BAHA: Bone-Anchored Hearing Aid

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Abstract:

Bone-Anchored Hearing Aid (BAHA) has proven performance and advantages for patients with aural atresia or chronic ear drainage who cannot wear air-conduction hearing aids. The BAHA has both cosmetic and acoustic advantages over most conventional hearing aids and hence is becoming increasingly popular. Moreover, BAHA improves the quality of life and has also significantly reduces ear discharge. This extensive review of the literature pertaining to BAHA discus the history, the indications , the advantages, the prediction of the outcome and the complications of this device as well as comparing it to the conventional hearing aids.

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Introduction

Individuals with untreated hearing loss are more likely to report depression, anxiety and paranoia, and in addition, are less likely to participate in organized social activities when compared with those who wear hearing aids.[1-2] Hearing aid use is associated with significant improvement in social, psychologic, emotional, and physical aspects of the lives of hearing impaired persons with all degrees of hearing loss. This includes improvements in their relationships at home, their sense of independence, and their social as well in sexual functioning. [1-4]

Conductive hearing loss is a common type of hearing loss which, is not always amenable for surgical correction. Those patients are usually fitted with either conventional air or sometimes bone conduction hearing aids. However, difficulties arise when hearing loss is further complicated by chronic suppurative otitis media and/or otitis externa. In these particular situations, an ear mould is difficult or impossible to use. Some patients with bilateral conductive hearing losses who have complicating issues such as mastoid cavities, canal atresia, or revision ossiculoplasty continue to be a source of frustration for all involved in their care. In such patients the introduction of the bone-anchored hearing aid (BAHA) has proved to be an invaluable alternative rehabilitation resource. [5]

Hearing aids can be divided into two groups, distinguished by the principle of how sound is transmitted to the cochlea. The largest group is that consisting of air conduction (AC) hearing aids, with the other type being bone conduction (BC) hearing aids. The BC hearing aids are useful to a relatively small population of hearing impaired people, but nevertheless for this group often are the only satisfactory solution. The conventional bone conduction hearing aids use a steel spring headband to apply a vibration transducer against the skull to vibrate it. They are not in common use because of several drawbacks.

The implantation of a titanium screw into the mastoid portion of the temporal bone has made it possible to obtain a permanent and reaction-free rigid penetration of the skin. Connecting this titanium implant to a newly developed bone conduction hearing aid has allowed direct vibration transmission to the skull. At the time of development, this new hearing aid was named 'the bone-anchored hearing aid' (BAHA) and it is characterized by a single housing construction. The transducer piston of the BAHA is directly connected to the titanium screw by a low-profile coupling arrangement (5). This review article of BAHA will discus the history the indications , the advantages, the prediction of the outcome and the complications of this device as well as comparing it to the conventional hearing aids.

History of BAHA

In Sweden, Branemark found that if titanium screws were left undisturbed in bone, the osteocytes grow in close apposition to the titanium surfaces and provide firm anchorage without an intermediate connective-tissue layer. [6] This discovery, called “osseointegration”, has lead to the development of percutaneous titanium implants. In 1965, Branemark et al [7] reported successful application of osseointegration in dental and craniofacial reconstructive surgery. This was followed by a large amount of published data on commercially pure titanium implants supporting craniofacial reconstructions such as auricular, nasal, and orbital epitheses. Nine years later, Tjellstrom et al [8] introduced the concept of direct bone conduction which could be achieved by using a skin-penetrating coupling from an osseointegrated titanium implant in the mastoid bone. [9] Although, bone-conduction hearing aids were first described in the 18th century [10], the usage of Bone Anchored Hearing Aids as skin-penetrating implants was started in 1977. [11] The BAHA device became commercially available in 1987. Tjellstrom and Granstrom [12] modified the original technique of two stages procedure into a single-stage procedure in which the establishment of the skin-abutment interface was performed at the time of fixture implantation. The success of single-stage BAHA surgery in adults was statistically comparable to that obtained with two-stages implants in the same clinic.[13]

BAHA procedure was cleared by the U.S. Food and Drug Administration (FDA) in the summer of 1997. Lustig et al [14] evaluated the U.S. experience of the first 40 patients implanted with the BAHA in 12 tertiary referral medical centers. This was a nonblinded, retrospective muliticentre case series study. They reported the BAHA provided a reliable and predictable adjunct for auditory rehabilitation in appropriately selected patients, offering a

means of dramatically improving hearing thresholds in patients with conductive or mixed hearing loss who are otherwise unable to benefit from traditional hearing aids. Patient responses to the implant were uniformly satisfactory.

The advantages of the BAHA

The BAHA system uses an osseointegrated titanium implant to propagate sound directly to the inner ear through the skull, bypassing the impedance of the skin and subcutaneous tissues. Most patients express a clear preference for the BAHA over conventional bone-conduction hearing aids. [15] The device has been thoroughly evaluated by various implant groups. Since its introduction in 1977 until 2004, more than 15,000 patients have been fitted with BAHAs worldwide. [16]

A key advantage of the BAHA is that the ear canal is not occluded by ear-moulds, preventing humidity build up and skin irritation. [17] Certainly, there are obvious advantages of the BAHA over air conduction hearing aids when there is no external ear canal, such as in cases of congenital or acquired external canal absence. The expected outcome of BAHA surgery can be assessed preoperatively by using the head-band or test rod (sometimes also called the bite-bar), tremendously helping patient selection. Moreover, the absence of the interposed soft tissues in BAHA results in a better sound quality, requires less energy, and offers greater comfort than the traditional bone conduction hearing aids. [9] Hakansson [18] summarized the audiometric results from 122 patients with an average follow-up time of 5.6 years. They found the improved quality of life reported by their patients is a combination of improved audibility and quality of sound (warble tone threshold, speech reception threshold, and discrimination in noise), improved comfort, and relief from middle ear and ear canal diseases occasioned by conventional hearing aids.

Predicting hearing ability with the BAHA

The BAHA introduces the sound into the mastoid bone directly (percutaneous), bypassing the damping effects of the skin and subcutaneous tissues (transcutaneous). [20] The BAHA is expected to be better in many respects [20] since the titanium screw delivers sound directly to the skull without soft tissue interference. The headband or test rod, although crude in many ways, still offers an easy, fast and objective way of assessing bone conduction capacity which allows the patient to directly experience bone conducted sound, and so helps in decision making for him/her.

As a guideline for general patient selection, objective audiologic criteria may be used for predicting success with the BAHA. Generally, for conductive or mixed hearing loss, the patient should have adequate sensorineural reserve measured by a bone-curve of at least 45 dB HL, and an unaided speech discrimination score (word recognition score) greater than or equal to 60%. [21] Håkansson et al (22) reported their 10-year experience with 147 patients in Sweden. They divided their patients into three groups based on their pure-tone average (PTA) bone thresholds; 0 to 45 dB, 46 to 60 dB, and >60 dB. They noted a strong relationship between PTA bone conduction thresholds and successful rehabilitation. In the group with the best cochlear reserve (PTA <45 dB), 89% felt their hearing was subjectively improved after BAHA, and 8% felt their hearing was worse. Conversely, in the groups with progressively less cochlear function (46– 60 dB and >60 dB), 61% and 22% respectively of patients reported subjective hearing improvement. Further, on average, speech discrimination scores improved from 14% unaided, and 67% with a traditional hearing aid, to 81% with the BAHA. This increased to 85% if people with a sensorineural loss >60 dB HL were excluded, and to 89% if subjects with a PTA >45 dB were excluded. These authors recommended that a “high success rate” with the BAHA could be achieved if patients have a PTA bone curve of <45 dB, and this has become the manufacturers recommendation. BAHA cordelle is more powerful bone-anchored hearing aid, which also can aid thresholds in the high frequency range better than with the classical BAHA. [23]

Indications

Bone-anchored hearing aids are relatively expensive devices (approximately $10,000). Therefore, it is important to assess the quality of life in BAHA users and to identify the group of patients who are likely to derive maximum benefit, which is essential to making policy decisions regarding funding and prioritization of different patient groups for BAHA. [24] Current criteria include otological indications such as congenital malformations of the external and middle ear, chronically

discharging ear, conductive hearing losses attributable to ossicular disease, or as an alternative if the patient is unable to be aided with conventional air-conduction aids.

In adults, the majority of patients who required BAHA are those who suffer from chronic otitis media and mastoiditis and were unable to tolerate traditional air conduction hearing aids or in whom these were contraindicated due to either recurrent otorrh-oea, otitis externa or aural stenosis. Single sided deafness is relatively a new indication which is getting more and more common indication for BAHA. [10]

In the pediatric age group, the most common indication for BAHA is congenital aural atresia, a group which has the highest satisfaction of all users (14;25). This may reflect the fact that these patients perceive any improvement as beneficial, whereas other groups often have been aided by other means, or have experienced normal hearing. Generally, patients in this group tend to have better cochlear reserve than other groups. Moreover, BAHA avoids the several potential complications of surgical reconstruction of congenital atresia, an operation fraught with difficulty in young children with acceptable results only in expert hands. BAHA, usually as a softband delivery, can also be a temporary solution before canal reconstruction can be performed more safely at an older age. [26]

Unilateral conductive hearing loss

A unilateral severe conductive hearing loss (HL) (40- to 60-dB HL) with a second normal-hearing ear is not uncommon. If fit with a BAHA, these patients will have binaural hearing where the two cochleae can be independently stimulated enough to allow sound localization to occur(1;2;27). These studies found that the BAHA contributes significantly to sound localization and suggest that the sound perceived by the cochlea nearest to the BAHA can complement that perceived by the other ear enabling directional hearing in patients with unilateral severe conductive hearing loss.

Documented benefits

Many studies have documented a high degree of satisfaction in relation to sound amplification, listening to radio or television news, listening to music, speech perception in quiet conditions, during conversation with one person in noisy surroundings and conversation at home. [28-33] Most patients (90 per cent of BAHA users) used their BAHA for more than eight hours a day, and every day of the week (93 per cent of BAHA users). [31,34] Even borderline BAHA candidates (mean BC thresholds in the better hearing ear > 45 dBHL in the frequency range 0.5-4 kHz) have demonstrated BAHA benefits compared to their previous aid, both audiologically and in terms of comfort and reduction in ear discharge. [35] In children, despite limited thickness of the temporal bone, the BAHA provides a safe and effective means of rehabilitation of conductive or mixed hearing loss. [36,37] Moreover, BAHA offers a third treatment option for otosclerosis in patients who cannot or will not undergo stapedectomy and experience difficulty with conventional hearing aids[38] as well as patient with Paget's disease. [39]

Many studies have used various instruments to assess BAHA benefit. The Glasgow Benefit Inventory has been used in many studies, and has documented significantly enhanced general well being (patient benefit), improved patient's state of health (quality of life) and that the BAHA was considered a success by patients and their families. [25,40] General Quality of Life (QOL) scores shows similar results. [29] Arunachalan et al [28] used the validated Glasgow Benefit Inventory (GBI) to quantify the changes in life quality of BAHA patients. They enrolled 60 consecutive BAHA patients. The general benefit score was + 40 which is comparable to middle ear surgery, but just below benefit measured from cochlear implantation. The social benefit was + 27 with only + 10 for the physical score. This study was the first to demonstrate that there was significant increase in the quality of life from BAHA. Interestingly the BAHA device has sometimes demonstrated 'overclosure' of the preoperative bone-conduction threshold of the better hearing ear [14], and has the potential to relieve tinnitus in the same way as air-conducted sound [41], in addition to a low susceptibility to electromagnetic interference. [42]

Children and BAHA

The majority of children fitted have had conductive hearing loss resulting from craniofacial abnormalities; the most common abnormality being mandibulofacial dysostosis (Treacher Collins syndrome). [43] BAHA is a very effective hearing

option for children with conductive hearing loss. [43-45] The major limitation is the relative thinness of the pediatric skull (average ٢,٥mm) which requires shorter screw lengths. Also, the surgeon is faced with continuous growth of the skull, and the fact that the majority of children who are candidates for this type of hearing aid often have abnormal skull contour. [12,46,47] In this population, the susceptibility to trauma and difficulties in post-operative care increase the failure rate of osseointegration to 15%. Therefore, BAHA surgery is usually done in ٢-stages, often with two fixtures routinely implanted, one as a "backup", since the fixture implant makes up only 10% of the cost of the operative procedure. [43,45]

Young children or non surgical candidates can still benefit from BAHA by using the Soft-Band. [26] Although, with bone augmentation techniques it is possible to find space for 3-mm implants even in 1-year-old children, the surgeon should be ready for any intra-operative trauma to the dura and sigmoid sinus. [48]

Children with Down's syndrome are good candidate of BAHA when conventional hearing aids have failed. [49] Sheehan et al [49] found a high level of satisfaction with the BAHA amongst patients, parents and careers when they evaluated 43 children with Down's syndrome. They concluded that the BAHA is a valuable method of hearing amplification in children with Down's syndrome, and while it should not be considered as a primary method of amplification, it is invaluable in the overall management of individuals with Down syndrome after conventional hearing aids and/or ventilation tubes have been tried and failed.

Bilateral BAHAs

Binaural hearing may be considered as important to an individual as binocular vision. [50] Bilateral BAHA, like bilateral hearing aids and bilateral cochlear implants, are still not acknowledged as an adding benefit by some practitioners. Bilateral fitting of BAHAs is a practice that appears to be dictated by the knowledge and attitudes of local otolaryngologist and audiology teams and most certainly is affected by cost issues. [50]

It has been demonstrated that there is an improved sound localization ability and better speech-in-noise perception with bilateral air conduction aids. [51;52] Binaural hearing with bone conduction is a subject of controversy. One argument is that the bilateral application of any bone-conduction device may not be useful because the intracranial attenuation of skull vibrations is so small that even one bone conduction device will stimulate both cochleae at the same time with almost the sound power. Moreover, stimulation via bone conduction at the lower frequencies may result in higher stimulus levels at the contralateral cochlea. [53,54] Nevertheless, promising results have been reported in diotic summation (improved speech recognition in quiet) and the ability to separate sounds in the binaural listening condition, improved sound localization and improved speech recognition in noise when the speech and noise signals are separated in [16,54,55-60] space. In addition, the use of bilateral bone-anchored hearing aids has been shown to significantly enhance the general well being (patient's benefit) and improve the patient's subjective state of health (quality of life). [61]

Unilateral inner ear deafness

The head shadow effect is an important phenomenon which occurs when the head is between the auditory signal and the better hearing ear. In this case, the head attenuates the signal intensity reaching the better hearing ear by 10 to 16 dB in frequencies above 1000 Hz. [62,63]Therefore, people with unilateral deafness have difficulty hearing people on their deaf side. In addition, they have an inability to localize sound, and difficulty in understanding speech with background noise.

A unilateral sensorineural hearing loss or dead ear has been considered by some to be a relatively minor handicap which does not require help. If this was rehabilitated, then the traditional option was a CROS hearing aid. This has many drawbacks such as poor aesthetics and patient acceptance. [64-66]. The above studies have found that about 20% of hearing aid owners were dissatisfied or very dissatisfied with their CROS hearing aids, more than 10% did not use their hearing aid, more than 20% experienced stigma when they used their aid and almost all reported poor general performance in noisy environments.

The BAHA is increasingly used for single sided deafness (SSD) because it effectively eliminates the head shadow effect by bringing sound trancranially to the good ear. In SSD, BAHA shows significant benefits in situations involving background noise and reverberation and a reduced aversion to loud

sounds in comparison to the unaided and conventional CROS conditions [10;25;67-69]. These studies also were reassuring in finding that wearing the BAHA did not interfere with the function of the normal contralateral ear by the interference through bone conduction [70]. However, BAHA does not help sound localization and laterality judgment in SSD patients [71;72].

BAHA and conventional hearing aids

In 1994, Browning et al. [73] wrote "use of and benefit from a hearing aid are two separate issues, it is being not uncommon for a patient to be wearing a hearing aid with flat battery yet reports that it is of value. Therefore, It is important not solely to rely on patient report of use and benefit, but to back up these where possible with objective measures. The amount an aid is used is a combination of benefit along with need and motivation. The latter can be greatly influenced by the attitude with which an aid has been provided, enthusiasm being greater for new expensive models". As an example of this, Belus [74], reported the very interesting result that some BAHA patients had improvement in reception without the hearing aid connected to the abutment, which he called an "antenna" effect. This reinforces the comments above that subjective benefits are fraught with complicated factors affecting measured results. Despite this, an increasing number of studies have supported the advantage of BAHA compare to other hearing aids:

Conventional bone-conduction hearing aid

Conventional bone anchored hearing aid consists of a transducer and amplifier attached to a headband or spectacle frame. It is designed to press firmly against the skull vault. These hearing aids have remained unpopular due to their poor aesthetics, discomfort due to constant pressure from the transducer, and poor sound quality at higher frequencies [5;33]. In BAHA, sound transmission to the skull is direct. Therefore, it is possible to achieve the same hearing threshold as with transcutaneous conventional bone conduction but with a lower output of the transducer [75] and therefore less distortion [5].

Most studies which have compared patient's satisfaction following BAHA surgery with their experience with conventional bone-conduction hearing aids have shown results that are almost always in favor of BAHA [22;46,73,74,77,78]. Conventional bone-conduction hearing aids require high pressure on the skin to maintain good pressurized contact between the bone transducer and the mastoid bone, and this may cause serious problems such as headaches, skin irritation, pressure sores and head deformity leading to non-use especially in children. In addition, the sound quality is inconsistent due to shifting of the transducer over the mastoid bone. Sound dampening occurs between the conductor and the mastoid with conventional bone conduction aids, resulting in poor sound quality from soft tissue attenuation. Poor sound quality is of great concern in the rehabilitation of children because their conductive deafness is present when they are attaining speech and language. The speech recognition in general and speech-in-noise in particular are significantly better with BAHA than with conventional bone conduction hearing aids [76,79]. These considerations, plus the esthetic disadvantage of wearing a highly visible aid, make it particularly difficult to use conventional headband-mounted pressure aids successfully in general, and in the pediatric population in particular [43]

Air conduction hearing aids

Although some authors report that BAHA is significantly superior to air conduction hearing aids in all respects [80,82], some found no difference [82;83] but the majority reported conflicting results depending on the underlying disease process that mandated the hearing [73;78;79;84,85] aid. However, even studies with ambiguous results have found that BAHA was more favourable than AC hearing aids in patients with chronically discharging [79;83;84] Ears.

Complications

Relatively little has been published about the difficulties encountered during the insertion of osseointegrated implants for the attachment of bone anchored hearing aids (BAHA) or the complications encountered after surgery. Snyder et al [86] identified the complicating medical factors for graft loss. They include smoking, steroid use and diabetes. However, they had a small study size which did not allow statistical correlation.

Current techniques of fixture implant-tation and osseointegration are associated with minimal complication rates [87]. However the health of the titanium implant and the ultimate

success of the BAHA depend heavily upon meticulous surgical care and cleaning of the abutment. However, complications of BAHAs can be considered in two categories: intra-operative and post-operative complications.

Intra-operative complication:

Intraoperative complications are more common in children because most of them have craniofacial abnormalities [43]. Despite this, the rate of implant survival and adverse skin reactions are comparable to the adult implant group [11;46;48]. One common complication is dural exposure which can result in a CSF leak. Another complication is sigmoid sinus injury and bleeding. These complications limit the length of the fixture that can be implanted but do not seem to preclude osseointegration (88). Some surgeons perform bone augmentation to thin temporal bones and a two stages procedure to protect the implant in children [47].

Post-operative complications

Post-operative complications are few but require frequent visits to the clinic. The commonest complications are local infection and inflammation at the implant site as well as a failure to osseointegrate. Holgers et al [89] classified the skin reactions into:

0 = No irritation
1 = Slight redness
2 = Red and moist, no granulation tissue
3 = Red and moist with granulation tissue
4 =Revision of skin penetration necessary

Loss of the osseointegrated fixture from the skull is a serious complication. Many cases of fixture loss have been reported as a result of trauma, especially in paediatric patients and those with poor hygiene [90]. Soft tissue overgrowth or sagging with gravity may interfere with the mating of the BAHA transducer to the abutment. This can be avoided by generous soft tissue reduction especially in the superior part. Partial loss of graft can be handled by local wound care consisting of wet-to-dry dressings, and the open wound around the implant eventually heals by secondary intention. The other option which can be considered in case of big defect or total loss of the graft is to repeated the skin graft which can be harvested from the nearby region after shaving or from a distal hair-free area.

Percutaneous implants may be lost for various reasons; most frequently because of loss of osseointegration, trauma, infection, bone disease or radiation. This loss could reach up to10% in long term follow up [11]. Only a few studies have evaluated the retrieved craniofacial implants and performed histomorphometric measurements, which makes it difficult to reach final conclusions regarding the histological process of abutment loss [91-93].

Knowledge of the rare possible complications is of importance for the treatment and follow-up of patients with BAHA. Two cases of intracerebral abscess [94;95] and one metastatic carcinoma [96] after BAHA placement has been described in the literature. Although, these are rare complications, they are fatal and CT or MRI should be initiated in any case with neurologic symptoms, therapy resistant headaches, or if local evidence of infection persists.

The BAHA related pain is a rare complication but may required removal. Mylanus et al [93] reported seven retrieved craniofacial implants and found all of them were stable before removal. They found less mature bone under the flange as well as bone formation and resorption in the majority of the implants. Inflammatory cells were observed in the interface between bone and metal and especially under the implant flange which was the only clear common phenomenon in all seven retrieved implants. This may explain the patients' experience of pain. In most patients, the complaints diminished or disappeared after removal of the implants. Other unusual complications reported in the literatures are sudden dizziness with mobile phone use [97], sensitivity to wind noise and lack of a phone connection [98] and continuous growth of the bone [46].

Conclusion

The BAHA device has been thoroughly evaluated by various implant groups. These studies showed that, in audiological terms, the BAHA is superior to conventional bone conduction devices. In comparison with air conduction devices, the results are ambiguous, but in certain groups the BAHA is clearly superior and it can reduce aural discharge. Bilateral BAHA application in conductive hearing loss leads to binaural sound processing and the application of the BAHA as a transcranial CROS (contralateral routing of signal) device in

unilateral deafness effectively minimizes head shadow effects.

The BAHA is an excellent hearing aid which has proved its usefulness over time if candidates are selected properly and surgery been done meticulously. However, the financial costs are relatively high because of the surgical procedure involved and in the absence of competition,. This is the major drawback of this excellent hearing aid in the developing countries.

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