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Bone anchored hearing aid (BAHA).

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AHTA

Adelaide Health Technology Assessment

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PRIORITISING SUMMARY

REGISTER ID: **000140**

NAME OF TECHNOLOGY: **BONE ANCHORED HEARING AID**

PURPOSE AND TARGET GROUP: **HEARING AID DEVICE FOR PEOPLE WITH SINGLE SIDED DEAFNESS (SSD)**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☒	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Australia		✓	
France	✓		
The Netherlands	✓		

IMPACT SUMMARY:

Entific Medical Systems provides the Bone Anchored Hearing Aid (BAHA®) System, with the aim of treating deafness. Although the technology has been available for over 25 years, the US Food and Drug Administration recently approved its use for a new indication, single sided deafness (SSD).

BACKGROUND

The BAHA® is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA® system is based on bone conduction technology, whereby sound is conducted through the bone rather than via the middle ear.

The BAHA® System combines a sound processor with a small titanium fixture implanted in the mastoid bone behind the ear where it osseointegrates. After a healing period a percutaneous abutment is attached to the fixture.

To date, BAHA® has also been used for people with bilateral conductive hearing loss due to conditions such as otosclerosis and for hearing impairments related to congenital disorders (ie Down's Syndrome).

The BAHA® sound processor 'snaps' into the abutment which is attached to the bone fixture. The BAHA® device is placed on the deaf ear side behind the ear, and transfers sound through bone conduction, stimulating the cochlea from the normal hearing ear. The BAHA® enables

the user to hear and understand sounds from both sides of the head where previously the head shadow effect totally masked certain sounds. This ultimately results in the sensation of hearing sound from the deaf side (Figure 1).

Figure 1. BAHA® sound processor (printed with permission Entific Medical Systems

The single sided deafness (SSD) indication for the BAHA® is intended for patients who suffer from unilateral sensorineural deafness in one ear while the other ear has normal hearing. The aim is to improve speech recognition. Normal hearing is defined as Pure-Tone Audiometry (PTA) AC threshold (through earphones) equal to or better than 20dB measured at 0.5, 1, 2 and 3 kHz.

CLINICAL NEED AND BURDEN OF DISEASE

Single Sided Deafness is the term given to unilateral sensorineural deafness. The causes of SSD include trauma, disease and surgical intervention such as removal of an acoustic neuroma or severe Ménière's disease. According to the Acoustic Neuroma Association (NSW) over 300 people are diagnosed with acoustic neuroma in Australia each year (Acoustic Neuroma Association, NSW 2005). It is not possible to ascertain the prevalence of SSD in Australia as there are no population-based data. In South Australia alone, 77 per 10,000 (n = 247) are totally deaf in one ear only (Taylor et al 1997). This includes congenital hearing impairment as well as acquired or age-related hearing impairment.

It is estimated that 89 children are born each year with unilateral permanent childhood hearing impairment (predominantly congenital) out of approximately 246,394 registered births per year in Australia (Merlin et al 2004).

DIFFUSION

The BAHA® is an established technology that is commonly used for people with conductive or mixed hearing impairment throughout Australia. However, there has been only one procedure performed in Western Australia for the new indication of Single Sided Deafness.

COMPARATORS

Currently the only treatment available for sensorineural hearing loss is a traditional CROS (contralateral routing of offside signal) hearing aid. These are placed inside the ear canal or behind the ear. The CROS aids are transcutaneous and work by exerting pressure against the skull. This technique utilises hearing aid microphones worn in both ears and sends sound from the deaf ear to the hearing ear.

Traditional CROS aids are associated with a number of practical problems that may result in limited use or patient rejection. They can be uncomfortable to wear and are not suitable for patients without a functioning ear canal or with chronic ear infections. As the BAHA® is held

in place by a clip and directly integrated with the skull bone, there is no need for a head band, or pressure against the skin of the head, which is required with a traditional CROS hearing aid.

The BAHA® may be implanted in children as young as eight years old without the need to replace the device, as is required with a CROS hearing aid where multiple ear moulds are fitted to accommodate changes in ear size.

EFFECTIVENESS AND SAFETY ISSUES

See complete volume of Prioritising Summaries for definitions of Levels of Evidence.

1. BAHA vs unaided hearing impairment

Snik et al (2002) assessed the impact of the BAHA® on eight people with inoperable, unilateral conductive hearing loss. In this study (level IV Intervention evidence), sound field localisation and speech recognition was assessed at least 10 weeks after the BAHA® was fitted. The cause of SSD in 2 of the 8 patients was congenital and for the remaining six patients, hearing loss was acquired. Although hearing improved in all patients, a greater effect was reported in those patients with acquired hearing loss. All six patients with acquired hearing loss and one of the two patients with congenital hearing loss showed statistically significant improvements in speech-to-noise ratio (SNR) exceeding 1.7dB. A change of 1 dB in SNR represents a change of about 17% in sentence recognition.

In a study by Wazen et al (2001), nine patients with unilateral conductive or mixed hearing loss were fitted with a BAHA® on the affected side (level IV Intervention evidence). Pre- and post-implantation evaluations included audiological testing and responses to a standardised hearing handicap questionnaire. All patients reported a significant improvement in their hearing handicap scores, with speech recognition performance in BAHA-aided conditions comparable to the patients' best scores when in an unaided condition. All patients had tonal and spondee (bisyllabic word enunciated with equal stress on both syllables) threshold improvement with BAHA® when compared with pre-treatment. It was not possible to independently assess this data at the time of writing.

2.BAHA vs aided hearing impairment

Both Niparko et al (2003), and Wazen et al (2003) tested the BAHA® in two separate studies (10 and 18 patients respectively) of people with unilateral deafness and compared to a minimum of a 1-month trial with a conventional CROS hearing aid (level IV Intervention evidence). Performance was assessed using speech reception thresholds, speech recognition performance in noise, the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Single Sided Deafness questionnaires. Wazen et al reported that 14/18 (83%) of participants had profound hearing loss as a consequence of removal of an acoustic neuroma. Other participants had experienced a failed stapedectomy, a complication of chronic otitis media and a sudden hearing loss. The duration of the SSD ranged form 0.5 to 27 years. In the Niparko study, in 7/10 patients unilateral deafness was caused by acoustic neuroma excision, in 1/10 patients by meningitis, and by sudden sensorineural hearing loss in two patients.

There were no adverse events reported with the implantation of the BAHA®. Both studies reported greater improvements in speech recognition in noise, as measured using the Hearing in Noise Test, in the BAHA® aided group compared to the CROS aided group. Comparison of the CROS versus BAHA® performance on the APHAB also showed BAHA® aided hearing was better. Table 1 provides data from the Wazen et al (2003) study.

Table 1. Responses to abbreviated profile of hearing aid benefit (APHAB) questionnaire in 2 device conditions, relative to unaided scores (n = 13)

Condition		Ease of Communication	Reverberation	Background noise	Aversiveness of sound
CROS -aided	Mean (SD)	4.88 (15.17)	9.38 (11.78)	8.94 (16.25)	-18.07 (24.54)
BAHA - aided	Mean (SD)	6.47 (14.19)	15.55 (14.31)	18.92 (17.25)	9.23 (28.65)

It is worth noting that the data reported in this study do not give a direct comparison between the CROS aid and the BAHA® device.

The follow-up periods in available studies investigating the effectiveness of BAHA® on single sided deafness did not extend beyond two months. Furthermore, although there were no adverse events arising from the implantation and maintenance of the device in the above studies, several studies do note that the device requires a high level of hygiene at the implant site to avoid infections. The ability to maintain a clean device may be used as a criterion to exclude some patient groups.

COST IMPACT

The cost of the device in Australia is approximately $9300 (BAHA® distributor, Shine Medical). This price does not include the cost of the procedure, usually involving 30-60 minute surgery and a local anaesthetic.

Australian Hearing currently receives Commonwealth funding for BAHA® procedures in eligible patients for indications apart from Single Sided Deafness. A South Australian audiologist has indicated that the surgical cost to implant the device is approximately $3000 and that the subsidised cost of device is $3000 (personal communication, Australian Hearing, South Australia).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

Although it is clinically possible to implant the BAHA® in children as young as eight years, (the United States has approved its use in children aged five and over), it is worth noting the potential safety concerns arising from young childrens' activities such as engaging in contact sports or common falls that could impact on the device. Given that the BAHA® implant is placed close to the brain, a head trauma could produce further risks or damage.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

There is a lack of controlled studies, with adequate follow-up periods, directly comparing the BAHA®-aided hearing with CROS-aided hearing.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Acoustic Stimulation/instrumentation
Audiometry, Pure-Tone
Bone Conduction/ physiology
Hearing Aids
Hearing Loss
Hearing Loss, Conductive/ rehabilitation
Sound Localization
Speech Perception/physiology