DOI: 10.7860/JCDR/2023/62729.18289

Review Article

Ear, Nose and Throat Section

Bone Anchored Hearing Aid: A Narrative Review

SONAAKSHI KUSHWAHA[1], PRASAD DESHMUKH[2]

BY-NC-ND

ABSTRACT

Bone Anchored Hearing Aid (BAHA) is a small vibrator that can be reversibly attached to a Titanium (Ti) screw and implanted behind the ear. It uses the bone conduction channel to activate the cochleae by converting sound into the vibration of the screw. The two main indications are conductive hearing loss and unilateral deafness when using traditional hearing aids is not possible, as a rehabilitative or mixed hearing loss with a moderate perceptual component. For patients with canal atresia, Single-sided Deafness (SSD), and chronically discharged ears despite treatment, the BAHA implant is an option. Combination hearing loss is a crucial indicator for implanted hearing implants. Various options are accessible based on the bone conduction threshold. Patients with modest sensorineural impairment usually benefit from transcutaneous Bone Conduction Implants (BCI), while those with intermediate hearing loss may also benefit from percutaneous BCI devices. For combined, active middle ear implants are advised for hearing deficits with moderate and severe cochlear hearing loss. For individuals who need middle ear surgery or who are incompatible with other options for therapy, implants are a helpful and successful addition. Skin-drive Bone Conduction Devices (BCDs) are BCDs that vibrate the bone via the skin can also be separated into passive subcutaneous devices and traditional devices that are coupled, for instance, with soft bands with implanted magnets. BCDs that directly stimulate the bone, percutaneous devices, and dynamic transcutaneous devices are examples of direct-drive devices. The latter kind of apparatus uses embedded transducers to stimulate bone effectively via healthy skin. The BAHA, also known as the percutaneous direct-drive device (BCD), now rules the market. More direct-drive and skin-drive transcutaneous solutions are now being studied, partly due to problems with the transdermal implant and partly for aesthetic reasons.

Keywords: Hearing loss, Implant, Otological illness

INTRODUCTION

A typical hearing aid may be effectively fitted to most deaf people by inserting an occlusive ear mould into the external ear canal. Despite satisfying audiological requirements, some hearing-impaired individuals may find it challenging to wear a standard hearing aid. For instance, patients with congenital middle ear deformity or agenesis, who have restriction of the external ear canal cannot utilise an ear mould [1]. Furthermore, those with Chronic Suppurative Otitis Media (CSOM) who are hearing-impaired have ear drainage, which often grows worse when an occlusive ear mould is worn. Another group of people who frequently have difficulties while wearing a standard hearing aid are those who have a canal wall down the mastoidectomy cavity [1]. Therefore, the typical hearing aid's occlusive ear mould is the principal obstacle to hearing restoration in several otological illnesses for these individuals, BAHA offer a practical substitute for conventional hearing aids, and do not require external ear canal closure. Unilateral deafness has most recently been added to the list of circumstances that call for a BAHA [1]. For these individuals, the BAHA is positioned on the deaf side, and sound is transmitted to the functioning cochlea by bone conduction. Patients report greater levels of satisfaction with the BAHA than they do with a conventional hearing aid [1].

The titanium fixture and the sound processor are the two components of the BAHA implant. The titanium fixture is fixed to the processor by a skin-penetrating abutment. Recently, a more compact version of the sound processor was created, boosting its visual appeal [2]. Tjellstrom first proposed the idea of titanium osseointegration in 1977 for bone conduction hearing aids [2].

The major requirements for the implants are potential faultless listening, low failure rate, high reliability, low visibility, minimum surgical risk and affordable price. Clients were initially only administered active middle ear prosthesis, whose medical conditions prevented them from benefiting from conventional hearing aids. Patients with conductive and mixed hearing impairments can now be treated because of the round window-vibroplasty procedure [3-6].

Historical Development

More than 80 years have passed since the invention of middle ear implants. In order to stimulate the ossicles with a magnetic field, Wilska injected iron particles into the eardrum in 1935 [Table/Fig-1] [7-11].

Year	Achievement/Work
1959	Rutschman J applied ten milligram magnets to the malleus, which was vibrated by an electromagnetic coil [7].
1973	Frederickson et al., from the University of Washington in the United States placed the first mechanical implant [8].
1977	Finally, the "Bone Anchored Hearing Aid" (BAHA)-the first set of partly implanted hearing systems- was created.
1988	In order to improve hearing, Heide et al., placed a magnet at the ossicles and an induction coil at the outer hearing canal. Middle ear implants with piezoelectric transducers were developed as a consequence [9].
1993	Perkins and Shennib created the Earlens tympanic contact transducer in 1993 using a SmCo magnet that was inserted into a soft silicone lens at the tympanic membrane.
1996	Siemens Company originally created the Symphonix Sound bridge system, which was later redesigned by Ball as the Vibrant Sound Bridge (VSB). Later, the system was included to the Med-El Company's product line, and the company created the present function. Fish carried out the initial implantation in 1996 on a patient who had only sensory hearing loss [10].
1998	The first fully implanted hearing device was the TICA LZ 3001 ("totally implantable cochlear amplifier") of the Implex Company that came on the market [10].
2000	The VSB was the first AMEI for those with sensorineural hearing loss that the FDA has authorised [10].
1821	The first bone conduction hearing device was created by Itard and consisted of a sort of megaphone attached to the patient's teeth [10].

1925	The first patent was granted for the "Bone Conduct Vibrator" (BCV) [10].
1970s 1977-78	Data of the first three patients with a bone anchored hearing implant were initially presented in 1977, after the creation of a tooth implant with bone conductive capability. The device has been sold under the name Bone Anchored Hearing Aid (BAHA) since 1978 [10].
1986-87	The first international workshop on bone anchored implants took place The BAHA gadget initially became marketed in 1987 [10].
1997	The FDA in the US approved the BAHA procedure. The first 40 patients implanted with the BAHA at 12 tertiary referral medical centres in the United States were studied by Lustig LR et al., [11].
2005	The BAHA implants were purchased by Cochlear Company. It created the first BAHA using a directional microphone and a digital audio processor.
2012	The world's first active Bone Conduction Implant (BCI) was introduced by Med-EL [10].

[Table/Fig-1]: Year-wise historical developments of active middle ear implants [7-11].
BCI: Bone conduction implants

Principles

In a manner similar to how a tuning fork works, the cochlea is stimulated by BAHA through bone conduction. In contrast to a traditional hearing aid, pathological diseases of the external and middle ear are bypassed, thus they do not affect hearing. The cochlea is stimulated by bone conduction as a result of many physical processes [12]:

- Sound radiation in the external ear canal (predominantly at high frequencies)
- Exertion of the inner ear liquids and the tympano-ossicular chain (predominantly at low frequencies)
- Spaces of the inner ear being compressed (predominantly at mid frequencies)

The latter two occurrences are numerically the most significant for BAHA, and the degree of sensorineural hearing loss will ultimately set a ceiling on hearing gain. The use of a BAHA does result in sound radiation in the ear canal, however, this sound energy is substantially reduced when it reaches the inner ear because of the pathologic condition of the middle ear. The contralateral cochlea is stimulated as sound waves travel through the skull's bones. To get beyond the limits of transcutaneous devices, such a bone conduction hearing aid put into a headset or eyeglasses, the BAHA employs a percutaneous titanium bone-integrated fixture. Most intriguingly, the BAHA doesn't experience Larsen's effect or acoustic feedback [12].

Indications

People with conductive and mixed hearing impairments can be rehabilitated using the BAHA. This includes those who have a persistent ear infection, those who have an absent ear canal or one that is very small due to a congenital ear deformity, an infection, or surgery, and those who have suffered a single-sided hearing loss following surgery for a vestibular schwannoma [13].

1. BAHA is typically the best treatment option for conductive hearing loss. This is because conductive loss frequently co-exists with different outer and middle ear abnormalities (such as atresia) or middle ear diseases like continually leaking ear, which prohibit the use of traditional hearing aids. The conductive component of hearing loss is averted with BAHA by transmitting sound vibrations from the BAHA through the skull to the cochlea.
2. For all individuals with mixed hearing loss, BAHA offers a two-pronged approach. It begins by bridging the air-bone gap by avoiding the conductive component. Second, it makes up for any sensorineural hearing loss that is still present. It is advised when the conductive component of the mixed hearing loss is larger than 30 dB since the total amplification needed for patients with a mixed hearing loss is less with BAHA than with traditional hearing aids [14,15].
3. Single-Sided Sensorineural Deafness (SSD): SSD causes significant communication difficulties for the patient due to inability to localise sound. The head shadow effect is eliminated by wearing BAHA on the deaf side, which transmits the signal straight across the skull via bone conduction. However, these individuals must have normal hearing in the opposite ear (20 dB HL air conduction pure tone averages). In these patients, BAHA improves directional 360-degree hearing. According to studies, BAHA users can perceive speech more clearly than contralateral routing of signal CROS users [16].

Complications

1. **Infection:** Local wound inflammation surrounding the abutment is often categorised as follows using Holger and colleagues' clinical grading method [13].

   Grade 0: No irritation

   Grade 1: Slight redness

   Grade 2: Red and moist

   Grade 3: Same as 2, but also with granulation tissue formation

   Grade 4: Skin irritation of such a degree that the abutment has to be removed.

   Depending on its severity, the skin response may require different treatments. A topical antibiotic ointment is advised for Grade 1 responses. Grade 2 responses may be treated by reapplying the healing cap and temporarily covering the affected region with antibacterial gauze. Revision surgery is required for responses of Grade 3 and 4 [13]. Children seem to experience inflammation around the abutment more frequently than adults do [17]. *Staphylococcus aureus* may be the cause of persistent, ongoing infections near the implant. Additionally, more serious infections such as intracerebral abscess and osteomyelitis with fixture loss might develop [18].
2. **Failure of osseointegration:** There may be variations in the signs and symptoms of osseointegration failure. In the worst case scenario, the abutment-fixture complex might be so flimsy that it comes free. The fixture may still be in place if a fibrous connection is present, but the patient could experience little to no sound or claim that the sound processor is distorting the sound. The abutment-fixture complex will spin freely while attempting to tighten the abutment in the office under these conditions. A variety of factors need to be considered for successful osseointegration. The right surgical method must be used during the initial procedure. The thickness of the bone is another crucial aspect. The thickness of the temporal bone is commonly correlated with the age of the patient at implantation and craniofacial morphology. Patients with craniofacial anomalies usually have little bone at the suggested implantation site. One cause for implant losses in the absence of any visible injury is idiopathic bone resorption at the bone-metal contact [19].
3. **Bone overgrowth:** When an unreachable loose abutment, bone expansion should be considered. Only children have bone expansion, especially between the ages of 5 and 11 [20].

Complications from BAHA implant surgery might develop during or after the procedure. Children's small skulls can lead to intraoperative issues including haemorrhage. Bone wax can be used to quickly stop bleeding caused by a dura injury. Sometimes the surgeon needs to drill three or four times before the fixture is properly positioned [2].

Only a little amount of information has been published regarding the challenges involved in placing osseous implants for BAHA attaching or the problems that may arise following surgery. The complicating medical variables for graft loss were found. They consist of diabetes, steroid use, and smoking. However, due to the small study size, statistical linkage was not possible [11]. Current fixture insertion

and osseointegration approaches have low rates of complications. However, the final factor is the Ti implant's health.

Careful surgical handling and abutment cleaning are essential to the BAHA's success. However, there are two types of BAHA problems: intraoperative complications and postoperative complications. Children are more likely to experience intraoperative difficulties than adults since most of them have deformities of the face and skull. However, the rate of implant survival and undesirable skin reactions is comparable to that of the group of adult implants. Dural exposure is a frequent problem that can cause a Cerebrospinal Fluid (CSF) leak. Injury and haemorrhage to the sigmoid sinus are additional complications. These issues restrict the duration of the implantable device, but do not appear to prevent osseointegration. Some surgeons conduct a two-stage operation to safeguard the implant in youngsters and bone augmentation to thicken children's temporal bones. Although postoperative problems are uncommon, they still necessitate periodic clinic visits. Local infection, inflammation, and failure to osseointegrate at the implant site are the most frequent side-effects. Numerous instances of fixture loss, following trauma have been documented, particularly in young patients and those with poor cleanliness. The BAHA transducer's ability to mate with the abutment may be hindered by soft tissue overgrowth or gravity-induced drooping. Generous soft tissue reduction, especially in the superior section, can prevent this. Local wound care with wet-to-dry dressings can treat partial graft loss, and the open wound around the implant eventually heals by secondary intention. The other alternative that may be taken into account in the event of a significant flaw or complete loss of the graft is to repeat the skin transplant, which can be taken from a distant hair-free area or a close area after shaving. In the literature, there are two occurrences of intracranial infection and one case of metastatic cancer following BAHA implantation [11]. Even though these consequences are uncommon, they can be deadly, thus a Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) should always be done if there are any neurologic symptoms, headaches that don't go away after treatment, or persistent local infection evidence. Other strange difficulties mentioned in the literatures include abrupt lightheadedness when using a phone, sensitivity to wind noise and no phone connection, and ongoing bone development [11].

Recent Developments

Sophono® and Baha® Attract are examples of "skindrive systems," which transmit vibrations via the skin, and Baha®, Ponto, BCI, and Bonebridge TM are examples of "direct-drive systems," which transmit vibrations directly to the skull bone [21]. The initial distinction between "direct-drive" and "skindrive" BCDs was created in order to group all currently available BCDs for hearing rehabilitation. All direct-drive BCDs bypass the skin by directly vibrating the skull bone. Skin-drive BCDs, also known as classic and passive transcutaneous BCDs, use the skin to convey vibrations. Similar market segments might be used to direct-drive BCDs, which are divided into percutaneous and active transcutaneous devices. Another type of BCDs called in-the-mouth BCDs stimulate the ear by vibrating a tooth's rather robust root that is fastened to the skull [21].

Direct-drive BCDs use a screw or flat surface connection to directly deliver their vibrations to the bone. The great majority of active transcutaneous and percutaneous devices are found in direct-drive BCD classes. An implanted transducer is an active device, but a BAHA is classified as a passive device (Class IIb in the EU-European Union) (AIMD in the EU and Class III in USA) [21]. The BAHA was the first Percutaneous direct-drive BCD. It was developed to overcome the drawbacks of the current technology (To eliminate skin compression problems and enhance rehabilitation by improving high-frequency sound transmission). In the BAHA, the sound processor is fixed to the skull bone using a Ti screw and an abutment. The BAHA activates the bone as a result, bypassing the need to vibrate the skin.

The BAHA audio processors, which are made by Cochlear Bone Anchored Solutions AB and Oticon Medical, have greatly advanced over time. The most current versions are Cochlear Bone Anchored Solutions' Baha® 3 Power and Baha® 4. The Ponto Plus series includes the newest Oticon Medical models. Most conductive, mixed, and SSD are authorised for the use of BAHAs on both adults and children (SSD).The BAHA devices include more sophisticated signal processing to improve speech comprehension in the presence of background noise. The BAHA, perhaps the most potent BCD device currently in the market, has been used by more than 150,000 people and offers efficient hearing rehabilitation [21].

The VSB sound processor and induction connection were used to drive a BEST transducer in the key preclinical research on cadavers that were supported by MED-EL and led to the first conclusion that a percutaneous system might be replaced by an active transcutaneous BCD. The development of fully functional active transcutaneous systems like the BCI and the Bonebridge™ systems was influenced by an important conclusion from these investigations: MPO in the transcutaneous solution was found to be adequately high compared to a percutaneous BAHA solution [21].

Advantages and disadvantages of Bone Conduction Implants (BCI) [10]:

1. **Passive BCI [10]:**
   - Baha Attract:

     Advantages: Up to 1.5 T compatible with MRI, good skin tolerance.

     Disadvantages: High contact pressure, skin thickness reduces the amplification.
   - Sophono Alpha [10]

     Advantages: Up to 3T MRI compatibility, excellent skin tolerance.

     Disadvantages: a large external component and poor amplification (45 dB are not obtained).
2. **Active BCI [10]**
   - Active percutaneous systems
     - Baha Connect

       Advantages: MRI friendly.

       Disadvantages: Possible screw extrusion; urgent medical attention is required.
     - Oticon Ponto

       Advantages: 3T MRI compatibility.

       Disadvantages: Extrusions of screws and intensive care.
   - Active transcutaneous systems [10]
     - Oticon BCI best transducer

       Advantages: 1.5 T compatible with MRI.

       Disadvantages: high contact pressure, a large audio processor
     - Med-EL Bonebridge

       Advantages: Traditional skin issues including infections and proliferative development at the anchoring site can be avoided thanks to transcutaneous transmission. Skin and hair thickness have no effect on the signal. It is 1.5 T MRI compatible.

       Disadvantages: The surgery is challenging since the implant is rather large. Often, it is impossible to prevent exposing the sinus and/or dura [10].

NEW TRENDS

Making hearing aids more aesthetically pleasing or as undetectable as possible are frequently the two directions in which their design is progressing. The visibility of wearing a hearing aid is decreased by switching from percutaneous to transcutaneous sound transmission. The difficulties of skin penetration, however, are what first spurred the development of transcutaneous devices. The only innovative devices mentioned in this review article that retain the integrity of the skin are active transcutaneous direct-drive BCDs (BCDs that transmit vibrations directly into the bone) and passive transcutaneous skin-drive BCDs (BCDs that transfer vibrations through the teeth). Therefore, implants with healthy skin are more frequent [4].

Through an inductive connection through the skin, the Maximum Power Output (MPO) in active transcutaneous BCDs is lowered by around 10-15 dB. This is a sizable loss, and the BAHA experience suggests that, if it cannot be made up for in any other way, a link-driven device's use should be severely curtailed in the event of such a loss. But research has indicated that the sensitivity rises at BC stimulation sites that are nearer the cochlea. The fit and adherence of the implanted transducer housing to the skull bone presents another difficulty. Utilising a Ti screw in the bone-bored hole is one possibility [22]. In humans, there is a considerable danger of damaging the facial nerve, semicircular canals, and other sensitive tissues when screws are inserted into deeper parts of the temporal bone. Because of the air cells that make up the mastoid part of the temporal bone, a screw connection would not last very long. The Bonebridge™ uses two osseointegrated screws to keep the transducer in place, one on each side of the transducer case, positioned at the surface of the skull bone and anchored in the outer compact bone. This strategy is secure and identical to what the BAHA employs.

The BAHA operation may now be completed in 10 to 15 minutes while receiving local anaesthesia because of punch approach. Most BCI and Bonebridge™ surgeries are performed under general anaesthesia. Numerous articles in the Bonebridge™ imply that difficulties linked to size might make surgery more difficult [21,23].

CONCLUSION(S)

The BAHA is perfect for those who have issues with their outer and middle ears, as well as for people who are unilaterally deaf and cannot wear traditional hearing aids. It is also far more pleasant to wear than any other sort of hearing aid solution, and once it has been correctly implanted, does not need to be adjusted. The current percutaneous direct-drive BCD (the BAHA) will continue to be used because of its excellent sound quality and high output power as a vital part of hearing therapy. Future intact skin solutions will probably displace some BAHA sales, and the most promising systems at the moment seem to be the active transcutaneous direct-drive BCDs (Bonebridge™ and BCI). To establish exact inclusion criteria and the possible benefits and drawbacks of these devices, additional in-depth clinical investigations are needed.

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PARTICULARS OF CONTRIBUTORS:
1. Medical Intern, Department of ENT, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
2. Professor and Head, Department of ENT, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Sonaakshi Kushwaha,
G-9, Indira Girls Hostel, JNMC, Sawangi, Wardha-442001, Maharashtra, India.
E-mail: sonaakshirox@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jan 20, 2023
- Manual Googling: May 11, 2023
- iThenticate Software: Jun 02, 2023 (15%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jan 16, 2023**
Date of Peer Review: **Apr 11, 2023**
Date of Acceptance: **Jun 05, 2023**
Date of Publishing: **Aug 01, 2023**