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Placement of the Baha osseointegrated implant in children

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KEYWORDS
Baha;
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The Baha osseointegrated implant provides bone-conducted hearing for children with significant conductive, mixed, or unilateral profound sensorineural hearing loss. The Baha system utilizes bone conduction through the skull to augment hearing. The transcutaneous Baha implant is screwed into the skull behind the ear and the sound processor attaches to the implant via a snap coupling. The system has revolutionized the rehabilitation of hearing loss associated with atresia.

The Baha osseointegrated implant is a treatment option for children with conductive, mixed, or unilateral profound sensorineural loss that would be difficult to treat adequately with traditional hearing aids. Children with bilateral atresia and bilateral chronic otitis media resulting in chronically draining ears are the most common recipients. Surgical atresia repair, which is technically challenging and requires favorable anatomy for a reasonable chance of hearing improvement, has largely been replaced by Baha implant placement.

First used in Sweden in 1977, the Baha osseointegrated implant utilizes a percutaneous titanium screw which is termed a fixture that allows bone to grow into the screw.[1] The device is approved by the Food and Drug Administration (FDA) for children aged 5 years or older for treatment of conductive, mixed, and profound unilateral sensorineural hearing loss (Figures 1 and 2). Bilateral implantation is also FDA approved. In the United States, the Baha was previously known as the BAHA, an acronym for Bone Anchored Hearing Aid. The name was changed due to the long standing reluctance of American insurance companies to provide payment for hearing aids. Center for Medicare Services' (CMS) coverage for Baha started in 2005. Most American insurance companies will now cover the procedure and the device is available in most developed nations. The Baha is the only currently available osseointegrated system that couples to a sound amplification device. It is manufactured by Cochlear Corporation, headquartered in Australia. The implant is made of titanium and is MRI compatible to 9.4 Tesla.[2]

Indications

Indications for Baha implantation are conductive hearing loss, mixed hearing loss, or unilateral profound sensorineural hearing loss, with good results achieved for all 3 indications.[3-6] Patients with bilateral atresia are usually excellent candidates for the device. In children under the age of 5, the Baha Softband is available which combines the Baha sound processor with a head band to provide bone conducted hearing. Before implantation, an audiologic Baha evaluation should be performed where the device is demonstrated to the patient using a head band.

Technique

Placement of the Baha osseointegrated implant in the pediatric setting is almost always performed in the supine posi-

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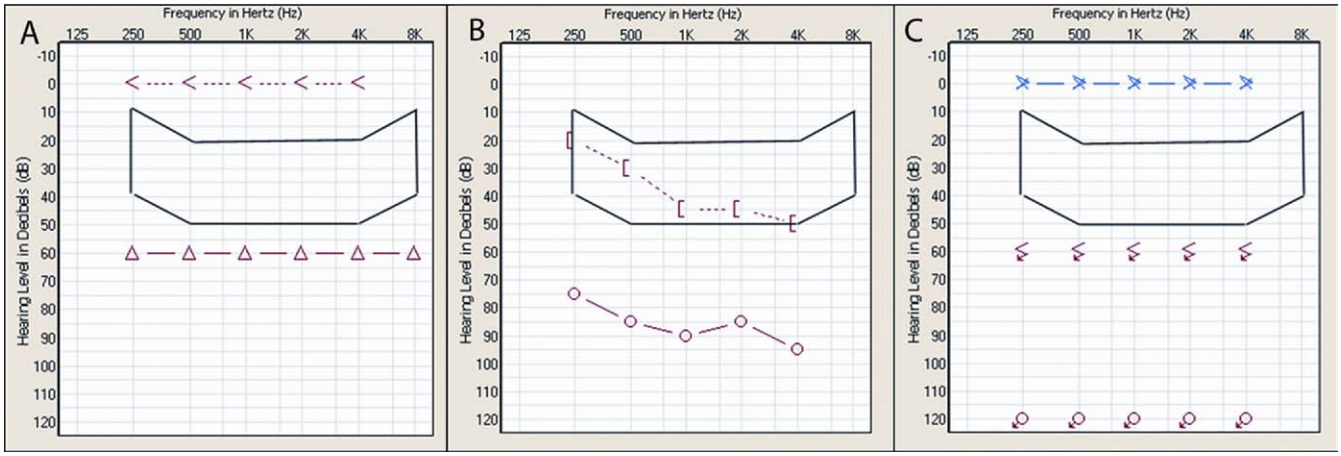

Figure 1 Indications for pediatric Baha implantation. (A) Conductive hearing loss. (B) Mixed hearing loss. (C) Unilateral profound sensorineural hearing loss. (Color version of figure is available online.)

tion in the operating room under general anesthesia. The procedure can be performed under sedation or even local anesthesia in older children or adults. Placement requires a proprietary drill system manufactured by the company. Insertion of the device involves (1) planning the skin incision(s) and flap or skin graft elevation followed by soft tissue flap elevation, (2) drilling a well in the skull, (3) wide undermining and removal of soft tissue, (4) placement of the implant(s), and (5) soft tissue rearrangement and wound closure, including placement and retention of a bolster or dressing. The procedure can be carried out in 1 or 2 stages. Two stage placements are usually performed in young children with a thin bony cortex and children with developmental or behavioral issues. Facial nerve monitoring is not necessary, with the exception of extremely dysmorphic children or those with evidence of an extremely lateral coursing facial nerve on computed tomography (CT). Preoperative imaging is not necessary, although most patients will have had a temporal bone CT scan as part of their evaluation. The procedure requires about 1 hour.

The Baha osseintegrated implant system has its own nomenclature and proprietary equipment (Figure 3). The screw that is placed in the skull is termed the fixture, and is available in 3 and 4 millimeter (mm) lengths. If the skull is of adequate thickness, the longer fixture is preferred. The fixture is hollow and is able to accept various external percutaneous attachments, termed abutments. The abutment is the attachment that screws into the fixture and is available in 5.5 and 8.5 mm lengths. The 5.5-mm length is used for most children, with the 8.5-mm length being reserved for obese patients and special circumstances. The implant system has numerous unique components, and the presence of a scrub nurse experienced with the system or a company representative is valuable.

The Baha fixture is usually placed 5.5 cm posterior and somewhat superior to the tragus (Figure 4), such that the top of the device will be roughly level with the superior aspect of the pinna. Placement location should take into account interaction with the patient's glasses. The center spot for the Baha fixture is marked and skin flaps or skin graft designed. The Baha system has its own dermatome which is powered by the drill system. This can be used to elevate a split thickness skin flap which is pedicled inferiorly or medially.

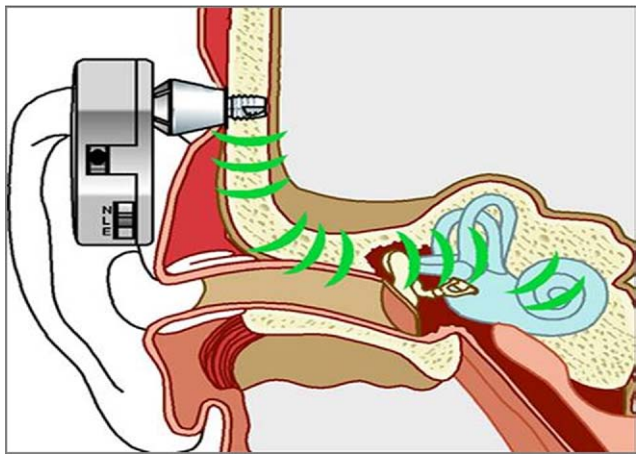

Figure 2 The Baha conducts sound through the bones of the skull. (Color version of figure is available online.)

Figure 3 The components of the Baha system. (A) Sound processor. (B) Abutment with snap coupling connection to processor. (C) Osseointegrated implant fixture. (Color version of figure is available online.)

Figure 4 Single stage Baha placement. (A) Marking of fixture site. (B) The proprietary Baha dermatome being used to raise a skin flap. (C) Skin and soft tissue flap is left pedicled while well is drilled. (D) Aggressive circumferential undermining with soft tissue removal. (E) Placement of the abutment-fixture combination using the proprietary Baha driver. (F) Plastic cap snap couples with abutment and can retain gauze placed medial to it. (Color version of figure is available online.)

Due to dissatisfaction with wound healing after Baha placement, numerous surgeons have published modifications of the original technique (Figure 5).[5,7,8] The author currently uses a modified French door incision (Figure 5E), elevating the skin flaps by hand. Ideally, the site around the Baha should be free of hair, which is more easily accomplished with dermatome-based techniques than with free hand elevation of flaps. In practice, residual hair surrounding the Baha site is rarely troublesome.

Once the skin incision is made, a soft tissue flap encompassing the layers between dermis and periosteum is elevated and left pedicled, usually inferiorly. The creation of the soft tissue pedicle can be cumbersome, but is most often utilized in small children where the underlying bone thickness or integrity remains in question. If the bone is found to be thin or weak, the soft tissue flap can then be replaced. In older children and adults, the soft tissue is often removed before drilling the well.

The proprietary Baha drill system is then used to drill a narrow guide well at 2000 revolutions per minute (RPM). The 4 mm drill bit has a removable plastic cap, which can be used to initially limit drilling to a depth of 3 mm. A probe is used to periodically check the bony integrity of the base of the drill hole. If dura is encountered, drilling is usually terminated. Once the guide well is drilled, the counter sink is performed. This utilizes a larger drill bit to create the final well into which the implant will fit. Copious irrigation is performed during drilling, and care is taken to maintain the well perpendicular to the skull.

Aggressive soft tissue removal is performed to encompass a rectangle about 40 mm in the anterior-posterior dimension and about 50 mm in the superior-inferior dimension. Soft tissue between the dermis and periosteum is removed in its entirety. Inadequate soft tissue removal is the most common cause of late complications, resulting in soft tissue and scar overgrowth of the implant area, impairing device function.

A 3- or 4-mm fixture is then chosen. If the bone is thinner than 3 mm, a 3-mm fixture can be left proud, with some of the thread exposed. Bone may grow up to surround the exposed thread. This may be facilitated by placing bone dust around the exposed thread. The threads of the fixture should not be handled or allowed to touch any other surface, as this reportedly affects the proprietary compound within the threads that facilitates in growth of bone and hence osseointegration. If a mastoid air cell is encountered, the fixture can still be placed if sufficient bony cortex is present. The same proprietary hand piece used for drilling the well is utilized for fixture insertion, with the appropriate fixture-handling attachment. Fixture insertion is accomplished at a setting of between 25 and 40 Newton centimeters, depending on the perceived quality of bone. Higher settings are used for stronger bone. Irrigation commences after the first full turn of the fixture, to avoid trapping saline in the well. The device will automatically stop turning when full insertion has been accomplished and the hand piece is pulled laterally, disengaging it from the fixture and the attached 5.5-mm abutment. The 5.5-mm abutment can be removed and replaced with the 8.5-mm abutment for children with thick soft tissue.

Soft tissue rearrangement is then completed by replacing the pedicled skin graft or flaps around or over the abutment. A dermatologic skin punch can be used to expose the abutment when using grafts or flaps that tent over the abutment. A plastic cap, which is provided with the implant, can be snapped into position onto the abutment and can be used to retain dressing placed underneath it. Alternatively, a bolster can be sutured into position. The patient is usually seen in clinic 1-3 weeks postoperatively, and the dressings removed or replaced. Further follow-up scheduling is predicated on the degree of graft/flap take. Activation of the processor is usually performed 3-6 months postoperatively, depending on bone thickness.

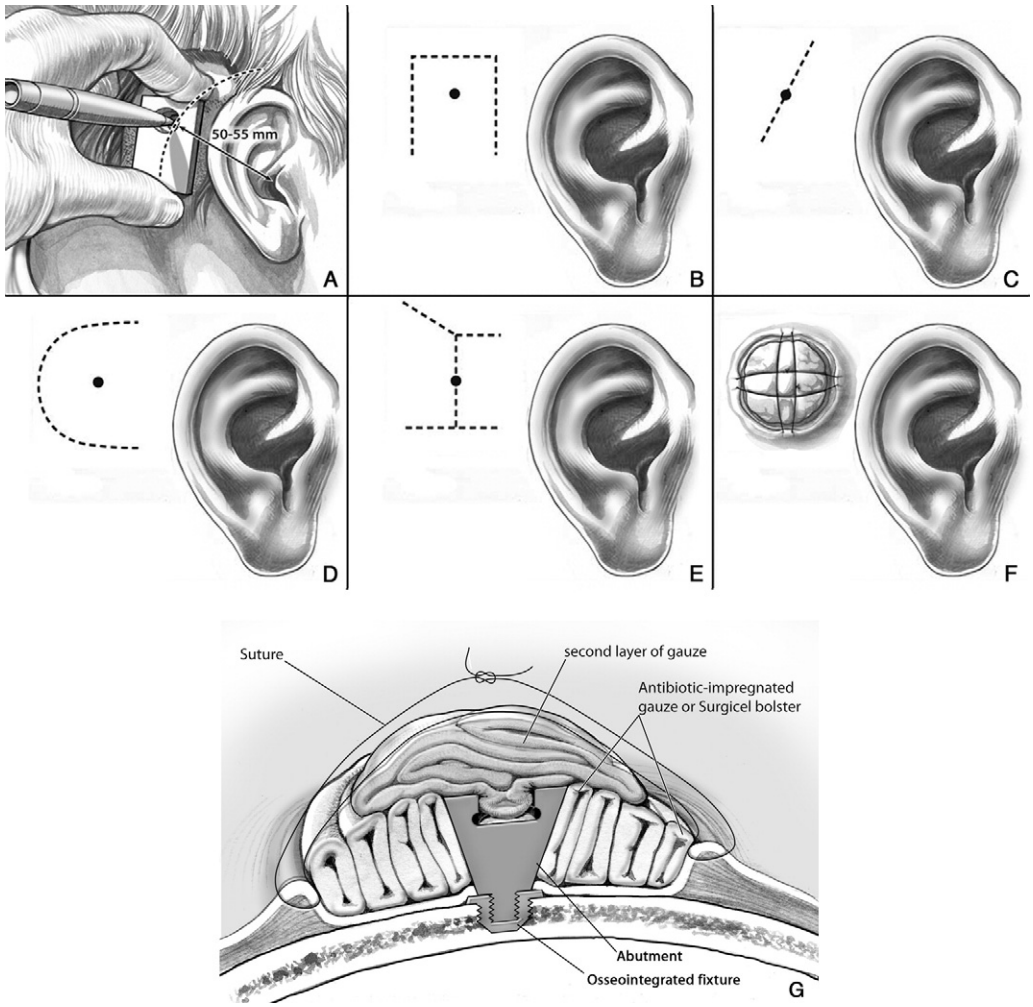

Figure 5 Alternative approaches to soft tissue rearrangement. (A) A template is used to plan the incision. (B) Inferiorly based skin flap. (C) Vertical incision.[8] (D) U-graft incision.[7] (E) Author's preferred incision. (F) A bolster of antibiotic impregnated held in place by 4 sutures. (G) Coronal section through skull and implants bolstered with gauze.

A 2-stage technique is performed in young children, or individuals expected to have thin bone or wound healing issues. The first stage, involves creating a flap or incision that allows access to underlying bone. Usually, the same skin incisions that will be utilized for the second stage are used for the first stage. The well and counter sink are drilled as described above, but an abutment is not left in the fixture. Instead, a healing cap is manually screwed into the fixture and the soft tissues closed over it. Three to 6 months are allowed to pass to allow osseointegration. The implant is then exposed and examined. The healing cap is removed and a fixture manually screwed into position with the proprietary screwdriver provided. Aggressive soft tissue removal is performed. Flaps or grafts are then put back into position and dressings applied, as for the 1-stage procedure.

A second fixture may be inserted in the 1-stage or 2-stage procedure. This provides a back up fixture if the primary fixture fails to osseointegrate. Double fixture placement is most often utilized in children with thin bone or bone of questionable quality.

Complications

The most common early complication is inadequate or compromised wound healing. Partial take of the skin graft can result in a wound that must heal by secondary intention. Due to the problems with the original skin graft technique, many surgeons have created their own soft tissue techniques, most of which involve elevation of slightly thicker flaps, usually performed freehand with a knife (deWolf).[5,7] A poorly healing Baha wound can be troublesome to surgeon and patient and can require extended periods of local debridement and topical antibiotic ointment. Rarely, oral or intravenous antibiotics might be necessary. The scarring associated with poor wound healing can result in the need for surgical revision focusing on further soft tissue removal to prevent overgrowth and burial of the abutment.

The most common late complication is soft tissue impingement on the abutment site, which can prevent snap coupling of the device to the abutment or through contact can impair the proper vibration of the Baha processor. The most common site of failure is the superior posterior aspect of the wound, as this area falls away while the patient is supine during surgery but

tends to fall towards the abutment when the patient is sitting or standing. Steroid injections or surgical revision can be used to reduce unwanted soft tissue encroachment.

Lack of osseointegration can occur in a small percentage of cases (deWolf 2008).[8] This can be due to poor quality of bone or thin bone. The secondary fixture can then be utilized or another attempt at surgical fixture placement made.

Discussion

The Baha osseointegrated implant system has revolutionized the care of children with conductive hearing loss, particularly those with bilateral atresia. The device provides a reliable rehabilitative option with excellent sound quality. The size of the processor continues to be a cosmetic concern, particularly in individuals with short hair. Variations of soft tissue rearrangement have resulted in improved postoperative wound healing. Experience with bilateral pediatric Baha implantation and implantation for single-sided deafness continues to accrue.

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