Medical Aspects of Bone Anchored Hearing Aids and Middle Ear Implants

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Bone Anchored Hearing Aids

The bone anchored hearing aid (BAHA™) is an excellent alternative for patients with conductive hearing losses who are unable to wear conventional hearing aids. Many of these patients either have a history of chronic suppurative otitis media, which is resistant to medical or surgical therapy, or a history of recurrent otitis externa and are unable to tolerate an earmold because it exacerbates the infection. A smaller number of patients are unable to wear a mold because of congenital or acquired atresia and wear a conventional bone conduction aid. The latter has several drawbacks, since it is difficult to wear. The constant pressure of the steel spring against the scalp, sufficient to obtain good energy transmission, produces a great deal of discomfort for the patient and can only be tolerated for short periods of time. It also has poor sound quality since the skin attenuates high frequency signals. Cosmesis is also a factor.

In 1969, Brånemark and colleagues published a report describing integration of a titanium implant in bone (Brånemark *et al.*, 1969). On the basis of this report, they developed a successful oral implant for anchoring dentures in an edentulous jaw (Brånemark *et al.*, 1977). Extra oral application of this osseointegration capability was developed by Tjellström in the same year, for the purposes of anchoring a hearing aid to the mastoid bone percutaneously (Tjellström *et al.*, 1983).

The Xomed Audiant, another bone anchored hearing aid, which modified Tjellström's technique by applying the latest technology of cochlear implants (i.e., transmission of sound transcutaneously through the skin) underwent trials in 1984. The internal device was a titanium-vanadium cup and bone screw assembly into which was attached a magnet encased in silicone that was surgically inserted into the mastoid bone. This was electromagnetically coupled to the external processor which transformed acoustic energy into an electromagnetic field that passed through the skin, resulting in vibration of the magnet and transmitting sound to the cochlea.

In 1987, therefore, two different systems were commercially available. Gates published in 1989 a report of 184 patients implanted with the Xomed Audiant by 132 otolaryngologists (Gates *et al.*, 1989). Unfortunately, only 96 patients met the preoperative hearing criteria approved by the US Food and Drug Administration (FDA). However, the conclusion was that the Audiant Bone Conductor indicated "a high degree of safety, patient acceptance, and ease of use."

The two systems were compared by the author, i.e., 24 transcutaneous and 11 percutaneous devices (Wade *et al.*, 1989), after reviewing the initial results with the transcutaneous implants (Wade *et al.*, 1989). It was clear from these studies that the transcutaneous device had numerous failings. Patients complained of a lack of power and had to resort to a body processor instead of

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the at-the-ear device, which they had expected to wear. Also with time, scar tissue developed around the internally placed magnet, decreasing the magnetic attraction with the result that the device would occasionally fall off. By the mid 1990s, Xomed stopped manufacturing the transcutaneous device.

Surgical Indications for BAHA

The surgical indications for implantations of the percutaneous BAHA™ are:

1. Patients who have congenital or acquired external canal atresia.
2. Patients who have chronic suppurative otitis media resistant to medical and surgical therapy and who have likewise undergone unsuccessful regular hearing aid management.
3. Patients who have chronic eczema or inflammation in the ear canal exacerbated by regular hearing aid wear.
4. Patients should be over 5 years of age.

Audiological Criteria

The audiometric criteria for BAHA™ as recommended by the manufacturer are:

1. Bone conduction pure tone averages (PTA) 500, 1000, 2000, and 3000 Hz not greater than 45 dB hearing loss for the Classic 300 or BAHA Compact, and 70 dB for the Cordelle II (Body Processor).
2. A maximum speech discrimination better than 60% when using a phonetically balanced word list.

Surgical Technique

The surgical procedure is not complicated and can easily be performed under local anesthesia within 45 minutes on an outpatient basis. The side chosen for implantation should be the one with the best bone conduction threshold, but if there is little difference between the two sides, consideration for telephone use, as well as for driving an automobile is recommended. (For example, for the driver, the side facing the passenger is

appropriate; for telephone, the side opposite to the hand used for writing would be preferred.

In the surgical set, a plastic indicator is helpful to choose the surgical site. It is important that the eventual placement of the BAHA™ is such that it does not abut on the helix. On the other hand, it should be placed as close to the ear as possible so that sounds posteriorly will not interfere.

Initially, the surgical procedure was performed in two stages, with the second stage, (i.e., attachment of the abutment to the titanium fixture) three to four months later. However, for adults, a one-stage surgical procedure is now recommended. Under local anesthesia, a 1.5 to 2.0 cm circumferential skin incision down to periosteum is made. A portion of periosteum in the center of the site is removed to allow the fixation of a 4 mm titanium fixture. Specially constructed instruments enable the surgeon to drill a hole at the fixture site, to thread the hole, and finally, to screw the fixture into place. A hairless piece of skin is then obtained from an appropriate acceptable graft site (i.e., most often behind the ear lobe) and sutured at the fixture site. The graft site is closed directly. A small perforation is created in the center of the graft and the abutment is then screwed into the fixture. A plastic healing cap is attached to the abutment and a cortisporin impregnated ¼ inch dressing is wrapped around the cap. At five days, the cap is removed and the site aerated for 20 minutes. The cap is then reapplied, along with a new dressing, for another five days at which time the cap, dressing, and sutures are removed. Although there have been a few variations in the surgical handling of the skin incision and the graft site, the basic above procedure has changed little from the original procedure described by Tjellström (Tjellström *et al.*, 1983).

Surgical Complications

Immediate surgical complications are few. Occasionally, a bloody tap may ensue requiring closure with bone wax. Relocation at an adjacent site is often successful, but may require an alternative smaller 3 mm fixture after testing the drill site with a probe to assess the proximity of the dura. A postoperative computed tomographic scan of the skull might be helpful in calculating the possible success of further surgery if a site was not found at the initial operation.

Apparent equipment failure may occasionally cause premature abandonment of the procedure.

This is often due less to the equipment, which is very sophisticated and reliable, than to the inexperienced operator. A learning curve for using the instrumentation definitely exists for both the surgeon and the scrub nurse. An experienced nurse with good digital dexterity is required, since most of the technically challenging manipulation of the surgical instrumentation is placed in the nurse's hands.

A late surgical complication, recognized after healing has occurred, is that insufficient subcutaneous tissue has been removed under the edges of the circumferential skin incision. A gradual slope from the skin edge to the abutment is ideal, permitting adequate cleansing of the area. This will result in a decline in the number of adverse skin reactions around the abutment site with less surgical revisions required later.

Postoperative Care

Ointment is generously applied to the graft until the skin has healed. After that, the skin around the abutment must be cleaned daily. Skin debris collects around the abutment and must be removed. If not, bacteria collect under the debris and infection occurs, producing edema of the surrounding tissues, and occasional granulation tissue. The latter may require cauterization. A soft baby toothbrush or an even finer, eyeliner brush with soap and warm water can be used to clean the skin adjacent to the abutment. Chronic irritation around the abutment may indicate that the abutment is loose, and judicious tightening of the abutment may resolve the problem.

Fitting Procedures

The fixture has to be fully osseointegrated prior to fitting with the sound processor (three months in adults and six months in children). Prior to fitting, the patient should be fully trained to use the sound processor and to attach the processor to the abutment.

Results

The results with the BAHA™ have been uniformly good. Over 6000 BAHA™s have been implanted worldwide, mostly in Europe. The author has implanted over 150 since 1990. A recent three-to 10-year review of 76 patients implanted at Markham Stouffville Hospital has confirmed these good results (Wade *et al.*, 2000).

This review included 76 patients ranging from seven to 74 years of age, with an approximately equal number of males and females. There were 64 patients with bilateral chronic ear disease and 12 patients with congenital atresia, six unilateral and six bilateral. It was noted that 48 of the 76 patients were still wearing their BAHA™ for more than eight hours a day with the exception of the six unilateral patients who wear it mainly at work, two to eight hours a day. Almost all of these devices are three to 10 years old.

Of these 48 patients, 47 participated in a satisfaction survey. On a scale of 1 to 10 (with 10 as the highest level of satisfaction), 96% ranked it 8 or greater. Fourteen patients were lost to follow up but nine of the 14 were wearing it successfully at least three years prior to being lost. Fourteen no longer wear their BAHA™ for a number of reasons. Three patients died but had been successful wearers for a minimum of three years; one had worn the device for eight years. Some could not afford repairs, which are not covered after the warranty period. Although all patients in the above program were fitted unilaterally, patients have been found recently to benefit from wearing these devices binaurally (Snik *et al.*, 1998). Also recently, the BAHA™ has been used as a cross aid for patients with profound unilateral sensorineural hearing loss with normal hearing in the opposite ear (Wazen *et al.*, 2001). The sound is transmitted directly through the skull via the BAHA™ to the normal inner ear.

The Markham Stouffville Bone Anchored Hearing Aid Program is fully funded (up to 20 per year) but, unfortunately, funds are not available to replace the device as it wears out or as the technology improves. On the other hand, conventional hearing aids are replaced approximately every three to five years.

In conclusion, the BAHA™ has been a wonderful addition to the armamentarium of the ear surgeon. For patients with chronic ear disease who are unable to wear conventional hearing aids, or those patients with congenital or acquired atresia, the BAHA™ is a very attractive alternative. As with any other new technology, recent advances have made this device even more patient friendly. The BAHA™ Compact not only has better fidelity than the Classic 300, but it is considerably smaller and therefore more cosmetically acceptable. It also has the new snap on coupling, replacing the bayonet coupling on the Classic 300, which required changing of the plas-

tic insert and O-rings on a regular basis. Patients found this quite difficult to perform without help. Finally, the new Cordelle II Body Processor is more powerful and superior to the former Cordelle I and its predecessor, the Super Bass Body Processor.

Middle Ear Implants

Middle ear implants (MEI) have been a long time coming and only recently have become commercially available. Experimental research has been ongoing since the early 1970s (Fredrickson *et al.*, 1973). Previously, the only implants available were bone anchored hearing aids (BAHATM), cochlear implants, and for those unfortunate few with neurofibromatosis type 2 and unable to benefit from cochlear implantation, the auditory brainstem implant. Despite ongoing research over the last 30 years, it was only recently that the FDA has approved MEIs. Implantable hearing devices, which have been used for patients who could not benefit from conventional hearing aids, can now for the first time directly compete with conventional aids, especially for those patients with moderate-to-severe loss mainly in the high-frequency region. However, patients with flat-moderate to moderate-severe losses, or ski-sloped losses from normal hearing at 250 to 500 Hz to severe-profound at 4000 Hz might benefit, depending on the device.

Although significant improvements have been made in conventional hearing aids, including the advent of digital technology, a number of intrinsic problems still remain. Patients frequently complain of difficulty understanding speech in background noise, feedback, occlusive effects, and poor sound quality. MEIs may circumvent a number of these issues by producing a more natural sound with less distortion and, at the same time, reducing occlusive effects and feedback problems.

Transduction mechanisms for MEIs have traveled a similar pathway in their development as the aforementioned BAHATM. MEIs also have two methods of transduction: piezoelectric and electromagnetic. Although there have been numerous implant research programs, there are presently five major players. Implex Totally Implantable Cochlear Amplifier (TICA) and St. Croix Medical EnvoyTM representing piezoelectric implants, and Otologics Middle Ear TransducerTM (METTM),

SoundTec Direct Drive Hearing SystemTM (SoundTec DDHSTM), and Symphonix Vibrant[®] soundbridge representing the electromagnetic devices. However, the totally implanted Implex TICA hearing amplifier implant has recently been discontinued and the St. Croix Medical EnvoyTM has not yet received FDA approval. Only the three electromagnetic based devices are being implanted in the United States. SoundTec DDHSTM and Symphonix Vibrant[®] soundbridge are presently commercially available, with Otologics METTM currently in clinical trials.

In piezoelectric devices, an external microphone transduces sound to an implanted middle ear crystal. The current transmitted to the crystal results in bending of the crystal, producing vibrations of the ossicular chain. The major advantage of this type of device over an electromagnetic device is that the components are smaller, permitting a totally implantable device. Unfortunately, they do not achieve the same degree of functional gain.

The electromagnetic middle ear implant is by necessity larger and presently only partially implantable, although it is likely that a totally implantable model is not too many years away. These implants typically have an external coil, which is connected to a microphone, an amplifier, and an implanted component containing a magnet, either attached to the ossicular chain or the energy electromechanically drives the ossicular chain.

The SoundTec DDHSTM has two components: an external device consisting of an analog behind-the-ear sound processor, an electromagnetic coil incorporated into a custom deep ear canal mold (an in-the-ear and in-the-canal have been developed and will soon be available), and the internal component, which is a magnet attached to the head of the stapes.

The METTM Ossicular Stimulator uses an electromechanical middle ear implant coupled to an external sound processor. The implanted internal unit consists of an electronic receiver attached to the transducer. This vibrates a probe inserted into a laser-made hole in the incus, which becomes fixed to the latter by fibrous tissue.

The Symphonix Vibrant[®] soundbridge has an external audio processor and the internal implanted portion is called the vibrating ossicular prosthesis (VORP). The VORP consists of an electromagnetic transducer that is attached to the patient's incus and electrically connected to the internal receiver. The internal receiver is coupled to the audio processor by telemetry.

Surgical Implications

With the exception of SoundTec DDHS™, the other four previously mentioned MEIs require a general anesthetic and a mastoid approach. SoundTec DDHS™, on the other hand, can easily be performed under local anesthesia within 45 minutes or so with minimal potential postoperative complications. A transcanal stapedotomy-type approach into the middle ear is used. The incus is placed on tension by means of a two-handed technique (i.e., the incus is held on stretch with one hand while a sharp joint knife is used in the other to separate the incus from the stapes). The implant is then carefully placed on the head of the stapes. A 10-week healing period is allowed prior to fitting a custom-made ear mold/coil assembly. Any middle ear surgeon performing regular stapedotomy operations will feel comfortable performing this procedure.

Few complications are expected with surgery for SoundTec DDHS™ implantation. There is a possibility of trauma to the inner ear by vigorous manipulation of the stapes. However, very sharp, specially designed instrumentation should minimize this trauma. Other complications are primarily those of any tympanotomy approach, including potential infection, persistent perforation of the tympanic membrane, and trauma to the facial nerve. A conductive hearing loss may occur due to failure of the incustapedial joint to heal. This is unlikely and might be estimated to occur in less than 1% of cases.

The four other MEIs (the two piezoelectric and two electromagnetic devices) require mastoid approaches, which necessitate a two to three hour operation under a general anesthetic. The ossicular chain was dismantled in most cases with the Implex TICA and all of the St. Croix Medical™, by design, producing a conductive hearing loss superimposed upon the typical moderate-to-severe high-tone sensorineural hearing loss seen in the ideal candidate.

However, it should be noted that nearly all of the implants produce some degree of conductive component postsurgery: the Otologic MET™ device due to slight increased stiffness of the chain, and the Symphonix Vibrant® soundbridge and the SoundTec DDHS™ due to increased mass on the chain. These latter mentioned electromagnetic implants only produce a small increase in the air bone gap and removal of same would restore

their function back to normal, whereas the piezoelectric implants produce large air bone gaps and permanent damage.

Any mastoid operation has possible complications, which include the potential for facial nerve damage. Access to the middle ear with the Symphonix Vibrant® soundbridge device requires a facial recess approach that creates an opening from the mastoid into the middle ear, adjacent to the facial nerve, which is a millimeter or two away. However, despite the proximity of the facial nerve, middle ear surgeons familiar with the intact canal wall approach to chronic ear disease and cholesteatoma are on very familiar territory with this surgical procedure. Damage to the facial nerve would be approximately 1% or less in these surgeons' hands. This surgery would likely necessitate at least an overnight stay in the hospital and approximately a week to 10 days postoperative recovery. Typically, there is an eight-week postoperative period before the external portion of the devices are programmed and activated for the patients. Each individual operation will likely have its own unique set of postoperative complications. They will become more evident as these procedures become more widespread.

The Symphonix Vibrant® soundbridge was the first to receive FDA approval, recently followed by SoundTec DDHS™. Otologics MET™ will likely soon follow. Therefore, it presently appears to be an *electromagnetic world*. The future for MEIs remains very interesting. As to whether they all will prevail, who knows? Costs will likely be a major factor when competing with a very competitive hearing aid industry. At present the SoundTec DDHS™ can compete on a cost basis.

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