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Introduction to Anatomy and Physiology

Hearing loss is a prevalent health issue worldwide that increases in severity and prevalence with age. Individuals who suffer from it often have a difficult time communicating with others, which can lead to social isolation. The most common treatment uses sound amplification devices called conventional hearing aids. The main function is to raise the volume or magnify the sound in the current environment. These medical devices can have a significant impact on patients' lives [1].

There are two main kinds of conventional hearing aids: air conduction and bone conduction. Bone conduction hearing aids consist of a microphone, an amplifier, and a transducer that functions as a loudspeaker inside the external auditory canal, also known as the ear canal. The transducer works as a bone oscillator and transmits a vibration to the inner ear, which is responsible for hearing, from sound that is collected by the microphone. In order to transduce the sound into a vibration, the hearing aid is then implanted near the temporal bone.

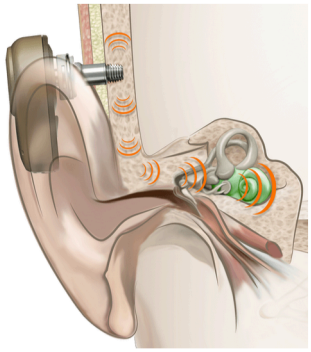

Figure 1. Diagram of how bone conduction hearing aids work

As Figure 1 shows, a small implant and sound processor are placed in the bone behind the ear. Once the sound processor is in contact with the implant, the implant picks up sound waves and transforms them into sound vibrations that are sent through bone. This allows for a clearer sound as the skin does not dampen the sound vibrations [2]. There is not much movement in this area, and due to the fact that the device is surgically implanted into the bone, there is not much worry for structural concern.

Not every patient with hearing loss is a candidate for this type of hearing aid. The patient needs to meet audiometric criteria, how much hearing loss has occurred, and medical indications, which are physiological requirements to be able to properly use the hearing aid. The audiometric criteria include pure tone audiometry causing conductive or conductive hearing loss with bone conduction less than 45 dB and, a speech discrimination score of greater than or equal to 60%, and hearing loss in at least one ear. The normal degree of hearing loss is 0-25 dB, which means the patient must have moderate hearing loss (41-55 dB) or less [3]. This device is not applicable to individuals with more severe hearing loss. Medical indications include chronic ear disease, a congenital malformation, patients unable to use other hearing aids due to discomfort, and conductive hearing loss. If the patient does not meet these criteria, the device is unable to be used. This device also cannot be used in patients 5 and younger as they do not have the developmental anatomy to be able to support the device, patients with hearing reduction and bone conduction threshold greater than 55 dB, patients who are unable to maintain adequate hygiene, or those who have abnormal bone formation and a history of keloid formation, as these

conditions can affect the function and the implant site of the implantable bone conduction hearing aid [1].

Device Overview and Indications for Use

Device Introduction

Implanted bone conduction hearing aids, or implanted bone-anchored hearing aids (BAHAs), are classified under FDA product code *MAH* (Hearing Aid, Bone-Conduction, Implanted) [4], are implantable devices designed to assist individuals with conductive or mixed hearing loss, as well as those with single-sided deafness (SSD) [5]. Unlike traditional air conduction hearing aids, BAHAs transmit sound directly through bone conduction to bypass damaged or nonfunctional portions of the outer or middle ear, delivering sound vibrations to the functioning cochlea. This unique mechanism allows patients to perceive sound clearly, improving both speech recognition and sound quality, especially in noisy environments [6].

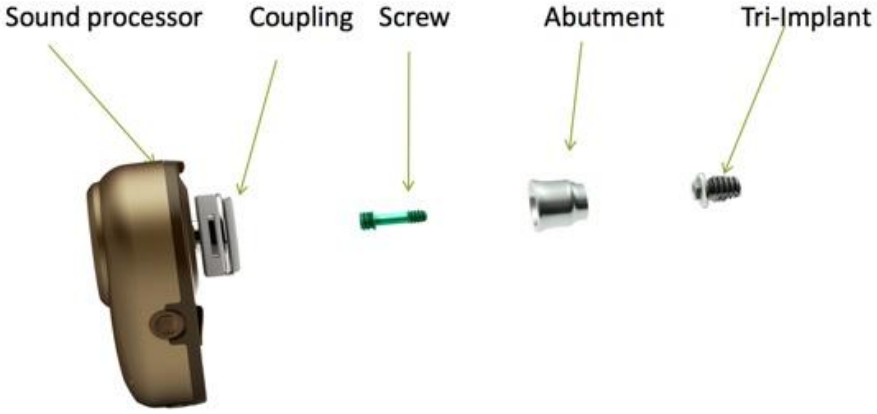

Figure 2. Components of BAHS devices and implant [6]

The BAHA system consists of three main components: an external sound processor, an abutment or magnet (depending on the model), and a titanium implant anchored into the skull as can be seen in Figure 2 above. Sound vibrations are captured by the processor and transmitted through the implant or abutment to the temporal bone, bypassing the conductive pathways typically affected in hearing loss; this process is depicted above in Figure 1. This direct pathway allows for a clearer and more consistent auditory experience compared to traditional hearing aids, which rely on amplifying sound through the impaired ear structures [5, 7].

Indications for Use

The BAHA is indicated for individuals with unilateral or bilateral conductive or mixed hearing loss who are unable to benefit from traditional air conduction hearing aids due to chronic ear infections, congenital defects, or anatomical issues such as atresia or microtia. It is also indicated for individuals with single-sided deafness (SSD) where one ear has severe-to-profound hearing loss, and the other ear is within normal limits. In such cases, the BAHA transmits sound from the deaf side to the hearing ear, overcoming the head shadow effect and improving sound localization in challenging listening environments [4].

Populations and Settings

BAHAs are appropriate for both adult and pediatric populations, although additional

considerations are necessary in children, especially those with craniofacial abnormalities. Due to the need for a stable implantation site, BAHA surgery is typically delayed in younger children until the bone is adequately developed to support osseointegration. The design for pediatric applications often involves a two-stage surgical approach or bone augmentation to accommodate thinner temporal bones and prevent fixture instability [4, 8]. For adults, BAHA is more straightforward and usually completed in a single procedure [4].

The device is commonly used in clinical, rehabilitative, and home settings, with its utility extending to social and work environments where background noise is prevalent. For individuals with SSD, the ability to overcome the head shadow effect enhances their ability to communicate effectively in daily scenarios. In pediatric populations, early intervention with a BAHA can significantly improve speech and language development, a critical factor in long-term cognitive and social outcomes [4, 8].

The BAHA's robust design ensures that it can withstand the rigors of everyday use, with minimal interference from environmental factors such as wind or water. Its ability to improve sound quality and speech understanding in noise makes it a particularly valuable tool in rehabilitative settings, and its design reflects a need for durability, patient comfort, and adaptability to various hearing conditions [4].

User Needs

Bone conduction hearing aids have demonstrated to positively impact the lives of patients who suffer from hearing loss. It is vital that a device be able to solve problems that users experience and reflect the needs of users as well.

In order to benefit users, bone conduction hearing aids must be able to provide an improvement in sound quality. Many users have reported that bone conduction hearing aids have improved their overall quality life [9] As reported by users, the quality of the sound produced from the device has been able improve speech intelligibility, finer sound comfort [9], speech clarity, and sound hypersensitivity, [10].

In addition, sound quality and production is important for users in relation to their personal safety. Many users have explained that using bone conduction hearing aids has made them feel more safe in their daily lives because the hearing aid is able to pick up noises from passing cars and ongoing traffic [10, 11]. Users are also able to more clearly hear when someone is near them and speaking to them [11].

As well, a device should be able to be adjusted, programmed, and deviate from its standard settings in order to meet the needs of different users, varying from their hearing loss and specific preferences. Users have expressed that making key adjustments in their devices programming settings has greatly improved the results of using bone conduction hearing aids [12]. Users have stated that the device is very helpful in all different types of environments, including restaurants, recreational centers, and their workplace [10, 12].

Furthermore, it is necessary for the device to provide bluetooth connections features. Bluetooth connection must be able to promote connectivity between the bone conduction hearing aids and

the users devices, such as their smartphone. Users have reported that the seamless connection between their personal devices and hearing aids has allowed them to take phone calls, listen to music, and stream various entertainment services [10, 12]. Users are also able to use an app on their device in order to control and personalize their sound processor [13]. Additionally, users have expressed that while battery life can be affected by bluetooth usage, the overall battery life of the device is convenient for users [12].

While it is important to recognize the significant impact that bone conduction hearing aids have had on patients and solving different issues, it is simultaneously necessary to recognize possible drawbacks of the device, and take into consideration the thoughts, experiences, and complaints of the patients who use the device firsthand.

In order to improve the device, complaints from users must be taken into account. Users have expressed concerns in regards to sound localization and using the device in noisy environments as a limitation because sound coming from their hearing side is so loud at times that it drowns out sounds coming from their bone conduction hearing aid [14].

As well, studies have shown that individuals who use bone conduction hearing aids, are likely to face adverse skin reactions, due to implant surgery and reactions to the actual device. These skin complications can range from irritation, inflammation, and infection [15]. Depending on the severity of the reactions, patients could also undergo revision surgery for their implants [15].

In addition, users have demonstrated major concerns about the waterproof ability of the device. Users have reported that being around bodies of water, such as recreational pools, beaches, etc. causes them to be very cautious and at times, anxiety inducing, due to possibilities of falling in or being pushed [16]. Bone conduction hearing aids must have a degree of waterproofing ability in order to protect the device itself and lower the burden placed on users.

Identification of Standards

ASTM F2504-05(2022), an ASTM standard entitled “Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices” is recognized by the FDA and serves as a guideline for assessing the output and gain of implantable hearing devices. This ASTM standard is particularly important for ensuring that devices such as bone-anchored hearing aid (BAHA) function effectively. It provides a systematic approach to measure critical performance metrics that influence the user’s auditory experience. The adherence to such standards is essential, as it ensures the devices are not only effective but also safe for use in clinical settings. This helps in maintaining consistent quality and reliability across devices, offering reassurance to both manufacturers and users about the expected performance and safety [17].

UNE-EN ISO 11607-1:2020, an ISO standard named “Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier and packaging systems (ISO 11607-1:2019, including the corrected version from 2019),” sets standard for packaging materials and sterile barrier systems used with terminally sterilized medical devices, which also includes bone-anchored hearing aid (BAHAs). Recognized by the FDA, it ensures that such devices remain sterile up to the point of use. This standard is vital for BAHAs as it helps prevent microbial contamination, crucial for devices that interact with sterile body areas. Compliance

with this standard is key in ensuring the safety and effectiveness of BAHAs before they reach the market, safeguarding patient health [18].

Design Inputs & Product Requirements

Device must be able to provide users an output of up to 60 decibels (dB) sensorineural hearing level (SNHL). In order to provide users with a powerful device that is able to provide a wide range of broad and effectual sounds, as well as improve the quality of sound and other noises from various environments [9, 10, 13], the device must be able to meet and output a high SNHL level.

Device must be able to support bluetooth connection from users devices to their bone conduction hearing aids from up to 100 meters (m) away. In order to provide users with the ability to be able to hear sounds coming from their device, such as phone calls, entertainment services, and music [10, 12], the device must be able to provide users with a seamless wireless connection that is stable, even if users move away from their devices.

Device must have a battery that has a battery life that can last for up to two weeks. In order to ensure that users are able take full advantage of their hearing aids for multiple days at a time [12], it is crucial that the device has a long battery life to ensure that users can conveniently use their hearing device everyday while not having to change or swap out their devices batteries constantly.

Device must be programmable and able to execute at least 1000 operations per second. In order to ensure that users are able to customize settings in their hearing aids, depending on their preferences and level of hearing loss, further enhancing the results they get from their hearing aids [10, 12], it is crucial that the device allows for such programming adjustments to take place and at relatively quick speeds for maximum efficiency and results for users.

Device must be waterproofed and can be submerged in water up to 2 meters for up to 30 minutes with no damage occurring to the functioning of the system as determined by an able bodied user of the device. In order to provide users with an additional layer of protection for their hearing aid [16], the device should be waterproofed in order to protect users and their devices from water that could cause damage to the device.

A device requirement from ASTM F2504-05(2022) (also related to the ANSI S3.22 standard ‘Specification of Hearing Aid Characteristics’) that is applicable to BAHAs is that the maximum output sound pressure level (OSPL90) of the device, when tested with a 90 dB SPL input, must not exceed the manufacturer's specifications by more than 3 dB to ensure safe and effective performance when utilized by the user [17] The rationale for limiting the maximum output sound pressure level (OSPL90) of the device when exposed to a 90 dB SPL input is to ensure that the bone conduction hearing aid can handle loud sounds without producing excessive output, which could cause discomfort, auditory damage, or distortion. Adhering to the manufacturer’s specifications with a strict tolerance of no more than a 3 dB deviation ensures that the device consistently provides clear and accurate sound amplification, even in loud environments, while safeguarding the user's hearing from potential harm due to over-amplification. This also helps

maintain the device's overall reliability and performance, improving the user's auditory experience in daily life. This could be tested with the OSPL90 test.

A device requirement from ASTM F2504-05(2022) and ANSI S3.22 (Section 6.11S) for bone-anchored hearing aids (BAHAs) is that the harmonic distortion in the implantable middle ear hearing device (IMEHD) must be minimized. Specifically, when tested with sinusoidal inputs at frequencies of 500, 800, and 1600 Hz, the transfer function (E), which describes the relationship between the input transducer and processor and the output transducer, must not exceed a maximum level of E_{max} = -20 dB [17]. The rationale for establishing a requirement on harmonic distortion levels, specifically related to the transfer function (E) in IMEHDs, is to ensure optimal auditory performance and user satisfaction. By limiting the maximum level of E to Emax = -20 dB during testing with sinusoidal inputs at frequencies of 500, 800, and 1600 Hz, it can be ensured that the device maintains a high fidelity of sound reproduction. Minimizing harmonic distortion is crucial for preserving the clarity and quality of sound signals transmitted to the cochlea. High levels of distortion can lead to audible artifacts and a degradation of sound quality, which can significantly affect the user's ability to understand speech and enjoy a range of auditory experiences. Harmonic distortion in the IMEHD can be assessed by applying sinusoidal input signals at 500 Hz, 800 Hz, and 1600 Hz while measuring the output with a calibrated microphone and analyzing the results to ensure compliance with the specified limits.

A device requirement from ASTM F2504-05(2022) and ANSI S3.6 is that the IMEHD/BAHA must operate effectively within a frequency range of 250 Hz to 4000 Hz, defined as providing a minimum gain of 30 dB across the critical speech frequencies (250 Hz to 4000 Hz) while maintaining total harmonic distortion (THD) levels below 5% and a frequency response variation of no more than ±3 dB relative to the reference level of 94 dB sound pressure level [17]. A device requirement like this ensures that the IMEHD effectively amplifies sound within the critical speech frequency range of 250 Hz to 4000 Hz. A minimum gain of 30 dB at a reference level of 94 dB SPL is required to enhance speech intelligibility for effective communication. Maintaining THD below 5% preserves sound quality, preventing distortions that could hinder speech perception. A frequency response variation of ±3 dB guarantees consistent performance across the range, enhancing user comfort and safety. These criteria align with established audiological standards, ensuring the BAHA delivers optimal auditory outcomes for users. The effectiveness of the IMEHD across varying frequencies can be tested by applying sinusoidal input signals at specified frequencies (250 Hz to 4000 Hz) at 94 dB SPL, measuring the output to ensure a minimum gain of 30 dB, total harmonic distortion below 5%, and a frequency response variation within ±3 dB.

A device requirement from ASTM F2504-05(2022) and related to ANSI S3.16 is that the IMEHD must have an equivalent input noise level (a measure of the background noise that a hearing device generates in the absence of any sound input) not exceeding 30 dB SPL to ensure that ambient noise does not interfere with the amplification of desired sounds [17]. The rationale for this requirement is that high levels of input noise can mask important auditory signals, making it difficult for users to discern speech and other critical sounds in everyday environments. By limiting the equivalent input noise level, the IMEHD ensures that users experience clearer and more intelligible sound. The equivalent input noise level of the IMEHD

can be tested by measuring the output noise in an anechoic chamber with no external sound input, ensuring it does not exceed 30 dB SPL.

The packaging should ensure the sterility of the hearing aid up to use with a SAL of 10-6 in accordance with UNE-EN ISO 11607-1:2020 [18]. All this implies is that the probability of any microbial units present on the device after sterilization is infinitesimal-less than one in a million. For this, we would have to test the packaging through biological indicators and stimulate the conditions that it may come into in order to ensure sterility.

In accordance with UNE-EN ISO 11607-1:2020, The resistance of packaging to rupture pressures of up to 200 kPa[18]. The package must be able to resist normal pressure during shipment and manipulations to maintain the hearing aid safe and clean. This is tested by applying pressure to the packaging while observing for leaks or weaknesses in the packaging through various methods to visually identify possible issues, such as dye tests.

In accordance with UNE-EN ISO 11607-1:2020,The seals applied should be such that they are able to resist opening with a force of not less than 1.5 N/ 15mm of seal length, ensuring tightness in such a way that contaminants will not enter yet not requiring an inordinate force to open, which could be hazardous in medical situations[18]. This would be further confirmed by measuring the force required to peel the seals apart in a special machine that pulls on them with consistency.

In accordance with UNE-EN ISO 11607-1:2020, the Moisture Barrier Performance of the packaging shall not exceed Water Vapor Transmission Rate of 0.2g/m2/24 hr [18]. The intent of this requirement is that the Sterile Barrier System will provide an appropriate block to moisture, important in preventing the degradation of the components of the hearing aid prior to use. Testing may be conducted using standardized moisture permeability testing equipment to determine the rate of water vapor transmission through the package material.

The packaging system shall provide a clear visibility window that allows at least 90% visible light transmission in accordance with UNE-EN ISO 11607-1:2020 [18]. This condition is necessary to enable healthcare providers to inspect the condition of a device without opening the package and compromising the sterility of the device. In that respect, this requirement may be tested by using a spectrophotometer to measure the amount of light that passes through the visibility window of packaging.

The device must demonstrate no toxicological attributes in accordance with UNE-EN ISO 11607-1:2020, wherein the test results must show a maximum toxicity score of 0 on the grading scale. These tests are used when contact with the device allows for the absorption of toxic substances and the degradation of products. This test revolves around giving animals a single dose of the test sample and observing the changes in the animal's health, specifically looking for signs of toxicity over 3 days. For this test, none of the animals should show signs of acute systemic toxicity [18]. The rationale is that the material of the hearing aid should be safe to come in contact with the body. This device should also not leak any toxic substances that could compromise the health of the user. This is taken into consideration when sterilizing devices.

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