Bone Anchored Hearing Aid Gruppo Otologico

A **bone-anchored hearing aid** is a type of hearing aid based on bone conduction. It is primarily suited to people who have conductive hearing losses, unilateral hearing loss and people with mixed hearing losses who cannot otherwise wear 'in the ear' or 'behind the ear' hearing aids. The name Baha is a trademark.

Background

Hearing impairment is the most common physical disability in the industrialized world. There are two different reasons for poor hearing. One is due to lack of function in the inner ear, the cochlea, the other when the sound has problems in reaching the nerve cells of the inner ear. An example of the first is the age-related hearing loss. A patient born without external ear canals is one example of the latter and here it is obvious that a conventional hearing aid with a mould in the ear canal opening is not possible to use. These patients often have a normal inner ear function as the external ear canal and the inner ear are developed at different stages during pregnancy. As the inner ear is normal, sound conducted via the skull bone could give normal/near normal hearing.

A vibrator with a steel spring over the head or in heavy frames of eyeglasses pressed towards the bone behind the ear has been used to bring sound to the inner ear. This has however several disadvantages like discomfort and pain due to the pressure needed. The sound quality is also impaired as much of the sound energy is lost in the soft tissue over the skull bone. This is especially true for the higher sound frequencies so important for speech understanding in noise.

Patients with chronic ear infection where the drum and/or the small bones in the middle ear are damaged often have hearing loss but difficulties to use a hearing aid fitted in the ear canal. Direct bone conduction through a vibrator attached to a skin penetrating implant will overcome these disadvantages.



Dr Brånemark, Dr Tjellström and Dr Håkansson

In 1977 the first three patients were implanted with a bone conduction hearing solution by Dr Anders Tjellström at the Ear –Nose- and Throat department at Sahlgrenska University Hospital in Gothenburg, Sweden. A 4 mm long titanium screw was inserted in the bone behind the ear and a specially designed bone conduction hearing aid was attached. The initial results were very good and since then about 100,000 patients all over the world have been treated according to this principle.

The implant in the bone is made of titanium and will osseointegrate according to the research performed by professor Per-Ingvar

Brånemark. The hearing instrument is impedance matched and developed by professor Bo Håkansson at Chalmers University of Technology in Gothenburg, Sweden under the name of Baha. The initial design has been refined and improved first by the industrial partner Entific and later by Cochlear Bone Anchored Solutions both in Gothenburg. Since 2009 the Danish hearing aid company Oticon has also developed a device based on the same principle. Osseointegration has been defined as the direct contact between living bone and an implant that can take a load. No soft tissue at the interface.

With Entific selling the trademark to Cochlear, Cochlear turned the acronym BAHA into a full-fledged trademark name, so to avoid unnecessary confusion between the "BAHA" as a type of sound processor and technology and the Baha as an hearing aid. This choice was motivated by the policy of insurances to distinguish between sound processors and a full bone conduction implant system for coverage's purpose [citation needed]. The other major brand of bone conduction device is manufactured by well-known hearing aid manufacturer, Oticon Medical.

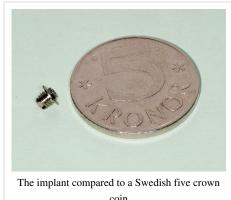
Use and operation

Bone-anchored hearing aids use a surgically implanted abutment to transmit sound by direct conduction through bone to the inner ear, bypassing the external auditory canal and middle ear. A titanium prosthesis is surgically embedded into the skull with a small abutment exposed outside the skin. A sound processor sits on this abutment and transmits sound vibrations to the titanium implant. The implant vibrates the skull and inner ear, which stimulate the nerve fibers of the inner ear, allowing hearing.



A removable BAHA sound processing device in place, attached to the abutment.

Both Cochlear and Oticon Medical's Baha bone conduction hearing solutions utilize a bone-anchored sound processor that convert incoming sound into vibrations. Cochlear Baha utilises a snap-lock coupling which allows them to clip onto the implanted abutment, The Oticon Ponto uses a spring based coupling. The sound processor units run on small circular batteries which last approx 6 to 14 days. The coupling is designed to detach upon impact as a safety feature to prevent damage to the bone or surrounding tissues.^[3]



Indications for Baha

Chronic ear disease

This is a fairly common condition often associated with continuous or intermittent drainage from the ear canal. As a rule these patients also have a hearing loss and often need amplification. A conventional air conduction aid with a mold placed in the ear canal opening is often impossible to wear due to the drainage - and may even provoke drainage. If the hearing loss is significant an air conduction aid may have difficulty to overcome the dysfunction of the eardrum and middle ear bones. The solution for these patients is a bone conduction hearing device bypassing the middle ear and stimulating the inner ear directly through the skull. Transmission of sound in the bone is very good with minimum of attenuation and very little distortion. In fact the hair cells of the inner ear cannot tell if the sound is coming the normal way through the external ear canal and middle ear or via vibrations in the bone.

Single sided deafness

A person who is deaf on one side regardless of reason often has difficulties with his/her hearing even if the other ear is normal. This is especially true in demanding situations such as listening in noisy surroundings and when several people are speaking the same time. A Baha could be of good help in lifting the head shadow to the deaf side. Hearing impairment in only hearing ear is another difficult hearing condition. Conventional ear surgery always involves a risk of hearing loss due to the surgical procedure. Most ear surgeons are thus reluctant to perform surgery on only hearing ear. The Baha surgery involves no such risk and is often a good solution. A study found that an extended trial a BAHA system with a headband prior to surgery led to more realistic expectations. In the study of 50 patients, only 50% wished to proceed to surgery. [4]

External ear canal problems

Irritation in the external ear canal can be due to inflammation or eczema and makes it impossible or very uncomfortable to use a conventional air conduction aid. Direct bone conduction could be a very good option.

Malformations

Patients with malformations are not always suitable for reconstructive surgery. Treacher-Collins patients could have significant malformations with ossicular defects and also have an abnormal route of the facial nerve. These structures as well as the inner ear could be at danger at surgery.

Down Syndrome patients often have a narrow ear canal and also middle ear malformation leading to impaired hearing. It has been suggested that some part of the mental retardation seen in these patient is partly due to their poor hearing.

The surgery can only take place once the skull is at least 2.5 mm thick. ^{[5][6]} Children who suffer certain syndromes may have a slighter build, thinner bone or unusual anatomy, whereas other children may have a thicker skull at a younger age and therefore it is difficult to give an age estimate.

In Canada, stage one surgery for Baha has been implanted into children as young as 13 months at the Hospital for Sick Children in Toronto. Stage two surgery has been done as early as 22 months. In the U.S., the Food and Drug Administration (FDA) only approves Baha implantation of children aged 5 years or older.

For infants and young children prior to surgery the sound processor can be worn on a head band or soft band which the infant wears to hold a Baha against the skull.

Benefits

The benefits of Bone Anchored Hearing Aid such as Baha are well documented. By bypassing the outer or middle ear, Baha can increase hearing in noisy situations and help localise sounds. The benefit is not only improved speech understanding, hearing with Baha results in a natural sound with less distortion and feedback when compared with conventional hearing aids. [7][8][9][10][11] The ear canal is left open for comfort, and helps to reduce any problems caused by chronic ear infections or allergies. In patients with Single-sided sensorineural deafness (SSD), Baha sends the sound via the skull bone from the deaf side to the inner ear of the hearing side. This transfer of sound gives a 360-degree sound awareness.

Surgical procedure

Note: Newest surgical style with a single one inch long incision is much less invasive than pictured herein. Shaving of large area of the head is no longer necessary.

In adults, surgery is often performed under local anesthesia and as an outpatient procedure. The bone behind the ear is exposed through straight incision or with the help of a special designed dermatome. A hole, 3 or 4 mm deep depending on the thickness of the bone, is drilled. The hole is widened and the implant with the pre-mounted coupling is inserted under generous cooling to minimize the inevitable surgical trauma to the bone.

Most surgeons perform a reduction of the subcutaneous soft tissue. The rationale for this is to reduce the mobility between implant and skin to avoid inflammation at the penetration site. This reduction of the soft tissue has been questioned and some surgeons only perform a minimum of soft tissue work. Three to six weeks later the audiologist will fit and adjust the hearing processor according to the patient's hearing level.

The surgical procedure has been described in detail by Tjellström et al. 2001^[12]

Everyday handling of skin at implant site

A skin penetration has to be taken care of. It could be compared with brushing one's teeth. If neglected there is a great risk of inflammation around the Baha coupling. Daily cleaning routine is of great importance. This is often more easy to do if there are no hair follicles close to the coupling. The use of a mild ointment is also often recommended.

One important feature with the Baha is that if a patient for whatever reason do not want to continue with the arrangement it takes the surgeon less than a minute to remove the whole thing. The Baha will not restrict the wearer from any activities such as outdoor life, sporting activities etc.

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4 days post op

Drawbacks

The main drawbacks of BAHA systems are: risk of skin infection, accidental or spontaneous loss of the bone implant, and patient refusal for treatment due to stigma. [13]

The surgical procedure is simple both for the surgeon and the patient. Very few and minor risk are at hand for the experienced ear surgeon. Minimal discomfort and pain is reported. Some numbness of the area around the implant is not uncommon as small superficial nerves in the skin are sectioned during the procedure. However, these problems



When the healing cap is in place

often disappear after some time. There is no risk of further hearing loss due to the surgery.



Although designed to come off the post should they be contacted, the sound processor unit are quite fragile if impacted.

Both manufacturers have warranty and repair policies. An audiologist or the manufacturers may provide "loaner" unit.

Special concerns in small children

Hearing is of utmost importance for a normal speech and social development. See review paper by Lieu 2004. ^[14] The skull bone in children is often very thin and also softer than in the adult. Surgery is thus often delayed until the age of 4-5 years. In the meantime the child with bilateral atresia will be fitted with a sweatband round the head called the Baha Softband with a coupling for a Baha. This is often made already at the age of one month. These small babies often tolerate this arrangement very well. For further reading se Papsin et al. 1997. ^[15]

The surgical reconstruction of a malformed or missing external ear canal is much easier when the child is older. One important advantage with the Baha is that the procedure is reversible. A child can be fitted first with a Softband and at the age of 4-5 years get an implant for a Baha. When the patient is older and radiographic examination has shown that the prospects for reconstructive surgery is good and can be successfully made, it is very easy to remove the implant.

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]]==Costs==

In America the cost of the Baha device is approximately \$ 4000. In The Netherlands the cost of the device is approx € 3000 (in 2008). The cost of the titanium implant, surgery and aftercare from surgeon and audiologist must also be considered. In America surgery cost can cost as much as \$ 30,000 including the device and can vary depending upon the type and hospital. In the UK the procedure is usually offered on the NHS, although not all areas will do this for patients who retain hearing in one ear.

Manufacturers

At present there are three device brands available: Cochlear BAS, Oticon Medical, and Sophono, Inc. The sound processors are basically the same, with differences in design, features, and atachment type.

Cochlear markets the Baha 3 System, Oticon markets the Ponto Pro and Ponto Power brand receivers, and Sophono offers the Alpha System. Cochlear and Oticon units attach onto the titanium abutment and act as receivers sending sound through the implant to the skull and to the inner ear. The two brands are distinguished from each other easily by appearance as the Baha 3 BP100 is rectangular and the Ponto is teardrop shaped. Cochlear has registered the name Baha as a trademark. [1]

The Alpha System from Sophono uses implanted magnets to secure the processor behind the ear. The magnets lie completely under the skin and allow for the implant site to close and heal completely, so no abutment is necessary.

Models

There are different types of systems. The Baha Classic and Compact will not be manufactured anymore. In 2012 the following types are available: the Cochlear Baha Cordelle, Divino and Intenso. In 2009 the Baha 3 (BP100) and Ponto pro were released. In May 2011 Oticon Medical launched a more powerful version of the Ponto Pro the Ponto Pro Power. Cochlear released the Baha 3 BP110 Power Sound Processor which can be fitted to the same patients as the Intenso.

- Cordelle II. A bodyworn Baha for people with a severe hearing loss who need more amplification than the other Bahas available. The Cordelle II consists of a transducer which snaps onto the abutment and a bodyworn unit. This is the only Baha to have an induction telecoil receiver built in.
- Baha Classic 300. This is the older Baha device which has been mostly superseded by the Compact and Divino but is still worn by those with more severe and mixed hearing losses. This was discontinued in February 2007.
- Baha Compact. Rated as identical to the Classic but found to be slightly less powerful by a few users. The
 Compact is 33% smaller than the Classic and has added AGCo and improved shielding from mobile telephone
 signals.
- Baha Divino. Released in July 2005 this was the first digital Baha which had a built-in directional microphone.
- Baha Intenso. More power and clearer sound quality in all types of listening environments plus far less irritation from feedback.
- Cochlear Baha 3 BP100 Sound Processor) released in 2009 the BP100 is a fully programmable, multi channel digital sound processor
- Cochlear Baha 3 BP110 Power Sound Processor released in 2011 the Baha 3 Power is a higher powered version
 of the fully programmable digital sound processor

OTICON:

- · Oticon Medical
- Ponto Pro introduced in 2009 is a more streamlined teardrop shaped baha receiver from a well known manufacturer of hearing aids, Oticon.
- Ponto Power was added by Oticon in 2011 as a higher-powered version of Ponto Pro, offering more volume with no discernable feedback.

SOPHONO

- Alpha 1: Released in 2006 in Europe and 2011 in the US. Curved shape, omnidirectional microphone.
- Alpha 2: Introduced late 2012. Symmetrical, rectangular shape for use on either ear, dual microphones for
 directionality plus omnidirectional for ambient sounds, comes with a coupon for free Skinit decal sticker. Both
 come in four different colors: silver, black, champagne, or brown.

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External links

- Baha implant activation video (http://www.youtube.com/watch?v=Oc363rpDVIE) Folk musician Patrick Costello filmed the activation of his Baha implant.
- The Ear Foundation's BAHA pages (http://www.earfoundation.org.uk/hearing-technologies/baha). Detailed information about BAHA technologies from the UK-based charity.
- French BAHA website (http://www.infobaha.fr/). Site francophone dédié à l'aide auditive à ancrage osseux: Baha, Ponto, Alpha 1
- Sophono Alpha System (http://sophono.com/products/alpha-1-m/)

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