From the Department of Otorhinolaryngology, Head and Neck Surgery

at the University of Lübeck

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Indication, surgical procedure and clinical performance of the new active osseointegrated implant system, the Osia™ System

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This thesis is dedicated to my parents.

For your endless love, support, and encouragement, for everything.

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1 Introduction

An unborn baby reacting to his mother's voice is perhaps the earliest measurable act of communication of a human's life.

Studies detected measurable fetal movements and changes in heart rate in response to sound at about 25-27 weeks of gestational age [1]. The auditory perception by the human fetus develops early in the uterine life, which makes it one of the first senses acquired [2], [3], [4], [5].

The auditory system was engineered miraculously to function and perform with remarkable microelectronics. The ear perceives sound and extracts information from the surroundings, whether animate or inanimate. The ear's wide range of features, such as sound localization, signal frequency organization, transduction and amplification of the acoustic stimulus, and the cochlear ability to process and conduct the sound with a microscopic dimensional motility, make the hearing organ simply magnificent [1], [6], [7].

A variety of hearing disorders and anomalies affect the life of millions of people around the world. According to the WHO, nearly 20% of the global population experience some degree of hearing loss. 430 million of them have disabling hearing loss. It is expected that by 2050, there could be over 700 million people with disabling hearing loss.

1.1 Anatomy and Physiology of the Auditory System

The auditory system consists of two main components: the peripheral and central auditory systems (Figure. 1-1 and Figure. 1-2). The peripheral system includes the external ear, the middle ear, the cochlea, and the auditory nerve. The central auditory system includes the cochlear nucleus, the superior olivary complex, the lateral lemniscus, the inferior colliculus, the medial geniculate body, the auditory subcortex, the cortex and the interhemispheric pathways [8].

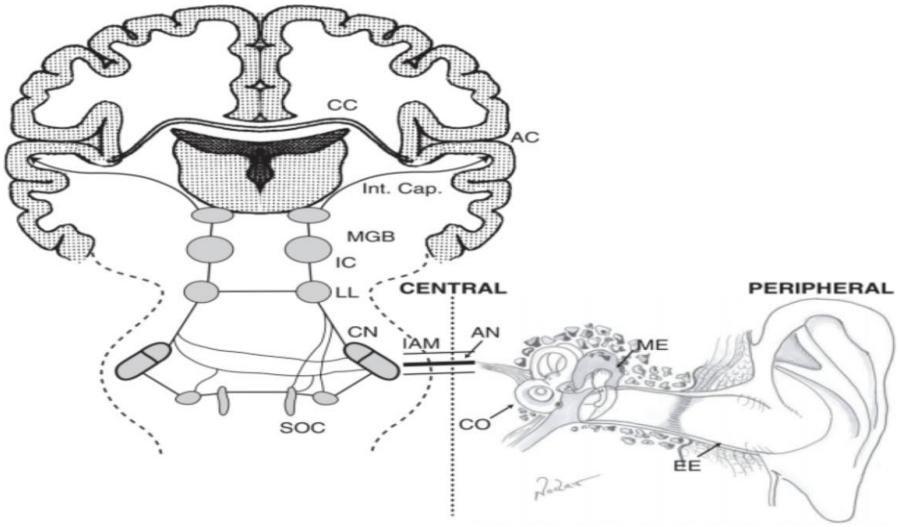


Figure 1-1 A drawing of the peripheral and central auditory system: EE = external ear and canal, ME = middle ear, Co = cochlea, AN = auditory nerve, IAM = internal auditory meatus, CN = cochlear nucleus, SOC = superior olivary complex, LL = lateral lemniscus, IC = inferior colliculus, MGB = medial geniculate body, Int. cap. = internal capsule, AC = auditory cortex, CC = corpus callosum. Source: Musiek and Baran, the auditory system, anatomy, physiology, and clinical correlates [8].

The auricle receives sound waves from the external environment, which are defined as pressure pulses of vibrating air molecules. Hertz (Hz) is the unit for the vibration frequency of sound waves and represents the number of vibrations per second. The human ear can detect frequencies between approximately 20 Hz and 20 kHz. The intensity of sound is measured in decibels (dB); the range of human hearing on a decibel scale is from 0 to 130 dB [9].

The unique configuration of the auricle serves as a collector of sound energy. This remarkable anatomic structure of the auricle facilitates the formation of sound bundles and directs these along a 3,5 centimeters auditory canal to the tympanic membrane. The response is maximal within the high-frequency range (around 5000 Hz). This property allows differential enhancement and amplification of acoustic stimuli before entering the external auditory meatus. The external auditory canal generates an ear canal resonance (enhancement of the acoustic signal) typically at a frequency of 3000 to 4000 Hz, which is important for the natural perception of sound [10].

The acoustic stimulus reaches the tympanic membrane, which forms the lateral wall of the middle ear, causing it to vibrate. At this point, the electrical stimulus is transformed into a mechanical vibration. The middle ear includes the ossicular chain, which is formed by the three smallest bones in the human body: malleus, incus, and stapes. A part of the sound is reflected by a mechanism called acoustic impedance. The greater the mass and the stiffness of the membrane and the ossicular chain is, the greater the mechanical resistance and therefore the impedance. The surface area difference between the tympanic membrane (55 mm^2) and the footplate of the stapes (3,2 mm^2) produces a remarkable sound amplification. This physiological amplification is necessary to overcome impedance and allow transmission between the air in the middle ear and the fluid-filled cochlea (perilymph). The morphological arrangement and interaction of the middle ear ossicles serve as a lever system, generating a mechanical advantage and contributing to the signal amplification.

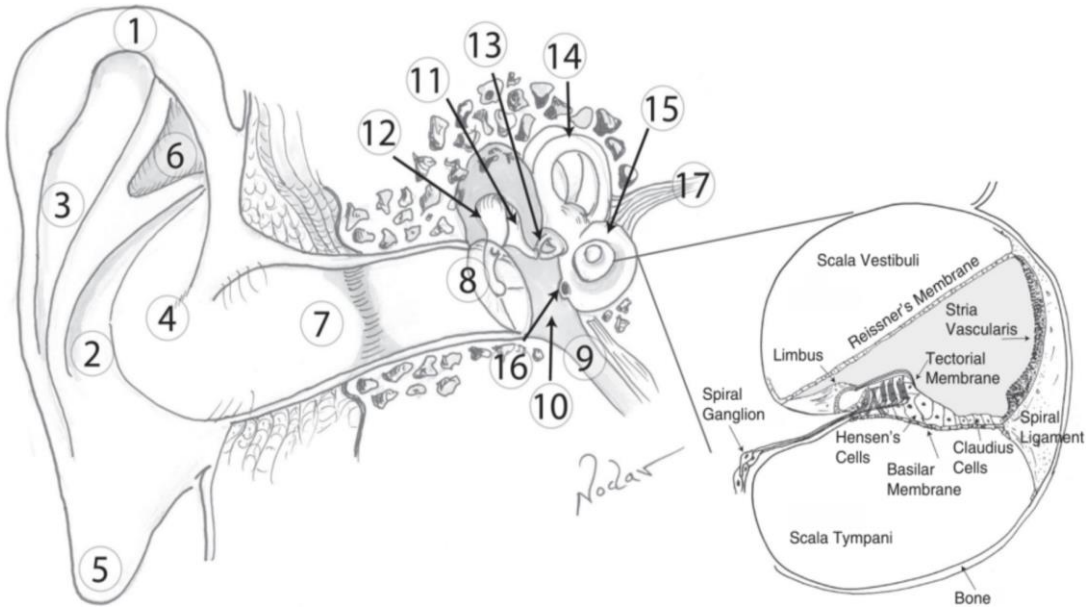


Figure 1-2 A drawing of the peripheral auditory system and a cross section of the cochlea: 1 = helix, 2 = antihelix, 3 = scaphoid fossa, 4 = concha, 5 = lobe, 6 = triangular fossa, 7 = external auditory meatus, 8 = tympanic membrane, 9 = Eustachian tube, 10 = middle ear space (tympanum), 11 = incus, 12 = malleus, 13 = stapes, 14 = superior semicircular canal, 15 = bony cochlea shell (otic capsule), 16 = round window, 17 = eighth nerve. Source: Musiek and Baran [8, p. 3].

The movement of the stapes applies a vibratory input into the cochlea through the oval window. At this point, a traveling wave (TW) is elicited in the endolymph within the cochlear duct, which moves along the entire length of the basilar membrane. Within the cochlear duct lies the organ of Corti on the basilar membrane. This important structure is responsible for the transduction of auditory signals. The TW causes the stereocilia of outer hair cells (OHCs) in the organ of Corti to deflect at its upper border against the tectorial membrane (TM). This deflection produces a depolarization of hair cells. This shearing or bending effect is essential in the cochlear transduction pro- cess. The pressure applied to the cochlear fluid is produced through a piston-like action of the stapes. This pressure is about 22 times the initial pressure directed to the tympanic membrane with an acoustic gain of approximately 27 dB [11]. Depolarization of hair cells triggers the release of neurotransmitters (glutamate in case of inner hair cells IHCs) through the synapse and generates electrical impulses. These electrical signals are conveyed through the auditory sensory neurons to the auditory cortex in the temporal lobe [8, pp. 1–20], [11].

Numerous diseases and anomalies could disrupt this complex piece of engineering, resulting in different types of hearing disorders.

1.2 Hearing Loss

According to the World Health Organization (WHO), over 1.5 billion People live with hearing loss globally. It has been estimated that this number could rise to over 2.5 billion by 2050. The prevalence of hearing impairment in Germany according to the WHO criterion is approximately 11.1 million persons [12]. The Robert Koch Institute (RKI) reported in 2012 that 21.5 % of the German adult population suffer from hearing impairment [13, pp. 54–57].

Hearing loss could have various negative physical and psychological outcomes, which have a direct impact on the patient's life. Arlinger reviewed the negative consequences of uncorrected hearing loss on different aspects of life of the affected person. People suffered from isolation, reduced social activity, and increased symptoms of depression. These were reflected in a poorer quality of life [14].

A person is said to have hearing loss if he or she is not able to hear as well as someone with normal hearing. There are a variety of hearing loss causes, which include congenital or early onset childhood hearing loss, chronic middle ear infections, noise induced hearing loss, presbycusis and toxic hearing loss [15].

Hearing loss is classified according to the diseased part of the auditory pathway into three main categories (Figure 1-3):

1. Conductive hearing loss
2. Sensorineural hearing loss
3. Mixed hearing loss

A conductive hearing loss indicates that the pathology usually lies in the external or middle ear, whilst a sensorineural hearing loss suggests that the diseased part lies in the inner ear or the auditory pathway and cortex. A mixed hearing loss indicate the presence of both conductive and sensorineural impairment components [11].

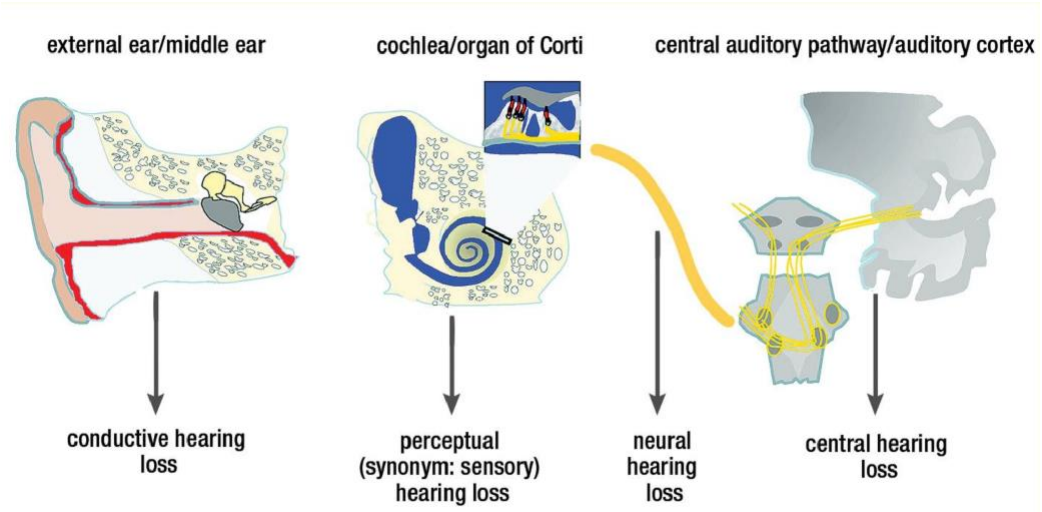


Figure 1-3 Classification of hearing impairment according to the level of lesion. Source: Prof. Dr. med. Dr. h. c. Thomas Zahnert, Dtsch Arztbl. Int. 2011 June [15].

1.2.1 Conductive Hearing Loss

This type of hearing impairment could be caused by any pathology between the pinna and the external auditory meatus to the foot of stapes [16]. These lesions result in a total or subtotal disruption of the air conduction of the acoustic stimulus.

Someone could have a conductive hearing loss if the sound transmitted through air is diminished while the bone conduction is normal. The condition is diagnosed typically using the pure tone audiometry. The threshold of bone conduction of sounds lies typically at or below 20 dB, whereas the intensity of stimulus required for hearing via air conduction is greater than 20 dB. The result is demonstrated with an air-bone gap of more than 10 dB. The size of the air-bone gap indicates the severity of conductive hearing loss with a maximum value of 65 dB [11], [17].

An abnormal embryonic development of the first and second branchial arches and the first branchial cleft results in aural atresia, which causes a complete disruption of the air conduction [18]. Various pathologies in the middle ear cause a conductive hearing loss such as acute and chronic otitis media with or without effusion, cholesteatoma, ossicle discontinuity, and otosclerosis. Conductive hearing loss is the most common type in children, which is usually caused by otitis media with effusion [19], [20].

1.2.2 Sensorineural Hearing Loss

Sensorineural hearing loss results from pathologies causing damage to the hair cells within the cochlea, the vestibulocochlear nerve or the auditory cortex [21].

This type of hearing loss could be congenital or acquired. Congenital causes may be syndromic (such as Usher, Alport, Pendred and Stickler) or non-syndromic. The non-syndromic hearing loss accounts for 70 % of cases and is transmitted predominantly (75-80 %) as an autosomal

recessive trait [22]. A congenital hearing loss may be caused by several maternal infections such as CMV, Toxoplasma gondii, rubella virus, HSV and Treponema pallidum [23].

Common causes of acquired sensorineural hearing loss include: presbycusis, Meniere's disease, ototoxicity induced by medications, noise-induced hearing loss, meningitis, inner ear concussion and vestibular schwannoma. Most cases of sudden sensorineural hearing loss have no identifiable cause and are classified as idiopathic [24].

Single Sided Deafness (SSD)

Single sided deafness presents the most severe form of unilateral sensorineural hearing loss. The etiology includes damage to the hair cells within the cochlea or the neural pathway resulting in deafness or hearing level of 90 dB HL or greater in the affected ear, with normal or near normal hearing in the contralateral ear [17].

The incidence of children with unilateral hearing loss is 1 in 1000 in newborns, which constantly increases with age to reach 1 in 5 in adolescents [25], [26], [27]. The incidence of acquired single sided deafness in adults is estimated to affect 12 to 27 per 100,000 persons in the general population [17], [28].

The Lesion is located mostly in the sensory epithelium of the cochlea and its hair cells. Less commonly, lesions affect the retrocochlear region in the spiral ganglion, the cochlear nerve and nucleus. The presence of otoacoustic emissions (OAEs) and cochlear microphonics (CMs) determines the site of the causing lesion. The absence of these signals indicates that a large portion of hair cells are damaged [29]. In contrast, the neural pattern of hearing loss, resulting from a lesion in the cerebellopontine angle like a vestibular schwannoma as an example, is characterized with measurable OAEs and CMs [30]. In adults, acquired single sided deafness has also an unknown etiology. Possible causes are trauma, ototoxic medications, viral or vascular diseases, Meniere disease or as a postoperative complication [11].

1.2.3 Mixed Hearing Loss

A combined damage to the outer or middle ear and inner ear results in a mixed hearing loss. It is defined as having a bone conduction threshold greater than 20 dB Hearing Level (HL) and an air bone gap greater than 10 dB [11], [17].

1.2.4 Grading of Hearing Impairment

The WHO proposed a grading system that included four grades of hearing impairments ranging from mild to severe. The current classification is based on a previous version from 1991 [31] and is shown in Table 1-1. This grading system is based on hearing thresholds obtained via the pure tone audiometry (Figure 1-4).

Hearing loss is classified according to the extent of hearing loss, as follows:

- Mild hearing loss: Hearing threshold of 25 to 40 dB
- Moderate hearing loss: Hearing threshold of 41 to 60 dB
- Severe hearing loss: Hearing threshold of 61 to 80 dB
- Profound hearing loss or deafness: Hearing threshold of more than 81 dB

Table 1-1 WHO's grades of hearing impairment

Grade of impairment	Corresponding audiometric ISO value (a,b)	Performance	Recommendations
0: No impairment	25 dB or better	No or very slight hearing problems, able to hear whispers	No
1: Slight impairment	25-40 dB	Able to hear and repeat words spoken in normal voice at 1 m	Counseling, hearing aids may be needed
2: Moderate impairment	41-60 dB	Able to hear and repeat words using raised voice at 1 m	Hearing aids usually recommended
3: Severe impairment	61-80 dB	Able to hear some words when shouted into better ear	Hearing aids needed. If no hearing aids available, lip-reading should be taught
4: Profound impairment	81 dB or greater	Unable to hear and understand even a shouted voice	Hearing aids may help in understanding words. Additional rehabilitation needed. Lip-reading and sometimes singing essential
dB: decibel; Hz: Hertz; ISO: International Organisation for Standardization; m: meter; WHO: World Health Organisation			
a: in the better ear b: average of 500, 1000, 2000 und 4000 Hz			
Source: Global Burden of Disease Expert Group on Hearing Loss [32]. This table has been customized for this study.			

The Global Burden of Disease (GBD) expert group on hearing loss proposed a revised classification in 2010, in which the normal hearing limit was reduced from 25 to 20 dB. The new recommendations addressed 6 different degrees of bilateral hearing loss with a separate category for unilateral hearing impairment. A consistent change of 15 dB between different degrees was adopted and considered significant. Relying solely on the hearing threshold of the pure tone audiogram is insufficient for determining the cause of hearing loss and evaluating the condition of the central auditory nervous system [31], [32].

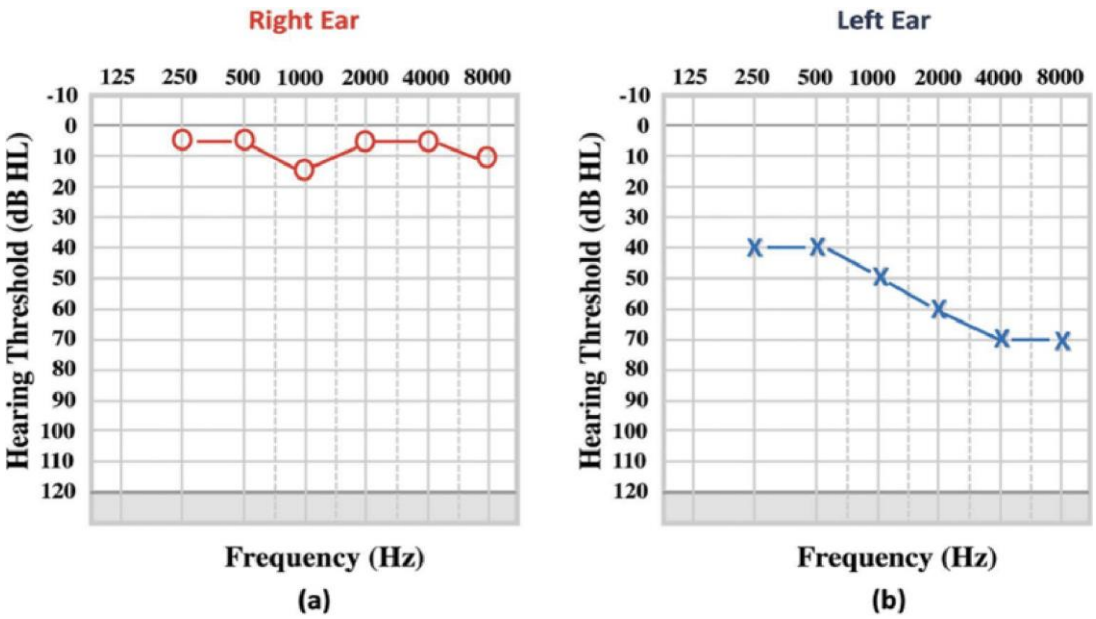


Figure 1-4 Audiogram examples showing hearing thresholds at various frequencies. showing (a) normal hearing and (b) mild to moderate hearing loss. Source: Zhao, Fei & Mayr, Robert. (2021) [33].

There are three main types of hearing aids used for rehabilitation with patients who suffer from hearing loss: air conduction (AC) hearing aids, bone conduction (BC) hearing aids and active middle ear hearing aids (AMEI) [34].

In the next section, we will review the mechanism of bone conduction, as well as the indications and types of currently available bone conduction hearing aids.

1.3 Bone Conduction Hearing Devices (BCHD)

Aural rehabilitation using bone conduction hearing devices, also known commonly as bone anchored hearing aids (BAHA), has a longstanding tradition. The devices are surgically implantable or semi-implantable and have been utilized for hearing improvement over the past 40 years [35]. The first implantation of a BAHA was performed by Prof. Dr. Anders Tjellström in 1977 in Sweden. Since then, a remarkable improvement of this type of hearing aids has been achieved [36].

BAHA operate by converting sound waves into mechanical vibrations, which are transmitted to the cochlea, bypassing pathologies in the external and middle ear. Vibrations at the level of basilar membrane elicit, as mentioned earlier, action potentials in the dendrites of the cochlear nerve, which will further propagate to the auditory cortex in the temporal lobe (area 41 and 42). Stenfelt and Goode in 2005 concluded five factors contributing to bone conduction hearing: sound radiated into the external ear canal, middle ear ossicle inertia, inertia of the cochlear fluids, compression of the cochlear walls and pressure transmission from the cerebrospinal fluid. They added that the inertia of the cochlear fluid seems to be the most important factor [37].

The indications of bone conduction hearing devices include conductive or mixed hearing loss or single sided deafness with a normal hearing in the contralateral ear. Advances in the field of bone conduction rehabilitation provided a new line of therapy for hearing difficulties, which could not be improved with conventional hearing systems. These devices should be considered in patients, who are not able to use conventional hearing aids due to various conditions such as chronic ear discharge, chronic otitis media or externa and aural atresia. In cases of single sided deafness, sound signals propagate via bone conduction transcranially to the contralateral, normal hearing cochlea [38].

Bone conduction hearing devices are classified into two main groups: percutaneous and transcutaneous devices. This classification is based on the presence or absence of a skin-penetrating abutment [38].

1.3.1 Percutaneous Bone Conduction Devices

This type of hearing aids is based on direct transmission of signals through a bone-anchored abutment without signal attenuation through skin and subcutaneous tissue [39]. The surgery is straightforward and can be performed under local anesthesia [40].

The main complications associated with this system are infection and local inflammation. Other adverse effects include wound healing disorders, dehiscence, ulceration, and device extrusion [41], [42], [43], [44], [45]. Holgers et al. (1998) classified the local skin reaction around the abutment into five categories, which range from no skin reaction (grade 0) to a clear skin infection (grade IV). Severe skin infections in grade IV necessitate a surgical intervention to remove the implant [46].

There are currently two available percutaneous bone conduction devices: the Cochlear Baha Connect System (Cochlear Bone anchored Solutions AB, Sweden) and the Oticon Ponto System (Oticon Med AB, Sweden). Percutaneous BCHD consist of three main parts: external sound processor, skin penetration abutment and osseointegrated implant [38].

1.3.1.1 Baha Connect System (Cochlear Company)

The company Cochlear presented this system to the market in 1977 as the first percutaneous, osseointegrated System. It consists of a titanium osseointegrated implant BI300 with a length of 3 or 4 mm, an abutment BA400, and an external processor. The abutment is available at different lengths to accommodate various skin thicknesses. Sound processors have been upgraded over time. The Baha 6 Max sound processor has a small size with a fitting range up to 55 dB sensorineural hearing level (SNHL) [38], [47].

1.3.1.2 Oticon Ponto (Oticon Medical Company)

The Oticon Ponto was first introduced to the market in 2009. The available series include Ponto 3, Ponto 4, and Ponto 5. Various sound processors are available for each series, including the regular edition, Power, and SuperPower. These are suitable for patients with bone conduction hearing thresholds up to 45 dB HL, 55 dB HL and 65 dB HL, respectively [40], [48].

1.3.2 Transcutaneous Devices

Transcutaneous devices are further subdivided into active and passive implants according to the site of elicited vibrations. In passive devices, vibrations are generated at the external sound processor level and then transmitted transcutaneously through the intact skin to the implanted device. Whereas in active transcutaneous devices, the external auditory process produces electrical impulses, which propagate through the intact skin from the sound processor to the implanted device. The vibrations originate directly from the implanted device itself, which is in direct contact with the skull bone [38].

1.3.2.1 Passive Transcutaneous Devices

The general principle of this system illustrates the transmission of electromagnetic signals generated in the sound processor through the intact skin to the implanted component of the device. The absence of abutment reduces skin related adverse effects [40], [49].
The sound processor is attached to the titanium implant placed under the intact skin through a magnetic force. This magnetic force may lead to various pressure induced adverse effects involving the skin and subcutaneous tissue. These complications hinder the device's usability, hence resulting in a decrease in the daily average use of the sound processor [38], [50].

Despite the significant hearing improvement, studies showed a signal attenuation up to 25 dB especially at high frequencies between 6000 and 8000 Hz, when compared to percutaneous devices [51], [52].

The currently available transcutaneous devices are the Baha Attract System (Cochlear Bone-Anchored Solutions, AB, Sweden) and Alpha 2 MPO System (Medtronic, Ireland).

1.3.2.1.1 Baha Attract (Cochlear Company)

The Baha Attract was introduced by Cochlear to the market in 2013. The system consists of an internal magnet (BIM400 Implant Magnet) which attaches to a fixation screw (BI300 Implant). The Baha Attract system uses the same BI300 implant as the percutaneous Baha Connect. The implants were designed to lie completely under an intact skin without an abutment. Besides, both Baha Attract and Baha Connect utilize the same external processor. The most advanced Baha sound processor can compensate for a sensorineural element up to 65 dB HL [38], [53], [54], [55], [56].

1.3.2.1.2 Alpha 2 MPO-System (Medtronic, USA)

The Alpha 2 MPO-System (Medtronic, USA) was first released in 2006 [57]. The implant consists of two magnets hermetically sealed in a titanium case. The implant is fixed under the skin within a shallow bone bed with five screws. The sound processor receives sounds from the environment and transfers these through the intact skin to the magnetic bone implant. The Transcutaneous Energy Transfer (TET) enables a further transfer of the signals to the patient's cochlea. The Alpha 2 MPO ePlus sound processor is suitable for patients with a conductive hearing loss up to 45 dB HL with an ideal candidacy up to 35 dB [38], [40], [58].

1.3.2.2 Active Transcutaneous Devices

Active transcutaneous devices are semi-implantable devices which offer the advantage of active transduction of signals under the intact skin.

The currently available devices include the Bonebridge (Med El, Austria) and the most recently introduced Osia System (Cochlear Bone-Anchored Solutions, AB, Sweden).

1.3.2.2.1 Bonebridge (Med El, Austria)

The first generation of Bonebridge (BCI 601) was released to the market in 2012 and the second version BCI 602 in 2019. The implantable part consists of a magnet, a receiving coil, a sound processor or demodulator and a bone conduction floating mass transducer (BC-FMT) with an electromagnetic technology [38], [40], [59]. Electromagnetic signals are transmitted from the sound processor to the implanted transducer. The transducer transforms these signals into direct mechanical vibrations. These vibrations are directly applied to the temporal bone, hence reducing signal attenuation. Besides, the absence of abutment minimizes the associated skin and soft tissue complications [38], [59], [60], [61].

The device is indicated by conductive or mixed hearing loss with a bone conduction hearing threshold better than or equal to 45 dB HL or as a routing device for the contralateral side in cases of SSD [60], [61], [62], [63].

Table 1-2 Overview of bone conduction hearing devices

<table>
<tr><td colspan="5">Bone Conduction Hearing Devices
(BCHD)</td></tr>
<tr><td colspan="2">Percutaneous BCHD</td><td colspan="3">Transcutaneous BCHD</td></tr>
<tr><td>Baha Connect
(Cochlear)
  </td><td>Oticon
Ponto
  </td><td colspan="2">Passive Transcutaneous</td><td>Active Transcutaneous</td></tr>
<tr><td colspan="2"></td><td>Baha Attract
(Cochlear)
  </td><td>Alpha 2 MPO
(Medtronic)
  </td><td>Bonebridge
(MedEl)
  </td><td>Osia
(Cochlear)
  </td></tr>
</table>

Source: based on Rahne and Plontke 2022, the table has been customized by the author specific for this study.

1.3.2.2.2 Osia System (Cochlear Bone-Anchored Solutions, AB, Sweden)

The new Cochlear™ Osia system is the most recent active transcutaneous device, which was introduced to the market in 2019. The System consists of a Piezo Power transducer which is fixed to an osseointegrated implant (BI300) and an external sound processor. The Piezo Power transducer is made of piezoelectric layers which expand and contract, producing mechanical vibrations when an electric voltage is applied. The first generation transducer OSI100 had a flexible lead between the transducer and the coil. The second generation OSI200 has a stable connection between the transducer and the coil. The new design facilitates the surgical procedure and reduce feedback noises [64]. The BI300 implant is a common component used in other Cochlear™ products. The external Osia2 sound processor has a smaller size compared to the first generation and features an updated signal processing [65], [66].

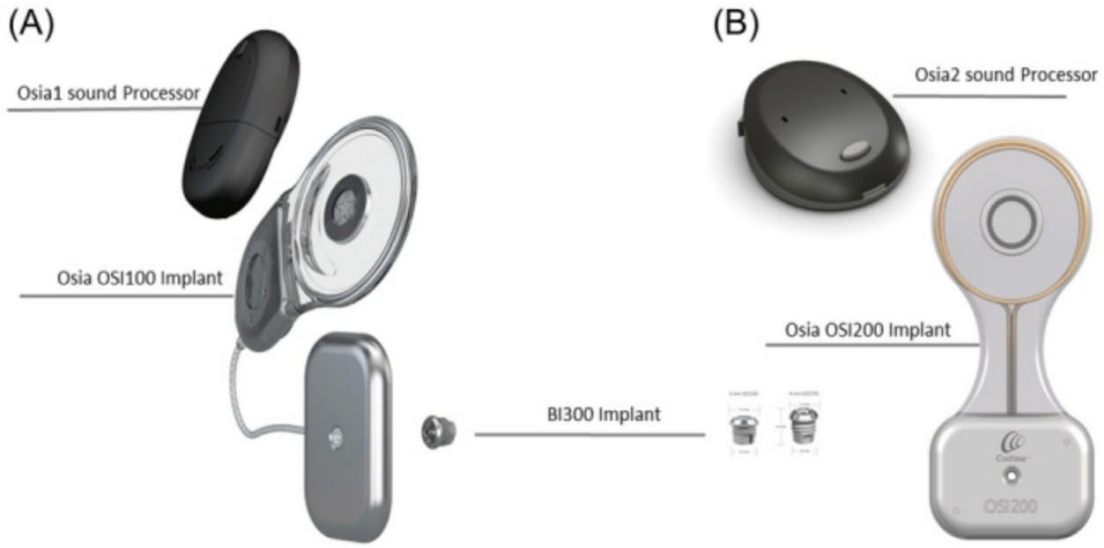


Figure 1-5 Cochlear Osia system implant OSI100 and OSI200 with BI300 implant and audio processor.

Device Description and mechanism:

The Osia system consists of two components: The external component includes a sound processor with the associated accessories. The function of the sound processor is to pick up the surrounding sounds and transfer them to the implant through a digital inductive link.

The processing unit comprises two microphones for receiving sounds, a custom integrated circuit with digital signal processing (DSP), a visual indicator and a button allowing control of key features and a battery (Figure 1-6). The materials being used are Polyamid 12 (PA12) for the sound processor enclosure and the magnet housing, besides gold coated magnets. The Osia 2 processor unit weighs 7.8 g and has the following dimensions: length 36 mm, width 32 mm, depth 10.4 mm. It is provided with a high power 675 (PR44) zinc air dispensable battery and weighs 9.4 with the

battery. The sound processor receives sounds with a frequency range between 100 Hz and 7 kHz, with the ability to produce a sound output between 400 Hz and 7 kHz.
The wireless connection link operates in the 1.4 GHz ISM band using GFSK (Gaussian frequency-shift keying) and a proprietary bidirectional communication protocol [65], [67].

The internal part includes a coil to receive and forward the electrical signal to the actuator. At the actuator, the signals are coded into vibrations, which are then transmitted via the BI300 Implant to the cochlea through bone conduction. The actuator is connected to the BI300 Implant, which in turn is osseointegrated with the skull bone [68]. Figure 1-7 provides an overview of the Osia OSI200 Implant with its various components.

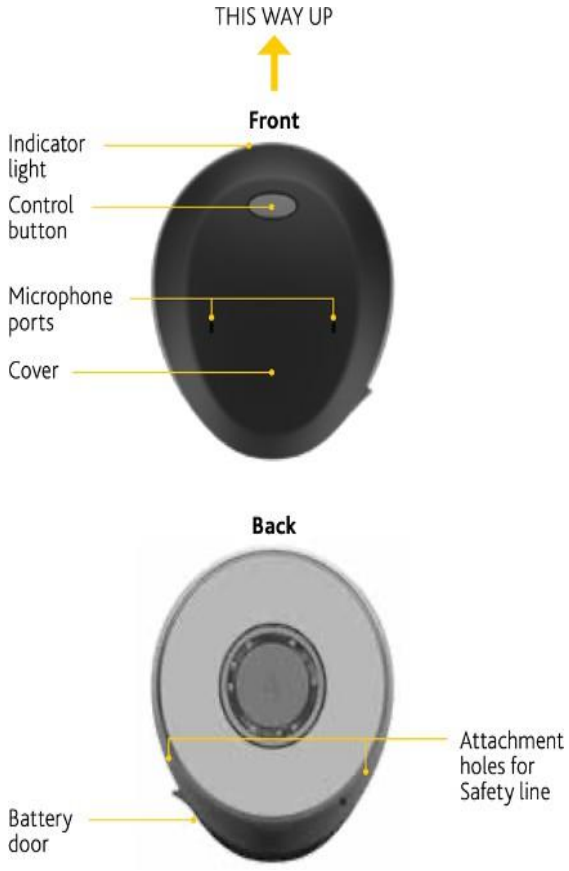


Figure 1-6 Cochlear Osia 2 sound processor with its different components (user manual).

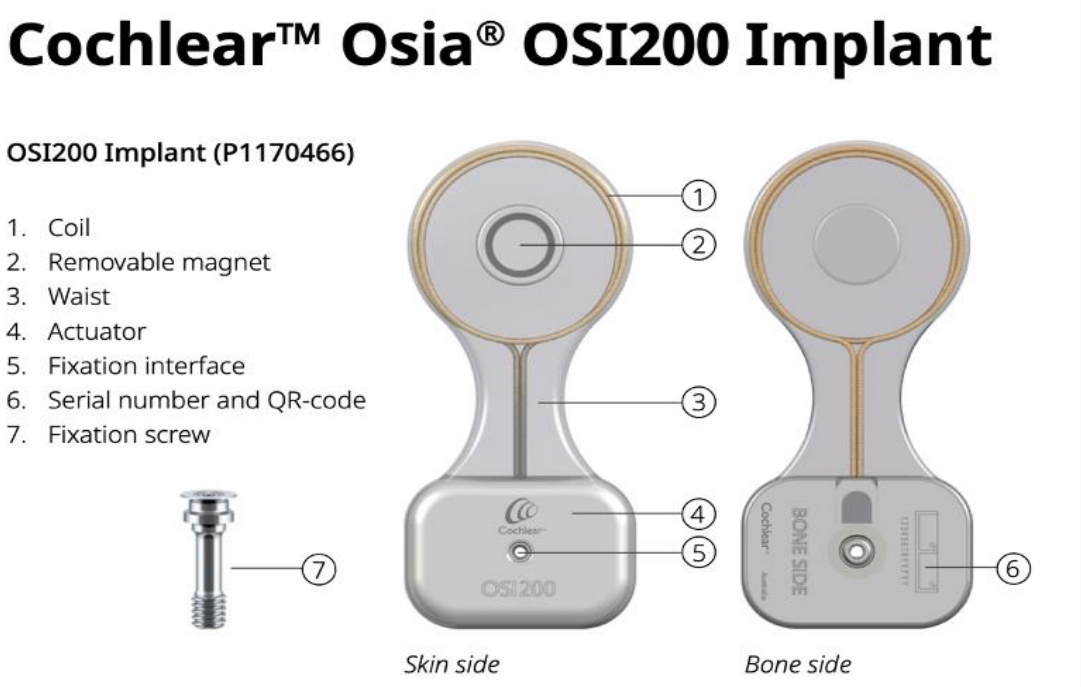


Figure 1-7 Cochlear Osia OSI200 implant (Phyician's Guide OSI200 Implant). [69]

The BI300 Implant is available in 3 mm and 4 mm lengths (Figure 1-8.).

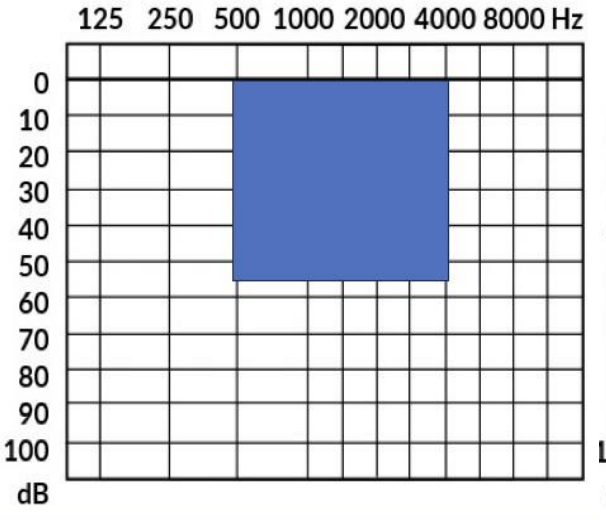
The system is supplied from the manufacture with its compatible instruments and accessories, which include an OSI200 Implant template to ensure an appropriate position of the OSI200 und BI300 implants, a conical guide drill (3-4 mm) and two widening drills (3 mm und 4 mm).

Figure 1-8 Cochlear BI300 implant (user manual).

Audiological Indication Criteria:

The Osia system is indicated for patients with a conductive hearing loss or a mixed hearing loss, provided that the bone conduction hearing thresholds at the main speech frequencies 4PTA (500 Hz, 1 kHz, 2 kHz and 4 kHz) are 55 dB or better. In cases of single sided deafness, the contralateral hearing threshold must be within 20 dBHL [70], [71], [72]. Vibrations are transmitted through the skull bone to the contralateral normal ear; therefore, any hearing impairment of the contralateral side could disrupt this mechanism [73]. Figure 1-9 illustrates the audiological indication criteria.

a) Diseased Ear



b) Contralateral Normal Hearing Ear

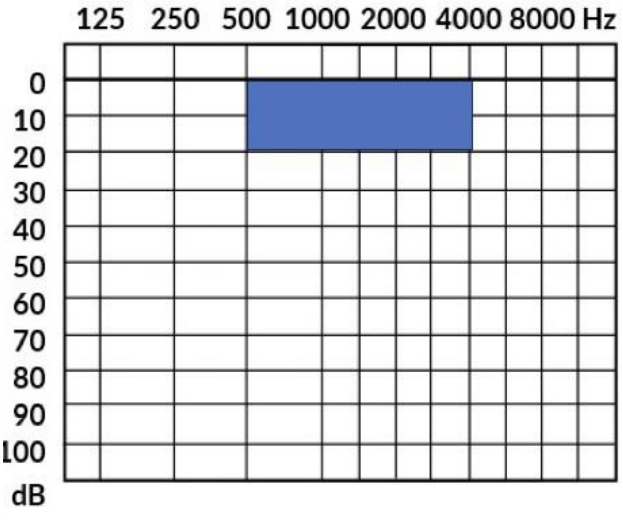


Figure 1-9 Audiological indication criteria include: a) Conductive hearing loss or mixed hearing loss with a maximum inner ear hearing impairment up to 55 dB, b) Single sided deafness with a normal hearing level at the contralateral side. This Figure was adapted from the candidate selection guide for the Cochlear Osia System and designed by the author specific for this study.

1.4 Aim of the Study

The new Cochlear Osia™ system is considered the most recent active transcutaneous bone conduction hearing system in the market. The objective of this work is to present the clinical applications of the Osia system and to evaluate the surgical and audiological outcomes. All subjects included in this retrospective study suffered from a conductive or mixed hearing loss mostly after several previous ear surgeries.

At the department of Otolaryngology, Head and Neck Surgery at Lübeck University, we performed seven surgeries with Osia OSI200 implants, marking the highest number of implants in northern Germany at the time of the study. In this work, we address the necessary preoperative preparation, the surgical procedure, possible risks and complications and the aesthetic outcome. To assess the benefits of this system and its impact on the patient's life, a comparative analysis of audiological values pre- and postoperatively was conducted. In addition, a self-administered survey was utilized to assess changes of various aspects of the patient's quality of life following the intervention.

In summary, this study illuminates the clinical use of the Osia system, its effect on hearing improvement and the patient's self-perceptions of the overall well-being through patient-reported outcomes.

The following questions are addressed in the study:

(1) Which audiological results and outcomes could be obtained in the frequency range of pure tone audiometry (functional gain)?

(2) What is the percentage improvement in speech intelligibility in the free field in quiet and with noise?

(3) Does the hearing-related quality of life (HRQoL) improve after the implantation of the Osia system?

(4) How to assess the direct bone conduction through an active transcutaneous transmission?

(5) What are the possible risks and complications related to the operative procedure that may occur during or after the surgery?

In the following, we would like to discuss our study results in the indications, the surgical procedure and the clinical performance of the new Osia System.

2 Patients and Methods

In this section, we present the study design and course, specific instruments and implant placement guidelines, the audiometric testing methods, the questionnaire inventory and the statistical methods used.

2.1 Study Design

2.1.1 Ethical and Legal Statement

Our study was approved by the Local Ethics Committee at Lübeck University with the registration number: 2023-179_1 and conducted in agreement with the Declaration of Helsinki (2013 version). In addition, an informed consent was obtained from all included patients prior to surgery.

2.1.2 Patients

In 2021 and 2022, 7 Osia OSI200 implantations were performed in 5 adult patients, in which two patients received bilateral implants (n=7). The average age of patients included in the study was 34 years. Patients suffered from mixed and conductive hearing loss after multiple ear surgeries following cholesteatoma. In one case, a percutaneous bone-anchored hearing aid (Ponto, Oticon) had to be removed because of a severe skin reaction. One patient suffered from an external auditory canal atresia with a subsequent conductive hearing loss.

2.1.3 Course of the Study

During the initial visit, a detailed medical history was obtained from all patients. In addition, an exact audiological assessment was performed by all participants. This assessment included: a pure-tone audiometry PTA and a Freiburg speech intelligibility test.

In the postoperative evaluation, unaided and aided bone conduction (BC) at the frequencies 250, 500, 1000, 2000, 3000, 4000 und 6000 Hz and air conduction (AC) thresholds at the frequencies 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz were measured. To determine the speech intelligibility improvement postoperatively, the Freiburg monosyllabic test was performed in free field at 65 dB in quiet and in the presence of a narrow band noise at 60 dB. In addition, patient reported outcomes were collected using validated questionnaires to include the patient's analysis of changes regarding hearing and its impact on the quality of life. Furthermore, we address the specific surgical instruments provided from the manufacturer, the recommended position of the OSI200 implant and the external sound processor.

2.2 Instruments and Optimal Placement Guidelines

Cochlear™ provided various instruments that help with the preparation of the implantation site and the fixation and insertion of both the BI300 and OSI200 implants.

Figure 2-1 Cochlear Osia system [144].

2.2.1 Preparation of Implant Site

According to the manufacturer, the optimal position of the sound processor is at the level or slightly above the superior part of the pinna. This position is intended to ensure an optimal acoustical outcome. In each surgery, two OSI200 implant templates are needed. The first template is used in the non-sterile field to mark the correct site if the OSI200 und BI300 implants on the skin. The second OSI200 implant template is used in the sterile field to check if the pocket size is suitable and ensure the correct the position of the actuator.

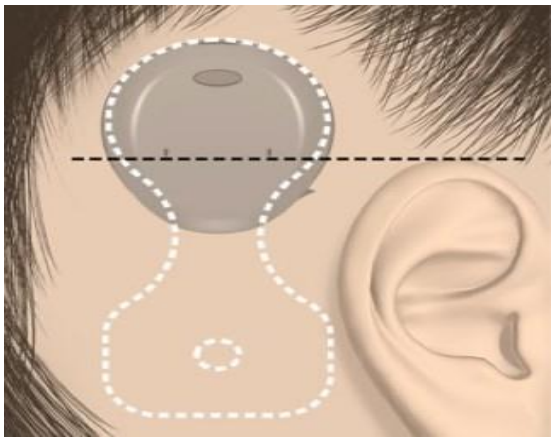


Figure 2-2 Optimal sound processor position.

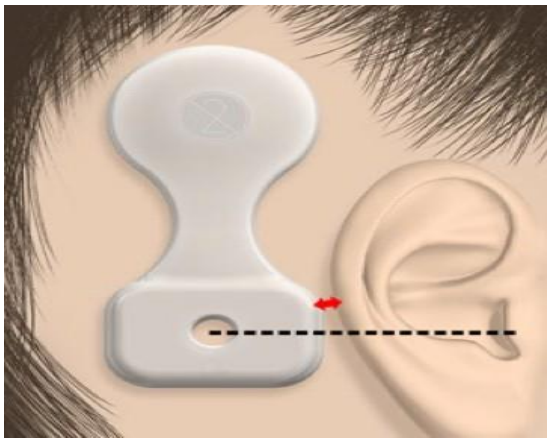


Figure 2-3 Optimal OSI200 implant position.

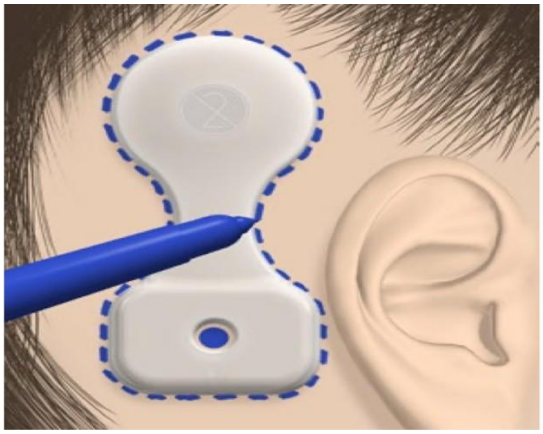


Figure 2-4 Marking of OSI200 und BI300 sites.

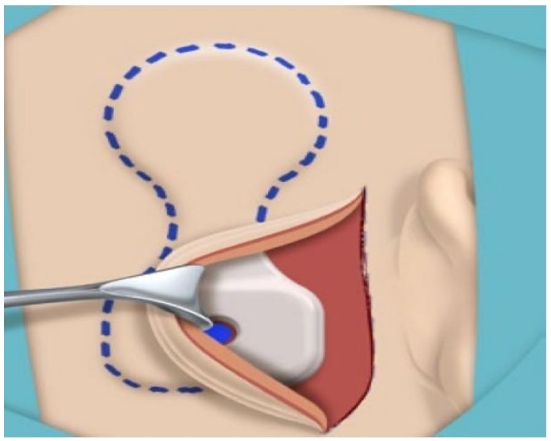


Figure 2-5 Checking the pocket size with OSI200 template.

Source: Physician's Guide OSI200 Implant [68].

2.2.2 BI300 Implant Specific Instruments

For the BI300 implant placement, two types of drills are provided. A conical guide drill with a 3-4 mm spacer which can be used first. Afterwards, the drilling can be continued with the corresponding widening drill (3 or 4 mm) depending on the depth reached with the guide drill. The BI300 implant is picked up and inserted using a specific implant inserter [68].

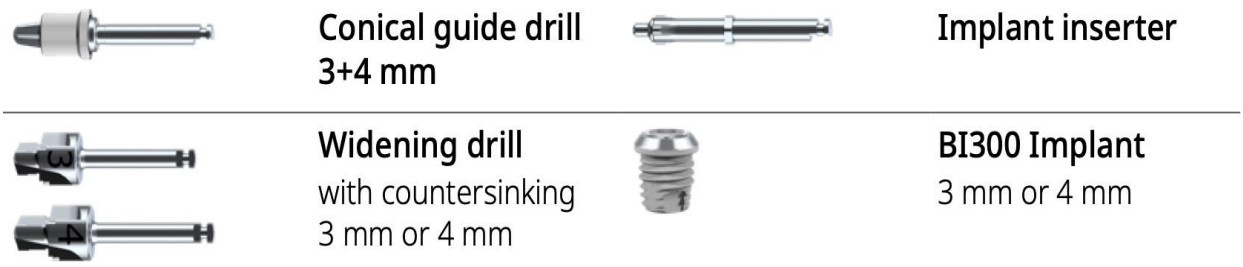


Figure 2-6 shows BI300 implant specific reusable instruments. (Source: Physician's Guide OSI200 Implant) [68]

2.2.3 OSI200 Implant Specific Instruments

A bone bed indicator is provided to check for interfering bone projection. The indicator is placed on the BI300 implant and rotated 360° clockwise. Bone projections should be removed to insure a proper signal transmission between the actuator and the BI300 implant.

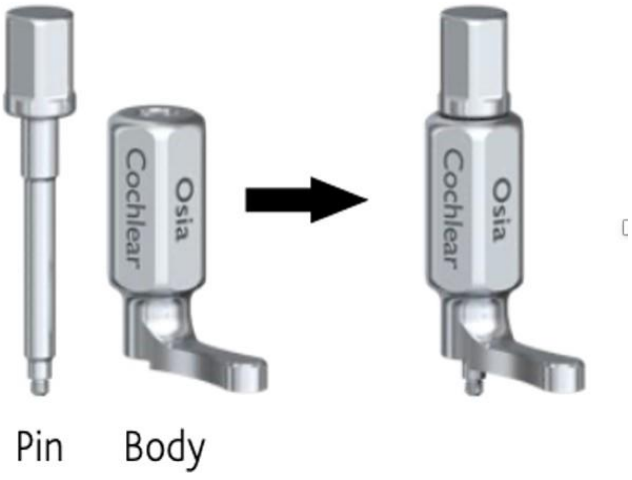


Figure 2-7 Bone bed indicator (17 mm) used to ensure an adequate clearance above bone level. The indicator is delivered in two parts (body and pin) that must be combined before use. Source: Physician's Guide OSI200 Implant [68].

In the OSI200 sterile package, two fixation screws are available, but only one is necessary to fix the OSI200 implant to the BI300 implant. A screwdriver UniGrip 95 mm is used to pick up the fixation screw from the implant blister pack and to screw the fixation screw into the actuator. For the fixation of the actuator on top of the BI300 implant, a machine screwdriver UniGrip 25mm and multi wrench with ISO adapter are needed [68], [74].

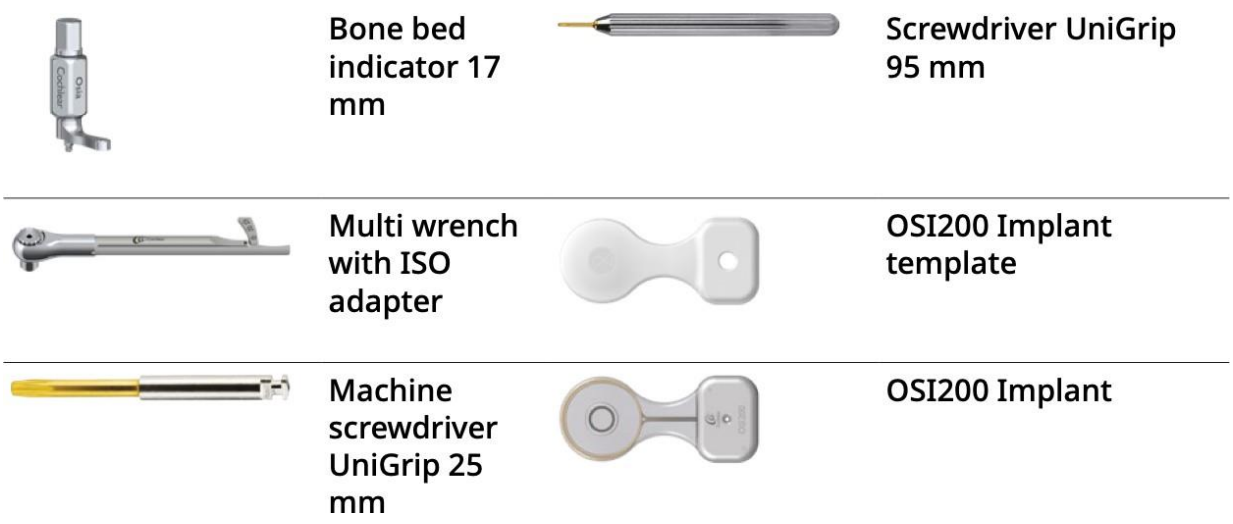


Figure 2-8 shows OSI200 implant specific instruments. Source: Physician's Guide OSI200 Implant [68].

2.3 Audiological Methods

2.3.1 Pure Tone Audiometry (PTA)

A pure tone audiometry was used historically to assess hearing across a range of frequencies, which are important for daily life activities. This method evaluates the severity and the type of hearing loss to assist physicians with determining the differential diagnosis, the prognosis of the condition and eventually planning the treatment strategy [8], [75].

The word 'audiometry' was first used in 1879 by Richardson, and the first audiometry chart was created by the German otologist Arthur Hartmann in 1885, where he plotted left and right tuning fork responses and the percentage of hearing [75]. Since the manufacturing of audiometers in the 1930s, a huge technological progress has occurred. Nevertheless, the fundamental principles have remained unchanged over the last 50+ years. However, there are well known limitations of the pure tone audiometry. It provides no information in cases of involvement of the primary auditory cortex or regarding the auditory processing of real-world signals such as speech and music [8].

The auditory assessment includes testing both the air and bone conductions. In air conduction, the sound travels into the external auditory canal, passing through the tympanic membrane, vibrating the ossicular chain to reach the cochlea. Afterwards, the auditory stimulus will propagate through the cochlear nerve to reach the auditory cortex [11].

The sound can also be transmitted as vibrations in the skull bone and soft tissues that cause the bone around the cochlea to vibrate and result in perception of sound [37].

Both pure tone and speech audiometry were carried out by certified audiometrists, typically in a soundproofed booth to eliminate external sounds. The device used is Auritec AT900 (Auritec GmbH, Hamburg) with its compatible software. The Audiometer generates acoustic stimuli with various frequencies, which are then transmitted to the patient through both air conduction and bone conduction headphones.

Hearing thresholds are measured in decibels Hearing Level (dB_{HL}) and represent the quietest sound at different frequencies that a patient can hear at least 50% of the time [76]. The so-called Hughson-Westlake method is used to test hearing level typically at decreasing intensity in 5- or 10-dB steps until the tone becomes inaudible and then at increasing intensity until becoming audible again [77]. Another way to measure hearing thresholds is the automated, modified Békésy tracking method [77], [78]. Hearing thresholds up to 25 dB are considered normal, however some people would be able to hear lower than 0 dB_{HL} [76].

Hearing levels are tested typically at the following frequencies: 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hertz. This range covers the speech-relevant spectrum, which spans from 500 to 4000 Hertz [79]. It is recommended to start testing at 1000 Hertz, as the patient faces less difficulties recognizing the tones at this frequency. Afterwards, testing will classically take the following sequence: 1000, 2000, 3000, 4000, 6000, 1000 (repeat), 500 and 250 Hz. The measured pure tone thresholds are visualized on an audiogram to facilitate interpretation, in which, the frequencies ranging from 250 to 8000 Hertz are plotted on the X-axis in Hertz, the hearing thresholds are plotted on the Y-axis in decibels Hearing Level [11].

To summarize the audiometric findings, a pure tone audiometry (PTA) is used internationally at the 4 main frequencies 500, 1000, 2000 und 4000 Hertz. Bone conduction and air conduction measurements at these main frequencies are abbreviated as $4PTA_{BC}$ and $4PTA_{AC}$, respectively.

A pure tone audiometry was performed as part of the preliminary examination for the purpose of establishing the indication and usually repeated two days prior to surgery. For the study, both hearing thresholds were considered identical to maintain consistency.

In order to issue a hearing aid prescription, according to the German hearing aid guidelines, the indication must be fulfilled, which includes in cases of a unilateral hearing rehabilitation:

(1) Hearing loss of the worst ear in pure tone audiometry (DIN ISO 8253-1) of at least 30 dB (SPL) at one or more frequencies between 500 and 4000 Hz.
(2) In speech audiometry the speech recognition score (SRS) with headphones (DIN ISO 8253-3) of the worst ear at 65 dB_{HL} should not exceed 80 %.

The same indication applies for the best ear in case of bilateral hearing rehabilitation (Guideline implantable hearing aids 09/2018) [80].

A hearing aid rehabilitation is indicated, if a conventional hearing aid cannot be used, or if a long-term benefit is expected [81], [82].

Some of the common problems faced by patients with a conductive hearing loss using a conventional hearing aid are chronic otitis media, external auditory canal stenosis and chronic otorrhea. An implantable hearing device is also indicated if the conventional hearing aid fails to adequately improve the hearing deficiency, particularly in cases of a conductive or a combined hearing impairment following conditions such as chronic otitis media, cholesteatomas and middle ear surgeries [83].

In addition, a single sided deafness can be also an indication for an implantable hearing system, if the conventional CROS/BiCROS hearing aids don't achieve a sufficient rehabilitation [84].

The type of hearing loss is determined with the air conduction (AC) and bone conduction (BC) thresholds. A sensorineural hearing loss is described if the AC and BC thresholds lie beyond the normal limits, however within 10 dB of each other.
In cases of a conductive hearing, the bone conduction falls within the normal range with an at least 15 dB difference between the AC and BC (air-bone-gap (ABG) [17].

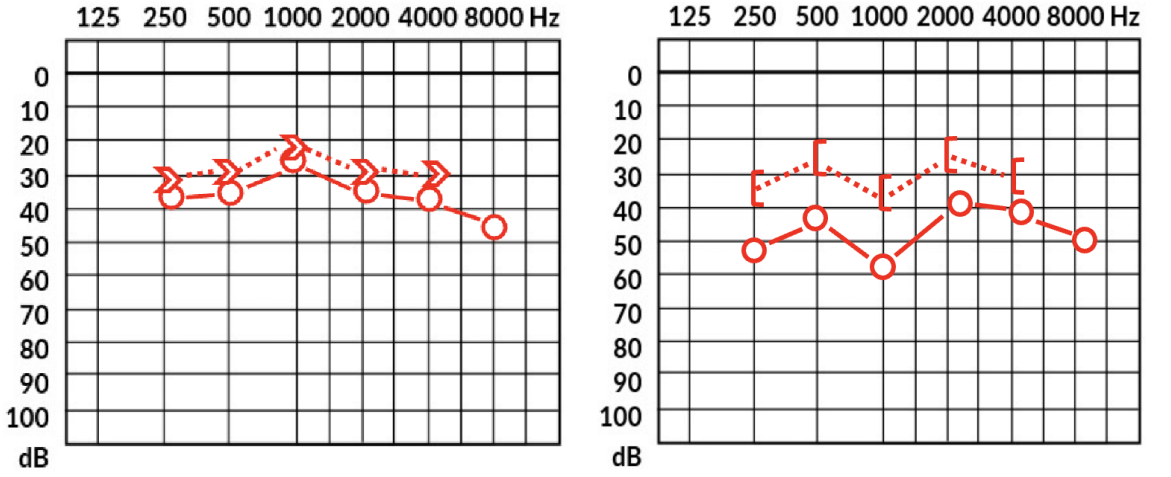
Table 2-1 Audiometric symbols

	Setting	Right	Left
Air Conduction	unmasked		
	masked		
Bone Conduction	unmasked		
	masked		
Free Field Unaided Threshold			
Free Field Aided Threshold			

Source: based on Lehnhardt and Laszig 2009, the table has been customized by the author specific for this study.

Pathologies in the external or middle ear cause an air bone gap (ABG) to various extents. A maximal ABG of 60 dB is seen in cases such as a complete ossicular chain discontinuity or an external auditory canal atresia. These conditions result in a complete blockage of the sound transmission via air conduction [11].

The hearing loss is considered mixed if the configuration of the audiogram includes both conductive and sensorineural impairment components in one or more frequencies [17].



a) Sensorineural hearing loss b) Mixed hearing loss

Figure 2-9 Examples of audiograms. Source: based on Lehnhardt and Laszig 2009, the diagrams have been customized by the author specific for this study.

Applying an acoustic stimulus to one ear with a sufficient intensity may cross to the cochlea of the opposite ear. This signal-crossover to the contralateral side produces false audiometric results [17]. The volume of sound intensity attenuated by crossing from one ear to the other is known as interaural attenuation. To prevent cross-hearing, the non-test ear is masked by applying a noise during the measurement. Clinical masking is required when the difference in hearing thresholds between ears is greater than the interaural attenuation. The interaural attenuation for bone conduction is negligible and assumed to be 0 dB [85]. On the other side, the interaural attenuation for air conduction testing using a supra-aural earphone is 40 dB. Insert-earphones produce greater attenuation between ears with around 55 dB [86].

The necessity for masking must be expected, with certain exceptions, when the difference between hearing thresholds of ears exceeds 50 dB [85]. An over masking may occur when the masking noise crosses back from the non-test ear to the test ear. Ralph F Naunton was the first to describe this phenomenon, which has since been known as ‘Naunton's masking dilemma’ [87].

The postoperative measurement of aided hearing thresholds was conducted in the free sound field (FF). The audiometric thresholds were measured using frequency-modulated tones, known as warble tones. Warble tones help to minimize the interference caused by steady waves in the testing room, allowing more reliable measurements [88].

The measurement of functional gain is calculated as the difference between aided and unaided thresholds at each specific frequency and is defined as the relative decibel difference [89], [90]. The calculated functional gain at the pure tone average frequencies (500, 1000, 2000 und 4000 Hz) is abbreviated as $4PTA_{FG}$.

2.3.2 Speech Audiometry

The most frustrating outcome of hearing loss is the loss of speech recognition, which has a direct impact on the quality of life. While a pure tone audiometry examines hearing ability of pure tones, the speech audiometry assesses speech intelligibility and discrimination and determines the qualitative perception of spoken words by the patient in a real-world environment. Besides, it plays an important role during the hearing aid fitting. Other useful applications are the diagnosis of peripheral and central hearing disorders and the evaluation of a certain surgical procedure by comparing pre- and post-operative results. Together with the pure tone audiogram, the speech audiometry forms the backbone of the audiological examination [91].

The testing is performed in a sound-proof booth with recorded word lists presented to the patient at different intensities via headphones or loudspeakers. The use of headphones allows for separate examination of each side and masking the non-test ear. The word lists are presented usually at 20 to 30 dB greater than the pure-tone average for the frequencies 500, 1000, 2000, and 4000 Hz. Afterwards, the sound volume is changed to +10, +20, -10 and -20 dB or more from this level [91].

The speech audiometry tests usually used in clinical practice are the speech detection threshold (SDT), the speech recognition threshold (SRT) and the word recognition score (WRS). Threshold tests confirm the pure tone audiometry thresholds and determine the speech detection threshold (SDT), also known as speech reception threshold, which corresponds to the level at which speech is audible to a person in 50% of cases. The SDT employs threshold tests to confirm hearing thresholds obtained with the pure tone audiometry. The speech recognition threshold (SRT), also known as the speech perception threshold, is the lowest hearing level at which an individual can recognize and correctly repeat 50% of the speech material, typically involving disyllabic words. The word recognition score (WRS) is the percentage of words correctly repeated by the patient. A list of monosyllabic words is presented to the patient at the speech recognition threshold + 30 dB_{HL} (supra-threshold speech perception). The percentage of correctly repeated words is referred to as the discrimination score, while the percentage of incorrectly repeated words is termed the discrimination loss [92], [93].

The Freiburg intelligibility speech test is one of the most used speech tests in German-speaking countries. According to DIN 45621, the test was introduced 70 years ago by Hahlbrock in 1953 [94]. It has been used primarily to determine the speech perception threshold (based on two-digit numbers) and the ability to discriminate speech at suprathreshold presentation levels (based on monosyllabic nouns) [95].

The speech material was presented to the patient through both headphones and loudspeakers, with the patient asked to repeat afterward. The maximum speech recognition score (SRS) was obtained prior to surgery. It's defined as the subject's maximum score, no matter how loud the volume is turned up [91]. The usual used words are numerical words (polysyllable) and monosyllabic nouns. The numerical words are generally easier to understand. A healthy individual can correctly hear all numbers at a volume of approximately 30 dB and monosyllables at a volume of 50 dB [11]. The word recognition score was tested with a sound intensity at 65 dB_{HL} in quiet and in the presence of narrow band noise at 60 dB_{SPL}, applied to the patient via a loudspeaker. Both the speech material (S) and the noise (N) were presented from a loudspeaker positioned 1 meter in front of the patient at an angle of 0° (S0N0). Masking was applied using a headphone to prevent cross-hearing through the non-test ear. The results of the Freiburg intelligibility speech test were compared in free field before surgery (unaided) and after surgery (aided with Osia). The test played an important role in fulfilling the diagnostic criteria and indicating the need for hearing implants.

As mentioned earlier, the word recognition score should not exceed 80% at 65 dB_H in order to prescribe a hearing aid or hearing implant, following the German guidelines (DIN ISO 8253-3).

The test results are plotted on a graph (Figure 2-10), illustrating the percentage of speech discrimination (WRS) on the y-axis in response to the corresponding acoustic intensity on the x-axis. Hearing disorders determine the shape of the graph. A normal hearing ear produces a sigmoid-shaped curve with a steep near-vertical portion in the middle. In a conductive hearing loss, the curve is parallel to that of a normal ear but shifted to the right. A sensorineural hearing loss diminishes speech discrimination and consequently the maximum speech recognition score. The gradient of the middle portion of the curve is often less and a plateau is reached regardless of increase in the sound presentation level 'plateau effect'. In a retrocochlear lesion, the speech recognition improves with intensity increase up to a point, after which speech recognition deteriorates with further increase in the intensity, which is called 'rollover' [11], [91], [92], [93].

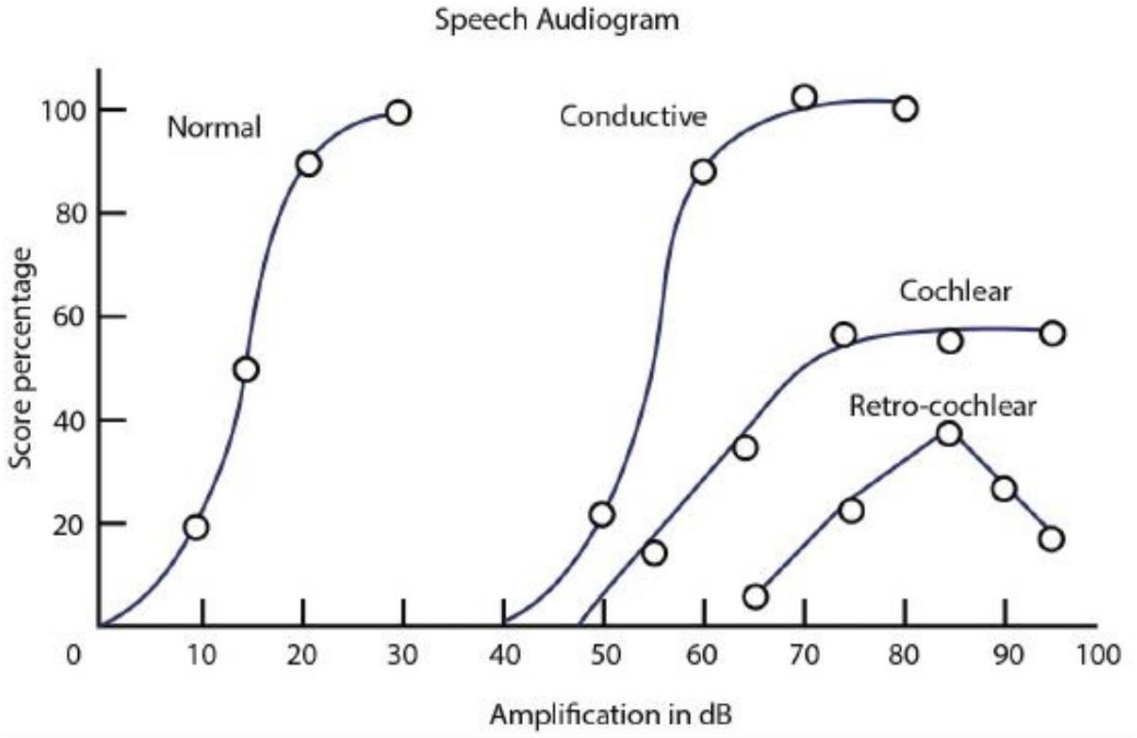


Figure 2-10 Examples of speech audiometry curves, the speech audiometry in a conductive hearing loss is shifted to the right, the maximum SRS is still 100% as discrimination is preserved (0% discrimination loss). A cochlear pathology usually shows a plateau effect, with a maximum SRS below 100% despite a rise in intensity. A retrocochlear pathology demonstrates a phenomenon called 'rollover', in which the speech recognition decreases as intensity increases. Source: Figure adapted from Key Topics in Otolaryngology by Nick et al., 2019 [91].

2.4 Patient Reported Outcomes

The Glasgow Benefit Inventory (GBI) was conducted to allow a subjective evaluation of hearing development and its impact on the quality of life. This questionnaire was completed by patients and used in the statistical analysis.

Glasglow Benefit Inventory (GBI)

The Glasgow Benefit Inventory is an 18-item questionnaire developed especially for the otorhinolaryngological (Orl) interventions to measure the patient benefit and the change in health status [96]. The original GBI was developed in 1996 to be patient-oriented and to register and compare changes in health status, whether positive or negative [96], [97].

In the first publication in 1996, Robinson and his colleagues implemented the GBI in five otorhinolaryngological interventions retrospectively: middle ear surgeries to improve hearing, tonsillectomy, rhinoplasty, provision of a cochlear implant and middle ear surgery to eradicate ear activity [96].

The GBI has gained since then a huge popularity in Otorhinolaryngology [97], [98]. Hendry et al. published in 2015 a systematic review of 117 reports regarding the use and value of GBI to address impact on health and quality of life after interventions [98]. Since the original report, there have been numerous publications assessing the patient benefit using the GBI, not only postoperatively, but also for non-surgical interventions. For example: after endoscopic sinus surgery [99], [100], bone anchored hearing aids [101], [102], [103], [104], [105], [106] and cochlear implants [107], [108]. Some authors conducted retrospective studies that used the GBI in medically managed Meniere's disease [109] or in patients after a sialendoscopy [110], [111].

The GBI is divided into three different subscales: twelve questions dealing with the general changes in health status including the psychosocial aspects. Three questions address social support, the remaining three questions address changes in physical health status including the need to take any medications and the number of doctor visits or consultations after the intervention [98].

Each question has five different possible answers. The questions are answered using a 5-point Likert scale ranging from a marked deterioration (1 point) to a large improvement (5 points) in health status. To avoid a response bias, half the questions are graded from a large deterioration to a large improvement and the other half is sorted in the other order.

For the evaluation, the mean score of each group is subtracted by 3 and multiplied by 50. The obtained value ranges from -100, which projects a maximum worsening of overall health status, to +100 by maximal improvement after intervention [96], [97].

2.5 Statistical Methods

A biometric consultation was conducted at the Institute of Medical Biometry and Statistics to assist in choosing the appropriate method for data presentation. The statistical calculations and analysis were performed using the statistical programs IBM SPSS Statistics 29.
A one-sample t-test was used for the purpose of the comparison within the groups, and to determine whether the differences between them are statistically significant. A repeated measures ANOVA was implemented to compare the means of more than two groups and determine whether these means are statistically different from each other. Results with P-values lower than 0.05 were considered statistically significant. The mean values of the calculated data are provided with their corresponding standard deviation.

3 Results

3.1 Patient Demographic Data

In 2021 and 2022, 7 Osia implantations were performed in 5 adults, 2 patients received bilateral implants. The mean age of patients at the time of implantation was 34 (SD ±13,7) years. The youngest patient had the surgery at the age of 17 years, the oldest at the age of 52 years (Tab. 3-1).

With respect to etiology of hearing loss, four ears suffered from a conductive hearing loss (CHL) after multiple ear surgeries following cholesteatoma, three ears suffered from a mixed hearing loss (MHL). Figure 3-1 summarizes the etiology by the subjects included in the study.

A bilateral hearing loss was present by the youngest patient since birth. In one case, a percutaneous bone-anchored hearing aid (Ponto, Oticon) had to be removed because of a severe skin reaction. One patient suffered from an external auditory canal atresia with a subsequent conductive hearing loss.

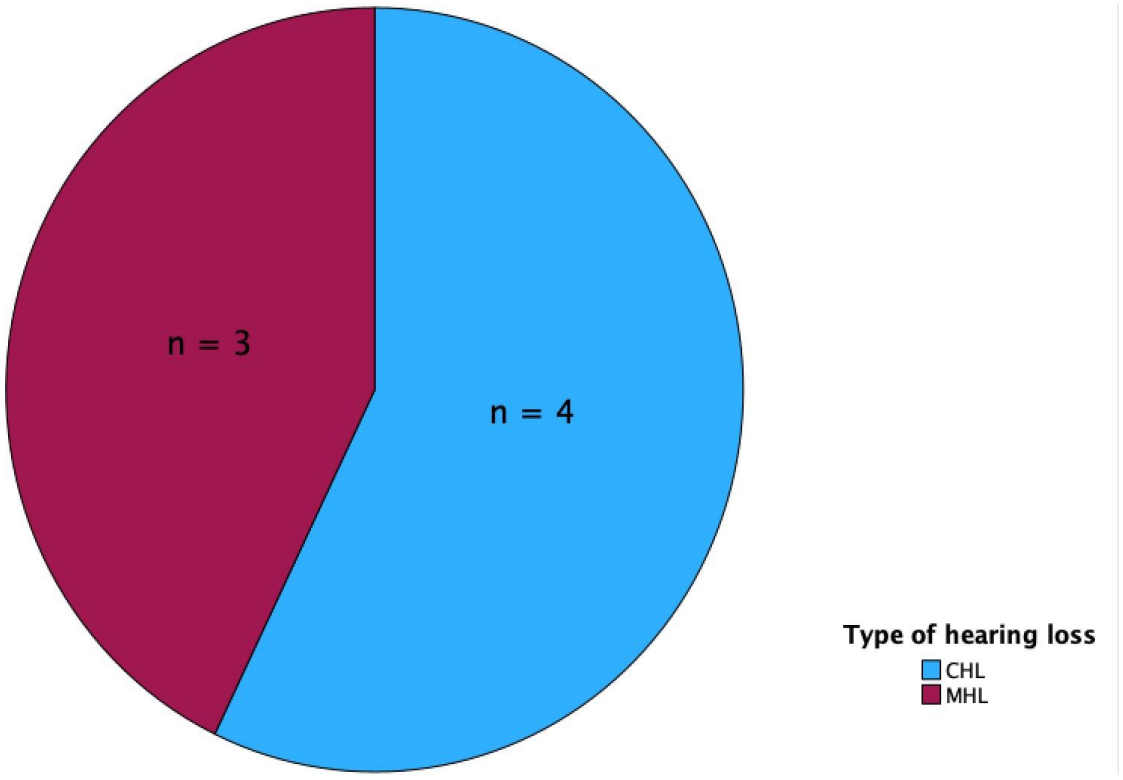


Figure 3-1 Type of hearing loss.

Table 3-1 Age of patient at time of implantation

	N	Minimum	Maximum	Mean	Std. Deviation
Age of patient at time of implantation	7	17	52	33,57	12,765
Valid N (listwise)	7				

3.2 Surgery

3.2.1 Preoperative Preparation

A thoughtful preoperative preparation is necessary to assess the feasibility of the procedure and to ensure its compatibility to the clinical condition. This assessment aims to predict the best possible auditory outcome and reduce surgery-related morbidities.

In all subjects, a high-resolution cranial CT scan was readily available due to prior ear conditions, mostly cholesteatomas. This allowed a meticulous evaluation of the petrous bone status and plan the position and dimension of the implant. Important adjacent structures such as the internal carotid artery, the sigmoid sinus, the course of the facial nerve, and the external auditory meatus were considered.

A proper assessment of the bone condition plays an important role in cases with previous ear surgeries such as a radical mastoidectomy. In this regard, the measurement of bone thickness is significant at the level of BI300 implant/ transducer. The skin flap thickness should be kept at or less than 9 mm to ensure a good magnet retention of the external sound processor.

3.2.2 Surgical Procedure

After obtaining an informed consent from the patients, all surgeries were conducted under general anesthesia following the instructions provided by the manufacturer of the device. The surgery time varies between 42 and 101 minutes for the unilateral Osia implantation and 135 minutes for the bilateral implantation.

At first, a surgical marking pen and a caliper were used to mark the preauricular incision site. The location of the OSI200 Implant was marked by using the template provided from the manufacturer. To mark the location of the BI300 implant on the bone following the manufacturer's instructions, a needle with a marketing ink ''methylene blue'' was inserted through the hole of the actuator area of the OSI200 template down to the bone. The soft tissue thickness was measured using a thin hypodermic needle, a skin thinning was not necessary in all cases (Figure 3-2).

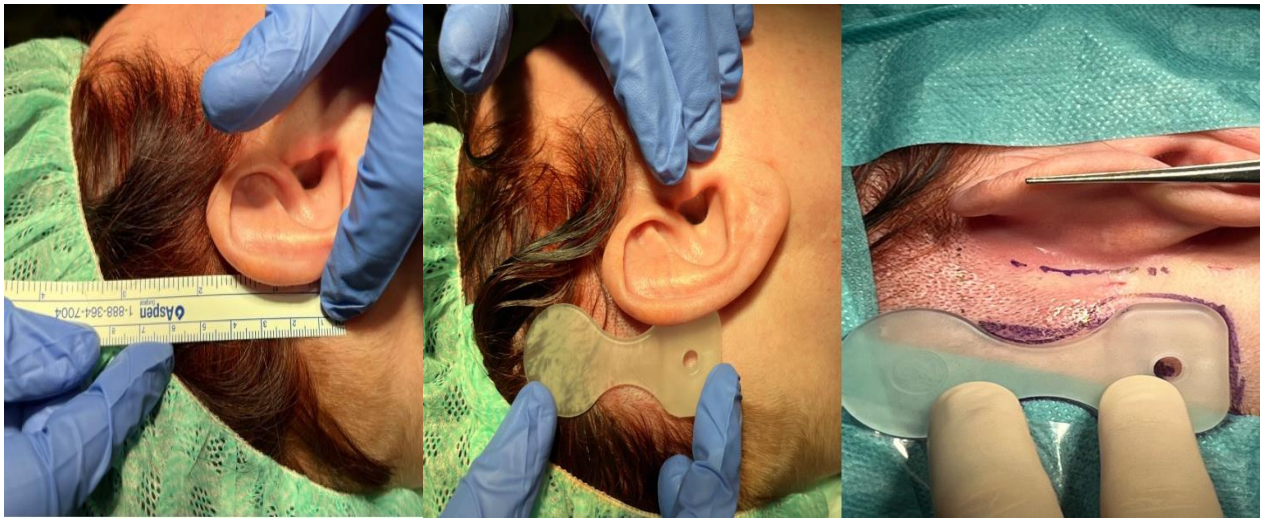


Figure 3-2 Planning the postauricular incision and the position of the OSI200 implant. A sterile template was used to mark the position of the OSI200 implant. Approximately 1 cm was kept between the incision and the edge of the implant according to standard recommendations. The skin and pericranial incisions should not be overlapped. Source: ENT Department UKSH Lübeck.

Before making the incision, a local anesthetic agent with epinephrine was applied at the marked incision line. A retroauricular C-formed incision was performed parallel to the helical rim. As suggested by the manufacturer, a 10-15 mm distance between the incision and the edge of the implant was kept reducing the tension on the skin. The incision cuts through all layers followed by a subperiosteal dissection. A periosteal flap was raised posteriorly to create a coil pocket. To plan the optimal implant position, a sterile template was inserted to check the pocket size (Figure 3-3).

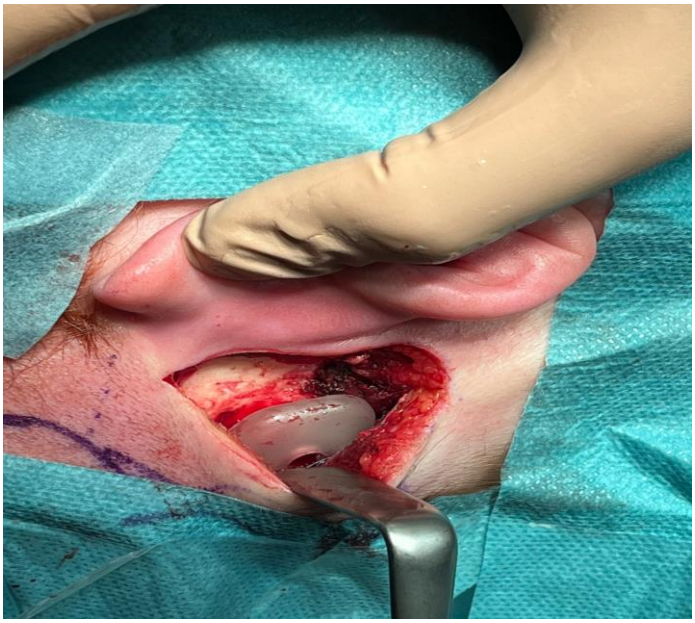


Figure 3-3 Showing a postauricular incision with a large posterior periosteal flap. The periosteal flap is raised with a retractor to ensure an adequate bone surface for seating the OSI200 implant. The sterile template is inserted to check the pocket size. Source: ENT Department UKSH Lübeck.

An optimal position of the OSI200 implant was taken into consideration, according to the manufacturer, the actuator should be close to and in horizontal line with the ear canal or slightly superior, without contact to the pinna.

In most cases, an implant well of 3-4 mm in the bone was prepared to lower the implant in the bone bed. Drilling started at the middle of the planned position for the floating mass transducer. Next, a conical guide drill with a 3mm spacer was used at 2000 rpm perpendicular to the bone surface, with an adequate bone thickness, the drilling was continued with the wider spacer (4mm) to reach a depth of 4 mm, followed eventually with the widening drill. The drilling was carried out in a perpendicular manner with a continuous irrigation and cooling of the bone (Figure 3-4).

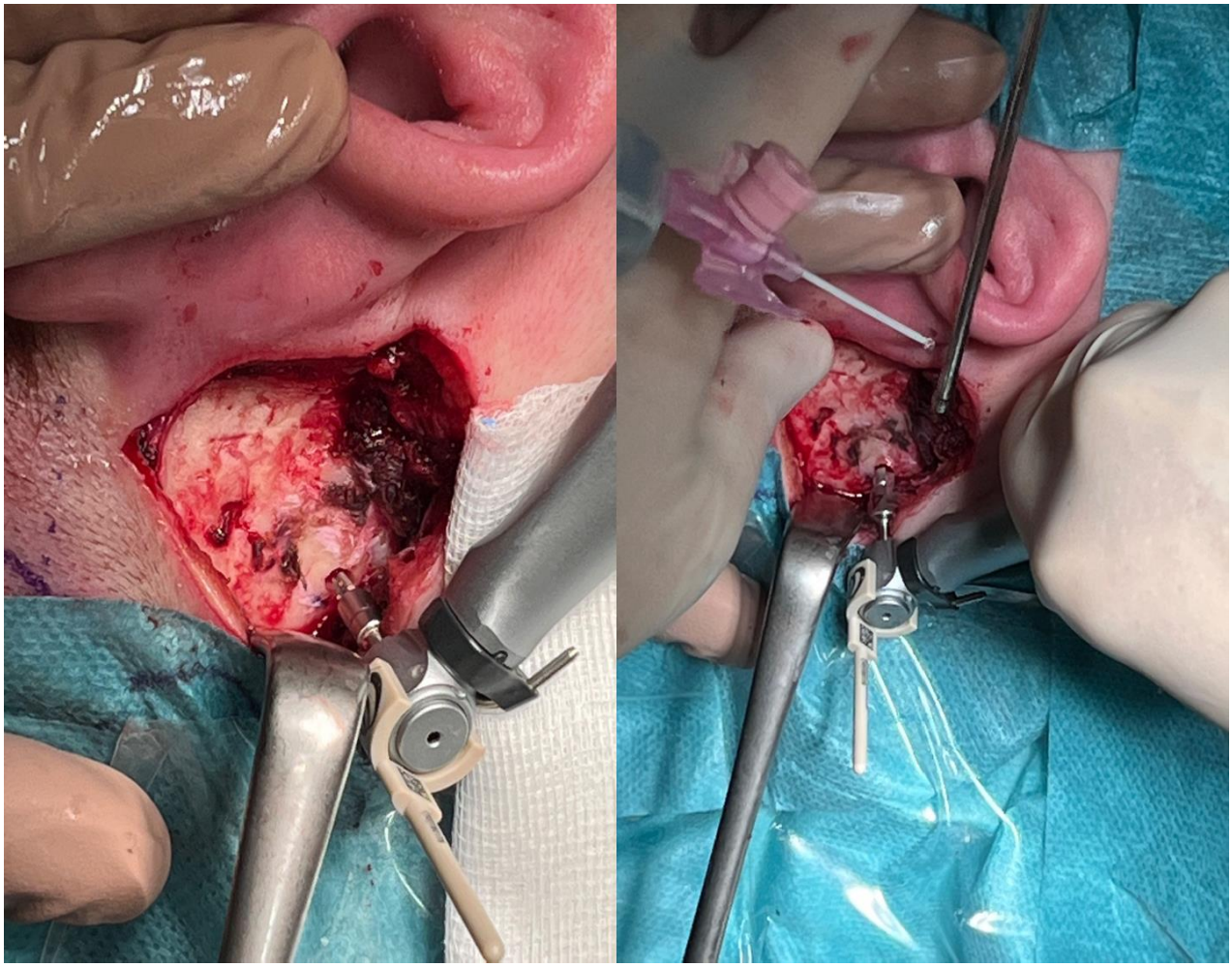


Figure 3-4 Sequential drilling procedure demonstrating guide drill use with the spacer being removed (left), followed by widening drill to 4 mm depth (right). Source: ENT Department UKSH Lübeck.

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In all cases, a transmastoid approach was chosen, where the BI300 implant was inserted in the sinodural angle. The insertion and fixation of the BI300 implant was performed with a torque wrench limited to 20-30 Ncm (Figure 3-5). The surface of the actuator site was evaluated using the bone bed indicator (Figure 2-7). Bone projections were removed with the drill to ensure a correct mounting of the OSI200 implant, which is essential for a good transmission. Figures 2-6 and 2-8 show the instruments used for inserting und fixing the implants. Afterwards, the OSI200 implant was inserted into the subperiosteal pocket, the actuator was fixated on top of the BI300 implant with a screwdriver UniGrip 25mm with a maximal torque of 25 Ncm (Figure 3-6).

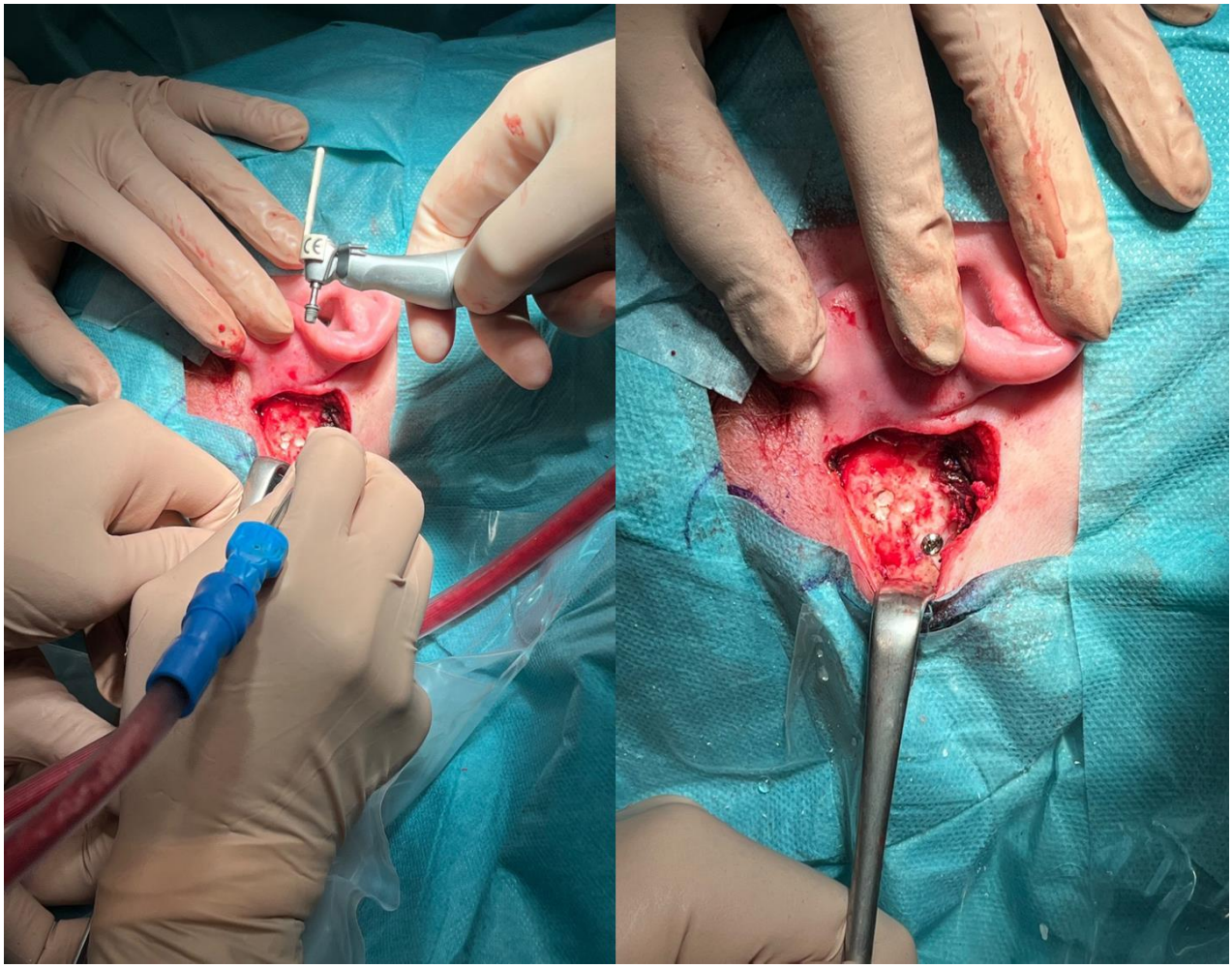

Figure 3-5 Showing the placement of the BI300 implant. Source: ENT Department UKSH Lübeck.

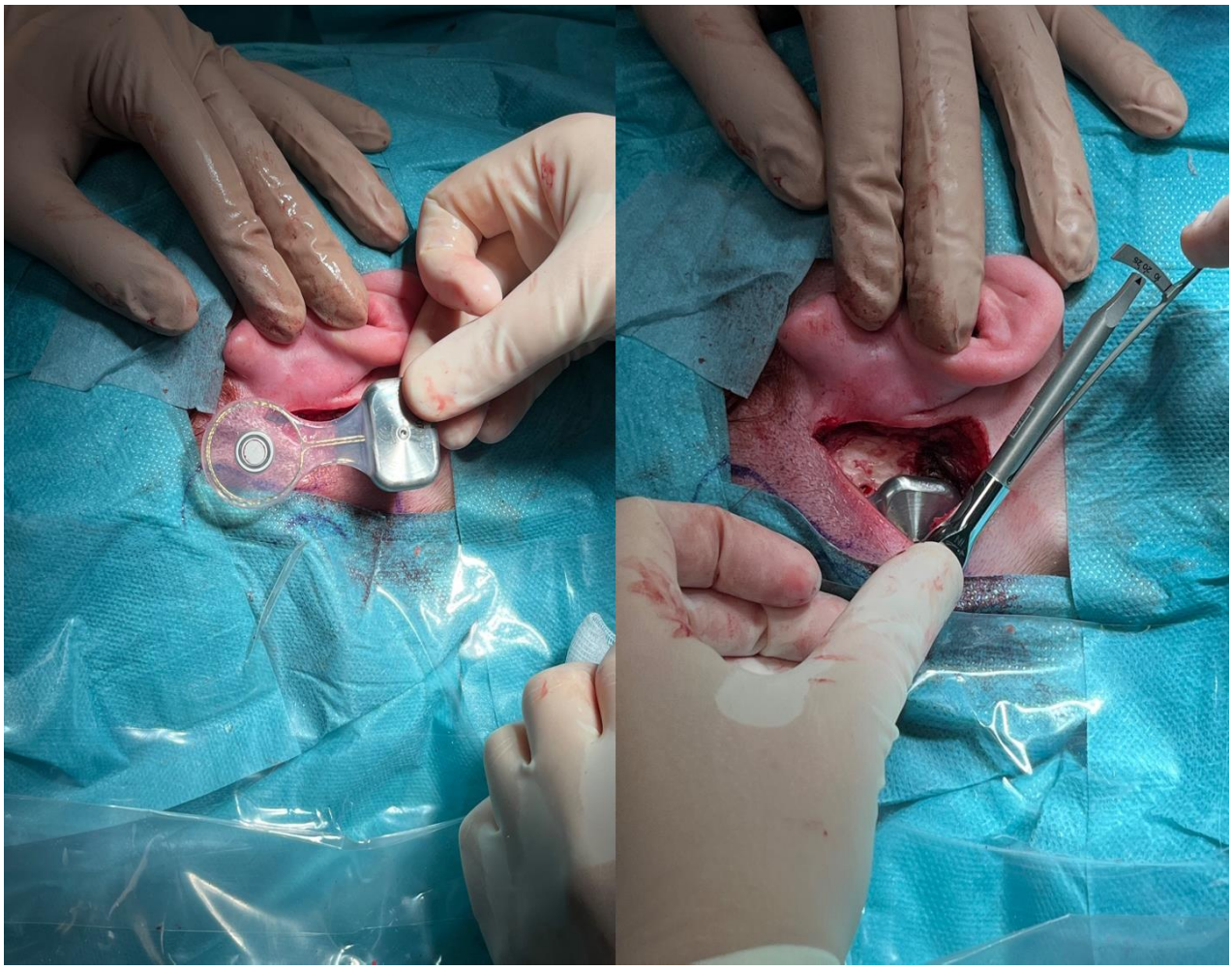

Figure 3-6 Showing placing the OSI200 implant. The center of the actuator is fixed to the BI300 implant with a screwdriver UniGrip 25 mm manually at 25 Ncm torque. Source: ENT Department UKSH Lübeck.

Finally, the closure of the skin and soft tissues over the implant was performed in two separate layers with resorbable and non-resorbable sutures (Figure 3-7). All wounds were dressed with a circular head bandage to avoid hematoma.

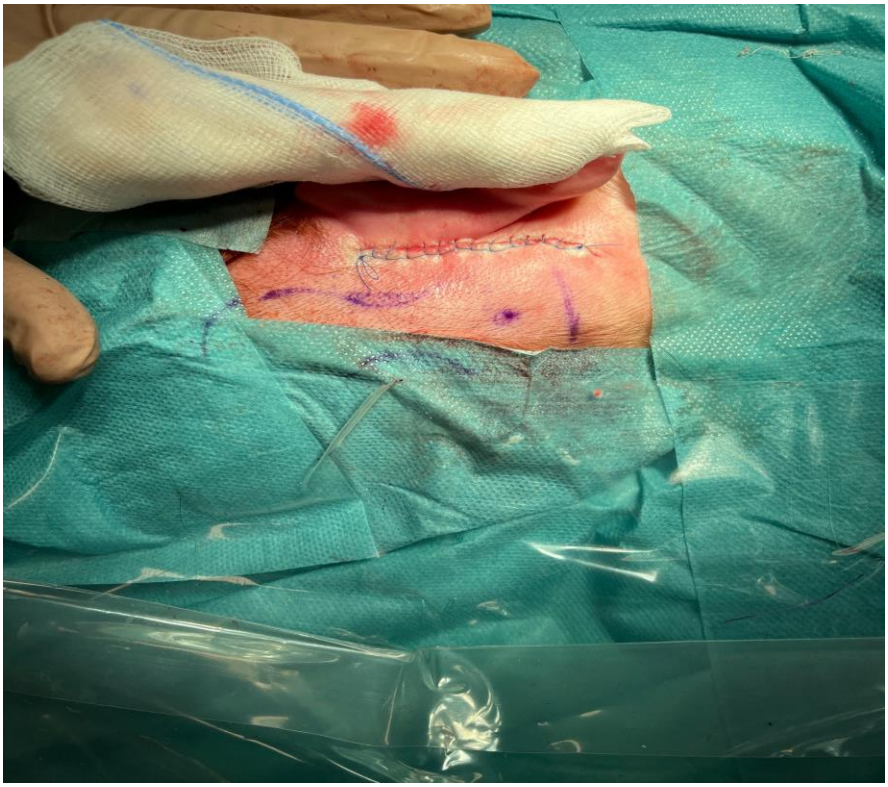

Figure 3-7 Showing closure of the skin with a continuous locking non-absorbable suture. Source: ENT Department UKSH Lübeck.

3.2.3 Post-Operative Management

All patients were monitored postoperatively in the intermediate care unit and were released after a hospital stay of 3-4 days without postoperative complications. The sutures were removed between the 10th and 14th day postoperatively. A presentation at our outpatient clinic was scheduled for the activation of the device around the 4th week after surgery.

The patient follow-ups in our outpatient clinic were arranged at 1m, 3m, 6m, 9m and 12m after activation. Unfortunately, not all patients attended the scheduled visits. During the follow ups, aided hearing thresholds were tested with Pure Tone Audiometry (PTA) and Freiburg intelligibility speech test in quiet and with noise.

3.2.4 Surgical Outcome

The aesthetic result was convenient for all patients. All surgeries were successful, no postoperative complications including wound healing problems were reported. Performing an implant well reduced the protrusion caused by the transducer significantly. A skin reduction was not necessary in any case. In one case, a technical problem with the sound processor was recorded which was resolved by visiting the hearing-aid acoustician.

3.3 Audiological Outcomes

In the following, we present the audiological outcomes after surgery which are measured subjectively using the pure tone (PTA) and the speech audiometry.

The following nomenclature is used for the audiological data: hearing thresholds in bone conduction (BC) and air conduction (AC) were demonstrated at 0.5, 1, 2 und 4 kHz (4PTA). These represent the four main frequencies in the international literature. Measurements of bone conduction and air conduction hearing thresholds at these frequencies are abbreviated as $4PTA_{BC}$ and $4PTA_{AC}$ respectively.

The audiological functional gain (FG) was calculated as the difference between the average free-field warble-tone thresholds with Osia and the preoperative unaided air conduction hearing thresholds. The functional gain at the main speech frequencies is abbreviated as $4PTA_{FG.}$

The difference between air conduction and bone conduction audiometric thresholds is known as air-bone-gap ($4PTA_{ABG}$). A significant air-bone-gap indicates the presence of a conductive hearing pathology.

3.3.1 Pure Tone Audiometry

By the audiological assessment, the bone conduction (BC) was a representative for the inner ear function. On the other hand, the air conduction (AC) reflected the efficiency of the external auditory canal and the middle ear. A mixed hearing loss was detected by impairment of both methods of sound conduction.

The measurements were obtained at 0.25, 0.5, 1, 2, 4 and 6 kHz, however the findings at the most relevant frequencies for speech discrimination (4PTA) are demonstrated next in this section.

The following values represent the bone conduction measurements pre- and postoperatively (Figure 3-8):

The pure inner ear performance was reflected through the measured bone conduction preoperatively and showed a mean hearing threshold $4PTA_{BC}$ of 14.9 ± 12.2 dB_{HL} (500 Hz 21.4 ± 14.9 dB_{HL}, 1 kHz 10.7 ± 7.3 dB_{HL}, 2 kHz 22.9 ± 7.6 dB_{HL}, and 4kHz 20 ± 9.6 dB_{HL}).

The bone conduction was also measured postoperatively and showed a mean hearing threshold $4PTA_{BC}$ of 13.6 ± 12.7 dB_{HL} (500 Hz 12.9 ± 5.7 dB_{HL}, 1 kHz 12.1 ± 10.4 dB_{HL}, 2 kHz 25.7 ± 17.2 dB_{HL}, and 4 kHz 19.3 ± 11.3 dB_{HL}).

The difference between the two bone conduction measurements $4PTA_{BC\text{-}Diff}$ was 0.8 ± 10.6 dB_{HL} (500 Hz -8.6 ± 15.2 dB_{HL}, 1 kHz 1.43 ± 13.76 dB_{HL}, 2 kHz 2.86 ± 17.0 dB_{HL} and 4 kHz -0.71 ± 6.7 dB_{HL}). The post operative mean bone conduction values showed no significant difference to the preoperative mean bone conduction values. A repeated-measures ANOVA was conducted to compare bone conduction hearing thresholds before and after surgery at various frequencies. The statistical analysis revealed no significant difference between the two conditions ($F(1,42) = 0.285$, $p > .05$). The safety of this procedure is documented by the absence of significant bone conduction difference, with a value less than 1 dB ($p = 0.596$), when comparing pre- and postoperative measurements.

In table 3-2, the mean preoperative and postoperative bone conduction measurements are shown at different frequencies with its corresponding standard deviation.

Table 3-2 Measurements of preoperative and postoperative bone conduction at different frequencies

Frequencies	preoperative BC		postoperative BC		F	p-value
	Mean	SD	Mean	SD		
250	6.43	3.78	7.86	6.365		
500	21.43	14.92	12.86	5.67		
1000	10.71	7.32	12.14	10.35		
2000	22.86	7.56	25.71	17.18	0.285	0.596
4000	20.00	9.57	19.29	11.34		
6000	19.29	14.56	17.14	14.10		

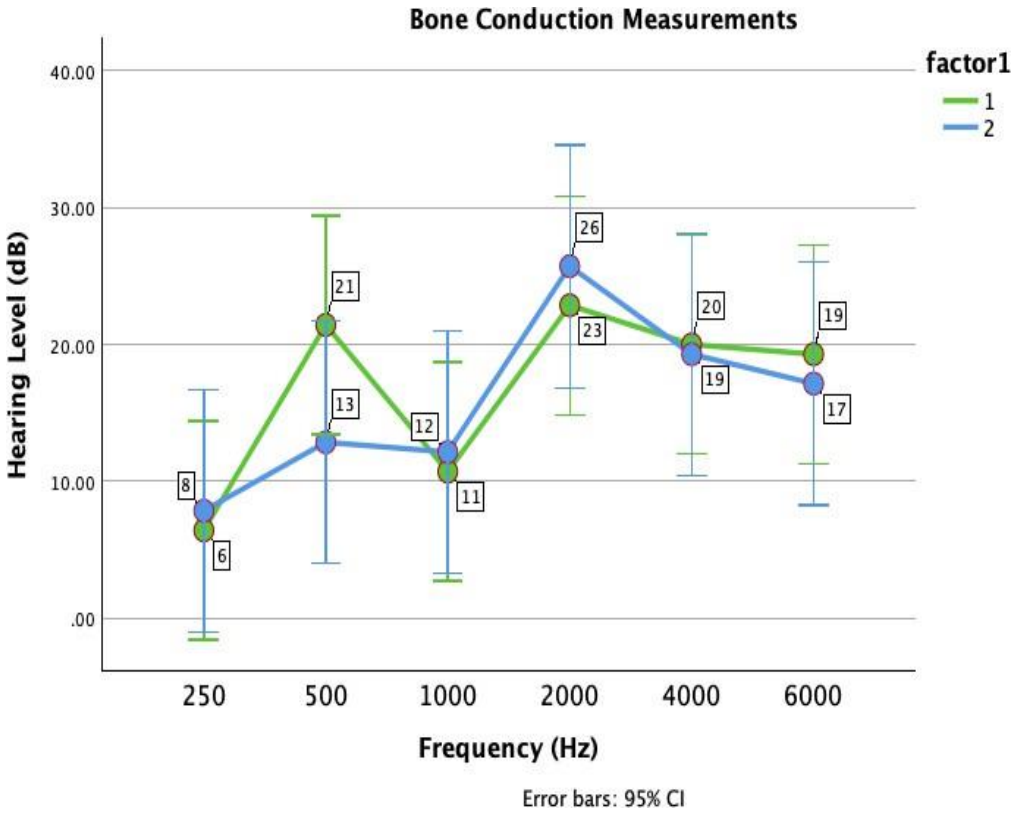

Figure 3-8 Bone conduction measurements. Mean preoperative (green) and postoperative (blue) bone conduction hearing thresholds; the mean values are shown ± standard deviation.

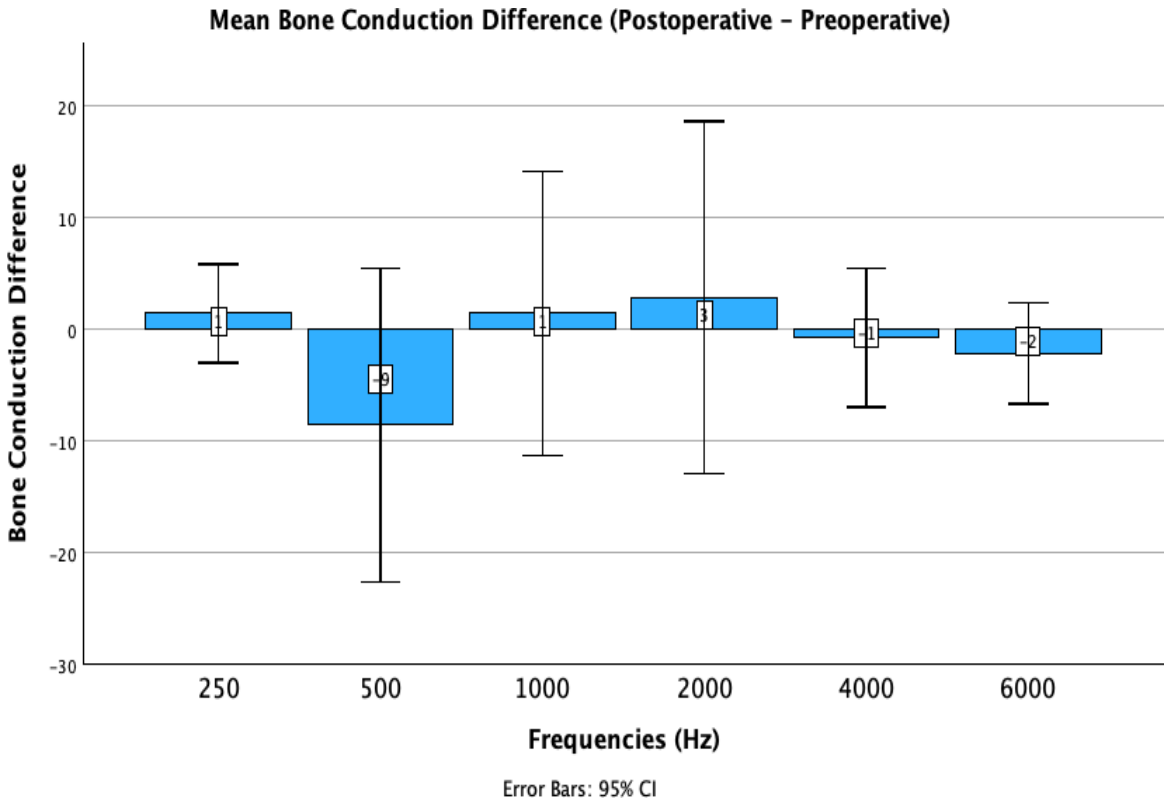

Figure 3-9 Bone conduction differences are measured by subtracting the preoperative bone conduction threshold values from the postoperative values. The mean values are shown with the standard deviation at each frequency.

The bone conduction difference represents the change in bone conduction thresholds postoperatively compared to preoperatively. Negative values indicate a positive change in bone conduction hearing thresholds after surgery, while positive values indicate a negative change. However, the sign convention of the values is negligible in this context, as no impact of the device on the bone conduction is expected after surgery. The values represent the absolute change in bone conduction rather than addressing improvement or deterioration in the bone conduction (Figure 3-9).

The following values represent the air conduction measurements:
The pure tone audiometry registered a preoperative air conduction mean threshold $4PTA_{AC}$ 66.3 ± 16.4 dB_{HL} (500 Hz 65.7 ± 18.4 dB_{HL}; 1 kHz 53.6 ± 14.1 dB_{HL}; 2 kHz 58.6 ± 11.4 dB_{HL} and 4kHz 65.7 ± 15.9 dB_{HL}).

A postoperative measurement of air conduction is meaningless, as no change in the audiometric thresholds is suspected. Such changes or rather improvements could be seen in middle ear surgeries. Figure 3-10 shows the mean preoperative bone and air conduction hearing thresholds with the corresponding standard deviation at various frequencies.

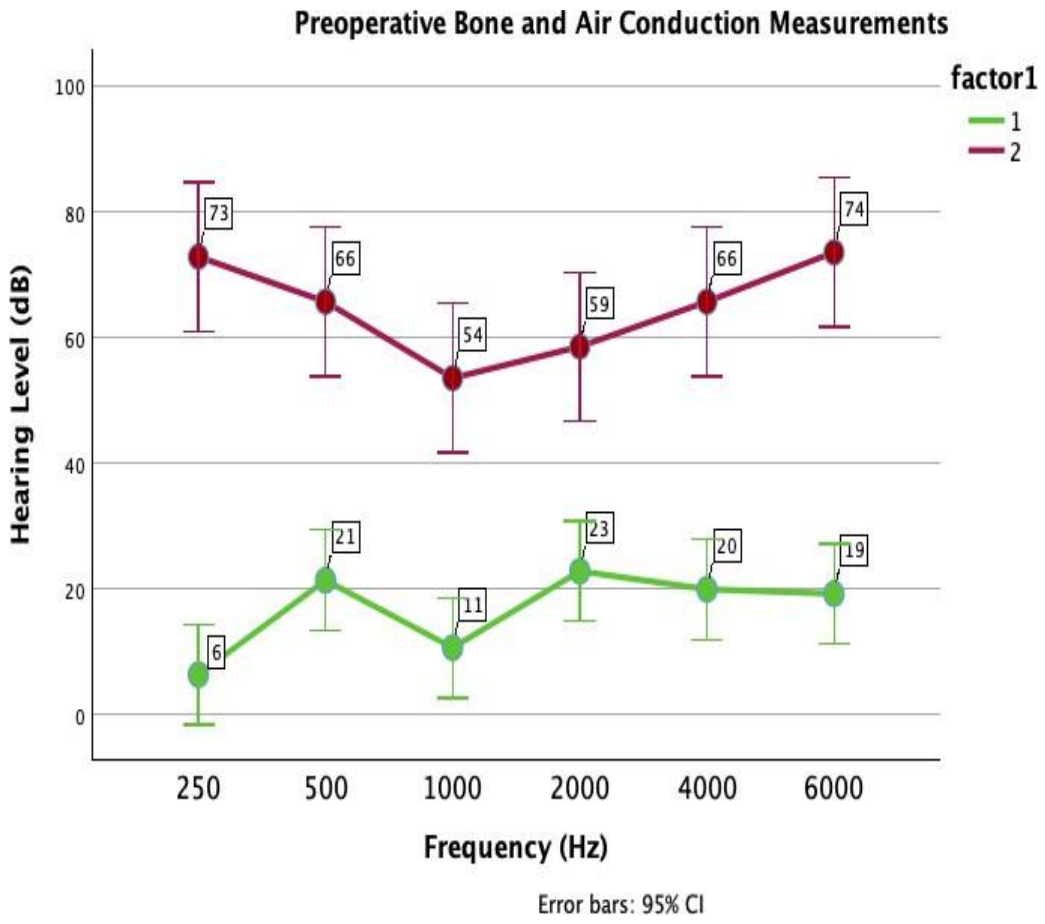

Figure 3-10 Preoperative bone and air conduction measurements: mean preoperative BC (green) and mean preoperative AC (red) are shown ± standard deviation.

As mentioned earlier, the type of hearing loss is determined by the air bone gap which is the difference between the air conduction and bone conduction thresholds. A significant air-bone-gap was calculated $4PTA_{ABG}$ 48.2 ± 16.4 dB_{HL} (500 Hz 44.3 ± 9.8 dB_{HL}; 1 kHz 42.9 ± 11.9 dB_{HL}; 2 kHz 35.7 ± 12.7 dB_{HL} and 4kHz 45.7 ± 11.7 dB_{HL}). This finding indicates a conductive component, and considering the normal bone conduction hearing thresholds imposes a conductive hearing impairment primarily (Fig. 3-11).

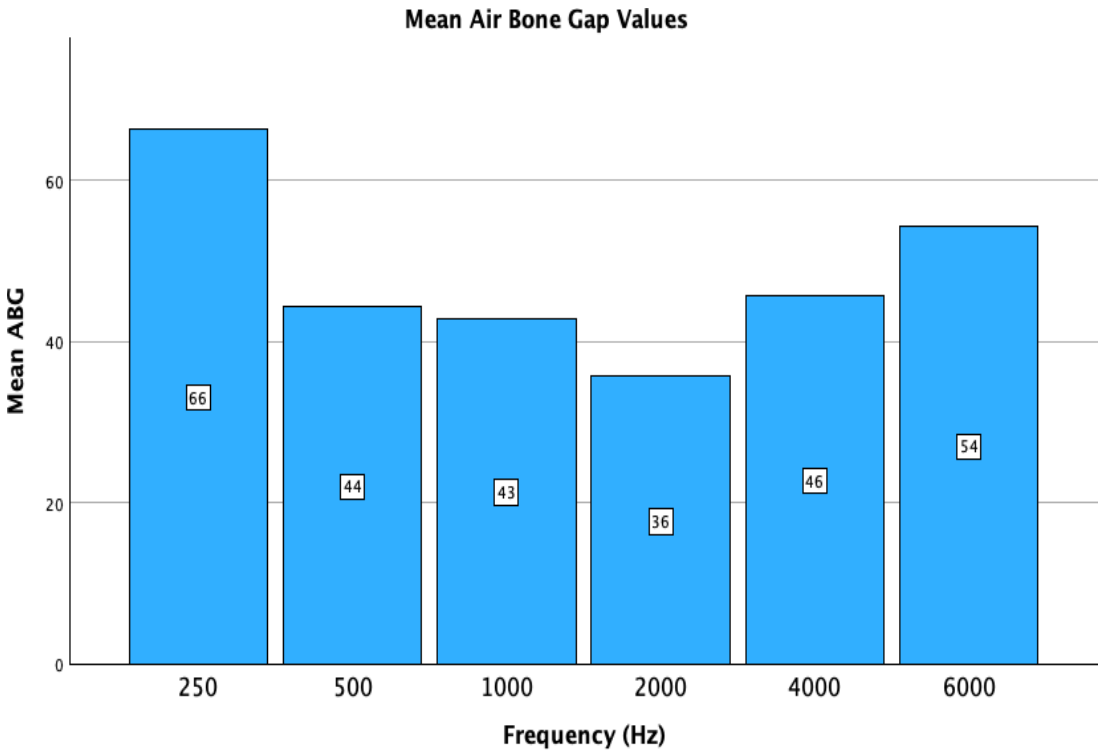

Figure 3-11 Mean air bone gap values at various frequencies.

3.3.2 Functional Gain

As mentioned earlier, the pure tone audiometric hearing thresholds measured in the unaided situation prior to surgery showed a mean value of 66.3 ± 16.4 dB_{HL} (500 Hz 65.7 ± 18.4 dB_{HL}; 1 kHz 53.6 ± 14.1 dB_{HL}; 2 kHz 58.6 ± 11.4 dB_{HL} and 4kHz 65.7 ± 15.9 dB_{HL}). In the aided situation, the measured hearing thresholds with Osia in the free sound field using warble tones had a mean value of 27 ± 10.9 dB_{HL} (500 Hz 24.3 ± 4.5 dB_{HL}; 1 kHz 20.7 ± 6.1 dB_{HL}; 2 kHz 22.1 ± 8.1 dB_{HL} and 4kHz 31.4 ± 12.1 dB_{HL}). The measured values are shown in Figure 3-12.

The functional gain produced with Osia was calculated by the difference between the aided hearing levels (Osia on) obtained in the free sound field using warble tones and the unaided hearing levels (Osia off).

A mean functional gain $4PTA_{FG}$ of 39.3 with a standard deviation of 16.7 was achieved after Osia implantation. We concluded that the surgery improved the aided thresholds with a measurable functional gain at the following corresponding frequencies $4PTA_{FG}$: 500 Hz 41.43 ± 17.3 dB_{HL}; 1 kHz 32.9 ± 11.9 dB_{HL}; 2 kHz 36.4 ± 14.4 dB_{HL} and 4kHz 34.3 ± 11.3 dB_{HL} (Figure 3-13). The noticeable effect of Osia on hearing is evident at all frequencies, indicating its efficacy in hearing rehabilitation through the entire speech spectrum.

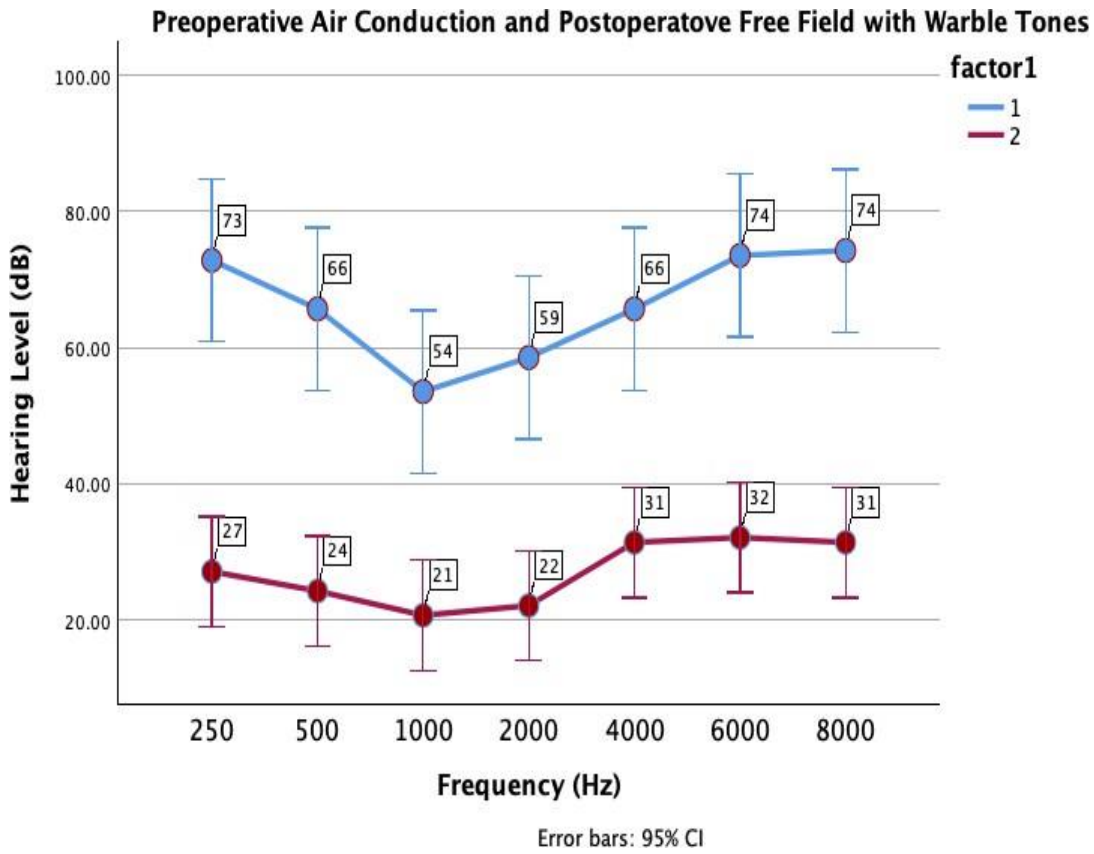

Figure 3-12 Preoperative air conduction measurements (blue) and postoperative free field measurements with warble tones (red). The mean values are shown ± standard deviation.

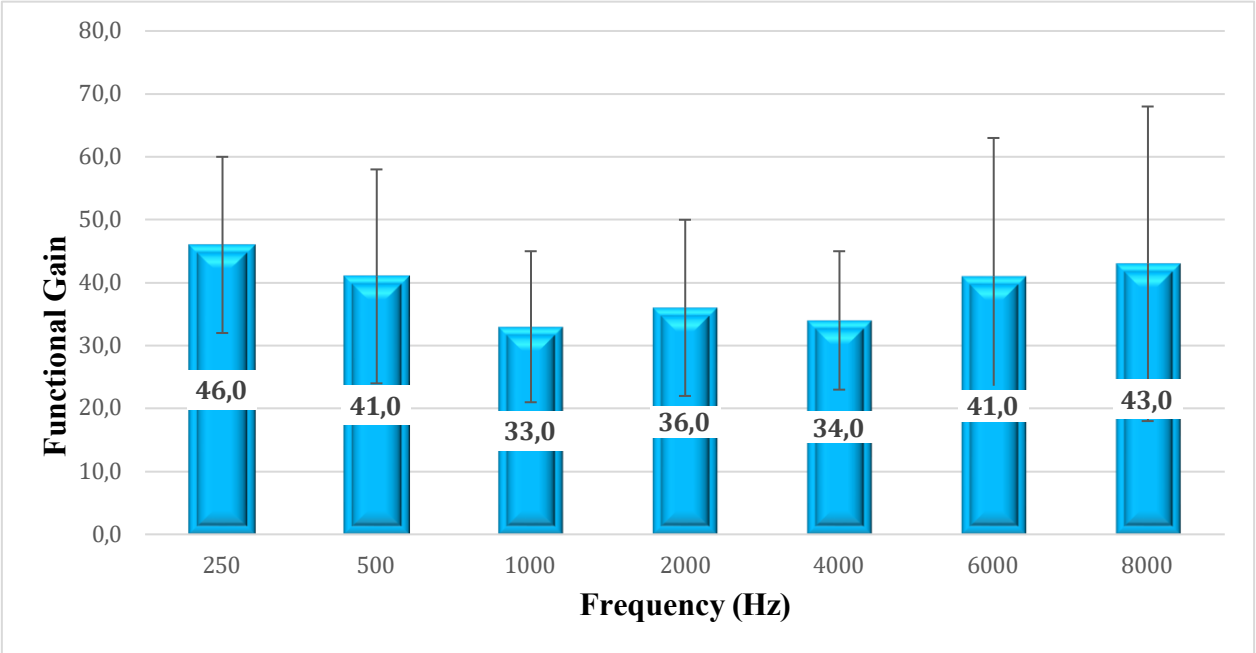

Figure 3-13 showing the mean functional gain values 4PTA-FG at different frequencies.

The mean air conduction measurements compared to the sound-field thresholds with warble tones at different frequencies are shown in table 3-3:

Table 3-3 Measurements of preoperative air conduction and sound-field thresholds with warble tones

Frequencies	**Preoperative AC**		**Sound-Field Thresholds with Warble Tones**		F	p-value
	Mean	SD	Mean	SD		
250	72.86	16.04	27.14	6.36		
500	65.71	18.35	24.29	4.50		
1000	53.57	14.06	20.71	6.07		
2000	58.57	11.44	22.14	8.09	254.4	<0.001**
4000	65.71	15.92	31.43	12.15		
6000	73.57	16.00	32.14	13.18		
8000	74.29	16.94	31.43	17.49		

A repeated-measures ANOVA was conducted to compare preoperative air conduction hearing thresholds with postoperative sound-field thresholds with warble tones at various frequencies. The statistical analysis revealed a significant difference ($F(1,42) = 254.4$, $p < .001$), indicating a substantial functional gain. There was no significant interaction observed regarding the improvement of hearing across the frequencies, with a p-value of 0.774. This indicates that changes in hearing did not vary significantly across the tested frequencies after intervention.

3.3.3 Speech Intelligibility

The speech intelligibility assessment was conducted using the Freiburg monosyllabic test in free field, following the guidelines outlined in DIN ISO 8253-3. The word recognition scores (WRS) were obtained under two conditions: in quiet and with the presence of narrow band noise. The speech material is presented with a sound intensity at 65 dB_{SPL} and with a narrow band noise applied at 65 dB_{SPL}. Both speech and noise are presented from a loudspeaker positioned 1 meter in front of the patient at a 0° angle (S0N0).

The included postoperative assessments were conducted at the following schedule: after initial activation (First Fit, 4 weeks after surgery), 1 month, 3 months, 6 months, 9 months and 12 months after initial activation. The routine control appointments were not attended by all patients regularly. However, we obtained the missing audiological test results from the respective hearing centers. It has also been shown that the number of patients who attended the follow-up visits had been reduced as early as 6 months after activation to 3 patients by the 12th month after activation.

3.3.3.1 Speech Intelligibility in Quiet

Prior to surgery, the speech intelligibility of the Freiburg monosyllabic test in quiet with 65 dB SPL was 3.12 % with a standard deviation of 2.13.
Figure 3-14 presents the word recognition scores (WRS) in quiet using the Freiburg speech test, displayed in percentage at 65 dB_{SPL} in free field. After implant activation, a significant improvement in word recognition scores was observed, with scores increasing form 3.12 % ± 2.13 (unaided) to 93.5 % ± 9.4 (aided) in speech intelligibility.

In the follow-up assessments, the following speech recognition values were recorded respectively: 1M: 96.4 ± 6.2 % (n=7); 3M: 95.7 ± 6.0 % (n=7); 6M: 94.1 ± 5.8 % (n=6); 9M: 96.2 ± 4.7 % (n=5); 12M: 95.0 ± 5.0 % (n=3).

The word recognition scores in free field Freiburg without noise at 65 dB_{SPL} were compared among different times using a repeated measures ANOVA. The statistical analysis revealed no significant difference ($F(5,28) = 0.476$, $p > .05$). Speech intelligibility remained relatively constant at the different time measurements, all showing a significant improvement compared to the preoperative measurements. The absence of significant variance indicates a consistence performance of Osia in enhancing speech intelligibility over the duration of the study. In figure 3-14 and table 3-4, the word recognition scores are shown at different time points: preoperatively, at initial fitting, and during the following months after activation.

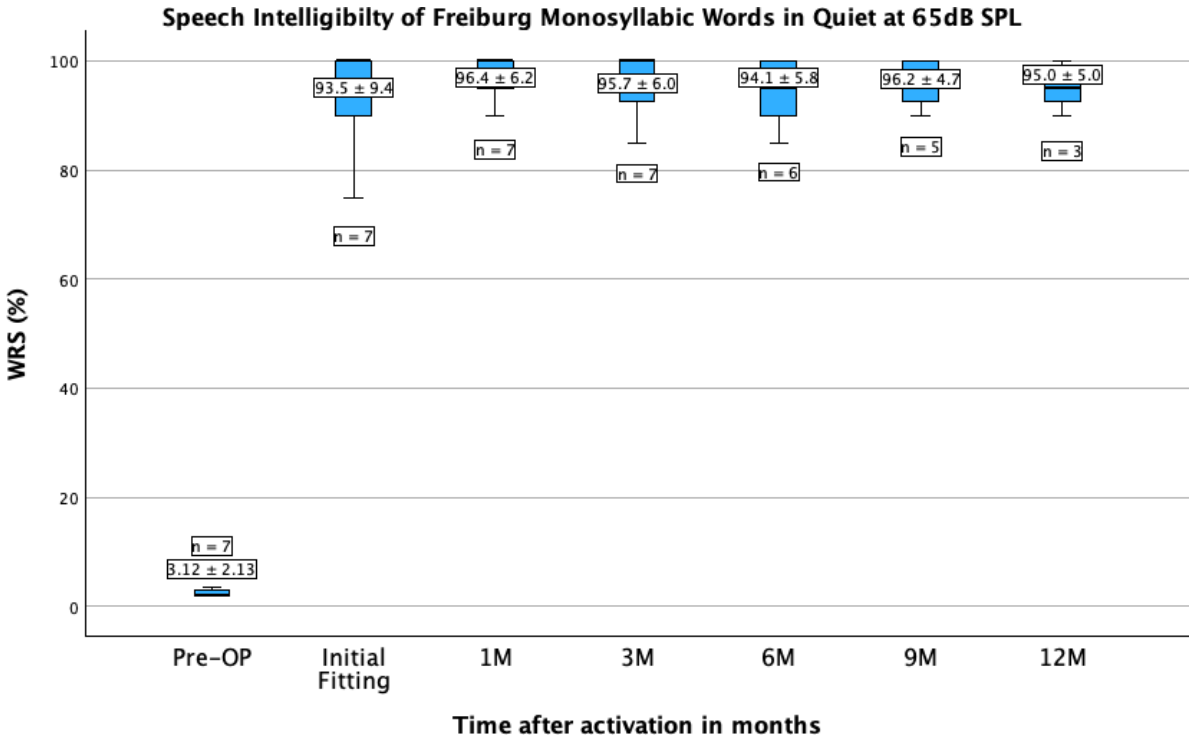

Figure 3-14 WRS represented in percentage in quiet at 65 dB SPL using the Freiburg monosyllabic test.

Table 3-4 Word recognition scores in free field Freiburg in quiet at 65dB SPL

Time in Months	Mean	SD	F	p-value
Pre-OP	3.12	2.13		
Initial Fitting	93.57	9.45		
1	96.43	6.27		
3	95.71	6.07	0.476	0.787
6	94.17	5.85		
9	96.25	4.79		
12	95.00	5.00		

3.3.3.2 Speech Intelligibility in Noise

The assessment of speech intelligibility in real life situations and daily interactions necessitate the presence of background noise while testing. We measured the word recognition scores in free field with a sound intensity at 65 dB_{SPL} and simultaneously with the presence of narrow band noise at 60 dB_{SPL}.

The following values were obtained from the Freiburg monosyllabic test and are displayed in figure 3-15: After initial activation: 58.0 ± 9.4 % (n=7); 1M: 60.0. ± 8.1 % (n=7); 3M: 60.0 ± 15.2 % (n=7); 6M: 59.1 ± 16.8 % (n=6); 9M: 61.2 ± 13.1 % (n=5); 12M: 63.3 ± 23.0 % (n=3).

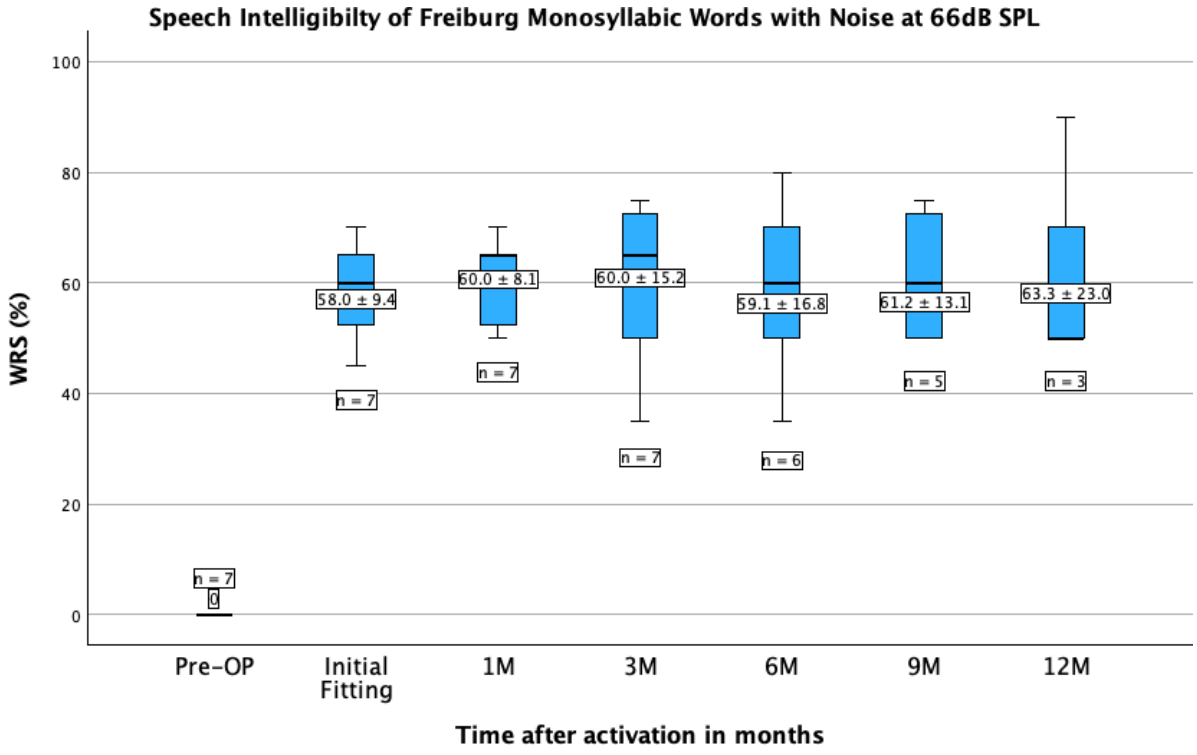

Figure 3-15 WRS in noise using the Freiburg monosyllabic test, displayed in percentage at 65 dB SPL with 60 dB narrow band noise in free field.

As shown, a significant improvement of the speech Intelligibility threshold was also observed with 60 dB noise immediately after activation. All subjects demonstrated a significant increase in speech understanding in noise in all the following months after Osia implantation.

3.4 Patient-reported outcomes

The subjective benefit with Osia was rated using the Glasgow Benefit inventory (GBI), which was explained previous section (2.4).

The means and standard deviations of the GBI scores were reported. The total GBI score was 24.30 (± 7.98). The general, social, and physical health subscale scores measured were 35.91 (± 8.94), 8.25 ± (16.25), and – 4.17 ± (8.33), respectively, as provided in table 3-5 und figure 3-16.

Table 3-5 Descriptive statistics of the GBI

Scale	Minimum	Maximum	MV	SD	Median	P-Value
TS	13.88	33.33	24.30	7.98	25.00	0.009**
GS	22.83	41.66	35.91	8.94	39.58	0.004**
CS	0	33.00	8.25	16.50	0	0.391 ns
PS	-16.66	0	-4.17	8.33	0	0.391 ns

A one sample t-test compared the mean values of the GBI subscales (total score, general score, social score and physical score). The statistical analysis revealed a significant difference found in both the total and general subscales (p-value < 0.01, indicating a subjective improvement in the quality of life and the daily activities correlated with hearing enhancement.

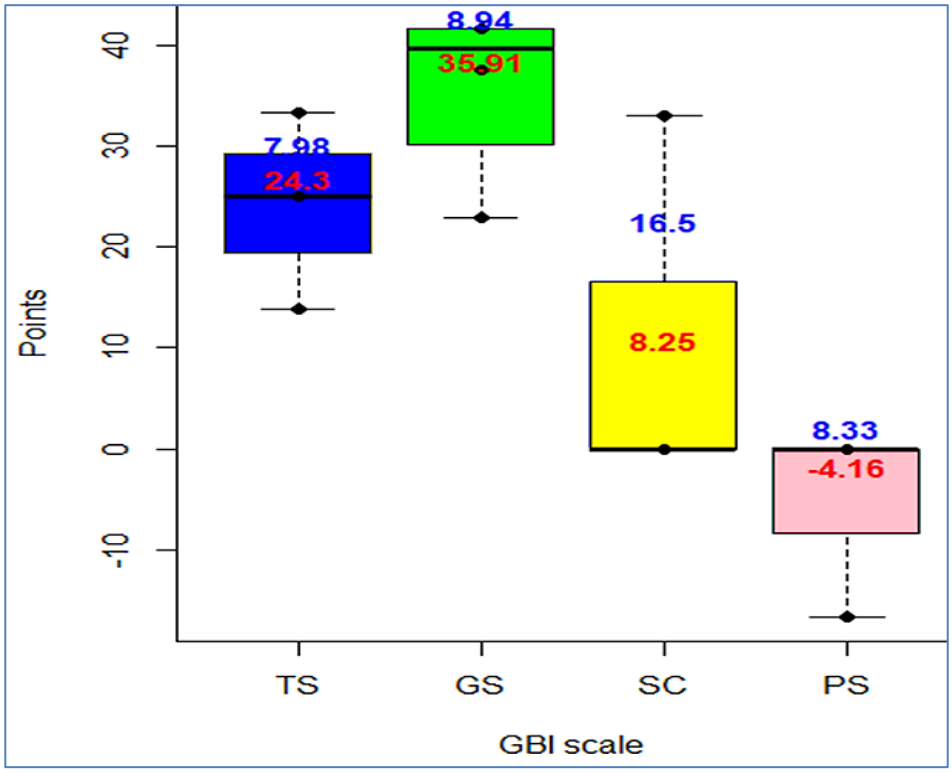

Figure 3-16 Total, general, social and physical subscale scores of the GBI.

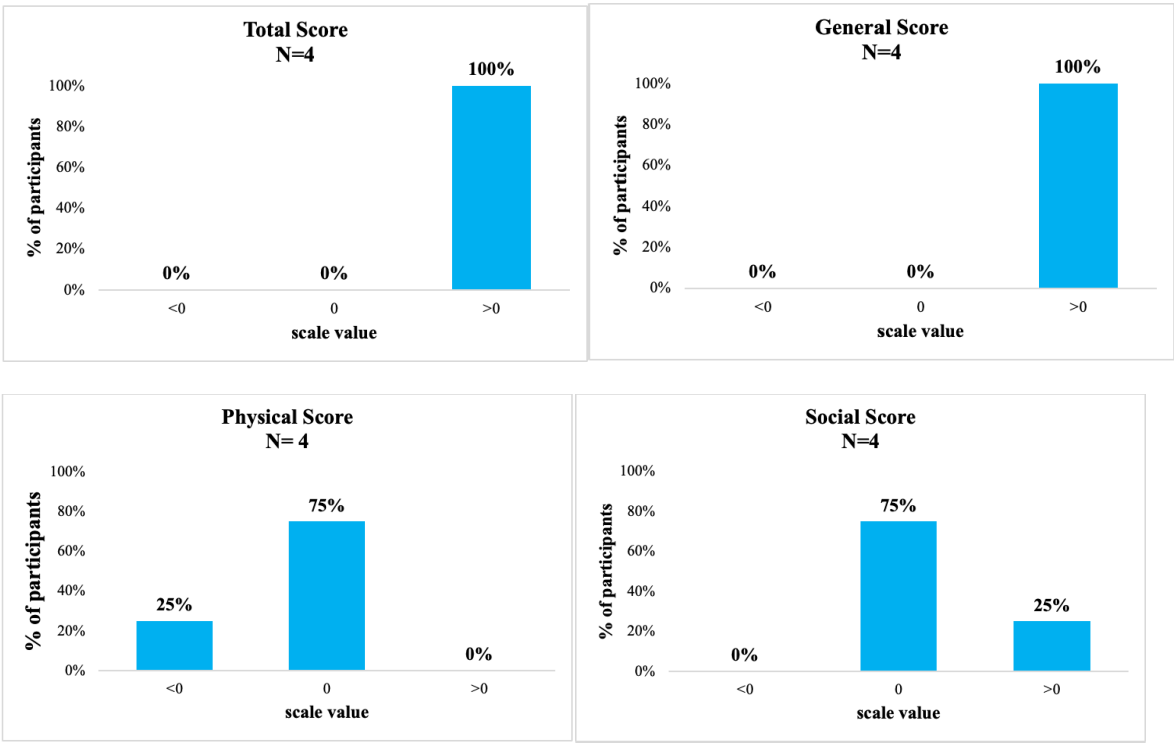

Figure 3-17 Percentage distribution of patients with negative benefit (<0), no benefit (0) and post-intervention benefit (>0) according to the scales of the GBI.

The total score of the Glasgow Benefit Inventory indicated that every patient observed positive changes in their well-being and overall satisfaction following the intervention. The highest level of benefit was expressed by all patients on the general subscale of the assessment. Three patients reported no improvement in both the physical and social subscales, while one patient experienced a decline in the physical subscale and another patient showed an improvement in the social aspect (Figure 3-17). Statistically, there was no significant difference observed in the social and physical subscales scores (p-value > 0.05).

4 Discussion

In this section, we will evaluate our data in the context of the published results from studies addressing the Osia System. The discussion focuses on the surgical procedure, safety and adverse effects, audiological outcomes and patient-reported outcomes.

4.1 Surgical Procedure

For the unilateral Osia implantation, the surgery time from skin incision to closure varied between 42 and 101 minutes. In a single case, the procedure required 135 minutes for a bilateral implantation. Published data showed similar surgery durations. For example, Rauch et al. (2021) reported a mean surgery time of 64,4 minutes (SD ±23) for unilateral Osia implantation and 160 minutes (SD ±49) with bone polishing in a study which included 22 adult patients [112]. Similarly, Briggs et al. (2022) reported a mean surgery time of 52,8 minutes (SD ±13,3) with bone polishing in 12 out of 29 subjects in the overall population [113]. Arndt et al., (2021) had a surgical time between 30 and 60 minutes [112].

All our surgeries were conducted under general anesthesia following the manufacturer's guidelines. A retroauricular C-shaped incision parallel to the helical rim was chosen by all surgeries. The recommended incisions from the manufacturer are the postauricular, inferior postauricular and posterior C-shaped incisions. In literature, all types of incisions were performed, taking into consideration anatomical variations and previous ear surgeries. Alnoury and Daniel (2023) used a transverse skin incision over the implant rather than the previous recommended incisions. Afterwards, a biplane dissection of subcutaneous, muscular and periosteal tissues at two different levels to prevent device exposure. The study was conducted in seven children with aural atresia and described a minimal invasive Osia implant surgery (MOSIA) with using an endoscope for the device fixation. The authors reported that this technique reduces dissection, postoperative pain, scarring and postoperative numbness. The biplane dissection reduces the risk of device exposure. There was a skin dehiscence in one case. However, the implant did not become exposed despite the external skin dehiscence. Furthermore, the method was recommended by the authors for microtia and atresia patients, as it minimizes dissection and preserves the skin donor site for an auricular reconstruction [114]. Deep et al. (2022) described two types of modified incisions in a study of 25 patients, who received the Osia system. The authors explained that the aim of these modifications is to avoid placing the incision at the site of wound tension, particularly along the anterior-inferior corner of the device especially if the device is placed too inferior. The first incision is a linear horizontally placed incision over the intended site of the implant screw. The second alternative is the inverted-U incision that comes across the waist of the device. The authors did not report any surgical or postoperative wound complications using the modified incisions [115]. Other skin incision alternatives were proposed by Chew et al. (2023) after performing 30 Osia implantations. The authors explained that placing the incision across the waist or surface of the actuator achieves a wider surgical field allowing greater surgical efficacy and reduces surgical trauma. The authors concluded that the preferred 'Sheffeld-S' incision across the waist of the implant optimizes the surgical field and provides a tension-free wound closure with an aesthetically well hidden scar within the hairline. It provides an adequate exposure for planning and placement of the implant, and for any bone polishing or recessing if required [64].

In all our surgeries, some degree of bone polishing was necessary to create a smooth surface under the actuator and ensure a good transmission. Other authors have outlined the necessity of polishing or recessing in most of the cases [112], [116], [117]. Furthermore, Arndt et al. (2021) mentioned that an implant well of 4-5 mm was prepared in most surgeries to lower the implant. The low profile of the piezoelectric actuator allows for minimal bone removal compared with other active transcutaneous systems, which require the electromagnetic actuator to be recessed [113].

Following the manufacturer's recommendation, the BI300 implant was placed in the sinodural angle in all cases included in our study. The OSI200 implant position is mostly optimal with the actuator close to and in horizontal line with the ear canal or slightly superior without touching the pinna. Anterior placement of the implant may lead to difficulties for some patients when wearing glasses. Therefore, some discretion is required to decide whether recessing of the actuator is required [118]. A retrosigmoid position could be also chosen in cases of previous ear surgeries. Previous operations may affect wound healing at the recommended implantation site because of the thinned subcutaneous tissue and the displaced temporal muscle. Willenborg et al. (2022) recommend placing the implant outside the region of prior surgery, especially behind the mastoid. Previous repetitive procedures can lead to reduce in the thickness of soft tissues which may cause healing disorders and device exposure due to the potential risk of compromised blood supply [119].

4.2 Safety and Adverse Effects

The results of this study indicate the safety of the surgery and coincide with the data published until now [71], [72], [118], [119], [120], [121], [122], [123]. The system was proved to be safe in adults and pediatric patients as well [124]. An extended follow-up data over a 24-month period demonstrates that the Osia 2 system also remains safe over time [125].

Our audiological results did not show any alteration of the bone conduction hearing thresholds after implantation. Other published studies have confirmed that the implantation of Osia has no negative influence on the hearing thresholds of both the implanted ear and the contralateral ear [112], [118], [119].

The surgery proceeded smoothly in all patients, without any reported adverse effects. In the literature, diverse adverse effects were documented, including issues associated with the device as well as complications arising from the procedure, or both. However, because of the direct-drive stimulation to the bone, a constant static pressure against the skin is not required to ensure a good transmission. This reduces the pressure related complications such as numbness and discomfort [61], [126], [127].

In the published data from Lau et al. (2020), two postoperative wound infections were reported. One settled down with antibiotics, whilst the other resulted in a small wound dehiscence, which was treated with a secondary suture. One patient (on clopidogrel by atrial fibrillation) had an acute subdural haemorrhage on the 18th day postoperatively. A discussion at the neurosurgical multidisciplinary meeting concluded that the subdural hemorrhage was not directly related to the implantation [118].

Gawęcki. et al. (2022) compared in a study eight adult patients with bilateral mixed hearing loss, who were randomly divided into two groups. Group 1 was implanted with Osia and group 2 was implanted with Baha Attract. The authors reported that in all cases, the surgery was successful

and the healing uneventful. Three months after the surgery, the operated area was free of pain in all cases, but in one Osia patient and one Baha patient, skin sensitivity was still limited [116]. Rauch et al. (2022) reported two serious adverse events in a study that included 22 patients. In one patient, Osia had to be explanted due to prolonged wound infection postoperatively. In the other case, a reimplantation was necessary because of a wound infection at primary diagnosis of acne inversa [72].

A search of the FDA MAUDE database examined device malfunctions, patient injuries, inciting events and subsequent interventions, revealing 83 reports related to different active implantable bone conduction hearing systems. Of all adverse events reported with Osia, three (8.8 %, 3/34) were reported concerning malfunctions, while 31 (91.2%, 31/34) were reported for patient injuries. The most reported adverse events included lack of conduction or hearing (n = 26, 28.6%), infection (n = 14, 15.4%), and intermittent or reduced conduction or hearing (n = 12, 13.2%). The study found that Osia implants were involved in most reported patient injuries with active bone conduction implants. Infection, wound formation and pain were among the top reported injuries [128].

Goldstein et al. (2021) reviewed collected data during a controlled-market release (CMR) of the Cochlear™ Osia 2 System as well as outcomes at single, tertiary private practice Oncology/Neurotology Centre. Five complications were observed during the CMR in the 44 performed surgeries on 43 recipients (one bilateral), none of which were device related. The most serious complication involved exposure of the dura with bleeding from the transverse sinus. Despite this event, the BI300 implant fixture was successfully placed in this patient. Besides, there were two postoperative wound infections, both treated successfully with antibiotics. Lastly, there were two postoperative hematomas. One resolved via application of cold compresses, and the other was treated by needle aspiration. At the Centre for Neurosciences, none of the 6 operated patients had any postoperative surgical complications [71].

Florentine et al. (2022) reported two postoperative complications limited to mild skin complications in overall 14 patients, four of them underwent a bilateral placement. These complications included two cases of mild edema and seroma over the implant site. In both cases, the complications were resolved without any surgical intervention [124].

Chew et al. (2023) reported no surgical complications in a study which included 30 patients, 10 of them had the device implanted bilaterally [64].

Deep et al. (2022) reported no surgical complications or postoperative wound complications in a study of 25 patients, which involved the use of linear or inverted-U modified incisions, as described previously [115].

Szabo et al. (2023) reported in their study no intraoperative complications, such as dura or sigmoid sinus injury, bleeding or liquorrhea. Postoperative complications such as hematoma, seroma, infection or other wound healing problems were not detected during the follow up. Pain complaints were negligible. The study included five patients who received the first-generation of Osia system after a previous use of the BAHA Attract system [129].

Willenborg et al. (2022) reported no intraoperative complications in a study that included 6 patients. However, in one patient, the implant had to be removed before the initial fitting due to wound dehiscence with pyogenic inflammation. The authors explained that multiple previous operations (CI and BAHA connect) were performed close to the implantation site. The wound healing deficit was caused probably due to decreased subcutaneous tissue thickness, displaced temporalis muscle and subsequently impaired blood flow at the site of the implantation [119].

Similarly, Mylanus et al. (2020) reported that the postoperative healing was uneventful in all 51 patients, except for one subject. In this particular case, an infection developed at the implantation site on the third postoperative day, which subsequently developed into skin necrosis and dehiscence. Despite attempts to salvage the implant through salvage surgical debridement, rotational flap and antibiotic treatment, the implant had to be removed on the 55th day after implantation. The authors mentioned that this complication constituted the only procedure-related serious adverse event (SAE). Non-serious adverse events, such as pain, numbness, vertigo, swelling, tension at the implant site, warmth at the sound processor site, hematoma and bleeding, were also mentioned. All these events were resolved by the end of the 12-month investigation period [117].

Cowan et al. (2023) reported the following adverse events related to the device or procedure: pain behind the implant, skin irritation and prominence of the posterior inferior edge of the system. Some of the patients included in the study experienced discomfort from the sound processor heating up, increased tinnitus, two reports of non-use and two reports of frustration. The severity of adverse effects varied between mild and moderate. The majority of described adverse effects were resolved by the end of study [125].

Alnoury et al. (2023) described an endoscopic minimally invasive Osia implant surgery (MOSIA) in a study that included seven children. The authors reported a one case of intraoperative sigmoid bleeding, which was controlled with bone wax and changing the implant site, without any signs of CSF leak. Another patient had a partial dehiscence at the skin incision at the first week after the surgery, which healed spontaneously with no device exposure. All wounds healed with no dehiscence or device exposure one month after surgery [114].

The published data confirmed that surgical and postoperative complications are rare [64], [72], [117], [119]. Transcutaneous systems typically result in lower complication rates compared with percutaneous systems [130].

4.3 Audiological Outcomes

The new active transcutaneous BCHI has proven to be an effective method for rehabilitation for patients with CHL, MHL or SSD. Our data demonstrated an improvement in the mean PTA4 hearing thresholds compared with the preoperative unaided hearing situation. Similarly, the improvement in speech tests, both in quiet and with noise, was statistically significant. Published data confirm an evident audiological benefit after Osia implantation [71], [112], [113], [117], [118], [119], [121], [124], [129], [131], [132].

The Osia system delivered a functional gain $4PTA_{FG}$ of 39.3 dB when comparing the aided and the unaided situation. Likewise, improvements in the aided pure tone audiometry thresholds were evident in other studies.

Willenborg et al. (2022) described an improvement in the mean pure tone audiometric thresholds in 6 patients with single sided deafness after implantation of Osia. The Osia system improved the preoperative mean hearing threshold from 56.8 ± 1.4 dB HL to 25.3 ± 2.2 dB HL after implantation [119].

Similarly, the study conducted by Lau et al. (2020) that included ten patients, two patients with single sided deafness, three with conductive hearing loss and five with mixed hearing loss, showed a significant audiological gain after Osia implantation. The mean gain was 86.5 dB ± 10.6

dB for single sided deafness, 31 dB ± 17.3 dB for mixed and 22 ± 9.5 dB for conductive hearing loss. The overall mean gain in hearing with the implant was 39.4 ± 28.3 dB [118].

Briggs et al. (2022) reported an improvement of 28.4 dB in the PTA, particularly prominent at higher frequencies (36.1 dB at 6000 Hz). The Osia system achieved an average gain of 13.9 dB compared with the Baha 5 Power on a Softband [113].

Mylanus et al. (2020) stated a significant improvement in hearing thresholds for the two included subgroups (MHL/CHL and SSD) at all tested frequencies (0.25-8 kHz) and PTA4, with the largest improvement at frequencies above 3 kHz [117].

Goycoolea et al. (2020) reported that the average functional gain for all frequencies was statistically higher for Osia system (36.88 dB) than for Baha 5 Power on a Softband in the preoperative testing (30.57 dB). Moreover, the largest and significant differences between functional gain results were obtained at higher frequencies [131].

Szabo et al. (2022) reported comparable results. Osia performance was better compared to the BAHA Attract at each frequency, especially over 2000 Hz. The mean hearing threshold obtained when aided with a BAHA 5 sound processor on Attract was 43 ± 8.6 dB HL, whereas the Osia system provided a mean aided hearing threshold of 28 ± 4.3 dB HL [129].

In a study by Nevoux et al. (2023), similar results were obtained with six patients undergoing the conversion of a BAHA Attract to an Osia system. The unaided hearing thresholds improved from 73 to 27 dB HL with Osia, producing a functional gain of 46 dB. The superiority of the Osia system over BAHA Attract was evident at higher frequencies (>4 kHz). The amplification of Osia was maintained up to 8 kHz (26 dB) [132].

This matches the finding by Rauch et al. (2022), in which the Osia system showed an increased 4PTA of around 7 dB against the preoperative thresholds obtained using warble tones for BAHS (Baha BP110 or Ponto Pro Power) on a Softband. A significant improvement was evident especially at higher frequencies [72].

Goldstein et al. (2021) reported a mean hearing gain of 58.5 dB by comparing the preoperative unaided (85.8 dB HL) and postoperative aided hearing thresholds (27.3 dB HL). Using the Osia 2 System showed an average PTA4 gain of 9.6 dB compared to Cochear™ Baha Attract and 10.2 dB compared to Cochlear™ Connect systems. An additional high-frequency gain of 19.3 dB at 6000 Hz was found with the Osia 2 system when compared with the previous mentioned systems [71].

A significant improvement with a mean gain of 42.8 ± 4.9 dB SPL was also observed by Gawęcki et al. (2022) after Osia implantation. The measured mean gain in PTA for the Baha Attract was 38.8 ± 8.5 dB SPL. The authors did not find any evident differences between Osia and Cochlear™ Baha Attract in terms of free field pure tone audiometry improvements. However, they mentioned that the average age in the Osia group was higher and the initial hearing performance was worse [116].

These results suggest the higher performance of the Osia system compared with passive transcutaneous systems because of the lack of skin attenuation. The skin attenuates the bone conduction stimulus by 10-20 dB in patients, particularly with increasing frequency [133]. It should be noted that a lower transcutaneous transmission at higher frequencies (>4 kHz) at the mastoid compared to the BAHA location was evident [134], [135]. In relation to signal attenuation at high frequencies, Florentine et al. (2022) found that aided audiograms after Osia 2 system placement exhibited no high frequency roll-off [124].

Kim et al. (2023) examined the audiological outcomes of the Osia system with Baha Attract and Bonebridge in recipients with either CHL/MHL or SSD. In the CHL/MHL group, the effective gain of the Osia system (11.1 ± 14.9 dB) surpassed that of the Baha and Bonebridge (2.7 ± 12.6

dB) at 2 kHz. The effective gain of the Osia system was significantly superior to that of the composite cohort of Baha Attract and Bonebridge group across all frequencies, although statistical significance was observed only at 2 kHz. Besides, the Osia system tended to tolerate the worst bone conduction thresholds, up to the level of 61 dB. In the SSD group, the functional gain of Osia at 4 kHz (37.5 ± 3.1 dB) was higher than that of the Baha and soundbridge group (26.9 ± 3.0 dB). The study demonstrated significantly larger audiological gains of the Osia system than other BCHIs in both SSD and MHL patients [121]. The utilized piezoelectric transducer in Osia produces a greater output at higher frequencies compared with electromagnetic transducers [136]

Similarly, our study showed significant improvements in speech recognition in quiet and in noise compared with the preoperative condition. The speech recognition was tested using the Freiburg monosyllabic test at a sound level of 65 dB SPL in a quiet environment. Osia provided a significant improvement in speech recognition up to 93.5% ± 9.4 immediately after activation. The speech recognition scores were measured at 1M, 3M, 6M, 9M and 12M after implantation. The speech recognition improvement was stable and did not differ significantly at different time measurements. A significant improvement of the speech recognition was also observed with 60 dB broadband noise immediately after activation. This finding was consistent with results obtained by Mylanus et al. (2020)[117].

Willenborg et al. (2022) reported an improvement in speech intelligibility in quiet, tested with the Freiburg monosyllabic word test. The mean WRS at 65 dB in quiet increased from 3.0 ± 6.7 % unaided to 95.0 ± 3.5% aided with the Osia [119].

In a study that was conducted over a 24-month period, Cowan et al. (2023) reported that the Osia 2 system remains effective over time. No statistically significant differences were found in paired comparisons between the 6-month follow-up and 24-month follow-up data, indicating stable improvements in speech intelligibility in noise for patients with MHL/CHL and SSD [125].

In the study conducted by Lau et al. (2020), the mean SRT improved significantly from 38.1 dB ± 7.8 dB unaided to 22.7 ± 4.6 dB aided with Osia [118].

Nevoux et al., (2023) reported that the Osia system provided superior improvements in WRS compared to BAHA Attract, which were prominent at higher frequencies (> 2 KHz) [132].

Goldstein et al. (2021) reported an average improvement of 57% of the functional gain in speech perception by comparing the aided versus unaided sound-field Consonant-Nucleus-Consonant (CNC) words scores [71].

Gawęcki et al. (2022) reported an evident improvement in speech audiometry (Polish monosyllabic word test), both in quiet and noise, compared to the unaided situation. In comparison between the Osia system with the Baha 5 Power processor in a Softband, there were no evident differences between the two groups in terms of speech audiometry improvements. As mentioned earlier, the authors added that there were some differences in the age and preoperative hearing status before the surgery between these groups; because the mean age of the Osia group was higher, and the initial hearing performance was worse. A similar hearing improvement for both devices was an indication that the Osia was a better choice [116].

In the study conducted by Nevoux et al. (2023), speech understanding in both quiet and with noise was clinically improved reaching a mean signal-to-noise ratio (SNR) of less than 1 dB at 12 months with the Osia system [132].

Szabo et al. (2022) confirmed a significant improvement in speech audiometry after Osia implantation. The mean speech recognition threshold and mean word recognition testing improved significantly from unaided values of 62 ± 25 dB and 76 ± 25 dB, respectively to aided values of 28.8 ± 8 dB HL and 42 ± 10 dB HL, respectively. Although mean thresholds of the Osia system

were better, no significant difference was detected between the Osia and Baha Attract results (BAHA 5 sound processor on Attract) [129].

The study of Briggs et al. (2022) showed that the Osia system provided statistically significant and clinically relevant improvements in speech intelligibility in noise and in quiet compared with the unaided situation. Besides, significant improvements in speech intelligibility in quiet and in noise were also observed compared with the preoperative condition with Baha 5 Power SP on a Softband. These changes were clinically important at 50 dB SPL, but not when listening in a noisy background [113].

Our findings align with published data, indicating that speech tests corroborate with results obtained from the free-field pure tone audiometry. While the superiority of the Osia system over passive transcutaneous systems (Baha Attract) not always statistically evident in speech tests, there was an evident better performance in the pure tone audiometric results, particularly at high-frequencies due to lack of skin attenuation [72], [117], [129], [131], [132]. The ability to improve hearing for frequencies above 3 kHz is important to understand speech in background sounds and is also important for the sound localization [137]. Results of bilateral Osia recipients showed comparable benefit to unilateral users [112].

4.4 Patient-reported Outcomes

In this study, the subjective benefit after Osia implantation was measured using the Glasgow Benefit inventory (GBI). The GBI revealed a clinically relevant und statistically significant improvement in the total GBI score. The highest and most significant improvement was reported by all patients on the general subscale of the assessment. In the physical and social subscales, our patients reported no significant differences compared to the preoperative status, which might be due to the low number of reports. In the study conducted by Goycoolea et al. (2020), improvements were evident in the total GBI score and in all three subscales. The highest score was observed in general health status, followed by social status and the lowest score was seen in physical status [131].

In the literature, various questionnaires were employed to allow patients to evaluate the impact of the Osia system on their hearing and quality of life. Therefore, we set other published data regarding patient-reported outcomes in context. Studies showed significant subjective improvements after Osia implantation in hearing benefit and health-related quality of life compared to the preoperative situation [70], [71], [113], [116], [120], [121], [125].

The abbreviated profile of hearing aid benefit (APHAB) measured speech understand in various everyday environments, using the following subscales: ease of communication (EC), reverberation (RV), background noise (BN) and negative reactions to environmental noise (aversiveness (AV) of sounds) [138], [139]. Published data showed significant improvements in the APHAB subscales [113], [116], [119], [120], [132]. Briggs et al. (2022) reported that the improvements included all measured domains other than aversiveness, in which decreasing scores have been correlated with increasing hearing loss [113]. This finding coincides with the results obtained by Mylanus et al. 2020, Willenborg et al. 2020 and Marszal et al., 2021. Adapting to the new hearing system may lead to reduced aversiveness to loud sounds over time [117]. This increase in the aversiveness is not unique to Osia, and was evident with other bone conduction implants [140], [141], [142], [143]. The results of Nevoux et al. (2023) yielded an improvement in all the subscales and the global score of the APHAB questionnaire with the Osia system. Hearing related problems in the APHAB scale were significantly reduced after implantation [116]. The changes were more

significant with the Osia system compared to Baha 5 Attract [116], [132]. The study by Cowan et al. (2023) showed stable hearing status across all APHAB subscales up to the 24-month follow-up [125].

Similarly, significant improvements were evident across all parameters (speech, spatial, and quality) of the SSQ-12 questionnaire [113], [116], [117], [120], [125], [132]. Gawęcki et al. (2022) reported that, contrary to the APHAB-results, changes in the SSQ were slightly favorable for the Baha 5 Attract group compared to the Osia group [116]. In the study conducted by Kim et al. (2023), CHL/MHL patients reported greater subjective benefits in the SSQ compared to SSD patients [121]. Goycoolea et al. (2020) observed improvements in the scores measured at follow-up points, suggesting that the perception of benefit could continue to improve over time [131]. Mylanus et al. (2020) noted that the SSD group also showed an improvement in spatial hearing, despite the heavily impaired ability to localize sound due the non-functioning cochlea [117].

These improvements were also reflected in the Health Utility Index-3 (HUI-3) data [113], [117], [132]. Goldstein et al. (2021) used the Hearing Handicap Inventory for the Elderly (HHIE-S) to examine changes in hearing disability. The average pre-activation HHIE-S was 24, suggesting a mild to moderate hearing handicap compared to an average post-activation HHIE-S of 7, suggesting no hearing handicap [71]. These results were consistent with the outcomes of a study, which was conducted in the United Kingdom by Lau et al. (2020). The mean Glasgow disability score improved from 52% (preimplantation) to 20.3% (postimplantation). The change was statistically significant and indicated a decrease in hearing disability [70].

A good patient compliance and comfort level was reflected in the reported daily use hours [117], [125]. The mean daily use in subjects with MHL/CHL and SSD was 12.2 and 9.3h/d, respectively [117].The daily use of Osia was significantly higher than the daily use reported in previous multicenter clinical investigation of a passive transcutaneous BCHI [113], [117], [126].
A lower average daily usage of Osia was reported: 8.6 h/d by Briggs et al. (2022) and 8.2 by Cowan et al. (2023), respectively. A separate comparison of the regular usage rate of Osia users with that of Baha and Bonebridge users, for CHL/MHL and SSD patients, showed a significantly higher rate in favor of Osia for the SSD patients. The usage rate of the Osia system for the CHL/MHL participants showed no significant difference from that of the Baha and Bonebridge users [121].

The results of patients-reported outcomes from various questionnaires in the literature confirmed our findings and were consistent with the audiological outcomes.

4.5 Limitations

Due to the retrospective study design, some data could not be collected from patients or were not retrievable. A prospective or a multicenter study would be suitable to overcome such limitations. Although our clinic is recognized for having the highest number of OSI200 implantations in northern Germany during the study, the relatively small sample size limits the ability to draw definitive conclusions. Future studies with a larger sample size and long-term follow-ups are encouraged to draw definitive conclusions. This includes conducting comparative studies of the recently announced updated version OSI300 implant with other active transcutaneous bone conduction hearing devices, such as the Bonebridge, regarding audiological indication criteria, hearing improvements, and surgical performance during implantation.

5 Conclusions

Recent innovations in the field of bone conduction hearing implants provided a new line of therapy for patients with hearing disabilities. In this work, we present the first study in northern Germany that investigated the most recent active transcutaneous bone conduction Osia system, which was introduced to the market in 2019.

The Osia system utilizes piezoelectric technology that produces mechanical vibration at the actuator when an electric signal is applied. These Vibrations are transmitted afterwards to the cochlea overcoming pathologies involving the external and middle ear. The indications of Osia include conductive or mixed hearing loss or single sided deafness with a normal hearing level in the con- tralateral ear.

The study analyzed the early outcome of the device, who received OSI200 implants at the department of Otolaryngology, Head and Neck Surgery at Lübeck University. The included patients suffered from mixed and conductive hearing loss after multiple ear surgeries, provided that the bone conduction hearing thresholds at the main speech frequencies 4PTA are 55 dB or better.

We reviewed different components of the Osia system and the specific instruments required for performing the surgical procedure. Additionally, the study explained surgical steps und technique in a great amount of detail.

The audiological assessment included pure-tone audiometry and speech intelligibility using the Freiburg monosyllabic test. The testing was conducted in free field at 65 dB in quiet and with narrow band noise at 60 dB_{SPL} to simulate real life situations. The Glasgow Benefit Inventory (GBI) was implemented to assess the impact of OSIA from the patient's perspective on overall quality of life as whole and on the ease in daily activities affected by changes in hearing.

The surgery proceeded smoothly without any notable complications. Our data demonstrated a significant improvement in the mean 4PTA hearing thresholds compared with the preoperative unaided hearing situation. Similarly, the improvement in speech intelligibility in quiet and with noise was statistically significant. Patients reported a significant improvement in hearing performance, which was reflected in their quality of life.

In conclusion, the new Osia system provides a safe and effective therapeutic option using active transcutaneous conduction to help patients suffering from conductive or mixed hearing loss, as well as for those with unilateral single sided deafness.

6 References

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7 Appendices

7.1 List of Figures

7.2 List of Tables

7.3 Congress Contribution and Poster

Visual Presentation:

Albiris M. Z. (2022) Alternative to Bone-Anchored Hearing Aid: OSIA2, at the 115th Lecture Event of the Schleswig-Holstein Association of Ear, Nose and Throat Physicans on Saturday, Mat 21, 2022.

Poster:

Albiris M. Z., Leichtle A., Bruchhage K-L. (2023) Indication, surgical procedure and clinical performance of the new active osseointegrated implant system, Osia® System, a retrospective study at the 94. Jahrestagung der DGHNO, Kopf- Halschirurgie. Leipzig, 17-20.05.2023.

Albiris M. Z., Leichtle A., Bruchhage K-L. (2024) Osia: The Newest Active Transcutaneous Hearing Rehabilitation Method, HörHanse Tag. Media docks Lübeck, 07.06.2024.

7.4 Ethics Application

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Aktenzeichen: 2023-179_1
09.02.2023 / CL

Verkurztes Verfahren - Amendment
Antragsteller: Dr. med. Daniela Hollfelder
Titel: Evaluation der audiologischen Ergebnisse, Lebensqualitiit und Kliirung einer moglichen veriinderten Horanstrengung bei Patienten mil Horgeriit / Prozessor durch Veriinderung der Mikrofoneigenschaften in ruhiger und geriiuschvoller Umgebung
Hier: Ihre Einreichung vom 07.02.2023, Amendment 2_Osia

Sehr geehrte Frau Dr. med. Daniela Hollfelder,

Die Ethik-Kommission nimmt die nachtriiglichen Anderungen zustimmend zur Kenntnis.

Mil freundlichen GrOBen

Prof. Dr. Alexander Katalinic
Vorsitzender der Ethik-Kommission

Vorgelegte Dokumente
1) Amendement 2_Osia_Holl1elder.pd1vom 07.02.2023

7.5 Patient Information Sheet and Consent

UKSH Campus Lübeck - Klinik für HNO	Einwilligung HÖR- & IMPLANTATSPRECHSTUNDE	Seite *1* von 1
	Verteiler: QMB – Klinik für HNO	**Gültig ab: 06.12.2019**
		Name Pat.

Sehr geehrte Patientin, sehr geehrter Patient, liebe Eltern,

die Hals-Nasen-Ohrenheilkunde des Universitätsklinikums Schleswig-Holstein ist bestrebt seine Patientinnen und Patienten nach den neuesten wissenschaftlichen und medizinischen Kenntnissen und Methoden zu behandeln. Diese Kenntnisse und Methoden können nur durch wissenschaftliche Forschung und Lehre verbessert und weiterentwickelt werden. Hierzu ist die Forschung mit Patientendaten unerlässlich. Es ist zum Beispiel notwendig neue Behandlungsverfahren mit bereits etablierten Methoden zu vergleichen. Das ist nur möglich, wenn zu diesem Zweck die medizinischen, radiologischen und audiologischen Daten der Patientinnen und Patienten zum jetzigen Zeitpunkt oder zu einem späteren Zeitpunkt ausgewertet werden dürfen. Hierfür kann es notwendig sein, externe radiologische Daten anzufordern, audiologische Daten von dem behandelnden Akustiker oder einer mitbehandelnden (Reha-) Klinik für die Auswertung mit einzubeziehen und Daten mit der Technischen Hochschule Lübeck, der Akademie für Hörakustik in Lübeck auszutauschen. Die Daten werden gelöscht, sobald der Forschungszweck dieses gestattet. Eine wissenschaftliche Veröffentlichung erfolgt stets in anonymisierter Form. Zudem können Informationen aus einer Photodokumentation auch bei Rückfragen an den Hersteller des Implantats weitergeleitet werden, oder gesondert abgenommenes Blutbild und/oder Gewebe und Stuhlproben, welches im Rahmen eines operativen Eingriffs gewonnen werden, analysiert werden. Ich/Wir bin/sind einverstanden, dass die gefertigten Photographien für Veröffentlichungen und/oder auf der UKSH Homepage verwendet werden dürfen.

Eventuell benötigen wir für die wissenschaftliche Forschung auch die medizinischen Daten aus Ihren Behandlungsunterlagen. Dabei müssen wir das Patientengeheimnis beachten, dass Ihre medizinischen Daten vor unbefugter Kenntnisnahme durch Dritte schützt. Deshalb möchten wir Sie heute vorsorglich um Ihre Einwilligung bitten.

Diese Einwilligung gilt für die jetzige Behandlung und künftige Behandlungen mit gleichem Krankheitsbild in der Hals-Nasen-Ohrenheilkunde des Universitätsklinikums Schleswig-Holstein.

Sie können die Einwilligung jederzeit widerrufen. Ihnen entstehen keine Nachteile, wenn Sie die Einwilligung nicht erteilen oder diese widerrufen. Fragen hierzu beantwortet Ihnen gerne die behandelnde Ärztin oder der behandelnde Arzt oder der Datenschutzbeauftragte des Universitätsklinikums Schleswig-Holstein.

Erklärung der Patientin, des Patienten, der Eltern / Erziehungsberechtigten,

(1) ☐ Ich willige ein, dass das Universitätsklinikum Schleswig-Holstein, Abteilung der Hals-Nasen-Ohren-Klinik, -wie oben beschrieben- meine medizinischen Daten (Messwerte, Blutwerte, Gewebe und Fotodokumentation) **zum jetzigen oder zu einem späteren Zeitpunkt für Forschungszwecke nutzen darf.**

(2) ☐ Ich willige ein, dass meine **Patientendaten an die HNO Universitätsklinik,** Schleswig-Holstein, Ratzeburger Allee 160, 23562 Lübeck **weitergeleitet** werden dürfen. Ich erkläre mich in diesem Rahmen mit der Verarbeitung meiner personenbezogenen Daten einverstanden.

_____

Datum, Unterschrift

Ihre Einwilligungen erfolgen freiwillig. Sie können Ihre Einwilligungen jederzeit ohne Nachteil zurückziehen.
Dann werden Ihre Daten gelöscht, wenn dem keine anderen rechtlichen Regelungen entgegenstehen (z B ärztliche Dokumentationspflicht).
Sie haben das Recht auf Auskunft, Löschung und Sperrung bezüglich Ihrer Daten.

Erstellt am: 05.12.2019		Geprüft am: 06.12.2019	Freigegeben am 06.12.2019
Name: Daniela Hollfelder		Name/Abt.: Dr.med. D. Hollfelder	Name/Abt: PD Dr. med. K.-L. Bruchhage

7.6 GBI Questionnaire Overview

H R- IMPLANTAT POST OPERATIVHR QJJALrrY OF LIFE FRAGEBOGEN MIT IMPLANTAT GBI ERWACHSENE/ JUGENDUCHE ab 16 Jahren	UK SH UNIVERSITATSKLINIKUM Schleswig-Holstein

NAME
DATUM
UNTERSCHRIFI'

Bine kreuzen Sie eine Antwon an. Es gibt kei.ne fulschen und ke.ine richt:igen Antworten. **Wir** mochten Ilrre Eiruchatzung Ihrer Lehensqualirat MIT dem Hor - Implantat.

1.GBI ERWACHSENE JUGENDI!CHE ab 16	**Hat c1a lmpl.....Amwirbmpm.aaf di.aw... 'wia Slia lwdnn..te nJnp tml7**				
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2.GBI ERWACHSENE fUGENDI!CHE ab 16	**Hatclai IhrLI!lbim.. ,m ·mt oc1l!ll' axhlaclma:t?**				
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3.GBI ERWACHSENE JUGENDLICliE ab 16	**Sahm. Sia dar Z-aknnft.mlt dar mabrodar**				
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4.GBI ERWACliSENE fUGENDUCHE •b 16	**r.t.lhmm. nacJ- lmplmtat:im clea Jl&.,Implmms • 2'.aDDmN!D.eln in Illinar Grappe -.nn. Mwchan Dlllhr-odarwmdprplliD&hi'**				
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H R - IMPLANTAT
POST OPERATIVER Q.UALITY OF LIFE FRAGEBOGEN
MIT IMPLANTAT
GBI

ERWACHSENE / fUGENDIJCHE ab 16 Jahren

UK SH UNIVERSITÄTSKLINIKUM Schleswig-Holstein

5.GBI ERWACHSENE JLIGENDLICHE ah 16	Vldllpn: Sm Milt Om,.1mphmmtton ._ B&--Implntatw ilbar mllhr oclerwmpr				
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6.GBI ERWACHSENE JUG£ DUCHE ab 16	MD&m• • mtPdan• RNm•Ztwnnnff'Nin admm lelclmi£,odilr				
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7.GBI EllWACHSENE JUGE DLICHE ab 16	MalDIIIDSl&!i,dwSieMltdet-ImplmtPdandMHnri-Impl.....-mehrodm-wmrlg8r UDim'IL DIZDDg"\'OD lhnlll Fnn.mdm W1111111111!1D7				
	viel IIlfillr Unterstiitzung LJ	mehr Unterstiitzung LJ	keine Verande.rung	weniger Unl:erstiitzung LJ	viel weniger Unterstiitzung LJ
8.GBI ERWACHSENE JUGENDUCHE •b 16	Wmm. Sia laltmrImplmradmW Jmt.-I:mplanta:twhlnfftpr... wmiprhlnftpr"lm 0mm R.. .•O:.....,tau wuman Grlndm?				
	viel haufig LJ	haufiger LJ	ke.ine Verlind@rung	weniger hliufig LJ	viel weniger Mu:fig LJ
9.GBI ERWACHSENE JUGENDLJCHE ah 16	Sahm Sia Milt dar Implam:atton a. .Jmpl..... SmD.....hen-IDlt mabr oda-W'lllrlpr ▬▬ ▪ ▪ IP"'				
	m:iit viel mehr Selostvertrauen LJ	mitmeh:r Selbstvertrauen LJ	kein@ Veriinderung	mit weniger Selbstvenrauen LJ	m:iit viel weniger Selbsrvenrauen LJ
10.GBI ERWAC!:ISENE JUGE DLICHE ab 16	PllblmSuimehtmtdir· -• ·· c1M Hllr-,. ▪ ml'lbrodiir- unafcber?				
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HOR- IMPLANTAT
POST OPERATIVER QJJALITY OF LIFE FRAGEBOGEN
MIT IMPLANTAT
GBI

ERWACHSENE/ fUCENDLICHE ab 16 Jahren

11.GBI ERWACHSENE JUGENDLICHE ab 16	**Qbt m llllt dP lmpl.ntwtkm dm B61'-Jmp1111bb'11111hr odarwmpr Leata. diamb. amSui Smpn Da'ban7**				
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12.GBI ER\VACHSENE JUGE DLICHE ab 16	**ladm Sia Nit dar Ytmplam:adan dm HJ!l'-Tmpbm1m 1.IDBpr adar'Wl!ddprhla:Bgm 1Mr11tnftpn undlnfehl.-7**				
	viel hlltufiger LJ	haufiger LJ	keine Verand.erung I I	wenige:r haufig LJ	viel wen.iger haufig LJ
13.GBI ERWACHSE E JUGENDLICHE ab 16	**Mmmm.Sia llllt &irlmplaomkm .- Bllr-Implmtm, ep1am Wl!llcban. Grll:D&m, mabrodlll' Wlmipr 111111.8d i.-7**				
	viel mehr Medikamente ☐	meh:r- Medilrameme	kein@ Veriinderung	weruger Medikamente ☐	viel weniger Medlikam.ente LJ
14.GBI ERWACHSENE fUGE DIJCHE ab 16	**Slnd Sia *lalt* &r.Jmpbmmdon -t. fflll.,Impl....mabrm&ll!l&m. mit lleh .U. odar ndkled.m7**				
	viel zufriedener LJ	zufriedener LJ	keine Veranderung I I	weruger zufrieden	vielweniger zufrieden LJ
15.GBI ERWACHSENE JUGE DLI HE ab 1.6	**Malnm S.. ct. Sia Dllcll da.Impbmt•dan cla Hllr--Implmtat1"11111hr adarwampr lhm,1111111 .amg clmrh lhm1amlHII hatmn7**				
	viel rnehr Untentutzung LJ	rnehr Untentiitzu.ng ☐	keine Vei:andenmg 1-1	weruger Untentii:tzung LJ	viel werugei: Unterstiitzun.g LJ
16.GBI ERWACHSENE JUGE DIJCHE ab 16	**Bmpftnclen Sill! Nit darlmplamatkm clamh--Implmtat1 T1mo pm.clbeb:Hclvm Pmblama al, mlllhrlt&lmd!adarallwmdalll'lb'kmldJ**				
	viel srorendei: LJ	stfuender LJ	kei.ne Verarulerung I I	weniger stfuend LJ	viel weniger storend LJ

HOR- IMPLANTAT POST OPERATIVBR Q.UALITY OF LIFE FRAGEBOGEN MIT IMPLANTAT GBI ERWACHSENE/ JUCENDLICHE ab 16 Jahren	

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	an vielmehr Anlas.s:en	anmehr Anlassen	keine Verandenmg	an weniger Anlass:en	an viel weniger Anlas:s:en
	☐	☐	I I	☐	☐

18.GBI ERWACfISE E JUGENDLI HE ob 16	Nmpn.S.Mlt..-Implrnw:lon .wlffir-Implntmttlllbrodar- ..... dam. am.am ....ttllt'baft-lfchmi 1111				
	neige viel mehr dazu	neigemehr dazu	keine Verii.nderung	neige weniger dazu	neige viel weniger dazu
	☐	1-1	1-1	LJ	LJ

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