The Journal of Laryngology & Otology (2013), ***127***, *1214–1221.*

doi:10.1017/S0022215113002144

SHORT COMMUNICATION

The Bonebridge semi-implantable bone conduction hearing device: experience in an Asian patient

W S S TSANG[1], J K Y YU[1], K S S BHATIA[2], T K C WONG[1], M C F TONG[1]

[1]*Department of Otorhinolaryngology, Head and Neck Surgery, and The Institute of Human Communicative Research, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong SAR, China*
[2]*Department of Diagnostic imaging and Interventional Radiology, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong SAR, China*

Abstract

For over three decades, bone conduction hearing aids have been changing the lives of patients with impaired hearing. The size, appearance and fitting discomfort of early generations of bone conduction hearing aids made them unpopular. The advent of bone-anchored hearing aids in the 1970s offered patients improved sound quality and fitting comfort, due to the application of osseointegration. However, the issue of post-operative peri-abutment pin tract wound infection persisted. The Bonebridge system incorporates the first active bone conduction device, and aims to resolve peri-abutment issues. Implantation of this system in an Asian patient is presented.

Key words: Hearing Aids; Hearing Loss; Osseointegration; Bonebridge

Introduction

The role of bone conduction devices in treating hearing loss has been well established since the late twentieth century. The development of bone-anchored hearing aid (BAHA) systems, which incorporated the concept of osseointegration discovered by Brånemark, enabled improved comfort and fine sound quality, and represented a major milestone in the evolution of bone conduction hearing assistance.[1] Rapid refinements of the BAHA system have continued to bring patients significant improvements. However, despite years of technological advancement the problem of post-operative peri-abutment wound infection has persisted.

Although the prevalence of post-operative peri-abutment wound infection has remained at approximately 5 per cent, this complication has a significant negative impact on the clinical application and popularity of the BAHA system.[2] It may be the case that, faced with the proposition of a life-long commitment to post-operative wound care, many otherwise suitable patients will opt instead for an air conduction hearing aid, despite its functional inferiority to a BAHA.

In response to the problem of peri-abutment wound infection, a semi-implantable bone conduction device, the Bonebridge system, has been developed (Med-El, Innsbruck, Austria).

The Bonebridge system has two components: an external audio processor (Figure 1) and a bone conduction implant (Figure 2). The latter element consists of a receiver coil, a demodulator and a transducer. The signal from the audio processor is sent transcutaneously to the bone conduction implant, so that the transducer (more fully termed a bone conduction floating mass transducer) vibrates in a manner that is tailored to the patient's hearing requirements.

The external audio processor is attached to the skin by magnetism. It contains microphones, a digital signal processor and a battery. Its audio output signal is transmitted transcutaneously via electromagnetic signals (instead of via a mechanical conduction system), obviating the need for an open pin tract site at the skin, as required in the BAHA system. Patients therefore do not need to perform daily peri-abutment wound care. In this way, the Bonebridge system aims to resolve the issue of post-operative peri-abutment pin tract wound infection.

The therapeutic range of the Bonebridge system is similar to that of the Cochlear Baha Compact and Baha BP100 implants (Cochlear, Sydney, Australia). It is suitable for patients with conductive or mixed hearing loss, as indicated by bone conduction thresholds of 45 dB HL or better at 0.5, 1, 2 and 3 kHz, on audiometric testing (see Figure 3). The Bonebridge system can also provide sound re-routing for unilateral sensorineural deafness, provided the remaining, functioning ear is capable of detecting air-conducted sound at or below 20 dB HL at 0.5, 1, 2 and 3 kHz, on audiometric testing. The manufacturers recommend the following criteria for implant candidacy: patients should be 18 years of age or older, with anatomy that allows for appropriate placement of the Bonebridge system as determined by computed tomography (CT) scanning, and without retro-cochlear or central auditory disorders.[3] Thus, the Bonebridge system appears to be suitable for patients with many types of hearing loss, provided their residual hearing is within the appropriate therapeutic range.

In this report, we present the first Bonebridge implantation case performed in Asia. The patient was a 58-year-old woman with bilateral substantial conductive hearing loss.

Accepted for publication 12 February 2013 First published online 29 October 2013

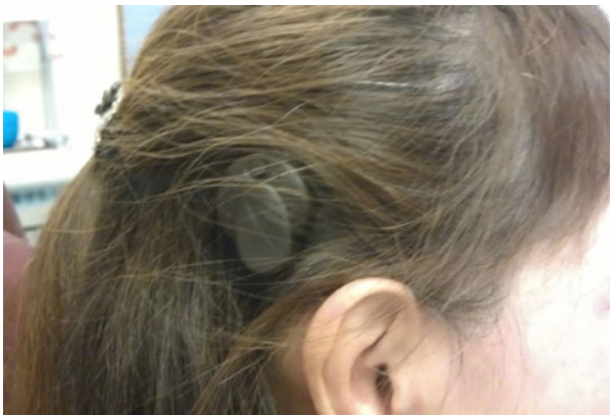

FIG. 1
Photograph showing the external audio processor of the Bonebridge system.

She was a singer and dancer and performed regularly in nightclubs. She had undergone a left mastoidectomy for cholesteatoma more than 10 years previously, while her right ear had been fitted with a traditional air conduction hearing aid following an unsuccessful tympanoplasty. She opted for a Bonebridge system implantation on her right side, as her current hearing aid produced much discomfort and gave poor quality sound amplification, especially in noisy environments. In addition, the occlusion effect of the ear mould produced considerable discomfort and recurrent episodes of otitis externa. In addition, stigmatisation by her peers, as the wearer of a visible hearing aid, caused her to wear the device less than recommended: her daily usage was never more than 6 hours.

Technique

Ethical approval

Ethical approval was obtained from the Joint Chinese University of Hong Kong New Territories East Cluster Clinical Research Ethics Committee, Hong Kong, China.

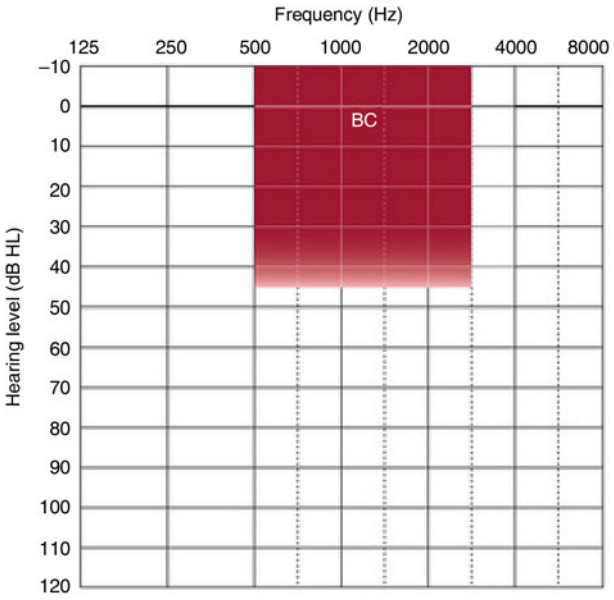

FIG. 3
Audiological selection criteria for the Bonebridge system (area marked in red), for patients with conductive or mixed hearing loss. BC = bone conduction

Pre-operative patient preparation

Computed tomography. The patient was sent for temporal bone CT scanning; CT navigation planning was undertaken during the same session. The best placement site for the bone conduction implant was marked on the CT images (Figure 4).

Audiology. Before surgery, the patient underwent a series of audiological assessments, including the following: (1) pure tone audiometry (both air and bone conduction); (2) functional gain measurement in the sound field, using her usual right-sided hearing aid; (3) speech recognition testing in both quiet and noisy environments, using the Cantonese Hearing in Noise Test with and without the existing hearing aid.

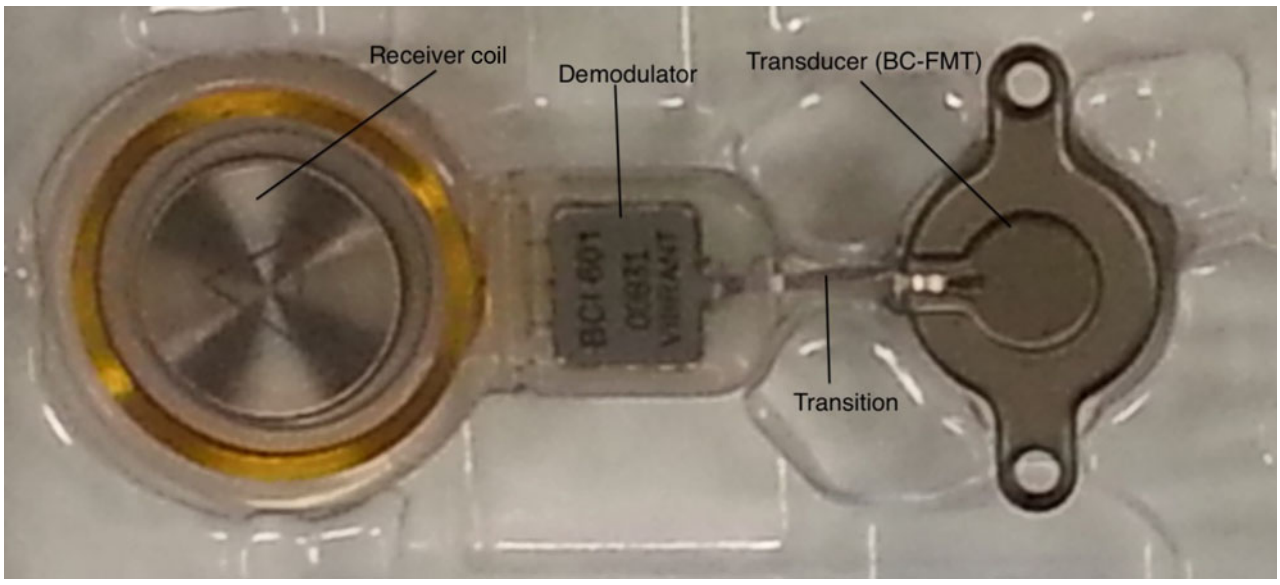

FIG. 2
Photograph showing the components of the bone conduction implant. BC-FMT = bone conduction floating mass transducer

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

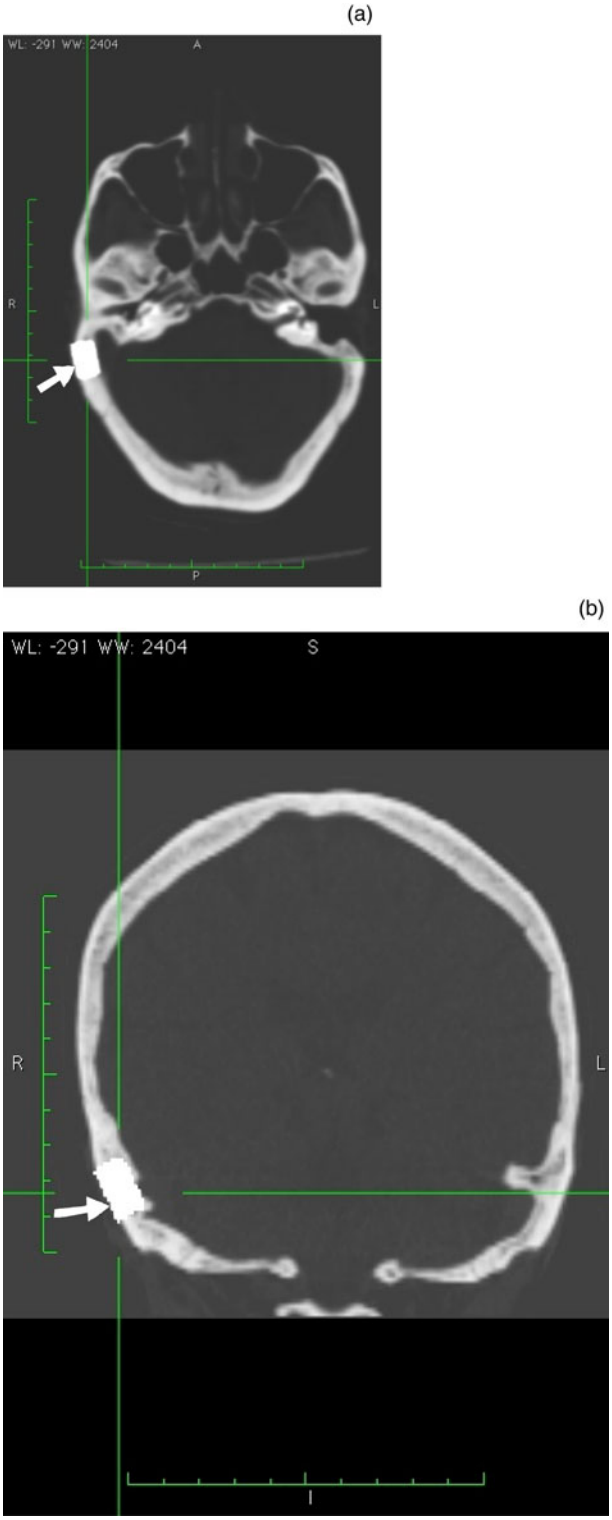

FIG. 4
(a) Axial and (b) coronal computed tomography images showing the position of implant placement (arrow). A = anterior; R = right; L = left; P = posterior; S = superior; I = inferior

Surgical preparation

Sizers (dummies) provided by the manufacturer assisted with correct placement of the bone conduction implant. These comprised a designated coil sizer (C-sizer) and a transducer sizer (T-sizer) (Figure 5).

The polypropylene C-sizer helped determine the optimal bone conduction implant site on the head, prior to skin incision. The T-sizer was a template comprising a polypropylene body and two titanium drill guides. The functions of the T-sizer were: (1) to outline the exact size of the bone conduction implant seat before drilling; (2) to verify the size of the seat before implant placement; and (3) to act as a drilling guide to ensure the correct orientation and distance between the two anchor holes, and the correct depth of the anchoring holes.

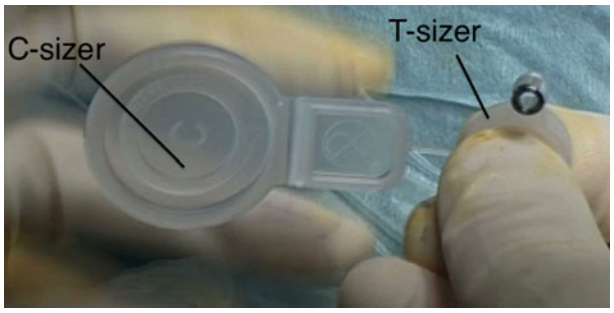

FIG. 5
Photograph showing connection of the C-sizer to the T-sizer.

The C- and the T-sizer could be connected together to represent the complete bone conduction implant and to assist identification of the best placement site.

Surgery

The surgery was performed at the otorhinolaryngology department, New Territories East Cluster hospital, Hong Kong, under general anaesthesia. A Brainlab navigation system (Brainlab, Feldkirchen, Germany) was employed intra-operatively to enable real-time anatomical monitoring and to facilitate location of a suitable implant site. Aided by the navigation system, and using the C- and T-sizers, an appropriate placement site was identified on the patient's head and marked with a surgical pen (Figure 6).

Surgery was commenced by making an incision along the post-auricular skin crease. Haemostasis was achieved with diathermy. Soft tissue dissection was carried out to create a surgical field with complete exposure of the whole mastoid, posterior bony canal wall and temporal line.

Before bone drilling, the C- and T-sizers were used to confirm the best placement site. The surgical navigation system was used to re-confirm the best drilling site

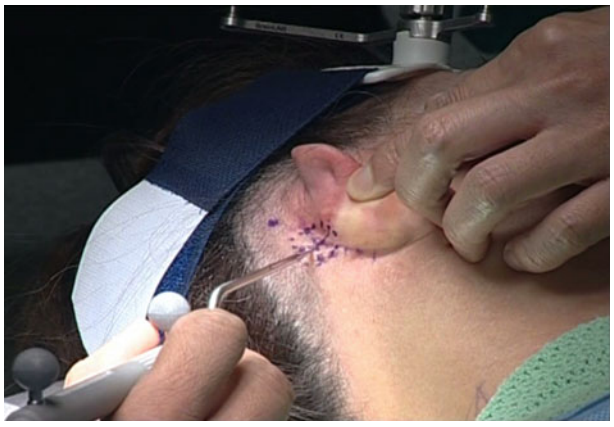

FIG. 6
Surgical photograph showing marking of the implant placement site, with assistance from the surgical navigation system.

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

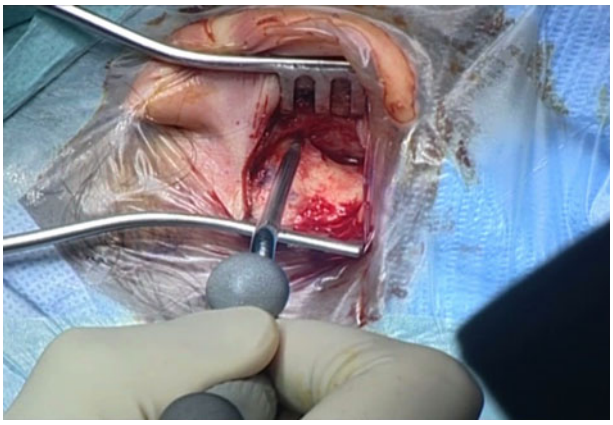

FIG. 7

Surgical photograph showing confirmation of the implant placement site, using the surgical navigation system, following the initial post-aural incision.

(Figure 7). A bone recess was created near the sinodural angle of the mastoid (Figure 8). Special care was taken when drilling in proximity to vital structures such as the sigmoid sinus, the tegmen and the dura; a diamond burr was used when approaching these structures. As the bone conduction floating mass transducer was 8.7 mm thick and 15.8 mm in diameter, a bone recess of slightly larger dimensions was created, in which the T-sizer was positioned with its 'arms' resting on the skull (Figure 9). Oversize drilling would have affected the placement of the anchoring screws, hence the anchoring of the bone conduction floating mass transducer. The drilling position was checked regularly using the surgical navigation system, in order to minimise the risk of damage to nearby vital structures.

Using the T-sizer as a drilling guide, fixing points were created with a specially designed drill with a depth stop that ensured a hole depth of no more than 3.9 mm. We then prepared a sub-periosteal pocket to accommodate the coil and demodulator of the bone conduction implant. No drilling of the bone bed was needed for implantation of the demodulator.

The bone conduction implant was oriented with the magnet protruding towards the skull, and was bent to fit its required final position (the angle of the bone conduction implant could be altered ±90° in the horizontal plane and

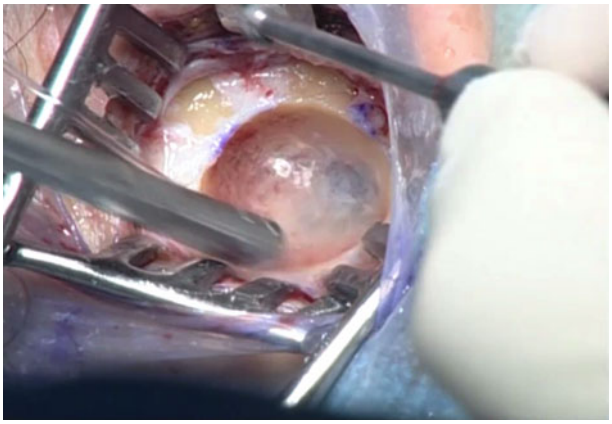

FIG. 8

Surgical photograph showing the creation of a bone recess to house the bone conduction implant floating mass transducer. Note the position of the sigmoid sinus, appearing as a blue shadow.

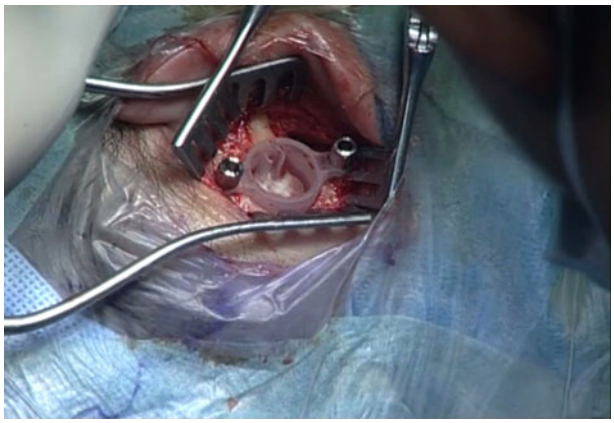

FIG. 9

Surgical photograph showing placement of the T-sizer within the bone recess, in order to establish the site of the fixing holes.

−30° in the vertical plane). The implant coil and demodulator were placed under the periosteum, so that they would lie beneath the desired external location of the audio processor (Figure 10). The bone conduction floating mass transducer was then placed into the prepared bone recess and secured with cortical screws in each anchor hole (Figures 11 and 12). A torque wrench was used in the final stage of screw fixing to help prevent over-tightening.

Before closure, we ensured that the total skin flap thickness was no more than 7 mm, using the skin flap gauge provided. No trimming of the skin flap was required, but would have been performed if necessary. The skin wound was closed in double layers and a head pressure dressing was applied for 24 hours.

No intra- or post-operative surgical complications were encountered. The patient complained of mild wound pain and dizziness in the early post-operative period. All these symptoms were resolved with medical treatment. She was discharged home with antibiotics and analgesics, and reviewed one week after the surgery, by which time the post-auricular wound had completely healed.

The device was activated two weeks after surgery. The Amade audio processor (Med-El) was programmed using Connexx 6.4.5 software (Siemens Audiological Engineering, Munich, Germany) equipped with a Symfit database (Rev.

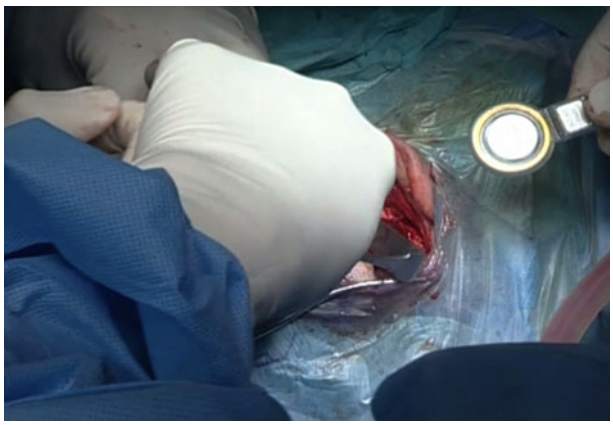

FIG. 10

Surgical photograph showing insertion of the bone conduction implant into the subperiosteal pocket.

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

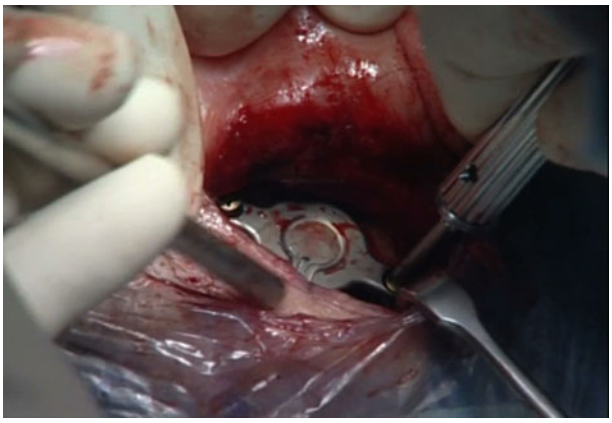

FIG. 11
Surgical photograph showing fixation of the bone conduction implant using cortical screws.

6.1; Med-El). The default desired sensation level amplification strategy was applied during the first fit.

The patient returned for review and fine tuning one month later, to ensure that her hearing was at the most comfortable (self-evaluated) level.

Results

Pre- and post-operative hearing thresholds

Any change in residual hearing was evaluated by comparing the pre-operative, unaided air and bone conduction thresholds with the post-operative, unaided air and bone conduction thresholds, using audiometric testing at frequencies from 250 Hz to 8 kHz. The results revealed no obvious change at any frequency. Figure 13 shows the pre- and post-operative air and bone conduction thresholds.

Functional gain improvement

Aided hearing benefit was evaluated by comparing the unaided and aided thresholds using warble tones in the sound field at frequencies from 500 Hz to 4 kHz, one month after surgery. The non-implanted ear was plugged and muffled during testing. An obvious improvement was noted at all the testing frequencies from 500 Hz to 4 kHz. Functional gain (i.e. the difference between the unaided and aided thresholds) varied from a minimum of 10 dB to a maximum of 40 dB (Figure 14). The aided improvements were also compared with the improvement obtained from the patient's previous hearing aid; results showed that the Bonebridge system out-performed the pre-operative hearing aid by at least approximately 5 dB at the majority of the test frequencies (Figure 14).

Speech recognition threshold improvement

Improvement in aided speech comprehension was evaluated using the Cantonese Hearing in Noise Test in both quiet and noisy situations.

Figure 15 shows the patient's speech recognition threshold results in a quiet environment with speech presented from the front, from the implant side (right ear) and from the non-implant side (left ear), with and without

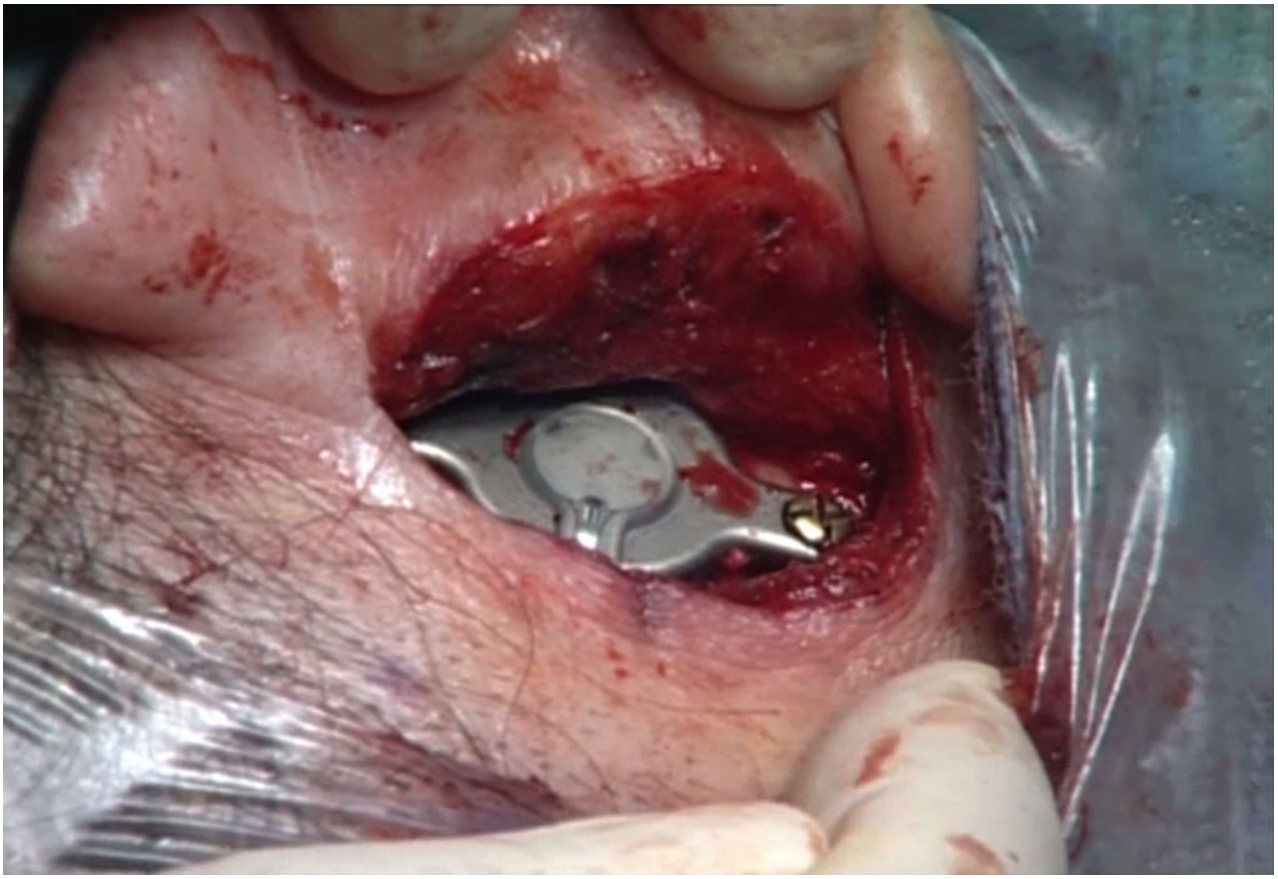

FIG. 12
Surgical photograph showing the final position of the bone conduction implant.

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

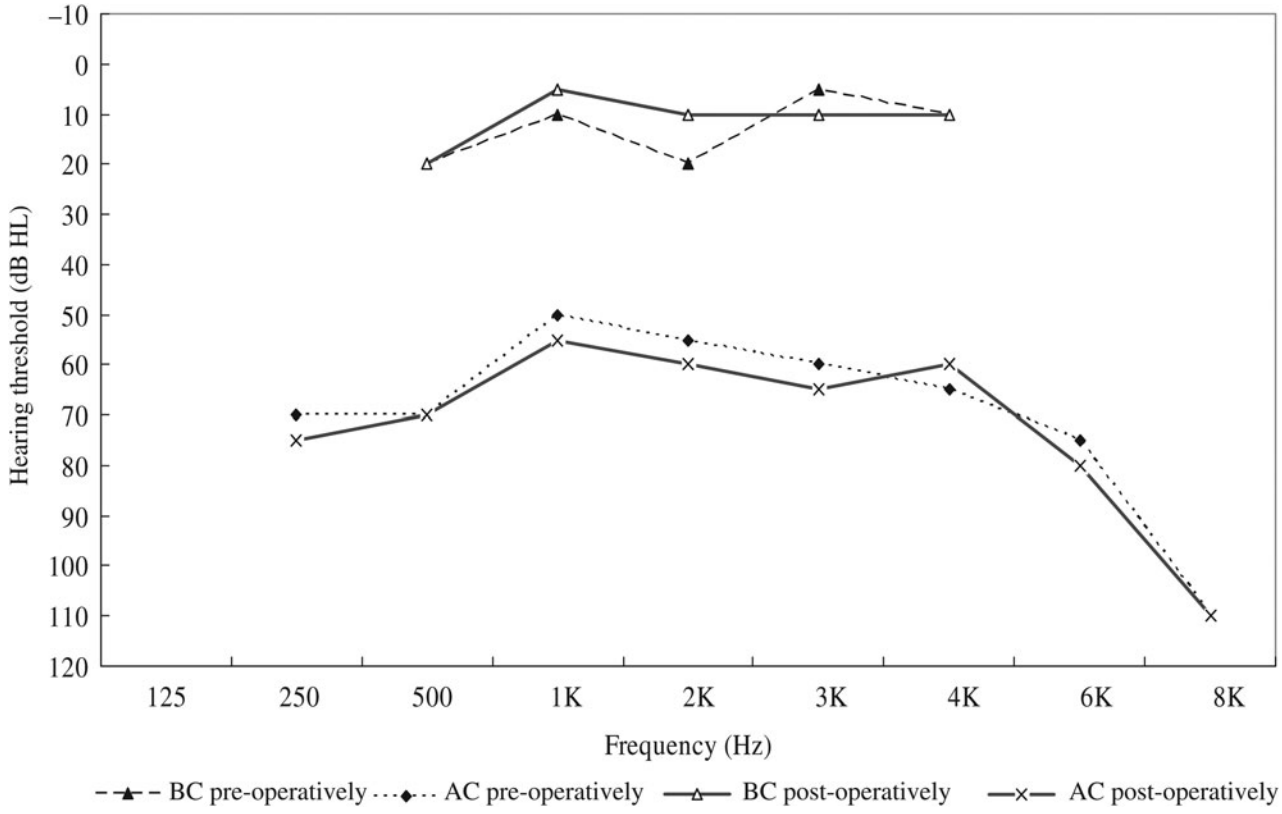

FIG. 13

The patient's pre- and post-operative air conduction (AC) and bone conduction (BC) thresholds. K = 1000.

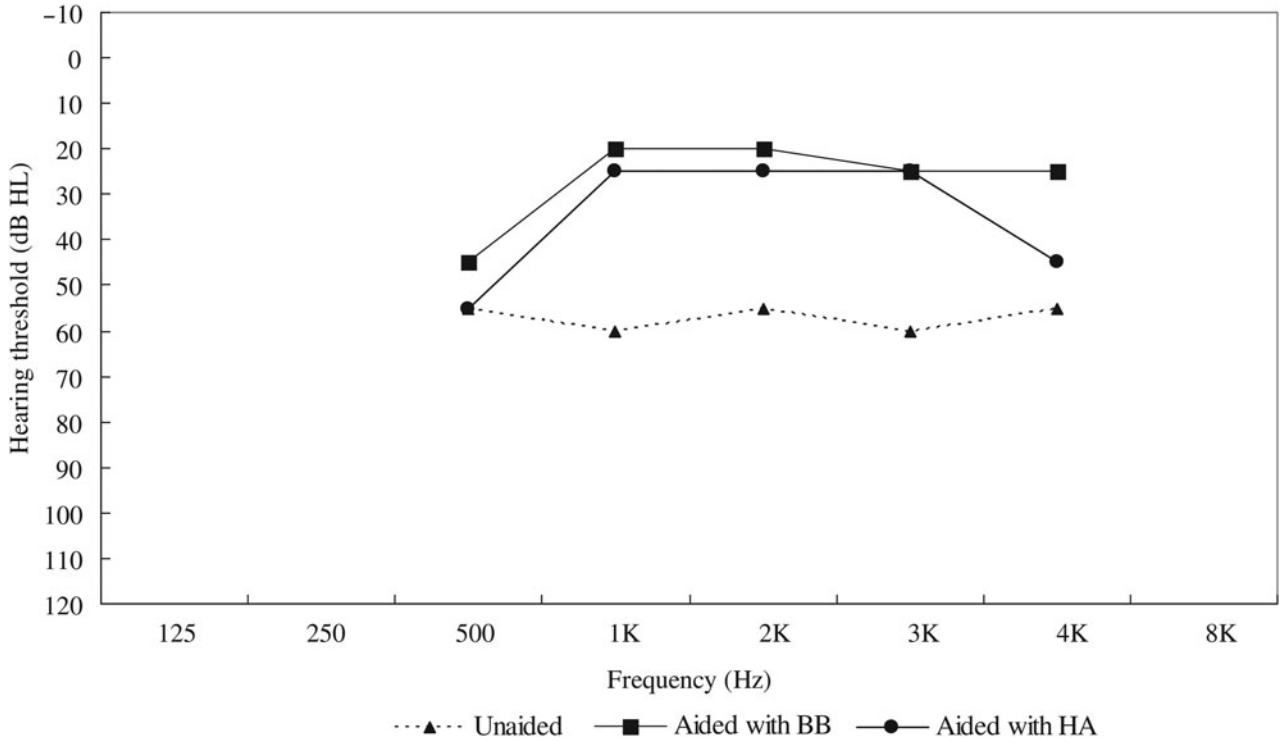

FIG. 14

Graph showing sound field thresholds from 500 Hz to 4 kHz, for the right ear, under the following conditions: unaided (pre-operative); aided with a convention hearing aid (HA) (pre-operative); and aided with the Bonebridge system (BB) (one-month post-operative).

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

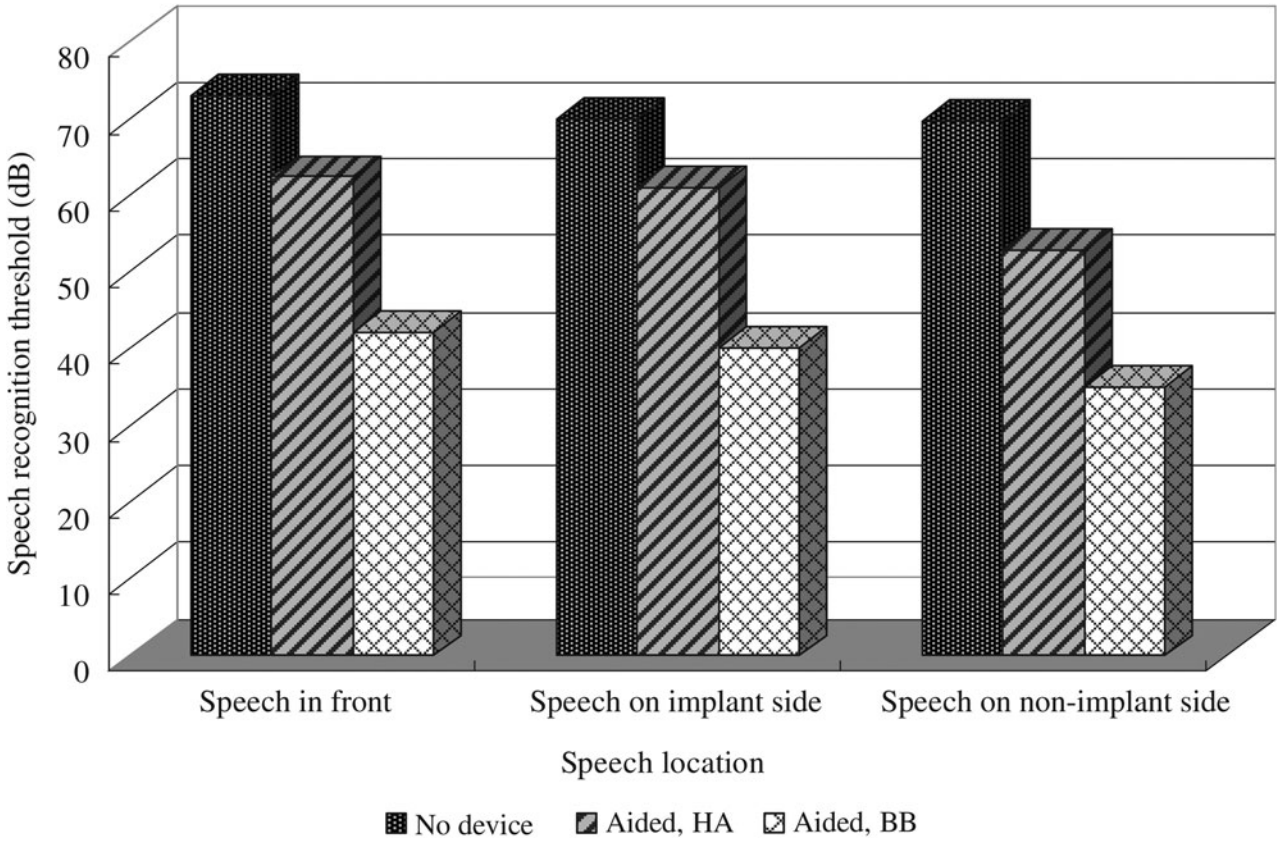

FIG. 15

Graph showing mean speech recognition thresholds in quiet conditions when speech was presented from the front, from the implant side (right ear) and from the non-implant side (left ear), under the following conditions: unaided (pre-operative); aided with a conventional hearing aid (HA) (pre-operative); and aided with the Bonebridge system (BB) (one month post-operative).

the pre-operative hearing aid and the Bonebridge system aid (evaluated one month after activation). The non-implanted ear was plugged and muffled during testing. As shown, while the pre-operative hearing aid provided an average speech recognition threshold improvement of 12 dB across the various speech locations, the Bonebridge system produced an average speech recognition threshold improvement of 32 dB.

Figure 16 shows results (presented as signal to noise ratios) for speech testing in noisy conditions, for speech presented from the front together with noise presented either from the front, from the implant side or from the non-implant side. Use of the Bonebridge system improved binaural 'squelch' in all listening conditions, that is, the speech recognition threshold improved compared with

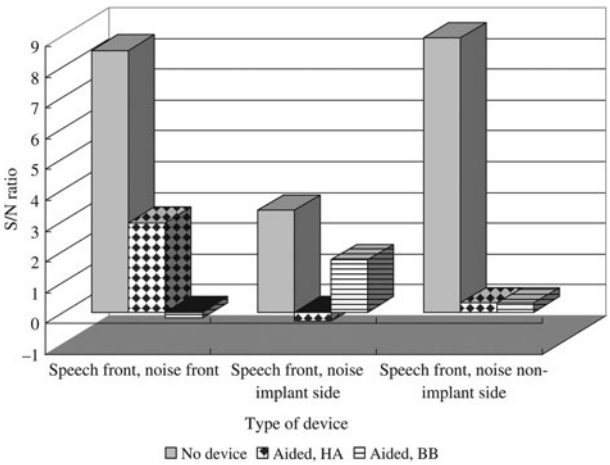

FIG. 16

Graph showing mean signal to noise (S/N) ratios for speech in noisy conditions, when speech was presented from the front together with noise presented from the front, from the implant side (right ear) or from the non-implant side (left ear), under the following conditions: unaided (pre-operative); aided with a conventional hearing aid (HA) (pre-operative); and aided with the Bonebridge system (BB) (one month post-operative).

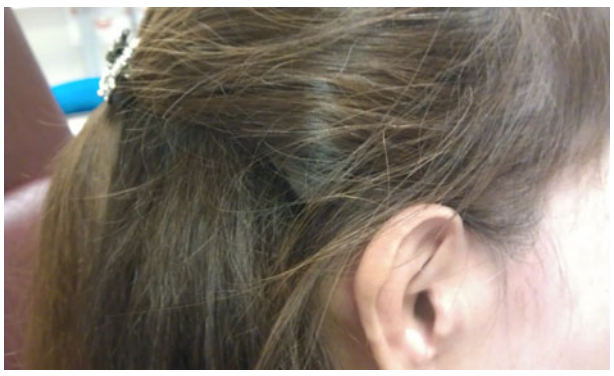

FIG. 17

Photograph showing the external audio sound processor, well hidden under the patient's hair.

https://doi.org/10.1017/S0022215113002144 Published online by Cambridge University Press

the unaided condition. When noise was presented from the implant side, the use of the pre-operative hearing aid on the non-implant side assisted hearing, enabling a 2 dB improvement in speech recognition threshold. Overall, substantial improvement in speech recognition was observed.

At the time of writing, the patient was using the Bonebridge system for over 8 hours a day. She reported that the sound quality of the Bonebridge system was natural and clear, and that the system improved speech recognition in most listening situations. She was especially pleased with the Bonebridge to help her during singing and dancing performances, as well as its cosmetic acceptability.

Discussion

This paper presents the first case of implantation of a monaural Bonebridge system in an Asian, Cantonese-speaking patient with substantial bilateral conductive hearing loss. Preliminary results from this patient suggest that the Bonebridge system is a safe and effective treatment option for adults with conductive hearing loss. This patient had well preserved hearing thresholds after surgery and suffered no intra-operative or post-operative complications.

In our experience, surgical implantation of the Bonebridge system was simple and easy to master, in comparison with middle-ear implants such as the Vibrant Soundbridge and Carina systems, which require delicate and technically demanding surgical work with the ossicles or round window.[4,5]

Careful CT planning was undertaken before the implantation procedure; this is highly recommended. We suggest that surgeons work closely with their radiology colleagues to identify the best implant placement site on the CT scan. During the operation, the surgeon must be vigilant in order to avoid damage to vital structures such as the dura and sigmoid sinus. Complication rates may be further minimised with the assistance of a CT surgical navigation system. In our patient, the only post-operative sequelae were wound pain and dizziness, which resolved without active intervention.

Our patient found the Bonebridge external audio processor easy to use and more appealing cosmetically. It was small enough to be well hidden under her hair (Figure 17). Having this type of concealable implant may allow patients to avoid the stigma associated with hearing aid usage, raising their self-esteem and improving the quality of their social lives.

In addition, unlike traditional percutaneous bone anchored hearing aid the use of the Bonebridge system eliminates post-operative pin tract infections, which greatly enhances the patient's quality of life as it obviates the need for daily implant wound care.

From an audiological point of view, our patient's Bonebridge system enabled substantial hearing improvement (10 dB–40 dB), relative to the unaided condition. Compared with the patient's pre-operative hearing aid, the Bonebridge system allowed a additional 5 dB functional gain, while speech recognition thresholds in quiet conditions were on average 2.7 times better. The speech recognition threshold improvement in noise was however slightly better for the original hearing aid, compared with the Bonebridge system. However, overall the patient benefited from additional speech understanding, especially in quiet conditions, after being fitted with the Bonebridge system.

Conclusion

This 58-year-old, Asian woman with bilateral substantial conductive hearing loss underwent successful implantation with a Bonebridge semi-implantable bone conduction hearing device. There were no peri- or post-operative complications. The patient received substantial hearing benefits from her new device.

These results support the recommended adult selection criteria for the Bonebridge system.

Acknowledgement

This study was partly funded by Med-El Hong Kong Asia Pacific Headquarters.

References

1 Tjellström A, Håkansson B, Granström G. Bone-anchored hearing aids: current status in adults and children. *Otolaryngol Clin North Am* 2001;**34**:337–64
2 Reyes RA, Tjellström A, Granström G. Evaluation of implant losses and skin reactions around extraoral bone-anchored implants: A 0- to 8-year follow-up. *Otolaryngol Head Neck Surg* 2000;122:272–6
3 Med-El: Who is a candidate for the Bonebridge™? In: http://www.medel.com/int/show/index/id/924/title/Candidacy/ [12 September 2013]
4 Tsang WS, Yu JK, Wong TK, Tong MC. Vibrant Soundbridge system: application of the stapes coupling technique. *J Laryngol Otol* 2013;**127**:58–62
5 Martin C, Deveze A, Richard C, Lefebvre PP, Decat M, Ibañez LG *et al*. European results with totally implantable carina placed on the round window: 2-year follow-up. *Otol Neurotol* 2009;**30**:1196–203

Address for correspondence:
Prof Michael C F Tong,
Department of Otorhinolaryngology, Head and Neck Surgery
6/F Clinical Sciences Building,
Prince of Wales Hospital,
New Territories, Hong Kong

Fax: +852 21458876
E-mail: mtong@ent.cuhk.edu.hk

Prof Michael Tong takes responsibility for the integrity of the content of the paper
Competing interests: The study was partly funded by Med-El Hong Kong Asia Pacific Headquarters. Previously, K S S Bhatia had received an honorarium as a speaker in a workshop affiliated with Med-El, and M C F Tong had received unrestricted education support from Med-El to attend a 2013 academic meeting on cochlear implantation.