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Surgical implantation of the Sophono transcutaneous bone conduction system

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Bone conduction implantable devices are an effective means of rehabilitation for ipsilateral conductive hearing loss and in a contralateral routing of signal (CROS) configuration for single-sided deafness. Percutaneous systems provide excellent sound quality but suffer from the complications of recurrent infection, skin overgrowth, and cosmetic concerns. The Sophono transcutaneous bone conduction system uses an internal retention magnet to hold an external force plate and sound processor to the scalp, allowing for transcutaneous bone conduction and stimulation of the cochlea. Implantation consists of a simple incision, drilling a shallow recess for the bilobed magnet in the cranium, and securing of the implant with standard plating screws. Surgical considerations such as placement, flush positioning to the bone, and maintaining or augmenting overlying tissue thickness are important to ensuring postactivation wearability. Fitting considerations such as time to fitting, magnet strength determination, and graduated wearing schedules are also critical to patient outcomes.

Introduction

Surgically implantable bone conduction devices have been available for many years. The Xomed Audiant was approved by the Food and Drug Administration (FDA) in 1986 and consisted of an internal implantable magnet and external magnetically coupled processor.[1,2] The percutaneous Baha (Entific) was developed and approved by the FDA in 1996.[3,4] This device was widely adopted, and the Baha application was acquired by Cochlear Corp. This was followed by the development of a competing percutaneous device, the Ponto system by Oticon. Although pain with use was not typical of the percutaneous systems, recurrent infection, skin breakdown, skin overgrowth, and osseointegration issues have been noted.[5-7] This has prompted a revisit of the transcutaneous approach with the development of the Sophono transcutaneous bone conduction system and subsequent FDA approval in 2011.[8]

Candidacy criteria

The Sophono system works by providing sound to the cranium through an external baseplate held to the scalp with internal magnets. The magnets are not the transmitters of

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sound, rather the baseplate vibrating the scalp transmits sound through the tissues to the ipsilateral ear with conductive or mixed losses, or contralateral ear with single-sided deafness. As such, the Sophono transcutaneous system has some diminution of sound transmission compared with percutaneous configurations and this should be considered in assessing candidacy.

Current candidacy guidelines for the Sophono system suggest a bone conduction puretone average (500, 1000, 2000, and 3000 Hz) of 45 dB HL or better for cases of conductive hearing loss. Current percutaneous systems can be fit to losses as high as 65-dB HL puretone average for conductive or mixed losses. The advances in the external processor may push candidacy for the transcutaneous Sophono to higher threshold levels.

Candidacy for single-sided deafness indicates that the contralateral ear should have normal hearing with a puretone average of 20 dB HL or better. The implanted side should have a severe to profound hearing loss. The clinician should take into consideration any potential for the patient to develop hearing loss in the normal ear, as this would affect use of the Sophono device in this CROS configuration.

Operative technique

The Sophono internal retention device consists of dual circular magnets with attached flanges for securing to bone (Figure 1). The magnets are 2.6-mm thick and are recessed in a well so that the superficial surface lies flat with surrounding bone. The 4 radiating flanges and the single center screw hole are used with standard 1.7-mm × 4-mm plating screws to secure the device. Surgical placement of the magnet uses techniques and instrumentation familiar to many otolaryngologists and can be readily incorporated into one's practice.

Similar to other bone-anchored hearing devices, the Sophono magnets should be placed at an angle 45° from horizontal, approximately 55-60 mm from the external

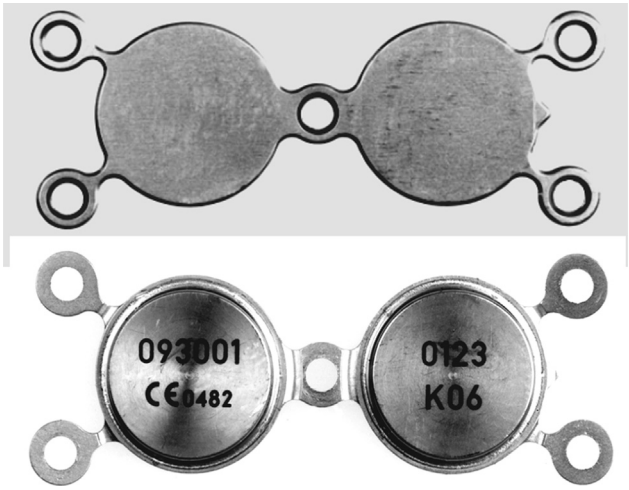

Figure 1 The internal implantable magnets. Upper view is the superficial surface and lower view shows the 2 magnets that are recessed in 2 circular wells.

Figure 2 Intraoperative view of device secured in position behind a left ear. The distance from the helix, curvilinear incision placed posterior to the device, and placement more superior than with percutaneous devices can be noted.

auditory meatus (Figure 2). The magnets should be sufficiently posterior to the edge of the helix to avoid contact by the external device after fitting. If possible, attempt should be made to place the magnets along the flattest area of the cranium in the postauricular region. This typically is found in a position slightly higher than 45° off the external meatus. If there has been a prior mastoidectomy or suboccipital craniotomy, magnet position may need to be adjusted accordingly.

The skin incision can be linear or a curvilinear skin flap. We have transitioned to a linear incision to better facilitate perpendicular placement of all fixation screws, which can be difficult if the curvilinear incision is not large enough. Further, the magnet implant, at the time of this manuscript preparation, served as the template for positioning, and we have found the flanges susceptible to bending if it needs to be tucked under flaps to gauge exposure. The linear incision allows direct visualization of the entire implantation site and access to all flanges and fixation holes. It can easily be extended superiorly or inferiorly to accommodate a need for greater exposure or for repositioning of the implant. We set the incision just off midline of the magnetic implant so the scar does not lie in the immediate center of the force plate. We do not thin skin and recommend up to 1 cm of skin thickness. The surgical manual suggests 4-6 mm, yet we feel that thicker tissue can mitigate postoperative pain and improve wearability.

The skin incision is carried directly down to pericranium and the pericranium is vertically incised and retracted to expose the bone. The device is used as a template and positioned vertically. The position of the wells for the magnets is marked with a surgical marker by outlining the device. A 4- or 5-mm cutting bur can be used to develop the wells. The edges of the wells should make a right angle with the floor of the well to mirror the magnet shape. A matchstick bur is useful for this part of the procedure, but a small cutting or diamond bur also works sufficiently.

The wells should allow the magnets to recess fully and be easily placed. They do not need to fit the magnets tightly. The wells should not be too large, else it will interfere with placement of the fixation screws. We typically shape one well at