Semi Implantable Bone Conduction Devices: challenges and developments

BY RUPAN BANGA

Bone conduction mechanisms and history of bone conduction aids

Bone conduction hearing devices work by stimulating hair cells via the bone conduction hearing pathways. These pathways are less well understood than the air conduction pathways, but recent research has shown that contributing factors include sound radiated to the external ear canal, inertia of middle ear ossicles and cochlear fluids, compression of the cochlear walls and transmission from the cerebrospinal fluid [1].

Bone conduction amplification has been in evidence as far back as the 16th Century when rod devices were used to transmit vibrations via the teeth. The development of the carbon microphone and magnetic receiver in the early 20th Century lead to the advent of the bone conduction vibrator [2]. This can be worn on a tight fitting headband placed against the mastoid or on a spectacle mount. Disadvantages of these conventional bone conduction devices include the unacceptable cosmetic appearance and discomfort associated with pressure. In addition, a significant amount of amplified sound energy is dispersed within the soft tissues of the scalp [3].

Percutaneous bone conduction devices and osseointegration

The challenges faced by traditional bone conduction aids lead to the idea of directly coupling the transducer to the skull. Branemark first developed the concept of osseointegration of a titanium metal screw in bone when he was doing research on blood flow in the rabbit. This involved using a titanium inspection chamber inserted into the rabbit tibia, but when it came to removing the chamber for reuse, he discovered that this was very difficult due to the osseointegration [4].

The first bone anchored hearing device (BAHD) was fitted by Tjellström in 1977 [5]. The design of the implant has changed over time in response to research determining the factors that influence osseointegration. Macroscopically, an increased diameter and modified threading are thought to have improved the implant stability and microscopically, a roughened surface provides a larger surface area for more direct contact with the bone [6]. Objective measurement of osseointegration (and by inference implant stability) has been a topic of discussion as this has implications in the early loading of implants. Currently, resonance frequency analysis (RFA) is being used to monitor stability changes over time and there is increasing evidence to support earlier loading of implants [7, 8]. Cone beam computed tomography (CT) has been used in the assessment of osseointegration of intra-oral implants as it exposes patients to a lower radiation dose compared with conventional CT. This may have applications in the temporal bone for the future [9].

Indications

Initially the concept of the percutaneous BAHD was introduced for those patients with bilateral acquired or congenital mixed or conductive hearing losses (CHL), who were for practical reasons unable to wear conventional air conduction aids. As the benefit of BAHD has been evaluated clinically, these indications have expanded over time and more recently evidence of the benefit to patients with unilateral hearing losses (of both a conductive and sensorineural nature) is emerging [10-12].

Challenges with percutaneous bone conduction aids

Despite being more commonly accepted than the conventional bone conduction hearing devices, the BAHD does leave patients with a visible percutaneous abutment, which for some is cosmetically unacceptable. Additionally, the percutaneous abutments are associated with peri-abutment soft tissue reactions and fixture failures in a proportion of patients [13]. Recent years have seen different abutment shapes and lengths being advocated to minimise complications, and recent studies are now reporting that minimal or no soft tissue reduction with a longer abutment length has superior results [14]. Cochlear® have launched a hydroxyapatite coated abutment. Experimental studies have shown that the coated abutments promote enhanced dermal adherence and hence fewer skin problems [15].

Transcutaneous bone conduction devices

Concern surrounding the appearance of peri-abutment skin problems has lead to the development of transcutaneous bone conduction devices with similar indications to the skin penetrating or percutaneous devices. As there is no percutaneous abutment, there is reduced risk of skin reaction and trauma. However, the audiological candidacy criteria are more conservative when compared with the percutaneous devices.

Passive devices

1. The Alpha 1 and 2 by Sophono™ is a semi implantable system that relies on magnetic coupling between implanted and external magnets. A recent study from Nijmegen confirms that the percutaneous BAHD has an output that is 10-15dB higher than that of the Sophono [16].
2. The Baha® Attract is an implantable magnet that is attached to an osseointegrated titanium fixture. An external magnet is then coupled via the scalp. Clinical trials are currently ongoing, but there are no published human studies at the time of writing.

Active device

The Bonebridge™ system from Med-El is an intact skin device with an implantable floating mass transducer (FMT) that is retained in the mastoid temporal bone by two screws that do not rely on osseointegration. An external sound processor is coupled to internal magnets and the candidacy criteria are similar to the above transcutaneous devices. As the floating mass transducer is fairly large, pre operative CT imaging is recommended to establish sufficient bone depth and optimal placement. Case reports in the literature are encouraging [17].

Transcutaneous devices may be a relative contraindication in patients that require regular magnetic resonance imaging (MRI). A maximum of 3-Tesla scanners can be used with the Sophono™, and 1.5-Tesla scanners with the Baha® Attract and the Bonebridge™. If more detailed images are required then the magnet needs to be removed prior to imaging. As the devices are significantly larger than the percutaneous systems, a large artefact (up to 10 cm) can be seen on imaging.

Middle ear implant with round window application

The Vibrant SoundbridgeTM (VSB) from Med-El was originally developed for patients with mild to moderate sensorineural hearing loss. It is a semi implantable active middle ear implant. The FMT is the active component of the internal vibrating ossicular prosthesis and was originally intended to be clipped to the incus in an intact ossicular chain. For the last ten years there have been reports of coupling the FMT to the round window (or ossicular chain remnants), expanding the audiological indications to include conductive and mixed hearing losses. The round window technique (VSB-RW) involves placing the FMT onto the round window membrane after cutting off the titanium clip and widening the round window niche. Challenges include damage to the inner ear with resultant sensorineural hearing loss and loss of the coupling resulting in reduced amplification [18].

Single sided deafness (SSD) (Ave BC 0.5,1,2,3 contralateral side)

BC<20dBHL	Percutaneous BAHD or Transcutaneous device

CHL and mixed loss unilateral or bilateral (Ave BC 0.5,1,2,3)

BC <20 dBHL	Percutaneous BAHD or transcutaneous device
BC 20-40 dBHL	Percutaneous BAHD, transcutaneous device, VSB-RW
BC 40-55 dBHL	BAHD or VSB-RW
BC 55-65 dBHL	Trial of Baha® Cordelle

Guidelines for the selection of mechanical bone conduction hearing devices in adults

Since BAHDs were first introduced in the 1970s, there have been numerous developments to percutaneous devices. In addition, there are several other devices available on the market making device selection challenging (if funding is available). Below is a summary of choices available for patients that we use in Birmingham:

- If patient requires regular MRI scans – percutaneous BAHD
- If considering Bonebridge – pre operative CT imaging required, (if previous mastoid surgery may not be suitable bone thickness).

The development of these newer transcutaneous devices provides clinicians and patients with new treatment choices, however the longer term results from larger studies are not yet available. These devices are more expensive when compared to the traditional percutaneous BAHD and hence funding may become difficult in the current financial climate.

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Declaration of Competing Interests

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