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Modern Advances in Bone Conduction–Hearing Devices

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Abstract

Purpose of Review This review summarizes the options available for bone conduction–hearing devices for patients with conductive or mixed hearing loss and single-sided deafness. We address patient candidacy and review the benefits and disadvantages of currently available technology.

Recent Findings Percutaneous osseointegrated devices provide the most efficient sound conduction and best hearing fidelity at the cost of skin inflammation in some patients. Transcutaneous devices obviate these skin issues at the expense of loss of sound fidelity due to attenuation of sound across the skin and soft tissue. Active transcutaneous devices place a microphone externally with the actuator internally against the bone to improve sound conduction.

Summary Bone conduction–hearing devices provide excellent options for patients with conductive or mixed hearing loss or single-sided deafness. Choice of device depends on audiometric criteria and patient preference. Clinicians must be aware of the advantages and disadvantages of these devices to properly counsel patients.

Keywords Conductive hearing loss · Single-sided deafness · Bone conduction · Bone conduction hearing devices · Osseointegrated bone conduction–hearing devices

Introduction

Vibrational energy of sound, the compression and rarefaction of air molecules, can be transmitted to the fluids of the cochlea through the ear canal, ear drum, and middle ear impedance matching system (air conduction) or directly to the cochlear fluids through bone conduction. Bone conduction hearing is based on the concept of direct bone transmission of this vibrational energy to the cochlea. Acoustic energy is transferred through the bones of the skull to the fluids of the inner ear, bypassing the external and middle ear. Bone conduction–hearing devices (BCHDs) take advantage of this mechanism by converting sound energy to vibrational energy delivered directly to the skull, thereby resulting in traveling waves across the basilar membrane of the cochlea—exactly like that produced by air-conducted sound [1]. Bone conduction–hearing devices (BCHD) can be useful for patients with conductive or mixed hearing loss, or for those with single sided deafness to route sound to the contralateral cochlea. These devices offer surgical ("osseointegrated") and non-surgical options for hearing habilitation and rehabilitation. Fundamental to the surgical devices is an osseointegrated implant and a specially designed impedence matched electromagnetic temporal bone stimulator—i.e., a transducer or processor, also called a receiver/stimulator. This review describes candidacy criteria for BCHDs and the devices currently available.

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Bone Conduction Mechanism

Hearing through bone conduction is highly complex as multiple physiologic mechanisms contribute to the hearing process. Five major pathways likely play a role, including (1) sound reverberation through the external auditory canal; (2) middle ear ossicular inertia; (3) cochlear fluid inertia; (4) compression of the cochlear walls; and (5) pressure

transmission through the cerebrospinal fluid (CSF) [2]. These factors are interrelated, making it difficult to isolate one from the other; however, cochlear fluid inertia is thought to be the predominant mechanism [2]. Regardless of the mechanism, once these vibrations reach the cochlea, the acoustic energy will travel down the basilar membrane from the base to the apex as with air-conducted sound [1]. Fundamental to bone-conducted hearing is a direct coupling of the stimulator to the bone to avoid any attenuation of the acoustic energy, especially if it travels through the skin and soft tissue. The dampening effect from the soft tissue can lead to an approximate 7 to 20 decibel (dB) discrepancy depending on the presented frequency [3, 4]. This dampening effect is especially applicable to the higher frequencies where the consonant sounds are encoded. These sibilant sounds are important for understanding speech, especially in noisy surroundings. Other factors including stimulus location, skull resonance, aging effects, and prior mastoid surgery can affect hearing through bone conduction, although not as significantly as attenuation through the soft tissue [5–7].

Patient Selection

Two groups of patients are candidates for BCHD:

1. Patients with conductive or mixed hearing loss, with bone conduction thresholds no greater than 45 dB HL for patients with mixed hearing loss.
2. Patients with single-sided deafness.

Conductive or Mixed Hearing Loss

There are numerous causes of a conductive or mixed hearing loss. Chronic ear disease, otosclerosis, and congenital ear canal and middle ear malformations represent the most common causes. Patients with a 30 dB or greater conductive component may benefit from BCHD—especially if they are a poor candidate for conventional hearing aids. The bone-anchored-hearing aid was originally designed for patients with bilateral or unilateral mixed or conductive hearing loss who are not candidates for conventional hearing aids or a candidate for reconstructive surgery. Suitable candidates are those with chronically draining ears refractory to medical management, ears that start to drain when an occlusive hearing aid mold is needed, or ears with a history of multiple prior middle ear surgeries with a persistent conductive or mixed loss. Additionally, patients with a canal wall down cavity that experience acoustic feedback or are difficult to fit with a conventional hearing aid are good candidates for BCHDs.

A conductive hearing loss in an only hearing ear presents a particularly challenging problem. If the conductive loss is 50–60 dB with normal bone conduction thresholds, a conventional hearing aid may have difficulty overcoming the air bone gap. Middle ear surgery to address the conductive loss may improve the hearing; however, surgery puts the only hearing ear at risk for a sensorineural hearing loss which may leave the patient with significant hearing loss or even deaf. A BCHD does not put the inner ear at risk and is a safe option for these patients.

Patients with aural atresia almost always have normal or near normal cochlear function. Reconstructive surgery for the atretic ear is challenging with outcomes depending on the patient's anatomy and the surgeon's experience. The Jahrsdoerfer grading scale rates patients on a scale from zero to 10. For patients with a Jahrsdoerfer score of 6 or poorer, a BCHD may be an excellent option [8]. In younger children, a BCHD on a soft band can be used successfully with surgery delayed until the child is older. Children can therefore benefit from hearing with the BCHD until they are old enough for a decision regarding the best means of hearing rehabilitation. The benefits of placing a BCHD on a child with unilateral aural atresia are unclear. Compliance can be an issue for children, and the academic and long-term benefits of these devices in this population of children are unknown [9•]. Certainly, a BCHD in a child with bilateral aural atresia strongly supports auditory/verbal speech language development.

There are many options for managing otosclerosis. While most patients will opt for either stapes surgery or a conventional hearing aid, a BCHD is also a reasonable option. BCHDs avoid the risks associated with stapes surgery, including sensorineural hearing loss, taste disturbance, or dizziness [10]. These devices may be especially advantageous in those needing revision stapes surgery where the risk of sensorineural hearing loss is higher.

Single-sided Deafness

Single-sided or unilateral deafness is not uncommon. The exact incidence of sudden sensorineural hearing loss is unknown, but estimates range from 11 to 77 per 100,000 people per year [11]. Patients with single-sided deafness will experience communication difficulties—even if the contralateral ear functions normally. Difficulty with sound localization, understanding speech in noise, and the "head shadow" effect are common complaints in those with single-sided deafness. While most BCHD will have little effect on sound localization or understanding speech in noise, BCHDs are effective at eliminating the head shadow effect, which can be useful in certain situations. With more recently developed active transcutaneous devices (see below), there may be some improvement in hearing in noise because of the improved high-frequency transmission of sound associated with these devices [12]. This improvement is limited and

will be affected by the signal-to-noise ratio and the location of the sound of interest in relation to the implanted device.

Devices

The phenomenon that a vibrating object can transmit sound through the body was first described in the 1500 s by Girolamo Cardano [13, 14]. Despite over 700 years passing, the fundamental concept of BCHD remains the same. Metal rods or spears were the first bone conductive hearing "devices" repurposed as assistive devices for those with hearing loss. In the early 1900s, the carbon microphone was developed followed by the development of the mastoid transducer—the first early equivalent to the modern BCHD. These early devices were held in place with a steel spring, headband, or along the frame of the wearer's eyeglasses [14]. These devices were cumbersome and subject to a significant sound attenuation through the skin and soft tissue. In 1977, Andres Tjellström and collegues were the first to implant a percutaneous titanium device utilizing an osseointegrated screw to directly couple a mastoid transducer to the bones of the skull [15•]. This early technology launched the modern era of BCHD.

The importance of osseointegration in modern BCHDs is paramount—without osseointegration, most of these devices would not function. Osseointegration is the direct contact between bone and an implant that can withstand a functional load [16]. This was first described by Per-Ingvar Brånemark for dental implants for the treatment of edentulous patients. Commercially pure 99.75% titanium has been the material of choice from the beginning. During the machining of these implants, the surface will be covered in an oxide layer within seconds, essentially rendering them ceramic. This oxide layer provides the unique biocompatibility for osseointegration with the surrounding osteocytes. Given high electrochemical value of titanium oxide, any foreign material that may come into contact with the implant will be attracted to it [17]. Foreign material on the implant will lead to a failure of osseointegration. It is imperative not to allow any foreign material to contact the implant during surgical implantation. Excessive heat during implantation can lead to apoptosis of the surrounding osteocytes, also leading to delayed healing and potential failure. The screw-shaped design of the implant provides the initial stability during the healing process. Also, any micromovements during healing will lead to soft tissue encapsulation and failure of integration.

Modern BCHD are divided into non-surgical and surgically placed devices. Surgically placed devices are further divided into percutaneous and transcutaneous. Percutaneous devices utilize a percutaneous abutment traversing the soft tissue and skin of the scalp allowing for a direct coupling between the transducer and the bone of the skull. No skin or soft tissue attenuation is seen with a percutaneous system. Transcutaneous devices can either be active or passive. Passive transcutaneous devices have an implanted subcutaneous portion of the device in direct contact with the bone. A separate external vibrating transducer is held in place with a magnet, and vibrations are transmitted transcutaneously to the implanted portion of the device. Some soft tissue attenuation is expected with the passive transcutaneous system. By contrast, the active transcutaneous system contains an external microphone and processor which routes sound via transcutaneous electromagnetic signals to an implanted, vibrating device directly in contact with the bone. Currently available devices will be discussed below.

Non-Surgical Extrinsic Devices

For patients who are not surgical candidates or those not interested in surgery, non-surgical options for bone conduction are available. These devices are attached to the patient using a metal head band, a soft band, eyeglasses, adhesive, or other mechanism and will transmit sound via vibrations through the skin and soft tissue to the underlying bone. Given the attenuation of acoustic vibratory energy through the skin and soft tissues (especially in the higher frequencies), these devices are not as effective as the osseointegrated bone conduction devices (OIBCDs) [4]. To minimize sound attenuation, these devices are often held tightly to the head which may make them uncomfortable for long periods of wear [18].

The FDA has approved surgically implantable BCHDs (OIBCDs) for children 5 and over. Younger children can benefit from non-surgical devices. Non-surgical devices are also appropriate for adults in whom surgery is contraindicated or those adults not interested in surgery. These devices can be used in patients with unilateral or bilateral conductive loss with a bone conduction threshold equal to or better than 25 dB or in those with single-sided deafness. Non-surgical devices can also be used as a simulator in the pre-implantation evaluation for patients considering a surgically implanted device. Non-surgical extrinsic devices can be useful for patients to better understand the benefits, sound quality, and utility of BCHD.

Processors for surgically implanted devices, such as the Cochlear Baha® processor (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden) [19] or the Ponto® series (Oticon Medical AB, Askim Sweden) [20], can be attached to a soft band, metal arc, or other attachment mechanism. Two devices can be worn if bilateral amplification is needed. The AD-HEAR (MED-EL, Innsbruck, Austria) is another non-surgical extrinsic device that is secured with an adhesive worn over the mastoid process. The adhesive is designed to

be worn for 3 to 7 days and avoids the pressure-induced discomfort of the other devices.

Bone conduction technology is also commercially available for consumer purchase. Bone conduction headphones such as those manufactured by Shokz®, Lionact®, Relaxyo®, and Tayogo®, and others are available for purchase on Amazon.com.

Surgically Implanted Devices

Percutaneous Devices

Percutaneous implants provide a direct connection between the transducer and the skull—allowing for efficient signal transmission at all frequencies with minimal or an absence of impedance through the soft tissue. These implants are surgically placed under either local or general anesthesia using a variety of surgical approaches. Single-stage procedures are common in adults with healthy bone; however, for children or those with poor bone mineralization such as post-radiation bone, a two-stage procedure should be considered. Historically, percutaneous implants are given 3 months for osseointegration before loading with a transducer; loading just days after implantation has also been reported without sacrificing implant stability [21, 22].

The major disadvantages and complications of percutaneous implants is the potential for failure of osseointegration, implant extrusion, and adverse skin reactions. Complication rates vary widely and are associated with surgeon experience and technique, and patient characteristics including age and factors predisposing them to infection or poor wound healing [23, 24]. Adverse skin reactions and soft tissue infections are the most common complications associated with percutaneous implants. This can been seen in up to 84% of patients. Most of these adverse reactions are minor and do not cause significant issues for patients [24]. The Holgers classification (Table 1) grades the skin complications associated with percutaneous implants from zero to four [25]. While most patients will experience either Holgers zero or one, close to 40% may experience grade two or higher complications [26]. Many of these patients can be managed conservatively with frequent cleaning around the implant site and/or with the use of topical steroid cream [23]. Placing a longer abutment may also aid in prevention of skin overgrowth. If the adverse reaction is severe, revision surgery or even removal of the implant with possible conversion to a transcutaneous device (see below) may be necessary. Failure of osseointegration is more common in pediatric patients. For this reason, in pediatric patients, surgery is often performed in two stages: the first to place the implant and allow for osseointegration and the second to place a skin penetrating abutment through the skin. Additionally, when performing implantation in pediatric patients, a second sleeper implant is often placed at the first stage to improve the chances of an implant osseointegrating. The second stage placing the abutment is generally performed 2–3 months after the first stage.

Table 1 The Holgers classification for skin complications following percutaneous device placement [24]

Grade	Description	Management
0	No irritation	Remove epithelial debris if present
1	Slight redness	Local treatment
2	Red and slightly moist tissue (no granuloma)	Local treatment
3	Reddish and moist (may have granulation tissue)	Revision surgery indicated
4	Infection	Removal of skin penetrating implant necessary

The Cochlear ™ Baha® Connect system (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden) [19] and the Oticon Ponto® System (Oticon Medical AB, Askim Sweden) [20] are both currently available in the USA. Both devices consist of an osseointegrated implant, a skin-penetrating abutment of varying lengths from 6 to 14 mm, and an external sound transducer (processor). Both devices can be used for patients with either mixed or conductive hearing loss and for those with single-sided deafness. For those with mixed hearing loss or single-sided deafness, the degree of accepted sensorineural hearing loss depends on the power of the device processor. Superpower processors, able to overcome 65 dB, are available for this purpose.

Passive Transcutaneous Devices

Passive transcutaneous systems were designed to avoid the cosmetic challenges and disadvantages of a skin-penetrating percutaneous abutment including the inflammatory reaction of the skin around the abutment. These systems utilize an osseointegrated implant like the percutaneous devices, but a subcutaneous magnetic plate is attached to the implant avoiding the need for a skin penetrating abutment. The external processor is attached to the implant via a strong magnet. The vibratory energy passes through the skin and soft tissue to reach the osseointegrated implant, allowing transmission through the skull.

Skin complications are significantly less common with these devices. However, like the non-surgical devices, some soft tissue attenuation of sound is expected. This attenuation is most apparent at the high frequencies and may be as much as 25 dB at 6000 to 8000 Hz when compared to the percutaneous implants [27, 28]. In addition, because the force required to hold the processor to the magnet has to be high

to both avoid unwanted dislodgement and to minimize soft tissue attenuation, pain and soft tissue irritation can be common. Magnet strength can be reduced to avoid or minimize this effect. For some patients, this may lead to noncompliance and/or inability to wear the device. In children, there is a risk of the processor falling off on the playground. In severe cases, if the amount of pressure applied by the magnet is greater than the patient's capillary pressure, the skin may have inadequate blood supply, and soft tissue necrosis with exposure of the implant can occur [29].

Both the Baha® Attract System (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden) [19] and the Alpha 2 MPO System (formerly SOPHONO™) (Medtronic, Dublin, Ireland) [30] are the available passive transcutaneous devices. Both devices are applicable for those patients with mixed or conductive hearing loss or those with single-sided deafness. Due to the magnet, care must be taken if the patient requires an MRI. The Baha® Attract System is approved for use in a 1.5 Tesla MRI while the Alpha 2 MPO is approved for up to 3 Tesla. A sizeable artifact or shadow will be generated. If needed, both magnets can be surgically removed to accommodate a higher power MRI or decrease the artifact.

Active Transcutaneous Devices

Arguably the most significant advancement in bone conduction technology since the development of the osseointegrated implant has been the development of active transcutaneous devices. These devices maximize the benefits of both percutaneous and passive transcutaneous implants while avoiding skin and soft tissue complications and sound attenuation through soft tissue. Active transcutaneous devices consist of an external processor and an internal device (receiver-stimulator) attached to an osseointegrated implant within the bone. Sound signals received by the microphone are transferred by an electromagnetic induction coil across the skin to the internal receiver-stimulator—analogous to that of a cochlear implant. The internal receiver-stimulator then generates the mechanical forces necessary for bone conduction minimizing soft tissue attenuation and significantly decreasing the magnet strength necessary to keep the microphone attached over the implant.

The Bonebridge ™ (MED-EL, Innsbruck, Austria) [31] and Osia® OSI200 System (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden) [32] are the currently available active transcutaneous devices. The Bonebridge ™ implant consists of an external microphone with magnet, internal receiving coil, processor, and a floating mass transducer which generates the mechanical vibrations responsible for bone conduction. The floating mass transducer is attached to the skull via two cortical bony fixation screws that do not require osseointegration. The Osia® OSI200 utilizes an osseointegrated implant, the same implant utilized by the percutaneous implant (Baha Connect®) or the passive transcutaneous Baha Attract®. The mechanical vibrations necessary for bone conduction are generated by a piezoelectric transducer. Both devices are approved and useful for patients with mixed or conductive hearing loss or for those with single-sided deafness. Because the vibrational component of these active transcutaneous devices is directly coupled to bone, attenuation of sound is far less than the passive transcutaneous devices with better gain in the high frequencies. The FDA has approved these active transcutaneous devices for patients 12 and over in the USA.

Future of Bone Conduction

Compared to spears and metal rods, the leap to active transcutaneous bone conduction devices has been significant. Future advances in BCHDs will likely push closer to the ideal BCHD—a completely implantable device without an external processor or transducer with minimal to no sound attenuation through the soft tissues. Improved device technology may also expand audiometric and anatomic indications for BCHDs, ultimately improving access to hearing health and improving patient quality of life. With currently available technology, improvement in hearing specific quality of life is already being demonstrated for patients with both mixed or conductive hearing loss and for patients with single-sided deafness [33, 34, 35••]. Time and continued clinical research will determine if cochlear implantation is superior to bone conduction for single-sided deafness.

Duration using the device is significantly associated with improvement in quality of life, with those with higher utilization time demonstrating greater improvements in quality of life [33]. It can be assumed that with the further application of active transcutaneous devices, greater improvements in quality of life will be seen. Active transcutaneous devices offer not only better sound quality with no soft tissue attenuation, but also offer reduced skin and soft tissue irritation as the magnet does not need to be as strong as the passive transcutaneous devices.

For patients with bilateral conductive or mixed hearing loss traditionally, a BCHD was only implanted on a single side. Given the proposed mechanism for bone conduction hearing, it was thought that unilateral implantation was adequate as sound would be routed to both the ipsilateral and contralateral cochleae. While sound will be routed to the contralateral inner ear, conduction to the ipsilateral ear is more efficient due to its proximity to the ipsilateral cochlea [36, 37]. In clinical practice, bilateral BCHDs offer improved understanding in noise, including better sound quality and reduced noise disturbance, and improved sound localization [38, 39]. This improved hearing likely ultimately leads to improvement in quality of life.

Totally implantable devices offer major advantages when compared to those that are currently commercially available. The external portion of the device is exposed to the environment and may be damaged when exposed to extremes in weather, may be lost or damaged from dislodgement [40, 41]. If the external portion needs to be removed due to these environmental extremes, water exposure, perspiration, or sleeping, for example, the ear will be essentially "off-line" during this time. Additionally, the external portion can be bulky or cumbersome for some patients, or they may prefer not to wear the processor during certain social situations.

Several challenges exist for totally implantable devices including powering the device, sound detection, and device component management [40, 41]. Active transcutaneous devices are powered like a cochlear implant which rely on electromagnetic induction from the processor to the receiver-stimulator to power the device. A totally implantable BCHD will need an internal power source or battery that will be able to hold enough power for the device for the day and recharge quickly if necessary. The totally implantable BCHD will also need a way to receive environmental sound. Options for microphone placement include placing it subcutaneously, within the ear canal, or utilizing the ossicular chain itself as a microphone. Totally implantable active middle ear implants may be able to be repurposed for this application [42]. Finally, if the entire device is implantable, this means that more components of the device will need to be implanted. Devices will need to be engineered such that if a single component malfunctions, repair or replacement would need to be minimized.

Soft tissue conduction has been proposed as an alternative to bone conduction with experimental studies investigating sound transmission through the eye, soft tissue of the neck, or directly on the dura [43–45]. Ultimately, the final common pathway of stimulating these soft tissue structures results in hearing by conventional bone conduction mechanisms [46]. While soft tissue stimulation is likely not an alternative to conventional bone conduction pathways, it may offer an avenue to technological advancement in future BCHDs.

Conclusion

Bone conduction hearing relies on direct bone coupling of the vibrational energy of sound to bone and ultimately to the fluid-filled cochlea. A recent consensus statement on bone conduction–hearing devices and active middle ear implants supports the clinical use of these devices and provides guidance for the proper candidacy evaluation, fitting, maintenance, and technical specifications of these devices [47••]. Significant advances in technology have improved both the quality and wearability of BCHDs. Active transcutaneous devices maximize the benefits of both percutaneous and passive transcutaneous devices and are currently the most advanced options for BCHDs. Future research will likely build on this technology to further advance BCHDs.

Declarations

Conflict of Interest The authors declare no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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47.•• Meier H, et al. Consensus statement on bone conduction devices and active middle ear implants in conductive and mixed hearing loss. Otol Neurotol. 2022;43:513–29. **An excellent, overarching consensus statement from a wide range of hearing healthcare professionals (otologists, audiologists, health policy scientists, and industry representatives) addressing implantable and non-implantable solutions for conductive hearing loss. All areas of patient care are considered from audiological, surgical, and healthcare policy perspectives.**