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 250 Hz 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-EI) 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 abutm ent, 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 with¹:
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.