The Journal of Laryngology & Otology

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Bonebridge transcutaneous bone conduction implant in children with congenital aural atresia: surgical and audiological outcomes

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Abstract

Objectives. To investigate the surgical and audiological outcomes of the Bonebridge transcutaneous bone conduction hearing implant among children with congenital aural atresia.

Methods. Six children were recruited and underwent Bonebridge transcutaneous bone conduction implant surgery. The patients' audiometric thresholds for air conduction, bone conduction and sound-field tests were assessed pre-operatively and at six months post-operatively. Patients' satisfaction was assessed at six months post-operatively with the Hearing Device Satisfaction Scale.

Results. No major complications were reported. Mean aided sound-field thresholds improved post-operatively by more than 30 dB for 0.5–4 kHz ($p < 0.05$). Mean unaided air conduction and bone conduction thresholds differed by less than 5 dB post-operatively (compared to pre-operatively) for 0.5–4 kHz; these findings were not significant ($p > 0.05$). All patients were satisfied (scores were over 90 per cent) with the implant in terms of functional outcome and cosmetic appearance.

Conclusion. Bonebridge transcutaneous bone conduction implant surgery is safe and effective among children with congenital aural atresia with conductive hearing loss.

Introduction

Congenital aural atresia is characterised by hypoplasia or aplasia of the external auditory canal at birth. It may occur sporadically or as part of syndromes such as Goldenhar or Treacher Collins syndromes.[1] The incidence of congenital aural atresia is 1 in 10 000 live births.[2] The condition is often associated with microtia and middle-ear anomalies, and occasionally with inner-ear anomalies.[3] Twenty-five per cent of congenital aural atresia cases occur bilaterally.[2]

There are two main issues to be addressed in children with congenital aural atresia: the aesthetic issue and the functional problems. Affected patients will have conductive hearing loss due to the canal atresia, with or without middle-ear deformity. Bilateral cases need to be addressed more urgently than unilateral occurrences to restore normal hearing, in order to ensure proper speech and language development.

For cases younger than five years, bone conduction hearing aids should be fitted for hearing amplification before the child reaches a suitable age for various surgical treatments. In terms of audiological outcomes, Jovankovičová *et al.* reported that atresiaplasty or surgical reconstruction of an atretic ear showed an inconsistent functional outcome, regardless of the possible operative complications.[4] If one considers a 20–30 dB hearing threshold as a successful outcome, the reported success rates of atresiaplasty have varied from 12 per cent to 71 per cent in different studies.[4] Surgical success depends largely on the malformation severity.[5] Evans and Kazahaya reported that 93 per cent of patients still required a hearing aid or implant post-atresiaplasty.[6] Common complications encountered during canaloplasty include canal restenosis, skin graft lateralisation, and, less commonly, post-operative hearing deterioration and intra-operative facial nerve injury.[2,4]

Bone conduction hearing implants offer a better treatment option for conductive hearing loss patients with aural atresia, especially those with high grade aural atresia, with higher acoustic gain and less risk of surgical complications.[7] One study reported an average hearing threshold improvement of 37.45 dB in patients with a bone conduction implant, versus a gain of only 12.42 dB in post-atresiaplasty patients.[4]

The implantable hearing device options for aural atresia patients with conductive hearing loss include: a percutaneous osseointegrated bone-anchored hearing aid (BAHA), a middle-ear implant system (e.g. Vibrant® Soundbridge™) and a transcutaneous bone conduction implant (e.g. Bonebridge).[8]

A BAHA consists of a percutaneous vibration transducer, which is coupled to a titanium implant anchored in the skull bone to stimulate the inner ear transcranially. Despite promising functional gain, problems frequently arise from the junction of the skin and

Main Article

Dr I P Tang takes responsibility for the integrity of the content of the paper

Cite this article: Ngui LX, Tang IP. Bonebridge transcutaneous bone conduction implant in children with congenital aural atresia: surgical and audiological outcomes. *J Laryngol Otol* 2018;**132**:693–697. https://doi.org/10.1017/S0022215118001123

Accepted: 6 March 2018
First published online: 16 July 2018

Key words:
Bone Conduction; Hearing Aids; Correction Of Hearing Impairment; Treatment Outcome

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titanium. A meta-analysis by Kiringoda and Lustig reported an incidence of skin reactions in adult or mixed populations of 16–38 per cent, with an incidence as high as 78 per cent in children.[9] The incidence of implant infections ranged from 1 per cent to 50 per cent, and implant loss rates ranged from 2 per cent to 17 per cent.[9] Furthermore, osseointegration issues or head trauma resulted in higher fixture loss rates in children, with revision surgery rates of 17–44 per cent.[10] A retrospective study by Kraai *et al.*, which involved 27 children with percutaneous osseointegrated bone conduction implants, reported that 89 per cent of the children experienced some form of complication post-implantation, and nearly half underwent revision surgery.[11] Siau *et al.* reported that 30 per cent of patients who were eligible for a BAHA rejected BAHA implantation because of cosmetic concerns, including the size of the abutment and subsequent hair loss.[12]

The percutaneous complications of BAHA can be avoided with an active middle-ear implant and transcutaneous bone conduction implant. A middle-ear implant consists of a floating mass transducer, which is connected mostly to the stapes, and infrequently to the incus, round window or oval window, to stimulate the cochlea directly.[13] The advantages of a middle-ear implant over a transcutaneous bone conduction implant include stimulation solely of one cochlea and greater power in the higher frequencies.[14] However, middle-ear implant surgery involves manipulation of the ossicles, with possible risks of surgical trauma and permanent sensorineural hearing loss.[8] Other potential complications include post-operative implant displacement due to scar tissue development and taste disturbance as a result of chorda tympani nerve damage.[8] Transcutaneous bone conduction implant surgery is easier than middle-ear implant implantation.[14] Furthermore, the Bonebridge transcutaneous bone conduction implant is magnetic resonance imaging (MRI) compatible up to 1.5 T, whereas the middle-ear implant is not MRI compatible.[14]

The Bonebridge (Med-El, Innsbruck, Austria) was launched onto the European Union market in September 2012 and was subsequently approved by the Communauté Européenne for implantation in children aged five years and above.[15] In Malaysia, the first Bonebridge implantation was performed in 2012. The Bonebridge is an active transcutaneous bone conduction implant system that transmits sound waves through cranial bone directly to the inner ear.[16] It consists of an external part (audio processor) and internal implanted parts (bone conduction implant). The audio processor contains a microphone and a digital signal processor, powered by a standard hearing aid battery. The internal part consists of a demodulator that processes the signal, a receiver coil and an active electromagnetic bone conduction floating mass transducer that transforms the electrical signal into mechanical vibrations.

Bonebridge implantation is indicated in adults and children aged five years and above with conductive or mixed hearing loss, who can still benefit from sound amplification. The pure tone average bone conduction threshold (measured at 0.5, 1, 2, 3 and 4 kHz) should be 45 dB HL or less. Bonebridge implantation is also indicated in those with single-sided sensorineural deafness. The pure tone average air conduction threshold in the contralateral ear (measured at 0.5, 1, 2, 3 and 4 kHz) should be 20 dB HL or less.[15]

The absence of retrocochlear or central auditory disorders, and presence of suitable anatomy for bone conduction implant placement, must be confirmed via computed tomography (CT) prior to transcutaneous bone conduction implant surgery.

Bonebridge implantation has proved increasingly popular. Only a few studies have investigated this transcutaneous bone conduction implant in children. This study aimed to investigate the surgical and audiological outcomes of Bonebridge transcutaneous bone conduction implantation among children with congenital aural atresia.

Materials and methods

Study design

This study was conducted in a tertiary referral centre from January 2013 to December 2016, using a prospective, intra-subject repeated measures design in which each subject was his or her own control.

Patients

Six patients aged 11–18 years were enrolled into this study within the study period. Patient demographics and medical parameters are shown in Table 1.

The patients were selected according to the following criteria: children aged 5–18 years; presence of congenital canal atresia; fulfilled criteria for transcutaneous bone conduction implant surgery, as described above (bone conduction threshold below 45 dB HL at frequencies between 0.5 kHz and 4 kHz); and benefit from a bone conduction hearing aid trial.

Surgical technique

The surgical technique has been extensively described elsewhere.[16] The transcutaneous bone conduction implant surgery was carried out under general anaesthesia. A pre-operative CT scan was performed to analyse the thickness and consistency of the temporal bone, sigmoid sinus and dura, so as to determine the optimum location for the bone conduction floating mass transducer and screws. The bone conduction floating mass transducer is normally placed at a sinodural angle, which has the least interference with the sigmoid sinus and dura. In cases of an under-pneumatised mastoid or prior mastoidectomy, the bone conduction floating mass transducer can be placed in the retrosigmoid region or above the temporal line, in view of limited space at the sinodural angle.

Device fitting

The first fitting of the audio processor was initiated as soon as the wound had completely healed, at about three to five weeks after implantation. The audio processor was programmed with Connexx 6.5 fitting software (Siemens Hearing Instruments, Piscataway, New Jersey, USA) in conjunction with Symfit 6.1 software (Med-El), using a programming cable connected to a Hi-Pro Box hearing aid programmer (GN Otometrics, Taastrup, Denmark). The target gain was evaluated using the bone conduction thresholds of the implanted ear.

Data collection and statistics

Patients were monitored for any surgery-related complications for up to six months post-implantation.

Patients were tested pre-operatively (unaided) and at six months post-operatively (aided). Audiometric pure tone thresholds for air conduction (through headphones) and bone

https://doi.org/10.1017/S0022215118001123 Published online by Cambridge University Press

Table 1. Demographic data and medical parameters

Pt no.	Age at implantation (years)	Sex	Implanted ear	Type of hearing loss	Aetiology of hearing loss	PTA4 BC in pre-implanted ear (dB HL)	PTA4 AC in pre-implanted ear (dB HL)	PTA4 HL in post-implanted ear (dB HL)
1	11	F	L	CHL	Bilateral canal atresia	11	66	28
2	18	M	L	CHL	Bilateral canal atresia	20	82	23
3	18	M	L	CHL	Bilateral canal atresia	13	61	30
4	17	F	R	CHL	R canal atresia	15	67	30
5	16	M	L	CHL	Bilateral canal atresia	8	75	23
6	15	M	L	CHL	L canal atresia	12	82	21

Pt no. = patient number; PTA4 = mean audiometric pure tone thresholds for frequencies 0.5, 1, 2 and 4 kHz; BC = bone conduction; AC = air conduction; HL = sound-field hearing level; F = female; L = left; CHL = conductive hearing loss; M = male; R = right

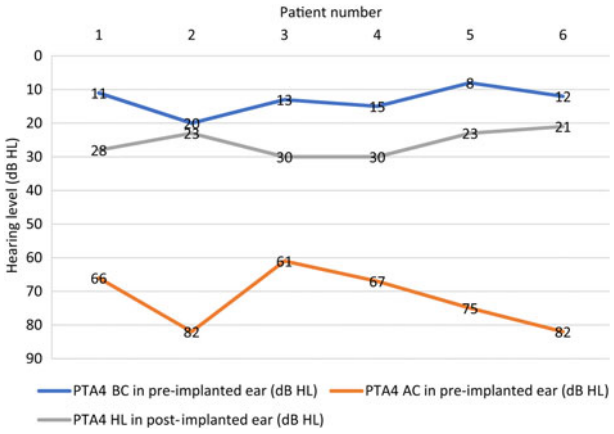

Fig. 1. Hearing level (audiometric pure tone thresholds for frequencies 0.5, 1, 2 and 4 kHz (PTA4)) pre-operatively (air conduction (AC) and bone conduction (BC)) and post-operatively (sound-field hearing level (HL)) for the implanted ear in the six patients.

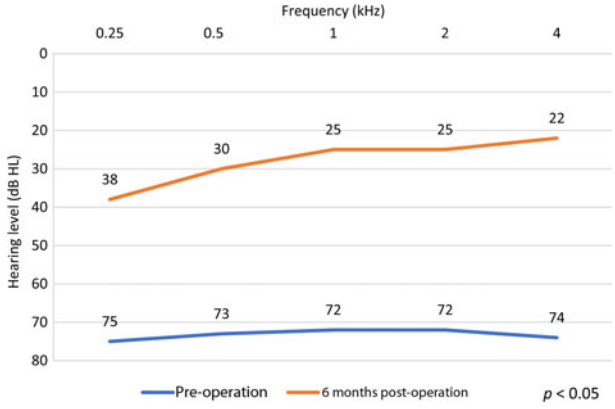

Fig. 2. Mean sound-field thresholds for the implanted ear, pre-operation (unaided) and six months post-operation (aided).

conduction (through a bone conduction vibrator) were evaluated at 0.25–8 kHz. Sound-field tests were conducted through a loudspeaker placed 1 metre in front of the patient at 0.25–8 kHz, with the contralateral ear covered with earmuffs.

The data were analysed with SPSS® statistics software version 22. Paired sample *t*-tests were utilised to evaluate pre-operative and six-month post-operative differences in terms of mean air and bone audiometric thresholds and mean sound-field thresholds.

Patients' satisfaction was evaluated six months post-operatively with the Hearing Device Satisfaction Scale. The answers were transformed into percentage scores, which ranged from 0 per cent (not satisfied) to 100 per cent (very satisfied).

Results

Six children (four males and two females) with conductive hearing loss due to canal atresia, aged 11–18 years, were included in the study. Four of the patents (66.7 per cent) had bilateral canal atresia.

The bone conduction floating mass transducer was placed at the sinodural angle in five cases (86.7 per cent) and at the retrosigmoid region in one case (13.3 per cent).

No major complications were reported. One patient (13.3 per cent) had mild infection at the surgical site; this was treated with local and oral antibiotics, and the patient recovered within one week.

Sound-field testing showed significant changes at six months post-operatively (compared to pre-operatively; $p < 0.05$) for 0.5–4 kHz, with a functional gain ranging from 31 dB to 61 dB, and a mean hearing threshold of 46.3 dB (Figures 1 and 2). Mean audiometric thresholds for bone conduction (Figure 3) and air conduction (Figure 4) showed no significant changes at six months post-operatively (compared to pre-operatively; $p > 0.05$) for 0.5–4 kHz (Figures 3 and 4).

Patient device satisfaction ranged from 91 per cent to 98 per cent (Figure 5).

Discussion

Transcutaneous bone conduction implant surgery is indicated in children with conductive or mixed hearing loss due to pinna abnormalities and canal atresia, either bilateral or unilateral. Compared to a percutaneous bone conduction implant, a transcutaneous bone conduction implant leaves the skin intact and does not require long-term skin care. Children are able to participate in activities such as swimming without the risk of skin infection at the implant site. Furthermore, the audio processor can be easily worn and handled by children, reducing the parental burden. The audio processor has a streamlined

https://doi.org/10.1017/S0022215118001123 Published online by Cambridge University Press

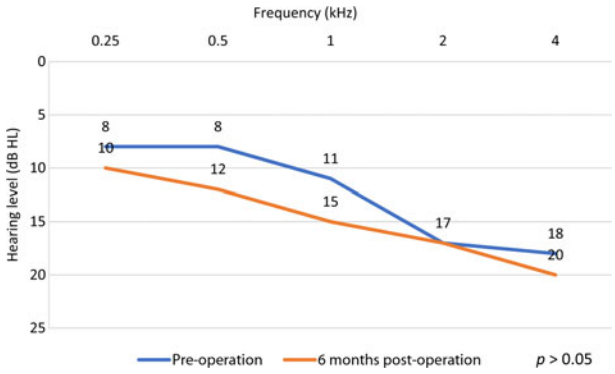

Fig. 3. Mean bone conduction thresholds for the implanted ear, pre-operation (unaided) and six months post-operation (aided).

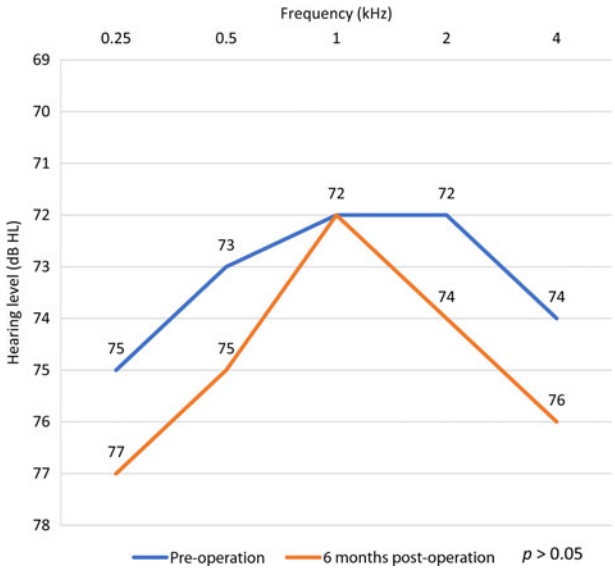

Fig. 4. Mean air conduction thresholds for the implanted ear, pre-operation (unaided) and six months post-operation (aided).

design and can be hidden under the hair, with no cosmetic concerns. Moreover, children with a transcutaneous bone conduction implant can keep up to date with the latest technology as the audio processor is replaceable.

Safe surgery

Our study showed that Bonebridge transcutaneous bone conduction implantation has an acceptable level of safety in terms of the surgical techniques and complications, with little risk of major intra-operative or post-operative complications. In a systematic review by Sprinzl and Wolf-Magele, which included 12 studies with a total of 117 patients, no major complications were reported.[15] The rate of minor adverse events after transcutaneous bone conduction implant surgery was 5.12 per cent and the rate of revision surgery was 0.85 per cent.[15]

Another systematic review, by Zernotti and Sarasty, also found no reports of severe complications in transcutaneous bone conduction implant cases, and most of the complications reported could be prevented with refined technique and good pre-operative planning.[17] The flap necrosis or infection risk was similar to that in other implantation surgery (e.g. cochlear implant surgery), and could be minimised by performing the

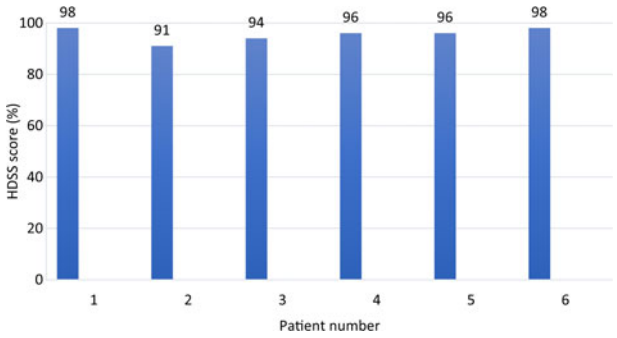

Fig. 5. Hearing Device Satisfaction Scale (HDSS) scores for the six patients (0 per cent = not satisfied; 100 per cent = very satisfied).

double flap with good vascularisation and minimal incisions.[17] Risk of injury to the meninges or sigmoid sinus was generally avoidable with meticulous surgery.[17]

Lassaletta *et al.* investigated post-operative pain in patients who underwent transcutaneous bone conduction implant surgery; they reported that implantation did not cause any significant post-operative pain, irrespective of sinus or dura compression.[18]

Audiological outcome

This study showed promising functional gain: the mean aided sound-field thresholds improved by more than 30 dB for 0.5–4 kHz, which is comparable with other studies. A systematic review of 7 studies with 58 subjects reported a functional gain ranging from 24 dB to 37 dB.[15] Another systematic review of 5 studies with 20 patients reported a functional gain of 24 dB to 43 dB.[17] Baumgartner *et al.* reported a significant improvement in aided thresholds post-operatively, with improvement in speech perception, as measured by word recognition scores and speech reception thresholds for 50 per cent word intelligibility in sentences, of approximately 67.6 per cent and 27.5 per cent respectively.[10] Rahne *et al.* stated that transcutaneous bone conduction implant surgery also resulted in a significant improvement in speech recognition in noisy environments and sound localisation.[19]

Hearing preservation

Our study showed that mean unaided air conduction and bone conduction thresholds pre-operatively and six months post-operatively differed by less than 5 dB for 0.5–4 kHz, which was within the test–retest variability range.[20] These non-significant changes post-implantation confirm that patients' residual unaided hearing was not damaged by the treatment. The aforementioned study by Baumgartner *et al.*, which investigated the short-term safety of transcutaneous bone conduction implantation in children, also reported that patients' residual unaided hearing did not deteriorate with the treatment.[10]

Patient satisfaction

All six patients in our study were very satisfied with the implant. The Hearing Device Satisfaction Scale scores ranged from 91 per cent to 98 per cent, with a mean score of 95.5 per cent. In interviews, patients revealed that they were satisfied with the aided hearing threshold improvements and considered the cosmetic appearance of the audio processor

https://doi.org/10.1017/S0022215118001123 Published online by Cambridge University Press

acceptable. The study by Baumgartner *et al*, which comprised 12 children, reported a mean Hearing Device Satisfaction Scale score of 88 per cent.[10]

- The Bonebridge transcutaneous bone conduction implant provides an alternative audiological rehabilitative option for children with conductive hearing loss due to congenital aural atresia
- This transcutaneous bone conduction implant surgery is safe and effective
- Proper pre-operative planning and good techniques are crucial for successful surgical and audiological outcomes

Conclusion

In conclusion, the Bonebridge transcutaneous bone conduction implant is safe and effective in children with conductive hearing loss due to congenital aural atresia. Proper pre-operative planning and good techniques ensure a safe procedure without major complications and a significant audiological benefit post-operatively.

Competing interests. None declared

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