

A critical review of the bone-anchored hearing aid: indications, candidate evaluation and efficacy

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INTRODUCTION

In the UK, one in six people has some form of hearing loss, making it one of the most prevalent causes of disability.⁽¹⁾ Due to the effect this disability can have, not only on the individual, but also society as a whole, the World Health Organisation predicts that within the next 20 years, adult acquired-hearing loss will be in the top ten UK disease burdens.⁽¹⁾ Over 14 children a week in the UK are born with a substantial hearing loss,⁽²⁾ making this a very important issue.

There are, currently, a variety of treatment options available to people with hearing loss, ranging from relatively cheap, yet successful, air-conduction hearing aids to more complex options, such as the bone-anchored hearing aid (BAHA), reconstructive surgery and cochlear implants.

BAHAs can provide a solution for some individuals with conductive or mixed hearing loss, as they bypass the external and middle ear, where the cause of the hearing loss often is, transmitting sound directly to the inner ear via the bone. As a result of recent advances in this technology, the number of indications for the BAHA has increased.

This literature review aims to examine the BAHA, by investigating the device, the indications for implantation, the importance of candidate evaluation, and the efficacy of the device, when compared with other commonly used interventions.

The consequences of hearing loss can be numerous: the effect on the individual's ability to communicate; the disadvantages regarding education and employment; and the stigma related to deafness. Therefore, a solution enabling these people to hear well enough to communicate, reducing these challenges, is a positive one, for the individual and potentially society. BAHAs have the ability to do this for an increasing number of people.

Hearing relies upon transmission of sound through air; via the external auditory canal. Individuals who are unable to use air conduction can benefit from the use of a hearing aid which utilises bone conduction. The BAHA is a hearing device based on this principle,⁽³⁾ transmitting sound via an osseointegrated titanium implant. BAHAs were first used in clinical practice in the 1970s,^(4,5) after development in Sweden, and have been available commercially since 1987.⁽³⁾

Many studies have reported that the BAHA is more efficient than other treatment options, such as transcutaneous bone-conduction hearing devices, and reconstructive surgery, and can prevent complications, such as those associated with

in-ear air-conduction hearing aids, and as a result of this, indications for BAHA have increased.

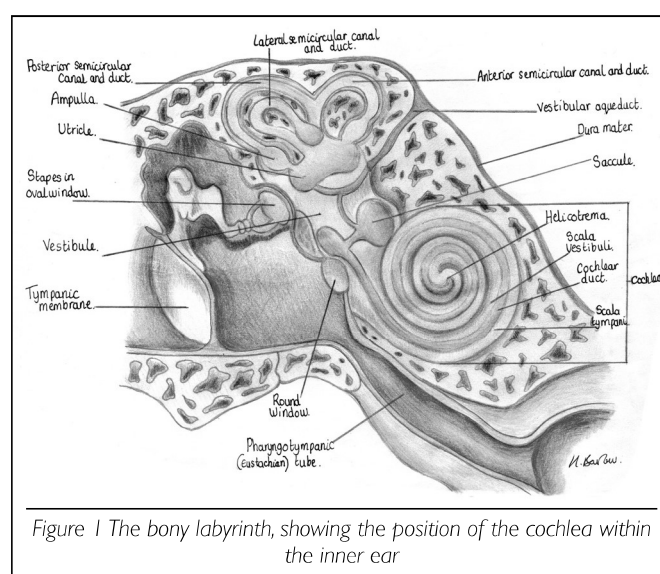
This review investigates potential indications for BAHA implantation, and the candidate evaluation process. A number of studies will be reviewed examining the efficacy of the BAHA in comparison with alternatives. Although causes of single-sided deafness are mentioned, this review will focus on unilateral BAHA implantation for bilateral deafness.

DISCUSSION AND RESULTS

Anatomy of the inner ear and the physiology of hearing

The ear consists of three anatomical regions; the external, middle and internal ear. The external ear consists of the pinna, external auditory canal and tympanic membrane. The middle ear transmits vibrations from the tympanic membrane into the internal ear via three movable bones: the malleus, incus and stapes.

The internal ear contains the receptors for hearing, and is composed of a number of cavities within the petrous section of the temporal bone. This is made up of three main areas: the semicircular canals and vestibule, containing equilibrium receptors, and the cochlea, containing hearing receptors. The cochlea is a coiled bony structure that twists on itself around the modiolus. Circling the modiolus is the endolymph-filled cochlear duct, creating two canals on either side: the perilymph-filled Scala Vestibuli and Scala Tympani. Diagrams of this can be seen below in figures 1 and 2.



Sound receptors are located within the organ of Corti (spiral organ in figure 2), which rests on the basilar membrane, between the cochlear duct and Scala Tympani. The organ of

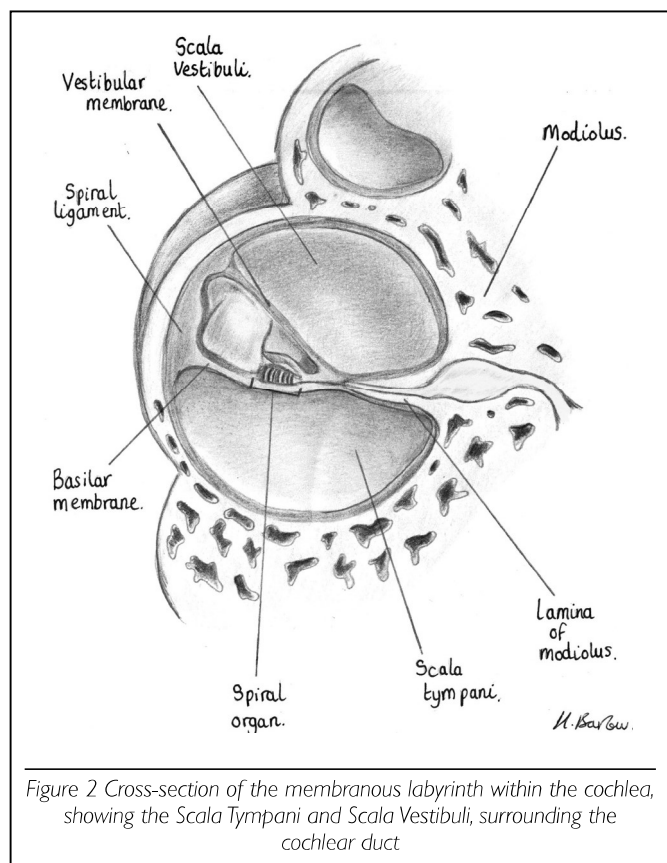


Figure 2 Cross-section of the membranous labyrinth within the cochlea, showing the Scala Tympani and Scala Vestibuli, surrounding the cochlear duct

Corti works as a transducer, converting sound waves into nerve impulses. It is composed of coiled epithelium made up of supporting cells – a single row of inner hair cells and three rows of outer hair cells. The hair cells are covered with stereocilia, connected by tip links, and are embedded within the tectorial membrane. The inner hair cells synapse with over 90% of the first order sensory neurons within the cochlear nerve, which send auditory information to the brain.

Sound is caused by tiny air pressure variations, the frequency of which determines the pitch of sound, and the amplitude determines loudness. Sound enters the external acoustic meatus and moves the tympanic membrane medially, causing movement of the three auditory ossicles. These bones increase the force produced by the sound wave, creating a wave within the perilymph of the Scala Vestibuli and then Scala Tympani, deforming their walls, resulting in pressure waves within the cochlear duct, leading to movement of the hair cells and their stereocilia. This generates nerve impulses, which pass along axons of the sensory neurons of the cochlear branch of the vestibulocochlear nerve, eventually reaching the primary auditory area of the cerebral cortex.

What is BAHA? And what are the main indications?

The BAHA is a bone-conduction hearing device which enhances natural bone transmission of sound. It consists of a transducer, worn just behind the ear, which picks up sound from the environment; a connecting abutment, the part of the implant protruding through the skin, connecting the implant to the transducer; and a titanium implant, which is placed within the temporal bone,⁽⁶⁾ transmitting sound directly to the inner ear, bypassing the ear canal and middle ear. Because of the percutaneous connection of the transducer to the titanium screw within the skull, high-quality sound transmission occurs.

BAHAs can be a successful solution for people with conductive or mixed hearing loss, or single-sided deafness. Hearing loss can be termed 'mild', 'moderate', 'severe' or 'profound'. This classification is based upon the quietest sound an individual is able to hear across a range of frequencies, the greater the threshold, the worse the loss of hearing.

Table 1 below shows the hearing thresholds found in normal hearing and in each level of hearing impairment.

Severity of hearing loss	Hearing threshold level (dB)	Description of impairment
Normal hearing	0-20	No/minimal hearing problems
Mild hearing loss	20-40	Can repeat words spoken 1m away (normal speaking voice)
Moderate hearing	41-70	Can repeat words spoken 1m away (voice raised)
Severe hearing loss	71-95	Able to hear some words when shouted
Profound hearing loss	>95	Unable to hear any words when shouted

Table 1 The hearing thresholds associated with each level of hearing loss^(7,8)

There is an increasingly broader spectrum of individuals able to benefit from being fitted with a BAHA. Below are a number of pathologies that are currently being treated.

Conductive and mixed loss

Congenital aural atresia is a relatively common condition characterised by absence of the ear canal, and *microtia* is the absence or deformation of the external ear.^(9,10) Reconstructive surgery is often seen as first-line treatment; however, if this is not possible, BAHA has proven to be an excellent alternative.⁽¹¹⁾ In fact, multiple studies concluded that BAHA results in a significantly better audiologic outcome, when compared to surgical reconstruction, as well as resulting in fewer complications, and consequently fewer follow-up visits.^(12,13)

Chronic suppurative otitis media is unresolving infection of the middle ear, common in those with poor eustachian tube function.⁽¹¹⁾ This is the most common cause of hearing loss in adults fitted with BAHAs.⁽⁷⁾ BAHA is a successful alternative to in-ear air-conduction hearing aids in these individuals, as the ear canal is not obstructed, reducing the chance of further infections.⁽¹⁴⁾ Similar advantages are seen in providing a patient with external otitis (inflammation of the external ear canal) with a BAHA, as in-ear hearing aids are likely to be unsuitable.⁽¹¹⁾ Studies have shown that BAHA fitting substantially reduces costs and the amount of treatment required by individuals with chronic otitis media or externa.⁽¹⁵⁾

Cholesteatoma is a keratin-producing mass of epithelium, most commonly found in the middle ear, that can be congenital or acquired. If acquired, it usually occurs as a result of middle-ear infections or poor eustachian tube function. If left, the cholesteatoma can swell and damage the ossicles within the middle ear.^(10,11)

Otosclerosis is the abnormal growth of bone within the middle ear, commonly leading to reduced movement of the stapes, reducing sound transmission to the inner ear, characteristically leading to low frequency loss. BAHA is seen as a safer way to

restore hearing in these individuals, as middle-ear surgery carries risks of causing further damage.⁽¹¹⁾

Single-sided deafness

Individuals with unilateral deafness often have poor directional hearing, and find conversation difficult if background noise is present, reducing speech comprehension.⁽¹⁶⁾ In unilateral deafness, a BAHA can bypass the deaf ear, taking sound to the other working cochlear, overcoming the head shadow effect, leading to binaural hearing.^(14,16)

An acoustic neuroma is a benign tumour of the vestibulocochlear nerve. One of the earliest symptoms is unilateral sensorineural hearing loss.^(10,11) Surgery is usually performed; however, this often results in deafness on that side. Other causes of single-sided sensorineural deafness treated with a BAHA are Ménière’s disease and ototoxic drugs. Congenital single-sided deafness can also cause communication difficulties in young children, and studies have shown success in BAHA implantation in these children.⁽³⁾

Implementation criteria-candidate evaluation, and device consideration

Although there are an increasing number of indications for providing an individual with a BAHA, not all individuals with the conditions mentioned are able to receive one. An assessment must be made by a multidisciplinary team (MDT) which will ultimately decide whether the implementation of the BAHA is acceptable.

Tables 2 and 3 outline the criteria and contraindications for being given a BAHA, set out by the NHS commissioning board. However, there is also significant variation between trusts relating to criteria regarding the provision of funding for BAHAs, often leading to uneven provision. The question of funding is extremely important as BAHAs are significantly more costly than most alternatives – it is estimated that the cost per candidate for the first year (including audiological assessment, surgery, the device and post-operative consultations) is around £6,618.⁽⁷⁾ They are, unsurprisingly, most cost-effective in individuals who experience the greatest auditory improvement, making meeting criteria and pre-operative evaluation paramount.⁽⁷⁾

The BAHA fitting process is not simple, and requires the cooperation of the patient and an MDT working alongside them. Initially, a detailed history must be taken, regarding general health, hearing loss, speech development and hearing aid use.

An audiological assessment is carried out on each individual – including pure-tone audiometry, speech audiometry, and sound-field testing.

Pure-tone audiometry shows the individual’s air- and bone-conduction thresholds. Tones are played at different frequencies and volumes – the threshold is the lowest volume at which the individual can detect sound half of the time.⁽¹⁰⁾ This test must demonstrate a significant air-bone gap in order for a BAHA to be suitable⁽⁷⁾ – studies have shown that individuals with an air-bone gap ≥ 30 dB are likely to experience significantly better hearing with a BAHA.^(6,14)

Figure 3 is a graph, illustrating the audiological results found in an individual with a conductive hearing loss. The lower line shows their air-conduction hearing threshold, and the upper line shows bone conduction – there is a significant air-bone

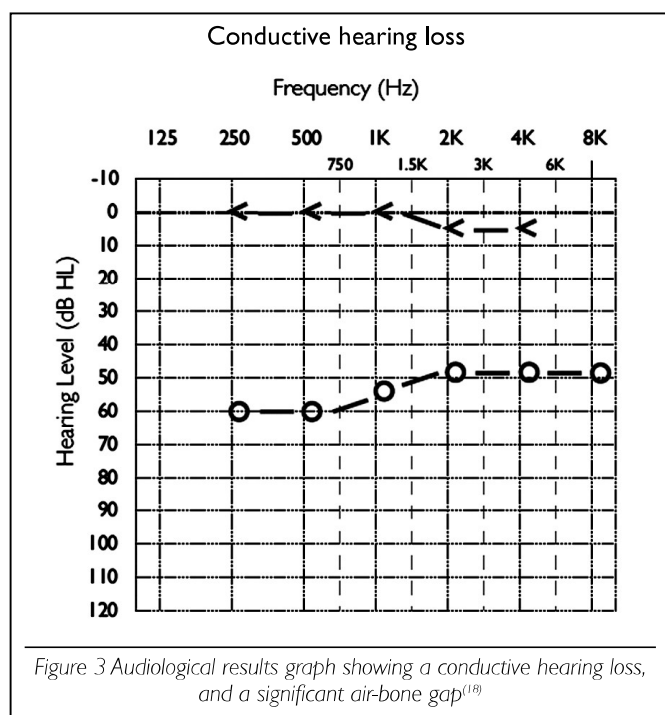
Criteria to be met for the unilateral provision of a BAHA (funding will be given when MDT assessment leads to recommendation, and the following criteria is confirmed)	
1	The patient has: <ul style="list-style-type: none"> • bilateral conductive/mixed hearing loss OR • bilateral conductive/mixed hearing loss with one ear hearing better than the other; and where the type of hearing loss does not allow the use of two air-conduction hearing aids OR • unilateral conductive hearing loss with stenosis (patient is unlikely to benefit from corrective surgery/has had unsuccessful surgery/cannot tolerate air-conducting hearing aids) OR • profound unilateral sensorineural hearing loss
2	The patient is unsuitable for alternate treatments (eg, due to a congenital abnormality of middle/external ear; chronic draining ears meaning the use of air-conduction devices is unsuitable, bilateral conductive hearing loss due to disease of the ossicles)
3	Audiological test results: <ul style="list-style-type: none"> • conductive/mixed hearing loss with a bone-conduction pure-tone average threshold less than or equal to 45dB (for the Devino device), 55dB (Intenso device), 70dB (Cordelle II device) • air-conduction pure-tone average less than or equal to 40dB • maximum speech discrimination word score more than 60%
4	The individual has had the necessary counselling, understands the benefits and limitations of the device, and is willing to look after the device longterm
5	The individual will be able to ensure that the area around surrounding the fixture site is clean (either alone or with the help of another)
6	There are no contraindications (see below)
<i>Table 2 Criteria for the implantation of BAHA⁽¹⁷⁾</i>	

Contraindications to BAHA	
Absolute	Potential (may prevent patients from adequately looking after their BAHA)
Bone disorder (the skull is too thin to bear the BAHA)	Psychiatric disorders
Candidate is <3 years of age	Immature personality
	Alcohol or drug abuse
<i>Table 3 Absolute and potential contraindications to BAHA⁽¹⁷⁾</i>	

gap, the upper line is the hearing threshold that the individual has the ability to have once a BAHA is fitted.⁽¹⁸⁾

Speech audiometry assesses how well the individual hears speech,⁽¹⁸⁾ and can be carried out using headphones, to test air conduction, and bone-conduction vibrators, to assess bone conduction – the speech threshold is the lowest volume at which the individual can repeat 50% of words.⁽¹⁰⁾

Sound-field testing demonstrates the potential benefit of BAHA implantation. A BAHA processor is attached to a testband, and is placed on the mastoid.⁽¹⁸⁾ Sound is then transmitted through the temporal bone, as it would be postsurgery. However, this is transcutaneous; therefore sound transmission is lessened as it travels through the skin. This should be explained to the candidate, as they should expect better results with the osseointegrated BAHA (2-15dB, depending on the individual and sound frequency).⁽¹⁸⁾ For a more realistic experience, it is important to wear the transcutaneous processor in a range of environments,⁽¹⁸⁾ and is recommended that a headband is worn for extended periods of time, to enable the candidate to further understand what life with a BAHA is like.



The individual must then be counselled, ensuring that they know what to expect from the procedure and device, as well as what is expected of them post-implantation. Areas of importance are: benefits of a BAHA; the procedure and potential adverse effects; expectations of the device – ensuring that these are realistic; and, crucially, aftercare instructions.⁽¹⁵⁾ Once it is evident the individual has taken on board this information, following a successful audiological assessment, and provided they do not fall into one of the contraindication categories, they may be considered suitable for implantation.

Once the decision has been made to go ahead, it must be decided which transducer is used. A number of transducers are currently available, the decision as to which is likely to provide the greatest benefit is based upon the individual's audiogram, but also depends on the type of hearing loss, and the priorities of the individual, such as obtrusiveness of the transducer vs improved clarity of speech.⁽¹⁸⁾

The BPI00 or BAHA Divino offers 25% speech improvement, and can be used when the bone hearing threshold is no greater than 45dB. The BAHA Intenso is larger, but more powerful, and can be used in those with a hearing threshold up to 55dB. The Cordelle II has a body-worn amplifier, which connects to the ear level transducer, providing amplification for those with thresholds up to 70dB. The wide range of available products enable a greater proportion of people to benefit.⁽¹¹⁾ Devices are now digital, meaning each transducer can be adapted according to individual hearing thresholds.⁽⁷⁾

The efficacy of BAHAs. A comparison between BAHA and conventional devices, and adverse effects associated with implantation

Numerous studies have looked at the efficacy of BAHAs, comparing audiometric results and quality of life between those fitted with a BAHA and those with an alternative, such as air-conduction devices and traditional bone-conduction devices, and those with unaided hearing who are unable to benefit from other forms of hearing aid.

BAHA vs unaided hearing

The results of studies comparing those with unaided hearing with individuals using a BAHA are, unsurprisingly, positive. A 2007 study reported an audiometry result that the authors stated was statistically significant – a mean improvement of 28dB in average sound field thresholds at all frequencies, after three months of BAHA use, compared with results of unaided hearing.⁽¹⁹⁾ They also found that speech recognition thresholds were improved by over 30dB with a BAHA.

An earlier study, in 1969, investigated individuals with otosclerosis, reporting that average sound-field warble-tone thresholds improved from 49.4dB to 30.6dB with the BAHA, and that sound-field discrimination scores improved by 10%.⁽²⁰⁾ Another study, in 2000, reported a particularly positive result, when studying pure-tone audiometry thresholds in participants with congenital aural atresia.⁽²¹⁾ BAHA application led to thresholds improving from an average of 64dB to just 19dB.⁽²¹⁾

Overall, these results show the considerable improvement resulting from BAHA implantation, suggesting the great impact this could have on individuals who are unable to benefit from other hearing aids.

BAHA vs air-conduction hearing aids (ACHA)

Most people with hearing loss can benefit somewhat from air-conduction hearing aids, as they amplify sound, transmitting it directly down the ear canal.⁽⁷⁾ However, an obstructed ear canal, as found in individuals with aural atresia, may prevent in-ear air-conduction hearing aids being fitted, and the symptoms of chronic suppurative otitis media may be exacerbated by reduced ventilation; it has been shown that this can lead to additional sensorineural loss, caused by damage to the cochlear.⁽¹⁴⁾ For people who cannot use the ACHA, BAHA implantation is a good option. However, for those who currently use an ACHA, numerous studies have been undertaken, investigating the potential improvement in audiometric results provided by a BAHA.

A study in 1996 investigated mean sound-field warble-tone thresholds and found a statistically significant improvement with BAHA, particularly in those with congenital hearing loss (13dB improvement with BAHA); there was also a reasonable reduction in those with chronic suppurative otitis media (7dB).⁽²²⁾ They also investigated speech audiometry, reporting a statistically significant improvement in mean sound-field discrimination scores for individuals with congenital deafness (57% with ACHA, 82% with BAHA), but not in the chronic suppurative otitis media group.

A 2009 study also reported statistically significant results, showing that results improved with the BAHA by between 5-15dB between 1-4kHz.⁽²³⁾ However, the 1969 study reported that BAHAs improved mean sound-field warble-tone thresholds minimally in individuals with otosclerosis (by less than 3dB).⁽²⁰⁾

It would appear that hearing improvement is related to the size of the individual's air-bone gap. A 1998 study concluded that with an air-bone gap greater than 30dB, BAHA would provide better results than an ACHA.⁽²⁴⁾

Factors other than audiological results were also investigated. A 2004 study investigated the number of otolaryngology visits for draining ears, and reported a reduction, from an average of 12.7 visits in individuals with an ACHA, to just 3.3 with the

BAHA.⁽²⁵⁾ Quality of life scores were also calculated. No overall statistically significant changes were found using the SF-36 questionnaire; however, it was concluded that mental health was improved slightly, and disability was significantly reduced.⁽²⁵⁾ The 1998 study also reported that 80% of patients had a reduced incidence of ear infections, and described this as the BAHA's 'most important advantage'.⁽²⁴⁾

Overall, there appears to be a reasonable improvement in audiological results in individuals with congenital hearing loss; however, in other subgroups results are more equivocal, and depend quite significantly upon the individual's air-bone gap. It would appear that ACHAs can be effective, and perhaps are the aid of choice in those who are able to wear one, due to ease of implementation, and a lower cost. However, a BAHA can offer a successful alternative to those who cannot.

BAHA vs traditional bone-conduction hearing aids (BCHA)

Traditional bone-conduction hearing aids provide another alternative to air-conduction hearing aids in individuals who cannot benefit from these. A transducer is placed against the mastoid, and transmits sound to the cochlear in a similar way to the BAHA. However, as sound is transmitted first through the skin and underlying tissue, and then through the bone, its quality is diminished.⁽²⁶⁾

One theory for the improved hearing thresholds with a BAHA is sound quality remaining more acceptable at higher volumes, resulting in decreased saturation by loud sounds. Improved results in voice audiometry have been accredited to better functioning at high frequencies (most commonly used in speech perception).⁽¹⁴⁾

A number of studies have been carried out to investigate the difference in sound transmission between these devices. The study in 2000 showed a 37% improvement with the BAHA when studying pure-tone audiometry thresholds in individuals with congenital aural atresia.⁽²¹⁾ The 1996 study reported a statistically significant improvement of over 7dB with a BAHA when investigating mean sound-field warble-tone threshold.⁽²²⁾ A 1992 study investigated speech audiometry, and reported that the maximum phoneme score was 12.6% better with a BAHA.⁽²⁷⁾

A number of more practical problems have also been associated with the BCHAs. A common complaint has been the irritation and headaches caused by the pressure of the transducer against the head, required for successful bone transmission.⁽²⁵⁾ Another complaint relates to the aesthetics of the BCHA – a bulky headband is often required, making the device difficult to hide.⁽²⁸⁾ Implantation of the BAHA avoids these problems.

Overall, it would appear that the majority of individuals would be able to benefit from changing from a conventional BCHA to a BAHA. They are likely to experience improved audiological results, and are able to avoid some of the unwanted issues associated with BCHAs.

Adverse effects

As with any surgical procedure, BAHA implantation does have some associated adverse effects, such as infection, bleeding and those associated with anaesthetic exposure, as well as those more specific to the procedure. However, various studies have shown that even the more common effects are still quite rare. One problem is the possible loss of the implant. Another 2000

study followed 31 adults, and reported the loss of seven (19.4%) implants after a median of 42 months, due to trauma and severe dermatitis.⁽²⁹⁾ However, a 1994 study reported a loss of just 6.1% of implants, when following 33 participants for between nine and 25 months,⁽³⁰⁾ and a 1997 study reported the loss of 6.8% of implants.⁽³¹⁾

Skin reactions following placement of the abutment is also a recorded effect; however, upon observing 1,236 skin reactions, a 1990 study reported that 93.2% of participants experienced no skin irritation, and 4.1% had only slight skin irritation.⁽³²⁾ The 1997 study reported similar results, with 87.5% of participants experiencing no skin irritation.⁽³¹⁾

Overall, BAHAs appear to have minimal adverse effects, as well as a number of very positive features.

CONCLUSION

The BAHA is evidently a successful advancement in auditory science, and has the ability to change an ever increasing number of lives for the better. Numerous studies have reported improved results with the BAHA, stressing that the device provides a brilliant alternative for those unable to benefit from traditional devices, particularly those with chronic otitis or aural atresia who cannot be fitted with air-conduction hearing aids.

One point that must be stressed is the need for careful selection of candidates, and the importance of detailed guidelines outlining the criteria which must be met before an individual is even considered. It is clear that not all individuals with hearing loss are able to benefit from a BAHA. However, careful candidate evaluation can highlight those who will benefit most, reducing ineffective implantation and increasing cost-effectiveness. Thorough counselling can also ensure that potential candidates have realistic expectations and are aware of the implications, further increasing likelihood of success.

Although a commissioning policy exists, BAHA provision and funding eligibility differs considerably between trusts within the UK, leading to a vast variation in the services available, and the number of individuals receiving funding. A nationwide audit and database listing all BAHA candidates would provide information on such issues, and may lead to a more robust set of national guidelines, reducing unnecessary variation, and ensuring that all individuals who may benefit from the device have the opportunity to do so.

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