Clinical Forum

Implantable Bone-Conduction Hearing Device: Practical Considerations

Bruce A. Weber*
Jackson Roush†

Abstract

An implantable bone conduction hearing device can be of significant benefit to carefully selected patients with noncorrectable conductive hearing losses. However, for some patients the device has significant limitations. This paper presents several practical issues that need to be considered before a decision is made regarding implant surgery. It is recommended that, whenever possible, air conduction hearing aids remain the first option considered when a patient's conductive hearing loss cannot be resolved through traditional medical management.

Key Words: Audiant, bone conduction, conductive hearing loss, hearing aids, implantable hearing device

In most cases, conductive hearing impairments can be successfully treated by conventional otologic management. For those patients with a noncorrectable conductive impairment, an air conduction (AC) hearing aid usually provides adequate improvement in hearing. There are some patients, however, for whom an AC hearing aid is contraindicated because of chronic drainage, atresia, stenosis, or major postsurgical alterations in the mastoid and external ear. For such individuals, traditional management has involved the use of conventional bone-conduction (BC) hearing aids. Unfortunately, patients are frequently dissatisfied with these devices because they are often viewed as unsightly, uncomfortable and difficult to keep in position.

Recently, a new alternative has become available for patients with noncorrectable conductive hearing impairments. The U.S. Food and Drug Administration (FDA) has approved an implantable bone conduction hearing device developed by Hough and his colleagues at the Central Ear Research Institute in Oklahoma City (Dormer et al, 1986; Hough et al, 1986b, 1986c). The device is now marketed commercially by the Xomed-Treace Corporation as the “Audiant Bone Conductor” (Audiant). Previous reports (Hough et al, 1986a; Johnson et al, 1988) have discussed the physical characteristics of the Audiant in detail so they are only briefly mentioned here.

The implantable portion of the Audiant consists of a small rare-earth magnet imbedded in the head of a titanium bone screw. The screw is surgically inserted into the temporal bone, usually under local anesthesia. The battery powered external sound processor contains a microphone, amplifier, inductive coil, magnet, and volume and tone controls. Sound is delivered transcutaneously in the form of electromagnetic signals to the internal magnet/screw. The Audiant is currently available in either a body-worn unit or an at-the-ear (ATE) instrument. Unlike a conventional hear-
ing aid, the Audiant converts air-borne sounds to bone conducted signals within the skull. Improved performance is achieved if the device successfully eliminates or substantially reduces the patient's conductive component.

The manufacturer recommends four specific audiometric selection criteria for the implanted ear: 1) average bone-conduction thresholds for frequencies 500 Hz, 1000 Hz, and 2000 Hz no worse than 25 dB HL with no single BC threshold, at any of these frequencies, poorer than 40 dB HL, 2) average air-conduction thresholds for the same frequencies no better than 40 dB HL, 3) a speech discrimination score no less than 80 percent in quiet, and 4) an air-conduction speech reception threshold no better than 40 dB HL.

Although the audiometric selection criteria are straightforward, a number of other factors should also enter into the decision regarding whether an individual patient's needs are best served by the Audiant. This paper shares the authors' views based on their clinical experiences utilizing the Audiant bone conductor with conductively impaired patients.

### Defining a Good Candidate

The manufacturer's selection criteria, described above, should be viewed as the minimum audiometric requirements for the more powerful body-worn Audiant. Unrealistic expectations are likely to result if the criteria are viewed as establishing a clear-cut dividing line between excellent candidates and those who do not qualify for implantation. Rather than a dichotomy, there is a continuum regarding anticipated benefit from the Audiant. A patient who barely meets the audiometric selection criteria should be viewed as a marginal or borderline candidate. Marginal candidates are likely to experience marginal improvement with the Audiant. If the surgeon and audiologist elect to recommend implantation, the probability of limited benefit from the Audiant must be thoroughly discussed with the patient.

### Selecting between the Body-Worn and the At-The-Ear Device

The manufacturer's recommended patient selection criteria were developed for the body-worn Audiant, which is powered by two AA size batteries. It is well documented that the newer at-the-ear (ATE) Audiant, which uses a 675 hearing aid battery, is approximately 10 to 15 dB less powerful than the body-worn device (Campos, 1988; Johnson et al, 1988). Despite this difference in output, the manufacturer's recommended selection criteria are the same for the two devices. This can lead to the mistaken impression that the ATE is simply a smaller version of the body-worn device. In our experience, patients with bone-conduction thresholds approaching the 25 dB criterion do not receive satisfactory benefit from the ATE Audiant even at maximum output. To reduce the likelihood of an unsatisfied ATE user, some modification of the selection criteria is needed to take into account the lower output of the ATE. This might be accomplished by accepting an average bone-conduction threshold no greater than 15 dB for the ATE and no greater than 25 dB for the body-worn device.

This modification of the ATE selection criteria for the implant ear will likely exclude consideration of the device for some patients, directing them instead to the more powerful body-worn Audiant. This may result in fewer patients electing to proceed with implantation.
Implantable Bone-Conduction Hearing Device/Weber and Roush

Figure 1 Comparison of warble tone thresholds from a 53-year-old male obtained with the at-the-ear and the body-worn Audiants. Also shown are the patient's unaided air- and bone-conduction thresholds for the implanted ear. Since the patient has a profound bilateral sensorineural hearing loss for frequencies above 2000 Hz, no thresholds are noted for the higher frequencies.

because, not surprisingly, essentially all Audiant candidates find the ATE more cosmetically acceptable. Though the cosmetic factor is of major importance prior to implantation, it is not uncommon for patients to report dissatisfaction with the output level of the ATE and to express second thoughts about the selection of the smaller unit. Figure 1 shows the thresholds for one Audiant patient who was initially fitted with the ATE Audiant. With his ATE, a 15 to 20 dB air-bone gap remained in the low frequencies. Understandably, the patient was not fully satisfied with the performance of the device and, as a result, he seldom wore it. When the patient's ATE was replaced with the body-worn device, the air-bone gap was essentially closed and he was much more satisfied with its performance. Tollos and Wade (1989) reported similar experiences, noting that 21 of 24 patients preferred the body-worn instrument after a trial with both devices. Even patients with excellent bone-conduction sensitivity may prefer the body-worn device over the ATE Audiant because of improved ability to discriminate low intensity speech (Roush and Rauch, 1990). Consequently, prior to implantation, all candidates should be fully informed about the limited output of the ATE and counseled regarding the advantages and disadvantages of the more powerful body-worn device. Obviously, a balance must be main-

Magnet Strength

There are currently three magnet strengths for the external coil. The strongest one provides the greatest magnetic attraction and minimizes the chances of it falling off during active body movements and head turns. The stronger magnet, however, also increases the likelihood of skin irritation if the Audiant is worn for extended periods. Thus, there is a trade-off between secure attachment to the head and likelihood of skin irritation.

Wade et al (1989) found that the skin irritation is likely to occur if the Audiant is worn full-time during the day. Therefore, they recommend that the external processor be removed periodically to rest the skin between the external and internal magnets. Even when patients are placed on a program to gradually increase skin tolerance, they must be counseled that it may not be possible to wear the device more than a few hours at a time without a 15 to 20 minute break.

Although periodic interruptions may not pose a problem for adults, the Audiant is also FDA approved for use with children as young as 3 years of age. We have not personally attempted to use the Audiant with children under the age of 12 years; however, it can be predicted that young children would not be as likely to notice and report the early signs of skin irritation (warmth, redness, and tingling). Consequently, an adult caretaker would need to assume responsibility for monitoring the skin area over the implant site. To date, there are no published reports describing the use of the Audiant with young children.

Patients commonly report that the Audiant has become detached during some physical activity, and most indicate concerns regarding secure attachment. Some report that they elect not to wear the device at times when it could be of benefit because of their concerns about loss or damage. As Johnson et al (1988) note, the manufacturer provides a flexible stem attachment, which can be bent to the contour of the patient's pinna to provide additional support. This reduces, but does not eliminate, the attachment problem. Further Audiant design modifications are currently being evaluated by the manufacturer.
Predicting Postimplant Satisfaction

It is widely known that some individuals who appear to be good candidates for conventional air-conduction amplification are very unsatisfied with their appropriately fitted hearing aid. With hearing aids, patient dissatisfaction can usually be resolved through an equitable refund policy. With the Audiant, however, it is not as easy to reverse the process because of the elective surgery required and the long-term nature of the implantation. As a result, considerable effort must be made to screen out potentially dissatisfied users prior to surgery. To achieve this, improved methods are needed to predict successful Audiant use. A questionnaire designed to probe specific problem areas and expected benefits might be useful in this regard. It might also be helpful to allow Audiant candidates to experience the use of a conventional bone-conduction hearing aid. Though not an exact duplication of the transcutaneous input from the Audiant, such a trial would provide experience with a similar bone-conducted signal. Caution must be exercised, however, since too high a gain setting on the BC aid might lead to unrealistic expectations by potential Audiant users, especially those electing the ATE instrument. Further, research is needed to develop specific protocols useful in predicting postimplant satisfaction.

Normal Hearing in the Nonimplanted Ear

The Audiant now has FDA approval for use with patients having normal hearing in one ear and a conductive hearing loss meeting the established implant criteria in the other ear. Although this application is potentially useful as a means of improving binaural hearing, we believe that it should be undertaken cautiously. The Audiant may be of benefit in noisy situations where the desired signal is directed to the poorer ear; however, it is also possible that the Audiant may actually interfere with the understanding of speech in some listening situations. Because bone-conducted signals from the Audiant reach both cochleae, the Audiant wearer may experience reduced understanding if the device transmits competing noise via bone conduction to the normal ear. At present, there is insufficient published data to predict the effectiveness of the Audiant for patients with normal hearing in one ear. Further research is needed to predict patient satisfaction in this application.

Predicting Long-Term Benefit

Because of its limited output, patients routinely wear the ATE Audiant at maximum output. Even at full volume, however, a common complaint is that the signal level is insufficiently loud. The manufacturer is well aware of this limitation and is aggressively seeking ways to increase the output of the ATE Audiant while retaining its small size. Recently the manufacturer introduced a larger diameter internal magnet, which is expected to increase the output level by 5 to 7 dB. This increase should apply to both the ATE and body units. At this time the new, larger internal magnet has not yet received broad clinical application, so it is too early to determine if this will have a significant impact on the concerns and recommendations presented above. At present, the limited output of the Audiant must be taken into consideration, especially when attempting to predict the long-term benefits for older patients who are likely to experience a further decline in their sensorineural status.

Insurance Coverage

Unlike the cost of a hearing aid, which is rarely included in medical insurance coverage, the costs related to the Audiant are potentially covered by many policies. Insurance companies, however, vary markedly in their classification of the Audiant. Some companies define it as a surgically implanted device and provide full coverage. Others view the Audiant as a hearing aid or experimental device and disallow all claims. Because of the uncertainty regarding insurance or other third party coverage, it is essential to pursue this matter prior to implantation. Preauthorization minimizes potential problems regarding coverage of the expenses related to the Audiant.

When insurance coverage is provided, it is routinely for 80 percent of the billed charges. The customary charges, including hospital expenses, professional services and the Audiant itself, total approximately $6,000 (Gates et al, 1989). Therefore, patients must be informed that they are likely to have out-of-pocket expenses exceeding $1,000, even if the insurance carrier agrees to provide coverage.
In addition to the original costs involved, patients should also be reminded that the Audiant, like any other hearing instrument, may be lost or damaged. Special insurance policies for conventional hearing aids are available; however, because of the relatively few Audiants currently in use, no insurance carrier, to our knowledge, has yet established a policy to cover this device. Thus, beyond the manufacturer’s one year warranty there is currently no coverage for replacement or repair. Patients need to pursue such coverage through homeowners insurance, possibly as a separate rider.

CONCLUSIONS

The implantable bone-conduction hearing device can be of significant benefit to some patients with noncorrectable conductive hearing losses. However, the device has significant limitations and these should be fully discussed with each potential candidate. Unless medically or physically contraindicated, an air-conduction hearing aid, with an appropriate acoustic coupling, should be the initial option considered when a conductive hearing loss cannot be improved medically or surgically. For a properly selected and well informed patient, whose aided options are limited to bone-conducted input, the implantable device offers a useful alternative to conventional bone-conduction hearing instruments.

REFERENCES


