

## **Bone-conduction hearing devices in people with hearing impairment**

### **QUESTIONS TO BE ADDRESSED:**

1. Are the following bone-conduction hearing devices:  
(i) transcutaneous e.g. Sophono, BAHA 4 Attract, (ii) Bonebridge, (iii) SoundBite clinically effective in people with hearing impairment compared with no intervention or with any other hearing device?
  
2. Are the following bone-conduction hearing devices:  
(i) transcutaneous e.g. Sophono, BAHA 4 Attract, (ii) Bonebridge, (iii) SoundBite cost effective in people with hearing impairment compared with no intervention or with any other hearing device?

## Abbreviations and Definitions:

APHAB:	Abbreviated Profile of Hearing Aid Benefit questionnaire
AV:	aversiveness
BN:	background noise
BAHA:	bone anchored hearing aid
BCHD:	bone conducting hearing device
EC:	ease of communication
GBI:	General Benefit Inventory which evaluates changes in health status after ENT surgery (range -100 maximum negative benefit, 0 no benefit and +100 maximum benefit)
GCBI:	Glasgow Children's Benefit Inventory which evaluates quality of life (range -100 maximum negative benefit, 0 no benefit and +100 maximum benefit)
HDSS:	Hearing Device Satisfaction Scale questionnaire (range 0% not satisfied to 100% very satisfied)
HINT:	Hearing In Noise Test which evaluates ability to determine 50% correct words in sentences in noise, -1dB is equivalent to a 10% improvement
NR:	not reported
PTA:	pure tone audiometry
RV:	listening in reverberation
SRT:	speech recognition/reception/response threshold
SRT50%:	speech reception threshold for 50% word intelligibility in sentences
SSD:	single sided deafness
UHL:	unilateral hearing loss
WRS:	word recognition score

## SUMMARY:

- **Background**

- Conventional hearing aids are fitted within the ear canal, delivering amplified sound to the ear drum but they are unsuitable for people with single-sided deafness (SSD), conductive hearing loss and ear canal abnormalities.
- Bone conducting hearing devices (BCHDs) bypass the outer and middle ear, delivering sound waves to both inner ears and cochlear. They are held in place behind the ear by glasses, a headband or by a percutaneous bone anchored hearing aid (BAHA).
- Percutaneous BAHAs involve a surgically implanted titanium plate with a titanium screw (abutment) permanently coming out through the skin to which a sound processor can be attached.
- Problems with percutaneous BAHAs are that the skin requires daily hygienic care and there can be skin overgrowth around the abutment, skin infection and loss of the abutment.
- Two new alternatives are transcutaneous hearing aid systems and SoundBite
- Transcutaneous hearing aid systems use a magnetic implant in the bone behind the ear so there is no abutment through the skin, instead the external sound processor magnetically attaches to the device.
- This review looks at three types of transcutaneous devices called the Sophono Alpha 1, the Bonebridge and BAHA 4 Attract that are available for people aged five years and above with conductive hearing loss, single-sided deafness and mixed hearing loss.
- The Sonitus SoundBite Hearing System does not require a surgical implant but consists of a microphone in the ear connected to a sound processor behind the ear which transmits signals to a dental device which converts them to vibrations, which are conducted to the both inner ears and cochlear. It is available for adults with single sided deafness or conductive hearing loss.
- This rapid evidence review presents the available evidence of the efficacy and cost effectiveness of these new devices compared to no intervention or any other hearing device.

- **Clinical Effectiveness**

- No systematic reviews, meta-analyses or randomised controlled trials were identified.
- One cross-over study and 17 case series from European countries and the US met the inclusion criteria but all were small, ranging from three to 34 in sample size. One study had a control group, the others compared the same individual either before and after the device was fitted or with and without the aid at the time. All studies were small and at high risk of selection bias. Most were uncontrolled or lacked randomisation, meaning that there is insufficient evidence to draw firm conclusions on comparative clinical effectiveness.
- Compared to unaided hearing, the transcutaneous devices improved hearing pure tone audiometry (by about 20-30dB), a clinically important gain (studies not suitable for pooling).
- Transcutaneous BCHD versus percutaneous BAHA was evaluated in one small comparative case series<sup>1</sup>. Six children who had a percutaneous BAHA BP100/Divino had marginally better audiological outcomes than six children fitted with Sophono but this was not reported to be statistically significant. Pure tone audiometry (PTA) was 33 dB vs 36 dB (p= not reported (NR)), speech recognition threshold (SRT) 23 dB vs 30 dB (p=NR) and word recognition score (WRS) at 65 dB, 91% vs 84% (p=NR). Both devices were significantly better than unaided.
- SoundBite versus percutaneous BAHA was evaluated in one small cross-over study of nine adults who had already been fitted with a percutaneous BAHA device and may have been subject to bias<sup>2</sup>. Hearing threshold was 10dB better using SoundBite (p=NR) but there was no difference between them for speech localisation or speech perception in babble. A significantly positive response was reported for SoundBite compared to the percutaneous BAHA on each subscale of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, namely ease of communication (EC), listening in reverberation (RV), listening with background noise (BN) or aversiveness (AV), (p<0.05).
- Transcutaneous BCHD was compared to a conventional BCHD (hearing glasses or using a headband) in three case series<sup>3,4,5</sup>. In two of them involving 10 adults and six children and adolescents, Sophono was superior on PTA, SRT and quality of life according to the General Benefit Inventory (GBI) and Glasgow Children's Benefit Inventory (GCBI)<sup>3,4</sup>. In the other case series of six children, PTA was similar for Sophono and a BCHD on a headband<sup>5</sup>. Both devices were significantly better than unaided in all three studies.
- No studies were found that compared SoundBite with a conventional BCHD.
- Sophono was significantly better for PTA by between 29.7dB and 43dB and SRT by between 28 dB and 34.1 dB than unaided hearing in eight case series involving 53 children, 16 adults and 12 people of unreported age, with aural atresia, chronic ear disease, conductive, sensorineural or mixed hearing loss<sup>1,3,4,5,6,7,8,9</sup>.
- BAHA 4 Attract had a significantly better free-field hearing threshold by 19 dB and free-field speech recognition by 19dB in one case series of nine people with bilateral mastoidectomy compared to unaided hearing<sup>10</sup>.
- Bonebridge compared to unaided hearing was assessed in four small case series of 21 adults and three adolescents with single sided deafness (SSD), conductive or mixed hearing loss. Each study reported on selected outcome measures but all found Bonebridge significantly better than unaided hearing – PTA improved by between 35.6 dB and 36.5 dB and SRT by 36.2 dB<sup>11,12,13,14</sup>.
- SoundBite gave clinically significant benefit over unaided hearing in three small case series according to the APHAB score which was between 64% and 77%<sup>15,16,17</sup>, but objective audiological evidence was either inconsistent or lacking.

- **Cost Effectiveness**

- No cost effectiveness studies were identified that addressed whether transcutaneous hearing devices or SoundBite were cost effective in people with hearing impairment compared with no intervention or with any other hearing device.

- **Safety**

- Transcutaneous BCHD are not compatible with all types of MRI. Sophono product information details which MRI conditions are safe, Bonebridge can be used up to 1.5 Tesla and it is not to be used with Baha 4 Attract<sup>18,19,20</sup>.
- Sophono
  - Eight case series reported on safety outcomes for Sophono Alpha 1 use<sup>1,3,4,5,6,7,8,9</sup>. This included between 89 and 189 people. The main side effect was pain and/or redness in the skin over the magnetic implant which was reported in 13 people.
  - Pain resolved in eight people by using a lower magnet strength<sup>1,3,4,5,6,7</sup>.
  - Two children had skin breakdown despite only using magnet strength 1, and this took either revision surgery or other measures to heal over six to eight months<sup>6</sup>.
  - For the others, it did not resolve in one person who became a non-user, one child continued to have pink skin with no pain and one child had a new baseplate but this caused a pinpoint ulcer which was managed with a moleskin placement<sup>4,5,6</sup>.
  - There were also some cases (N not reported) of pressure over the implant which resolved with shimming<sup>9</sup>.
- Baha 4 Attract
  - One small case series of 12 adults reported on safety of Baha 4 Attract and no major complications or safety concerns were identified. Minor complications included haematoma (N=1) which was treated with aspiration, skin erythema with pain (N=1) and pain (N=3) which resolved by reduced magnet strength<sup>10</sup>.
- Bonebridge
  - Four case series reported on safety of Bonebridge and no major complications or safety concerns were identified in the 24 participants<sup>11,12,13,14</sup>. All minor complications resolved spontaneously or with treatment including a haematoma near the implant (N=1), transient tinnitus (N=1), headache and vertigo (N=1), seroma (N=1) and a minor skin infection (N=1)<sup>11,14</sup>.
- SoundBite
  - Four case series reported on the safety of SoundBite and no major complications or safety concerns were identified in the 56 participants<sup>15,16,17,21</sup>.
  - Mild palate indentations occurred in 8/22 people using SoundBite for 6 months<sup>16</sup>.
  - One minor fungal infection using SoundBite resolved with treatment<sup>17</sup>.

- **Activity and Cost**

- No data available at the time of writing.

- **Equity**

- No issues identified.

## 1 Context

### 1.1 Introduction

Conventional hearing aids are fitted within the ear canal, delivering amplified sound to the ear drum. However, they are unsuitable for people with single-sided deafness (SSD) and people who are unable to have a hearing aid in their ear canal due to developmental problems such as congenital aural atresia or following surgery.

The alternative option was to use a bone conducting hearing aid (BCHD) which is held in place behind the ear and conducts sound waves through the bone which are then picked up by the inner ear<sup>22</sup>. The soundwaves can be picked up by either ear, thus in SSD, soundwaves from the side of deafness can be conducted via the bone to the good ear. In conductive and mixed hearing loss, the bone conduction bypasses the outer and middle ear, delivering the soundwaves to the inner ear and cochlear.

Traditionally, bone conducting hearing aids were held in place using either glasses or a headband<sup>22</sup>. In the 1980s a more permanent solution was devised called Bone Anchored Hearing Aids (BAHA)<sup>22</sup>. This involves surgical placement of a titanium fixture into the bone behind the ear with a titanium screw permanently coming out through the skin. A sound processor can then be attached to this percutaneous abutment. The skin requires daily hygienic care and the main complications of BAHAs are skin overgrowth around the abutment, skin infection and loss of the abutment.

Recently, two different types of hearing devices have been developed in an attempt to combat these complications. One is a transcutaneous hearing aid system which involves surgical implantation of a magnetic plate into the bone behind the ear. There is no abutment through the skin, instead the external sound processor magnetically attaches to the device. There are three types of available transcutaneous devices called the Sophono Alpha 1, the Bonebridge and BAHA 4 Attract.

The other new device is the Sonitus SoundBite Hearing System which can be used for adults only. This bone conduction hearing system does not require a surgical implant. It consists of a behind the ear device, a microphone in the ear and transmits to a dental device which conducts the sound to the inner ear.

This rapid evidence review presents the available evidence of the efficacy and cost effectiveness of these new devices compared to no intervention or any other hearing device.

## 1.2 Existing national policies and guidance

There are no current policies or guidance from the National Institute for Health and Care Excellence (NICE) regarding bone conduction hearing devices in people with hearing impairment.

## 2 Epidemiology

BAHAs have been indicated for the following types of conductive, sensorineural and mixed hearing loss:

- Congenital aural atresia (incomplete development of the external ear<sup>22</sup>) and microtia<sup>6</sup>.
- Chronic suppurative otitis media<sup>6</sup>
- Chronic otitis externa<sup>6</sup>
- Unilateral profound hearing loss<sup>6</sup>
- Unilateral mixed hearing loss<sup>6</sup>
- Failure of conventional hearing aids<sup>6</sup>
- Trauma resulting in hearing loss<sup>6</sup>
- Unsuitable ear canal for a conventional hearing aid such as<sup>23</sup>:
  - in a radical mastoid cavity
  - an extremely narrow ear canal
  - ear canal closure after radical mastoidectomy,
  - lateral temporal bone resection or
  - extensive cranial base surgery

According to the NHS Newborn Hearing Screening Program from December 2012 to December 2013, the incidence of bilateral permanent childhood hearing impairment (PCHI) was 7,658 and unilateral PCHI was 4,601<sup>24</sup>.

For adults aged 18 to 80, a recent estimate using the 2011 Census and 1995 National Study of Hearing found that the UK prevalence of hearing loss of 35 dB or more in the better ear is around one in 12, or 3.8 million (95% Confidence Interval [CI] 2.8 to 5.3 million). The estimated prevalence of hearing loss of at least 40 dB in the better ear is one in 17, or 2.7 million<sup>25</sup>.

### 3 The intervention

The new bone-conducting hearing devices that are now available are either transcutaneous bone anchored hearing aids or a non-surgical hearing aid called SoundBite. Transcutaneous bone anchored hearing aids are designed for people aged five years and older. Unlike percutaneous bone conducting hearing aids, there is no metal abutment going through the skin. Instead, a magnetic implant is placed in the bone behind the ear, and the skin is sutured over it. After four to six weeks, an external sound processor can magnetically attach to the implant. The strength of the attraction can be altered so that there can be a higher level during sporting activities. It is taken off during showering and swimming. There are three available types of transcutaneous bone anchored hearing aids – Sophono Alpha, Baha 4 Attract and Bonebridge. The other non-surgical device, SoundBite involves a small hearing aid and a dental attachment. It is only indicated for use by adults. All four devices are described below.

#### Sophono Alpha

The Sophono Alpha system comprises a magnetic implant and external processor and is intended for people with conductive hearing loss, single-sided deafness and mixed hearing loss. It is recommended for people with bone conduction hearing thresholds better than 45dB or in the case of SSD, for people who have hearing thresholds better than 20dB in the hearing ear<sup>18</sup>.

A small implant of two joined magnets is screwed into the bone behind the ear. After four to six weeks, an external sound processor can be attached magnetically to the implant. This processor converts sound into vibrations which are transmitted through the skin to the skull bone. The vibrations are then picked up by the both inner ears and cochlea. The skin above the magnet is thinned out to a thickness of 4 to 5 mm to reduce the attenuation of the skin<sup>18</sup>.

Figure 1: Sophono Alpha 1<sup>18</sup>



#### Baha 4 Attract System

The Baha 4 Attract system consists of a single magnet implant and external sound processor, with a similar mechanism of action to the Sophono Alpha 1. It is indicated for people with conductive, mixed and SSD. It is also licenced to be used bilaterally<sup>20</sup>.

Figure 2: Baha 4 Attract System<sup>20</sup>

### Bonebridge

The Bonebridge is a combination of a surgical implant behind the ear and an external processor. It is intended for people with conductive and mixed hearing loss<sup>19</sup>.

An audio processor picks up sound waves using microphones. It is held in place by magnetic attraction to an implant in the temporal region of the skull. The processor converts the sound waves into signals which are transmitted to the implant. Unlike the Sophono Alpha 1 and Baha 4 Attract, the signals are converted into vibrations by the implant and they are then conducted by the bone to both inner ears and cochlea<sup>19</sup>.

Figure 3: Bonebridge system<sup>19</sup>

### SoundBite

The SoundBite device does not involve surgery and is intended to help adults with SSD or conductive hearing loss regain spatial hearing ability<sup>26</sup>.

It consists of a microphone positioned in the ear canal of the poorer ear with a transmission unit behind the ear. This device uses a digital signal processor to process the sound and transmit the signals to a device fitted to the upper back teeth. The mouth device turns the signals into vibrations which are conducted from the teeth via bone to both inner ears and cochlea. The removable mouth component of the unit is custom made to fit around the teeth so that the person can still eat and drink<sup>15</sup>. Both units have rechargeable batteries.

Figure 4: Sonitus Medical SoundBite<sup>26</sup>



## 4 Findings

### 4.1 Evidence of effectiveness

Medline, Embase, Cochrane, TRIP and NICE Evidence Search were searched from 2004 onwards for systematic reviews, meta-analyses, randomised controlled trials, prospective non-randomised clinical studies and health economics studies comparing the bone conducting hearing devices: Sophono, Bonebridge, Baha Alpha system and SoundBite with no intervention or any other hearing device.

No systematic reviews, meta-analyses or randomised controlled trials were identified. One cross-over study and seventeen case series met the inclusion criteria, which were carried out in Europe and the US, none from the UK. All of the studies were at high risk of bias and all were small, ranging from three to 34 in sample size. Only one study had a control group, all of the others compared the same individual either before and after the device was fitted or with and without the aid at the time. Most studies reported on cases retrospectively that had been treated in their clinics, rather than prospectively setting out to assess the efficacy and safety of the devices.

The efficacy of each device will be described in turn.

#### **Sophono Alpha 1 - efficacy**

Eight case series were identified involving 53 children, 16 adults and 12 people of unreported age. Indication for bone conduction hearing device was heterogenous and included aural atresia, chronic ear disease, conductive, sensorineural or mixed hearing loss. All studies were at high risk of bias:

- A comparative case series [Hol 2013]<sup>1</sup>, of 12 children, the majority with aural atresia was identified. Hearing was compared in six children who had a percutaneous BAHA BP100/Divino with six children fitted with Sophono. All of the audiometry results were better for percutaneous BAHA than Sophono despite the percutaneous BAHA group having worse unaided pure tone audiometry (PTA) thresholds. PTA was 33 dB HL percutaneous BAHA versus 36 dB HL Sophono ( $p = \text{not reported [NR]}$ ), speech recognition threshold (SRT) was 23 dB HL percutaneous BAHA vs 30 dB HL Sophono ( $p = \text{NR}$ ) and word recognition score (WRS) at 65 dB was 91% percutaneous BAHA vs 84% Sophono. ( $p = \text{NR}$ ).
- In a case series [Magliulo 2014]<sup>3</sup> of 10 adults with subtotal petrosectomy for chronic middle ear disease, Sophono was superior to a conventional BCHD (hearing glasses). PTA was 42.1 dB HL Sophono vs 53.6 dB HL conventional BCHD ( $p < 0.0001$ ), SRT was 38 dB Sophono vs 45 dB conventional BCHD ( $p < 0.01$ ) and WRS at 65dB was 87.1% Sophono vs 78% conventional BCHD ( $p < 0.01$ ). The Sophono was viewed positively according to the General Benefit Inventory (GBI): general benefit +45.3 (+20.8 to +75), social benefit +11.6 (0 to +33.3) and physical benefit +44.9 (+16.6 to +66.6).



- In a case series [Marsella 2014]<sup>4</sup> of six children and adolescents with bilateral conductive or mixed hearing loss, Sophono gave better results than a conventional BCHD. PTA was 32.5 dB HL Sophono vs 38 dB HL conventional BCHD (p=NR) and speech perception score was 93% Sophono vs 89% conventional BCHD (p=NR). Five children reported improved quality of life according to the Glasgow Children's Benefit Inventory (GCBI) but one child discontinued due to pain.
- In a case series [Denoyelle 2013]<sup>5</sup> of six children with aural atresia, Sophono was significantly better than the unaided condition across all audiometry tests, and similar to a BCHD on a headband in terms of PTA<sup>5</sup>. PTA was 28.5 dB Sophono vs 71.5 dB unaided (p=0.0313) and 29.5 dB with headband BCHD, ability to understand 50% of speech at 65dB was 37.5 dB Sophono vs 70.8 dB unaided (p=0.0313) and speech in noise tests in free field, real life conditions was 50.17 dB Sophono vs 58.17 dB unaided (p=0.0313). All children and parents were either "satisfied" or "very satisfied" with results.
- A case series [O'Neil 2014]<sup>6</sup> of 10 children with aural atresia or chronic ear disease and cholesteatoma found Sophono improved PTA to 20.2 dB vs 60.3 dB unaided (p=NR).
- A case series [Centric 2014]<sup>7</sup> of five children with conductive or sensorineural hearing loss found Sophono improved PTA to 25 dB HL vs 57 dB HL unaided (p=NR) and SRT improved to 28 dB HL Sophono vs 56 dB HL unaided (p=NR).
- In a case series [Seigert 2013]<sup>8</sup> of 14 children and six adults with aural atresia, Sophono improved PTA to 29.7dB HL vs 58.7 dB HL unaided (p=NR) and free-field speech understanding at 65dB to 76.8% Sophono vs 15.3% unaided (p=NR).
- In a case series [Seigert 2011]<sup>9</sup> with audiological follow up for 12 people mostly with aural atresia, Sophono improved PTA by 31.2 dB HL compared to unaided (p=NR) and free-field speech understanding to 72.1% Sophono vs 12.9% unaided (p=NR).

**Table 1: Efficacy of Sophono Alpha 1**

Study	Patients	Intervention	Comparator	Outcomes
Hol 2013 <sup>1</sup>  Netherlands, single centre  Comparative case series	12 children with unilateral congenital aural atresia (N=11), or ossicular chain anomaly (N=1)  Unaided PTA in the Sophono group was ≥53 dB HL (mean 58 dB HL) and ≥61 dB HL (mean 69 dB HL) in the BAHA group	Sophono Alpha 1 N=6	Cochlear BAHA BP100/Divino N=6	<b>Mean follow-up for Sophono 325 days (range 145 to 740 days). Mean follow-up for BAHA 592 days (range 194 to 1,190 days).</b>  <b>PTA:</b> 33 dB HL BAHA vs 36 dB HL Sophono (p=NR).  <b>Speech recognition threshold (SRT):</b> 23 dB HL BAHA vs 30 dB HL Sophono (p=NR).  <b>WRS at 65 dB:</b> 91% BAHA vs 84% Sophono (p=NR).
Magliulo 2014 <sup>3</sup>  Germany, single centre  Case series	10 adults with subtotal petrosectomy for chronic middle ear disease  Unaided PTA ≥60 dB	Sophono Alpha System 1 N=10	Unaided N=10, conventional BCHD (hearing glasses), N=5	<b>Post-op assessment time not provided</b>  <b>PTA:</b> 42.1 dB HL Sophono vs 71.8 dB HL unaided pre-op (p=NR).  42.1 dB HL Sophono vs 53.6 dB HL conventional BCHD (p<0.0001).  <b>Speech recognition threshold (SRT):</b> 38dB Sophono vs 72.1 dB unaided pre-op (p<0.001).  38 dB Sophono vs 45 dB conventional BCHD (p<0.01).

				<p><b>WRS at 65 dB:</b> 87.1% Sophono vs 3% unaided pre-op (<math>p&lt;0.001</math>).</p> <p>87.1% Sophono vs 78% conventional BCHD (<math>p&lt;0.01</math>)</p> <p><b>GBI:</b> General benefit +45.3 (+20.8 to +75), social benefit +11.6 (0 to +33.3), physical benefit +44.9 (+16.6 to +66.6)</p>
<p>Marsella 2014<sup>4</sup></p> <p>Italy, single centre</p> <p>Case series</p>	<p>6 children and adolescents with bilateral conductive (n=5) or mixed (n=1) hearing loss</p> <p>Unaided PTA <math>\geq 60</math> dB</p>	Sophono N=6	<p>Conventional BCHD N=6, Unaided N=6</p>	<p><b>Audiology assessed after 2 months, GCBI assessed after 4 months</b></p> <p><b>PTA:</b> 32.5 dB HL Sophono vs 38 dB HL conventional BCHD vs 63 dB HL unaided (<math>p=NR</math>).</p> <p><b>Speech perception score:</b> 93% Sophono vs 89% conventional BCHD vs 67.5% unaided (<math>p=NR</math>).</p> <p><b>GCBI:</b> +42 (0 to +62.5), 1 patient discontinued use due to pain</p>
<p>Denoyelle 2013<sup>5</sup></p> <p>France, single centre</p> <p>Case series</p>	<p>6 children with congenital aural atresia</p> <p>Unaided PTA <math>\geq 61.25</math> dB</p>	Sophono Alpha 1 N=6	<p>BCHD on a headband N=6, Unaided N=6</p>	<p><b>Assessed 6 months post-op</b></p> <p><b>PTA:</b> 28.5 dB Sophono vs 71.5 dB unaided (<math>p=0.0313</math>).</p> <p>28.5 dB Sophono vs 29.5 dB BCHD on headband (<math>p=NR</math>).</p> <p><b>Speech reception threshold</b> <b>SRT<sub>50%</sub> at 65dB:</b> 37.5 dB Sophono vs 70.8 dB unaided (<math>p=0.0313</math>)</p> <p><b>Speech in noise tests in free field, real life conditions:</b> 50.17 dB Sophono vs 58.17 dB unaided (<math>p=0.0313</math>)</p> <p><b>Satisfaction questionnaire:</b> use of device 5 to 12 hours per day, all children and adults were either "satisfied" or "very satisfied" with results.</p>
<p>O'Neil 2014<sup>6</sup></p> <p>US, single centre</p> <p>Retrospective case series</p>	<p>10 children with aural atresia (N=7), or chronic ear disease and cholesteatoma (N=3)</p> <p>Unaided PTA <math>\geq 35</math> dB</p>	Sophono N=10, 14 ears	<p>Unaided N=10</p>	<p><b>Assessed preoperatively and on average 68 days after Sophono fitting</b></p> <p><b>PTA:</b> 20.2 dB Sophono vs 60.3 dB unaided (<math>p=NR</math>).</p>
<p>Centric 2014<sup>7</sup></p> <p>US,</p> <p>Retrospective case series</p>	<p>5 children with conductive (N=4) or sensorineural (N=1) hearing loss</p>	Sophono N=5	<p>Unaided pre-op N=5</p>	<p><b>Assessed at 6 weeks compared to pre-op</b></p> <p><b>PTA:</b> (N=4) 25 dB HL Sophono vs 57 dB HL unaided (<math>p=NR</math>).</p> <p><b>Speech Response Threshold</b></p>

	Unaided PTA ≥40 dB  Audiological data unavailable for 1 child who was too young and 1 child who had no pre-op responses in the operated ear			(SRT): (N=3) 28 dB HL Sophono vs 56 dB HL unaided (p=NR).
Siegert 2013 <sup>8</sup>  Germany, single centre  Case series	20 people (14 children, 6 adults) with congenital atresia  Unaided PTA ≥42.5 dB	Sophono N=20	Unaided N=20	<b>Assessed 0.2 to 46.6 months post-op</b>  <b>PTA:</b> 29.7dB HL Sophono vs 58.7 dB HL unaided (p=NR).  <b>Free-field speech understanding at 65dB:</b> 76.8% Sophono vs 15.3% unaided (p=NR).
Siegert 2011 <sup>9</sup>  Germany, single centre  Case series	>100 people, mostly with congenital aural atresia.  Audiological follow-up N=12, age not reported  Unaided PTA not reported	Sophono N=12	Unaided N=12	<b>Assessment time not provided</b>  <b>PTA:</b> Average hearing gain 31.2 dB HL compared to unaided (p=NR).  <b>Free-field speech understanding at 65 dB:</b> 72.1% Sophono vs 12.9% unaided (p=NR).

#### Baha 4 Attract System - efficacy

One small case series [Iseri 2014]<sup>10</sup> was identified which compared the BAHA 4 Attract System with no intervention, and it was of poor quality:

- Nine people with bilateral mastoidectomy had significantly better free-field hearing threshold of 26 dB using BAHA 4 Attract versus 45 dB unaided (p<0.001), and free-field speech recognition of 37 dB with BAHA 4 Attract compared to 56 dB with no intervention (p<0.001).

**Table 2: Efficacy of Baha 4 Attract System**

Study	Patients	Intervention	Comparator	Outcomes
Iseri 2014 <sup>10</sup>  Turkey  Case series	12 people, with bilateral mastoidectomy (2 children, 9 adults) or bilateral aural atresia (1 child)  Unaided PTA ≥30dB  Outcomes only for 9 people, ages not reported.	BAHA 4 Attract N=12	Unaided N=9	<b>Post-op assessment time not provided</b>  <b>Free-field hearing threshold:</b> (N=9) 26dB BAHA 4 Attract vs 45 dB unaided (p<0.001)  <b>Free-field speech recognition:</b> (N=9) 37 dB BAHA 4 Attract vs 56 dB unaided (p<0.001)

## Bonebridge - efficacy

Four small case series were identified which compared Bonebridge to the unaided condition in 21 adults and three adolescents with single sided deafness (SSD), conductive or mixed hearing loss. All studies were of poor quality:

- A case study [Sprinzi 2013]<sup>11</sup> of 12 adults with conductive or mixed hearing found that Bonebridge improved WRS at 65 dB, Bonebridge 92.9% percent correct vs 14.2% unaided (p<0.001). SRT for understanding 50% of speech was improved to 36.6 dB with Bonebridge vs 61.9 dB unaided (p<0.001). Participants were positive about Bonebridge in their responses on the Hearing Device Satisfaction Scale, with average satisfaction of 79% (range 49% to 99%).
- A case study [Manrique 2014]<sup>12</sup> of five adults with conductive, mixed or SSD found that PTA was improved with Bonebridge to 31.25 dB vs 66.87 unaided (p<0.001). Word discrimination in quiet conditions was also improved with Bonebridge to 86.2% vs 66.2% unaided (p=0.016).
- One case study [Barbara 2013]<sup>13</sup> of four adults with mixed hearing loss found that PTA was improved with Bonebridge to 35 dB Bonebridge vs 71.5 dB unaided (p=NR). SRT also improved with Bonebridge to 41.25 dB vs 77.5 dB unaided (p=NR).
- One case study [Hasepass 2014]<sup>14</sup> of two adolescents with conductive hearing loss found that Bonebridge improved 50% speech reception threshold to 29 dB compared to 53.5 dB unaided (p=NR). In one adolescent with SSD, Bonebridge improved speech recognition when speech was presented from the unilateral deaf side and noise from the normal hearing side, as well as when speech and noise were presented from the front. Unaided hearing was better than Bonebridge when speech was presented to the normal hearing side and noise from the unilateral deaf side.

**Table 3: Efficacy of Bonebridge**

Study	Patients	Intervention	Comparator	Outcomes
Sprinzi 2013 <sup>11</sup>  Germany and Austria, 4 hospitals  Case series	12 adults with conductive (N=7) or mixed (N=5) hearing loss  Unaided PTA ≥30 dB	Bonebridge N=12	Unaided N=12	<b>Assessed at 3 months</b>  <b>Word recognition score in 65dB:</b> 92.9% Bonebridge vs 14.2% unaided (p<0.001)  <b>Speech reception threshold SRT<sub>50%</sub>:</b> 36.6 dB Bonebridge vs 61.9 dB unaided (p<0.001)  <b>Hearing Device Satisfaction Scale (HDSS):</b> 79% (range 49% to 99%)
Manrique 2014 <sup>12</sup>  Spain, single centre  Case series	5 adults with conductive/mixed hearing loss (N=4) or SSD (N=1)  Unaided PTA ≥51 dB	Bonebridge N=5	Unaided N=5	<b>Post-op assessment time not provided</b>  <b>PTA:</b> 31.25 dB HL Bonebridge vs 66.87 dB HL unaided (p=0.01)  <b>SRT (disyllabic word discrimination) in quiet:</b> 86.2 ± 7.5% Bonebridge vs 66.2 ± 11.4% unaided (p=0.016)
Barbara 2013 <sup>13</sup>  Italy, single centre  Case series	4 adults with mixed hearing loss  Unaided PTA ≥51 dB	Bonebridge N=4	Unaided N=4	<b>Pre-op and 6 months post op assessment</b>  <b>PTA:</b> 35 dB Bonebridge vs 71.5 dB unaided (p=NR)  <b>SRT (speech reception threshold):</b> 41.25 dB Bonebridge vs 77.5 dB unaided (p=NR)
Hasepass 2014 <sup>14</sup>	3 adolescents with unilateral hearing	Bonebridge N=3	Unaided N=3	<b>Assessed 6 months post op</b>

Germany, single centre	loss. Conductive (N=2), SSD (N=1)			<b>Speech reception threshold SRT<sub>50%</sub>:</b> Conductive hearing loss (N=2), 29 dB Bonebridge vs 53.5 dB unaided.
Case series	Unaided PTA ≥49 dB			<b>Oldenburg Sentence Test for speech reception threshold at 65dB:</b> SSD (N=1), speech and noise from the front was better for Bonebridge -5.6 dB vs -3.1 dB unaided and speech from the deaf side and noise from the normal side -5.0dB Bonebridge vs +0.5 dB, but speech from the normal side and noise from the deaf side was better unaided, -11.2 dB unaided vs -8.9 dB Bonebridge.

### SoundBite - efficacy

One small cross-over study<sup>2</sup> and three case series were identified, all of poor quality. In addition, it is unclear if the 22 adults in the 6 month trial had also been in the 30 day trial:

- The cross-over study [Moore 2013]<sup>2</sup> involved nine adults with unilateral hearing loss (UHL) who had worn a BAHA for between one and seven years. Hearing threshold was about 10dB lower using SoundBite compared to BAHA (p=NR) but there was no difference between them for speech localisation or speech perception in babble. A significantly positive response was reported for SoundBite compared to the BAHA on each subscale of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, namely ease of communication (EC), listening in reverberation (RV), listening with background noise (BN) or aversiveness (AV), (p<0.05). However, the improvement seen for people using SoundBite may have been biased by the recruitment process. All participants had volunteered to try SoundBite through advertisements and it may be that they volunteered because of dissatisfaction with their device and the improvements could have been subjective on the new system. It should be noted that the benefit scores recorded for the BAHA were lower than have previously been reported for these devices and were inconsistent with the participant's ability to understand speech in noise.
- In a case series [Murray, Popelka et al 2011]<sup>15</sup> of 28 adults, after 30 days, SoundBite was 25% better than unaided hearing in background noise when this was directed at the good ear (p<0.001). It was 23% worse with SoundBite when the background noise was directed at the poor ear (p<0.001). There was no difference if the noise came from the front or when there was no background noise. Patient reported outcomes using the APHAB found that 64% (N=18) had a clinically significant improvement of 22 points or more on either EC, RV or BN. However, no participant had a clinically significant improvement of 5 points or more on all 3 of the EC, RV and BN scores. A further non-validated questionnaire found that 75% reported that they "prefer" or "very much prefer" SoundBite to nothing while 89% reported an overall improvement in quality of life.
- In the six month case series [Murray, Miller et al 2011]<sup>16</sup>, possibly an extension of the 30 day trial, objective hearing tests were not performed. Subjective improvements using SoundBite were found on the APHAB score with mean global benefit of 21.3 at 3 months and 23.1 at 6 months (both p<0.001). A clinically significant improvement of 22 points or more on either EC, RV or BN scores at 6 months was reported for 77% (N=17) of participants. A clinically significant improvement of 5 points or more on all 3 of the EC, RV and BN scores at 6 months was reported for 59% (N=13) of participants. Responses to a non-validated questionnaire found over 90% of participants reported improvement in seven out of eight items and over 86% of participants reported satisfaction for 4 out of 5 items. Dissatisfaction with ability to eat while wearing the SoundBite was reported by 36% of participants.
- In a case series [Gurgel 2013]<sup>17</sup>, 34 adults with unilateral acquired sensorineural hearing loss had a trial of SoundBite for six months. The reporting of PTA outcomes was unclear. A clinically

significant improvement in APHAB score was found in 76% of participants ( $p < 0.001$ ). In a non-standardised, non-validated questionnaire, 91% of participants preferred wearing the device to not wearing the device. Twelve people had acoustic feedback, this was resolved for six of them following device adjustments.

**Table 4: Efficacy of SoundBite**

Study	Patients	Intervention	Comparator	Outcomes
Moore 2013 <sup>2</sup>  USA, multi-centre  Crossover study, random allocation for which device was worn first	9 adults with a current BAHA for UHL  Recruited through advertisements  Hearing PTA of $\leq 25$ dB HL in the good ear and $\geq 75$ dB HL in the poor ear	SoundBite N=9	Current BAHA:  Oticon Medical Ponto Pro(N=2), CochlearBP100(N=4), Cochlear Divino(N=1), Cochlear BAHA Compact(N=1), Cochlear Intenso(N=1)	<b>Assessed on day 1 and day 30 for each device.</b>  <b>Hearing threshold:</b> about 10dB lower for SoundBite compared to BAHl at each frequency tested ( $p=NR$ )  <b>Sound localisation:</b> 50% accuracy after 30 days, no significant difference between devices ( $p=NR$ )  <b>Speech perception in babble:</b> no significant difference between devices; marginal improvement over unaided ( $p=NR$ )  <b>APHAB score:</b> average scores for each subscale were higher for SoundBite than BAHA( $p < 0.05$ )
Murray, Popelka et al 2011 <sup>15</sup>  US, multicentre  Case series	28 adults with acquired single sided deafness  Hearing PTA of $\leq 25$ dB HL in the good ear and $\geq 70$ dB HL in the poor ear	SoundBite N=28	Unaided N=28	<b>Assessed on day 1 and day 30</b>  <b>Hearing in noise test (HINT):</b> no difference between SoundBite and unaided when there was no noise or when the noise was directed at the front. SoundBite better than nothing when the noise was directed at the good ear -1.7dB day 1 ( $p < 0.001$ ) and -2.5dB day 30 ( $p < 0.001$ ). SoundBite worse than nothing when the noise was directed at the deaf ear +2.1 dB day 1 and +2.3 dB day 30 ( $p < 0.001$ ).  <b>APHAB score:</b> 64% (N=18) of participants had a clinically significant improvement of 22 points or more on either EC, RV or BN scores using SoundBite. None had a clinically significant improvement of 5 points or more on all 3 of the EC, RV and BN scores using SoundBite.  <b>Non-validated questionnaire:</b> 75% reported that they "prefer" or "very much prefer" SoundBite to nothing, 89% reported an overall improvement in quality of life.
Murray, Miller et al 2011 <sup>16</sup>	22 adults with acquired single sided	SoundBite N=22	Unaided N=22	<b>Assessed at 3 months and 6 months</b>

US, multicentre  Case series	deafness  Hearing PTA of $\leq 25$ dB HL in the good ear and $\geq 70$ dB HL in the poor ear  None used any device before			<p><b>APHAB:</b> Mean global benefit 21.3 at 3 months and 23.1 at 6 months, (both <math>p &lt; 0.001</math>). 77% (N=17) had a clinically significant improvement of 22 points or more on either EC, RV or BN scores at 6 months. 59% (N=13) had clinically significant improvement of 5 points or more on all 3 of the EC, RV and BN scores at 6 months.</p> <p><b>Non-validated questionnaire:</b> over 90% of participants reported improvement for 7 out of 8 items, over 86% of participants reported satisfaction for 4 out of 5 items. 36% were dissatisfied with ability to eat while wearing the SoundBite.</p>
Gurgel 2013 <sup>17</sup>  US, multi-centre  Case series	34 adults with unilateral acquired sensorineural hearing loss  Hearing PTA of $\leq 25$ dB HL in the good ear and $\geq 75$ dB HL in the poor ear	SoundBite N=34	Unaided N=34	<p><b>Assessed at 6 months</b></p> <p><b>PTA:</b> Unclear reporting.</p> <p><b>APHAB score:</b> 76% had a clinically significant improvement of 22 points or more on either EC, RV or BN score or 5 points or more on all 3 of the EC, RV and BN scores. Mean scores using SoundBite improved significantly for EC, RV, BN and global benefit (all <math>p &lt; 0.001</math>)</p> <p><b>Non-standardised, non-validated questionnaire:</b> 91% of participants preferred wearing the device to not wearing the device</p> <p><b>Acoustic feedback:</b> (N=12), resolved after adjustments for 6 participants.</p>

## 4.2 Trials in progress

The following clinical trials in progress were identified through searching [www.clinicaltrials.gov](http://www.clinicaltrials.gov) on 19<sup>th</sup> September 2014:

[NCT01822119](#) Clinical Performance of a Transcutaneous Bone Conduction Hearing Solution (Baha Attract System). Study completed March 2014.

[NCT02022085](#) Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear Baha Attract System). Currently recruiting, estimated completion April 2017.

[NCT01858246](#) A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid with Bonebridge. Currently recruiting, estimated completion January 2017.

[NCT01933386](#) Evaluation of Benefit for Treatment of Single Sided Deafness (SSD) Between Two Bone Conduction Prosthetic Devices; Osseointegrated Implant Versus Maxilla Anchored Removable Oral

Appliance (“SoundBite”). Study not yet open for participant recruitment but was planned to start in September 2013 and to be completed in February 2014.

[NCT01807559](#) SoundBite Hearing System 24 Month Multi Site Patient Use Study. Currently recruiting, estimated completion was August 2014.

[NCT01445977](#) SoundBite Hearing System Long Term Multi Site Patient Use Study. Ongoing, but not recruiting. Estimated completion was September 2013.

### **4.3 Evidence of cost-effectiveness**

No cost-effectiveness studies were identified.

### **4.4 Other data sources (e.g. local audit reports)**

None identified.

### **4.5 Safety**

Transcutaneous BCHDs are not compatible with all types of MRI. Sophono product information provides the conditions in which MRI is considered safe but no information was available for Baha 4 Attract or Bonebridge.

#### **Sophono Alpha 1 – safety**

Eight case series reported on safety outcomes for Sophono Alpha 1 use. This included between 89 and 189 people (it is not clear if all complications were recorded for the one study with over 100 participants<sup>9</sup>). The main difficulty was pain and/or redness in the skin over the magnetic implant which was reported in 13 people. This resolved in eight people by using a lower magnet strength<sup>1,3,4,5,6,7</sup>. For the others, it did not resolve in one person who became a non-user<sup>4</sup>, one child continued to have pink skin with no pain<sup>5</sup> and one child had a new baseplate but this caused a pinpoint ulcer which was managed with a moleskin placement<sup>6</sup>. Two children had skin breakdown despite only using magnet strength of one<sup>6</sup>. One of them had skin necrosis and breakdown which required revision surgery and took six months to heal. The other had cellulitis and skin breakdown which took eight months to heal following treatment with antibiotic ointment, reduced magnet strength to zero and additional padding. There were also some cases (N not reported) of pressure over the implant which resolved with shimming<sup>9</sup>.

As the implant is metallic, there are concerns that it would prevent the ability to have an MRI scan. The Sophono company have outlined that MRI can be used for the newest model, Sophono Alpha 2 under the following conditions<sup>18</sup>:

- All external components should be removed including the Otomag Alpha Sound Processor, Magnetic Spacer, Headband or Softband before entering the MRI environment
- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum whole-body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled Mode for a maximum scan time of 15 minutes of continuous scanning (per pulse sequence).



**Table 5: Safety of Sophono Alpha 1**

<b>Study</b>	<b>Patients</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes</b>
Hol 2013 <sup>1</sup>  Netherlands, single centre  Comparative case series	12 children with congenital unilateral conductive hearing loss	Sophono Alpha 1 (N=6)	Cochlear BAHA BP100/Divino N=6	<b>Mean follow-up for Sophono 325 days (range 145 to 740 days). Mean follow-up for BAHA 592 days (range 194 to 1,190 days).</b>  <b>Complications:</b> no skin reactions, 1 BAHA implant lost, no Sophono implant losses. Minor pressure discomfort for 1 Sophono patient with magnet strength 3 (1.6N) which was fine when changed to magnet strength 2 (1.3N). Four other Sophono users then used magnet strength 2 (1.3N) and one used magnet strength 4 (1.9N).
Magliulo 2014 <sup>3</sup>  Germany, single centre  Case series	10 adults with subtotal petrosectomy for chronic middle ear disease	Sophono Alpha System 1 (N=10)	None	<b>Post-op assessment time not provided</b>  <b>Complications:</b> No adverse skin reactions and no implant losses. Discomfort pressure and mild pain (N=2) with magnet strength 3 resolved with strength 2.
Marsella 2014 <sup>4</sup>  Italy, single centre  Case series	6 children and adolescents with bilateral conductive (n=5) or mixed (n=1) hearing loss	Sophono (N=6)	None	<b>Assessed intra-operatively, after 1 and 2 weeks and after 1 and 2 months of Sophono use</b>  <b>Complications:</b> dura exposed during drilling, alternative position drilled (N=1). Skin ulceration (N=1) from using one level 4 magnet all day and at night, combined with incorrect application; following healing (45 days later) changed to level 2 and used for shorter periods. Pain and reddened skin (N=1), became a non-user.
Denoyelle 2013 <sup>5</sup>  France, single centre  Case series	6 children with high-grade ear atresia	Sophono Alpha 1 (N=6)	None	<b>Assessed during 12 to 19 months follow-up</b>  <b>Complications:</b> no surgical complications; slight skin redness (N=2) with magnet strength 2, resolved with strength 1 (N=1); pink skin with no pain after 18 months (N=1)
O'Neil 2014 <sup>6</sup>  US, single centre  Retrospective case series	10 children with aural atresia (N=7), or chronic ear disease and cholesteatoma (N=3)	Sophono (N=10, 14 ears)	None	<b>Assessed during 11.6 months follow-up (4.5 to 24 months)</b>  <b>Complications:</b> no surgical complications; significant pain and redness (N=5/14 ears). Of these, cellulitis or pressure necrosis with skin breakdown occurred (N=2 ears), despite magnet strength 1. Revision of surgery was required (N=1) and took 6 months to heal. In the other case (N=1), antibiotic ointment, reduced magnet strength to 0 and additional padding was

				required and it took 8 months to heal. In another case, a new baseplate caused a pinpoint ulcer which was managed with a moleskin placement. In the other 2 cases, reduced magnet strength to 1 (N=2).
Centric 2014 <sup>7</sup> US, single centre Retrospective case series	5 children with conductive (N=4) or sensorineural (N=1) hearing loss	Sophono Alpha 1 (N=5)	None	<b>Assessed during 4.8 months follow up (2.9 to 6.6 months)</b>  <b>Complications:</b> minor incision site infection (N=1), pressure over implant (N=1) improved with reduced magnet strength.
Siegert 2013 <sup>8</sup> Germany, single centre Follow-up case series	N=20 (14 children, 6 adults) with congenital atresia	Sophono (N=20)	None	<b>Assessed 0.2 to 46.6 months post-op</b>  <b>Complications:</b> None.
Siegert 2011 <sup>9</sup> Germany, single centre Case series	N>100, mostly due to congenital aural atresia.  Audiological follow-up N=12	Sophono (N>100)	None	<b>Post-op assessment time not provided</b>  <b>Complications:</b> Slight pressure marks in some cases (N not reported) which healed after shimming and slight force reduction of the base plates

#### Baha 4 Attract - safety

One small case series of 12 adults reported on safety of Baha 4 Attract and no major complications or safety concerns were identified<sup>10</sup>. Minor complications included a haematoma (N=1) which was treated with aspiration, skin erythema with pain (N=1) and pain (N=3) which resolved by reduced magnet strength. The product information does not recommend that MRI scan can be performed with the implant in place<sup>20</sup>.

**Table 6: Safety of Baha 4 Attract**

Study	Patients	Intervention	Comparator	Outcomes
Iseri 2014 <sup>10</sup> Turkey Case series	N=12, bilateral mastoidectomy (2 children, 9 adults) or bilateral aural atresia (1 child)	BAHA Attract (N=12)	None	<b>Complications:</b> haematoma (N=1), treated with aspiration. Skin erythema with pain (N=1), pain (N=3), all resolved by reduced magnet strength.

#### Bonebridge - safety

Four case series reported on safety of Bonebridge and no major complications or safety concerns were identified in the 24 participants<sup>11,12,13,14</sup>. All minor complications resolved spontaneously or with treatment including a haematoma near the implant (N=1), transient tinnitus (N=1), headache and vertigo (N=1), seroma (N=1) and a minor skin infection (N=1)<sup>11,14</sup>. The Bonebridge product information recommends that it is MRI conditional up to 1.5 Tesla<sup>19</sup>.

**Table 7: Safety of Bonebridge**

<b>Study</b>	<b>Patients</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes</b>
Hassepass 2014 <sup>14</sup>  Germany, single centre  Case series	3 adolescents with unilateral conductive hearing loss, (N=2) or SSD(N=1)	Bonebridge N=3	None	<b>Assessed during 6 months post op</b>  <b>Complications:</b> pressure sensitive haematoma near the caudal implant, resolved after treatment and speech processor could be used 6 weeks after operation (N=1)
Manrique 2014 <sup>12</sup>  Spain, single centre  Case series	5 adults with conductive/mixed hearing loss (N=4), or SSD (N=1)	Bonebridge N=5	None	<b>Post-op assessment time not provided</b>  <b>Complications:</b> None.
Sprinzl 2013 <sup>11</sup>  Germany and Austria, 4 hospitals  Case series	12 adults with conductive (N=7) or mixed (N=5) hearing loss	Bonebridge N=12	None	<b>Assessed at 3 months</b>  <b>Complications:</b> transient tinnitus (N=1), headache and vertigo (N=1), seroma (N=1), minor skin infection (N=1), all resolved with treatment
Barbara 2013 <sup>13</sup>  Italy, single centre  Case series	4 adults with mixed hearing loss	Bonebridge N=4	None	<b>Assessed over 6 months</b>  <b>Complications:</b> None

**SoundBite - safety**

Four case series reported on the safety of SoundBite and no major complications or safety concerns were identified<sup>15,16,17,21</sup>. This included fifty-six adults who were assessed over a six month period<sup>16,17,21</sup>. Eight of them had minor soft tissue indentations on the palate similar to that seen in people who wear dentures but this was not considered to be clinically significant<sup>16</sup>. One person had minor mouth soreness, which was diagnosed as a fungal infection and resolved with treatment<sup>17</sup>.

**Table 8: Safety of SoundBite**

<b>Study</b>	<b>Patients</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes</b>
Murray, Popelka et al 2011 <sup>15</sup>  US, multicentre  Case series	28 adults with acquired single sided deafness	SoundBite N=28	Unaided	<b>Assessed at 30 days</b>  <b>Complications:</b> None

Murray, Miller et al 2011 <sup>16</sup>  US, multicentre  Case series	22 adults with acquired single sided deafness	Teeth with SoundBite attached N=22	Unaided	<b>Assessed during 6 months follow up</b>  <b>Complications:</b> Minor temporary soft tissue changes similar to those seen in people wearing dentures (N=8) with SoundBite use.
Miller 2011 <sup>21</sup>  US, single centre  Case series	22 adults with acquired single sided deafness	SoundBite N=22	Unaided	<b>Assessed at 6 months</b>  <b>Complications:</b> Minor soft tissue indentations on the palate similar to those seen in people wearing dentures (N=5) with SoundBite use. No change in periodontal pocket depth, or gingival recession, alveolar support or root resorption.
Gurgel 2013 <sup>17</sup>  US, multi-centre  Case series	34 adults with unilateral acquired sensorineural hearing loss	SoundBite N=34	Unaided N=34	<b>Assessed during 6 months follow up</b>  <b>Complications:</b> minor mouth soreness (N=1), diagnosed as a fungal infection and resolved with treatment.

#### 4.6 Summary of section 4

No systematic reviews, meta-analyses or randomised controlled trials were identified. One cross-over study and 17 case series met the inclusion criteria but all were small. One study had a control group, all of the others compared the same individual either before and after the device was fitted or with and without the aid at the time. All studies were of poor quality thus there is insufficient evidence to draw firm conclusions.

Transcutaneous BCHD versus percutaneous BAHA was evaluated in one small comparative case series using Sophono<sup>1</sup>. Six children who had a percutaneous BAHA BP100/Divino had marginally better audiological outcomes than six children fitted with Sophono but this was not reported to be statistically significant. Pure Tone Audiometry (PTA) was 33 dB vs 36 dB (p=NR), Speech Recognition Threshold (SRT) 23 dB vs 30 dB (p=NR) and Word Recognition Score (WRS) at 65 dB, 91% vs 84% (p=NR). Both devices were significantly better than unaided.

Transcutaneous BCHD was compared to a conventional BCHD (hearing glasses or using a headband) in three case series involving 10 adults and twelve children and adolescents. In two studies, Sophono was better for PTA (42.1 dB HL Sophono vs 53.6 dB HL conventional BCHD [p<0.0001])<sup>3</sup>, (32.5 dB HL Sophono vs 38 dB HL conventional BCHD [p=NR])<sup>4</sup> and equivalent in one (28.5 dB Sophono vs 29.5 dB with headband BCHD [p=NR])<sup>5</sup>. SRT was better with Sophono in one study (SRT was 38 dB Sophono vs 45 dB conventional BCHD [p<0.01])<sup>3</sup>. Speech perception was also better with Sophono in two studies, again using different measurements (WRS at 65 dB 87.1% Sophono vs 78% conventional BCHD [p<0.01])<sup>3</sup>, (speech perception score was 93% Sophono vs 89% conventional BCHD [p=NR])<sup>4</sup>. Quality of life was improved according to the General Benefit Inventory (GBI) and Glasgow Children's Benefit Inventory (GCBI)<sup>3,4</sup>.

Sophono was significantly better for PTA and SRT than unaided hearing in eight case series involving 53 children, 16 adults and 12 people of unreported age, with aural atresia, chronic ear disease, conductive, sensorineural or mixed hearing loss<sup>1,3,4,5,6,7,8,9</sup>.

BAHA 4 Attract had a significantly better free-field hearing threshold of 26 dB versus 45 dB unaided, ( $p<0.001$ ) and free-field speech recognition improved to 37 dB compared to 56 dB with no intervention ( $p<0.001$ ) in one case series of nine people with bilateral mastoidectomy<sup>10</sup>.

Bonebridge was compared to unaided hearing in four small case series of 21 adults and three adolescents with single sided deafness (SSD), conductive or mixed hearing loss. Bonebridge improved PTA in two studies (31.25 dB vs 66.87 dB unaided [ $p<0.001$ ])<sup>12</sup>, (35 dB Bonebridge vs 71.5 dB unaided [ $p=NR$ ])<sup>13</sup>. One study found WRS in 65dB background noise was better with Bonebridge (92.9% Bonebridge vs 14.2% unaided [ $p=NR$ ])<sup>11</sup> and one study found word discrimination in quiet improved with Bonebridge (86.2% vs 66.2% unaided [ $p=0.016$ ])<sup>12</sup> and another study found SRT improved with Bonebridge (41.25 dB vs 77.5 dB unaided [ $p=NR$ ])<sup>13</sup>. Two studies found Bonebridge was better than unaided for SRT for understanding 50% of speech (36.6 dB Bonebridge vs 61.9 dB unaided [ $p<0.001$ ])<sup>11</sup>, (29 dB compared to 53.5 dB unaided [ $p=NR$ ])<sup>14</sup>. In one study, participants were positive about Bonebridge in their responses on the Hearing Device Satisfaction Scale, with average satisfaction of 79% (range 49% to 99%)<sup>11</sup>.

SoundBite versus percutaneous BAHA was evaluated in one small cross-over study of nine adults who had already been fitted with a percutaneous BAHA device and so may have been subject to bias<sup>2</sup>. Hearing threshold was 10dB better using SoundBite ( $p=NR$ ) but there was no difference between them for speech localisation or speech perception in babble. A significantly positive response was reported for SoundBite compared to the percutaneous BAHA on each subscale of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, namely ease of communication (EC), listening in reverberation (RV), listening with background noise (BN) or aversiveness (AV), ( $p<0.05$ ). No studies were found that compared SoundBite with a conventional BCHD. SoundBite gave clinically significant benefit over unaided hearing in three small case series according to the APHAB score which was between 64% and 77%<sup>15,16,17</sup>.

No cost-effectiveness studies were identified.

In terms of safety, transcutaneous BCHD are not compatible with all types of MRI. The product information for Sophono outlines which MRI conditions are safe, and Bonebridge can be used up to 1.5 Tesla but MRI should not be used with Baha 4 Attract. The main safety issue identified for transcutaneous BCHDs was pain and/or redness in the skin over the magnetic implant which was reported in 17 people. This was resolved in 12 people by using lower magnet strength but it did not resolve in one person who became a non-user, one child continued to have pink skin with no pain and one child had a new baseplate but this caused a pinpoint ulcer which was managed with a moleskin placement. Two children had skin breakdown despite only using magnet strength of 1, and this took either revision surgery or other measures to heal over six to eight months. No major complications occurred in the users of SoundBite though mild palate indentations occurred in eight people akin to that seen with denture use.

## 5 Cost and Activity

According to the Hospital Episode Statistics (HES) data for 2012/13, there were 1,265 “attachments of bone anchored hearing prosthesis” performed in English NHS Hospitals and English NHS commissioned activity in the independent sector<sup>27</sup>. No further data available at the time of writing.

## 6 Equity issues

None identified.

## 7 Discussion and conclusions

1. Are the following bone-conduction hearing devices:

- (i) transcutaneous e.g. Sophono, BAHA 4 Attract, (ii) Bonebridge, (iii) SoundBite

clinically effective in people with hearing impairment compared with no intervention or with any other hearing device?

The transcutaneous bone conduction hearing devices Sophono, BAHA 4 Attract and Bonebridge appear to be clinically effective compared to no intervention, but this is based on a few, small studies. PTA improved by between 19 dB and 43 dB, SRT improved by 19 dB to 36.25 dB and WRS at 65 dB improved by between 59.2% to 84.1%. Quality of life improvements ranged from +42 on GBI, +45 on GCBI and 79% on HDSS. No studies were identified of high enough quality to determine their clinical effectiveness compared to any other hearing device. Safety issues include MRI limitations and potential to cause pain and damage to the skin overlying the implant.

SoundBite was found to be clinically effective in three small case studies according to subjective questionnaire results, the APHAB score was between 64% and 77%, but objective audiological evidence was either inconsistent or lacking. No studies were identified of high enough quality to determine their clinical effectiveness compared to any other hearing device. No major safety concerns were reported in the limited case studies identified.

2. Are the following bone-conduction hearing devices:  
(i) transcutaneous e.g. Sophono, BAHA 4 Attract, (ii) Bonebridge, (iii) SoundBite cost-effective in people with hearing impairment compared with no intervention or with any other hearing device?

No cost-effectiveness studies were identified.

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## 9 Search Strategy

Medline, Embase, Cochrane, TRIP and NICE Evidence Search were searched from 2004 onwards. Letters, editorials, conference abstracts, case reports, cadaver studies, studies in normal hearing and laboratory studies were all excluded.

The search strategy for Medline was:

1. hearing disorders/ or exp hearing loss/
2. deaf\*.ti,ab.
3. (hearing adj3 (loss or disorder? or difficult\* or impair\*)).ti,ab.
4. 1 or 2 or 3
5. Bone Conduction/ and Hearing Aids/
6. (bone anchor\* adj5 (aid? or device? or implant\* or system?)).ti,ab.
7. (bone conduct\* adj5 (aid? or device? or implant\* or system?)).ti,ab.
8. ((osseointegrat\* or osseo-integrat\*) adj5 (aid? or device? or implant\* or system?)).ti,ab.
9. baha?.ti,ab.
10. (ponto or bonebridge or alpha system? or SoundBite or sophono).ti,ab.
11. 5 or 6 or 7 or 8 or 9 or 10
12. 4 and 11
13. (bone conduct\* adj5 (hearing aid? or hearing device? or hearing system\* or hearing implant\*)).ti,ab.
14. (bone anchor\* adj5 (hearing aid? or hearing device? or hearing system\* or hearing implant\*)).ti,ab.
15. ((osseointegrat\* or osseo-integrat\*) adj5 (hearing aid? or hearing device? or hearing system\* or hearing implant\*)).ti,ab.
16. (bone conduct\* and (aid? or device? or system\* or implant\*)).ti.
17. (bone anchor\* and (aid? or device? or system\* or implant\*)).ti.
18. ((osseointegrat\* or osseo-integrat\*) and (aid? or device? or system\* or implant\*)).ti. and (hearing or deaf\*).ti,ab.
19. 12 or 13 or 14 or 15 or 16 or 17 or 18
20. limit 19 to english language
21. limit 20 to "reviews (maximizes specificity)"
22. limit 20 to "therapy (maximizes sensitivity)"

The search identified 228 studies which were sifted at abstract level by two analysts using the following inclusion/exclusion criteria. Twenty-seven of them were then assessed at full text and 18 studies were relevant to be included in this review.

### Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Meta-analyses Systematic reviews Randomised controlled trials Prospective non-randomised clinical study Other clinical study including retrospective case series Health economics studies Abstracts were excluded if transcutaneous bone-conduction hearing devices or SoundBite were not explicitly mentioned Studies published as abstract only (eg conference poster) were excluded
Patients	Children and adults with hearing impairment
Intervention	Bone-conduction hearing devices specifically: <ol style="list-style-type: none"> <li>(i) transcutaneous devices e.g. Sophono1, BAHA 4attract1</li> <li>(ii) Bonebridge*</li> <li>(iii) SoundBite*</li> </ol>
Comparators	No intervention Any other hearing devices including:

	<ul style="list-style-type: none"> <li>• air-conduction hearing aids;</li> <li>• other bone-conduction hearing aids e.g. percutaneous devices BAHA<sup>*</sup>, Oticon<sup>*</sup></li> </ul>
Outcome	<p>Any, including:</p> <ul style="list-style-type: none"> <li>• Successful implantation</li> <li>• Hearing quality (e.g. hearing threshold, sound localisation)</li> <li>• Quality of life, patient satisfaction</li> <li>• Functional outcomes (e.g. educational/learning outcomes)</li> <li>• Complications, Extrusion rates, Revision rates</li> <li>• Survival of device/its components</li> <li>• Cost/cost-effectiveness</li> </ul>
Language	English only

<sup>\*</sup>Registered trade names