Advances in the field of bone conduction hearing implants

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Abstract

The number of marketed bone-conduction hearing implants (BCHIs) has been steadily growing, with multiple percutaneous devices and transcutaneous devices now available. However, studies assessing efficacy often have small sample sizes and employ different assessment methodologies. Thus, there is a paucity of evidence to guide clinicians to the most appropriate device for each patient. This paper outlines audiological guidelines for the latest devices, as well as research from the most up-to-date clinical trials. We also outline the evidence base for some potentially contentious issues in the field of bone conduction, including bilateral fitting of BCHIs in those with bilateral conductive hearing loss (CHL) as well as the use of BCHIs in single sided deafness (SSD). Bilateral fitting of BCHIs have been found to significantly increase hearing thresholds in quiet and improve sound localisation but to give limited benefits in background noise. Studies conducted via multiple assessment questionnaires have found strong evidence of subjective benefits for the use of BCHIs in SSD. However there is little objective evidence of benefit for SSD patients from sound localisation and speech in noise tests.

INTRODUCTION

Per-Ingvar Brånemark's 1960 discovery that titanium could be reliably osseointergrated was crucial in the development of dental implants, and also spawned the development of the majority of modern bone-conduction hearing implants (BCHIs) [1]. In 1977, a collaboration made up of Sahlgrenska University Hospital, Chalmers University of Technology, and Brånemark Osseointegration Center started the design of the first BCHI [2]. This design consisted of a titanium screw, percutaneous abutment and transducer/sound processor. It had many advantages over its predecessors, including improved transmission of sound (particularly high frequencies) and elimination of discomfort occurring due to pressure on the skin via Softband devices [3]. Between 1985 (when the first 10 cases were reported by Håkansson [2]) and 2014, there have been approximately 150,000 patients treated with osseointergrated devices, [4] with 6000-7000 of those performed within the United Kingdom [5].

This paper summarises the audiological benefits and patient outcomes related to the latest available devices. Additionally, we highlight some of the latest evidence for the use of BCHIs in single sided deafness (SSD) as well as indications for the appropriateness of bilateral fitting of BCHIs in conductive hearing loss (CHL).

DEVICE CATEGORISATION

Since the original BCHI design, a number of different devices have been marketed but our focus will be on currently available devices which can be categorised in two main groups: skin-drive and direct-drive devices. Direct-drive devices include products such as the Bone anchored hearing aid (Cochlear Bone Anchored Solutions), Ponto (Oticon Medical) and the Bonebridge (Vibrant MED-EL, Innsbruck, Australia). These devices vibrate the skull via direct contact with the bone. Direct-drive devices can be subdivided into: percutaneous devices where an abutment is used (such as the BAHA and Ponto); and active transcutaneous devices, where the transducer is implanted (such as the Bonebridge). Skin-drive devices, including the Sophono and BAHA Attract, do not have a continuous link with the bone as vibrations are transmitted through the skin to an implanted magnet instead.

Direct-drive devices

Cochlear Bone Anchored Solutions' current designs are comprised of the BAHA 5, BAHA 3 Power and the Cordelle II. The BAHA 5 audiological fitting range can compensate for an average of 45 dB bone conduction thresholds across 0.5, 1, 2 and 3 kHz. In comparison, with the BAHA 3 Power, thresholds can be up to 55 dB. The Cordelle II, which uses of a body-worn sound processor, is appropriate for thresholds up to 65 dB over the same frequency range. A single-blinded study, comparing the BAHA 5 to previous generations of processors, found that 9 out of 10 patients rated speech understanding and sound quality good, with 7 out of 10 choosing the latest processor over its predecessors. This shows that improvements in device design are producing noticeable patient benefits [6]. Additionally, a postal questionnaire completed by 227 patients from the Birmingham BCHI program, found that 79.3 % of respondents preferred BCHIs over conventional aids or Softband in quiet, and 59.2 % in noise [7].

Oticon Medicals' percutaneous bone conduction hearing systems are the Ponto Plus and Ponto Plus Power. Recommended audiological fitting ranges for the Ponto Plus and Ponto Plus Power are that pure conductive and mixed hearing losses do not exceed an average bone conduction threshold of over 45 dB, and 55 dB, respectively. A small study of 12 patients by Olsen et al. [8] compared user preferences between the BP100 BAHA and the Ponto Pro. Both devices have now been upgraded by their respective manufacturers and thus the study's conclusions may no longer be valid. However, the Ponto Pro speech intelligibility was rated higher than the BP100, with eight of the twelve subjects preferring the Ponto Pro overall.

The Bonebridge (Vibrant MED-EL, Innsbruck, Australia) consists of an external sound processor and an internal bone conduction implant (BCI). The BCI has been conditionally certified for MRI imaging up to 1.5 Tesla and is approved for use in children of 5 years or older. The sound processor is worn externally and attached via a variable strength magnet to the patient's head. The BCI includes a floating mass transducer that produces mechanical vibrations transferred to the mastoid bone via two cortical screws. Combining audiological results from 45 patients in four different studies, there was a mean 29.4 dB gain in aided vs unaided pure tone audiogram results

[9–12]. Ihler et al's. [12] study of six patients found that there was a mean improvement of 36.1 in the Glasgow benefit inventory (GBI) postoperatively.

Skin-drive devices

The Sophono implant owned by Medtronic comprises of two magnets encased in a titanium frame. These are secured via five screws to the temporal bone after drilling a bony well for the frame to sit in. No percutaneous abutment is present and sound is instead transferred via transcutaneous energy transfer (TET), which is designed to minimise the attenuation caused by the skin between the implant and processor (attached via magnetic attraction) [13]. Studies of twenty patients with congenital unilateral and bilateral canal atresia, have evaluated outcomes from the Sophono device and found that free field PTA increased by 28.6 dB [14]. There was also a 61.6 % improvement in free-field speech testing (at 65 dB). A case series of eighteen patients found that audiological benefits were greatest for those with bilateral conductive hearing loss (21.9 dB), in comparison to those with a mixed hearing loss who had a relatively moderate gain of 5.5 dB [15].

The BAHA Attract system uses the same titanium implant as the percutaneous system, but instead of an abutment, a magnetic disk is attached subcutaneously. The external sound processor is then attached via the magnet. The recommended maximum BC threshold is 30 dB for the Attract system. A multicentre case series of twenty-seven patients fitted with the Attract system (17 with CHL, 10 with SSD), found a 17.9 dB improvement in PTA in those with CHL, and a 19.1 dB improvement in patients with SSD (although the none test ear was blocked) [16]. No significant difference was found in PTA when compared to Softband. However, speech understanding in noise was found to improve by 15 dB over the unaided condition and 3.8 dB compared to Softband testing. The abbreviated profile of hearing aid benefit (APHAB) questionnaire showed significant improvements in the background noise domain, the reverberation domain as well as the global score. Two of the twenty-seven patients reported mild/moderate pain after a long period of use, and four had mild erythema over the magnet site which resolved over time (one requiring a weaker magnet).

Device Selection

There are multiple factors which need to be considered when selecting an appropriate device (in consultation with the patients). Surgical aspects such as the quality of bone, mastoid size as well as the surgical time and difficulties should all be considered. Poor bone quality leaves patients with increased risk of failure [17]. While a small mastoid size may mean implantation with a device such as the Bonebridge is not appropriate, especially in children. Preoperative CT planning with 3D reconstruction to assess if implantation is possible (which can be mastoid or retrosigmoid) is recommended for Bonebridge. The length and difficulty of the procedure is a further factor where Oticon's minimally invasive Ponto surgery has shortened and simplified percutaneous fitting considerably. Patient acceptability is an additional major factor which takes into account aesthetics where transcutaneous devices generally are preferred; and cleaning and care of an abutment where relatively high proportions of patients feel this is an issue [7]. Lastly the audiological outcomes are of obvious importance, with current transcutaneous devices often lacking the power of percutaneous devices. Hol et al. [18] found that hearing thresholds were better via the percutaneous BAHA Divo when compared to the transcutaneous Sophono and Briggs et al. [16] failed to find a significant improvement in speech thresholds in quiet with the use of BAHA attract when compared to Softband.

BILATERAL VERSUS UNILATERAL FITTING

Binaural hearing relies on separation of inputs to each cochlea which facilitates interaural time differences (ITD) for low frequencies and interaural level differences (ILD) for high frequencies, produced by head-shadow [19]. However, vibrations from one BCHI travel not only to the ipsilateral cochlea but also to the contralateral cochlea. The universal transmission through the skull bone, which is successfully used to benefit patients with SSD, limits the ability of the auditory system to process binaural information potentially due to the interaction of the vibration waveform arriving to each cochlea in its relative phase and amplitude and it is often used as a reason for unilateral fitting [20]. However, bilateral BCHIs have been shown to have many advantages, both via objective audiological outcomes and subjective measures.

Audiological Outcomes of bilateral and unilateral BCHIs

Bilateral BCHIs have been shown to produce improvements in speech reception thresholds (SRTs) in quiet of 4-5.4 dB when compared to unilateral BCHI fitting [21–23], with similar improvements also identified for tone reception thresholds (TRT) in quiet [21,24]. This benefit appears to derive from the increased bone vibration generated by two devices working together. Evidence of benefits when listening to speech in noise were clear, but situation dependent. Bilateral BCHIs were advantageous when noise was diffuse, with a 2.8 dB speech-to-noise ratio (SNR) improvement when compared to unilateral BCHI fitting [21]. For a single localized noise sources the benefits of head shadow sometimes occurred for the unilateral BCHI control group as well as the bilateral group. So, when noise was presented to the aided side (in the unilateral group), the reported advantages of bilateral fitting were 2.5 [23] and 3.1 [21] dB SNR, but, if noise came from the unaided side, bilateral benefits were reduced to 0.8 dB [23] and -1 dB [21] SNR.

Binaural masking level difference (BMLD) results (which are a reflection of the ability to perform binaural processing of ITDs) were mixed. Air conduction BMLD results are in the range of 11 dB +/- 2 dB in normal hearing subjects [25], but Priwin et al. [21] found no benefit and Bosman et al. [23] found only a 6-6.6 dB BMLD at 125-500 Hz with no benefit at higher frequencies in bilateral BAHA users. Despite limited BMLD results, improvements in sound localisation with bilateral BCHIs over unilateral fitting are consistent. Sound localisation when using unilateral BCHIs has been found to be at extremely poor with significant improvements following bilateral fitting [21,23,24]. Snik et al. [26] identified a 53% improvement in sound localization over the unilateral condition.

Subjective Outcomes of bilateral and unilateral BCHIs

Bilateral BCHIs consistently show significant improvements in quality of life (QOL), with a 20-patient study finding a 38-point increase in the Glasgow Children's Benefit Inventory [27]. A further study of 93 bilateral BCHI patients using the Glasgow Benefit Inventory (GBI) found that benefit scores were significantly higher than in a unilateral BCHI population and that scores were similar to those collated after cochlear implantation [28].

Bilateral versus Unilateral fitting summary

There is good evidence that bilateral BCHI fitting improves speech/tone thresholds both in quiet and in noise, as well as sound localisation via the addition of interaural cues. Subjective outcomes have shown significant improvements in GBI, although the second BCHI increased it less that the first [29]. Future developments could include the use of phase inversion between BCHIs which, at low frequencies has the ability to increase signal summation [30]. Additionally, it may be possible to develop a cross-talk cancellation technology, allowing sound reaching the contralateral cochlea to be cancelled by an out-of-phase signal from the contralateral BCHI, thus allowing improved stereo separation and the restoration of interaural cues [31].

BONE CONDUCTION DEVICES IN SINGLE SIDED DEAFNESS

There are thought to be approximately 9,000 new diagnoses of SSD in the UK each year, with 24 % of sufferers having to give up work as a result [32]. Commonly reported issues from SSD patients include: social exclusion, associated with difficulties keeping up with group conversations; dangers as a pedestrian; as well as increased problems at the workplace [32]. Since sufferers have only one working cochlea they cannot process any interaural cues and so lack the ability to derive any of the normal benefits of binaural processing, such as improved sound localisation and understanding of speech in background noise [33]. Treatment options of SSD include education related to the best sitting positions in noisy environments to make the most use of monaural clues as possible. Hearing devices are also available in the form of a CROS (Contralateral Routing of Signal) hearing aid and a BCHI. Several countries have also approved cochlear implantation as a treatment option [34].

In 2002 the FDA approved the use of BCHI for SSD. Since then, there has been an increasing numbers of patients being treated with this method [37]. Although binaural hearing cannot be restored, the BCHI makes use of the relatively limited transcranial attenuation to allow sound from the deaf side to be transferred to the contralateral side. This aims to improve the detections of sound when the sound is laterally projected to the deaf side [38].

Patients with congenital SSD are an important subgroup which are at greater risk of learning problems at school when compared to those with normal hearing [35]. Prevalence rates of congenital SSD are estimated to be in the region of 0.1 % [36]. It has been theorised that these patients may not benefit as much from treatment with either BCHI or CROS, because such patients have always relied on a monaural strategy of processing pinna-induced spectral-shape cues. However research has failed to find significant evidence for this hypothesis, instead discovering that localisation ability in patients with SSD is dependent on high-frequency cues [34].

Despite much published literature, evidence for the benefit of BCHI in SSD is inconsistent with most subjective studies showing benefit, while most objective studies do not. A recent review concluded that there was a lack of high level evidence for both BCHI and CROS in SSD [39]. A summary of both subjective and objective results is presented in Table 1.

In the subjective studies, measures such as the APHAB have been widely used. This comprises assessment in a number of domains including: ease of communication; background noise; reverberation; aversiveness to loud noise; as well as a global score. Studies consistently found significant improvements in ease of communication and in the background noise domains. In contrast, scores tended to be poorer in the assessment of aversiveness to loud noise [40–45]. The single-sided deafness questionnaire is a further commonly used assessment tool which found that the majority of patients use their devices between 4-7 hours a day and that there was a perceived benefit in quality of life and in hearing (particularly in quiet) [40,43,44].

However, several objective studies have investigated BCHI via the use of the hearing in noise testing (HINT), the majority of which have found benefits only when speech is directed to the deaf ear. In this experimental configuration there is an improvement in thresholds due to compensation of the head shadow effect by BCHI. However in the converse condition where speech is directed to the hearing ear and noise the deaf ear, the hearing threshold worsens due to head shadow being compensated for [40–42,45,46]. Thus overall there is no benefit. Lin et al [45] reported that the increases in the beneficial condition were greater than the decreases in the detrimental condition, but these differences were not significant. One study of twenty-one patients with SSD and contralateral hearing loss did find significant improvements in speech recognition in both quiet and noise. Since the benefit in noise occurred regardless of a spatial separation between speech and noise, this benefit must be related to improvement in the stimulus audibility, and so might not be sustained if the stimulus were presented at a higher sound level.

Future devices may be able to improve HINT in BCHI users via communication with an additional microphone on the normal hearing side. Scene classification technology, currently used to benefit cochlear implant users [47] could then adaptively turn the BCHI on and off depending how favourable the signal to noise ratio is on the deaf side.

Table 1 Summary of study findings investing the use of BCHI for SSD treatment

Authors	**Objective Measures**			**Subjective Measures**					**Study Conclusions**
	HINT	**SRT**	**SL**	**APHAB**	**SSDQ**	**GHABP**	**SSQ**	**GBI**	
Lin et al [45]	×*		×	✓					Benefit
Linstrom et al [40]	×*			✓	✓				Benefit
Yuen et al [41]	×†			✓		✓			Benefit
Arndt et al [48]			×				×		No benefit
Dumper et al [42]	×			✓			×		Limited benefit
Martin et al [46]	×						×	×	No benefit
Wazen et al [49]	✓‡							✓	Benefit
Gluth et al [43]				✓	✓	✓			Benefit
Hol et al [44]			×	✓	✓		✓		Benefit
Bovo et al [38]		×							No benefit
Pai et al [37]							✓		Benefit

*Benefits only when noise front and speech lateralised to bad ear, †Benefits were found however HINT only performed with speech from deaf side, ‡Study was of SSD patients with contralateral hearing loss.

HINT = Hearing in noise testing, SRT = Speech reception threshold, SL = Source localisation APHAB = Abbreviated Profile of hearing aid benefit, SSDQ = Single-sided deafness questionnaire, GHABP = Glasgow hearing aid benefit profile, SSQ = Speech, spatial and qualities of hearing scale, GBI = Glasgow benefit inventory

Conclusion

The introduction of the Sophono, Bonebridge and BAHA Attract have identified a trend towards transcutaneous devices, with manufacturers of percutaneous devices such as the BAHA 5 and Ponto Plus creating sound processors with smaller profiles [4]. These innovations recognise the drive for devices to require less maintenance and be more aesthetically acceptable to patients. However, the current amplification ability of transcutaneous devices often falls short of the percutaneous competition. This indicates that percutaneous devises are potentially more appropriate when a patient has a significant sensorineural hearing loss component. For those with bilateral CHL, bilateral fitting of a BCHI may be appropriate, with studies showing increases in QOL measures and benefits in sound localisation and thresholds in quiet. Additionally, patients with SSD find significant benefits in multiple subjective measures. Evidence for objective audiological benefits was limited with benefits only in specific experimental configurations and when the contralateral ear had suboptimal hearing thresholds. The BCHI continues to be a highly valuable treatment option for patients. Smaller visible size, combined with improved sound processing and greater power, mean that future patients will have even higher patient satisfaction.

Disclosure

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