Bilateral bone-anchored hearing aid (BAHA) implantation for bilateral hearing loss

November 2013
Ears convert acoustic energy into electrical energy which is perceived by the brain as sound. Sound travels through the pinna (external ear) via the external auditory canal to the middle ear where the eardrum and ossicular chain (which consists of three small interlocking bones known as the malleus, incus and stapes) are located. The sound waves cause the eardrum and ossicular chain to vibrate, which amplifies the sound. The movement of the stapes creates movement in the cochlea (located in the inner ear), which in turn causes the sensitive hair cells within the cochlea to bend, generating electrical signals that are sent to the brain through the auditory nerve. Sound waves may reach the cochlea via air conduction (middle ear) or bone conduction (via the mastoid bone when the sound source is in contact with the head).  

When the functionality of the ear is impaired, medical or surgical interventions may be used to restore hearing. One of these is the bone-anchored hearing aid (BAHA) system, which is a well-established technology used to treat conductive, mixed and single-sided sensorineural hearing loss. BAHAs consist of a titanium plate anchored to the patient’s skull, an external sound processor (the hearing aid component of the BAHA system) and an external abutment that serves as a bridge between the titanium plate and the external sound processor. The external hearing aid detects and converts sound waves into vibratory signals, which are transmitted to the underlying plate and bone so that hearing can occur.

Patients typically undergo BAHA implantation in a single or two-stage surgical procedure, depending on their suitability. Patients without previous irradiation and good bone quality and thickness (> 3 mm) are usually eligible for implantation of the implant and abutment simultaneously, whereas others, including children, will undergo two procedures: one where the implant is placed and the other where the abutment is attached. The implantation procedure takes up to two hours under general anaesthesia and patients may be discharged from hospital on the same or the following day.

The focus of this Technology Brief is the use of bilateral BAHA implantation in people with bilateral hearing loss, which may improve auditory outcomes compared with the current gold standard of unilateral implantation. Although both cochleae receive stimulation with the use of a single BAHA device, it cannot be assumed that both receive the same level of stimulation. The purported benefits of bilateral BAHA implantation include overcoming the head-shadow effect that occurs for sounds directed at the unaided ear and the ability to have uninterrupted BAHA use if one of the devices malfunctions. The limitations of bilateral...
fitting include a significant increase in cost and the increased risk of adverse events associated with a second surgical implantation procedure.\textsuperscript{2}

**Company or developer**

There are several manufacturers of bone-anchored hearing aid devices. These include:

- Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden)—Baha® System
- Oticon Medical AB (Askim, Sweden)—Ponto bone-anchored hearing systems
- Sophono (Colorado, United States)—Alpha\textsuperscript{TM} System
- Vibrant Med-El Hearing Technology GmbH (Innsbruck, Austria)—Bonebridge.

**Reason for assessment**

Currently, unilateral BAHA implantation is used to treat bilateral hearing loss. However, bilateral implantation could lead to improved speech, language and educational outcomes, particularly in children, compared with unilateral implantation.

**Stage of development in Australia**

- [x] Yet to emerge
- [ ] Experimental
- [ ] Investigational
- [ ] Nearly established
- [ ] Established
- [x] Established but changed indication or modification of technique
- [ ] Should be taken out of use

**Australian Therapeutic Goods Administration approval**

- [x] Yes
  
  ARTG number (s) 123987; 191931; 198860; 203302
- [ ] No
- [ ] Not applicable

**Licensing, reimbursement and other approval**

There are currently four BAHA device systems on the Australian Register of Therapeutic Goods (ARTG) (Table 1).

All of these devices have received CE Mark approval and the BAHA\textsuperscript{®}, Sophono Alpha\textsuperscript{TM} and Ponto systems have also received United States Food and Drug Administration approval.
Table 1  BAHA devices with Therapeutic Goods Administration (TGA) approval

<table>
<thead>
<tr>
<th>ARTG number</th>
<th>ARTG start date</th>
<th>Manufacturer</th>
<th>Device name</th>
<th>Intended purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>123987⁴</td>
<td>5/12/2005</td>
<td>Cochlear Bone Anchored Solutions AB</td>
<td>BAHA® System</td>
<td>An amplifying device: when attached to an implant or headband it transmits sound to the cochlea through bone conduction.</td>
</tr>
<tr>
<td>191931⁷</td>
<td>9/11/2011</td>
<td>Sophono</td>
<td>Alpha™ System</td>
<td>For patients with conductive or mixed hearing losses who can still benefit from sound amplification. Bilateral fitting is applicable for most patients with symmetrical conductive or mixed hearing loss.</td>
</tr>
<tr>
<td>198860⁹</td>
<td>29/06/2012</td>
<td>Oticon Medical AB</td>
<td>Ponto</td>
<td>Designed to give patients improved hearing through direct bone conduction. It converts sound into vibrations that are transmitted via an abutment and implant (or softband/headband/testband) through the skull bone directly to the cochlea.</td>
</tr>
<tr>
<td>203302⁹</td>
<td>26/11/2012</td>
<td>Vibrant Med-El Hearing Technology GmbH</td>
<td>Bonebridge</td>
<td>For patients with either conductive or mixed hearing loss or patients suffering from single-sided sensorineural deafness.</td>
</tr>
</tbody>
</table>

The Medicare Benefits Schedule (MBS) includes the following items for BAHA implantation:

- **Osseo-integration procedure**—implantation of titanium fixture for use with implantable bone conduction hearing system device in patients with a permanent or long term hearing loss and unable to utilise conventional air or bone conduction hearing aid for medical or audiological reasons, and with bone conduction thresholds that accord to recognised criteria for the implantable bone conduction hearing device being inserted. Fee: $503.85; Benefit: 75% = $377.90, 85% = $429.35.¹⁰

- **Osseo-integration procedure**—fixation of transcutaneous abutment implantation of titanium fixture for use with implantable bone conduction hearing system device in patients with a permanent or long term hearing loss and unable to utilise conventional air or bone conduction hearing aid for medical or audiological reasons, and with bone conduction thresholds that accord to recognised criteria for the implantable bone conduction hearing device being inserted. Fee: $186.50; Benefit: 75% = $139.90, 85% = $158.55.¹⁰
Technology type | Device | Therapeutic
---|---|---

Patient Indication and Setting

Disease description and associated mortality and morbidity

The human ear can process sound frequencies ranging from 20 Hz to 20 kHz. An audiogram is used to measure hearing by recording the softest tone that is audible (hearing threshold) at each frequency, reported in decibel hearing levels (dB HL). People with normal hearing have a minimum audible tone of less than 20 dB across all frequencies.\(^1\) People with hearing loss will have a hearing threshold greater than 20 dBs. Hearing loss can be described as mild (defined by a hearing threshold of 20-40 dB), moderate (41-70 dB), severe (71-95 dB) or profound (greater than 95 dB).\(^1\)

There are three broad classifications of hearing loss:

- *Sensorineural hearing loss*, which results from damage to the hair cells of the cochlea (sensory) or to the auditory nerve (neural). This damage may be congenital or acquired. This type of hearing loss is usually permanent and is treated by amplifying the incoming sound;

- *Conductive hearing loss*, which occurs when sound is not conducted through the external auditory canal to the eardrum and ossicular chain because of a blockage or damage to the outer and/or middle ear. This type of hearing loss may be transient or permanent. Treatment may be medical or surgical; or

- *Mixed hearing loss*, which occurs when a patient has hearing loss from both sensorineural and conductive origins.\(^1\)

Hearing loss may be progressive (get worse over time) or sudden, and stable or fluctuating (get better and/or worse over time). In particular, sudden hearing loss requires immediate medical attention to determine its cause and treatment.\(^1\) The most common cause of hearing loss is exposure to loud noise, accounting for 37 per cent of all hearing loss in Australia.\(^1\)

Other conditions which are typically associated with hearing loss include otitis media (middle ear infection), ototoxic drugs, meningitis, measles, encephalitis, chicken pox, influenza, mumps and head injury.\(^1\)

Hearing loss costs Australia close to $12 billion per annum, and a large proportion of people with hearing loss are unable to work, resulting in lost productivity.\(^1\) In addition to costs to the economy, hearing loss affects quality of life and, in children in particular, may result in speech impairment and learning difficulties. The earlier hearing loss is detected and treated in children, the better their prospects of normal development.
**Number of patients**

According to the World Health Organization (WHO), over 360 million people are affected by hearing loss worldwide.\textsuperscript{16} Currently, hearing loss affects approximately 13 per cent of Australians\textsuperscript{14} and 10 per cent of New Zealanders.\textsuperscript{17} It is not known how many of these would be eligible for BAHA implantation.

In Australia, 9 to 12 infants per 10,000 live births are born with at least moderate bilateral hearing loss, and a further 23 infants per 10,000 will acquire a hearing deficit by the age of 17 years through injury or illness. Every year approximately 2,000 Australian children are fitted with their first hearing aid.\textsuperscript{14}

The incidence of hearing loss increases with age; approximately 50 per cent of people aged 60 to 70 years have hearing loss. This increases to over 70 per cent of people over 70 years and to over 80 per cent of people over 80 years.\textsuperscript{14}

**Speciality** Ear, nose and throat (ENT)

**Technology setting** General hospital, Specialist hospital

**Impact**

**Alternative and/or complementary technology**

Bilateral BAHA implantation can be considered an alternative or complementary technology for patients with conductive or mixed bilateral hearing loss. Bilateral BAHA fittings can be used as an alternative to unilateral fittings depending on the patients’ preference and/or clinical suitability. Bilateral fittings can also be considered a complementary technology because the additional BAHA implantation may improve audiologic outcomes compared with the current practice of unilateral implantation.

**Current technology**

There are pharmacological and medical therapies available for managing sensorineural, conductive and mixed hearing loss. The type of conservative therapies utilised will depend on the type of hearing loss\textsuperscript{1}, but generally they will include:

- Intra-tympanic inner ear steroid perfusion—used to treat Meniere’s disease\textsuperscript{1}, autoimmune inner ear disease and sudden sensorineural hearing loss. This treatment works by immune suppression and ion homeostasis. Immune-mediated cochlear tissue destruction results from many conditions associated with hearing loss, therefore, immunosuppression helps to protect and reverse hearing loss. Ion haemostasis assists in regulating fluids in the ear.\textsuperscript{18}

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\textsuperscript{1} Meniere’s disease is a condition where there is excess fluid in the inner ear which disturbs the ear’s balance and hearing mechanisms and causes symptoms including: vertigo, tinnitus, fluctuating hearing loss and a feeling of pressure or fullness in the ear due to fluid build-up.
- Antibiotics—used to treat bacterial infections which may be causing hearing loss (e.g. otitis media).
- Hyperbaric oxygen or carbon gas—used to treat sudden sensorineural hearing loss by increasing the concentration of oxygen in the blood to improve blood flow to areas affected by lack of oxygen.\(^\text{19}\)
- External hearing aids—which amplify sound. Some common problems associated with using external hearing aids include acoustic feedback, discomfort, ear occlusion, regular maintenance tasks, hygiene of the ear canal and perceived social stigma.\(^1\)

Similarly, the type of surgical interventions used to manage hearing loss depends on the type of hearing loss. They include:

- Canalplasty—creation of a new ear canal
- Tympanoplasty (with or without ossicular reconstruction)—repair of perforations of the eardrum using graft material (with or without repair of one or more of the bones comprising the ossicular chain, usually with titanium prostheses)
- Stapedectomy—replacement of the arch of the stapes bone when otosclerosis causes hardening
- Cochlear implants—a surgically implanted device that stimulates the hearing nerves within the cochlea
- BAHAs.\(^\text{20}\)

**Diffusion of technology in Australia**

Although the use of BAHAs is diffused in Australia, the use and funding of bilateral BAHAs in children and adults with bilateral hearing loss does not routinely occur. It does, however, appear to be possible from the ‘intended purpose’ of two of the BAHAs currently listed on the ARTG\(^7\) (Table 1). Bilateral fitting of the Sophono Alpha\(^\text{TM}\) System and Ponto bone-anchored hearing system is listed as applicable for most patients with symmetrical conductive or mixed hearing loss.\(^7\)
International utilisation

<table>
<thead>
<tr>
<th>Country</th>
<th>Level of Use</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Europe*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kazakhstan</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saudi Arabia</td>
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<tr>
<td>Singapore</td>
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<tr>
<td>South Africa</td>
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</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Including Belgium, Denmark, England, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Russia, Scotland, Spain, Sweden, Switzerland, Turkey, and Wales.

Cost infrastructure and economic consequences

All of the TGA approved BAHA devices appear on the Prostheses List:

- **BAHA® System**—minimum benefit $6,500 for the current generation sound processor and approximately $2,000 for the implant and abutment
- **Sophono Alpha™ System**—minimum benefit $6,500 for the sound processor and $1,930 for the implant
- **Ponto**—minimum benefit $6,500 for the sound processor and $1,930 for the implant and abutment
- **Bonebridge**—minimum benefit $6,500 for the sound processor and $1,035 for the implant.

A recent systematic review (2011) estimated the cost per case for unilateral BAHA implantation (equipment plus procedural costs) to be approximately A$29,500 for children and A$24,500 for adults. It is assumed that the cost for implanting two devices would be double, or close to double, this figure.

Currently, federal government funding for BAHA implantation in Australia is limited to one device per patient. If patients were to undergo simultaneous implantation, it is unlikely that

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2 Under the Private Health Insurance Act 2007, private health insurers are required to pay mandatory benefits for a range of prostheses that are provided as part of an episode of hospital treatment (or hospital substitute treatment) where a Medicare benefit is payable for the associated professional service (surgery).

3 £17,514 = $29,389.54 (GB£1 = A$1.68) (Source: http://www.xe.com/currencyconverter/)

4 £14,533 = $24,386.72 (GB£1 = A$1.68) (Source: http://www.xe.com/currencyconverter/)
hospital costs would differ greatly and the main cost addition would be that of the second device.

**Ethical, cultural or religious considerations**

There were no issues identified from the retrieved literature.

**Evidence and Policy**

**Safety and effectiveness**

One systematic review (Level III Intervention evidence) was identified as eligible for inclusion in this Technology Brief. The study reviewed 11 original studies where bilateral BAHA implantation takes place to treat bilateral hearing loss. Of the studies included in the systematic review, eight compared bilateral BAHA devices with a unilateral device (intra-patient) and three were case series studies. There was significant patient overlap in some of the included studies; this is reported below in Table 3. There were no additional relevant studies published after the latest search date of this systematic review.

**Janssen et al 2012**

The aim of this systematic review was to evaluate quality of life, patient-reported benefit, audiologic outcomes and adverse events in patients using two BAHA devices, with the purpose of determining the clinically observed advantages and disadvantages of bilateral BAHA implantation.

A literature search of EMBASE, MEDLINE and Evidence Based Medicine Reviews was carried out using comprehensive search terms to identify studies published from January 1977 to July 2011. Eleven studies met the selection criteria for the review (Table 2). Study selection and data extraction were undertaken independently by two authors and a third was available when consensus could not be reached.

**Table 2** Inclusion and exclusion criteria for Janssen et al 2012

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients of any age</td>
<td>Duplicate studies</td>
</tr>
<tr>
<td>Permanent bilateral conductive hearing loss</td>
<td></td>
</tr>
<tr>
<td>Received bilateral implanted (percutaneous) bone-anchored hearing aids</td>
<td></td>
</tr>
<tr>
<td>Level 4 evidence (case-series and poor quality cohort and case-control studies) or above</td>
<td></td>
</tr>
<tr>
<td>Publications of any language</td>
<td></td>
</tr>
</tbody>
</table>

Each included study was awarded a Quality Assessment Score (see Table 3) out of seven based on the following criteria: clearly reported inclusion/exclusion criteria; validated
assessment methods; use of appropriate comparison groups; observers blinded to condition; adequate sample size/power analyses; a well-defined, consecutive sample; and less than five per cent of patients lost to follow-up.

**Table 3** Characteristics of studies included in the systematic review

<table>
<thead>
<tr>
<th>Author, year (Location)</th>
<th>Study design (Quality Assessment Score)*</th>
<th>Patient number</th>
<th>Patient characteristics</th>
<th>Patient overlap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priwin et al, 2007(^{28}) (Sweden)</td>
<td>Non-randomised comparative (6)</td>
<td>22</td>
<td>Children, mean age 10.3 years; 13 male, 9 female; unilateral CHL in 13, bilateral CHL in 9.</td>
<td>None</td>
</tr>
<tr>
<td>Priwin et al, 2004(^{29}) (Sweden)</td>
<td>Non-randomised comparative (6)</td>
<td>12</td>
<td>Adults aged 27–68 years; 3 male, 9 female; 9 patients with MHL, 3 with CHL.</td>
<td>Same patients as Dutt et al 2002a(^{25}) and 2002b(^{24}). All patients also included in Ho et al.(^{27})</td>
</tr>
<tr>
<td>Dutt et al, 2002b(^{24}) (UK)</td>
<td>Non-randomised comparative (5)</td>
<td>11</td>
<td>Adults aged 22–54 years; 3 male, 8 female; bilateral symmetrical hearing loss.</td>
<td>Same patients as Dutt et al 2002a(^{25}). All patients also included in Ho et al.(^{27})</td>
</tr>
<tr>
<td>Bosman et al, 2001(^{32}) (Netherlands)</td>
<td>Non-randomised comparative (5)</td>
<td>25</td>
<td>Children and adults aged 12–69 years; 14 male, 11 female; bilateral CHL with some patients with mild-moderate SNHL.</td>
<td>Includes 3 patients from Snik et al(^{31}) and 4 patients from van der Pouw et al.(^{32})</td>
</tr>
<tr>
<td>Snik et al, 1998(^{31}) (Netherlands)</td>
<td>Non-randomised comparative (3)</td>
<td>3</td>
<td>Children and adults aged 14–42 years; 2 male, 1 female; bilateral MHL with high frequency SNHL component.</td>
<td>All patients included in Bosman et al.(^{32})</td>
</tr>
<tr>
<td>van der Pouw et al 1998(^{32}) (Netherlands)</td>
<td>Non-randomised comparative (4)</td>
<td>4</td>
<td>Children and adults aged 14–42 years; 2 male, 2 female; bilateral CHL.</td>
<td>All patients included in Bosman et al.(^{32})</td>
</tr>
<tr>
<td>Reuter et al, 1997(^{30}) (Germany)</td>
<td>Non-randomised comparative (2)</td>
<td>3</td>
<td>Children aged 6–14 years; 2 male, 1 female; type of hearing loss not reported—authors assumed bilateral CHL.</td>
<td>None</td>
</tr>
<tr>
<td>Hamann et al, 1991(^{36}) (France)</td>
<td>Non-randomised comparative (2)</td>
<td>15</td>
<td>Children and adults aged 5–45 years; sex not reported; type of hearing loss not reported—authors assumed bilateral CHL.</td>
<td>None</td>
</tr>
<tr>
<td>Dun et al, 2010(^{23}) (Netherlands)</td>
<td>Case series (4)</td>
<td>20</td>
<td>Children fitted before the age of 16 years; 10 male, 10 female; bilateral conductive or bilateral mixed HL, congenital or acquired.</td>
<td>None</td>
</tr>
<tr>
<td>Ho et al, 2009(^{27}) (UK)</td>
<td>Case series (4)</td>
<td>71</td>
<td>Adults 20–83 years; 31 male, 40 female.</td>
<td>Includes all 11 patients from Dutt et al 2002a(^{25}) and 2002b(^{24}).</td>
</tr>
<tr>
<td>Dutt et al, 2002a(^{25}) (UK)</td>
<td>Case series (5)</td>
<td>11</td>
<td>Adults 22–54 years; 3 male, 8 female; bilateral symmetrical HL.</td>
<td>Same patients as Dutt et al 2002b(^{24}). All patients also included in Ho et al.(^{27})</td>
</tr>
</tbody>
</table>

\(^{*}\)Maximum score possible = 7

HL: hearing loss; CHL: conductive hearing loss; MHL: mixed hearing loss; SNHL: sensorineural hearing loss.
A total of 168 patients were reported across the 11 included studies; of the 155 patients who received BAHAs, 146 had bilateral implants. The age of the patients ranged from 5 to 83 years, with 108 adults and 60 children receiving BAHAs. The overall Quality Assessment Score for the included studies ranged from 2 to 6 (maximum score possible was 7), with eight studies scoring at least four. The majority of the included studies had no patients lost to follow-up (n=8)\(^{22-25, 27-29, 31}\) (the attrition rate of the remaining three studies was not reported), stated their inclusion criteria clearly (n=8)\(^{22-29}\) and had a well-defined, consecutive sample (n=7).\(^{22-25, 27-29}\) All studies used validated assessment tools. One study used outcome assessors who were blinded to treatment allocation\(^ {29}\), while another conducted a power calculation to determine the adequate sample size.\(^ {28}\) The duration of follow-up for each of the included studies was not clearly reported.

**Safety**

There were no adverse events reported in any of the studies included in the systematic review (155 patients; 301 BAHAs); however, safety was not an outcome of interest in any of the included studies. Dun et al\(^ {23}\) excluded one patient from their study due to an extruded implant.

Due to the lack of safety evidence provided by the included studies, the authors of the systematic review conducted a second qualitative review of the Baha literature to obtain an estimate of BAHa complication rates. Intra- and perioperative complications associated with BAHa implantation were rare. Among three reviews, the first, with 149 patients, reported no adverse events\(^ {33}\); bleeding occurred in 3 per cent of 177 patients in the second review\(^ {34}\); and in the third review of 602 patients, one patient with Treacher Collins syndrome experienced post-anaesthetic laryngospasm requiring tracheotomy.\(^ {36}\) Minor postoperative complications, particularly soft tissue overgrowth and skin infections or reactions, were more common; the rate of these ranged from 9 to 24 per cent across six recent studies (the duration of follow-up in which these events were observed was not reported).\(^ {33, 35-39}\)

The authors of the systematic review concluded that patients undergoing unilateral BAHa implantation could expect a fairly high chance of experiencing a minor postoperative complication, which may require further surgical intervention. Although the literature did not provide details on the incidence of complications in bilateral BAHa implantation, the authors assumed that patients receiving two devices would be more likely to encounter minor postoperative complications that those receiving one implant.

**Effectiveness**

**Audiologic outcomes**

Eight (non-randomised comparative studies) of the 11 included studies reported audiologic outcomes.\(^ {22, 24, 26, 28-32}\) Two studies compared the detection of tonal stimuli in a total of 15 patients with unilateral versus bilateral BAHAs and reported a mean improvement of 2 to
15 dB with the latter; this was higher than the improvement in patients with unilateral fittings, particularly when sound was directed toward the unaided ear.\textsuperscript{28,29} Three studies examined speech recognition threshold (SRT) in quiet and found a mean improvement of 4 to 5.4 dB in a total of 60 patients with bilateral fittings, showing a higher level of improvement when compared with unilateral.\textsuperscript{22,26,29} In two of these studies, the overall SRT improvement was significant ($p \leq 0.001$).\textsuperscript{22,29} Word recognition in quiet (measured in a total of 12 patients) was also consistently better in patients with two BAHA devices (significance not reported), compared with patients with one device.\textsuperscript{24,30}

With regards to listening to speech in noise, three of the included studies found bilateral fitting was most useful when noise was coming from the front or rear or to the aided ear. When noise was directed to the unaided ear (in the unilateral group), there was no improvement in understanding speech and in some cases, it was considered more difficult.\textsuperscript{22,24,29}

Patients with unilateral BAHA fittings tended to perceive sound as coming from the same side as the device regardless of their position with respect to the sound source,\textsuperscript{22,29} whereas patients with bilateral BAHA fittings were better at sound localisation and lateralisation.\textsuperscript{22,28,29}

Binaural masking level difference tests (identifying a tone or word among competing background noise) were carried out in two studies.\textsuperscript{22,29} Both studies reported a significant release of masking in some patients. One study, in particular, found release of masking of 6 to 6.6 dB at the following frequencies: 125, 250 and 500 Hz between homophasic and antiphase conditions.\textsuperscript{29}

**Subjective outcomes**

Five of the 11 included studies reported patient perception of quality of life while using bilateral BAHAs.\textsuperscript{23-25,27,31} Of these, two were non-randomised comparative studies\textsuperscript{24,31} and three were case series studies\textsuperscript{23,25,27}.

The Glasgow Benefit Inventory\textsuperscript{5} (GBI) was used in two patient groups, both of which reported positive results in all categories of the GBI.\textsuperscript{23,27} In one group (of children), the highest scores were seen in the Learning and Emotion domains,\textsuperscript{23} while in the other group (of adults), the greatest improvements were registered in the General, Physical and Social domains.\textsuperscript{27} There were no differences in scores between patients with congenital or acquired hearing loss or between patients who underwent simultaneous or sequential bilateral implantation. In the child population, perception of the benefit was assessed after the first and second BAHA implant, and in all cases, the second BAHA was considered a greater success than the first.\textsuperscript{23} It is possible that this population’s greater appreciation for

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\textsuperscript{5} Glasgow Benefit Inventory: a patient-oriented, post-intervention, 18-item questionnaire developed to evaluate a patient’s health status after an otorhinolaryngological intervention.
the second BAHA implant may be due to learning curve and the fact they were already accustomed to using the first device.

Use of the BAHA devices was measured in three of the included studies: one non-randomised comparative\(^{31}\) and two case series.\(^{23, 25}\) In a study of 20 children, 90 per cent used both devices seven days per week.\(^{23}\) The remaining children used the devices for five to six days per week for the majority of their waking hours. Reasons for switching off one or both BAHA(s) included presence of background noise or device infection, risk of damage to the device (e.g. during sports or bathing) or when noise was coming from one side (e.g. whilst on the telephone).\(^{23}\) In the second study, a survey of an adult population found that all patients (n=11) used both devices for at least 8 to 12 hours a day, seven days a week.\(^{25}\) The third study, of three patients, found that two patients rated bilateral BAHA usage higher than unilateral usage for speech perception in noise and quiet, whereas one patient found no difference listening to speech in noise with one or two devices switched on.\(^{31}\) Particular patient preference in regards to unilateral versus bilateral usage can be seen in Table 4.

**Table 4: Patient preference for usage of one versus two BAHA devices\(^{23, 25, 31}\)**

<table>
<thead>
<tr>
<th>Conditions for using one BAHA device</th>
<th>Conditions for using two BAHA devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral sound source</td>
<td>Listening in quiet</td>
</tr>
<tr>
<td>Telephone</td>
<td>Listening to multimedia devices</td>
</tr>
<tr>
<td>Noisy surroundings (n=3)</td>
<td>At social/entertainment events</td>
</tr>
<tr>
<td></td>
<td>Noisy surroundings (n=8)</td>
</tr>
</tbody>
</table>

**Economic evaluation**

There do not appear to be any published economic analyses for unilateral versus bilateral BAHA implantation. A recent systematic review of BAHA for bilaterally deaf people conducted an economic analysis to estimate the cost-effectiveness of unilateral BAHA compared with bone conduction hearing aids only.\(^{11}\)

**Ongoing research**

There does not appear to be any ongoing research in the area of bilateral BAHA implantation in patients with bilateral hearing loss.

**Other issues**

There were no other issues identified in the retrieved literature.

**Summary of findings**

Overall, the data reported in the included systematic review came from eleven studies, originating from a select set of BAHA centres. There was significant overlap in patients
among the studies, which confounded the results. Despite this, both the objective (audiology) and subjective (patient preference and usage) outcomes reported among the 155 patients in the included studies were supportive of the benefits of bilateral BAHA fitting in patients with bilateral hearing loss. Based on this preliminary data, it can be assumed that it would be beneficial for patient outcomes to adopt the clinical practice of implanting two BAHA devices instead of one; however, given the likely significant increase in costs associated with this (not only for equipment but an increase in potential postoperative complications), further research into the cost-effectiveness of this option is needed before such a stance can be reliably taken. Future studies may wish to consider if there are particular patients who would benefit most from bilateral implantation, for example, younger patients or patients with greater bone conduction threshold symmetry, and should consider the durability and reversibility of the BAHA device.

HealthPACT assessment

Based on the lack of conclusive evidence as to the effectiveness of the bilateral device in terms of language and educational development in children, and with no clinical trials evaluating this outcome on the horizon, HealthPACT recommend that no further research on this technology be conducted on its behalf.

Number of studies included

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies 1

Total number of Level I studies 1

References


Bilateral bone anchored hearing aid (BAHA) implantation: November 2013


Search criteria to be used (MeSH terms)

BAHA
Bone conduction prosthesis*/implant*
Bone anchored hearing aid*/device*
Bilateral hearing loss