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Bone-anchored hearing devices: indications, outcomes, and the linear surgical technique

Stephen P. Cass, MD, Pamela A. Mudd, MD

From the Department of Otolaryngology, University of Colorado Denver, Aurora, Colorado.

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Bone conduction hearing systems utilize a surgically implanted osseointegrated fixture to create a method for direct transmission of vibration to the skull and cochlea via a bone conduction sound processor. They are indicated for use in persons over the age of 5 with conductive and/or mixed hearing loss and single-sided deafness. Bone anchored hearing devices are considered when use of a conventional air conduction hearing aid is not possible or effective. The operative technique includes two components—subcutaneous tissue reduction to create thin, immobile skin around the abutment, and bone work for fixture placement performed in such a way to maximize the opportunity for osseointegration. The indications, linear incision surgical technique, special considerations in pediatrics, postoperative care, complications and expected outcomes are presented.

Bone-anchored hearing systems uniquely combine the concepts of osseointegration and bone conduction auditory stimulation to improve hearing and communication abilities. Bone conduction hearing systems use an osseointegrated fixture surgically implanted to cranial bone to create a method for direct transmission of vibration to the cochlea via a bone conduction sound processor. The first bone anchored hearing system (Baha) was introduced by Tjellstrom et al, who established the first 3 patients in 1977. The Food and Drug Administration (FDA) approved use of the Baha for conductive and mixed hearing loss in 1996 and for single-sided deafness in 2002. There are 2 marketed bone-anchored hearing systems, the Cochlear Baha System and recently released Oticon Medical Ponto System.

Osseointegration

The concept of osseointegration was discovered and developed in Gothenburg, Sweden, by Brånemark and colleagues,[1] who recognized the potential for growth of bone tissue in contact with the surface of a titanium implant. Brånemark and colleagues defined osseointegration as a direct structural and functional connection between ordered living bone and the surface of a load-carrying implant. Most materials fail to osseointegrate and instead incite a foreign body reaction that leads to formation of a fibrous capsule around the material. Titanium has proven to be different, inciting osseointegration instead of foreign body reaction. Titanium is therefore the material of choice for osseointegration and the use of titanium implants in the dental implantation, first introduced in 1965, has exploded worldwide.[1] Osseointegration is reliably achieved in the Baha system with the use of commercially pure titanium (99.75%), which is machined, then covered with a thin oxide layer that is important for osseointegration.

Osseointegration initially occurs over the course of 6 to 12 weeks after fixture implantation but is also an ongoing dynamic process for the life of the implant. Many factors influence successful osseointegration, including the material, macro- and microstructure of the implant, the quality of bone at the site of implantation, and surgical factors.[2] It is critical that the implant remain completely immobile during the initial period of osseointegration; otherwise, osseointegration will fail with formation of a fibrous capsule around

Address reprint requests and correspondence: Stephen P. Cass, MD, Department of Otolaryngology, University of Colorado Denver, Academic Office 1, B 205, 12631 East 17th Ave, Aurora, CO 80045.
E-mail address: Stephen.Cass@ucdenver.edu.

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the implant instead of new bone formation. The initial stability of the implant is mechanically achieved through use of a screw-shape implant that is secured to bone with precise torque parameters. If osseointegration is successful, the implanted device becomes a "part" of the patient, and feels as natural as a fingernail or tooth.

Bone conduction hearing

Bone conduction hearing is unique in that it can produce clear sound perception regardless of outer and middle ear function, as long as the cochlea is intact.[3] Several factors contribute to bone conduction hearing, including the sound pressure within the external ear canal and middle ear, middle ear ossicle motion, and direct inner ear effects. Inertial effects of cochlear fluid relative to the vibrating bony cochlear capsule is the most important contributor to bone conduction hearing, and this effect produces basilar membrane motion that is the same as air conduction hearing.

Transcranial attenuation of bone conduction hearing refers to the decrement in sound energy that occurs when one side of the skull is stimulated and hearing thresholds in the cochlea on the opposite side are measured. This is chiefly relevant when bone-anchored hearing systems are used to route sound from the deaf side to the hearing ear in people with unilateral sensorineural hearing loss. Transcranial attenuation is frequency dependent; lowest for low-frequency vibrations and greatest for high-frequency vibrations. Overall, subjective attenuation measured in humans is best estimated to be approximately10 dB in the range of 0.25 to 4 kHz.[4]

Candidate selection

Current bone-anchored hearing systems are indicated for use in persons older than the age of 5 years with conductive and/or mixed hearing loss or with unilateral profound sensorineural hearing loss (single-sided deafness). Bone-anchored hearing devices are considered when use of a conventional air conduction hearing aid is not possible and when conventional systems [such as traditional external band bone conduction hearing aids and contralateral routeing of sound (Cros) hearing aids] are ineffective.

The Baha system was FDA approved in 1996 for use in conductive or mixed hearing loss. Baha is used most commonly in patients with cholesteatoma, chronic suppurative otitis media, and otosclerosis where the diseased ear drum and/or middle ear ossicles are not able to conduct sound to the cochlea and use of a conventional hearing device is not possible or effective. The other common situation is congenital aural atresia and microtia, where absence of the external ear, ear canal, and/or ear drum causes conductive hearing loss and a conventional hearing aid cannot be used. The advantage of Baha in conductive or mixed loss is the ability to provide sound to the cochlea at high fidelity and efficiency because direct bone conduction bypasses the conductive element of hearing loss and stimulates the cochlea directly.

In 2002, the US FDA approved the Baha system for single-sided deafness. Common factors leading to single-sided deafness include cerebellopontine angle tumor, idiopathic sudden sensorineural hearing loss, Meniere's syndrome, and congenital unilateral deafness. For single-sided deafness, the Baha sound processor picks up sound on the deaf side and sends it via bone conduction to the contralateral intact cochlea. In this way, the head shadow effect is eliminated leading to improved speech understanding and speech awareness.[5,6]

Audiologic criteria

Because all Baha systems have output limits to ensure useful sound perception, it is important to always carefully assess the level of sensorineural function of the cochlea desired to be stimulated. The audiologic criteria vary for conductive/mixed hearing loss and single-sided deafness. Several Baha sound processors are available that vary chiefly in their energy output and thus their indications.

Conductive hearing loss

Most candidates with purely conductive hearing loss will benefit from bone-anchored hearing systems. Persons with greater than 30 dB conductive hearing loss have better outcomes with Baha compared with air conduction aids. Baha should be placed on the side with the best cochlear hearing. Bilateral Baha placement is consider if conductive losses are symmetric with less than 15 dB intraaural difference.[7-9]

Mixed hearing loss

In general, candidates with >30 dB conductive hearing loss and mild-to-moderate sensorineural component of hearing loss can achieve satisfactory amplification with the Baha. The Cochlear BP100 is indicated for sensorineural hearing loss up to 45 dB, the Cochlear Intenso up to 55 dB, the body worn Cochlear Cordelle II up to 65 dB, and the Oticon Ponto up to 45 dB sensorineural hearing loss.

Single-sided deafness

Candidates with single-sided deafness should have normal hearing on the contralateral side (defined as air conduction thresholds equal to or better than 20 dB). The Baha is placed on the deaf side and bone conduction is routed to the normal hearing cochlea through the skull.[10]

Medical criteria

Several medical conditions make Baha a better option than traditional air-conduction hearing aids. These conditions include skin reactions or chronically draining ears, which are aggravated by air conduction hearing aids, congenital malformations, including microtia, ear canal stenosis where air conduction is not possible, radical mastoid cavity where feedback and dizziness can occur using air conduction devices, and in select syndromic hearing losses, such as Down's syndrome, Teacher Collins, and Goldenhar, where both function and anatomical considerations make Baha use favorable.

Contraindications

Failure to meet audiologic criteria

See the section "Audiologic criteria" for more information on criteria.

Poor bone quality

Failure of osseointegration is more likely to occur when bone quality is immature or abnormal. Pediatric bone has lower mineral content (eg, softer) and is generally thinner than mature adult bone. To compensate for these factors, children should generally undergo a 2-stage surgery. The staging interval allows for an extended period of osseointegration before skin penetration and loading. One rule of thumb is to extend the staging interval 3 months for each millimeter of bone thickness less than 4 mm. A relative contraindication also exists for patients with bone abnormalities, such as osteogenesis imperfecta, Paget's disease, severe osteoporosis, or osteopenia. Other common medical conditions that affect bone quality are external beam radiation, smoking, and chronic corticosteroid use.

Susceptibility to chronic skin reactions

The most common complication with bone-anchored hearing systems is related to soft-tissue reactions at the abutment site. Hygiene of the abutment site is of critical importance. Patients or caretakers must be able to follow hygiene instructions and to take part in a regular follow-up. Other medical conditions to consider include keloid and hypertophic scar tendencies, and any immune deficiency condition where susceptibility to infection is high (eg, uncontrolled diabetes mellitus, chronic immunosuppressive therapy, etc).

Preoperative planning

Patients should have consultation with an audiologist familiar with bone-anchored hearing systems. Basic audiometry, including pure tone audiogram with bone conduction and speech audiometry, should be performed. A trial of the Baha with the use of an external stimulation (soft band or external headband) is very useful and can help the candidate gain appreciation of the expected benefit of Baha placement and set expectations. It is important to note that with an external band, attenuation of sounds secondary to scalp thickness and hair can be up to 15 db. Because of this, the more powerful Intenso and Cordelle II devices are often used during simulations to offset the transdermal attenuation that will not be present with direct bone stimulation via osseointegration.

Device details

The Baha is a percutaneous semi-implantable osseointegrated hearing system. The transmission of sound to bone is accomplished via an osseointegrated titanium fixture surgically implanted in the temporal bone. The Baha system includes the titanium screw implant also called fixture; the percutaneous abutment, which is attached to the fixture either from the start (one stage), or secondarily (2 stage); and the sound processor.

There are several models of sound processor available, and their use depends primarily on the patient's average bone conduction thresholds. The Cochlear, Ltd Baha BP-100 uses digital processing of the acoustic signal; includes an automatic 12-channel wide dynamic range signal processor, noise reduction circuit, and directional microphone; and is effective up to 45 db average bone-conduction threshold. The Baha Intenso adds 10 dB more power output and is effective up to 55 dB average bone-conduction threshold. The Baha Cordelle II is a body-worn unit with 20 dB more output than the Baha 100 BP and is effective up to 65 dB average bone-conduction threshold. The Ponto is effective up to 45 dB average bone-conduction threshold.

Operative technique

The operative technique includes 2 components: subcutaneous tissue reduction to create thin, immobile skin around the abutment and bone work for fixture placement performed in such a way to maximize the opportunity for osseointegration. Several techniques are available to perform the necessary soft-tissue work and include techniques that use full-thickness skin flaps created manually (eg, U-flap or linear incision), and a technique that creates a split-thickness skin flap with a dermatome. The results of the different techniques have been reviewed and are largely equivalent. One key element common to all techniques is that sufficient subcutaneous tissue reduction must be performed to create thin skin tightly held to periosteum (nonmobile skin) that is stable overtime. This is where most errors in surgical technique occur because much more subcutaneous tissue than would initially seem necessary must be removed so that postoperative scalp thickening is prevented. There are sev-

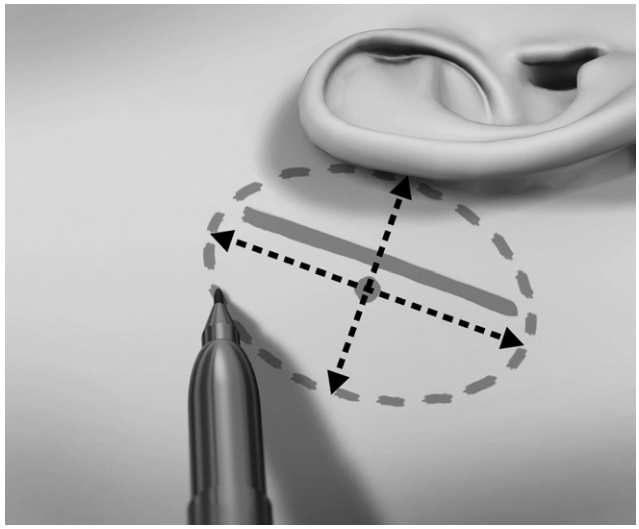

Figure 1 The site of fixture is located and marked with the surgical marking pen using the sound processor template. Optimal location is approximately 50-55 mm from the ear canal, posterior and superior to the auricle along the temporal line. A 40- to 60-mm skin incision is planned. The length of the skin incision can be varied according to the patient's scalp thickness (Incision = 6× scalp thickness is a good rule of thumb). To gauge this thickness, a 27-gauge needle is introduced through the skin and brought down to bone, the depth is then marked using a hemostat and the needle is withdrawn. The depth is then measured, and incision planned accordingly.

eral other surgeon-specific differences in surgical technique, the importance of which are unknown. These include the removal or replacement of periosteum at the implant site, whether to tack the skin flaps down to the underlying periosteum, and the absolute need for a hair free abutment site. The authors' suggested technique is the linear technique, used by Cor Cremerset al in Nijemgin, the Netherlands. Their extensive experience has been well studied and shown to be a simple, efficient, and effective approach.[11,12]

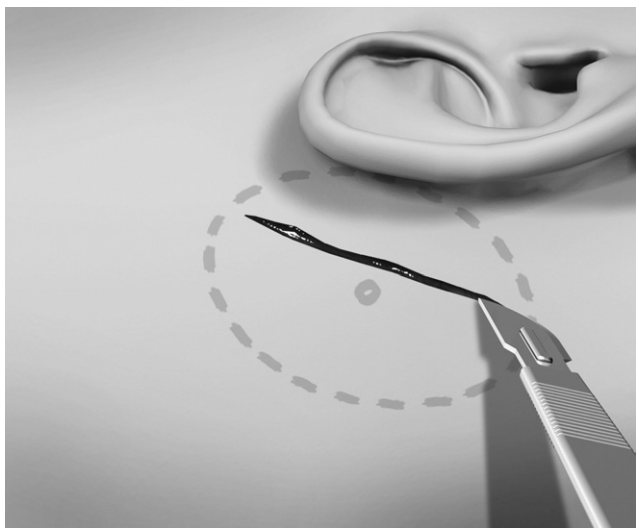

Figure 2 The surgical area is injected with 2% lidocaine with 1-100,000 epinephrine mixed in equal part with 0.5% Marcaine (10-20 mL is used) and the skin incised to the level of subcutaneous tissue.

Figure 3 Subcutaneous skin flaps are developed in the immediate subdermal plane (at the level of the hair follicles) using sharp dissection.

After obtaining consent for the procedure the patient is taken to the operating room. The procedure may be completed under local anesthesia with or without sedation, or with general anesthesia. This is both patient and surgeon preference. It is suggested all pediatric patients undergo general anesthesia. The procedure for most adults and older children is a single stage, as described to follow. The details of a 2-staged procedure, more commonly used in the pediatric population, are discussed in that section. The surgical site is prepped by shaving hair at the proposed implant site, and the patient is prepped and draped in standard sterile fashion.

The site of fixture is located and marked with the surgical marking pen using the sound processor template. Optimal location is approximately 50 to 55 mm from the ear canal, posterior and superior to the auricle along the temporal line. It is important that the sound processor does not touch the

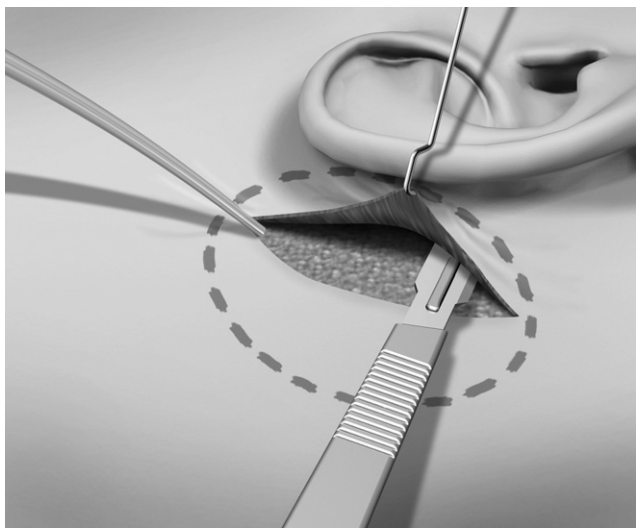

Figure 4 The width of each skin flap should be about ½ the length of the skin incision.

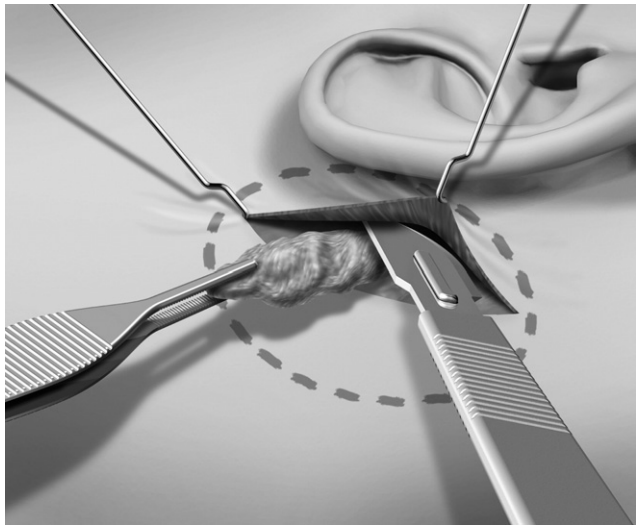

Figure 5 Subcutaneous tissue is removed down to and preserving the cranial periosteum. Electrocautery is used to assist in hemostasis. In general, the subcutaneous tissue removal should be in the range of 40 × 40 mm to 60 × 60 mm.

Figure 6 The periosteum is incised following the original skin incision. This allows for accurate positioning of the fixture outside of the skin incision. The fixture will be exteriorized via a separate 4-mm skin punch as the final step of the procedure.

auricle, overlie a previous mastoid cavity or craniotomy site, and in cases of auricular microtia, the fixture placement should be remote from any tissue that may be used for auricular reconstruction.

A 40- to 60-mm skin incision is planned. The length of the skin incision can be varied according to the patient's scalp thickness (Incision = 6× scalp thickness is a good rule of thumb). To gauge this thickness, the authors use a 27-gauge needle which is introduced through the skin and brought down to bone, the depth is then marked using a hemostat and the needle is withdrawn. The depth is then measured, and incision planned appropriately (Figure 1).

The surgical area is next injected in a radial fashion with 2% lidocaine with 1-100,000 epinephrine mixed in equal part with 0.5% Marcaine (Sanofi Winthrop—US, Bridgewater, NJ; 10-20 mL is used). The skin incision is made down to the level of the subcutaneous tissue (Figure 2).

Subcutaneous skin flaps are developed in the immediate subdermal plane (at the level of hair follicles) via sharp dissection (Figure 3). Subcutaneous skin flaps are created on both sides of the incision. The length of each skin flap should be half the length of the skin incision (Figure 4).

Subcutaneous tissue is removed down to and preserving the cranial periosteum. Electrocautery is used to assist in hemostasis. In general, the subcutaneous tissue removal should be in the range of 40 × 40 mm to 60 × 60 mm (Figure 5).

The periosteum is incised after the original skin incision. This allows for accurate positioning of the fixture outside of the skin incision. The fixture will be exteriorized via a separate 4-mm skin punch as the final step of the procedure (Figure 6).

Next, the fixture placement site is developed. Approximately 6 mm of periosteum is elevated at the site of the fixture placement. This can be done as a flap that is elevated, then replaced around the abutment site after the fixture is placed before closure (Figure 7).

A guide hole is created in cranial bone along the temporal line using a 1.8-mm drill bit with a 3-mm stop. The guide hole is probed to check if additional bone is present and if so, the guide hole is drilled further, to a depth of 4 mm. All drilling is performed under continuous irrigation at low speed to avoid thermal injury to the bone that could impair osseointegration. It is necessary to prudently drill in order not to penetrate the dura or the transverse dural sinus (Figure 8).

Next the guide hole is widened to 3.8 mm in diameter and a slight countersink created by use of the widening/countersink bit. The length of the widening bit should match the depth of the guide drill hole. Because 4-mm fixtures appear to have better long-team retention than 3-mm fix-

Figure 7 Approximately 6 mm of periosteum is elevated at the site of the fixture placement. This can be done as a flap which is elevated, then replaced around the abutment site after the fixture is placed.

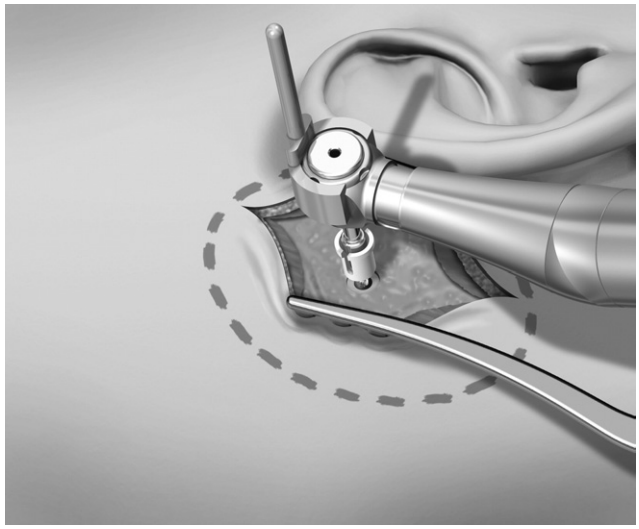

Figure 8 A guidehole is created in cranial bone along the temporal line with the use of a 1.8-mm drill bit with a 3-mm stop. The guidehole is probed to check whether additional bone is present and if so, the guide hole is drilled further, to a depth of 4 mm. All drilling is performed under continuous irrigation at low speed to avoid thermal injury to the bone that could impair osseointegration.

tures, a 4-mm fixture should be used in most cases. It is important to drill at a right angle to the surface of the skull, in line with projected abutment (Figure 9). The authors recommend that the countersink be minimal (simply etch the cranial bone) so that strong cortical bone is maintained, which facilitates the initial stability of the implant necessary for osseointegration (Figure 10).

The fixture is then secured to the bone. The fixture/abutment assembly is a self-tapping screw that is implanted using a torque-limiting drill set at 30-40NCm torque. Again, projected angle of the fixture must be maintained when drilling and securing the fixture. In a single stage procedure the abutment is secured to the fixture. Most commonly a 4-mm fixture is used with a 5.5-mm abutment. Once the fixture is secured, the strip of elevated periosteum should be replaced to surround the implant (Figure 11).

The skin incision is closed in an interrupted fashion with nylon and the abutment is exteriorized using a 4-mm skin

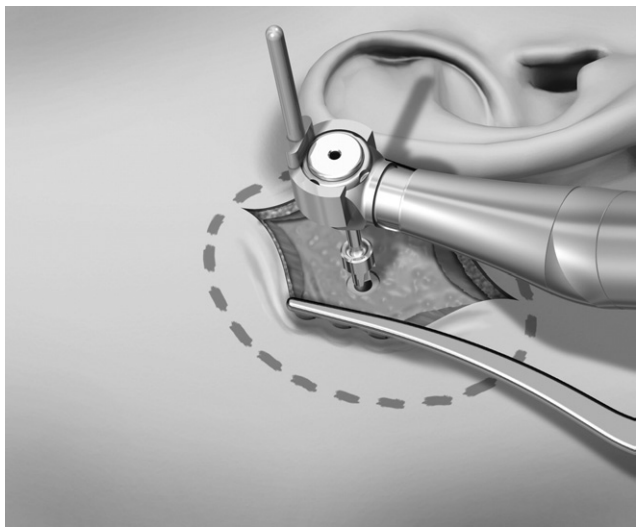

Figure 9 Next the guide hole is widened to 3.8-mm diameter and a slight countersink created with the widening/countersink bit. The length of the widening bit should match the depth of the guide drill hole. Because 4-mm fixtures have better long-team retention than 3-mm fixtures, a 4-mm fixture should be used in most cases. It is important to drill at a right angle to the surface of the skull, in line with desired angle of the abutment.

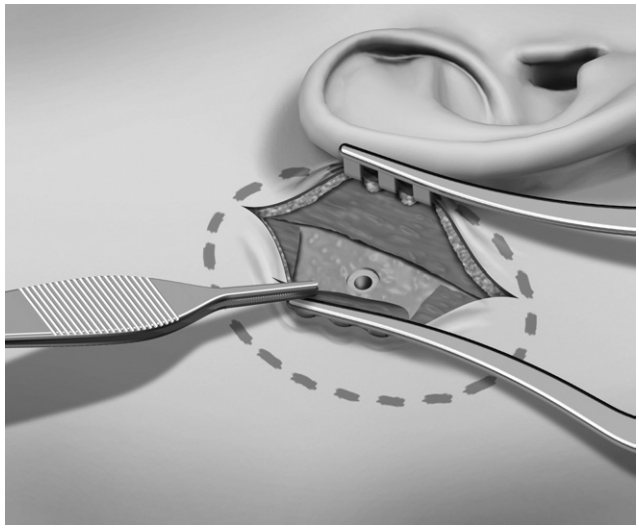

Figure 10 The countersink should be minimal (simply etch the cranial bone) so that strong cortical bone is maintained which facilitates the initial stability of the implant necessary for osseointegration.

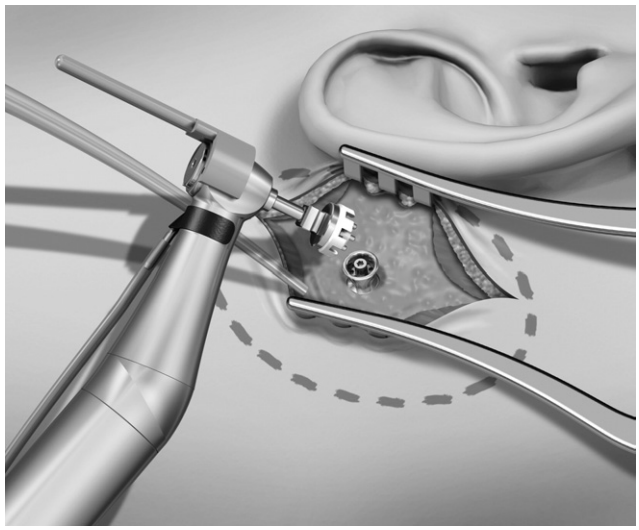

Figure 11 The fixture is then secured to the bone. The fixture/abutment assembly is a self-tapping screw that is implanted using a torque-limiting drill set at 30-40NCm torque. The projected angle of the abutment must be maintained during drilling and securing the fixture. In a single stage procedure the abutment is secured to the fixture. Most commonly a 4-mm fixture is used with a 5.5-mm abutment. Once the fixture is secured, the strip of elevated periosteum should be replaced to surround the implant.

Figure 12 The skin incision is closed in an interrupted fashion with nylon and the abutment exteriorized using a 4-mm skin punch.

punch. Alternatively, if the abutment is placed in line with the incision the implant can be brought out directly through the incision (Figure 12). The completed procedure is shown in Figure 13.

A conforming bolster-type dressing is applied with the use of antibiotic-impregnated gauze and is secured by the use of a healing cap. This dressing is used to keep the skin flaps down to the periosteum, eliminating all subcutaneous dead space (Figure 14).

Of note, the authors do not place sutures to tack the skin flap to the periosteum. Finally a mastoid-type dressing is placed. Postoperatively, the mastoid dressing is removed after 24 hours and the conforming dressing after 7 days. Sutures are removed at 7 days. The manufacturer recommends waiting 3 months before using the sound process. The author typically shortens this time to 6 weeks.[13]

Figure 13 Completed procedure.

Special considerations in pediatrics

In children with binaural congenital conductive hearing loss, intervention should take place as soon as possible after birth. This is possible with the use of the Baha sound processor attached to a Velcro headband (Baha Softband). The Baha Softband is introduced as soon as hearing loss is documented after birth and may be used up until the time the child is ready for surgical intervention. Placement of the osseointegrated fixture is FDA indicated for children ages 5 and older. The bone-anchored hearing system is used commonly in children with syndromic hearing loss and craniofacial syndromes. Audiologic criteria are similar to adults. The Baha Softband can help parents of pediatric candidates estimate the benefit of bone anchored hearing systems for the child. While it is possible to implant children younger than age 5 (off FDA label), it is a good idea to use the Softband for as long as possible before proceeding with fixture placement so the pediatric cranial bone can become thicker. For example, Priwin and Granström[14] reported children using the Softband for an average of 2-4 years before the surgical implantation of the osseointegrated bone anchored hearing system.

In children, special surgical considerations are taken into account because pediatric bone is thinner and softer with lower mineral content than adult bone. A child's skull makeup is 39% mineral and 37% water, whereas as an adult has 62% mineral and 13% water. A child at age 5 has an average skull thickness of 2 mm and at age 12, 3 mm of thickness. Therefore, in children, a 2-stage procedure is recommended with an osseointegration period of 3-6 months between stages.[15] In young children, the author bases the staging interval directly upon the bone thickness found at the time of surgery: 4 mm, 3 months; 3 mm, 6 months; 2 mm, 9 months, $<$2 mm, 1 year.

At the first stage, the skin over the implant site is incised, continuing through the subcutaneous tissue and periosteum.

Figure 14 A conforming bolster-type dressing is applied using antibiotic impregnated gauze and this is secured with the use of a healing cap. This dressing is used to keep the skin flaps down to the periosteum, eliminating all subcutaneous dead space.

The fixture is placed as described and the soft tissue is closed without thinning of the subcutaneous tissue or bringing the abutment out of the skin. In young children, the cranial bone thickness is often less than 4 mm. The dura is encountered in 70% in all children 18 months to 16 years and in 100% of children less than 8 years of age.[14] In this situation, the implant is screwed in as far as dura then left "proud" and covered with periosteum or with GORE-TEX® membrane, both which will promote bone growth. New bone will form to fully secure the implant over time. A second fixture (sleeper) can be placed to serve as an osseointegrated backup because there is a greater rate of implant failure in this age group. Because the extrusion rate is much higher in children with 3 mm prosthesis versus 4 mm, 78% versus 13% of all failures,[16] a 4-mm fixture should be used in most cases regardless of the initial bone thickness. In the second stage, the abutment is placed after soft tissue reduction and skin penetration with skin punch. After a healing period of 2 or three weeks, a sound processor is fitted according to clinical standard.

In children with microtia who are planning or may be candidates for otoplasty in the future, the abutment should be positioned 70 cm posterior to the external auditory canal to allow for microtia repair without compromising blood supply.

Postoperative care

Aftercare is critical for long-term stability of the implant. The site should be cleaned daily with soap and water and a soft brush facilitates hygiene. If inflammation develops around the interface of the abutment and skin then additional care is required. This may include use of topical antibiotics or steroid containing ointments. Any granulation tissue that forms should be cauterized and if continued inflammation occurs, a steroid cream, such as clobetasol should be used chronically to prevent ongoing inflammation from causing soft tissue thickening and overgrowth of the abutment.[17] If soft tissue thickening occurs, the area can be injected with a steroid solution (eg, Kenalog), or occasionally revision surgery will be required.[18]

Complications and remedies

Intraoperative complications are rare (<1%) and most often are seen in children. In a 4-year review House and Kutz[19] reported on complications from bone-anchored hearing aids. No intraoperative or perioperative complications were noted in 149 patients who received the device between 2001 and 2005. Intraoperative occurrences may include bleeding from a dural sinus which typically ceases with implantation of the titanium fixture, dural tear or entry-which can result in cerebrospinal fluid leak, and need for second drill hole if the titanium fixture is not sitting correctly or tightly within the site. If air cells are encountered another guide hole should be drilled nearby.

Perioperative complications are also rare and may include subcutaneous hematoma, abscess formation or infection. More severe complications, including subdural hematoma and meningitis have been also been reported as isolated cases.

Postoperative complications include bone and soft-tissue reactions. The rate of extrusion ranges from 3%[10,19,20] to 10%[21] and are generally greater in children than adults. All fixture extrusions represent a failure of osseointegration and are influenced by the age of the patient, the surgical technique, and the state of the bone (ie, previous irradiation). Extrusion of the fixture within the first 3 months suggests a technical surgical issue. Failures over time are usually related to either trauma or chronic infection.[7] Pain at the abutment site may be a sign of impending implant failure or extrusion.

Soft-tissue reactions can be graded with use of the Holgers scale or a modified version.[22,23] Grade 0 = no irritation, grade 1 = slight redness, grade 2 = red and moist, grade 3 = red and moist with granulation tissue, and grade 4 = skin irritation to a degree such that the abutment has to be removed. Grade 2 and higher skin reactions occur at some time in approximately 25% of patients. These skin reactions typically require reeducation on hygiene or topical therapies. More severe skin reactions include formation of granulation tissue or skin thickening leading to growth of skin over the abutment occur less frequently in the range of 3% to 10% of patients.

Skin overgrowth occurs on average 12 months after surgery.[19] These skin reactions can be treated with cautery, steroid injections, or revision surgery. Revision surgery typically involves raising the entire flap, thinning the subcutaneous tissue and skin flap, and suturing the edges of the skin flap to the periosteum surrounding the abutment. Occasionally, a longer abutment (8.5 mm) is placed for skin overgrowth thought to be secondary to excessive scalp thickness. Patients with soft tissue complications may be instructed to wear the healing cap at night to avoid further growth or irritation.

Outcomes

Baha in conductive or mixed hearing loss

The use of the Baha in patients with unilateral conductive or mixed hearing loss has proven to be successful in achieving binaural hearing with only few complications and no interference with the function of the normal ear. Lustig and colleagues[24] reported closure of air-bone gap to 10 dB in 80% of patients, 5 dB in 60% of patients, and with over closure in 30% of patients.

In audiological terms, the Baha results are superior to those obtained with conventional bone conduction device. Air conduction hearing device should not be used with therapy resistant otorrhea. In patients with conductive hearing loss without chronic otorrhea or aural atresia (ie, inoperable otosclerosis, unilateral conductive hearing loss with

contralateral deafness), the Baha system is an appealing option. When the air bone gap exceeds 30 dB, audiological performance is likely better than with air conduction device.

In studies that include patients with aural atresia, chronic otitis media, chronic otitis external and otosclerosis, hearing improvement with the Baha is very good; Lustig et al[24] report a mean pure tone average of 28 dB and a gain in hearing of 33 dB. Liepert and diToppa[25] report a similar average gain of 30 dB in speech reception threshold (SRT), and for Wazen et al,[26] the improvement in speech reception threshold (SRT) is from 52 to 27 dB.

The study of the level of satisfaction in patient with conductive hearing loss are well reported in the literature and concerning general satisfaction, the average scores are very good. The Baha is better than the other types of equipment with high indexes of satisfaction (index = 9 among 24 patients[25] index = 8.11 among 52 patients[27] and index = 8.3 among 165 patients[28]). Almost, 89% of the patients preferred the Baha to the conventional equipment tested beforehand.[6]

Baha in single-sided deafness

Baha amplification on the side of a deaf ear yields greater benefit in subjects with monaural hearing than does Cros amplification.[5] Advantages likely related to averting the interference of speech signals delivered to the better ear, as occurs with conventional Cros amplification, while alleviating the negative head-shadow effects of unilateral deafness. The advantages of head-shadow reduction in enhancing speech recognition with noise in the hearing ear outweigh disadvantages inherent in head-shadow reduction that can occur by introducing noise from the deaf side. The level of hearing impairment correlates with incremental benefit provided by the Baha. Patients with a moderate sensorineural hearing loss in the functioning ear perceived greater increments in benefit, especially in background noise, and demonstrated greater improvements in speech understanding with Baha amplification.[10]

Candidates with single-sided deafness receiving a bone-anchored hearing system indicate improvement in quality of life (70%), better performance at a dinner table, when a person sitting on their deaf side (88%), and better performance while talking to 1 person among a group of people (88%). The average satisfaction score was 8 on a 10-point scale.[29]

Conclusions

Bone-anchored hearing systems, based on the concept of osseointegration and the use of bone-conduction hearing, have benefited thousands of patients, both adult and child, with conductive or mixed hearing loss, and single sided deafness. The surgical technique is simple, yet widely varied and the results are consistent and very good at both hearing improvement as well as quality of life.

References

1. Brånemark R, Brånemark PI, Rydevik B, et al: Osseointegration in skeletal reconstruction and rehabilitation: A review. J Rehabil Res Dev 38:183-190, 2001
2. Albrektsson T, Brånemark PI, Hansson HA, et al: Osseointegrated titanium implants. Requirements for ensuring a long lasting, direct bone-to-implant anchorage in man. Acta Orthop Scand 52:155-170, 1981
3. Stenfelt S, Goode RL: Bone-conducted sound: Physiological and clinical aspects. Otol Neurotol 26:1245-1261, 2005
4. Nolan M, Lyon DJ: Transcranial attenuation in bone conduction audiometry. J Laryngol Otol 95:597-608, 1981
5. Niparko JK, Cox KM, Lustig LR: Comparison of the bone anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. Otol Neurotol 24:73-78, 2003
6. Hol MK, Bosman AJ, Snik AF, et al: Bone-anchored hearing aids in unilateral inner ear deafness: An evlaution of audiometric and patient outcome measurements. Otol Neurotol 26:999-1006, 2005
7. Snik AF, Mylanus EA, Proops DW, et al: Consensus statements on the BAHA system: Where do we stand at present? Ann Otol Rhinol Laryngol Suppl 195:2-12, 2005
8. Mylanus EA, Snik AF, Cremers CW: Opinions of bone anchored vs conventional hearing aids. Arch Otolaryngol Head Neck Surg 121: 421-425, 1995
9. McDermott AL, Dutt SN, Reid AP, et al: An intraindividual comparison of the previous conventional hearing aid with the bone-anchored hearing aid; the Nijmegen group questionnaire. J Laryngol Otol Suppl 28:15-19, 2002
10. Lin LM, Bowditch S, Anderson MJ, et al: Amplification in the rehabilitation of unilateral deafness: Speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otol Neurotol 27:172-182, 2006
11. de Wolf MKS, Hol MK, Huygen PL, et al: Clinical outcome of the simplified surgical technique for BAHA implantation. Otol Neurotol 29:1100-1108, 2008
12. Wilkinson E, Luxford W, Slattery W III, et al: Single vertical incision for Baha implant surgery: Preliminary results. Otolaryngol Head Neck Surg 140:573-578, 2009
13. Wazen JJ, Gupta R, Ghossaini S, et al: Osseointegration timing for Baha system loading. Laryngoscope 117:794-796, 2007
14. Priwin C, Granström G: The bone-anchored hearing aid in children: A surgical and questionnaire follow-up study. Otolaryngol Head Neck Surg 132:559-565, 2005
15. Granstrom G, Bergstrom K, Odersjo M, et al: Osseointegrated implants in children: Experience from our first 100 patients. Otolaryngol Head Neck Surg 125:85-92, 2001
16. McDermott A-L, Williams J, Kuo M, et al: A 15-year experience. Otol Neurotol 30:178-183, 2009
17. Falcone M, Kaylie D, Labadie R, et al: Bone-anchored hearing aid abutment skin overgrowth reduction with clobetasol. Otolaryngol Head Neck Surg 139:829-832, 2008
18. Van Rijswijk JB, Mylanus EAM: Intralesional triamcinolone acetonide injection in hypertrophic skin surrounding the percutaneous titanium implant of a bone-anchored hearing aid. J Laryngol Otol 122:1368-1370, 2008
19. House JW, Kutz JW: Bone-anchored hearing aids: Incidence and management of post-operative complications. Otol Neurotol 28:213-217, 2007
20. Shirazi MA, Marxo SJ, Leonetti JP: Perioperative complications with the bone-anchored hearing aid. Otolaryngol Head Neck Surg 134:236-239, 2006
21. Tjellström A, Granström G: Long-term follow-up with the bone-anchored hearing aid: A review of the first 100 patients between 1977 and 1985. Ear Nose Throat J 73:112-114, 1994

22. Holgers KM, Tjellstrom A, Bjursten LM, et al: Soft tissue reactions around percutaneous implants: A clinical study of soft tissue conditions around skin penetrating titanium implants for bone anchored hearing aids. Am J Otol 9:56-59, 1998
23. Wazen JJ, Young DL, Farrugia MC, et al: Successes and complications of the Baha system. Otol Neurotol 29:1115-1119, 2008
24. Lustig LR, Arts HA, Brackmann DE, et al: Hearing rehabilitation using the BAHA bone-anchored hearing aid: Results in 40 patients. Otol Neurotol 22:328-334, 2001
25. Liepert D, diToppa J: The NobelPharma auditory system bone anchored hearing aid: The Edmonton experience. J Otolaryngol 23:4111-4118, 1994
26. Wazen JJ, Caruso M, Tjellstrom A: Long term results with the titanium bone anchored hearing aid: The US experience. Am J Otol 19:737-741, 1998
27. Tringali S, Grayeli AB, Bouccara D, et al: A survey of satisfaction and use among patients fitted with a BAHA. Eur Arch Otorhinolaryngol 265:1461-1464, 2008
28. Badran K, Brunstone D, Arya AK, et al: Patient satisfaction with the bone anchored hearing aid: A 14 year experiment. Otol Neurotol 27:659-666, 2006
29. Wazen JJ, Spitzer JB, Ghossaini SN, et al: Transcranial contralateral cochlear stimulation in unilateral deafness. Otolaryngol Head Neck Surg 129:248-254, 2003