

AMERICAN ACADEMY OF OTOLARYNGOLOGY—  
HEAD AND NECK SURGERY FOUNDATION

# GERIATRIC CARE OTOLARYNGOLOGY



American Academy of Otolaryngology—Head and Neck Surgery  
*Working for the Best Ear, Nose, and Throat Care*  
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## Introduction

### Americans Are Growing Older—Are Physicians Ready?

Data from the U.S. Bureau of the Census, the World Health Organization, and the United Nations on U.S. and global trends in aging indicate that, in the United States, the proportion of the population aged 65 and older is expected to increase from 12.4 percent in 2000 to 19.6 percent in 2030, which translates into approximately 71 million persons. The number of those 80 years and older is expected to increase from 9.3 million to 19.5 million in 2030.

Concurrent with this substantial growth in the elderly population will be a requirement that physicians caring for geriatric patients must take into account the physiological changes in this demographic group. The senior patient often presents co-morbidities, many of which occur only in old age. Illnesses in the elderly can also exist with unusual symptoms or without common symptoms, and medical therapy may be difficult to prescribe because of possible adverse effects resulting from a combination of necessary medications. Surgical procedures in the elderly should be performed with caution, but outcome studies have proven time and again that healthy elderly patients continue to have surgical procedures performed without suffering major complications. Hence, age should not always be a deterrent in performing needed surgery on an elderly patient.

There is other good news regarding medical care for America's senior citizens. Of significance is that elderly Americans are becoming more knowledgeable regarding their health and treatment options. Already we find that an informed population of senior citizens will not only seek treatment for life-threatening medical disorders, but will also seek treatment for medical conditions that have

a significant impact on their quality of life. Many of these disorders occur in the ear, nose, throat, and related structures of the head and neck, thereby requiring the support of an otolaryngologist—head and neck surgeon.

The otolaryngologist—head and neck surgeon plays a key role in the diagnosis and treatment of disorders in the head and neck area. These specialists provide early detection of cancers; address vestibular and hearing problems; perform facial plastic and reconstructive procedures that can improve a patient's outlook; and conduct needed treatment of middle ear infection, sinusitis, and upper respiratory infections that can improve quality of life.

The American Academy of Otolaryngology—Head and Neck Surgery, the national medical society for more than 12,000 ear, nose, and throat specialists, previously produced *Primary Care Otolaryngology*, a guide for clinicians regarding the unique requirements demanded in diagnosing and treating ear, nose, and throat disorders. The Geriatric Committee of the Academy, with the support of the John Hartford foundation of the American Geriatric Society, now introduces an online publication, *Geriatric Care Otolaryngology*, as a companion to that monograph. This publication aims to provide expert guidance regarding the unique requirements for the diagnosis and treatment of ear, nose, and throat disorders in the elderly. The publication includes self-tests to add to the reader's educational experience.

A collection of essays that address the special considerations necessary for the diagnosis and development of treatment paradigms for the elderly are included in this online primer. They are authored by leading clinicians in the treatment of ear, nose, and throat disorders.

As the average age of our population increases, both otolaryngologist—head and neck surgeons and primary care providers will treat more elderly patients for head and neck disorders. The challenge for both specialists and generalists will be to offer the appropriate diagnosis and treatment for a patient who has undergone significant physiological changes. This online primer is an important first step for the American Academy of Otolaryngology—Head and Neck Surgery in identifying the special requirements for effective treatment of ear, nose, and throat disorders for the geriatric patient. It is the hope that Academy members and their physician colleagues will find the essays by experts in the field useful in their administration of patient care.

The essays are:

Essay 1.

**Hearing**

*When Surgery Is Appropriate for Age-Related Hearing Loss*

More than 28 million Americans have some degree of hearing loss. In some, hearing loss is caused by a medical disorder that can be treated by a surgical intervention. This essay discusses, among other things, the age when such surgery can be safe and effective.

Essay 2.

**Head and Neck Cancer**

*Quality of Life following Chemoradiation Therapy for Head and Neck Cancer*

A combination of chemotherapy and radiation has given hope to those diagnosed with this most deadly of cancers, in which more than one-half of all patients are older than 65 at the time of original diagnosis. The author discusses the severe impact this treatment has on quality of life, and the need to share this information with patients.

Essay 3.

**Voice**

*Dysphonia and the Aging Voice*

The loss of voice quality can be as devastating to the elderly patient as hearing loss. A leading expert in voice care discusses the diagnosis and treatment of this condition.

Essay 4.

**Swallowing**

*Patient Safety and Medicinal Therapy for Ear, Nose, and Throat Disorders*

Swallowing disorders can be debilitating or may necessitate a visit to an emergency room. This essay covers the risk factors and incidence of dysphagia among the elderly.

Essay 5.

**Facial Plastic Surgery**

*The Aging Face—*

*Benefits and Pitfalls of Botox® and Laser Skin Treatments*

An important discussion of cosmetic surgery procedures and nonablative techniques that have proven to be highly popular with an aging American population.

Essay 6.

**Rhinosinusitis**

*Surgical Management of Chronic Rhinosinusitis in the Geriatric Patient*

Thirty-seven million Americans suffer from acute or chronic rhinosinusitis. When medical therapy fails, surgery may be necessary. A leading expert discusses when the senior patient is a suitable surgery candidate and the appropriateness of functional endoscopic sinus surgery.

Essay 7.

**Sleep Disorders**

*The Most Effective Treatments for Snoring and Sleep Apnea*

New studies reveal that obstructive sleep apnea, prevalent among the elderly and obese, can lead to more severe illnesses and even death. New treatments are now available, but who should be a candidate for these new procedures?

Essay 8:

**Geriatric Polypharmacy in Otolaryngology**

*Patient Safety and Medicinal Therapy for Ear, Nose, and Throat Disorders*

Often medical therapy is the most effective treatment for ear, nose, and throat disorders. In suggesting therapies, consideration must be given to medications prescribed for other medical disorders.

# Hearing

When Surgery Is Appropriate for Age-Related Hearing Loss

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After reading this presentation the reader will understand the general operation and the audiometric and surgical indications for semi-implantable hearing aids, and be able to identify which patients meet the audiometric criteria for cochlear implantation.

## Historical Perspective

Traditional teaching has been that surgery was for conductive hearing loss and hearing aids were for Sensorineural Hearing Loss (SNHL). This notion is changing. This paper will provide information on most of the current indications for semi-implantable hearing aids and cochlear implants. Hearing improvement devices (hearing aids, surgical improvements, cochlear implants) will see increasing clinical application, so knowledge about their application is essential for otolaryngologists.

### There are four main roles possible for surgery in SNHL:

1. cochlear implants and auditory brainstem implants;
2. implantable hearing aids and semi-implantable hearing aids;

3. bone-anchored hearing aids, although the main indication is conductive hearing loss; and
4. application of medications to the inner ear with wicks and sponges, which are not discussed in this article.

The results of auditory brainstem implants are less impressive than those of cochlear implants and the patient numbers is small so this article will not deal with auditory brainstem implants. The severity of hearing loss as summarized in Table 1 is the most important factor in determining which modality is appropriate. The common vernacular for cochlear implantation indication (which is now outdated) as a severe-to-profound hearing loss means that the loss is greater than 70 dB.

New implantable hearing devices must undergo the Food and Drug Administration (FDA) approval process.<sup>1</sup> After the sponsor (manufacturer, physician, or medical center) develops the idea, the sponsor typically meets with FDA staff, who make recommendations on how to proceed depending on the nature of the new device. A new device is granted an Investigational Device Exemption (IDE) to conduct a trial on a small number of patients with approval of the investigator's Institutional Review Board (IRB). If the pilot study results show no particular safety issues, then a multi-institutional study is performed, which may lead to a premarket approval (PMA) study. The PMA study is an examination of the safety and efficacy of the device and can lead to what is typically referred to as FDA approval. For devices that are similar to currently approved products, the FDA may issue a clearance that also allows sale of the device.



**Table 1: Hearing loss severity**

Severity of Loss	Threshold (dB HL)
Normal	20
Mild	21-40
Moderate	41-55
Moderately severe	56-70
Severe	71-90
Profound	90

**Cochlear Implants**

The key concept of cochlear implants is that the hair cells and/or spiral ganglion neurons are stimulated electrically rather than by sound. Hearing aids amplify sound and stimulate the cochlea acoustically. This difference in stimulation mode means that the cochlear implant is not a hearing aid.

The concerns and uses are significantly different.

**A typical cochlear implant consists of the following components:**

1. A microphone, which converts sound energy to electrical energy. Some systems have two directional microphones but most have one omnidirectional microphone. The microphone(s) can be connected by cable or directly to the speech processor.
2. A speech processor, which contains a computer chip to digitize the electrical signal from the microphone and process it according to variable programmed instructions. The speech processor connects to the behind the ear housing if it is not physically part of the housing, and then to the transmitter.

3. A transmitter, which is an externally worn object that transmits the signal to the underlying receiver/stimulator. Transmission is usually transcutaneous through intact skin via FM radio waves, but in the past was percutaneous (through a surgical opening in the skin). It is held in place with a magnet.

4. A receiver/stimulator, which is implanted under the skin, typically superior and posterior to the pinna. It receives the FM electrical signal and connects to the electrodes in the cochlea. Some receiver/stimulators have ground electrode and neural response telemetry capability.

**Indications for Cochlear Implants**

Evolution of the indications for cochlear implant are reflected in the latest recommendations from the FDA<sup>2</sup>. Initial criteria were bilateral "severe to profound hearing loss" (90 dB) then "severe to profound" (70 dB) but currently the main criterion is poor speech understanding using sentence material. There are many cochlear implant candidates who have better thresholds than 70 dB but have poor speech recognition.

**Adults Criteria**

1. Be 18 years or older, with bilateral, severe to profound sensorineural hearing loss, i.e., 70 dB or greater PTA at 500, 1000, and 2000 Hz;
2. Have tried but have limited benefit from an adequately fitted binaural hearing aid; or
3. Have sentence recognition score of 50 percent or less in the ear to be implanted and 60 percent or less in the contralateral ear in best-aided conditions using HINT or CUNY tests.

### Pediatric Criteria

1. Be 12 months to 17 years of age.
2. Infants age 12-24 months should have bilateral, profound hearing loss with thresholds of 90 db or greater at 1000 Hz.
3. Children 24 months to 17 years should have bilateral severe to profound (greater than 70 dB) hearing loss.
4. Infants and older children should demonstrate lack of progress in simple auditory skills in conjunction with appropriate auditory amplification and participation in intensive aural habilitation for three to six months. Less than 0.14520 percent correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive and linguistic abilities.
5. A three- to six-month trial of appropriate hearing aids is required. If meningitis is the cause of hearing loss or if there is radiologic evidence of cochlear ossification a shorter hearing aid trial and earlier implantation may be reasonable.

Note: The earliest time for implantation is now as low as 12 months. Difficulty in determining the severity of the loss and a meaningful trial of hearing aids can be problems at this age.



## Cochlear Implant Results

Results of cochlear implantation have been impressive. An important measure of success of cochlear implantation is the ability to understand speech in the absence of speech-reading or other cues, such as when using a telephone.

Cray found that 95 percent of cochlear implant recipients could identify a dial tone, a busy signal, and voices.<sup>3</sup> Average telephone use per week was 5.4 hours and 85 percent could interact with strangers on the telephone within five months of receiving the sound processor.

Approximately 30 percent communicated via a cellular phone for personal use. Telephone use had increased over the past decade. Of course these excellent results may not always be achievable. Outcomes depend greatly on the nature of patients implanted, severity of hearing loss, quality of post-implant rehabilitation, and a variety of other factors. In fact, if results are too good it can be argued that implant criteria may be too strict, eliminating some candidates who may not be "stars" but still have significant benefit.

## Cochlear Implant Issues

Some cochlear implant controversies persist. Sometimes it is not clear which ear to implant when one ear has more residual hearing than the other.

The role of cochlear implants in children with multiple handicaps or in prelingually deafened patients is challenging. The deaf community still has some reservations about the use of cochlear implants as reviewed by Hintermair and Albertini<sup>4</sup>. They felt that parents are being forced to make decisions for their children without adequate information about alternatives and that they are unprepared for the consequences of these decisions.

## Cochlear Implant Complications

In one representative study, 2 of 30 children who received a CI developed meningitis.<sup>5</sup> In a survey of Latin American cochlear implant centers, of 3,768 cases reviewed, the following complications occurred: migration, 13 cases (0.35 percent); extrusion, 15 cases (0.4 percent); implant failure secondary to trauma, 18 cases (0.48 percent); device failure, 86 cases (2.28 percent); skin inflammation by magnet, 35 cases (0.9 percent); and infection, 26 cases (0.7 percent).<sup>6</sup> Even though cochlear implantation is the only reasonable option for many patients, the possibility of complications and poor results should be kept in mind.

## Future of Cochlear Implants

Cochlear implant technology continues to evolve but the main reason for improvements in cochlear implant performance appears to be the liberalization of patient selection criteria. Indications for cochlear implants have started to overlap with those for hearing aids. It is unlikely that large numbers of patients will choose cochlear implantation if a hearing aid would serve them just as well. For this reason it is likely that technology rather than patient selection will drive further improvements. Promising research regarding hair cell regeneration and cochlear physiology will likely impact cochlear implantation in the future.



## Implantable and Semi-implantable Hearing Aids

Sound is the sensation of vibration. Mechanical stimulation of the cochlea with an implantable device is a natural, logical way to augment hearing.

Loudspeakers and hearing aids introduce acoustic distortion so that "high-fidelity" amplification is problematic. The physical basis for middle ear hearing devices has been reviewed by Spindel.<sup>7</sup> Hearing aids, including implantable ones, sense sound energy using electrical techniques, amplify and/or otherwise process it, and then convert the energy back to a mechanical form that stimulates the cochlea.

Conventional hearing aids provide acoustic stimulation whereas implanted hearing aids typically provide direct mechanical drive to an ossicle using some attached device.

The two main electromechanical techniques used in implantable hearing aids are *piezoelectric* and *electromagnetic transduction*.

*Piezoelectric transduction* exploits the reciprocal relationship between electrical current and physical movement in certain materials. By bonding two piezoelectric materials together, a bimorph is created that vibrates in proportion to the current or voltage applied. Piezoelectric transducers can be of the "diaphragm" or "springboard" types but the principle is similar.

Piezoelectrics are precise, small, and accurate. Typically they have low power requirements so battery life can be prolonged. They also have disadvantages. For example, one part of the transducer must be rigidly fixed to the skull and the other to an ossicle, which causes ossicular

loading. If there is no current or insufficient current, the piezoelectric component is stiff and does not move. In the middle ear, this means that the device could actually affect hearing adversely. "No current" situations could occur if the battery is depleted or removed, if the user removes the external part of the device, or if the device fails. Device failure has occurred in some early models and is of concern. Some designs require surgical ossicular disruption, which should be considered carefully in case the device fails or must be removed.

*Electromagnetic transduction* relies on the movement of a magnet in an electrical field provided by wire coil as in a home stereo speaker. One end of the electromagnet device can be attached to an ossicle. Unlike the piezoelectric device, the other end does not need to be attached to the skull. The magnet can be outside the wire coil, called "extra-coil," or inside the coil, called "intra-coil."

The surgical technique for electromagnetic devices can be simpler than for piezoelectric devices depending on design. The magnet can remain in place and the rest of the unit removed in case of device failure. The magnet is attached to an ossicle and ossicular disruption may not be needed for electromagnetic devices. The magnet can be very lightweight so there is minimal loading on the ossicle.

The electromagnetic design also has disadvantages. In general, greater power is required for electromagnetic than for the piezoelectric design, so battery life is shorter. For optimal efficiency the coil and the magnet axes must be co-axial. In the intra-coil design this is inherent, but in the extra-coil design this can be a problem. In one extra-coil design only the magnet is implanted into the middle ear with some distance between the coil placed in the ear canal and the magnet, which can be attached to an

ossicle. The distance between the coil and the magnet must be very small, because the power drops off in proportion to the square of the distance between them. Minimizing the distance between the coil and magnet means that such a device has to be worn deep in the ear canal. If the user does not consistently insert the device to its full depth, adverse function can occur.

The intra-coil design permits perfect alignment of the coil and the magnet and removes the variability produced by the distance between them. The intra-coil device requires that the coil and magnet be attached to an ossicle whereas the extra coil design requires attachment of only the magnet. This design difference means that the intra-coil device is heavier than the extra-coil device and may produce some "loading" weight on the ossicle with resulting hearing loss. In addition, the intra-coil device must be hardwired to the processor, making the surgical implantation more complex.

#### **Advantages of the implanted or semi-implanted hearing aids over conventional in-the-ear aids include :**

1. better sound clarity,
2. avoidance of the occlusion effect,
3. reduced feedback,
4. greater functional gain,
5. perceived benefit in many listening situations (reverberation, background noise, sound distortion, and speech perception), and
6. reduced problems with cerumen and moisture issues because the external ear canal is open

#### **Disadvantages of implanted or semi-implanted hearing aids include the following:**

1. Surgery is required so implantation mandates greater concern about choosing a hearing aid than for conventional, removable hearing aids.
2. Surgical implantation may require ossicular loading and/or ossicular disruption, which could be irreversible. The usual risks of infection and other surgical complications are present.
3. Battery power and longevity of the device may be poor.
4. Long-term performance is unknown.
5. The required physical dimensions of the device must be small. This limits acoustic output so the devices are less useful as hearing loss becomes more severe.

6. Most implantable hearing aids are not compatible with magnetic resonance imaging (MRI) scans.
7. Implantable aids are typically more expensive than conventional aids. Medical insurance for repair and surgical removal for replacement are problems. Reinsertion may not provide results similar to those obtained after initial application.
8. Many implantable or semi-implantable hearing aids are not FDA approved.

### Bone Conduction

Bone conduction hearing aids must drive the entire skull so their power requirements are great. They have been traditionally used for conductive hearing losses but expanded indications for bone-anchored hearing aids are developing for sensorineural hearing loss as well. Single-sided deafness (SSD) from pathology, such as acoustic neuromas, or sudden sensorineural hearing loss are recent rationales made for bone conduction aids. This indication is controversial. Reported benefits for SSD patients include better sound localization and better sound clarity. Classic thinking has been that bone stimulates both cochleae simultaneously. If one cochlea does not work, it seems that the functioning cochlea would be fully stimulated or perhaps even overstimulated before effects are seen on the deaf side. It has been argued that a contralateral routing of signals (CROS) hearing aid would have the same effect.

On the other hand, many persons with SSD report improved speech understanding when using a special bone-anchored hearing aid test device. Are they impressed by a novel toy with a different frequency response than they are used to? Do they like the bone-anchored device because the occlusion effect and acoustic distortion produced by hearing aids are absent? If bone-anchored hearing aids provide better hearing for patients with SSD, why wouldn't they be better for bilateral sensorineural losses as well? Currently the answers are not known but evidence is accumulating and studies should soon be available to address the issue.

### Devices

#### *Bone-Anchored Hearing Aid (BAHA)*

The principal use for bone conduction hearing aids, including the BAHA, is conductive hearing loss. Traditional bone conduction hearing aids must deliver the sound stimulus across the skin and other soft tissues before reaching the bone, which attenuates the sound. Although increased power may partially overcome this attenuation, it is frequency dependent so distortion may occur. The magnitude of the problem varies among different patients because the tissue thickness and acoustic impedance properties vary. Variable acoustic impedance caused by skin results in variable phase shifts and intensity attenuations so amplification becomes complex. Electrical power needs for bone conduction aids are great, so battery life and user satisfaction are problems.

The BAHA stimulates the bone directly with a metal screw through the skin and into the skull. Surgery is required to place the metal fixture. A screw that is

osseointegrated provides better results than a simple screw. Osseointegration allows bone to grow tightly to the artificial implant. The titanium screw is called the "fixture" and this attaches to an "abutment" to which the patient attaches the external device.

For most patients the surgical procedure has been simplified from a two-stage procedure to a one-stage procedure. A very thin skin flap is created, currently with a dermatome, followed by careful drilling and tapping of a hole in the skull. In the one-stage procedure a dermatome is used to elevate a thin skin flap so that the device will be 50-55 mm from the external auditory canal. Then subcutaneous tissue deep to the flap is removed with a wide margin. A hole, three or four millimeters deep, is drilled with the guide drill, then countersunk. The fixture is placed with a slowly rotating drill. Finally, a biopsy punch is used to make an opening in the flap before closure. The procedure is followed by a waiting period of three to four months to allow osseointegration before using the device. The two-stage procedure is still recommended for children, and for patients with poor or thin bone or irradiated bone. After placement of the device the skin flap is replaced for three to six months to allow osseointegration. Then the fixture is identified, a cover screw removed, and the abutment fitted. The processor lasts about five years.

The BAHA is FDA approved for conductive hearing losses caused by congenital auditory atresia or conductive hearing loss in patients who have chronic ear infections (chronic otitis media or external otitis), in whom placing a traditional hearing aid would cause repeated infections. It is approved for children older than five years of age with single-sided sensorineural deafness.

The device is contraindicated for an average bone threshold worse than 45 dB at 0.5, 1, 2, 3 kHz for BAHA Classic 300, and Compact, and worse than 70 dB for the more powerful, body-worn Cordelle. It is also not recommended for persons who are noncompliant or have psychological problems.

In one study, all seven previous bone conduction aid users were satisfied with a BAHA. Five of 16 (31 percent) air conduction hearing aid users were not happy with their BAHA and reverted to their aid. There were no predictive factors.<sup>8</sup>

Recent reports indicate that persons who hear in only one ear can achieve improved sound localization and clarity of sound using BAHA on the same side of the skull as the hearing loss. In general there should be a credible effort to use a conventional hearing aid before BAHA is performed. The use of BAHA for tinnitus treatment has been recommended as well, but the rationale for this application is unclear and the literature thus far is not strongly supportive.

Does BAHA improve sound localization? CROS aids were compared to BAHA by Niparko et al., who found that BAHA delivered superior performance than the CROS hearing aid. However, they recommended longer follow-up to assess whether the advantages of the bone-anchored hearing aid outweigh the disadvantages of implantation surgery, costs, and device maintenance.<sup>9</sup> Wazen et al. reported that sound localization was not improved in BAHA patients implanted for SSD.<sup>10</sup>



### The advantages of the BAHA over other hearing aids include:

1. greater sound clarity and comfort than other bone conduction aids,
2. avoidance of the occlusion effect,
3. absence of feedback,
4. absence of any foreign objects in the ear canal that may cause external otitis,
5. the low risk of the surgery, and the compatibility of the device with MRI scans.

### BAHA has disadvantages that include the following:

1. surgery is required. Infection is possible but rates are low;
2. bone conduction thresholds must be good, otherwise stimulation is ineffective;
3. battery life is short;
4. occlusion effect is absent or minimal in conductive hearing losses.;
5. device may fail to osseointegrate. This may occur in 1-2 percent of normal persons and in up to 25 percent of children or of persons with poor-quality bone or thin skulls.

6. there can be psychological adjustments to having a screw in the skull.
7. some care to the operative site is needed and the patients typically cannot see that site themselves.
8. battery life is short (but batteries are readily available and changeable).
9. If the user does not use the device, removal can be difficult.

### Soundbridge

Med-El Corporation is now responsible for the Vibrant Soundbridge device. It is a semi-implantable hearing aid that received FDA approval in 2000. The device uses an intra-coil type of electromagnetic Floating Mass Transducer (FMT).

The FMT is surgically attached to the incus and connects to the internal processor via a hardware. Batteries last 12-16 days.

The Soundbridge consists of two parts:

1. the internal implant called the vibrating ossicular prosthesis (VORP) (implanted receiver unit, conductor link, and FMT); and
2. an external amplification system called the audio processor (microphone, sound processing system, modulator circuit, and battery).

The use of any hearing device mandates that a hearing loss be present; however, if the hearing loss is too severe, power and physical limitations may make a semi-implantable device, such as the Vibrant Soundbridge

preferable to a fully implanted device. According to FDA (2000) recommendations, a Soundbridge device may be indicated in persons 18 years of age and older with moderate to severe (40 to 70 dB) sensorineural hearing loss who desire an alternative to an acoustic hearing aid.<sup>11</sup> It is recommended that individuals have experience with a properly fitted acoustic hearing aid. Implantation should be done in the worse ear.

**Detailed audiometric indications for the Vibrant Soundbridge are listed below.**

1. Air conduction thresholds are in the range shown in table 2.
2. The pure tone average (500, 1000, and 2000 Hz) is greater than 30 dB in the ear to be implanted and the asymmetry of PTA between the two ears is less than 20 dB.
3. Air/bone gap is less than 10 dB.
4. Speech recognition score is 50 percent or greater.
5. Appropriate hearing aids have been used for four hours a day for at least three months.
6. The candidate has normal anatomy, has not undergone ear surgery, is 18 years or older and psychologically stable, and has no other ear disorders.

Contraindications for Soundbridge include conductive hearing loss, retrocochlear pathology, psychological problems, mental retardation, inability to follow up, or

skin conditions that would be aggravated by the magnet. The device appears to have a small ossicular loading effect, on the order of 2 dB.<sup>12</sup>

**Table 2: Air conduction range for Soundbridge device**

Frequency (Hz)	500	1000	2000	3000	4000	6000
Lower limit (dB HL) 10	10	15	25	40	40	
Upper limit (dB HL) 65	75	80	85	85	85	

**Soundtec® Direct System**

The Soundtec® Direct System device is an extra-coil electromagnetic device. A rare-earth magnet is surgically fixed to the incus and an attachment ring in the incudostapedial joint space. Placement requires ossicular disarticulation. The inductive coil is placed in a fitted ear mold deep in the ear canal to come as close as possible to the magnet. Although the occlusion effect could be present, there should be no acoustic feedback because the stimulus is not acoustic. The surgical procedure is easier than for any other implanted hearing aid.

**Indications for The Soundtec® Direct System device are:<sup>13</sup>**

1. bilateral, symmetric, moderate to moderately severe sensorineural hearing loss (see table 3).
2. bone conduction thresholds within 15 dB of air conduction thresholds.
3. high-frequency (1, 2, and 4 kHz) averages between 35 and 70 dB.

4. discrimination scores 60 percent or better.
  5. duration of hearing loss for two years without fluctuation.
  6. at least six months of hearing aid use and at least 45 days in the ear to be implanted.
  7. adequate ear canal size, motivation, cognitive skills, age 21-80 years.
  8. dissatisfaction with conventional hearing.
- Exclusion criteria for The Soundtec<sup>®</sup> Direct System<sup>®</sup> device include otitis externa, otitis media, retrocochlear pathology, malformations, previous middle ear surgery or disabling tinnitus, asymmetry of the high frequency average greater than 15 dB conductive, and unilateral or fluctuating hearing loss.

**Table 3: Air conduction range for Soundtec device**

Frequency (Hz)	500	1000	2000	3000	4000	6000
Lower Limit (dB HL) 0	10	35	50	50	40	
Upper limit (dB HL) 60	70	75	75	80	110	

Compared with optimally fit hearing aids, Hough reported that, for the subjects reviewed, The Soundtec<sup>®</sup> Direct System<sup>®</sup> DDHS provided an average improvement of 52 percent in functional gain (250-6000 Hz), 22 percent in aided thresholds, 3.8 percent for speech discrimination in quiet, 17 percent for speech in noise, 13.1 percent in articulation index scores, 28 percent in aided benefit, 27.3 percent in sound quality of speech, and a 16.7 percent

increase in overall subject satisfaction.<sup>14</sup> In addition, with The Soundtec<sup>®</sup> Direct System<sup>®</sup> DDHS, subjects reported absence of acoustic feedback, little or no occlusive effects, and more natural sound perception.

### **Envoy Device**

The Envoy device (St. Croix Medical) uses two piezoelectric crystals—the “driver” and the “sensor”—but is not yet FDA approved. The sound sensor is attached to the incus. This piezoelectric detects sound, converts it to an electrical signal, and sends the electric signals to the sound processor. The sound processor amplifies, filters, and otherwise processes the electric signal and then sends the modified electrical signal to the second “driver” piezoelectric on the stapes. Division of the incudostapedial joint and resection of part of the incus is required. The entire device is implanted but can be modified externally. The battery must be replaced under local anesthesia every three to five years. The device is recommended for mild to severe sensorineural hearing loss.

In a phase I trial with the Envoy device, Chen found that patients perceived benefits from the device including communication in background noise and word recognition.<sup>15</sup> Functional gain and speech reception thresholds were similar with the Envoy device and conventional hearing aids. Five of seven patients with Envoy implantable hearing aids had working devices at two months postactivation. The authors concluded that feasibility was demonstrated but it appears that more data are needed on this device.

### **Otologics Device**

The Otologics Middle Ear Transducer (MET) Ossicular Stimulator device involves the placement of an ossicular

stimulator directly into the body of the incus with a laser-drilled hole. Access is obtained via a mastoidectomy. The Otologics device has the CE mark but is not FDA approved. Several screws are placed into the simulator to firmly anchor it to the skull. The patient wears an external button device that contains a microphone, battery, and digital signal processor. The button detects sound, converts it to electrical energy, and transmits it across the skin to the internal processor. The internal processor connects to the MET.

#### Indications for the MET Ossicular Stimulator include:

1. bilateral moderate to severe (40-90 dB), nonfluctuating, nonprogressive, symmetric sensorineural hearing loss.
2. normal tympanogram.
3. no middle ear disease.
4. speech recognition scores better than 20 percent at 65 dB SPL.
5. postlingual, English speaker with good cognitive function.
6. auditory thresholds within limits shown in table 4.

**Table 4: Air conduction ranges for the Otologics device (adapted from manufacturer's graph)**

Frequency (Hz)	500	1000	1500	2000	3000	4000
Lower Limit (dB HL)	15	45	55	55	55	55
Upper limit						

Note that the MET Ossicular Stimulator has a larger upper limit threshold criteria than for implantable hearing aids so it may be useful in patients with larger hearing loss.

The Otologics device appears to provide high gain and wide-band amplification, but has some apparent disadvantages. The surgical procedure is elaborate and the large amount of implanted metal is discouraging. The instrument drives the incus directly so it may be useful for larger hearing losses (compare tables 1 and 2) but ossicular loading is expected.

#### Other Devices

The German Implex AG device involves stimulation of the incus by a diaphragm-type piezoelectric driver. There were some problems with feedback so a piece of the malleus was removed but the device is not on the market today. The Rion device from Japan uses a piezo-ceramic rod that is connected to the stapes with a hydroxylapatite strut and transcutaneous electrical stimulation of an internal receiver with an external audio processor. This device is not FDA approved.

The RetroX device from Belgium is a microphone, amplifier, processor, and titanium tube that connects the external auditory canal to the postauricular area. The ear canal is unoccluded so that sloping high frequency hearing losses may be particularly well aided. One study reported gains of only 9-10 dB, but improvement in understanding of speech in noise.<sup>16,17</sup>

Of 25 patients implanted with the RetroX device, another report indicated that four required explantation because of granulation tissue, two patients complained of acoustic feedback and needed supplementary fitting, and yet 23 of 25 subjects were either satisfied or even extremely



satisfied with the RetroX device. They reported improved hearing at 1, 2, 4, and 8 kHz. In quiet, the speech reception thresholds improved by 10 dB SPL. Speech intelligibility in noise improved by 15 percent for signal-to-noise ratios between -5 dB and +5 dB.<sup>17</sup> Overall, it appears that the RetroX device needs further evaluation. The device is not FDA approved.

The Tübingen device is a totally implantable communication assistance (TICA) device. The microphone picks up the sound signal transcutaneously from the external auditory canal, and amplifies and transduces the signal to vibrate the ossicular chain.

### **Future of Surgery for Sensorineural Hearing Loss**

There may be an increasing role for surgery in treatment of sensorineural hearing loss. It seems likely that implantable aids will be increasingly common as technology improves, but they will never replace conventional hearing aids.

The technology of cochlear implants will continue to improve, but the criteria are unlikely to overlap further with that of hearing aids. Probably the greatest advances in sensorineural hearing loss treatment in the future will be found in the application of drugs to the inner ear to promote hair cell growth. Such drugs may be administered either systemically or via tympanotomy, in which case surgery will be required.

## Quiz



1. A 50-year old man asks if a cochlear implant would help. He has bilateral sensorineural hearing loss and is having lots of trouble using his hearing aids. His thresholds are in the 60-65 dB range but his speech recognition scores are only 20 percent. Is he a candidate?

**Answer:** His thresholds are better than the usual criteria allow, but his speech recognition scores are below 50 percent so he is a suitable candidate.

2. What is the role for a bone-anchored hearing aid in sensorineural hearing loss?

**Answer:** Although the BAHA is most widely accepted for conductive hearing loss, it has been applied with success for single-sided deafness due to many causes—acoustic neuroma, trauma, sudden sensorineural hearing loss, or others.

3. A 45-year-old woman is not happy with her speech understanding with her in-the-canal hearing aid. Her thresholds are symmetric at about 45 dB. Are there surgical options for her?

**Answer:** A semi-implantable hearing aid may reduce the occlusion effect and is an option. Her auditory thresholds are appropriate.

4. What are the current audiometric indications for cochlear implantation in adults?

**Answer:** The main indications are severe to profound hearing loss (PTA at 500, 1000, and 2000 Hz 70 dB or greater) OR a speech recognition score of 50 percent. The latter indication is becoming more common.

5. How do semi-implantable hearing aids work?

**Answer:** Electromagnetic or piezoelectric techniques stimulate the ossicular chain and sometimes act as sound sensors as well.

6. What implantable options are there for an adult with chronic ear disease and symmetric, bilateral, mixed hearing loss with thresholds in the 60 dB range and bone thresholds at 30 dB?

**Answer:** Assuming that the conductive hearing loss is not amenable to traditional otologic surgery, the patient meets the criteria for the BAHA implant. Implantable hearing aids are excluded by the conductive hearing loss. The thresholds are in the range of acceptability for a regular BAHA.

## Glossary

### G

#### **Electromagnetic coils**

Devices that take advantage of the fact that current is generated in a coil if it is moved in a magnetic field. Conversely, a magnetic field is generated by applying current to the coil. Application of amplified current to a coil allows enhancement of the physical movement of ossicles if they are attached rigidly to a magnet. There are two general designs for electromagnetic coils: (1) extra-coil, where a magnet is outside the wire coil so that there is some distance between the coil and the magnet, and (2) intra-coil, where a magnet is inside the wire coil. The magnet can be attached to a structure such as an ossicle outside the coil, causing it to move.

#### **Floating mass transducer**

An electromagnetic design where the magnet and coil are in a single device fixed to an ossicle in an intra-coil design.

#### **Functional gain**

The difference between unaided and aided thresholds. Functional gain is an important concept for hearing aids. Conventional hearing aids can provide large gains but some users do not use all available gain because of distortion and feedback at greater volumes.

#### **Implantable hearing aid**

A device that uses acoustic energy (physical movement) to drive the ossicles to improve hearing in which there is no external component, only internal component(s). Strictly speaking there are very few truly implantable hearing aids; most often they are semi-implantable aids.

#### **Occlusion effect**

An effect produced by occlusion of the external auditory canal inducing a conductive

#### **Hearing loss**

This effect is a common problem in fitting hearing aids that must occlude the external ear canal. The occlusion effect causes a feeling of ear fullness or hollowness but slightly improved bone conduction thresholds. The occlusion effect is frequency-dependent, and is greater for low frequencies than high frequencies. Speech discrimination may be adversely impacted. Venting or open ear molds typically prevent the occlusion effect and are useful in attempting to reduce the low frequency gain in patients with high-frequency hearing loss. Venting may induce feedback in the hearing aid, typically around 3 kHz.

#### **Ossicular loading**

Refers to the situation where mass applied to an ossicle may cause conductive hearing loss when the device is not being used. Ossicular loading is important for devices that require a piece of hardware to be attached to an ossicle. Residual hearing is a related term that refers to the amount of conductive hearing loss induced by ossicular loading. If the user decides not to use the device, he or she may be forced to use it anyway if the device induces a conductive hearing loss. When batteries fail, the device fails, or the user removes the external hardware, implantable hearing aids are not activated and this may be a detriment to hearing.

Surgical removal of the implanted device may be required, although it is possible that conductive hearing loss may persist. Some device manufacturers have considered ossicular loading more seriously than others.

### **Piezoelectrics**

Materials that generate electrical current in proportion to physical application of force. Conversely they undergo physical change as a result of application of electrical energy.

Typically two such materials are bonded together to create a piezoelectric bimorph that generates electric output in proportion to mechanical deflection. Piezoelectrics can act either as sound sensors, providing an electric output depending on sound stimulation, or transducers, which produce physical deformation in proportion to electric current. In ear-related applications the two most likely types of piezoelectrics are the diaphragm type and, more commonly, the springboard type. Some other applications of piezoelectrics include microphones, record needles, and singing greeting cards.

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