal Atresia	19	86	36
20	31	M	L	SSD	Idiopathic	85	85	32

M= Male; F= Female; L= Left; Right; MIXED= Mixed hearing loss; CHL= Conductive hearing loss; SSD= Single-sided sensorineural deafness; SCC= Squamous cell carcinoma; PTA4= Average audiometric pure tone threshold for frequency at 0.5, 1, 2, 4kHz; BC= Bone conduction; AC= Air conduction; HL= Sound field hearing level

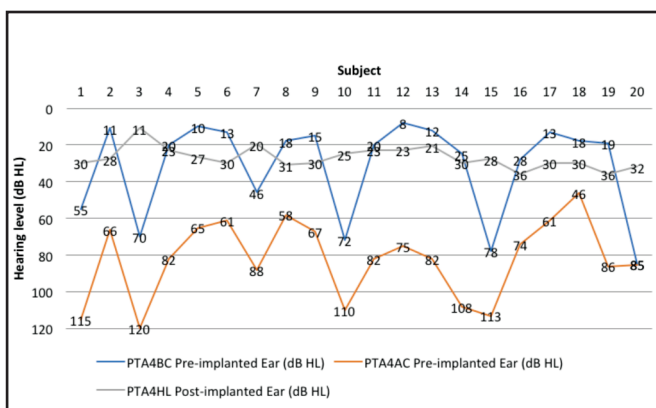


Fig. 1: Hearing Level (PTA4) Pre (AC & BC) & Post implanted Ear in 20 subjects.

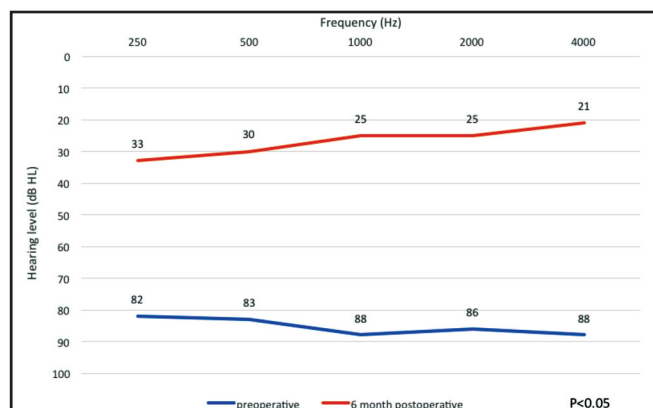


Fig. 2: Mean soundfield thresholds for the implanted ear: preoperative unaided compared with 6-month postoperative aided. P<0.05

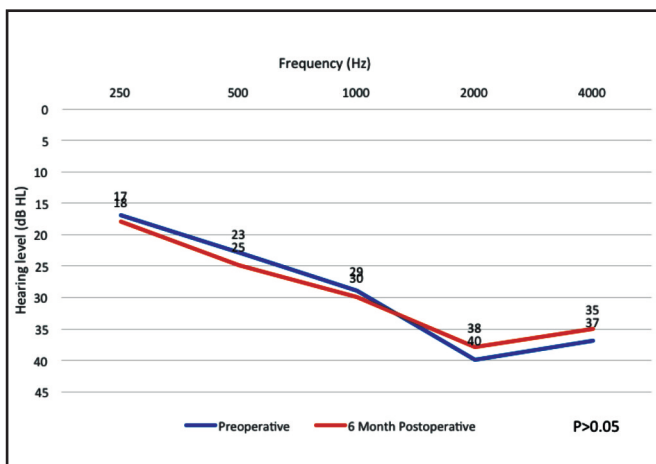


Fig. 3a: Mean bone conduction thresholds for the implanted ear: preoperative unaided compared with 6-month postoperative. P>0.05

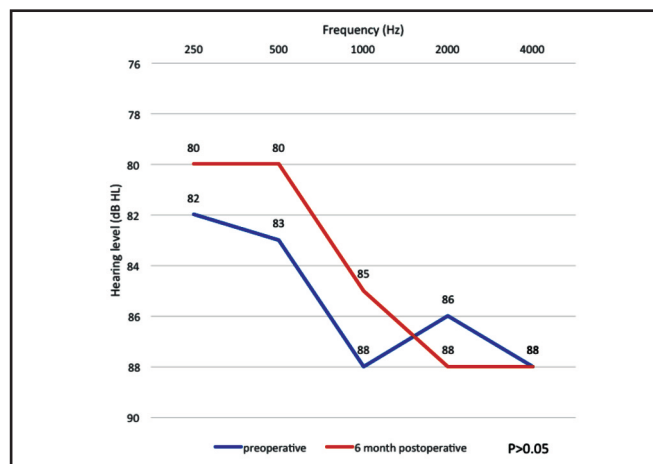


Fig. 3b: Mean air conduction thresholds for the implanted ear: preoperative unaided compared with 6-month postoperative. P>0.05

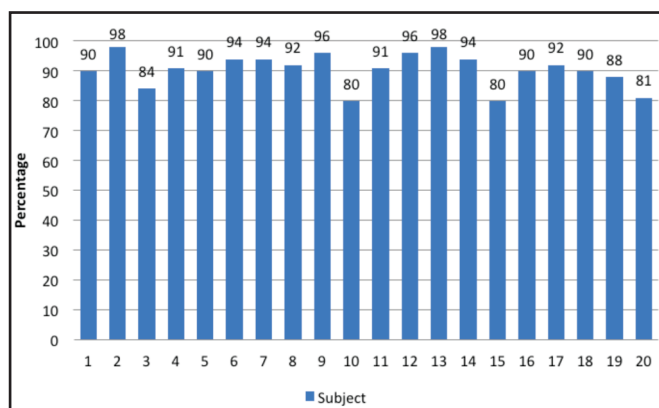


Fig. 4: Hearing Device Satisfaction Scale (HDSS) score of 20 subjects.

emphasized that most complications can be avoided with refined technique and good preoperative planning. Preoperative CT assessment of temporal bone is crucial to determine the radiological suitability and optimal site for BC-FMT.¹³

A prospective study by Schmerber et al involving 25 patients showed the safety of the Bonebridge at 1-year follow-up, with a very good cutaneous tolerance and preservation of residual hearing.¹⁴ From our study, the subjects' residual unaided hearing were not damaged by the BB implantation. The mean unaided AC and BC thresholds pre and six months post BB surgery differed by less than 5dB from 500 to 4000kHz, which was within the test-retest variability range.¹⁵ Baumgartner et al also reported preservation of patients' residual unaided hearing after the BB implantation.¹²

In terms of functional gain, our study showed a promising audiological benefit with the mean aided sound field thresholds improved more than 30dB from 500 to 4000kHz with the range from 11 to 36dB. For patients with conductive and mixed hearing loss, a systematic review by Sprinzl which included seven studies with 58 subjects reported a functional gain ranging from 24dB to 37dB.³ Schmerber et al reported an average functional gain of 26.1dB (at 500 Hz, 1, 2, 4 kHz) for 16 patients with mixed or conductive hearing loss. For single-sided deafness patients,¹⁴ Salcher et al concluded that an improvement in hearing in noise and quiet, and a decrease of head shadow effect can be expected with BB implantation.¹⁶

A recent study by Gerdes et.al. showed that the Bonebridge transcutaneous BCI is an audiological equivalent alternative to BAHA percutaneous BCI for conductive hearing loss patients with minor sensorineural hearing loss.¹⁷ There is a minor but insignificant difference of functional gain between Bonebridge (PTA =27.5 dB [mean]) and BAHA (PTA=26.3 dB [mean]); there is also no significant difference between Bonebridge and BAHA in terms of improvement in word recognition scores (WRS) and speech reception thresholds (SRT).¹⁷

All our patients were very satisfied with the implant with HDSS score at 6 months post operation ranged from 80% to

98% and a mean score of 90.45%. They were contented with the good audiological outcome and acceptable cosmetic appearance of the audio processor which has streamlined design and can be hidden under hair. The audio processor can be handled easily, even by children. Besides, the audio processor is replaceable which signifies that patients are always opened to latest technology. Sprinzl et al reported a high and stable long-term device satisfaction; with the HDSS score 79% at three months and 80% at 12-18 months of device use.¹⁸ A study by Siau et al to elucidate the reasons for patients' refusal to BAHA revealed that 30% of them rejected BAHA in view of cosmetic concern on hair loss, size of implant and abutment.¹⁹

CONCLUSIONS

In conclusion, BB implantation is safe and provides a valuable and stable functional gain in patients aged five and above with conductive or mixed hearing loss and single-sided hearing loss. This transcutaneous BCI system serves as an alternative to percutaneous BCI; with lower complication rate, faster device activation post operatively and better cosmetic appearance.

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