BONE-CONDUCTION HEARING DEVICES IN PEOPLE WITH HEARING IMPAIRMENT

QUESTIONS TO BE ADDRESSED:

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

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

SUMMARY:

Background

- Conventional external hearing aids can be generally subdivided into air-conduction hearing aids and bone-conduction hearing aids. Air-conduction hearing aids require the use of ear moulds, which may be problematic in patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mould. Bone-conduction hearing aids function by transmitting sound waves through the temporal bone directly to the inner ear (cochlea).
- Bone-conduction hearing aids are indicated for patients with conductive hearing loss, mixed hearing loss and single–sided deafness (SSD).
- Bone-conduction hearing devices (BCHDs) can be categorized as direct-drive, skin-drive, and in-the-mouth (e.g. SoundBite). The direct-drive devices are either percutaneous (e.g. BAHA®) and active transcutaneous devices (BCI and Bonebridge™), while the skin-drive devices are divided into conventional (external devices on softband, spectacles or steel spring) and passive transcutaneous devices (e.g. Sophono® Alpha 1 and BAHA® attract).
- External devices may be associated with either pressure headaches or soreness and percutaneous devices with complications such as skin reaction, skin growth over the abutment and wound infection, for this reason the trend in BCHDs is towards transcutaneous devices, where the skin is kept intact.

Clinical Effectiveness

- We identified eight unrandomised controlled studies of the effectiveness of BAHA® attract and Sophono® Alpha; two of these studies compared both devices with each other; three studies compared either BAHA® attract or Sophono® Alpha with other devices and three studies were before and after studies (pre- and post-implantation) of either device.
- The two studies that compared BAHA® Attract and Sophono® Alpha (n=17; n=12) found that both devices are more effective than the unaided situation and there was no difference in aided thresholds or speech discrimination scores between the two devices. However, these studies were small retrospective studies.

- One retrospective study (n=37) compared percutaneous BAHA® and BAHA® Attract and found that both devices were effective in the rehabilitation of hearing loss but better results were observed with the percutaneous device. Another comparative study (n=15) reported that Sophono® Alpha was non-inferior to percutaneous BAHA®. In a crossover study (n=18), Sophono® Alpha was also found to be no better than the contralateral routing of signal (CROS) hearing aid.
- Three studies (one of Sophono® Alpha and two of BAHA® Attract) (n=10; n=10; n=27)) found the two devices to be better than unaided situations in terms of aided thresholds, speech discrimination scores as well as quality of life outcomes.
- We did not find any studies that compared Bonebridge™ to other hearing devices. We identified a systematic review of 18 uncontrolled studies on Bonebridge™ (n=190) and three further uncontrolled studies (n=11; n=9; n=23) published after the search date for the systematic review. Improvements with Bonebridge™ were reported on a range of outcomes by all studies; however the interpretation of these improvements was complicated by missing information, for example on the comparators used and statistical significance of some of the results.
- One study of the use of SoundBite™ (n=127) found that the device had no effect on hearing threshold but improved APHAB[1] scores compared with the unaided situation.
- Generally, the studies of BAHA® Attract, Sophono® Alpha, Bonebridge™ and SoundBite™ led to improvements in patients with various types of hearing loss. However these findings are limited by the paucity of high-level evidence; all the studies were small, unrandomised studies, many of them retrospective, and subject to bias.

Cost Effectiveness

- We did not identify any studies assessing the cost-effectiveness of BCHDs.

Safety

- Safety outcomes were not well reported in the identified studies of BAHA® attract and Sophono® Alpha. Temporary skin erythema, infection along the incision, pain and tingling around implant were the most common problems associated with these devices. Headache and magnet falling off have also been experienced by patients implanted with BAHA® attract and Sophono® Alpha.
- Nine of 12 studies in the systematic review reported no adverse events with Bonebridge™. Adverse events reported for individual patients included wound-related issues, tinnitus, headache, vertigo and seroma.
- Minor device-related adverse effects associated with the use of SoundBite™ include pain, infection and discomfort issues with eating. No major events were reported with the use of SoundBite™.

1 Context

1.1 Introduction

Hearing [1]

The human ear has three main parts:

- the outer ear (which includes the visible, external ear, the auditory canal and the tympanic membrane or eardrum)

[1] The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a self-report questionnaire that is used to quantify the impact of a hearing problem on an individual's daily life.

- the middle ear (an air-filled space that contains the three small bones of the ossicular chain: the malleus, incus and stapes)
- the inner ear (cochlea, vestibule, and semicircular canals).

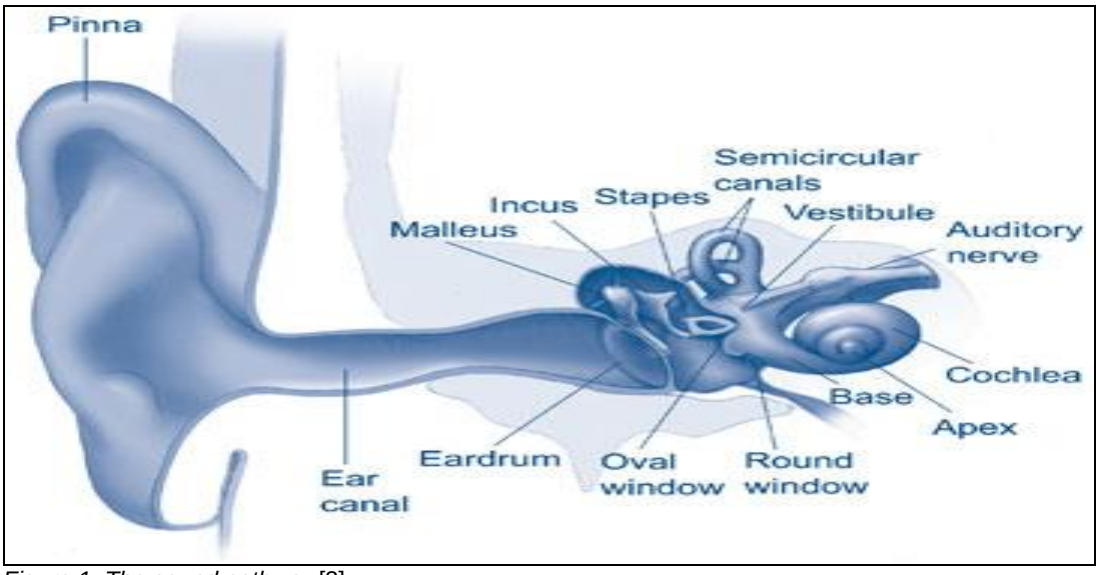


Figure 1: The sound pathway [2]

Hearing begins with the outer ear funneling sound waves towards the middle ear. When the sound waves reach the middle ear, they cause vibrations of the bones of the ossicular chain. These vibrations move cochlear fluid and hair cells within the inner ear, generating electrical signals that are transmitted to the brain via the auditory nerve and interpreted as sound [2]. Sound can be transmitted to the cochlea in two ways: by air conduction (through the auditory or ear canal), and by bone conduction (through the mastoid bones of the skull) [3].

Hearing loss

Hearing loss is diagnosed using auditory tests that compare the patient's air conduction and bone conduction hearing levels across different frequencies (high and low pitches) and thresholds (decibels) [1;4]. For people with normal hearing the minimal audible level (threshold) of a tone is less than 20 dB across all frequencies. People with higher thresholds are considered to have hearing loss, which may be classified into mild, moderate, severe and profound hearing loss (Table 1).

Table 1: Classification of hearing impairment by hearing threshold [5]

Hearing threshold (dB)	***Level of hearing impairment***
0-15	Normal hearing (children)
0-25	Normal hearing (adults)
15-25	Minimal hearing loss (children)
26-40	Mild hearing loss
41-55	Moderate hearing loss
56-70	Moderate-severe hearing loss
71-90	Severe hearing loss
91+	Profound hearing loss

The main types of hearing loss are:

- Sensori-neural hearing loss (SNHL) is the most common form of hearing loss [6;7]. It occurs where there is damage to the hair cells of the cochlea (sensory) or to the nerve pathway from the inner ear to the brain (neural). SNHL may be congenital (present at birth) or acquired and

is usually permanent. SNHL can be caused by damage or malformation of the cochlea and the sensitive hairs, exposure to excessive noise, vestibular schwannomas[2], viral infections, temporal bone fractures, Meniere's disease, ototoxic medications and the ageing process.
- Conductive hearing loss (CHL) occurs when sound is not conducted efficiently from the external auditory canal (EAC) to the middle ear. This is generally caused by a blockage or damage in the outer or middle ear (or both) and may be transient or permanent.
- Mixed hearing loss (MHL) occurs when both sensori-neural and conductive hearing loss are present.
- Central hearing loss is caused by damage to the central nervous system that affects the processing of auditory signals.

Sometimes, hearing loss is categorised by its cause. For example, age-related hearing loss is usually (in 90% of cases) caused by SNHL due to gradual damage to the hair cells of the inner ear over time [6]. Noise-related hearing loss is the second most common form of SNHL [8]. It is caused by occupational or recreational exposure to noise, such as loud music, motorcycles or the use of firearms. Hearing loss can also be described as bilateral or unilateral (single-sided); bilateral hearing loss is hearing loss in both ears while unilateral (UHL) or single-sided is when hearing is normal in one ear but there is hearing loss in the other ear. The hearing loss can range from mild to very severe. Either of these can occur in both adults and children.

Management of hearing loss

The management of hearing impairment will depend on the underlying cause. Options intended to improve quality of life include sign language, hearing aids, middle ear implant, cochlear implant or auditory brain stem implant [9].

Hearing aids

Conventional external hearing aids can be generally subdivided into air-conduction hearing aids and bone-conduction hearing aids.

Air conduction hearing aids: A conventional hearing aid is an electro-acoustic device that typically fits in or behind the wearer's ear, or worn on the body (clipped to clothing). It is designed to amplify and modulate sound for the wearer. More modern devices can fit in the wearer's ear canal and digital technology has enhanced sound processing [9;10].

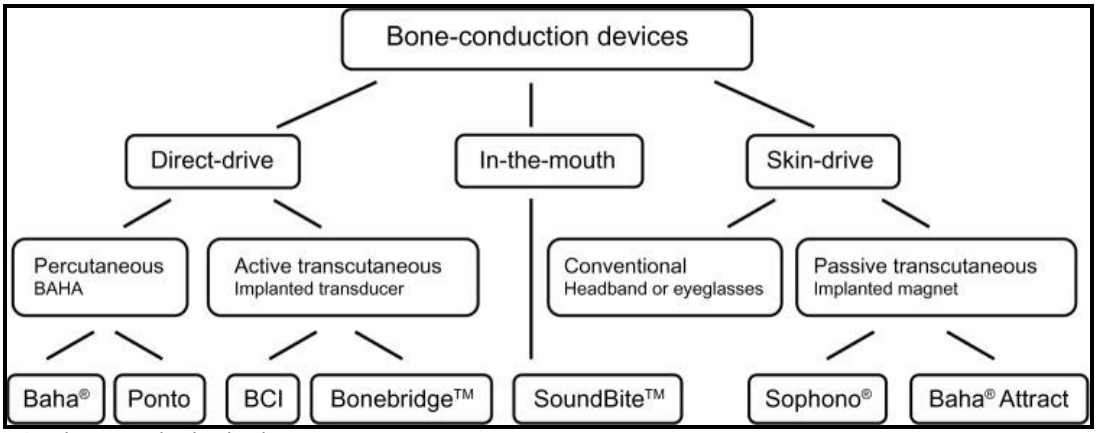
Bone-conduction hearing aids: Bone-conduction hearing aids are indicated for patients with conductive hearing loss, mixed hearing loss and single–sided deafness (SSD)[3] [11]. These function by transmitting sound waves through the temporal bone directly to the inner ear (cochlea).

Bone-conduction hearing devices (BCHDs) can be categorized as direct-drive, skin-drive, and in-the-mouth (e.g. SoundBite™). The direct-drive devices are either percutaneous (e.g. BAHA®) or active transcutaneous devices (BCI and Bonebridge™), while the skin-drive devices are divided into conventional (external devices on softband, spectacles or steel spring) and passive transcutaneous devices (e.g. Sophono® Alpha 1 and BAHA® attract). See figure 2 for categoriszation.

The external devices must be closely applied to the temporal bone, with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness. Also because of complications

[2] benign primary intracranial tumour of the myelin-forming cells of the vestibulocochlear nerve (8th cranial nerve)
[3] Single-sided deafness (SSD) or unilateral hearing loss (UHL) is a type of hearing impairment where there is normal hearing in one ear and impaired hearing in the other ear.

associated percutaneous devices such as skin reaction, skin growth over the abutment and wound infection, there is a trend towards transcutaneous BCHDs, where the skin is kept intact. [11; 12].



BCI – bone conduction implant

Figure 2: Categorisation of bone-conduction hearing devices

1.2 Existing national policies and guidance

We did not identify any guidance from the National Institute of Health and Care Excellence on bone-conduction hearing devices.

2 Epidemiology

It is estimated that there are approximately ten million people in the UK with a hearing impairment [13]. The prevalence of deafness by severity is shown in table 2. The prevalence of deafness varies with the age of the individual. The prevalence of a permanent hearing loss is one in 1000 for newborn children and two in 1000 for children aged 9 to 16 years [14]. The increase in prevalence with age is related to later diagnosis, late onset or progressive hearing loss.

Table 2: Estimated prevalence of hearing impairment in the UK population [14]

Classification	Prevalence in population	Numbers in the UK
Mild/slight	16.1%	7.6 million
Moderate	4.9%	2.3 million
Severe	1%	0.5 million
Profound	0.4%	About 200,000

The Royal National Institute for the Deaf reported that approximately 2 million people in the UK wear a hearing aid [14].

3 The intervention

Transcutaneous devices

Sophono® (Boulder, CO, USA) is a partially implantable bone-conduction hearing aid without a percutaneous abutment. It uses a retention magnet system where two magnets are implanted in the temporal bone, and fixated by five small titanium screws, and the sound processor is attached on the outside of the skin by magnetic attraction force. The vibrations of the transducer are

transmitted through the soft tissues, and the skin is most often thinned to 4–5 mm thickness (only in adults). In order to overcome skin problems related to high skin pressure, the Sophono® Alpha 1 uses a larger contact area than is used in conventional BCHDs. In this way, the static force is distributed over a larger area, which alleviates the skin compression that might lead to circulatory problems [12].

BAHA® Attract system got the CE mark and was cleared by the Food and Drug Administration at end of 2013, and has since then been available on the EU and US markets. The system consists of an implant magnet placed on the inside of the intact skin and this is attached to the skull bone with a screw. The BAHA® sound processor is then attached to a magnet plate on the skin via a soft pad to equalize the force distribution over the attachment surface [12].

The Bonebridge™ implant is a semi-implantable transcutaneous hearing system with two parts. The implantable part contains a magnet that holds the external audio processor in place and transmits the signal through a coil to the internal part [11].

SoundBite™ by Sonitus Medical (San Mateo, CA, USA) was developed mainly for SSD patients. A microphone is placed behind the ear on the deaf side, and the sound is sent wirelessly to an in-the-mouth transducer, transmitting vibrations to the upper back teeth. These vibrations are transmitted to the skull bone and received by the healthy cochlea. In this way, the healthy cochlea hears the sound from both sides [12].

4 Findings

A search of Medline, Embase, Cochrane Library, TRIP and NICE Evidence was performed on the 6th November 2015 for studies published in English in the last two years. Case reports, conference papers, letters and commentary were excluded. Details of the search strategy are provided in Section 7.

This topic was previously reviewed in 2014 [15]. Papers included in the previous review (search conducted 12th August 2014) are not included in this review.

Transcutaneous devices

BAHA® attract and Sophono® Alpha 1

We identified eight unrandomised controlled studies (with a total of 146 patients) of the effectiveness of BAHA® attract and Sophono® Alpha [16-23]. Two studies compared both devices with each other; three compared either BAHA® attract or Sophono® Alpha with other devices and three compared either device pre- and post-implantation.

Bonebridge™

We identified a 2015 systematic review on Bonebridge™ [24] which included 18 uncontrolled studies published up to June 2014. This review included both published studies and conference abstracts. Only the 18 studies considering the effectiveness and safety of Bonebridge™ are included. Other studies considering imaging or modelling methods or audio processor settings are not included in this review. We also identified three uncontrolled studies [25-27] on Bonebridge™ published after the search date of the systematic review.

SoundBite™

We identified one uncontrolled study of SoundBite™ [28].

4.1 Evidence of effectiveness

Outcomes measured

Functional gain (in dB) is a measure of benefit provided by the device and was the primary outcome in most studies. It is calculated by determining the difference between the unaided preoperative and aided postoperative pure-tone average[4] thresholds.

Speech outcomes were measured in a variety of standardised ways. For example, a 'speech detection level' is the softest level at which a person detects (rather than understands) speech sounds, whereas 'speech intelligibility in quiet' is determined using monosyllabic words presented at the conversational level (between 40-65 dB SPL). One error is counted each time an element is mispronounced or not repeated.

A variety of *patient related outcome* tools and scales are used. For example a 'Glasgow Benefit Inventory' was developed for otorhinolaryngological interventions and measures a patient's change in health status on an 18-item questionnaire completed by the patient. The Hearing Device Satisfaction Scale, Hough Ear Institute Profile and the Gothenburg Profile were used amongst others.

4.1.1 Evidence of effectiveness of Sophono® Alpha and BAHA® Attract

Comparisons of BAHA® attract with Sophono® Alpha 1(results are summarised in Table 3)

Baker et al [16] conducted an unrandomised controlled study involving retrospective chart review to compare the results of the effectiveness of two abutment-free devices (Sophono® and BAHA® attract) and examine their complication rates. The first eleven Sophono® implanted patients and the first six patients implanted with the BAHA® Attract at a single centre were included in the study. The study found improvements in both pure-tone averages (PTA); 41 and 37 dBHL and speech reception threshold[5] (SRT); 56 and 39 dBHL for BAHA® Attract and Sophono® Alpha 1 over unaided respectively. However, there was no difference between the two devices when the PTA (p=0.68) and SRT (p=0.56) data were directly compared. They also reported a lower complication rate for these abutment-free devices compared with devices featuring abutment.

Powell et al [17] compared audiologic and quality of life questionnaire outcomes (author-designed questionnaire) for two transcutaneous bone-conduction implants (Sophono® and BAHA® attract) in an unrandomised controlled study of 12 patients. The authors found no difference in aided thresholds or speech discrimination scores between the two transcutaneous bone-conduction devices.

Both of these studies were very small.

Comparison of BAHA® attract with other devices (results are summarised in Table 3)

Iseri et al [18] reported their findings from an unrandomised controlled multi-centre study of BAHA® and the BAHA® Attract System (n=37). Both groups had some minor complications such as skin irritations around the abutment and skin erythema over the magnet. Both groups benefited from the devices audiologically; however, when the groups were compared, better results were observed in the percutaneous bone-conduction group.

Comparisons of Sophono® Alpha 1 with other devices (results are summarised in Table 3)

Denoyelle et al [19] carried out an unrandomised controlled trial to study gain and cutaneous tolerance of the Sophono® Alpha 1 implant, used for unilateral hearing rehabilitation in 15 children with ear atresia, and to demonstrate non-inferiority compared to BAHA® on a test-band.

[4] The pure-tone average should approximate the speech reception threshold.
[5] The minimum intensity in decibels at which a patient can understand 50% of spoken words

The authors reported that the Sophono® Alpha 1 implant was non-inferior to the BAHA® on a test-band.

Laterme et al [20] carried out a crossover study to compare a contralateral routing of signal (CROS) hearing aid to a transcutaneous bone-anchored device (Sophono®) in 18 adult patients with a single-sided deafness (SSD). After a trial period of 60 days with CROS and seven days with Sophono Alpha 1 on a headband, 13 (72%) patients opted for Sophono® Alpha 1, two patients for CROS, and three rejected both rehabilitation methods. Audiological and quality of life (Glasgow Benefit Inventory, Abbreviated Profile of Hearing Aid Benefit and Glasgow Hearing Aid Benefit questionnaires) outcomes were measured at three and 12 months after the implantation. Both devices were found to improve these outcomes to the same extent.

Magliulo et al [21] assessed Sophono® Alpha System hearing aids in ten patients suffering from recurrent chronic middle ear disease who underwent subtotal petrosectomy. Audiometric tests were performed before and after Sophono® implantation and using a conventional hearing aid. Speech audiometry data (speech recognition threshold and word recognition score) were also collected. The study found that the hearing results showed better outcomes with the Sophono® Alpha System compared with unaided (mean PTA $p<0.0001$; mean SRT and WRS $p<0.001$) and the conventional bone-conduction aid ($p<0.05$).

These findings should be interpreted with caution as direct comparisons with the other devices were not carried out. The patient populations compared may be different in terms of need and preference (no randomisation was carried out) therefore the findings may not be generalisable.

Comparisons of BAHA® attract with unaided condition (results are summarised in Table 3)

Carr et al [22] assessed audiological and quality of life outcome measures of hearing rehabilitation of ten patients using the BAHA® Attract (n=10). The study found improvements in the Glasgow benefit inventory (GBI) scores post-implantation compared with pre-implantation in previously aided patients ($p=0.003$). However, there was no improvement in the audiological outcomes using word discrimination scores.

The main limitation of this study is that only preliminary results of this novel device were reported in a few patients with relatively short duration of follow-up.

Briggs et al [23] prospectively evaluated the clinical performance of the BAHA® Attract System in a multi-centre setting. A total of 27 adult patients with a conductive or mild mixed hearing loss or single-sided sensorineural deafness were included in the study. Patients were followed for nine months after implantation. The study evaluated efficacy in terms of hearing performance compared with unaided hearing and with hearing with the sound processor (SP) on a Softband. The study showed improvements in PTA ($p<0.0001$) and APHAB scores at 9 months (global score $p=0.038$, background noise $p=0.035$, reverberation $p=0.016$) compared with pre-operative unaided hearing. Speech recognition was similar or better than tests performed with the same SP on a Softband. Good soft tissue outcomes were reported, without major pressure-related complications.

The findings should be interpreted with caution as they do not relate to relative effectiveness compared to other devices. The studies were also very small therefore the results may not be generalisable.

4.1.2 Evidence of effectiveness of Bonebridge™

The results of the Bonebridge™ studies are presented in Table 4.

In a systematic review of 18 uncontrolled studies, Sprinzl and Wolf-Magele [24] assessed the effectiveness of Bonebridge™ in 190 adults and children with conductive, mixed or single-sided deafness. For patients with conductive and mixed deafness the review reported improvements in functional gain, speech perception in quiet and 50% speech reception threshold. Improvements in word recognition were also reported with improvements maintained at follow-up or 12 months or more. For single-sided deafness, improvements were reported in word and speech recognition. However, a limitation of this review is that the comparator for the reported improvements was not clearly stated and statistical significance for any changes was not reported. It is therefore difficult to interpret these results.

Rahne et al [25] was a retrospective review of 11 patients with conductive or mixed hearing loss receiving Bonebridge™. They reported improvements in sound-field threshold compared to unaided pre-operative scores, improvements in word recognition compared to best-aided pre-implantation scores and improvements in hearing in a noisy environment and angle detection error compared to unaided.

Laske et al [26] was a prospective review of nine patients with single-sided deafness receiving Bonebridge™. Improvements were reported in functional benefit in noise and speech understanding in noise compared to unaided.

Riss et al [27] was a retrospective review of 23 patients with combined hearing loss, atresia or single-sided deafness receiving Bonebridge™. Improvements were reported in, word recognition in quiet, when compared to unaided, but no difference in functional gain was reported.

These three small uncontrolled studies reported improvements in a range of outcomes compared to unaided or best-aided pre-implantation scores. No studies compared Bonebridge™ to other hearing devices.

4.1.3 Evidence of effectiveness of SoundBite™

In a prospective, multi-site study, Gurgel et al [28] assessed the safety and effectiveness of the SoundBite™ in patients with SSD (see Table 5 for summary). After fitting, patients were instructed to use the device regularly and then complete questionnaires after six and 12 months. At the end of the trial period, patients completed both a self-assessment and the abbreviated profile of hearing aid benefit[6] (APHAB) questionnaires. A total of 81 subjects completed the study. The authors reported that hearing thresholds remained the same throughout the study. They also reported that APHAB results showed a significant benefit ($p < 0.001$) in categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed a high satisfaction among participants, with 93.8% of patients likely to recommend the device. Dissatisfaction was highest with regard to patient's ability to eat with device, with only 55.6% satisfied. No serious adverse events were reported during the study.

The authors of the study only present patient-reported outcomes which are subject to bias by nature. Also without a control arm, it is difficult to draw any firm conclusions.

[6] The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a self-report questionnaire that is used to quantify the impact of a hearing problem on an individual's daily life.

Table 3: Summary of evidence on BAHA attract and Sophono devices

Study	Population	Intervention	Comparator	Results
Baker et al 2015 [16] Retrospective case series Single centre USA	Children with conductive, sensorineural, mixed hearing loss and SSD n= 17 Mean age at implantation =10.7 years (SD for Sophono® group = 3.3 BAHA® attract =4.5)	Transcutaneous BAHA® attract n=6	Transcutaneous Sophono® Alpha n= 11	**PTA** improvement (BAHA attract vs. Sophono) 41 dB HL vs. 37 dB HL p= 0.6811 **SRT** improvement (BAHA attract vs. Sophono) 56 dB HL vs. 39 dB HL p= 0.5626
Powell et al 2015 [17] Retrospective study Australia	Children & adults with conductive, sensorineural, mixed hearing loss and SSD n= 12	Transcutaneous BAHA® attract n=6	Transcutaneous Sophono® Alpha n= 6	**Mean aided thresholds** – NS **Speech discrimination scores in quie**t; NS p=0.33 **Speech discrimination scores in noise**; NS p=0.87
Iseri et al 2015 [18] Multicentre retrospective study Turkey	Children and adults with conductive hearing loss n= 37	Percutaneous BCI n= 21 Mean age =38±14.5 years	Transcutaneous BAHA® attract n= 16 Mean age =28±17.2 years	**Audiometric data (pBCI vs. tBCI)** Mean hearing gain with SRT = 36.7 dB vs. 24.0 dB p=0.02 in favour of pBCI Mean hearing gain with FsHT = 32.9 dB vs. 31.0 dB p=0.38 **GBI score (pBCI vs. tBCI)** Total Glasgow score = 42.7 vs. 40.5 p=0.56
Denoyelle et al 2015 [19] Prospective study Single centre France	Children with SSD n= 15 Median age = 97 months Range = 61 to 129 months	Transcutaneous Sophono® Alpha	Percutaneous BAHA®	**At 6 months** Sophono: Mean aided ACPTA = 33.49±4.89 dB BAHA: Mean aided ACPTA = 32.89±5.86 dB Mean difference = 0.60 ± 6.91 (95% Confidence interval -3.22 to 4.42) Sophono non-inferior to BAHA® since this value was lower than the priori defined non-inferiority margin (i.e. 8.25 dB)

Leterme et al 2015 [20] Prospective crossover study Multicentre France	Adult patients with SSD n= 18	Transcutaneous Sophono® Alpha 1 n= 13	CROS hearing aid n= 18	NS
Magliulo et al 2015 [21] Uncontrolled study Italy	Adult patients who have undergone petrosectomy n= 10 Mean age =47.8 years	Transcutaneous Sophono® Alpha	Unaided Previous use of conventional hearing aid	**Audiometry data (pre vs. post implantation)** Mean PTA = 71.8 vs. 42.1 dB p<0.0001 **Speech recognition threshold (pre vs. post implantation)** Mean SRT = 72.1 vs.38 dB p<0.001 Mean WRS = 3% vs. 87.1% p<0.001 **Comparison with conventional hearing aid; p<0.001 in favour of Sophono® Alpha 1 (no details reported)**
Carr et al 2015 [22] Retrospective study UK	Adult patients with conductive, mixed hearing loss or SSD n=10 Mean age= 45.8 Range= 21 to 60 years	Transcutaneous BAHA® attract	Unaided at analysis Some patients were aided before surgery	**Word discrimination scores (WDS)**; NS **COSI** 86% of patients reported hearing 95% of the time with device 50% of patients reported that sound quality as ‘very good’ and 50% as ‘good’ **No statistical information reported** **GBI** **GHADP – Glasgow hearing aid difference profile for patients aided before implantation** Disability decreased from 59% to 11% p=0.03 **GHABP - Glasgow hearing aid benefit profile for patients unaided before implantation** Disability decreased but not significant p=0.125

Briggs et al 2015 [23] Cohort study Multicentre USA	Adult patients with conductive, mild mixed hearing loss or single-sided sensorineural deafness n= 27	Transcutaneous BAHA® Attract	Unaided	PTA improvement at 9 months (pre vs. post) 18.4 dB HL p<0.0001 APHAB scores at 9 months (pre vs. post implantation) Global score p=0.038 Background noise p=0.035 Reverberation p=0.016 No details were reported

ACPTA – air-conduction pure tone average; APHAB- abbreviated profile of hearing aid benefit; BAHA – bone-anchored hearing aid; COSI - clinically oriented scale of improvement; CROS – contralateral routing of signal; FsHT – frequency-specific hearing threshold; GBI – Glasgow benefit inventory; NS – not significant; pBCI – percutaneous bone-conduction implant; PTA – pure-tone average; tBCI – transcutaneous bone-conduction implant

Table 4: Summary of evidence on Bonebridge

Study	Population	Intervention	Comparator	Results
Sprinzl & Wolf-Magele (2015) [24] Systematic review including 18 uncontrolled studies	Patients with conductive or mixed hearing loss or single-sided deafness (adults and children) N=190 The minimum and maximum ages of participants in the included studies (where stated) were 5 and 76 respectively	Bonebridge™	For most outcomes the comparator for assessment was not specified	**Audiometric and speech outcomes for patients with mixed or conductive hearing loss** **Functional gain (7 studies)** Ranged from 24dB to 37dB **Speech perception in quiet (5 studies)** Significant improvement from <25% increasing to a range of 77% to 93% **50% speech reception threshold (4 studies)** Mean improvement of 19dB to 36dB **Speech recognition in noise (3 studies)** On average, no difference between Bonebridge™ and pre-operatively worn hearing aids 1 study reported that improvements in functional gain, word recognition scores and speech reception threshold at 3 months follow-up were maintained at 12 to 18 months follow-up Improvement in word recognition was better after 13 to 24 months (70%) than after 6 months (46%) in 1 study

				2 studies reported high levels of device satisfaction (around 80%) with follow-up of 12 to 24 months **Single-sided deafness** 1 study reported improvement in word recognition scores (from 18% to 90%) and speech recognition thresholds (34.5dB to 32.3dB) 2 studies reported an improvement in speech recognition in noise 2 studies found that patients were generally happy with their device
Rahne et al (2015) [25] Retrospective review Single centre Germany	Patients with conductive or mixed hearing loss N=11 Median age 44 years (range 5 to 76)	Bonebridge™	Unaided Best-aided pre-implantation	**Mean (SD) sound-field threshold** Improvement post-operatively with Bonebridge™ (28.2dB HL (SD 8.2dB)) compared to unaided pre-operative (62.0dB HL (SD 16.0dB)) ($p<0.001$). An improvement of 33.4dB **Mean (SD) word recognition score** Post-implantation statistically significant improvement compared to best-aided pre-implantation ($p<0.01$) • Pre-implantation unaided: 10.0% (SD 19.0%) • Pre-implantation best-aided: 66.0% (SD 15.0%) • Post-implantation with Bonebridge™: 87.5% (SD 8.9%) Statistical test for post-implantation with Bonebridge™ compared to pre-implantation unaided not reported **Hearing in a noisy environment (mean (SD) SRT)** • Improvement with Bonebridge™ (-3.3dB (SD 1.8dB)) compared to unaided for front presentation of noise (-2.3dB (SD2.6)) ($p<0.05$) • Improvement with Bonebridge™ (-6.1dB (SD 3.1dB)) compared to unaided for contralateral presentation of noise (1.3dB (SD2.1)) ($p<0.001$)

				Angle detection error[7] Improvement with Bonebridge™ (37% (SD38%)) compared to unaided (27% (SD20%)) (p<0.05)
Laske et al (2015) [26] Prospective review Single centre Switzerland	Patients with single-sided deafness N=9 Mean (SD) age 52 years (range 18 to 69) Mean follow-up 16 months (range 11 to 22)	Bonebridge™	Unaided	**Functional benefit in noise (assessed by OLSA)** • Improvement with Bonebridge™ compared to unaided at 6 months (mean SNR difference -2.1dB, p<0.05) and 12 months (mean SNR difference -2.2dB, p<0.05) • No difference between Bonebridge™ and unaided at 1 month **Speech understanding in noise (assessed by SNR**[8]**)** • Improvement for Bonebridge™ (-3.38) compared to unaided (-1.73) when sound presented to the implanted side (p<0.05) • No difference when sound presented from the front or to the non-implanted side **Patient benefit** • Overall mean scores on BBSS and SSQ-B indicated a positive benefit with Bonebridge™[9] • 1 of 9 patients reported no benefit with Bonebridge™ on BBSS
Riss et al (2014) [27] Retrospective review Single centre Austria	Patients with combined hearing loss, atresia or single-sided deafness N=23 Mean age 41 years (range 6 to 80)	Bonebridge™	Unaided	**Functional gain** Mean (SD) functional gain 28.8 dB (±16.1) with Bonebridge™ compared to unaided (statistical significance not reported) **Word recognition in quiet** • Improvement in mean (SD) word recognition at 65dB from 4.6% (±7.4) unaided to 53.7% (±23.0) with Bonebridge™ (p<0.001)

[7] Ability to localise sound

[8] The difference of the sound signal level at which 50% of the words were repeated correctly with a constant noise level of 65dB

[9] The Bern Benefit in Single-Sided Deafness Questionnaire (BBSS) and Speech, Spatial and Qualities of Hearing Questionnaire B (SSQ-B) ask patients to compare their hearing abilities in an aided versus unaided condition on a scale ranging from -5 (much worse) to +5 (much better). The BBSS uses ten questions, the SSQ-B uses 49 questions

				• Improvement in mean (SD) word recognition at 80dB from 33.0% (±30.0) unaided to 77.5% (±19.0) with Bonebridge™ (p<0.001)

BBSS – Bern Benefit in Single-Sided Deafness Questionnaire; dB – decibel; HL – hearing level; OLSA – Oldenburg Sentence Test; SD – standard deviation; SNR – signal-to-noise ratio; SRT – speech reception threshold; SSQ-B – Speech, Spatial and Qualities of Hearing Questionnaire B

Table 5: Summary of evidence on SoundBite

Study	Population	Intervention	Comparator	Results
Gurgel et al 2015 [28] Prospective cohort study Multicentre, USA	Adult patients (> 18 years mean age not reported) with SSD n=127 (81 analysed)	SoundBite™	Unaided	**Results at 12 months** **Hearing thresholds;** No change **APHAB score (aided vs. unaided)** EC; 15.1 vs.31.4 p<0.001 RE; 23.1 vs. 44.2 p<0.001 BN; 38.6 vs.65.1 p<0.001 AV; 31.0 vs.42.0 p<0.001 GL; 25.6 vs.46.9 p<0.001 **SSD questionnaire (unvalidated)** 90.1% preferred wearing device vs. not 87.5% reported improvement in overall QoL 55.6% satisfied with ability to eat with device

APHAB- abbreviated profile of hearing aid benefit; AV – aversiveness; BN - background noise; EC - ease of communication; GL - overall global hearing score; RE - reverberation,

4.2 Trials in progress

Our search of clinicaltrials.gov in January 2016 identified one ongoing trial NCT01858246: A randomised controlled trial comparing bone anchored hearing aid with Bonebridge™. Estimated study completion date January 2017.

4.3 Evidence of cost-effectiveness

We did not identify any studies assessing the cost-effectiveness of bone-conduction hearing devices.

4.4 Safety

BAHA® attract and Sophono® Alpha

Safety outcomes were not well reported in the identified studies of BAHA® attract and Sophono® Alpha. Temporary skin erythema, infection along the incision, pain and tingling around implant were the most common problems associated with these devices. One study reported headache in one patient after implantation of Sophono® Alpha before activation, the patient demanded explantation of the device. One study reported two cases of patients experiencing magnets falling off both the BAHA® attract and Sophono® Alpha.

Bonebridge™

Safety outcomes for Bonebridge™ are summarised in table 6.

Table 6: Safety outcomes for Bonebridge™

Study	Results
Sprinzl & Wolf-Magele (2015) [24] Systematic review including 12 studies (n=117) with safety outcomes	9 of the 12 studies reported no adverse events over a follow-up period of ≥6 months 3 studies reported a total of 6 safety events with follow-up of 10 to 11 months including: • Prolonged wound healing process requiring superficial surgical revision (1 patient) • Mild wound pain and dizziness in post-operative period (1 patient) • Tinnitus in post-operative period (1 patient) • Headache and vertigo after discharge (1 patient) • Seroma (1 patient) • Minor skin infection (1 patient) Rate of minor events calculated as 5.12%
Rahne et al (2015) [25] Retrospective review of 11 patients	1 patient required surgery for chronic fibrosing mastoiditis No other minor or major complications were observed with over 24 month follow-up
Laske et al (2015) [26] Prospective review of 9 patients	1 patient had prolonged swelling in the wound region which resolved without intervention 1 patient had a post-operative wound infection requiring oral antibiotics

SoundBite

The study of SoundBite™ by Gurgel et al did not report any serious adverse effects. The authors report five minor device-related adverse events including dome disconnection, pain, infections and dental issues. They also reported cancer-related death, shingles and lichens planus deemed unrelated to the device.

4.5 Summary of section 4

We identified eight studies of the effectiveness of BAHA® attract and Sophono® Alpha; five of these were comparative studies and three were before and after studies.

The two studies that compared BAHA® Attract and Sophono® Alpha concluded that both devices are more effective than the unaided situation and that there was no difference in aided thresholds or speech discrimination scores between the two devices. However these studies were small retrospective studies and the comparison was indirect therefore the results may not be generalisable.

One study compared percutaneous BAHA® and BAHA® Attract; the authors reported that both devices were effective in the rehabilitation of hearing loss however, they observed better results in the percutaneous device. This retrospective study only included 37 patients. Another comparative study reported that Sophono® Alpha was non-inferior to percutaneous BAHA®. Sophono® Alpha was also found to be no better than the CROS hearing aid.

Three studies (one of Sophono® Alpha and two of BAHA® Attract) found the two devices to be better than unaided situations in terms of aided thresholds, speech discrimination scores as well as quality of life outcomes. However, without a control arm it is difficult to draw any firm conclusions.

We identified a systematic review of 18 uncontrolled studies on Bonebridge™ and three further uncontrolled studies published after the search date for the systematic review. No studies compared Bonebridge™ to other hearing devices. Improvements with Bonebridge™ were reported on a range of outcomes by all authors; however the interpretation of these improvements was complicated by missing information, for example on the comparators used and statistical significance of some of the results.

One study of the use of SoundBite™ found that the device had no effect on hearing threshold but improved APHAB scores compared with the unaided situation.

Generally, the studies of BAHA® Attract, Sophono® Alpha, Bonebridge™ and SoundBite™ led to improvements in patients with various types of hearing loss. However these findings are limited by the paucity of high-level evidence; all the studies were small, many of them retrospective and subject to bias.

Safety outcomes were not well reported in the identified studies of BAHA® attract and Sophono® Alpha. Temporary skin erythema, infection along the incision, pain and tingling around implant were the most common problems associated with these devices. Headache and magnet falling off have also been experience by patients implanted with BAHA® attract and Sophono® Alpha.

Nine of 12 studies in the systematic review reported no adverse events with Bonebridge™. Adverse events reported for individual patients included wound-related issues, tinnitus, headache, vertigo and seroma.

Minor device-related adverse effects with the use of SoundBite™ include pain, infection and discomfort issues with eating. No major events were associated with SoundBite™.

We did not identify any studies assessing the cost-effectiveness of bone-conduction hearing devices.

5 Discussion and conclusions

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

There is some evidence for the clinical effectiveness of the transcutaneous bone-conduction hearing devices BAHA® Attract, Sophono® Alpha and Bonebridge™ compared to no intervention (unaided). However this evidence is based on a few very small unrandomised studies and the statistical information on the observed improvements on quality of life or activities was generally not reported. There is evidence from small studies to suggest that there is no difference in the improvements achieved in aided thresholds or speech discrimination scores between BAHA® Attract and Sophono® Alpha. However these findings are based on indirect comparison. Sophono® Alpha appears to be as effective as percutaneous BAHA® while one study suggests that percutaneous BAHA® is more effective than the BAHA® Attract.

One study of the use of SoundBite™ found that the device had no effect on hearing threshold but improved APHAB scores compared with the unaided situation.

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

We did not identify any studies on the cost-effectiveness of bone-conduction hearing devices.

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7 Search Strategy

Table 7: Population, Intervention, Comparator and Outcomes (PICO)

Patients/ population	Children and adults with hearing impairment
Intervention	Bone-conduction hearing devices specifically: i) Transcutaneous devices e.g. Sophono®, BAHA® 4 attract ii) Bonebridge™ iii) SoundBite™
Comparison	No intervention Any other hearing devices including: • Air-conduction hearing aids • Other bone-conduction hearing aids e.g. percutaneous devices BAHA®, Oticon™
Outcomes	Any, including: • Successful implantation • Hearing quality (e.g. hearing threshold, sound localisation) • Quality of life, patient satisfaction • Functional outcomes (e.g. educational/ learning outcomes) • Complications, extrusion rates, revision rates • Survival of device / its components • Cost / cost-effectiveness

Search date: 15th December 2015
Databases searched: PubMed, Embase, Cochrane, TRIP and NICE Evidence Search
Limited to studies published in English in last two years. Papers included in the previous review of this topic (search conducted 12th August 2014) are not included in this review
Case reports, conference papers, letters and commentary and editorials excluded.

Embase Search Strategy

1. *hearing disorders/ or exp hearing impairment/
2. deaf*.ti,ab.
3. (hearing adj3 (loss or disorder? or difficult* or impair*)).ti,ab.
4. 1 or 2 or 3
5. exp bone conduction hearing aid/
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