PAEDIATRIC BONE CONDUCTION HEARING SOLUTIONS

PAST, PRESENT AND THE FUTURE IN A TERTIARY PAEDIATRIC SETTING

MAX SALLIS OSBORNE

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Paediatric Bone Conduction Hearing Solutions
Past, Present and the future in a Tertiary Paediatric setting
Max Sallis Osborne

Thesis RijksUniversiteit Groningen

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Past, Present and the future in a Tertiary Paediatric setting

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For Rufus and Alexander - Dream Big

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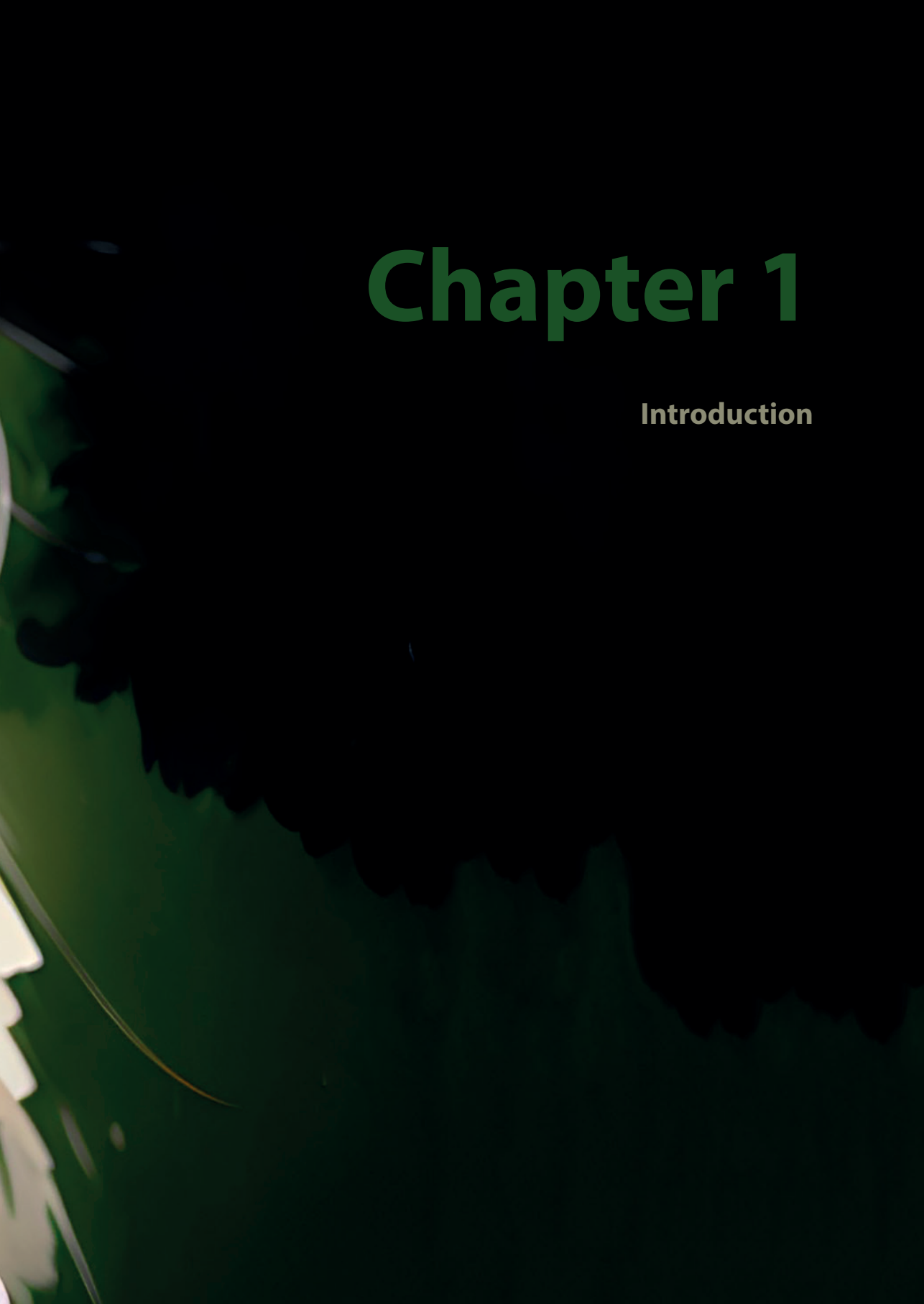

Chapter 1

Introduction

Introduction

History

The concept of augmenting hearing via bone conduction was first introduced over 300 years ago [1], and as technologies and understanding have developed so too has the application of bone conduction hearing devices (BCHD). The fundamental concepts have remained the same, whereby sound is transmitted to the inner ear by the vibration of a processor in contact with the skull, bypassing the normal auditory canal in those individuals with congenital or acquired absence of the ear canal or those with pathology preventing effective sound conduction.

Physiology of Hearing

Air conduction hearing relies on the mechanism of effective vibration of the tympanic membrane caused by changes in air pressure generated by sound. This enters the external auditory canal and is converted to mechanical movement of the ossicular chain and ultimately the stapes footplate. This mechanical movement is then transduced into the movement of fluid within the cochlea causing deflection of the basilar membrane and stimulation in the Organ of Corti with generation of action potentials which in turn are transmitted to the auditory processing centre leading to the perception of sound. The maximal point of deflection is determined by the frequency of the tone as the sound wave travels towards the apex of the basilar membrane [2].

Bone conduction hearing relies on the same stimulation of the basilar membrane by generating a pressure gradient around a specific point along it. As with air conduction, the maximal point of deflection and its subsequent propagation is determined by the frequency of the tone and there is no physiological difference between these points in either air or bone conduction [3,4]. The stimulation occurs due to multiple alternative mechanisms which generate the pressure gradient across the basement membrane [5]. The physiological principal of the generation of the pressure gradients is grounded by the asymmetry in the movement of inner ear fluid within the scala vestibuli (SV) and scala tympani (ST) due to both volume and impedance, which are both higher in the SV [6].

Physiological Principles

In 2005 Stenfelt and Goode proposed five contributing physiological factors influencing bone conduction hearing [7].

1. Cochlear fluid inertia – proposed as the most influential factor in bone conduction hearing. The pressure gradient is created by the vibration of the cochlea and resulting movement of the round window and oval window in a compensatory fashion. This movement is larger toward the round window due to lower impedance [8].

2. Compression, deformation, and distortion of the cochlear wall via direct vibration effect [9]
3. Sound energy vibration of soft tissues of external ear and middle ear ossicles. This is transmitted to the cochlear via the stapes footplate [10]. As the ossicular chain is suspended between the annular ligament and the tympanic membrane the movement is dependent on the frequency and is reduced above the ossicular chain's resonant frequency.
4. Pressure transmission from the cerebrospinal fluid
5. Sound transmission through the external ear canal

These fundamental physiological principles are capitalised on in the application of BCHD in modern audiological rehabilitation and over time significant technological developments have enabled rapid progression in design and application. [Figure 1]

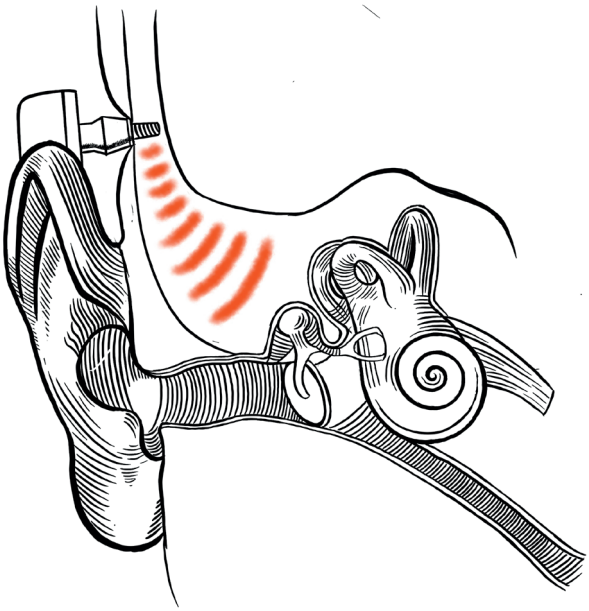

Figure 1: Vibration pathway from processor to inner ear.

Application of hearing physiology in BCHD

BCHD are comprised of two parts, a processor that converts sound to a digital signal and a mount or attachment connecting this device to the overlying skin or directly to the temporal bone.

The processor is comprised of a microphone, amplifier, digital processor, and a transducer. Here, sound is converted into a digital signal which drives a floating mass transducer. This vibration energy is then transmitted to the skull by the proximity of the vibrating processor to bone. Over time the footprint of the processor has reduced (34mm to 26mm), as has the technological application and connectivity to other electronic devices such as smart phones and computers.

The processor can be held in place on the mastoid bone by either non-surgical or surgical options and can be provided either unilaterally or bilaterally in the treatment of conductive hearing loss, mixed hearing loss or a single sided sensorineural deafness.

Non-Surgical Hearing Systems

Non-surgical mounts have been widely applied due to their simplicity, flexibility, and low cost. They are easily removable and replaceable based on the social or acoustic needs of the patient. The simplest solution uses a soft headband made from stretch fabric which is washable. An alternative to this is a hard headband mount which provides a greater contact pressure than the softband. It has been demonstrated that although a pressure of 2N is required to ensure an effective transmission of bone conducted sound [11] increasing the contact force provided limited (< 3dB) gain and that it is volume rather than contact force which is of greater importance [12]. Therefore, a softband is preferrable because of improved patient comfort and wearing time. Softband options are provided by Oticon ™ supporting the Ponto processor, Cochlear TM Baha® Start, Alpha MPO ePlus™ and the contact mini-™ (BHM Austria).

In the 1960's technological improvements reducing the size and weight of the electronic component allowed the sound processor to be mounted to spectacles. This type of mount still exists today and can provide both unilateral and bilateral mounting options and is particularly useful if eye glasses interfere with standard behind the ear hearing aids.

More recently the Sound Arc (Baha® Cochlear) was released, designed to be worn above the ears and behind the head. A semi rigid light-weight frame holds a connection disk in place to which the processor is mounted, and this again can be bilateral if required. This style of device has gained popularity in recreational sports where the application of bone conduction headphones (Shokz [13]) allow for an open ear canal. This is particularly useful where the user wishes to remain aware of their surroundings while undertaking a sporting activity such as running or cycling.

Although audiologically effective, subjective feedback from patients demonstrates poor compliance with headbands due to concerns about the aesthetics. This can be a particular deterrent to many older children with self-perception issues and concerns about integrating

with their peers. Eye glass mounted options have specific limitation due to the weight of the processor. This is even more pronounced in patients with microtia, many of whom may not have sufficient external pinna to hold their eyeglasses level with the additional weight. Furthermore, microtia is often asymmetrical and pinna position may be lower making the use of eye glasses very unsightly and impractical [14,15].

With the headband options, migration of the sound processor away from an optimal position over the mastoid bone reduces its efficacy [16]. It can also increase artifact production by movement over the patient's own hair, clothing, head dresses or hats. This often leads to the position of the processor being far from the mastoid process and therefore the cochlea. This becomes more pronounced for those children requiring eye glasses or those with variations in skull shape and contour.

When compared to the unaided condition, both soundfield thresholds and speech reception thresholds are improved with the application of a softband and sound arc, with no significant difference being demonstrated between the two [17,18].

An adhesive bone conduction system was designed as an alternative to these. It is comprised of two components - a novel sound processor and an adhesive adaptor. The sound processor attaches to the adhesive adaptor via a preformed snap coupler in the centre of the adhesive pad.

The adhesive pad is placed onto the hairless post auricular skin, directly over the mastoid bone and is replaced every 3-5 days to maintain adequate adhesion to the skin. This adhesive adaptor is designed to prevent sound processor migration and removes the requirement for an unsightly and tight-fitting headband. To date, reports of outcomes with the adhesive hearing system in adults and children demonstrated high levels of user satisfaction with improvement in pure tone threshold (functional gain of 23 dbHL and speech recognition of 23 dB SPL [19-22]. However, there is significant variation in the longevity of the adhesive pad and a narrow fitting range of <25dB BC PTA.

Historically novel devices such as 'Sound bite hearing system,' have been trialed but with limited success. The soundbite processor is mounted on a dental splint where sound is conducted through the maxilla and indirectly to the mastoid bone. At this time these bone conduction solutions are not widely offered for hearing rehabilitation, although have been repurposed and applied in the military setting in the United States of American.

Limitation of non-surgical options

Whatever the mounting option applied, transmission relies on the vibration signals from each processor through intact skin and soft tissues that overlie the skull, resulting in two limitations which decrease the effective amplification:

1. Signal attenuation – especially at high frequency
2. Limited wearing time due to the external pressure effect of the mounting option

Although taking into account the acoustic limitations of non-surgical mounts, their use in early rehabilitation for conductive hearing losses has distinct advantages. As a temporary solution, they can be used on an extended trial basis to introduce patients into the concept of bone conducting hearing aids, as often patients have limited knowledge or experience of this technology and may be skeptical of its application. With the advent of a trial period, patients are encouraged to gain experience with a bone conducting processor and their various mounting options.

In the adult population, trials of non-surgical mounts have the advantage of preoperatively demonstrating the hearing benefit a patient may expect and thus improve engagement with the overall process in a step toward an ultimate surgically mounted option.

In children there is the further advantage of being an ongoing rehabilitation option for those who may be too young to undergo surgery and those who are non-compliant with standard hearing aid options. For many children, especially those with additional care needs or cognitive impairment, the trial of a non-surgical mount provides excellent predictions of audiological results rather than conventional pure tone and speech audiology. Additionally in those children with microtia or anotia, it preserves the post auricular skin envelope until the child can engage autonomously with decisions regarding future pinna reconstruction options.

Surgically Implanted Hearing Systems

Surgically implanted Bone anchored hearing implants (BAHI), utilise the same transduction processors whereby sound is converted to a digital signal and ultimately mechanical vibration which is transmitted directly to the skull. Classically these are divided into Percutaneous (skin penetrating) and Transcutaneous (skin preserving).

Percutaneous Processors

Percutaneous devices were introduced in 1977 by Tjellström [23] and became commercially available in 1987. A skin penetrating abutment is attached to an anchoring fixture screw in the skull to which a sound processor is attached, bypassing the attenuation caused by skin and overlying soft tissue [Figure 2]. Originally described surgical techniques involved complete

split thickness skin grafts both with and without a dermatome use [24,25] to reduce soft tissue depth overlying the implanting area. Over time the approach now focuses on tissue preservation avoiding the possible complications caused by skin flap necrosis [26,27] and thus reducing skin complications [28]. Linear incision techniques have been shown to have a faster healing time and to inflict less pain than dermatome techniques [29,30]. Currently the use of tissue preservation techniques is reported to have the best soft tissue outcomes [31]. Oticon introduced minimally invasive Ponto Surgery (MIPS) which has been shown to have comparable soft tissue outcomes to linear incision techniques [32,33,34] and reduced tissue reaction in some centres to 4.5%, [35] however others have reported fixture failure rate of up to 35% [36].

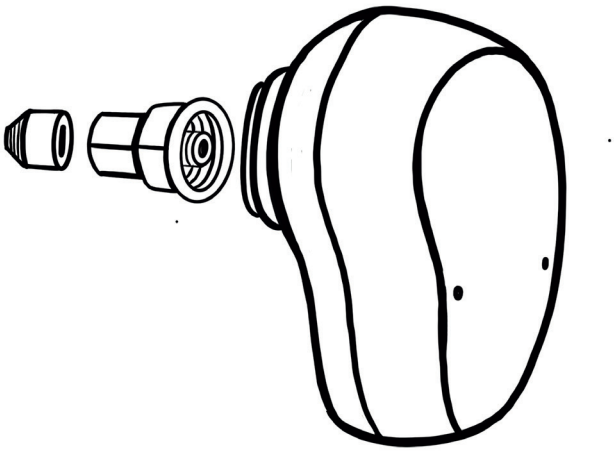

Figure 2. Components of a percutaneous bone conduction hearing device: comprise of implantable titanium screw, skin penetrating abutment and sound processor.

Direct contact with the temporal bone creates two immediate benefits: firstly, better audiological results in both sound field thresholds and speech recognition. Secondly the power of the processor can be increased without complications of migration or significant skin irritation.

Limitations of BAHI include peri-abutment soft tissue reactions and fixture loss through either trauma or failed osseointegration, both of which are demonstrated to be higher in paediatric populations [37,38]. Soft tissue reaction is classically monitored and described by the application of the Holgers score (0-4) [39] which shows a wide variation in incidence depending on the surgical technique utilised, the abutment used for mounting the processor and finally subjective reporting by clinicians.

Skin reactions require special consideration in the paediatric population. Pubertal hormonal changes result in sebaceous hypertrophy and an associated skin overgrowth which may require a longer abutment [40]. There is also an acceptance that the lifestyle and behaviour of children can result in an anticipated proportion of abutment loss secondary to trauma [41]. This underlies the philosophy of sleeper fixture insertion at the time of the primary procedure. Any fixture loss can be replaced quickly without any delay associated with waiting for osseointegration of a new implant.

Physiological factors and Osseointegration

Successful implantation is dependent upon osseointegration of the implanted fixture with the surrounding bone which occurs during wound healing, and is defined by three factors; (i) the formation of a stable support and absence of relative motion between the implant and surrounding tissues, (ii) the apposition of bone to the implant without intervening soft tissue, and (iii) the tissues closest to the implant surface are identified as normal bone and marrow constituents (at light and electron microscopic levels [42].

These factors are in turn influenced by implant geometry (macro, micro and nano scale), drilling protocol, osteotomy configuration, surface, and material properties, surrounding bone quality as well as systemic and local characteristics of the host [43]. Patient-related conditions such as high BMI, diabetes, osteogenesis imperfecta, previous radiotherapy of the temporal bone, various co-morbidities and smoking have been implicated in higher rates of implant loss [44,45,46].

For this reason, despite the overall low incidence of implant failure, there is a need to further enhance the implant stability and osseointegration, and thereby survival rates. Furthermore, some centres advocate early or even immediate loading of processors in adults [47,48,49,50] and at 6 weeks in children [51]. This too, leads to increased demands on implant stability and accelerated osseointegration.

The common strategy for addressing these challenges, both for dental, orthopaedic and BAHI applications, have been two-fold, (i) increased implant diameter and primary implant-to-bone contact and (ii) application of surface modification to the implant. The use of wider diameter implants was shown to improve outcomes in dental implantation with lower implant failure rates [52,53]. Application of wide diameter BAHI (4.5 mm diameter) has been found to have comparable adverse skin reaction rates to the previous generation implants (3.75mm diameter) and associated with increased survival [54,55,56,57].

The wider diameter increases the surface area contact between the implant and temporal bone thereby providing a greater primary stability with the aim to promote a reduction in

spontaneous fixture loss. Implant surface modification has been the main strategy to promote biological reactions to accelerate and promote its integration with bone.

In dental applications, most surface modifications employ techniques that increase the roughness of the surface [58] with benefits in terms of a stronger bone response and better clinical results compared with non-modified implants [59].

A recent review reported a survival rate of 1166 BAHI implants of various designs, of 97.7% over an average follow-up time of 17 months across a predominantly adult population [60]. For adult populations, the failure rates for wide diameter implant systems are reported between 2.6-4.2%. [61,62,63,64]. Recent meta-analysis supports these findings in children demonstrating a 17.1% loss in small-diameter implants compared with a 5.9% for wide-diameter implants [65].

Currently Available Percutaneous BAHI [66]

Cochlear™ Baha® Connect System
(Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden) [67]

4.5mm wide BI300 titanium fixation screw (3-4mm length) + BA400 hydroxyapatite – coated abutment (6-14mm length)
Processors available - Baha® 5 (45 dB HL), Baha® 5 Power (55 dB HL), and the Baha® 5 SuperPower (65 dB HL). Baha® 6 (55 dB HL)

Oticon Ponto System
(Oticon Medical AB, Askim, Sweden) [68]

4.5mm wide BHX titanium screw (3-6mm length) + abutments (6, 9, 12 and 14 mm length)
Processors available - Ponto 3 (45 dB HL), Ponto 3 Power (55 dB HL) and Ponto 3 Superpower (65 dB HL), Ponto 4 (45 dB HL), Ponto 5 Mini (45 dB HL) and Ponto 5 Superpower (65 dB HL).

Processor development

Substantial developments in connectivity and streaming have been made in all processors, seamlessly integrating with apps and accessories to improve patient satisfaction. This also aids streamlining the fitting process where wireless and remote fitting can be undertaken.

Oticon Ponto (Oticon Medical AB, Askim, Sweden) Ponto, the latest version of the Ponto (Oticon processor) the 5 mini, focuses on reducing size and weight rather than increasing power and maximal output. The processor has decreased in size over time from a footprint of 34x21x11mm (Ponto 3) to 26x19x11mm (Ponto 5 mini) with a weight reduction from 14g to 13.2g respectably.

Cochlear Baha® (Cochlear Bone Anchored Solutions AG, Mölnlycke, Sweden) processor have decreased in size while simultaneously maintaining maximal power output and increasing the fitting range from 45db SNHL to 55 dB SNHL. The footprint of this processor decreased from 30x21x12mm 11.6g in the Baha® 4 to 26x19x12mm 11.5g in the Baha®6.

Audiological benefit

Audiological gain is not an ideal parameter when comparing different BCHDs. Some authors prefer to use aided hearing thresholds as a better parameter for comparison. A literature review shows there is little consensus on this topic.

In 2019, Snik et al undertook meta-analysis of published data and found that the gain was 10dB higher in the Baha®5 sound processor when compared to the Ponto 3 sound processor [69]. Snik et al concluded that this difference in gain was due to the maximal power output being 9 dB higher in the Baha® 5. Interestingly there was no significant difference between these two processors' word recognition scores presented at 65 dB SPL [70].

Transcutaneous Processors

Transcutaneous devices provide sound transmission through intact skin to remove the skin complication created by a skin penetrating abutment. First developed in 1986 by Hough et al [71] these systems are comprised of two components. An implanted fixture which is implanted into the temporal bone to which a magnet is attached. The overlying skin is closed. An external processor with an external magnet is then connected to allow for transmission of either vibration stimuli or digital information. Although Hough's initial system the Xomed Audiant was eventually withdrawn from the market due to high retention pressures combined with insufficient amplification, the concept remained viable and new systems were brought to market in 2013.

In the modern setting, transcutaneous systems are available in two categories;

- The vibrating mass transducer is implanted under the skin and signals sent via electromagnetic induction from the external processor to it (**active device**)
- The transducer is placed externally, and the vibration is transmitted through the intact skin and soft tissue (**passive device**).

These options minimise skin complications caused by a skin penetrating abutment. However, the retention forces of the magnets required to stabilise them on the skin surface can cause pain and irritation. Up to 38% of the adult population reported skin numbness, pain or discomfort in the first 6 months after implantation [72] and there are reported cases of skin necrosis from this type of device [73]. A similar rate of skin irritation has been reported in paediatric populations (16%) [74].

A slow increase in magnet strength from the point of fitting is advised to improve wearing time and acclimatise the skin to the processor. This irritation can be compounded by the vibration caused by passive devices, which also need to overcome the attenuation of the soft tissue and skin: As with non-surgical BCHDs, this can result in paraesthesia or numbness [75]. Magnets are available in a variety of strengths which can be tailored to the patients' needs. Over the initial 12 months of use, it has been observed that the overlying soft tissue becomes thinner due to the compression forces effect of the magnets, and this has the additional benefit of thus reducing the required magnet retention strength [76].

Surgical approaches to these devices are more invasive than with percutaneous systems, requiring either a larger subcutaneous pocket to be created or a bony well to be drilled into the temporal bone to secure the transducer. The position of these devices can be limited by anatomy, and this needs special consideration in children who have a small skull and small mastoid, those individuals who had previous mastoid surgery and also in children with microtia.

Another consideration is the compatibility for MRI. Although most systems are compatible up to 1.5 Tesla as with cochlear implants, the presence of the magnet can also interfere with Magnetic Resonant Imaging creating large imaging shadows and this may necessitate removal of the internal magnets if an MRI of the head is be undertaken.

Currently Available Transcutaneous BAHI

Subcutaneous transducer (active system) [77]

- Osia® System — Cochlear Bone-Anchored Solutions AB, Mölnlycke, [78]

Implant	OSI200 system fixed to BI300 Osseointegrated screw
Surgical consideration	Bone polishing may be required.
MRI	compatible: OSI200 1.5 Tesla, OSI300 3 Tesla
Processor	Osia® 2 (55 dB HL)

- BONEBRIDGE TM — MED-EL, Innsbruck, Austria [79]

Implant	BCI602 floating mass transducer.
Surgical consideration	Drilling of a Pre sigmoid bone bed required. Cortical fixation screws. (No osseointegration)
MRI	compatible: 1.5 Tesla
Processor	SAMBA 2 (45 dB HL)

Currently under development

- Sentio System — Oticon Medical, Askim, Sweden
  - Implant: Sentio Ti
  - Surgical consideration: Bone bed required
  - MRI: compatible: 1.5 Tesla
  - Processor: Sentio 1

External Transducer (passive system)

- Baha® Attract — Cochlear Bone-Anchored Solutions AB, Mölnlycke, [80]
  - Implant: BIM400 magnet fixed to BI300 osseointegrated screw
  - Surgical consideration: Overlying soft tissue >6mm, no contact of magnet to bone
  - MRI: compatible: 1.5 Tesla (11 cm shadow)
  - Processor: Baha® 5 (45 dB HL), Baha® 5 Power (55 dB HL), and the Baha® 5 SuperPower (65 dB HL). Baha® 6 (55 dB HL)
- Sophono/Alpha 2 MPO ePlus™ — Medtronic, Minneapolis, USA [81]
  - Implant: Two internal magnets with five screws fixation
  - Surgical Consideration: Shallow bony bed
  - MRI: compatible: 3 Tesla (5cm shadow)
  - Processor: Alpha 2 MPO ePlus™ (45 dB HL)

Audiological Comparisons of BCHD

Selection of processor and mounting options is specific to each patient's audiological, and rehabilitation needs and with the increasing options brought to market it can be challenging to make conclusions on which is ultimately the best choice for the patient. To overcome these challenges, significant audiological research has been published comparing these products. However, comparison between these studies has its own limitations due to the vast variability in mounting and processor options being studied. In fact, patient preference is often the main factor in decision making.

The fundamental principles of a BCHD hierarchy remain unchanged: The best audiological outcomes are gained through direct contact of a vibrating processor with the skull and, the fitting range is determined by the maximum output.

Percutaneous and active transcutaneous BCHDs therefore have significant audiological benefit over softband mounting, ADHEAR and passive devices as they do not need to overcome the

attenuation caused by the overlying skin and soft tissues. A significant difference of 5-20db is observed between 1-4 kHZ when comparing softband mounting to percutaneous mounted devices, associated with a SRT improvement of 4- 7 dB which translates into a 20-40% difference in speech understanding [82,83]. However, as these studies utilised different processors for this analysis direct comparison is challenging.

A study comparing the same Baha® 5 processor in a matched patient group with single sided deafness concluded that word understanding and phoneme recognition scores at both 62 and 47 dB SPL were significantly worse for the softband group as compared to the percutaneous group by 16%. Furthermore, the greatest deviations were in the high frequencies above 2000 Hz [84]. In mixed hearing losses [85] and in conductive hearing losses [86] less of an improvement was demonstrated.

For a conductive loss of <25db, both the passive Baha® Attract and ADHEAR have comparable audiological performance to a softband system without the requirement of pressure. Aided sound field thresholds of 33+/- 6 in Baha® Attract, 32+/-9 ADHEAR and 27+/-6 in softband were reported and, no significant difference in speech understanding in both the quiet (20dB) and in noise (54dB) found [87].

With regards to the superiority of percutaneous verses active transcutaneous, there is ongoing debate of which provides the best rehabilitation option. When comparing the percutaneous Oticon Ponto system to the active transcutaneous Med-EL bone bridge it was found that the Bonebridge® performed slightly better in the mid-frequencies, while the Ponto had superior results for the lowest and the highest frequencies. The PTA_4 improvement was 31.0 ± 8.0 dB for Bonebridge®, and 31.5 ± 2.8 dB for the Ponto system. However, there was no statistically significant difference between the two devices. [88]

Passive systems provide excellent audiological rehabilitation however limited by the maximal output as compared to percutaneous option. Hol et al 2013 demonstrated that although either option provides audiological benefits, percutaneous options provided better sound field thresholds, speech recognition and speech comprehension combined with a 10 dB higher output [89].

In 2015, M Iseri et al demonstrated poorer transcutaneous audiological outcomes when compared to the percutaneous BAHI due to the indirect connectivity between the processor and implant [90]. These conclusions were again supported in 2019 by Kohan et al who compared average audiological results in (dB) between two different passive transcutaneous devices and the percutaneous Baha® system. Again, this showed the percutaneous Baha® to be better at low and mid frequencies. Interestingly it also compared different versions of the

Baha® processor on these mounting options providing a direct comparison in audiological outcomes between the mounting systems and the processor used. It concluded that The Baha® 5 processor had better audiological results than its predecessor Baha® 4 when mounted on either the Baha® connect (31 vs 49) or Baha® Attract (22 vs 35) [91]. Overall, the best audiological results were seen in the percutaneous system with the processor with the highest maximal output [92].

With the recent release of the Osia® system by Cochlear, further comparison can be made between this active device and its passive Baha® Attract system. Both speech audiometry and free field were greater in the subcutaneous implanted device (42.8 dB SPL) compared to the Baha® Attract (38.8 dB SPL). In addition, superior quality of hearing was reported with the use of the Osia® system [93].

The potential benefits of this system combine the ease of implantation without the requirement of a bone well. A 4.5mm wide fixation screw with a good survival rate is likely to make this the preferred option for patients in the future. Audiological outcomes are comparable to available data for percutaneous options. To the author's knowledge there is currently no available published data directly comparing this device to percutaneous options, and further research to establish this would be illuminating. The additional benefit of this system is the low skin complication rates which can often accompany skin penetrating abutments and ease of maintenance.

Overall selecting the appropriate device for an individual patient is complex and is influenced by a combination of audiological, subjective and objective factors including patients choice [94]

Application of BCHI in the paediatric population

The positive impact of overcoming a conductive hearing loss on a child's language acquisition and social development with the use of BAHI is well documented [95-102]. As hearing technology develops, breakthroughs have been made in both active and passive transcutaneous bone conduction systems with improving audiological outcomes [103-110].

In addition, there are many reports of improvement in quality of life as well as better speech and language acquisition [111,112,113]. The benefits of bilateral implant insertion, in particular with sound localisation and speech recognition, are now well appreciated [114,115,116].

However, complications associated with paediatric BAHIs continue: Lack of engagement from the child to accept such a hearing solution, peri-abutment soft tissue reactions and fixture

(implant) loss through both trauma and failed osseointegration, have been demonstrated to be higher in paediatric populations [117,118].

Skin reactions require special consideration in the paediatric population. Pubertal hormonal changes result in sebaceous hypertrophy and an associated skin overgrowth which may require a longer abutment and attention to the soft tissues [119].

As the population of implanted paediatric patients is heterogeneous and often accompanied by systemic co-morbidities as well as additional childcare needs from a medical, learning, and social aspect, the burden of care for percutaneous implants may be a limiting factor. Unlike in the adult population where hearing rehabilitation options are offered based on audiological test results, undertaking these tests in children poses additional challenges.

The validity of subjective hearing tests such as play audiometry, VRA or PTA in young children requires conditioning of a child to provide a response to indicate hearing thresholds. Speech assessments and hearing in noise tests require patient to repeat sentences or words and is dependent on the child's age and ability to understand and repeat a complex sequence of instruction in an unfamiliar and noisy environment.

Many children who require audiological rehabilitation are too young, restricted by co-morbidities or have additional learning needs to gain any meaningful results from many of these tests and so their application is limited. Auditory Brainstem response test (ABR) thresholds can be utilised to guide implantation. However, in the paediatric population parental/carer and patient reported outcome measures bare far more weight in assessing the effectiveness of a BCHD. If an observed improvement is reported during the trial period, this can provide sufficient evidence to offer formal implantation for the patient. In many cases, such a device trial may take months or even years before the decision to move to implantation is taken.

To aid clinical decision-making, validated health benefit questionnaires are applied to provide objective evidence of any observed improvement. The Glasgow Children's Benefit Inventory (GCBI) [120] and an additional visual analogue scale (VAS) are often applied, and many other scoring systems have been proposed [121]. The responses from these can be subdivided to provide assessment relating to emotion, physical health, learning and vitality. This information is easier for parents/careers to relate to in terms of benefits to their child rather than just hearing thresholds and this helps guide them in making the decision to undertake implantation.

Transcutaneous implant systems reduce potential for skin complications traditionally associated with percutaneous implants. Such implant systems produce excellent audiological outcomes but still require the surgical implantation of either an osseointegrated fixture and/or

magnet or a bone conduction floating mass transducer [122-126]. Magnetic retention is also a consideration in children whose activities and lifestyles may result in displacement or loss of a processor held in place by magnetic force alone.

A comparative study comparing Baha® connect to Baha® Attract in paediatric patients found that 58% of patients with Baha® connect had complications in the first 12 months compared to no major complication (removing magnet strength issues) in the Baha® Attract group. These complications included high rates of skin overgrowth, infection, nursing phone calls and ENT visits with the Baha® connect group [127].

The latest studies into the application of the Osia® system in the paediatric population have demonstrated mean audiological benefit of 43.1 dB (+/- 10.2 dB), with a preference of this system over their previous percutaneous implants [128] and although morphometric studies show paediatric patients to have different anatomical skull dimensions to adults, this option is feasible and requires only a small alteration in positioning [129].

For those children with isolated microtia and canal atresia, the cosmetic considerations are extremely important. Care must be taken in choosing the placement of any implant system in such children to ensure that a sufficient post auricular skin envelope is maintained for potential future autologous reconstruction. Scaring in this region may compromise the option of reconstruction in later life as coverage of the neoauricle with local tissue might be insufficient [130,131,132]. Therefore, surgical options may be delayed until the child is older and non-surgical systems preferred and applied until this point.

Non-surgical transcutaneous hearing systems provide a simple and effective solution in both unilateral and bilateral conductive hearing loss. Although audiologically effective, subjective patient feedback highlights poorer compliance with headbands due to concerns about the aesthetics. This can be a deterrent for many older children with self-perception issues and concerns about integrating with their peers. Additionally, the retention pressure by headbands may produce some complications and limitations in daily usage [133].

The transcutaneous adhesive bone conducting ADHEAR system demonstrated high levels of user satisfaction and no skin irritations [134], as well as comparable results to conventional softband devices with regards to speech understanding and sound localization [135] however is limited to conductive hearing losses of >25dB.

Thesis Prelude

The paediatric BCHD was introduced to Birmingham Children's Hospital in 1988 and over the last 36 years has produced one of the largest cohorts of implanted paediatric patients in the United Kingdom. Previous research from this Institution has resulted in 6 preceding PhD theses in association with Radboud University, Nijmegen.

This thesis focuses on the clinical impact of the introduction of the Oticon wide diameter fixation screws and the clinical outcome in the paediatric population. This is compared to previously utilised narrow implants at the same centre. It then examines the impact of laser ablation on the surface of the implanted fixture with regards to clinical outcome and examines the relationship between survival rates and Resonance Frequency Analysis (RFA) in both the general paediatric population and patients with trisomy 21. Due to the availability of comparable data sets published previously from the same centre this thesis provides compelling evidence of how developments in implant design have directly impacted clinical outcomes in the paediatric population.

In addition, it cross examines the usefulness of RFA in predicting fixture failures in the paediatric population and its feasibility in real-world application.

Finally, this thesis investigates the audiological outcomes and impact on quality of life of the novel adhesive retained bone conduction hearing system (ADHEAR) at its introduction in 2015 and again in 2019. This longitudinal review allows for analysis of paediatric patient compliance, conversion rates to alternative systems, skin complications and limitations with regards to its application in the paediatric setting.

References

1. Berger KW. Early bone conduction hearing aid devices. Arch Otolaryngol. 1976 May;102(5):315-8
2. Paradoxical direction of wave travel along the cochlear partition J Acoust Soc Am, 27 (1955), pp. 137-145
3. von Békésy G. Experiments in Hearing. New York: McGraw-Hill; 1960
4. Stenfelt S, Puria S, Hato N, Goode RL. Basilar membrane and osseous spiral lamina motion in human cadavers with air and bone conduction stimuli. Hear Res. 2003 Jul;181(1-2):131-43
5. Dauman R. Bone conduction: an explanation for this phenomenon comprising complex mechanisms. Eur Ann Otorhinolaryngol Head Neck Dis. 2013 Sep;130(4):209-13.
6. J. Tonndorf Bone conduction: Studies in the experimental animals Acta Otolaryngol (Suppl. 213) (1966), pp. 1-132
7. Stenfelt S, Goode RL. Bone-conducted sound: physiological and clinical aspects. Otol Neurotol. 2005 Nov;26(6):1245-6
8. Stenfelt S. Acoustic and physiologic aspects of bone conduction hearing. Adv Otorhinolaryngol. 2011;71:10-21
9. J. Tonndorf Bone conduction: Studies in the experimental animals Acta Otolaryngol (Suppl. 213) (1966), pp. 1-132
10. S. Stenfelt, T. Wild, N. Hato, et al. Factors contributing to bone conduction: the outer ear J Acoust Soc Am, 113 (2003), pp. 902-912
11. von Békésy G. Experiments in Hearing. New York: McGraw-Hill; 1960
12. Hodgetts WE, Scollie SD, Swain R. Effects of applied contact force and volume control setting on output force levels of the BAHA Softband. Int J Audiol. 2006 May;45(5):301-8.
13. https://uk.shokz.com/
14. Saroul N, Akkari M, Pavier Y, Gilain L, Mom T. Baha-mediated rehabilitation of patients with unilateral deafness: selection criteria. Audiol Neurootol. 2014;19(2):85-90
15. Zawawi F, Kabbach G, Lallemand M, Daniel SJ. Bone-anchored hearing aid: why do some patients refuse it? Int J Pediatr Otorhinolaryngol. 2014 Feb;78(2):232-4
16. Dobrev I, Stenfelt S, Röösli C, Bolt L, Pfiffner F, Gerig R, Huber A, Sim JH. Influence of stimulation position on the sensitivity of bone conduction hearing aids without skin penetration. Iny J Audiol. 2016 Aug;55(8):439-46
17. Gawliczek T, Wimmer W, Munzinger F, Caversaccio M, Kompis M. Speech Understanding and Sound Localization with a New Nonimplantable Wearing Option for Baha. Biomed Res Int. 2018 Sep 25;2018:5264124
18. Verstraeten N, Zarowski AJ, Somers T, Riff D, Offeciers EF. Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the testband, and to the "snap" abutment. Otol Neurotol. 2009 Jan;30(1):70-5
19. Dahm V, Baumgartner WD, Liepins R, Arnoldner C, Riss D. First Results with a New, Pressure-free, Adhesive Bone Conduction Hearing Aid. Otol Neurotol. 2018 Jul;39(6):748-754

20. Favoreel A, Heuninck E, Mansbach AL. Audiological benefit and subjective satisfaction of children with the ADHEAR audio processor and adhesive adapter. Int J Pediatr Otorhinolaryngol. 2020 Feb;129:109729.

21. Almuhawas F, Alzhrani F, Saleh S, Alsanosi A, Yousef M. Auditory Performance and Subjective Satisfaction with the ADHEAR System. Audiol Neurootol. 2021;26(1):1-10.

22. Zernotti ME, Alvarado E, Zernotti M, Claveria N, Di Gregorio MF. One-Year Follow-Up in Children with Conductive Hearing Loss Using ADHEAR. Audiol Neurootol. 2021;26(6):435-444.

23. Tjellström A, Lindström J, Hallén O, Albrektsson T, Brånemark PI. Osseointegrated titanium implants in the temporal bone. A clinical study on bone-anchored hearing aids. Am J Otol. 1981 Apr;2(4):304-10

24. Tjellström A. Osseointegrated systems and their applications in the head and neck. Adv Otolaryngol Head Neck Surg 1989;3:39-70

25. Stalfors J, Tjellström A. Skin reactions after BAHA surgery: a comparison between the U shaped graft technique and the BAHA dermatome. Otol Neurotol 2008; 29:1109-1114

26. De Wolf MJ, Hol MK, Huygen PL, Mylanus EA, Cremers CW. Clinical outcome of the simplified surgical technique for BAHA implantation. Otol Neurotol 2008;29:1100-1108

27. Shapiro S, Ramadan J, Cassis A. BAHA Skin Complications in the Paediatric Population: Systematic Review with Meta-analysis. Otol Neurotol. 2018 Jun 15. doi: 10.1097

28. van der Stee EHH, Strijbos RM, Bom SJH, Hol MKS. Percutaneous bone-anchored hearing implant surgery: linear incision technique with tissue preservation versus linear incision technique with tissue reduction. Eur Arch Otorhinolaryngol. 2018 Jul;275(7):1737-1747.

29. Høgsbro M, Agger A, Johansen LV. Bone-anchored Hearing Implant Surgery: Randomized Trial of Dermatome Versus Linear Incision Without Soft Tissue Reduction--Clinical Measures. Otol Neurotol. 2015 Jun;36(5):805-11

30. Strijbos RM, Bom SJH, Zwerver S, Hol MKS. Percutaneous bone-anchored hearing implant surgery: dermatome versus linear incision technique. Eur Arch Otorhinolaryngol. 2017 Jan;274(1):109-117

31. van der Stee EHH, Strijbos RM, Bom SJH, Hol MKS. Percutaneous bone-anchored hearing implant surgery: linear incision technique with tissue preservation versus linear incision technique with tissue reduction. Eur Arch Otorhinolaryngol. 2018 Jul;275(7):1737-1747

32. Caspers CJI, Kruyt IJ, Mylanus EAM, Hol MKS. Six-Month Clinical Outcomes for Bone-Anchored Hearing Implants: Comparison Between Minimally Invasive Ponto Surgery and the Linear Incision Technique With Tissue Preservation. Otol Neurotol. 2020 Apr;41(4):e475-e483

33. Sardiwalla Y, Jufas N, Morris DP. Long term follow-up demonstrating stability and patient satisfaction of minimally invasive punch technique for percutaneous bone anchored hearing devices. J Otolaryngol Head Neck Surg. 2018 Nov 20;47(1):71

34. Calon TGA, Johansson ML, de Bruijn AJG, van den Berge H, Wagenaar M, Eichhorn E, Janssen MML, Hof JR, Brunings JW, Joore MA, Jonhede S, van Tongeren J, Holmberg M, Stokroos RJ. Minimally Invasive Ponto Surgery Versus the Linear Incision Technique With Soft Tissue Preservation for Bone Conduction Hearing Implants: A Multicenter Randomized Controlled Trial. Otol Neurotol. 2018 Aug;39(7):882-893

35. Holmes S, Hamiter M, Berry C, Mankekar G. Tissue Preservation Techniques for Bone-Anchored Hearing Aid Surgery. Otol Neurotol. 2021 Aug 1;42(7):1044-1050.

36. Limbrick J, Muzaffar J, Kumar R, Mulvihill D, Gaskell P, Addison O, Monksfield P, Banga R. Novel Minimal Access Bone Anchored Hearing Implant Surgery and a New Surface Modified Titanium Implant, the Birmingham Experience. Otol Neurotol. 2019 Dec;40(10):1326-1332

37. Tzortzis S, Tzifa K, Tikka T, Worrollo S, Williams J, Reid AP, Proops D. A ten-year review of soft tissue reactions around percutaneous titanium implants for auricular prosthesis. Laryngoscope. 2015 Aug;125(8):1934-9

38. Dun CA, Faber HT, de Wolf MJ, Mylanus EA, Cremers CW, Hol MK. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol. 2012 Feb;33(2):192-8

39. Holgers KM, Tjellström A, Bjursten LM, Erlandsson BE. Soft tissue reactions around percutaneous implants: a clinical study of soft tissue conditions around skin-penetrating titanium implants for bone-anchored hearing aids. Am J Otol. 1988;9(1):56-59

40. J. Doshi, A.L. McDermott, A. Reid, D. Proops, The 8.5 mm abutment in children: the Birmingham bone-anchored hearing aid program experience, Otol. Neurotol. 31 (2010) 612–614

41. Proops DA. The Birmingham bone anchored hearing aid programme: surgical methods and complications. J Laryngol Otol 1996 (suppl): 7-12

42. Shah FA, Thomsen P, Palmquist A. Osseointegration and current interpretations of the bone-implant interface. Acta Biomater. 2019 Jan 15;84:1-15.

43. Esposito M, Hirsch JM, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (I). Success criteria and epidemiology. Eur J Oral Sci. 1998 Feb;106(1):527-51.

44. Wilkie MD, Lightbody KA, Salamat AA, Chakravarthy KM, Luff DA, Temple RH. Stability and survival of bone-anchored hearing aid implant systems in post-irradiated patients. Eur Arch Otorhinolaryngol. 2015 Jun;272(6):1371-6.

45. Bezdjian A, Smith RA, Thomeer HGXM, Willie BM, Daniel SJ. A Systematic Review on Factors Associated With Percutaneous Bone Anchored Hearing Implants Loss. Otol Neurotol. 2018 Dec;39(10):e897-e906.

46. Horstink L, Faber HT, de Wolf MJ, Dun CA, Cremers CW, Hol MK. Titanium fixtures for bone-conduction devices and the influence of type 2 diabetes mellitus. Otol Neurotol. 2012; 33(6):1013–7

47. Wazen JJ, Babu S, Daugherty J, Metrailer A. Three-week loading of the 4.5mm wide titanium implant in bone anchored hearing systems. Am J Otolaryngol. 2016 Mar-Apr;37(2):132-5

48. Nelissen RC, den Besten CA, Faber HT, Dun CA, Mylanus EA, Hol MK. Loading of osseointegrated implants for bone conduction hearing at 3 weeks: 3-year stability, survival, and tolerability. Eur Arch Otorhinolaryngol. 2016;273(7):1731-1737

49. McLarnon CM, Johnson I, Davison T, et al. Evidence for early loading of osseointegrated implants for bone conduction at 4 weeks. Otol Neurotol. 2012;33(9):1578-1582.

50. McElveen JT Jr, Green JD Jr, Arriaga MA, Slattery WH 3rd. Next-Day Loading of a Bone-Anchored Hearing System: Preliminary Results. Otolaryngol Head Neck Surg. 2020 Sep;163(3):582-587.

51. McLarnon C, Johnson I, Davison T, et al. Resonance frequency analysis of osseo-integrated implants for bone conduction in a pediatric population - a novel approach for assessing stability for early loading. Int J Pediatr Otorhinolaryngol. 2014;78(4):641-644

52. Lee JH, Frias V, Lee KW, Wright RF. Effect of implant size and shape on implant success rates: a literature review. J Prosthet Dent. 2005 Oct;94(4):377-81

53. Mendonça JA, Senna PM, Francischone CE, Francischone Junior CE, Sotto-Maior BS. Influence of the Diameter of Dental Implants Replacing Single Molars: 3- to 6-Year Follow-Up. Int J Oral Maxillofac Implants. 2017 Sep/Oct;32(5):1111-1115

54. Kruyt IJ, Nelissen RC, Mylanus EAM, Hol MKS. Three-year Outcomes of a Randomized Controlled Trial Comparing a 4.5-mm-Wide to a 3.75-mm-Wide Titanium Implant for Bone Conduction Hearing. Otol Neurotol. 2018 Jun;39(5):609-615

55. Foghsgaard S, Caye-Thomasen P. A new wide-diameter bone-anchored hearing implant-prospective 1-year data on complications, implant stability, and survival. Otol Neurotol. 2014 Aug;35(7):1238-41

56. Nelissen RC, den Besten CA, Mylanus EA, Hol MK. Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial. Eur Arch Otorhinolaryngol. 2016 Jan;273(1):105-11

57. Nelissen RC, Stalfors J, de Wolf MJ, Flynn MC, Wigren S, Eeg-Olofsson M, Green K, Rothera MP, Mylanus EA, Hol MK. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. Otol Neurotol. 2014 Sep;35(8):1486-91

58. Palmquist A, Engqvist H, Lausmaa J, and Thomsen P. Commercially Available Dental Implants: Review of Their Surface Characteristics. J Biomater Tissue Eng. 2012;2(2):112-24.

59. Albrektsson T and Wennerberg A. Oral implant surfaces: Part 1--review focusing on topographic and chemical properties of different surfaces and in vivo responses to them. Int J Prosthodont. 2004;17(5):536-43.

60. Lagerkvist H, Carvalho K, Holmberg M, Petersson U, Cremers C, Hultcrantz M. Ten years of experience with the Ponto bone-anchored hearing system-A systematic literature review. Clin Otolaryngol. 2020 Sep;45(5):667-680.

61. Nelissen RC, den Besten CA, Mylanus EA, Hol MK. Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial. Eur Arch Otorhinolaryngol. 2016 Jan;273(1):105-11

62. Foghsgaard S, Caye-Thomasen P. A new wide-diameter bone-anchored hearing implant-prospective 1-year data on complications, implant stability, and survival. Otol Neurotol. 2014 Aug;35(7):1238-41

63. Kruyt IJ, Nelissen RC, Mylanus EAM, Hol MKS. Three-year Outcomes of a Randomized Controlled Trial Comparing a 4.5-mm-Wide to a 3.75-mm-Wide Titanium Implant for Bone Conduction Hearing. Otol Neurotol. 2018 Jun;39(5):609-615

64. den Besten CA, Stalfors J, Wigren S, et al. Stability, Survival, and Tolerability of an Auditory Osseointegrated Implant for Bone Conduction Hearing: Long-Term Follow-Up of a Randomized Controlled Trial. Otol Neurotol. 2016;37(8):1077-1083

65. Kruyt IJ, Bakkum KHE, Caspers CJI, Hol MKS. The efficacy of bone-anchored hearing implant surgery in children: A systematic review. Int J Pediatr Otorhinolaryngol. 2020;132:109906

66. Ellsperman, S.E. Nairn, E.M. Stucken, E.Z. Review of Bone Conduction Hearing Devices. Audiol. Res. 2021, 11, 207–219.

67. https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-baha-system/baha-implant

68. https://www.oticonmedical.com/uk/solutions/bone-conduction/ponto-system

69. http://www.snikimplants.nl/?p=731

70. Schwartz, J. MPO Available to the patient: A comparison of the Cochlear Baha® 5 Power, Cochlear Baha 5 SuperPower and the Oticon Medical Ponto 3 SuperPower. 26-4-2018 http://pronews.cochlearamericas.com/mpo-available-to-the-patient/

71. Hough J, Vernon J, Johnson B, Dormer K, Himelick T. Experiences with implantable hearing devices and a presentation of a new device. Ann Otol Rhinol Laryngol. 1986 Jan-Feb;95(1 Pt 1):60-5

72. den Besten CA, Monksfield P, Bosman A, Skarzynski PH, Green K, Runge C, Wigren S, Blechert JI, Flynn MC, Mylanus EAM, Hol MKS. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: Six-month results from a multicentre study. Clin Otolaryngol. 2019 Mar;44(2):144-157

73. Chen SY, Mancuso D, Lalwani AK. Skin Necrosis After Implantation with the BAHA Attract: A Case Report and Review of the Literature. Otol Neurotol. 2017 Mar;38(3):364-367

74. Dimitriadis PA, Carrick S, Ray J. Intermediate outcomes of a transcutaneous bone conduction hearing device in a paediatric population. Int J Pediatr Otorhinolaryngol. 2017 Mar;94:59-63.

75. Carr SD, Moraleda J, Procter V, Wright K, Ray J. Initial UK Experience With a Novel Magnetic Transcutaneous Bone Conduction Device. Otol Neurotol. 2015 Sep;36(8):1399-402

76. Nevoux J, Coudert C, Boulet M, Czajka C, Tavernier L, Daval M, Ayache D, Meller R, Rossetto S, Papon JF, Deveze A. Transcutaneous Baha Attract system: Long-term outcomes of the French multicenter study. Clin Otolaryngol. 2018 Dec;43(6):1553-1559

77. Ellsperman, S.E. Nairn, E.M. Stucken, E.Z. Review of Bone Conduction Hearing Devices. Audiol. Res. 2021, 11, 207–219

78. https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-osia-system

79. https://www.medel.com/en-gb/hearing-solutions/bonebridge

80. https://www.cochlear.com/mdr/en/home/products-and-accessories/baha-system/baha-implants/baha-attract-system

81. https://www.medtronic.com/us-en/healthcare-professionals/products/ear-nose-throat/hearing-systems/alpha-2-mpo-eplus.html

82. Verstraeten N, Zarowski AJ, Somers T, Riff D, Offeciers EF. Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the testband, and to the "snap" abutment. Otol Neurotol. 2009 Jan;30(1):70-5

83. Zarowski AJ, Verstraeten N, Somers T, Riff D, Offeciers EF. Headbands, testbands and softbands in preoperative testing and application of bone-anchored devices in adults and children. Adv Otorhinolaryngol. 2011;71:124-131

84. Snapp HA, Morgenstein KE, Kuzbyt B. Speech Perception Outcomes in Transcutaneous Versus Percutaneous Bone Conduction Stimulation in Individuals With Single-sided Deafness. Otol Neurotol. 2019 Sep;40(8):1068-1075.

85. Kurz A, Flynn M, Caversaccio M, Kompis M. Speech understanding with a new implant technology: a comparative study with a new nonskin penetrating Baha system. Biomed Res Int. 2014;2014:416205

86. Hol MK, Nelissen RC, Agterberg MJ, Cremers CW, Snik AF. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol. 2013 Aug;34(6):1071-5.

87. Skarzynski PH, Ratuszniak A, Osinska K, Koziel M, Krol B, Cywka KB, Skarzynski H. A Comparative Study of a Novel Adhesive Bone Conduction Device and Conventional Treatment Options for Conductive Hearing Loss. Otol Neurotol. 2019 Aug;40(7):858-864

88. Rigato C, Reinfeldt S, Håkansson B, Jansson KJ, Hol MK, Eeg-Olofsson M. Audiometric Comparison Between the First Patients With the Transcutaneous Bone Conduction Implant and Matched Percutaneous Bone Anchored Hearing Device Users. Otol Neurotol. 2016 Oct;37(9):1381-7

89. Hol MK, Nelissen RC, Agterberg MJ, Cremers CW, Snik AF. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol. 2013 Aug;34(6):1071-5.

90. Iseri M, Orhan KS, Tuncer U, Kara A, Durgut M, Guldiken Y, Surmelioglu O. Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study. Otol Neurotol. 2015 Jun;36(5):849-53

91. Kohan D, Ghossaini SN. Osseointegrated Auditory Devices-Transcutaneous: Sophono and Baha Attract. Otolaryngol Clin North Am. 2019 Apr;52(2):253-263.

92. Giannantonio S, Scorpecci A, Pacifico C, Marsella P. A functional and anatomical comparison between two passive transcutaneous bone conduction implants in children. Int J Pediatr Otorhinolaryngol. 2018 May;108:202-207

93. Gawęcki W, Gibasiewicz R, Marszał J, Błaszczyk M, Gawłowska M, Wierzbicka M. The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant - the Osia®. Braz J Otorhinolaryngol. 2022 May-Jun;88(3):289-295.

94. Rahne T, Plontke SK. Systematic and audiological indication criteria for bone conduction devices and active middle ear implants. Hear Res. 2022 Aug;421:108424

95. Lin L, Bowditch s, Anderson M J, May B, Cox KM, Niparko JK. Amplification in the Rehabilitation of Unilateral Deafness; Speech in Noise and Directional Hearing Effects with Bone-Anchored Hearing and Contralateral Routing of Signal Amplification. Otology & Neurotology; Feb 2006 – Vol 27 Issue 2;172-182

96. Priwin C, Jonsson R, Hultcrantz M, Granstrom G.Baha in children and adolescents with unilateral or bilateral conductive hearing loss a study of outcome. International Journal of Paediatric Otorhinolaryngology. 2006 71 (1): 135-145

97. Hol KM, Cremers CW, Coppens-Schellekens W, Snik AF. The BAHA softband. A new treatment for young children with bilateral congenital aural atresia. International journal of Paediatric Otorhinolaryngology 2005 Jul:69(7): 973-80

98. Judith E, Cho Lieu. Speech-Language and Educational Consequences of Unilateral Hearing loss in Children. Arch Otolaryngol Head Neck Surg. 2004; 130(5):524-530

99. Liu CC, Livingstone D, Yunker WK. The role of Bone conduction hearing aids in congenital unilateral hearing loss: A systematic review. Int J Pediatr Otorhinolaryngol. 2017;(94):45-51

100. Banga R, Doshi J, Child A, Pendleton E, Reid A, McDermott AL. Bone-anchored hearing devices in children with unilateral conductive hearing loss: a patient-carer perspective. Ann Otol Rhinol Laryngol. 2013 Sep;122(9):582-7

101. Lieu JE, Tye-Murray N, Karzon RK, Piccirillo JF. Unilateral hearing loss is associated with worse speech-language scores in children. Paediatrics 2010 Jun:125 (6): e 1348-55

102. Doshi J, McDermott AL. Bone anchored hearing aids in Children. Expert Rev Med Devices.2015;12(1):73-82

103. Jovankovičová A, Staník R, Kunzo S, Majáková L, Profant M. Surgery or implantable hearing devices in children with congenital aural atresia: 25 years of our experience. Int J Pediatr Otorhinolaryngol. 2015;79(7):975-9

104. Giannantonio S, Scorpecci A, Pacifico C, Marsella P. A functional and anatomical comparison between two passive transcutaneous bone conduction implants in children. Int J Pediatr Otorhinolaryngol. 2018;108:202-207

105. Bezdjian A, Bruijnzeel H, Daniel SJ, Grolman W, Thomeer HGXM. Preliminary audiologic and peri-operative outcomes of the Sophono™ transcutaneous bone conduction device: A systematic review Int J Pediatr Otorhinolaryngol. 2017;101:196-203

106. Briggs R, Van Hasselt A, Luntz M, Goycoolea M, et al. Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results from a Prospective, Multicentre, Clinical Investigation. Otology & Neurotology, 2015;36(5):834-841

107. Dimitriadis PA, Hind D, Wright K, Proctor V, Greenwood L, Carrick S, Ray J. Single-centre Experience of Over a Hundred Implantations of a Transcutaneous Bone Conduction Device. Otol Neurotol. 2017;38(9):1301-1307

108. Polonenko MJ, Carinci L, Gordon KA, Papsin BC, Cushing SL. Hearing Benefit and Rated Satisfaction in Children with Unilateral Conductive Hearing Loss Using a Transcutaneous Magnetic-Coupled Bone-Conduction Hearing Aid. J Am Acad Audiol. 2016;27(10):790-804.

109. Riss D, Arnoldner C, Baumgartner WD, Blineder M, Flak S, Bachner A, Gstoettner W, Hamzavi JS. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. Laryngoscope;124(12):2802-6.

110. Eeg-Olofsson M1, Håkansson B, Reinfeldt S, Taghavi H, Lund H, Jansson KJ, Håkansson E, Stalfors J. The bone conduction implant--first implantation, surgical and audiologic aspects. Otol Neurotol. 2014;35(4):679-85

111. Liu CC, Livingstone D, Yunker WK. The role of Bone conduction hearing aids in congenital unilateral hearing loss: A systematic review. Int J Pediatr Otorhinolaryngol. 2017;(94):45-51

112. Kim G, Ju HM, Lee SH, Kim HS, Kwon JA, Seo YJ. Efficacy of Bone-Anchored Hearing Aids in Single-Sided Deafness: A Systematic Review. Otol Neurotol. 2017 Apr;38(4):473-483

113. Doshi J, Banga R, Child A, Lawrence R, Reid A, Proops D, McDermott AL. Quality-of-life outcomes after bone-anchored hearing device surgery in children with single-sided sensorineural deafness. Otol Neurotol. 2013 Jan;34(1):100-3

114. Dun CA, De Wolf MJ, Mylanus EA, Snik AF, Hol MK, Cremers CW. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. Otol Neurotol 2010;31:615-623

115. Priwin C, Jo¨nsson R, M. Hultcrantz, G. Granstro¨m, BAHA in children and adolescents with unilateral or bilateral conductive hearing loss: a study of outcome, Int. J. Pediatr. Otorhinolaryngol. 2007;71:135–145.

116. Lieu JE, Tye-Murray N, Karzon RK, Piccirillo JF. Unilateral hearing loss is associated with worse speech-language scores in children. Paediatrics 2010 Jun:125 (6): e 1348-55

117. Tzortzis S, Tzifa K, Tikka T, Worrollo S, Williams J, Reid AP, Proops D. A ten-year review of soft tissue reactions around percutaneous titanium implants for auricular prosthesis. Laryngoscope. 2015 Aug;125(8):1934-9

118. Dun CA, Faber HT, de Wolf MJ, Mylanus EA, Cremers CW, Hol MK. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol. 2012 Feb;33(2):192-8

119. J. Doshi, A.L. McDermott, A. Reid, D. Proops, The 8.5 mm abutment in children: the Birmingham bone-anchored hearing aid program experience, Otol. Neurotol. 31 (2010) 612–614

120. Kubba H, Swan IR, Gatehouse S. The Glasgow Children's Benefit Inventory: a new instrument for assessing health-related benefit after an intervention. Ann Otol Rhinol Laryngol. 2004 Dec;113(12):980-6

121. Gan RWC, Daniel M, Ridley M, Barry JG. Quality of questionnaires for the assessment of otitis media with effusion in children. Clin Otolaryngol. 2018 Apr;43(2):572-583

122. McDermottAL, Williams J, Kuo M, Reid A, Proops D. The Birmingham paediatric bone-anchored hearing aid program; a 15 year experience. Otol Neurotol 2009 Feb;30(2):178-83

123. Fussey JM, Harterink E, Gill J, Child-Hymas A, McDermott AL. Clinical outcomes following Cochlear™ BIA300 bone anchored hearing aid implantation in children. Int J Pediatr Otorhinolaryngol. 2018 ;111:89-92

124. den Besten CA, Nelissen RC, Peer PG, Faber HT, Dun CA, de Wolf MJ, Kunst HP, Cremers CW, Mylanus EA, Hol MKA. Retrospective Cohort Study on the Influence of Comorbidity on Soft Tissue Reactions, Revision Surgery, and Implant Loss in Bone-anchored Hearing Implants. Otol Neurotol. 2015;36(5):812-8.

125. Van der Gucht K, Vanderveken O, Hamans E, Claes J Van Rompaey V, Van de Heyning P. Adverse skin reactions following percutaneous bone conduction implant surgery using the linear incision technique with and without subcutaneous tissue reduction. Acta Otolaryngol. 2017;137(2):149-153.

126. Shapiro S, Ramadan J, Cassis A. BAHA Skin Complications in the Pediatric Population: Systematic Review With Meta-analysis. Otol Neurotol. 2018 Aug;39(7):865-873

127. Oberlies NR, Castaño JE, Freiser ME, McCoy JL, Shaffer AD, Jabbour N. Outcomes of BAHA connect vs BAHA attract in pediatric patients. Int J Pediatr Otorhinolaryngol. 2020 Aug;135:110125

128. You P, Choi A, Drob J, Hunsaker SM, Liu YC, Silva R. Early Outcomes of a New Active Transcutaneous Bone Conduction Implant in Pediatric Patients. Otol Neurotol. 2022 Feb 1;43(2):212-218.

129. Posta B, Perenyi A, Szabo L, Nagy R, Katona G, Csakanyi Z, Rovo L, Bere Z. Pediatric morphometric study to guide the optimized implantation of the Osia® 2 implant system. Eur Arch Otorhinolaryngol. 2022 Mar 16. doi: 10.1007/s00405-022-07338-2. Epub ahead of print.

130. Storck K, Staudenmaier R, Buchberger M, Strenger T, Kreutzer K, von Bomhard A, Stark T. Total reconstruction of the auricle: our experiences on indications and recent techniques. Biomed Res Int. 2014;2014:373286.

131. Bajaj Y, Wyatt ME, Gault D, Bailey CM, Albert DN. How we do it: BAHA positioning in patients with microtia requiring auricular reconstruction. Clin Otolaryngol; 2005 Oct;30(5):468-71

132. Ali K, Mohan K, Lui YC. Otologic and audiology Concerns of Microtia Repair. Semin Plast Surg 2017 Aug;31(3):127-133

133. Reinfeldt S, Håkansson B, Taghavi H, Eeg-Olofsson M. New developments in bone-conduction hearing implants: a review. Med Devices (Auckl). 2015 Jan 16;8:79-93

134. Dahm V, Baumgartner WD, Liepins R, Arnoldner C, Riss D. First Results with a New, Pressure-free, Adhesive Bone Conduction Hearing Aid. Otol Neurotol. 2018 Jul;39(6):748-754

135. Gawliczek T, Munzinger F, Anschuetz L, Caversaccio M, Kompis M, Wimmer W. Unilateral and Bilateral Audiological Benefit With an Adhesively Attached, Noninvasive Bone Conduction Hearing System. Otol Neurotol. 2018 Sep; 39(8): 1025-1030

Chapter 2

Five year clinical outcomes and evaluation following implantation of the OticonTM wide bone anchored hearing system in 47 children.

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Abstract

Objectives

The Oticon™ wide implant system was launched in 2009 and used at Birmingham Children's Hospital from 2014. To evaluate clinical outcomes of the Oticon™ wide implant (Oticon Medical), with a focus on skin complication rates and fixture loss over a 5-year period in a tertiary paediatric hospital in the UK.

Methods

Retrospective 5-year longitudinal case record review of 47 children who were implanted with the Oticon™ wide implant system at Birmingham Children's Hospital (BCH) between January 2014 and January 2016.

Results

47 children (27 M:20F) were implanted with 70 Oticon wide implants 23 bilateral, 27 unilateral. Mean age at the time of implantation was 9y 6 m. The follow up was for a mean of 5.4 years. Significant soft tissue complications requiring treatment was found in 11% (n = 8) of loaded fixtures, abutment tightening on two patients, abutment exchange 6% (n = 4) and a 10% (n = 7) fixture failure.

Conclusion

The Oticon™ wide implant system produces favourable results with regards to peri-abutment skin complications, fixture stability and revision surgery rates when compared to similar cohorts of children studied at Birmingham Children's Hospital.

1. Introduction

Innovations in bone anchored hearing implant (BAHI) systems have resulted in more stable implants since their commercial introduction in 1987 [1]. Surgical techniques for paediatric BAHI have also developed from the original techniques involving complete split thickness skin grafts, both with and without a dermatome [2,3] through to modem day techniques now focusing on tissue preservation avoiding the possible complications caused by skin flap necrosis [4,5] and thus reducing skin complication [6-8]. Linear incision techniques have been shown to have a faster healing time and to inflict less pain than dermatome techniques [7,8]. Currently the use of tissue preservation techniques is reported to have the best soft tissue outcomes [6].

In 2009, Oticon Medical introduced a new BAHI system called the Oticon™ wide implant [9]. This system utilises an implant with an increased diameter of 4.5 mm which demonstrated improved outcomes in dental implantation with lower implant failure rates [10,11].

Application of this wider BAHI has been found to have comparable skin reaction rates to the previous 3.75 mm implants and in addition it was noted to be associated with increased survival [12-15]. The wider diameter of these implants increases the surface area contact between the implant and temporal bone providing a greater stability which results in a reduction in spontaneous fixture loss. Recent meta-analysis by Kruyt et al. supports these finding in children demonstrating a 17.1% loss in small-diameter implants compared to a 5.9% for wide-diameter implants [16] although many of the studies included in this utilised a differently designed wide implant. As a result of this evolving evidence some centres advocate early loading of processors in adults as early as 3 weeks [12,17-19] and at 6 weeks in children [20].

Complications associated with the previous generations of narrower BAHI include peri-abutment soft tissue reactions and fixture (implant) loss through both trauma and failed osseointergration. These have been demonstrated to be higher in paediatric populations [21]. With specific regard to wide (4.5 mm) implants, failure rates of 2.6-4.2% are reported in the adult population [12,15,22,23] and 5.9% in children [16].

Skin reactions require special consideration in the paediatric population. Pubertal hormonal changes result in sebaceous hypertrophy and an associated skin overgrowth which may require longer abutment placement [24]. There is also an acceptance that the lifestyle and behavior of children can result in an anticipated proportion of abutment loss secondary to trauma [25]. This underlies our tertiary paediatric centre's philosophy of sleeper fixture insertion at the time of the primary procedure. Any fixture loss can be replaced quickly without any delay associated with waiting for osseointegration of a new implant.

1.1. Objectives

To evaluate clinical outcomes of the Oticon™ wide BAHI system (Oticon Medical) implanted between January 2014 - 2016 with a focus on skin complication rates and fixture loss over a mean follow up period of 5.4 years at Birmingham Children's Hospital.

2. Methods

Retrospective 5-year longitudinal case record review of a cohort of 47 children who were implanted with the Oticon™ wide implant system at Birmingham Children's Hospital (BCH).

Following ethical approval from the local research and development department a retrospective case series review of all patients who had undergone implantation of the Oticon™ wide BAHI fixture was undertaken. Over the 5 year period, medical records were updated if patients, carers or medical professionals raised concerns requiring either consultation by medical or audiological staff. These records were then reviewed for references to these medical complications, specifically soft tissue reactions, revision rate, failure of fixture and loss of abutment from trauma. Follow up data was compiled in May 2020 and is reported in this paper resulting in a mean follow up period for this study of 5.4 years (range 4.2-6.3).

2.1. Patients

All children on the paediatric BAHI program at BCH who were implanted with the Oticon™ wide fixture between January 2014 and January 2016 were included in this study. No child was excluded from the review. The demographics were recorded including age (defined as age at first stage surgery in cases of sequential implantation), gender and significant comorbidities. The underlying aetiology for BAHI surgery was also noted.

2.2. Surgical technique

This centre's preferred methodology for implantation in children is a two-stage procedure. The first stage involved placing two fixtures (implants) on each required side, one acting as a sleeper. After a three month osseointegration period the second stage was performed when an abutment was placed on one of two implanted fixtures.

Two soft tissue surgical techniques were employed by the operating surgeons:

Surgeon 1: 'U' shaped incision for implant placement followed by a 4 mm skin punch with tissue preservation at second stage for abutment positioning.

Surgeon 2: Linear incision for implant placement followed by a linear incision with minimal soft tissue reduction for second stage for abutment positioning.

2.3. Post-operative care

Post-operative dressings were standardised for all children. Both surgeons used a porous semi-transparent, low adherent wound contact layer around the abutment. This is a flexible polyamide net which is coated with soft silicone (Mepitel) which was left over the wound for the 7 days post-operative period and held in place with a healing cap. A head bandage was routine for the first 24hrs. Routine follow up occurred at 1-2 weeks, 3, 6, 9, 12 months and yearly thereafter.

2.4. Statistical analysis

Data was recorded using Microsoft Excel (Redmond, WA, USA). Categorical data is reported as frequencies, and continuous data is reported with means, standard deviations, and ranges. Comparison of groups was undertaken by unpaired *t*-test and significance set at 0.01.

3. Results

3.1. Patient characteristics

A total of 47 children underwent BAHI implantation (BAHI) with the Oticon™ wide implant between January 2014 and December 2015. Twenty-three children (49%) were implanted bilaterally and 24 unilaterally giving a total of 70 implant systems to evaluate. The mean age at first stage procedure was 9yrs 6 months (SD 0.5, range 4yr-16yr 3months) on 27 males (57%) and 20 females.

It was found that congenital and acquired hearing loss predispose to the requirement for BAHI in 66% and 34% of patients, respectively. The most common indication for BAHI surgery was a congenital conductive hearing loss n = 29 (62%). 2% (n = 2) were due to either a congenital sensorineural or mixed hearing loss. Acquired conductive loss accounted for 30% (n = 30) and sensorineural 4% (n = 2). [Table 1]. Twenty-nine children (62%) had a significant associated medical co-morbidity or syndromes [Table 2].

Table 1: Basic demographics and indications for BAHI

	Number of Patients'	(%)
Total	47	100
Male	27	57
Female	20	43
Age Years	9.5 (4-16.3)	
Type of hearing loss		
Congenital		66
Conductive Hearing loss	29	62
Sensorineural Hearing loss	1	2
Mixed	1	2
Acquired		34
Conductive Hearing loss	14	30
Sensorineural Hearing loss	2	4
Aetiology of hearing loss		
CSOM	18	38
Bilateral Microtia	7	15
Unilateral Microtia	6	13
Microtia and Atresia	5	11
OC Dysmorphism	5	11
Profound SNHL (dead ear)	3	6
Mixed Hearing loss	1	2
Canal Stenosis	1	2
Secondary to cCHL	1	2

Table 2: Associated medical conditions.

Associated conditions	Number of patients	%
Chromosomal	14	30
Hemifacial microsomia	4	9
CHARGE	3	6
Cleft lip palate	3	6
Nagar syndrome	1	2
Aperts	1	2
Goldenhar syndrome	1	2
Branchio-oto-renal syndrome	1	2
Treacher Collins syndrome	1	2
Total	29	62

3.2. The surgery

A total of 70 implant systems were placed in 47 children between January 2014 and December 2015. All were two stage procedures.

Twenty-six (55%) patients (17 M, 9F) underwent a 'U' shaped incision of first stage followed by a 4 mm skin punch without skin reduction (Surgeon 1). Twenty-one (45%) (10 M, 11 F) underwent a linear incision for fixture placement and second stage (Surgeon 2). No statistical significance was found in age (p-0.42), fixture size (p-0.74, CI -0.37-0.26) or abutment length (p-0.22, CI 0.47-1.97) when comparing the two surgical methods. Therefore, further analysis of outcomes will consider the entire cohort together [Table 3].

Table 3: Patient demographics as divided by surgical technique applied.

	Overall	%	Surgeon 1 'U Shape'	%	Surgeon 2 'Linear'	%
Total Patients	47		26		21	
Male	27	57	17	65	10	48
Female	20	43	9	35	11	52
Age Years	9.5 (4-16.3)		9.9 (4.5---16.2)		9 (4-15.2)	
Bilaterally Fitting	23	24	14	54	9	43
Unilateral Fitting	24	51	12	46	12	57
Total number of fixtures loaded	70		40		30	
Implanted fixture size						
3mm	39	56	25	63	14	47
4mm	21	30	11	28	10	33
Missing date	10	14	4	10	6	20
Abutment Size						
6mm	16	23	8	20	8	27
9mm	38	54	24	60	14	47
12mm	6	9	4	10	2	7
14mm	2	3	2	5	0	0
Missing data	8	11	2	5	6	20

3.3. Implant characteristics

In total seventy fixtures were implanted (not including the sleeper fixtures) of these 49 (56%) we 3 mm and 21 (30%) 4 mm (30%) in size. Implant size is selected based on surgical findings and all 3 mm implant were chosen due to thin bone or exposed dura.

At the second stage these implants were fitted with abutments: lengths of 6 mm (23%), 9 mm (54%), 12 mm (8.6%) and 14 mm (2.9%) were used in this cohort.

Of the 70 implants originally loaded with an abutment, there were seven fixture failures (10%) including one child with isolated microtia who had two failures (first at 6 months post stage one surgery and a second at 9 months). All occurring following implantation with the 3 mm fixture. One other fixture failure was secondary to trauma at 7 months post-surgery. A sleeper fixture was quickly loaded in replacement.

3.4. Soft tissue outcomes

Peri-abutment skin related complications were reported to affect eight implants (11.4%). Four peri-abutment skin problems were treated with replacement of a longer abutment with subsequent resolution of the skin issues. Two peri-abutment skin reactions required antibiotic treatment and one peri-abutment skin overgrowth required revision surgery of skin reduction (1.4%).

Two (2.9%) of the total loaded abutments became loose and required tightening with the appropriate torque and equipment in outpatient clinic which resolved the issue. Finally, one abutment was lost without any associated fixture failure and a new abutment was placed [Table 4].

Table 4: Comparison between the two surgical groups

	Overall	%	Surgeon 1 'U Shape'	%	Surgeon 2 'Linear'	%
Recorded Complications						
Peri-abutment skin complication	8	11	4	10	4	13
Abutment exchange	4	6	2	5	2	7
Fixture failure	7	10	3	8	4	13
Loose abutment	2	3	0	0	2	7
Skin reduction	1	1	1	3	0	0

4. Discussion

The Birmingham Children's Hospital is a tertiary referral centre in the UK which can account for the heterogeneous population with multiple medical comorbidities and the spread of ages seen in this current study group. This is reflective of the previous experiences reported in Birmingham.

4.1. Comparison with other studies

To better understand the performance of the Oticon™ wide implant we can compare our current results to studies published from research undertaken on a similar patient demographic with the previous generations of BAHI at BCH. The largest comparable study was published in 2009 which included 174 children under the age of 16 years, who were implanted with the traditional Branemark flanged fixture. The outcomes were reported with a soft tissue complication rate of 17%, revision surgery 8% and 14% fixture loss [26], however at this time a split skin graft technique was used, and this fixture was of narrower diameter.

Recent review of the Cochlear™ BIA300 BAHI (4.5 mm) at BCH in children aged between 3 and 16 years demonstrated a 5% fixture loss. Significant soft tissue complications were noted which required additional visits to nurse practitioner in 77% of implants, systemic antibiotics treatment in 35% and a revision rate of 35% due to skin overgrowth [27]. Therefore, soft tissue outcome of the Oticon wide implant system is a significant improvement over this previous generation of implant with revision surgery required in only 1.4% of implants and soft tissue reactions in 11.4%. However, it is important to consider that complication rates are influenced not only by the shape of BAHI but also the surgical technique used. A dermatome was applied in 57% of patients in the BAI300 study which I no longer the current practice at BCH and the length of follow up varies between these three studies makes comparison limited. Even with this considered soft tissue complication have improved with the adoption of a wider implanted fixture.

Fixture failures of the Oticon wide implant is higher than that of the BAI300 at 10% and 5% respectively but this is likely due to the longer duration of follow up 5.4yrs vs a mean of 3.5yr and a smaller sample size in the previous study (n = 52). With a possible higher failure rate, the Oticon BAHI is still favourable due to the significant reduction is soft tissue compilation and implication this has on revision surgery and quality of life. Both studies provide evidence that a wider fixture improves on both survivability and soft tissue reaction in the population served by BCH.

In addition, direct comparison of implant outcomes of the trisomy 21 subgroup data can be made to previous findings at this centre. 12 Trisomy 21 patients were included in this study

with and of these 2 suffered with peri abutment skin issues (17%) and 1 fixture loss (8%). No revision surgery was required. Previous study in 2008 of 15 trisomy 21 patients demonstrated a 20% skin complication rate and a 0% fixture loss [28]. Therefore, the Oticon wide system does appear to also have favourable lower skin complication rates but a higher fixture failure rate in this subgroup. Comparison is again limited between these two studies as implant design and surgical techniques have changed over time.

There is still some discussion regarding the minimum age for implantation [29]. Since the introduction of the softband in 2002 [30] and adhesive hearing aid systems in 2015 there are now non-surgical alternatives to allow hearing rehabilitation in the very young so relieving pressure to implant early. Although these two systems provide comparable audiological results [31], the output is lower than that found in percutaneous option even when powered processors are utilised. Percutaneous BAHI provides a higher quality audiological output, an important consideration with regards to hearing rehabilitation especially in regard to speech and language development in young children.

In the under fives, there are reported soft tissue complication rate and revision rates of 42% and 25% respectively [32]. Our current review identified 5 children were under the age of five at implantation, one (20%) required revision, one (20%) required loading of sleeper following traumatic fixture loss and one (20%) reported skin complication. Spontaneous fixture loss was 0% in this group. In addition, concerns are raised regarding inadequate skull thickness in the very young which may prevent secure osseointegration. Thin calvarial thickness is also a common finding in children especially in those with a craniofacial abnormality such as Treacher-Collins syndrome and a minimum of 2.5-3 mm of skull thickness has been recommended as a minimum for a 3-4 mm fixture insertion to allow for osseointegration [33]. The results of this study are in keeping with the published literature regarding increased soft tissue complication rate in the paediatric population [26,27,28,29,33,34] and that BAHI implant losses do also appear to have a higher occurrence in the paediatric patients ($p < 0.005$) [29,35]. Other rare complications are reported in paediatric and adult patients which include subdural haematoma [36], intrusion injury [37,38] and intracerebral abscess [39], none of which were identified in our BCH cohort, but surgeons performing implantation should be aware of these occurring.

Limitations

The current study reports on long term outcomes of consecutively implanted children with the Oticon wide BAHI. The study includes surgeries performed between January 2014 and January 2016 and although retrospective in its data collection method the quality of information gathered was considered comprehensive as all patients' records were identifiable

and complications recording were complete. Retrospective studies however are limited to the nature of missing data.

The wide range of indications for surgery and physical and psychological comorbidity of recipients poses a potential for confounding results in this study, comparison to other published literature is limited due to the wide variation within our study cohort and should therefore be done with caution.

The absence of uniform standard for surgery was also limitation for the current study with two separated methods being applied to the cohort, one performing minimal soft tissue reduction at second stage. However, patient demographics, post operative protocol and routine follow up were identical between the two groups.

One difficulty in comparing outcomes of different studies is the variation in outcome reporting. An absence of uniform outcome reporting standards (Holger's score) is evident in this study limits conclusions drawn from direct comparisons and relies on different outcome measures such as antibiotic use. Soft tissue evaluation was performed by the same specialist nurse for all included patients and only those who required medical or surgical intervention were recorded as a complication.

5. Conclusion

The Oticon™ wide implant produces comparable results to previous studies regarding peri-abutment skin complications. However, it appears superior to previous implant systems adopted at BCH with regards to both skin complication and revision surgery rates. Fixture failure rate is higher when compared to previous alternative wide diameter implant however this did demonstrate significantly worse soft tissue complication in the paediatric population. The reduced complication rate corresponds to a reduction in the number of additional outpatient appointments and visits to the BAHI specialist nursing team.

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Declaration of competing interest

No authors involved with the paper have any actual or potential conflict of interest including any financial, personal or other relation ships with other people or organizations that could inappropriately in fluence, or be perceived to influence, their work.

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References

1. A. Tjellstrom, Osseointegrated systems and their applications in the head and neck, Adv. Otolaryngol Head Neck Surg. 3 (1989) 39-70.
2. L. Tietze, B. Papsin, Utilization of bone-anchored hearing aids in children, Int. J. Pediatr. Otorhinolaryngol. 58 (2001) 75-80.
3. J. Stalfors, A. Tjellstrom, Skin reactions after BAHA surgery: a comparison between the U shaped graft technique and the BAHA dermatome, Otol. Neurotol. 29 (2008) 1109-1114.
4. M.J. De Wolf, M.K. Hol, P.L. Huygen, E.A. Mylanus, C.W. Cremers, Clinical outcome of the simplified surgical technique for BAHA implantation, Otol. Neurotol. 29 (2008) 1100-1108.
5. S. Shapiro, J. Ramadan, A. Cassis, BAHA skin complications in the paediatric population: systematic review with meta-analysis, Otol. Neurotol. 39 (7) (2018 Aug) 865-873.
6. E.H.H. van der Stee, R.M. Strijbos, S.J.H. Born, M.K.S. Hol, Percutaneous bone anchored hearing implant surgery: linear incision technique with tissue preservation versus linear incision technique with tissue reduction, Eur. Arch. OtoRhino-Laryngol. 275 (7) (2018 Jul) 1737-1747.
7. M. H0gsbro, A. Agger, L.V. Johansen, Bone-anchored hearing implant surgery: randomized trial of dermatome versus linear incision without soft tissue reduction clinical measures, Otol. Neurotol. 36 (5) (2015 Jun) 805-811.
8. R.M. Strijbos, S.J.H. Born, S. Zwerver, M.K.S. Hol, Percutaneous bone-anchored hearing implant surgery: dermatome versus linear incision technique, Eur. Arch. Oto-Rhino-Laryngol. 274 (1) (2017 Jan) 109-117.
9. P. Westerkull, The Ponto-bone anchored hearing system, Adv. Oto-Rhino-Laryngol. 71 (2011) 32-40.
10. J.H. Lee, V. Frias, K.W. Lee, R.F. Wright, Effect of implant size and shape on implant success rates: a literature review, J. Prosthet. Dent 94 (4) (2005 Oct) 377-381.
11. J.A. Mendon a, P.M. Senna, C.E. Francischone, C.E. Francischone Junior, B., S. Sotto-Maior, Influence of the diameter of dental implants replacing single molars: 3- to 6-year follow-up, Int. J. Oral Maxillofac. Implants 32 (5) (2017 Sep/ Oct) 1111-1115.
12. I.J. Kruyt, R.C. Nelissen, E.A.M. Mylanus, M.K.S. Hol, Three-year outcomes of a randomized controlled trial comparing a 4.5-mm-Wide to a 3.75-mm-Wide titanium implant for bone conduction hearing, Otol. Neurotol. 39 (5) (2018 Jun) 609-615
13. S. Foghsgaard, P. Caye-Thomasen, A new wide-diameter bone-anchored hearing implant-prospective I-year data on complications, implant stability, and survival, Otol. Neurotol. 35 (7) (2014 Aug) 1238-1241.
14. R.C. Nelissen, C.A. den Besten, E.A. Mylanus, M.K. Hol, Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial, Eur. Arch. Oto-Rhino-Laryngol. 273 (1) (2016 Jan) 105--111.
15. R.C. Nelissen, J. Stalfors, M.J. de Wolf, M.C. Flynn, S. Wigren, M. Eeg-Olofsson, K. Green, M.P. Rothera, E.A. Mylanus, M.K. Hol, Long-term stability, survival, and tolerability of a novel osseointegrated

implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation, Otol. Neurotol. 35 (8) (2014 Sep) 1486-1491.

16. I.J. Kruyt, K.H.E. Bakkum, C.J.I. Caspers, M.K.S. Hol, The efficacy of bone anchored hearing implant surgery in children: a systematic review, Int. J. Pediatr. Otorhinolaryngol. 132 (2020) 109906, https://doi.org/10.1016/j. ijporl.2020.109906.

17. J.J. Wazen, S. Babu, J. Daugherty, A. Metrailer, Three-week loading of the 4.5mm wide titanium implant in bone anchored hearing systems, Am. J. Otolaryngol. 37 (2) (2016 Mar-Apr) 132-135.

18. R.C. Nelissen, C.A. den Besten, H.T. Faber, C.A. Dun, E.A. Mylanus, M.K. Hol, Loading of osseointegrated implants for bone conduction hearing at 3 weeks: 3- year stability, survival, and tolerability, Eur. Arch. Oto-Rhino-Laryngol. 273 (7) (2016) 1731-1737.

19. C.M. McLarnon, I. Johnson, T. Davison, et al., Evidence for early loading of osseointegrated implants for bone conduction at 4 weeks, Otol. Neurotol. 33 (9) (2012) 1578--1582.

20. C. McLamon, I. Johnson, T. Davison, et al., Resonance frequency analysis of osseointegrated implants for bone conduction in a pediatric population - a novel approach for assessing stability for early loading, Int. J. Pediatr. Otorhinolaryngol. 78 (4) (2014) 641--044.

21. C.A. Dun, H.T. Faber, M.J. de Wolf, E.A. Mylanus, C.W. Cremers, M.K. Hol, Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival, Otol. Neurotol. 33 (2) (2012 Feb) 192-198.

22. R.C. Nelissen, C.A. den Besten, H.T. Faber, C.A. Dun, E.A. Mylanus, M.K. Hol, Loading of osseointegrated implants for bone conduction hearing at 3 weeks: 3- year stability, survival, and tolerability, Eur. Arch. Oto-Rhino-Laryngol. 273 (7) (2016) 1731-1737.

23. C.A. den Besten, J. Stalfors, S. Wigren, et al., Stability, survival, and tolerability of an auditory osseointegrated implant for bone conduction hearing: long-term follow-up of a randomized controlled trial, Otol. Neurotol. 37 (8) (2016) 1077-1083.

24. J. Doshi, A.L. McDermott, A. Reid, D. Proops, The 8.5 mm abutment in children: the Birmingham bone-anchored hearing aid program experience, Otol. Neurotol. 31 (2010) 612--014.

25. D.A. Proops, The Birmingham bone anchored hearing aid programme: surgical methods and complications, J. Laryngol. Otol. 21 (1996) 7-12.

26. A.L. McDermott, J. Williams, M. Kuo, A. Reid, D. Proops, The Birmingham paediatric bone-anchored Hearing Aid program: a 15 year experience, Otol. Neurotol. 30 (2009) 178--183.

27. J.M. Fussey, E. Harterink, J. Gill, A. Child-Hymas, A.L. McDermott, Clinical outcomes following CochlearTM BIA300 bone anchored hearing aid implantation in children, Int. J. Pediatr. Otorhinolaryngol. 111 (2018) 89-92.

28. A.L. McDermott, J. Williams, M.J. Kuo, A.P. Reid, D.W. Proops, The role of bone anchored hearing aids in children with Down syndrome, Int. J. Pediatr. Otolaryngol. 72 (2008) 751-757.

29. T. Davids, K.A. Gordon, D. Clutton, B.C. Papsin, Bone-anchored hearing aids in infants and children under 5 years, Arch. Otolaryngol. 133 (2007) 51-55.

30. M.K. Hol, C.W. Cremers, W. Coppens-Schellekens, A.F. Snik, The BAHA Softband. A new treatment for young children with bilateral congenital aural atresia, Int. J. Pediatr. Otorhinolaryngol. 69 (7) (2005 Jul) 973-980.

31. M.S. Osborne, A. Child-Hymas, J. Gill, M.S. Lloyd, A.L. McDermott, First pediatric experience with a novel, adhesive adapter retained, bone conduction hearing aid system, Otol. Neurotol. 40 (9) (2019) 1199-1207.

32. K. Amonoo-Kuofli, A. Kelly, M. Neeff, C.R. Brown, Experience of bone anchored hearing aid implantation in children younger than 5 years of age, Int. J. Pediatr. Otolaryngol. 79 (2015) 474-480.

33. B.C. Papsin, T.K.S. Sirimanna, D.M. Albert, C.M. Bailey, Surgical experience with bone-anchored hearing aids in children, Laryngoscope 107 (1997) 801-806.

34. J. Mierzwinski, W. Konopka, M. Drela, P. Laz, M. Smiechura, M. Struzycka, M. J. Kusmierczyk, Evaluation of bone conduction implant stability and soft tissue status in children in relation to age, bone thickness, and sound processor loading time, Otol. Neurotol. 36 (2015) 1209-1215.

35. A. Bezdjian, R.A. Smith, H.G.X.M. Thomeer, B.M. Willie, S.J. Daniel, A systematic review on factors associated with percutaneous bone anchored hearing implants loss, Otol. Neurotol. 39 (10) (2018) 897-906.

36. N. Amin, A. Aymat-Torrente, Subdural Hematoma, A rare adverse complication from bone-anchored hearing aid placement, Otol. Neurotol. 38 (3) (2017 Mar) 360-363.

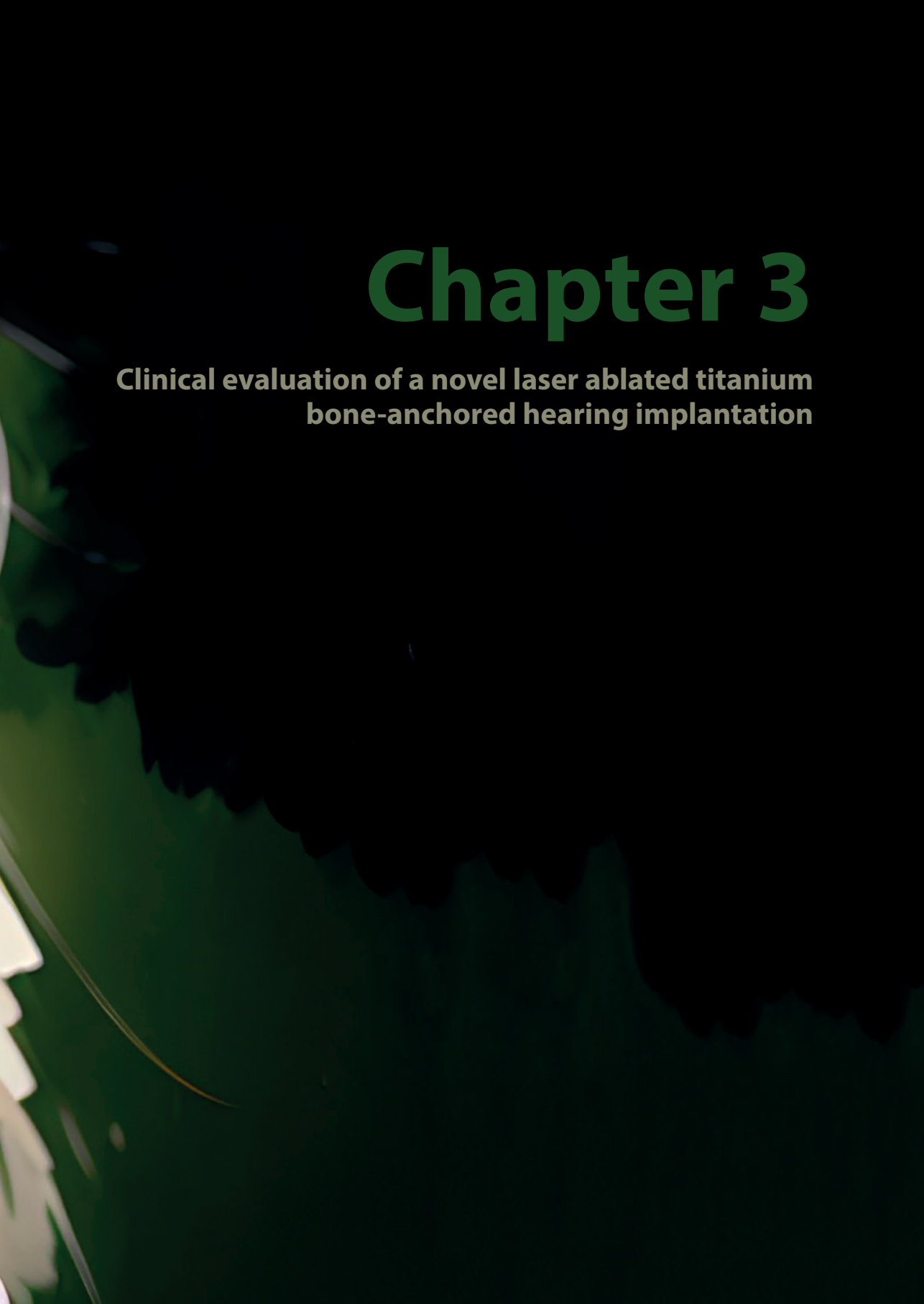
37. A.L. McDermott, J. Barraclough, A.P. Reid, Unusual complication following trauma to a bone-anchored hearing aid: case report and literature review, J. Laryngol. Otol. 123 (3) (2009 Mar) 348-350.

38. T. Deitrner, M. Krassort, S. Hartmann, Two rare complications in patients with bone anchored hearing aids, Laryngorhinootologies 82 (3) (2003) 162-165.

39. M. Scholz, H. Enfinger, A. Anders, B. Illerhaus, K. Matthias, K. Schmieder, A. Hardens, Intracerebral abscess after abutment change of bone anchored hearing aid, Otol. Neurotol. 24 (2003) 896-899.

Chapter 3

Clinical evaluation of a novel laser ablated titanium bone-anchored hearing implantation



Chapter 3.1

Clinical evaluation of a novel laser-ablated titanium implant system for bone anchored hearing systems in a paediatric population and the relationship of resonance frequency analysis with implant survival.

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Abstract

Objective

To evaluate the clinical outcomes of pediatric patients implanted a novel 4.5 mm wide laser ablated titanium bone anchored implant system and to evaluate the implant stability over the first 12-month period.

Study Design

A prospective, single-subject, repeated measure, cohort study. Participants served as their own controls. Setting: Community and tertiary referral hospital pediatric assessment center.

Patients

A total of 115 consecutive pediatric patients aged 4 to 15 years were implanted with 176 laser ablated titanium bone anchored implants from January 2016 to January 2019. Main Outcome Measure: Clinical outcomes, implant failure rates, and post implantation implant stability quotient (ISQ) scores were studied over the first 12-month period. Data were analyzed for statistical significance through mixed effect modeling, with the significance level *p* 0.01.

Results

A median 12-month survival of 96.6% was observed. Six implants (3.5%) were lost in total, one of these (0.6%) was lost due to trauma. Adverse skin reactions (Holgers grade 2–4) were observed in 4.4% of all postoperative visits, occurring in 22 individuals (19.1%). Neither the ISQ high (ISQH) nor ISQ low (ISQL) values increased significantly between the stage 1 and 2 surgeries. In contrast, the ISQ results, irrespective of abutment size, demonstrated an increasing trend from 49.1 to 57 over the 12 months review period. A statistically significant change was only demonstrated from the 3 months follow up onwards.

Conclusion

The use of 4.5 mm wide laser-ablated titanium bone anchored hearing implants resulted in superior survival rates and excellent clinical outcomes compared with previous implant systems.

1. Introduction

Since 1977, bone anchored titanium implants have been utilized for the attachment of percutaneous abutments allowing for fixation of sound processors for bone conduction hearing (1). Successful implantation is dependent on osseointegration with the surrounding bone during healing of the implant (2). Osseointegration is in turn influenced by implant geometry (macro, micro, and nanoscale), surface and material properties, drilling protocol, osteotomy configuration, surrounding bone quality, and systemic and local host characteristics (3,4).

It has been reported that the pediatric population has either lower or equal implant survival rates compared with adult populations (5) despite fewer patient-related conditions such as high body mass index (BMI), smoking, diabetes, previous local radiotherapy (6). Furthermore, some centers advocate early and immediate loading of processors in adults (7–11) and at 6 weeks in children (12). These factors underscore the need for accelerated osseointegration, increased stability, and higher survival rates of bone conduction hearing devices in children. One strategy is to increase the diameter and therefore the implant-to-bone contact, which is reported to reduce failure rates in oral implantations (10,13). Compared with the 3.75 mm previous generation implants 4.5 mm diameter wide bone anchored hearing implants (BAHIs) provided similar improvement in survival rates (8,14–16).

In the adult population, a recent systematic review of 1,166 BAHIs of various designs reported an overall survival rate of 97.7% over an average follow-up time of 17 months (17), supporting previous findings of failure rates between 2.6 and 4.2% in the adult population (8,10,16,18). In the pediatric population, wide diameter implants demonstrated a 5.9% implant loss compared with a 17.1% loss with narrow diameter implants (19), irrespective of any other design variation. Previous small-diameter generations of BAHI were also associated with higher peri-abutment soft tissue complications in pediatric populations resulting in requirements of longer abutments (5,20).

In dental applications, surface modifications techniques were developed that increased the roughness of the surface of the implant and demonstrated a stronger bone response and better clinical results compared with non-modified implants (3,21). Based on these findings the 4.5 mm wide diameter laser ablated titanium bone anchored implant system, was introduced in 2015. Using laser ablation, a distinct hierarchical structure is created with a combined macro- and microtopography. In addition, a superimposed nanotexture is confined to the valleys of the implant threads. This laser-ablation was designed to promoted stronger bone anchorage during the early healing period of osseointegration than a standard machined implant (22). A recent study evaluating this surface modified implant in adults reported an implant survival of

97% together with good soft tissue tolerability (23). The potential advantages or disadvantages of this new generation of BAHIs have not yet been evaluated in children.

Resonance frequency analysis (RFA) was introduced as a non-invasive, in situ method to assess the stability of BAHI in patients. The RFA of a small transducer rod (smartpeg) attached to the implant is converted into an implant stability quotient (ISQ) (between 1 and 100), where a higher number indicates higher stability. Two ISQ recordings are taken in perpendicular directions ISQ high (ISQH) and ISQ low (ISQL) which are generated due to the different bone characteristics in each direction (24). The ISQ of attached abutments is measured in an identical manner by placement of the smartpeg into the abutment center. ISQ values for BAHI demonstrate trends in stability in individual patients or cohorts over time, and clinical conclusions cannot be drawn from single ISQ values according to a review of 17 studies using ISQ (25). The role of stability measurement in children is still debated but has been used by some centers to help guide early loading in single-stage procedures (12,25).

The objectives of this study were to determine implant stability using ISQ at the fixture and abutment levels and implant survival over the first 12-month period in a cohort of 115 consecutive children fitted with the laser ablated Ponto BHX implant system.

2. Materials and methods

2.1 Study Population and Surgery

This was a prospective, single-subject, repeated measure, cohort study in which each participant served as their own control. Ethical approval was granted by the research and development committee (REC ref 11/WM/1054, IRAS project ID 145812). Participants aged between 4 and 15 years with unilateral or bilateral, conductive hearing loss eligible for BAHI were recruited at Birmingham Children's Hospital (Birmingham, England).

Following a formal consent process, 115 consecutive children were offered a place in the study. Patient demographics, underlying etiological indications for implantation and surgical techniques were recorded.

This center preferred two stage implantations in younger children. Single stage procedures were performed on seven patients (total nine implants). In all but five cases, two fixtures were placed on the indicated side, one acting as a "sleeper." Typically, a two-stage procedure consisting of a 3-month healing period between surgeries was used. All surgeries were performed by three consultant surgeons between January 2016 and January 2019. The following three surgical techniques were used: 1) linear incision for implant placement followed

by a linear incision without skin reduction for second stage; 2) a "U" shaped incision for implant placement followed by a 4-mm skin punch with no skin reduction for the second stage; 3) "S" shaped skin incision for stage one with no skin reduction followed by a 4-mm skin punch with minimal skin reduction for the second stage. Single-stage procedures were performed in an identical fashion.

2.2 Implant and Abutment

The implant was the laser ablated titanium bone anchored implant system Ponto Biohelix (BHX) (diameter, 4.5 mm; length 3 or 4 mm) (Oticon Medical AB Askim, Sweden). Ponto BHX with premounted abutments of lengths 6, 9, and 12 mm were used for single stage surgeries. Abutment lengths of 6, and 12 mm were used at the second stage surgeries for all other children.

2.3 Follow Up and Review

Second-stage surgery for abutment placement occurred following a minimum 3-month period. Reviews then occurred at weeks 1 and 2 and then at 3, 6, 9, and 12 months. Complications, revision rates, skin reactions according to the Holger Classification (26), loss of abutment, implant failures, and abutment level ISQs (Osstell ISQ, Osstell AB, Gothenburg, Sweden) were documented at each review. Holgers more than or equal to two were considered adverse skin reactions. Fixture- and abutment- level ISQs were recorded at each surgical stage and subsequently, only abutment-level ISQs were recorded. Two recordings were taken in perpendicular directions (ISQH and ISQL).

2.4 Statistics

All data were analyzed using Stata 16 version 16.1 (StataCorp LLC, TX). Categorical data are presented as n (%) and numeric data are presented as the mean (SD) and range or mean (95% CI). To assess the effect of time from surgery on the ISQ, a mixed effect model was applied, and comparisons were performed using the data from the time of surgery as the baseline. The results are presented as coefficients or means with the appropriate confidence interval, and the level of significance was set at $p = 0.01$.

3. Results

A total of 115 consecutive pediatric patients were implanted with the laser ablated titanium bone anchored implant system. The mean age was 8.8 years, with a slight female predominance (52%). Sixty-one children had bilateral implants and 54 had unilateral implants giving a total of 176 implants (3 mm implants n = 124, 4 mm n = 52). A two-stage implantation was performed in 108 patients (167 implants) whereas a single-stage procedure was performed in seven patients

(nine implants). In all but five cases, two fixtures were placed on the indicated side, one acting as a "sleeper." One implant was lost before the second-stage surgery; therefore, 175 implant systems were fitted with abutments and followed from this point. Patient demographics and systems implanted by each surgical technique are provided in Table 1 for direct comparison.

3.1 Second Stage Interval Analysis

The mean healing period between stage one and stage two was 14.3 weeks (SD 3.25; range, 9–24). The longer healing periods were used for patients with very thin bone (<2 mm) or due to social factors such as medical or school commitments.

3.2 Implant Survival

For the entire cohort, a median 12-month implant survival of 96.6% n = 169), implant failure rate of 2.8% (n = 5), and traumatic loss rate of 0.6% (n 1) were determined (Table 1). All but one implant loss occurred before the 6-month review, the exception being traumatic loss, which occurred between the 6 and 12 months reviews. Lost implant systems were replaced outside this study. All data from the patients up to the point of implant loss were included in the analysis.

There was no statistically significant difference in the implant survival rate for the group of implants installed with minor soft tissue reduction (31 implants) compared with those that had no soft tissue reduction (145 implants) (failure rates of 3.2 and 3.8%, respectively). Most implants were 3 mm long (n 124, 70.5%) and considered the fixture of choice when the thickness of calvarial bone was less than or equal to 2 mm. These fixtures were placed with a low torque of 25 to 30 Nm^2 and where possible positioned flush with the calvarial bone.

Spontaneous implant loss occurred in four female patients and one male patient aged 4 to 15 years (median 7). One 3-mm implant failed before the second stage of surgery, two implants (3 and 4 mm) failed by the 3-month review, and the remaining two (3-mm) failed by 6 months. Two patients within this group had undergone single stage procedures performed by two different operating surgeons which were recorded at the 3 and 6 month review points.

Table 1: Demographics and implant loss rates for all included patients and surgical approach subgroups.

	Total	Surgery method		
	n=115	'U' Shape (n=36)	'S' Shape +SR (n=21)	Linear +SR (n=58)
Sex, n (%)				
Male	55 (47.83)	16 (44.44)	10 (47.62)	29 (50.00)
Female	60 (52.17)	20 (55.56)	11 (52.38)	29 (50.00)
Side of surgery n (%)				
Bilateral	61 (53.04)	16 (44.44)	10 (47.62)	35 (60.34)
Left	21 (18.26)	6 (16.67)	6 (28.57)	9 (15.52)
Right	33 (28.70)	14 (38.89)	5 (23.81)	14 (24.14)
Age: mean (SD) (range)	8.8 (3.5) (4, 15)	9.1 (3.7) (4, 15)	9.0 (3.8) (4, 15)	8.4 (3.3) (4, 15)
Mean BMI centile (SD)	23.2 (13.3)	21.4 (11.2)	21.6 (9.9)	24.9 (15.4)
Implant length n (%)				
3 mm	124 (70.5)			
4 mm	52 (29.5)			
Abutment length n (%)				
6 mm	29 (16.5)			
9 mm	141 (80.5)			
12 mm	5 (3%)			
Total number of implants	176	52	31	93
Total number of abutments fitted	175	52	30	93
Implant failure n (%)	5 (2.8)	1 (1.9)	1 (3.2)	3 (3.2)
Traumatic failure n (%)	1 (0.6)	1 (1.9)	0	0
Total implant failures	6 (3.4)	2 (3.8)	1 (3.2)	3 (3.2)

Linear +sr = linear incision for implant placement followed by a linear incision with minimal skin reduction for the second stage."u' shaped = u-shape incision of the first stage, followed by a 4-mm skin punch without skin reduction. 'S'-shaped + sr= s shaped skin incision for the first stage with no skin reduction, followed by a 4-mm skin punch with slight skin reduction for stage two.

3.3 Soft Tissue Outcomes

Holgers Grade 0 was recorded in 54.7% of visits across the entire study group. During the 12-month follow-up, adverse skin reactions (Holgers grade 2–4) were observed in 4.4% of all postoperative visits, occurring in 22 individuals (19.1%). No association with surgical technique, age, sex, or BMI was identified. Pain was reported by one individual at the second postoperative review. Keloid scarring and scar overgrowth occurred in four (2.2%) implant systems; however, no revision surgery was required for any implant.

3.4 Implant Stability Quotient

Three implants had missing ISQ recordings from the time of implantation and 63 implants were missing ISQ data at the second stage surgery (Table 2). Single-stage procedures (n 9) did not have implant-level ISQ recorded at either surgical stage. Therefore, ISQ was measured in 164 implants at the implant level, i.e., first- stage surgery and 101 implants at the second stage surgery before abutment placement. Irrespective of the implant length the mean ISQH and ISQL demonstrated a nonsignificant increase between the first and second stages of 2 and 3.1 points, respectively (Table 2).

With respect to the abutment ISQ, the mean ISQH increased for the 6-, 9-, and 12-mm abutments by 2.5, 9.5, and 10.8, respectively (Fig. 1/Table 3). However, this increase was only statistically significant within the 9- mm cohort and from the 3 month review onwards. Combining the entire cohort of abutment length with an overall increase in ISQH of 8.43, statistical significance was reached at 3 months.

The mean ISQL increased by 5.2 and 10.1 for the 6- and 9-mm abutments, respectively, whereas it decreased by 3.9 in the 12-mm group. These changes were only statistically significant in the 9-mm group. Overall, an increase in ISQL of 9.03 was observed (Fig. 1/ Table 3).

3.5 Relationship Between Fixture Failure, BMI, and ISQ

The mean BMI centile of the fixture failure patients (22.7th centile SD, 7.9) did not differ from the mean for the entire cohort (23rd centile, SD 13.3). Statistical analysis of the relationship between atraumatic fixture failure and the ISQ was not performed due to the small sample size (n 5). However, no obvious correlation or relationship could be identified between ISQ at either fixture of abutment level and subsequent failure, the ISQ at all visits for each of these implants as demonstrated in Table 4.

Table 2: Mean ISQ at implant level, SD and range with p-value of change between these two measurement points irrespective of implant size.

	First stage	Second stage		
N =	164	101		
ISQ L			Change	p-value
Mean	62	65.1	3.1	0.06
SD	14.2	11		
Range	20-96	39-90		
ISQ H				
Mean	68	70	2	0.23
SD	14.4	11.2		
Range	9-98	44-90		

ISQ indicates implant stability quotient

Table 3: Mixed effect modelling to estimate the magnitude of the change in ISQ according to visit and abutment size. Statistically significant results are in bold.

	ISQ_LOW		ISQ_HIGH	
	Mean Change (95% CI)	p value	Mean Change (95% CI)	p value
6 mm				
Post op visit week 1	**-8.5 (-13.4, 3.6)**	0.001	**-8.2 (-13.0, -3.5)**	0.001
Post op visit week 2	2.2 (-3.3, 7.6)	0.44	0.3 (-5.0, 5.6)	0.92
3 months	3.2 (-1.8, 8.2)	0.21	3.5 (-1.3, 8.4)	0.16
6 months	-1.4 (-13.1, 10.4)	0.82	-1.4 (-12.9, 10.1)	0.82
9 months	6.3 (1.2, 11.4)	0.015	3.2 (-1.8, 8.1)	0.21
12 months	5.2 (0.1, 10.3)	0.045	2.5 (-2.4, 7.5)	0.32
9 mm				
Post op visit week 1	1.1 (-1.6, 3.8)	0.43	2.4 (-0.4, 5.2)	0.1
Post op visit week 2	-0.3 (-3.5, 2.9)	0.86	1.0 (-2.5, 4.4)	0.58
3 months	**7.7 (4.8, 10.5)**	<0.0001	**9.8 (6.8, 12.8)**	<0.0001
6 months	**8.0 (4.0, 12.0)**	<0.0001	**10.1 (5.8, 14.3)**	<0.0001
9 months	**9.7 (6.1, 13.2)**	<0.0001	**9.4 (5.7, 13.1)**	<0.0001
12 months	**10.1 (6.6, 13.4)**	<0.0001	**9.5 (5.8, 13.1)**	<0.0001
12 mm				
Post op visit week 1	1.2 (-3.8, 6.2)	0.63	9.5 (-0.4, 19.4)	0.06
Post op visit week 2	-3.4 (-8.9, 2.1)	0.23	4.1 (-6.6, 14.8)	0.45
3 months	-3.0 (-8.0, 1.9)	0.23	4.0 (-5.9, 13.9)	0.43
6 months	8.3 (0.1, 16.6)	0.048	21.8 (6.1, 37.4)	0.006
9 months	-8.5 (-16.7, -0.3)	0.042	-3.3 (-18.9, 12.4)	0.68
12 months	-3.9 (-10.0, 2.2)	0.21	10.8 (-1.4, 22.9)	0.08
All abutments				
Post op visit week 1	-0.21 (-2,55, 2,14)	0.86	1.05 (-1.42, 3.52)	0.40
Post op visit week 2	0.04 (-2.75, 2.83)	0.98	0.66 (-2.72, 3.60)	0.66
3 months	**6.51 (4.03, 8.99)**	<0.0001	**8.42 (5.80, 11.04)**	<0.0001
6 months	**6.85 (3.20, 10.49)**	<0.0001	**8.66 (4.82, 12.50)**	<0.0001
9 months	**8.82 (5.83, 11.82)**	<0.0001	**8.20 (5.08, 11.32)**	<0.0001
12 months	**9.03 (6.12, 11.95)**	<0.0001	**8.43 (5.36, 11.50)**	<0.0001

Table 4: ISQ and Holgers scores for each failed implant. (x indicates missing data, IL = Implant loss

	P1	P2	P3	P4	P5
Age	4	7	5	15	9
Sex	F	F	M	F	F
BMI centile	18.6	26.2	35	18.5	15.4
Implant size	3	3	3	3	4
Abutment size	9	9	9	6	9
Surgery 1					
Fixture					
ISQH	70	77	81	80	77
ISQL	70	67	80	71	56
Surgery 2					
Fixture					
ISQH	80	66	IL	80	77
ISQL	56	66	-	71	56
Abutment					
ISQ H	39	46	-	48	35
ISQ L	39	44	-	38	34
1 week post					
ISQ H	44	36	-	x	37
ISQ L	40	36	-	x	37
Holgers	0	2	-	x	0
2 weeks post					
ISQ H	67	x	-	x	x
ISQ L	60	x	-	x	x
Holgers	2	x	-	x	x
3 months					
ISQ H	40	IL	-	61	IL
ISQ L	40	-	-	59	-
Holgers	3	-	-	0	-
6 months	IL	-	-	IL	-

IL indicates implant loss; ISQ, implant stability quotient; x, missing data.

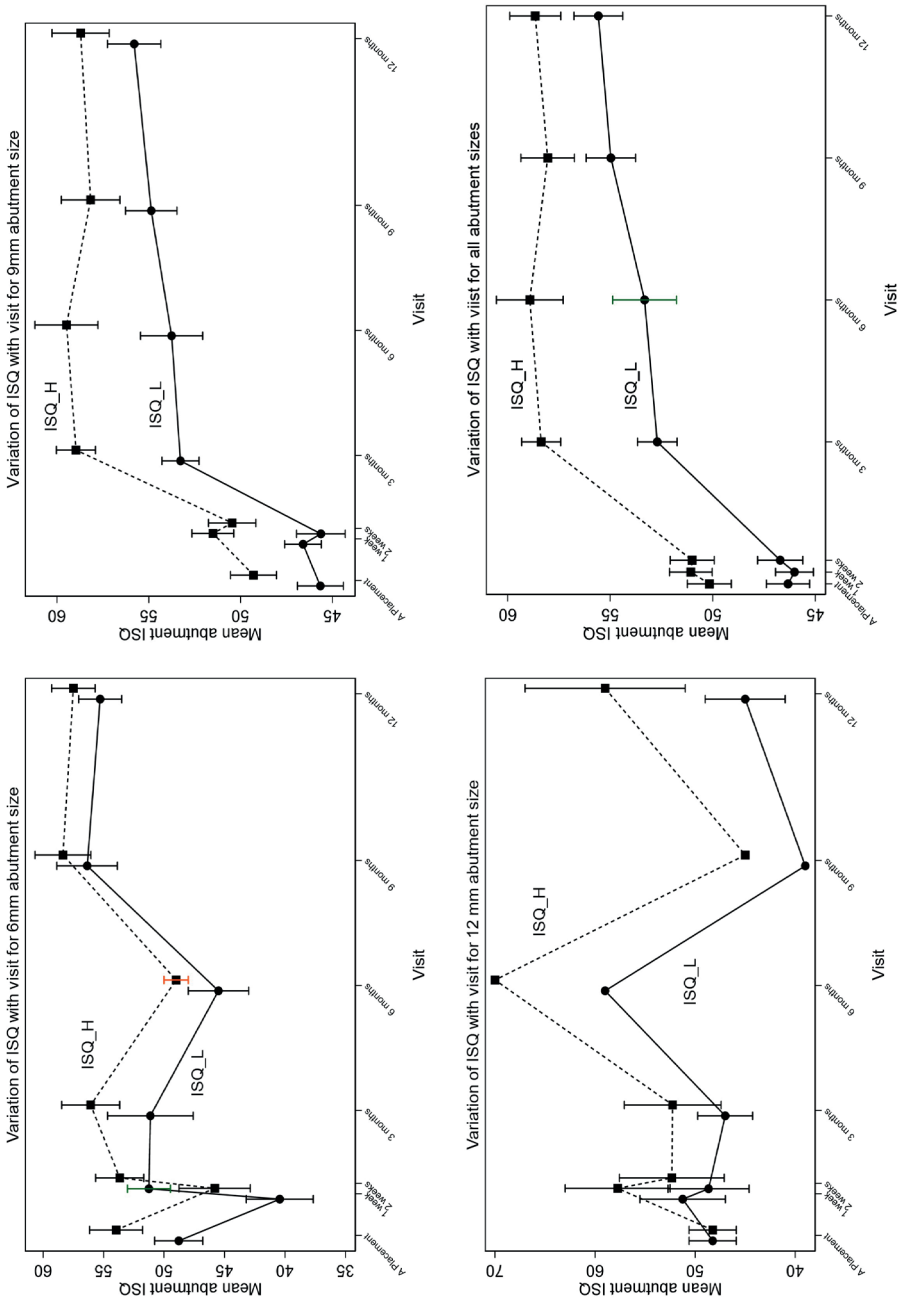

Figure 1: Change in mean ISQ and ISQ L at each review point according to abutment size. ISQ indicates stability quotient.

4. Discussion

To our knowledge, the current study is the largest published evaluation of wide implants BAHIs in pediatrics and the first study evaluating the clinical outcomes of the new Ponto BHX in children.

The present study revealed an implant loss rate of 3.4% in a pediatric population. A previous study on 182 children from BCH using two-stage surgery in 95% of the cases, demonstrated implant failures in 14% of loaded implants (27). In contrast to the present study, 3.75 mm machined implants were used and installed using a split skin graft technique. Moreover, the follow-up time was 15 years. However, the majority of implants were lost during the first 2 years and associated with wound breakdown and significant skin reaction, indicating the influence of implant design and surgical technique on the survival rate. In comparison to other results at our center, outcomes using the previous Ponto wide implant (without a laser ablated surface) showed a 10% implant failure rate in 75 implanted systems (28), indicating a benefit in terms of survival rate using the present implant surface with micro- and nanoscale features.
The results from the present study can also be compared with the use of a wide blasted implant (BIA300, Cochlear Nordic AB, Mölnlycke, Sweden) demonstrating 5% implant loss at our center (29). A recent meta-analysis of wide diameter implant systems in the pediatric population demonstrated a 5.9% fixture loss, whereas the corresponding result for the previous narrow BAHI implant was 17.1%, corroborating our findings (19).

The reduced revision surgery rate in the present study in comparison with previous results in our center using the small diameter implant, 0% versus 8% (27), is in line with the results in a recent systematic review (19) and far exceeds this center's experience with the Cochlear BIA300 implant, which demonstrated a significant 77% skin reaction rate and 35% revision rate (29). Taken together, the present study therefore demonstrates significant improvement in the implant loss and revision surgery rates (2.8 and 8.3%) as well as comparable soft tissue complications, compared with previous implant systems utilized.

Peri-abutment adverse skin responses are well-known side-effects in pediatric patients (19,27,28). These responses have been linked to hygiene, puberty, skin movement, and medical comorbidities, making children more prone to adverse soft-tissue complications com- pared with adults (19). In children under 5 years old, there is a disproportionate soft tissue complication rate of 15 to 42%, with an associated 10 to 25% revision rate reported (30,31). In our present cohort of 26 children under the age of 5 implanted with 40 BAHIs, two fixture losses were observed (5%) with soft tissue complications (Holgers 2–4) observed in three patients (11.5%). Taken together, the 4.5 mm wide laser ablated titanium bone anchored implant system appears to promote favorable results in this at-risk subgroup compared with the previous

Oticon wide implant. Overall adverse soft tissue reaction was noted in 19% of the patients and no revision surgery was required over the 12 months follow up. They only comprised 4.4% of all postoperative visits recorded indicating the transient nature of these reactions. In comparison with previous reports of adverse skin reactions in 17% of patients and revision surgery in 8% of patients (using similar implant widths but non-laser ablated surfaces), it is suggested that implant diameter does not influence the soft tissue outcome (27). Similar conclusions were reached in a review, demonstrating an equal incidence of adverse reactions (28%) in wide- and small-diameter implants (19).

The reduced revision surgery rate in the present study in comparison with previous results in our center using the small diameter implant, 0% versus 8% (32), is in line with the results in the review (19). In contrast, this centre's experience with the Cochlear BIA300 implant demonstrated a significant 77% skin reaction rate and 35% revision rate. However, it is important to consider that dermatome was applied in 57% of patients in the BAI300 study, a practice that was phased out when the Oticon wide system was introduced (29). Taken together, the present study therefore demonstrates significant improvement in the implant loss and revision surgery rates, as well as comparable soft tissue complications, compared with previous implant systems utilized at our center.

Another important factor to consider is the continued use of BAHIs as this is an excellent indication of the real- world application of hearing aids. If patients or carers found skin complications intrusive, they would discontinue their use. Our previous reports have shown that 97% were wearing the system daily with audiological benefit (27). Although the present study concerns a 12-month follow-up, at the time of submission, we have had a 99.1% retention rate as of January 2021 (2–5 years follow up). The one nonuser was influenced by peer pressure and esthetics.

The implant ISQ showed a nonsignificant increase between the first and second stages and an upward trend in the mean abutment level ISQ H and ISQ L, with statistical significance achieved from the 3-month review point onwards. Application of the ISQ is controversial, and previous publications support early loading in the pediatric population with ISQs above 60 and, similarly, in the adult population (10 –12). Nelissen et al. (25) suggest that conclusions cannot be drawn regarding individual ISQ values alone but rather that trends can be followed but only in individuals or groups in which variables remain the same, as implant systems vary widely in their designs. Hence, the application of absolute ISQ figures from one model of implant to another should be done with caution. Nevertheless, preclinical comparison of laser-modified BHX implants with machined implants failed to capture any difference in stability between the two implant types in terms of ISQ, despite a significantly higher removal torque required for the

BHX implant, underscoring the limitations of the ISQ measurement to distinguish the degree of osseointegration (22).

A limitation in the present study is the small sample size in both the 12-mm abutment and fixture failure groups. Each group lacks significant statistical power to identify trends with regards to ISQ levels. Due to the wide range of indications for surgery and physical and psychological comorbidities of the recipients in our study cohort, comparisons with other published literature should be done with caution. The variation in surgical technique is also considered a limitation although the patient demographics, postoperative protocol, and routine follow-ups were identical for the three groups. In addition, the impact of missing reviews should be considered when interpreting the results of this study. Explanations reside in the exceptionally large geographic area from which many patients are referred. Time away from school, organization of care for siblings, and the additional challenges to attend contributed to the missing data. The added burden of additional reviews was considered a further inconvenience, especially when parents and carers had no concerns regarding the implant site or hearing following abutment placement. This was confirmed with telephone consultations when investigating missing appointments.

It is concluded that the use of laser-ablated titanium implant for BAHIs in a large pediatric cohort resulted in superior survival rates and excellent clinical outcomes compared with previous implant systems utilized at BCH. Although absolute figures for the abutment-level ISQ increased over time, statistical significance was only demonstrated at 3 months. The absolute ISQ data did not provide an indication of probable fixture failure.

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References

1. Tjellstrom A, Lindstrom J, Hallen O, et al. Osseointegrated titanium implants in the temporal bone. A clinical study on bone-anchored hearing aids. Am J Otol 1981;2:304–10.
2. Shah FA, Thomsen P, Palmquist A. Osseointegration and current interpretations of the bone-implant interface. Acta Biomater 2019;84:1–15.
3. Palmquist A, Omar OM, Esposito M, et al. Titanium oral implants: surface characteristics, interface biology and clinical outcome. J R Soc Interface 2010;7 (suppl):S515–27.
4. Esposito M, Hirsch JM, Lekholm U, et al. Biological factors contributing to failures of osseointegrated oral implants. (I). Success criteria and epidemiology. Eur J Oral Sci 1998;106:527–51.
5. Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol 2012;33:192–8.
6. Bezdjian A, Smith RA, Thomeer H, et al. A systematic review on factors associated with percutaneous bone anchored hearing implants loss. Otol Neurotol 2018;39:e897–906.
7. McElveen JT Jr, Green JD Jr, Arriaga MA, et al. Next-day loading of a bone-anchored hearing system: preliminary results. Otolaryngol Head Neck Surg 2020;163:582–7.
8. Kruyt IJ, Nelissen RC, Mylanus EAM, et al. Three-year outcomes of a randomized controlled trial comparing a 4.5-mm-wide to a 3.75-mm-wide titanium implant for bone conduction hearing. Otol Neurotol 2018;39:609–15.
9. Wazen JJ, Babu S, Daugherty J, et al. Three-week loading of the 4.5 mm wide titanium implant in bone anchored hearing systems. Am J Otolaryngol 2016;37:132–5
10. Nelissen RC, den Besten CA, Faber HT, et al. Loading of osseointegrated implants for bone conduction hearing at 3 weeks: 3-year stability, survival, and tolerability. Eur Arch Otorhinolaryngol 2016;273:1731–7.
11. McLarnon CM, Johnson I, Davison T, et al. Evidence for early loading of osseointegrated implants for bone conduction at 4 weeks. Otol Neurotol 2012;33:1578–82.
12. McLarnon C, Johnson I, Davison T, et al. Resonance frequency analysis of osseo-integrated implants for bone conduction in a pediatric population - a novel approach for assessing stability for early loading. Int J Pediatr Otorhinolaryngol 2014;78:641–4.
13. Lee JH, Frias V, Lee KW, et al. Effect of implant size and shape on implant success rates: a literature review. J Prosthet Dent 2005; 94:377–81.
14. Foghsgaard S, Caye-Thomasen P. A new wide-diameter bone-anchored hearing implant: prospective 1-year data on complications, implant stability, and survival. Otol Neurotol 2015;36:1123–4.
15. Nelissen RC, den Besten CA, Mylanus EA, et al. Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial. Eur Arch Otorhinolaryngol 2016;273:105–11.

16. Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. Otol Neurotol 2014;35:1486–91.

17. Lagerkvist H, Carvalho K, Holmberg M, et al. Ten years of experience with the Ponto bone-anchored hearing system-a systematic literature review. Clin Otolaryngol 2020;45:667–80.

18. den Besten CA, Stalfors J, Wigren S, et al. Stability, survival, and tolerability of an auditory osseointegrated implant for bone conduction hearing: long-term follow-up of a randomized controlled trial. Otol Neurotol 2016;37:1077–83.

19. Kruyt IJ, Bakkum KHE, Caspers CJI, et al. The efficacy of bone-anchored hearing implant surgery in children: a systematic review. Int J Pediatr Otorhinolaryngol 2020;132:109906.

20. Doshi J, McDermott AL, Reid A, et al. The 8.5 mm abutment in children: the Birmingham bone-anchored hearing aid program experience. Otol Neurotol 2010;31:612–4.

21. Albrektsson T, Wennerberg A. Oral implant surfaces: Part 2–review focusing on clinical knowledge of different surfaces. Int J Pros- thodont 2004;17:544–64.

22. Shah FA, Johansson ML, Omar O, et al. Laser-modified surface enhances osseointegration and biomechanical anchorage of commercially pure titanium implants for bone-anchored hearing sys- tems. PLoS One 2016;11: e0157504.

23. Kruyt IJ, Banga R, Banerjee A, et al. Clinical evaluation of a new laser-ablated titanium implant for bone-anchored hearing in 34 patients: 1-year experience. Clin Otolaryngol 2018;43:761–4.

24. Sennerby L, Meredith N. Implant stability measurements using resonance frequency analysis: biological and biomechanical aspects and clinical implications. Periodontol 2000 2008;47:51–66.

25. Nelissen RC, Wigren S, Flynn MC, et al. Application and interpretation of resonance frequency analysis in auditory osseointegrated implants: a review of literature and establishment of practical recommendations. Otol Neurotol 2015;36:1518–24.

26. Holgers KM, Tjellstro¨m A, Bjursten LM, et al. Soft tissue reactions around percutaneous implants: a clinical study of soft tissue conditions around skin-penetrating titanium implants for bone-anchored hearing aids. Am J Otol 1988;9:56–9.

27. McDermott AL, Williams J, Kuo M, et al. The Birmingham pediatric bone-anchored hearing aid program: a 15-year experience. Otol Neurotol 2009; 30:178–83.

28. Osborne MS, Hoskison E, Child-Hymas A, et al. Five year clinical outcomes and evaluation following implantation of the Oticon™ wide bone anchored hearing system in 47 children. Int J Pediatr Otorhinolaryngol 2020;137: 110244.

29. Fussey JM, Harterink E, Gill J, et al. Clinical outcomes following Cochlear BIA300 bone anchored hearing aid implantation in children. Int J Pediatr Otorhinolaryngol 2018;111:89–92.

30. Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. Arch Otolaryngol Head Neck Surg 2007;133:51–5.

31. Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. Int J Pediatr Otorhinolaryngol 2015;79:474–80.

32. McDermott AL, Williams J, Kuo M, et al. Quality of life in children fitted with a bone-anchored hearing aid. Otol Neurotol 2009;30:344–9.

Chapter 3.2

Clinical evaluation and resonance frequency analysis of laser-ablated titanium bone-anchored hearing implant system in children with Down syndrome.

Osborne MS, Child-Hymas A, McDermott AL.
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Abstract

Objectives

To evaluate complication rates and resonance frequency analysis (RFA) of the stability of a new laser- ablated titanium Bone Anchored hearing Implant system in children with Down syndrome.

Methods

A prospective, single-subject, repeat measure, cohort study in which each participant served as their own control. Consecutive paediatric patients 4yrs- 15 years old, with a primary diagnosis of Down syndrome (trisomy 21) were implanted between January 2015–January 2020 with BHX Oticon wide implants. Evaluation of soft tissue reactions, fixture failure rates and post implantation Implant stability Quotient (ISQ) at both fixtures and abutment levels were studied over a 12-month period. Data was analysed for statistical significance through mixed effect modelling with significance set at $p = 0.01$.

Results

31 consecutive paediatric patients with a diagnosis of Down syndrome were implanted with 43 Ponto BHX Oticon™ implant system. Twelve children had bilateral implants and nineteen were unilateral. Over the 12 month follow up 2 fixtures (4.6%) were lost, and adverse skin reactions (Holgers >2) were recorded in 3.2% of all clinical reviews. Implant level stability quotient showed no statically significant change between first and second stage 71.1–71.7. Abutment level ISQ increased from 46.2 to 56.7 $p = 0.0001$ at the 12-month review point as compared to that recorded at loading.

Conclusion

Implant survival and adverse skin reactions were found to be in keeping with those in published literature and much improved compared to previous implant systems placed at this centre. Although abutment level ISQ showed an increase over the review period no correlation between this and implant loss can be concluded.

1. Introduction

Down syndrome (DS) was first described in 1866 by Doctor John Langdon Down and the additional 47th (Trisomy 21) chromosome resulting in the associated physical characteristics was discovered in 1959 by Professor Jérome Lejeune. Affecting 1:1000 live births there are approximately 40 000 individuals with DS living in the UK [1]. The most common pathologies in children with DS are obstructive sleep apnoea, otitis media, hearing loss and cardiac disease [2]. Overall, Hearing impairment is reported to affect as many as 24.9–90% [3–6] of this group of children and can be permanent (15–24.9%) or transient (22–30%) [4,7].

Otitis media with effusion (OME) resulting in a moderate to severe conductive hearing loss affect 43–75.4% of children with DS [6,8,9], although the prevalence is dependent on age of the child. At the age of one year, 93% have a significant middle ear effusion [9]. By age of 7 years, 60% are affected and a declining trend is seen thereafter [10]. Longitudinal follow up of children with DS with hearing impairment demonstrated 88.8% receive ventilation tube insertion during their childhood (prior to the age of 18), often requiring multiple replacement procedures (mean 3.5) [11]. The presence of OME in children with DS results in significantly lower hearing levels with a mean pure tone average of 33.4 dB HL compared to those children with DS without OME 21.7 dB HL ($p < 0.0001$) [12].

Treatment of persistent OME results in remarkable improvement in hearing. These treatments include myringotomy, ventilation tubes insertion and hearing aids, either digital behind the ear or bone conducting hearing system. Ventilation tubes are required in 28.9%, a 13-fold higher requirement in DS patients as compared to an age matched control [5]. Interestingly patients are often rehabilitated with hearing aids regardless of surgical intervention [13].

As the majority of DS children require two or more sets of ventilation tubes, long term complications are common, especially in those who require 3 or more replacements. These include chronic tympanic membrane perforation 36.6%, atelectasis 29.3% and cholesteatoma 14.6% [14]. Spontaneous closure of perforations occurs in 33% of DS children which is increased to a 54.8% closure rate following primary tympanoplasty [15].

Considering the higher risks of ventilation tube in children with DS (infection, early extrusion, perforation and general anaesthetic) the National Institute of Clinical Excellence (NICE) recommends hearing aids as the initial treatment of choice for hearing impairment secondary to OME. Ventilation tube placement should only be offered as an alternative following multidisciplinary team discussion [16].

Traditional air conduction hearing aids have their own limitations in this group of children and include narrow ear canals and impaction of wax, both of which may create significant rates of complications including infection and further conductive losses. In addition, any learning difficulties may influence the child's acceptance and tolerance of wearing any traditional hearing aid. The use of a bone anchored hearing implant (BAHI) and hearing device as an alternative aiding system has been shown to be a very acceptable form of hearing rehabilitation in this patient group [17,18] and with those with learning difficulties [19].

In 2009, Oticon™ Medical introduced the 4.5 mm Ponto wide bone anchored hearing implant (BAHI) [20] and this was later replaced in 2015 by the Ponto Biohelix (BHX) Oticon™ of the same 4.5 mm diameter which utilises OptiGrip™ Geometry and laser-ablated surface to improve stability and promote osseointegration. The application of wider diameter implant was initially shown to improve outcomes in dental implantation with lower implant failure rates [21,22].

Application of this wider BAHI has been found to have comparable skin reaction rates to the previous 3.75 mm implants and in addition it was noted to be associated with increased survival [23–26]. The wider diameter of these implants increases the surface area contact between the implant and temporal bone providing a greater stability which results in a reduction in spontaneous fixture loss. Recent meta-analysis by Kruyt et al. supports these finding in children demonstrating a 17.1% loss in small-diameter implants compared to a 5.9% for wide-diameter implants [27] although many of the studies included in this utilised a differently designed wide implant. As a result of this evolving evidence, some centres advocate early loading of processors in adults as early as 3 weeks [27–30] and at 6 weeks in children [31].

Complications associated with previous generations of narrow paediatric BAHI, particularly peri-abutment soft tissue reactions and fixture (implant) loss through both trauma and failed osseointergration, have been demonstrated to be higher in paediatric populations [32]. With specific regards to the wider (4.5 mm) implants, failure rates of 2.6–4.2% are reported in the adult population [23,26,29,33] and 5.9% in children [27].

In 1996 resonance frequency analysis (RFA) was introduced as a non- invasive, objective method to clinically test implant stability in-vitro and in-vivo. It measures the resonance frequency of a small transducer attached to an implant. A strong correlation ($r = 0.94$, $p < 0.01$) was observed between the observed frequency and the height of implant fixture exposed. A significant increase in resonance frequency was observed related to the increase in stiffness on implants in-vivo and the results correlated with the in-vitro findings [34].

RFA with regards to BHAI is measured by the attachment of a Smart Peg to the implanted fixture. This small aluminium rod has a magnet at its apex which can be stimulated by a handheld device emitting a magnetic pulse. The device measures the resonance frequency of this rod which is converted into an Implant Stability Quotient (ISQ) scale (1–100). A higher number indicates increased stability. Two recordings are taken in perpendicular directions ISQ high (ISQ H) and ISQ low (ISQ L), which are generated due to the different bone characteristics in each direction [35]. ISQ of the attached abutments can be measured in an identical fashion by placement of the smart peg into the centre.

2. Methods

2.1 Objectives

This study aims to review the morbidity associated with the Ponto BXH implant system, and to review the trends in ISQ over 12 months follow up period in children with DS.

2.2 Ethical consideration

Approval through the research and development committee (REC ref 11/WM/1054, IRAS project ID 145812) was granted.

2.3 Study population

A prospective, single-subject, repeat measure, cohort study in which each participant served as their own control. Participants aged between 5 and 16 years with unilateral or bilateral, conductive hearing loss eligible for BHAI were recruited from the patient body at Birmingham Children's Hospital (Birmingham, UK). Following a formal consent process, 31 consecutive children awaiting a BAHI with a diagnosis of DS were offered a place on the study. Patient demographics and underlying medical conditions were recorded, as were the indications for implantation and surgical technique.

In this paediatric centre, two stage implantation procedures are more commonly performed in younger children. Single stage procedures were performed on 3 patients (total 3 implants). In all cases, two fixtures were placed on the indicated side, one acting as a 'sleeper'. Typically, the two- stage procedure utilised a 3-month healing (osseointegration) period between surgeries. All surgeries were performed by three consultant surgeons between Jan 2016–Jan 2019.

In this study the procedure was performed using one of three techniques:

Method 1: Linear incision for implant placement followed by a linear incision with no skin reduction for second stage.

Method 2: A 'U' shaped incision for implant placement followed by a 4 mm skin punch with no skin reduction for second stage.

Method 3: 'S' shaped skin incision for stage one with no skin reduction followed by a 4 mm skin punch with slight skin reduction for second stage.

Single stage procedures were performed in an identical fashion.

Calvarial bone depth was measured indirectly by the subjective comparison to the bur and its guide. These devices are measured pre-operatively and as there is no variation in operating drill systems this remains uniform across all surgeons. No objective measuring device is used however the burr and guide provide the three important depths of assessment. The cutting end (ball) is 1 mm in depth, the guide cover is 2 mm and to the shaft of the burr 3+mm. These comparisons were used and recorded.

2.4 Implant and abutment

The implant was the Ponto BHX implant (diameter, 4.5 mm; length 3 or 4 mm) (Oticon Medical AB Askim, Sweden). Ponto BHX with pre-mounted abutments of lengths 6, 9 and 12 mm were used for single stage surgeries. Abutment lengths of 6, 9, and 12 mm were used at the second stage Surgeries for all other children.

2.5 Follow up and review

The second stage surgery for abutment placement occurred following a minimum of a three-month osseointegration period. Following abutment placement clinical review was arranged at week 1 and 2, then at a 3, 6, 9 and 12 month points. Complications, revision rates, skin reactions according to Holger Classification, loss of abutment, implant failures and abutment level ISQ (Osstell ISAM. Osstell AB, Goteborg, Sweden) were documented at each review. Holgers ≥2 were considered as adverse skin reactions. Fixture and abutment level ISQ were recorded at each surgical stage and subsequently only abutment level ISQ was obtained. Two recordings were taken in perpendicular directions (ISQ H and ISQ L).

2.6 Statistical analysis

All data was analysed using Stata 16 version 16.1 (StataCorp LLC, Texas USA). Categorical data were presented as n (%) and numeric data as mean (SD) and range or mean (95% CI). To assess the effect of time from surgery on the ISQ, a mixed effect model was applied, and comparisons were done using the data from the time of surgery as the baseline. The results were presented as coefficients or means with the appropriate confidence interval and p levels significance set at $p = 0.01$.

3. Results

A total of 31 consecutive paediatric patients requiring a BAHI with a comorbidity of DS were implanted with the Ponto BHX Oticon™ implant system. 12 children had bilateral implants and 19 had unilateral implants giving a total of 43 implants (3 mm implants n = 34, 4 mm n = 9). 3 patients had single stage surgery (3 implants); 28 patients had two stage surgery. Mean age at surgery was 8.5 years with a slight female predominance (51%).

The mean BMI centile was 19.1 [Table 1]. Acquired conductive hearing loss was the most common hearing loss aetiology 48% n = 15.

Over the course of the twelve months follow up, 2 fixtures were lost (4.6%) in two separate patients; the first by the 3-month review point and the second at 6 months. Both cases were spontaneous fixture losses due to failed osseointegration.

3.1 Second stage interval analysis

The mean healing period between stage one and stage two was 15.8 weeks (SD 3.57, Range 12–24). The longer healing periods were used for patients with very thin bone <2 mm or due to social factors such as medical or school commitments.

3.2 Implant survival

For the entire cohort, there was a median 12-month implant survival of 95.3% (n = 41), 4.6% implant failure (n = 2) and no traumatic loss [Table 1]. Both lost fixtures were 3 mm implants and losses occurred within 6 months of surgery. Lost implant systems were replaced outside this study. All data from the patients up to the point of implant loss were included in the analysis.

3 mm implants were used most frequently (n = 34, 79%) and were placed when the thickness of calvarial bone was ≤2 mm. These fixtures were placed with a low torque of 25–30 Nm2 and where possible, positioned flush with the calvarial bone.

Both spontaneous fixture loss occurred in female patients ages 14 and 15 years at the time of implantation. One occurred at the 3-month review and the other by 6 months. One of these patients had undergone a single stage procedure performed utilising a linear approach, the other via a two-staged s'shaped incision. Each procedure was performed by a different operating surgeon.

Table 1: Patient demographics. Implant data and fixture losses data for included cohort

		Surgeon			
		Total	Linear	S Shape	Liner +SR
Patient n		31			
Implanted fixtures n		43	16	8	19
Gender n (%)					
	Male	15	8	2	5
	Female	16	5	4	7
BMI mean centile (SD)		19.1 (3.39)	18.7 (3.14)	21.2 (4.35)	18.4 (3.01)
Side of surgery n (%)					
	Bilateral	12	4	2	6
	Left	7	3	2	2
	Right	12	5	2	5
Age: mean (SD)		8.5 (3.38)	7.8 (3.26)	8.7 (3.78)	9.17 (3.46)
Age: n (%)					
	4	4	2	1	1
	5	4	3		1
	6	2		1	1
	7	2	1		1
	8	2	1	1	
	9	7	2	1	4
	10	4	2	1	1
	11	1	1		
	12				
	13	1			1
	14	1			1
	15	3	1	1	1
Implant length n (%)					
	3mm	34	14	6	14
	4mm	9	2	2	5
Abutment length n (%)					
	6mm	5	2		3
	9mm	35	13	8	14
	12mm	3	1		2
Total number of systems		43	16	8	19
Fixture failure n (%)		2 (4.7)	1 (6.3)	0	1 (5.2%)

3.3 Peri-abutment soft tissue outcomes

Holgers grading system 0–4 [36] was measured at each review point, non-attenders to review were clinically assumed to have no adverse skin reaction. It is the experience of this BAHI team that parents seek reassurance and review if they have concerns regarding implant stability, skin reactions or hearing changes. Taking this into account, we therefore have considered their absence from review as reassuring. Adverse skin reactions were designated as Holgers grade 2–4. It is important to note that compliance rates to review appointments varied significantly between patients and appointment intervals 23.3–60.5%.

Over the 12 months follow up period, adverse skin reactions were only recorded for 8 children (3.2%) and these occurred at a single point and resolved by the following review. 6 patients included in this group, had adverse peri abutment skin reactions (grade 2 or above) occurring in the first two weeks following abutment loading without further issues. Two late skin reactions grade 2 were recorded at 6 and 12 month review points respectively. No preponderance to any of the surgical techniques used, age, gender or BMI was identified. No revision surgery was required in this cohort, and no fixture failure was associated with any adverse skin reaction at any time point.

3.4 Implant Stability Quotient

34 implants used were 3 mm and nine implants were 4 mm: Overall 43 implants were placed in total. 3 implants (2 × 3 mm and 1 × 4 mm) were placed via a single stage and therefore fixture ISQ was not performed. In these 3 cases the combined fixture/abutment unit was inserted as a single unit and a decision was made not to separate them for fixture ISQ measurements. 17 implants had missing ISQ readings at the implant level at either first or second stage implants resulting in 47% missing data point.

Of the 23 implants analysed the mean ISQ H decrease from 69.54 by 3.29 by stage 2 surgery, mean ISQ L demonstrates an increase of 1.73 from 62.9 at baseline by stage 2 surgery. Neither of these changes were found to be statistically significant $p = 0.63$ and 0.66 respectively.

3.5 Abutment ISQ

All 31 implants had abutment level ISQ recorded at the time of loading. Five 6 mm, three 12 mm and thirty-five 9 mm abutments were placed. Due to lack of power from the small sample size of both the 6 and 12 mm cohorts, no significant statistical conclusions can be drawn from conducting sub group abutment size analysis. Therefore, here we present the ISQ results irrespective of abutment size placed.

Table 1: Mean, ISQH and ISQ recording (95% CI) by visit.

Visit	ISQ_L: mean (95% CI)	p	ISQ_H: mean (95% CI)	p	All ISQ: mean (95% CI)	p
Placement	44.4 (41.2 to 47.7)	Comparator	47.9 (44.5 to 51.3)	Comparator	46.2 (43.5 to 48.9)	Comparator
Week 1	48.2 (44.5 to 51.8)	0.12	55.3 (51.5 to 59.2)	0.003	51.9 (48.9 to 54.9)	0.001
Week 2	45.3 (40.4 to 50.2)	0.77	49.4 (44.3 to 54.5)	0.62	47.4 (43.6 to 51.2)	0.56
3 months	54.6 (50.8 to 58.4)	<0.0001	59.4 (55.4 to 63.3)	<0.0001	57.4 (54.4 to 60.5)	<0.0001
6 months	52.0 (46.1 to 57.9)	0.025	60.5 (54.3 to 66.6)	<0.0001	55.4 (50.9 to 59.9)	<0.0001
9 months	49.3 (44.1 to 54.4)	0.11	53.5 (48.1 to 58.8)	0.078	50.7 (46.7 to 54.6)	0.038
12 months	55.4 (49.9 to 60.9)	0.001	56.9 (51.2 to 62.6)	0.006	56.7 (52.5 to 60.9)	<0.0001

Overall mean ISQ increased from 46.2 at loading to 56.7 at 12 months, ISQ H increased from 47.9 to 56.9 and ISQ L from 44 to 55.4. Although statistical significance varies at each review point, when compared to the baseline statistically significance is seen from the 3- month review point [Table 2, Fig. 1].

3.6 ISQ and fixture failure relationship

Statistical analysis of the relationship between atraumatic fixture failures and ISQ was not performed due to small sample size (n = 2). In addition, mean BMI centile of the fixture failure patients (19.9th centile SD, 1.9) did not differ from the mean for the entire cohort (19.1st centile, SD 3.3).

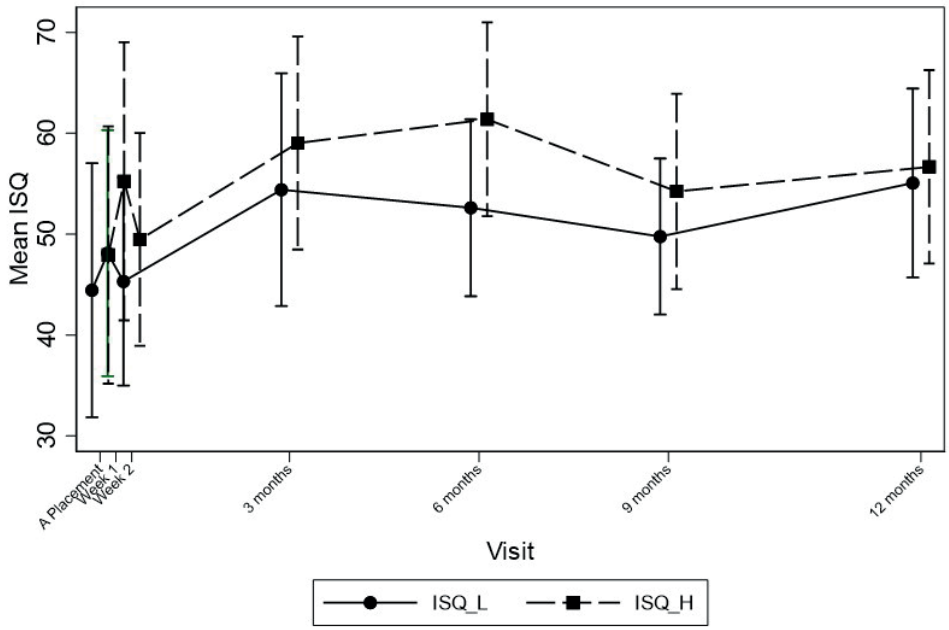

Figure 1: Line plot of change in ISQ recording with standard deviation at each review point. This demonstrates the change in ISQ recorded over time.

4. Discussion

The demonstrated high implant survival rate 95.3% and low adverse skin reaction rate 3.2% in this cohort is in keeping with published literature and indicate the influence of implant design and surgical technique on the survival rate. In comparison to other results at our centre, outcomes using the previous Ponto wide implant (without a laser ablated surface) showed a 10% implant failure rate in 75 implanted systems [37], indicating a benefit in terms of survival rate using the laser ablated implant. The results from the present study can also be compared with the use of a wide blasted implant (BIA300, Cochlear Nordic AB, Mölnlycke, Sweden) demonstrating 5% implant loss at our centre [38] however this BAI300 implant system was noted to have significant adverse skin reactions in 77% of patients.

A recent meta-analysis of wide diameter implant systems in the paediatric population demonstrated a 5.9% fixture loss, whereas the corresponding result for the previous narrow BAHI implant was 17.1%, corroborating our findings [27].

The use of two stage surgery remains popular in our centre especially for children with additional medical and educational needs such as those with Down syndrome. Whilst there is literature supporting single stage surgery in older children [39], two stage surgery offers a perfect healing environment whilst osseointegration occurs. There is no wound care or peri-abutment care required during the healing period and the child can easily wear their softband band post-surgery without concerns about interference with the 'healing' abutment. Families are involved in the pre-operative discussion regarding two stage versus single stage surgery and the need for two very short admissions for general anaesthesia and surgery has not been seen to be a deterrent.

There is evidence in the literature supporting early loading of implants in children using RFA to support their decision [40], however care must be taken when translating results from study populations that are not homogeneous with regards to patient demographics or co-morbidities. The osseointegration period is still in the order of 12 weeks in our centre and early loading of the implant is not a priority since the children continue to wear their softband. Good osseointegration is a priority in the aim of reducing fixture loss and the need for further surgery once the child has become confident in wearing their BAHI.

Implant survival and soft tissue outcomes can also be directly compared to a previous paediatric DS cohort from this same institution. In 2008 McDermott et al. followed up 15 patients over a 14-month period who were implanted using the narrower Brannemark flanged fixture system and demonstrated a no fixture failures, a 20% adverse skin response rate and a 6.7% revision surgery rate [17]. This previous work allows for a unique comparison being matched

with an identical geographical catchment area, audiological and support team. The current study shows that the new wider implant system demonstrates a significant improvement in a syndrome matched cohort with regards to both soft tissue reactions and revision surgery rates.

In addition, there is a significant improvement when compared to outcomes reported in 2005 by Sheehan et al. in which they evaluated BAHI surgery in children with DS. A 49% soft tissue complication and 9% implant failure rate was reported. In this study 43 individuals had been implanted in 18 centres across the UK and Ireland and included a cohort of 24 cases in patients under the age of 16 [18].

Paediatric patient groups pose a unique challenge. The characteristics of the temporal bone undergo change and development in early childhood. Osseointegration is influenced by bone density and trabecular-cortical bone ratios and, as skeletal bone shows dynamic changes in morphometric and compositional characteristics with age [41] this may influence both implant stability and ISQ results. Unlike the otic capsule, which is mature at birth, bone mineral density increases with age and occurs at different rates depending on the anatomical position within the cranial bones [42].

Takahashi et al. have demonstrated that the lateral surface of the mastoid (on which a BAHI is placed) is fully matured by 1.7 years of age, in comparison to the posterior cranial fossa and middle cranial fossa regions of the temporal bone which matures by the ages of 3.9 and 10.8 years respectively [41]. As the youngest participant included in our study was 4 years old, maturation of the lateral temporal bone should have occurred, however there is no published data on the maturation of the temporal bone in children with significant other medical comorbidities such as DS. Structural analysis of the temporal bone in DS patients has demonstrated mean volume changes of the epitympanum and mesotympanum which was significantly smaller than that of a control group [43] as well as hypoplasia and sclerosis of the mastoid bone [44]. It could be hypothesised that these bony changes may impact ISQ reading and osseointegration creating an artificially elevated recording. Therefore, as ISQ comparison is largely dependent on 2 assumptions:

The resonance of the smart peg is uniform across all individuals.

The absence of data confirming this in those patients with known variability in mastoid structure.

This raises questions regarding the validity for direct comparison between groups especially in our current DS cohort as no previous ISQ data has been studied or published in patients

with trisomy 21. Further research into ISQ variation in the developing temporal bone and within groups of different medical co morbidities would allow stronger conclusions to be drawn in the paediatric population.

In addition, although ISQ at the abutment level was demonstrated to increase over time there is no relationship concluded with regards to fixture failures, and although statistically significant, the clinical significance of our RFA finding is uncertain.

4.1 Conclusion

Implant survival and adverse skin reactions were found to be in keeping with levels in published literature and much improved compared to previous implant systems placed at this centre. Although abutment level ISQ showed an increase over the review period no correlation between this, and implant loss can be concluded. This study demonstrated a very low morbidity associated with the Ponto BXH implant system, and good clinical outcomes in children with Down Syndrome.

5. Limitations

The current study reports on long term outcomes of consecutively implanted children with the Ponto BXH Oticon BAHI who have an underlying diagnosis of DS.

The absence of uniform surgery technique was a limitation for the current study with three separate methods being applied to the cohort, two performing minimal/no soft tissue reduction at second stage. However, patient demographics, post-operative protocol and routine follow up were identical between the three groups.

Review appointment attendance and compliance of 23.3–60.5% was shown despite all parents and carers completing the research commitment contract. The impact of these missing reviews should be taken into consideration when reading the results of this study. The explanation for this variability is largely due to the exceptionally large geographic area from which many patients are referred. The additional travel time, absence from school/education and cost may have been an influencing factor.

It is important to consider the social implications for attending a review hospital appointment for study purposes even though all were made aware of the necessary appointments well in advance of their surgery. Time away from school, organisation of care for siblings and the additional challenges to attend for patients with extensive comorbidities and underlying medical conditions requiring yet more reviews with other medical specialties contributed to

the missing data collection. The added burden of additional reviews was considered a further inconvenience especially when parents and carers had no concerns regarding the implant site or hearing following abutment placement. This was confirmed with telephone consultations when investigation the missing appointments.

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Declaration of competing interest

No authors involved with the paper have any actual or potential conflict of interest including any financial, personal, or other relationships with other people or organizations that could inappropriately influence, or be perceived to influence, their work.

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References

1. The Down Syndrome Association. https://www.downs-syndrome.org.uk/about/ general/last accessed 24/05/2021.
2. M. Khalid-Raja, K. Tzifa, Current demand of paediatric otolaryngo-logy input for children with Down's syndrome in a tertiary referral centre, J. Laryngol. Otol. 130 (11) (2016) 995–1000.
3. B. McPherson, S.P. Lai, K.K. Leung, I.H. Ng, Hearing loss in Chinese school children with Down syndrome, Int. J. Pediatr. Otorhinolaryngol. 71 (12) (2007) 1905–1915.
4. M.M. Yaneza, K. Hunter, S. Irwin, H. Kubba, Hearing in school-aged children with trisomy 21 - results of a longitudinal cohort study in children identified at birth, Clin. Otolaryngol. 41 (6) (2016) 711–717.
5. G.F. Bernardi, C.T.F. Pires, N.P. Oliveira, R. Nisihara, Prevalence of pressure equalization tube placement and hearing loss in children with down syndrome, Int. J. Pediatr. Otorhinolaryngol. 98 (2017) 48–52.
6. K.L. Kreicher, F.W. Weir, S.A. Nguyen, T.A. Meyer, Characteristics and progression of hearing loss in children with down syndrome, J. Pediatr. 193 (2018) 27–33, e2.
7. E. Nightengale, P. Yoon, K. Wolter-Warmerdam, D. Daniels, F. Hickey, Understanding hearing and hearing loss in children with down syndrome, Am. J. Audiol. 26 (3) (2017) 301–308.
8. L. De Schrijver, V. Topsakal, M. Wojciechowski, P. Van de Heyning, A. Boudewyns, Prevalence and etiology of sensorineural hearing loss in children with down syndrome: a cross-sectional study, Int. J. Pediatr. Otorhinolaryngol. 116 (2019) 168–172.
9. E. Barr, J. Dungworth, K. Hunter, M. McFarlane, H. Kubba, The prevalence of ear, nose and throat disorders in preschool children with Down's syndrome in Glasgow, Scot. Med. J. 56 (2) (2011) 98–103.
10. M. Maris, M. Wojciechowski, P. Van de Heyning, A. Boudewyns, A cross-sectional analysis of otitis media with effusion in children with Down syndrome, Eur. J. Pediatr. 173 (10) (2014) 1319–1325.
11. V. Manickam, G.S. Shott, D. Heithaus, S.R. Shott, Hearing loss in Down Syndrome revisited - 15 years later, Int. J. Pediatr. Otorhinolaryngol. 88 (2016) 203–207.
12. Austeng ME, Akre H, Øverland B, Abdelnoor M, Falkenberg ES, Kværner KJ. Otitis media with effusion in children with in Down syndrome. Int J Pediatr Otorhinolaryngol. 2013 Aug;77(8):1329-32
13. S. Ghadersohi, J.B. Ida, B. Bhushan, K.R. Billings, Outcomes of tympanoplasty in children with down syndrome, Int. J. Pediatr. Otorhinolaryngol. 103 (2017) 36–40.
14. L.M. Paulson, T.S. Weaver, C.J. Macarthur, Outcomes of tympanostomy tube placement in children with Down syndrome–a retrospective review, Int. J. Pediatr. Otorhinolaryngol. 78 (2) (2014) 223–226.
15. S. Ghadersohi, J.B. Ida, B. Bhushan, K.R. Billings, Outcomes of tympanoplasty in children with down syndrome, Int. J. Pediatr. Otorhinolaryngol. 103 (2017) 36–40, 10.1016.
16. https://www.nice.org.uk/guidance/CG60/chapter/1- Guidance#management-of-ome-in-children-with-downs-syndrome Last accessed 06/001/2023,

17. A.L. McDermott, j Williams, M.J. Kuo, A.P. Reid, D.W. Proops, The role of bone anchored hearing aids in children with Down syndrome, Int J Pediatr Otolaryngol 72 (2008) 751–757.

18. P.Z. Sheehan, P.S. Hans, UK and Ireland experience of bone anchored hearing aids (BAHA) in individuals with Down syndrome, Int. J. Pediatr. Otorhinolaryngol. 70 (6) (2006 Jun) 981–986.

19. S.J. Kunst, M.K. Hol, C.W. Cremers, E.A. Mylanus, Bone-anchored hearing aid in patients with moderate mental retardation: impact and benefit assessment, Otol. Neurotol. 28 (6) (2007) 793–797.

20. P. Westerkull, The Ponto-bone anchored hearing system, Adv. Oto-Rhino-Laryngol. 71 (2011) 32–40.

21. J.H. Lee, V. Frias, K.W. Lee, R.F. Wright, Effect of implant size and shape on implant success rates: a literature review, J. Prosthet. Dent 94 (4) (2005 Oct) 377–381.

22. J.A. Mendonça, P.M. Senna, C.E. Francischone, C.E. Francischone Junior, B.S. Sotto-Maior, Influence of the diameter of dental implants replacing single molars: 3- to 6-year follow-up, Int J Oral Maxillofac Implants. 2017 Sep/Oct;32(5):1111-1115

23. I.J. Kruyt, R.C. Nelissen, E.A.M. Mylanus, M.K.S. Hol, Three-year outcomes of a randomized controlled trial comparing a 4.5-mm-Wide to a 3.75-mm-Wide titanium implant for bone conduction hearing, Otol. Neurotol. 39 (5) (2018 Jun) 609–615.

24. S. Foghsgaard, P. Caye-Thomasen, A new wide-diameter bone-anchored hearing implant-prospective 1-year data on complications, implant stability, and survival, Otol. Neurotol. 35 (7) (2014 Aug) 1238–1241.

25. R.C. Nelissen, C.A. den Besten, E.A. Mylanus, M.K. Hol, Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial, Eur. Arch. Oto-Rhino-Laryngol. 273 (1) (2016 Jan) 105–111.

26. R.C. Nelissen, J. Stalfors, M.J. de Wolf, M.C. Flynn, S. Wigren, M. Eeg-Olofsson, K. Green, M.P. Rothera, E.A. Mylanus, M.K. Hol, Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation, Otol. Neurotol. 35 (8) (2014 Sep) 1486–1491.

27. I.J. Kruyt, K.H.E. Bakkum, C.J.I. Caspers, M.K.S. Hol, The efficacy of bone- anchored hearing implant surgery in children: a systematic review, Int. J. Pediatr. Otorhinolaryngol. 132 (2020 May) 109906.

28. J.J. Wazen, S. Babu, J. Daugherty, A. Metrailer, Three-week loading of the 4.5mm wide titanium implant in bone anchored hearing systems, Am. J. Otolaryngol. 37 (2) (2016 Mar-Apr) 132–135.

29. R.C. Nelissen, C.A. den Besten, H.T. Faber, C.A. Dun, E.A. Mylanus, M.K. Hol, Loading of osseointegrated implants for bone conduction hearing at 3 weeks: 3- year stability, survival, and tolerability, Eur. Arch. Oto-Rhino-Laryngol. 273 (7) (2016) 1731–1737.

30. C.M. McLarnon, I. Johnson, T. Davison, et al., Evidence for early loading of osseointegrated implants for bone conduction at 4 weeks, Otol. Neurotol. 33 (9) (2012) 1578–1582.

31. C. McLarnon, I. Johnson, T. Davison, et al., Resonance frequency analysis of osseo- integrated implants for bone conduction in a pediatric population - a novel approach for assessing stability for early loading, Int. J. Pediatr. Otorhinolaryngol. 78 (4) (2014) 641–644.

32. C.A. Dun, H.T. Faber, M.J. de Wolf, E.A. Mylanus, C.W. Cremers, M.K. Hol, Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival, Otol. Neurotol. 33 (2) (2012 Feb) 192–198.

33. C.A. den Besten, J. Stalfors, S. Wigren, et al., Stability, survival, and tolerability of an auditory osseointegrated implant for bone conduction hearing: long-term follow-up of a randomized controlled trial, Otol. Neurotol. 37 (8) (2016) 1077–1083.

34. N. Meredith, D. Alleyne, P. Cawley, Quantitative determination of the stability of the implant-tissue interface using resonance frequency analysis, Clin. Oral Implants Res. 7 (1996) 261–267.

35. L. Sennerby, N. Meredith, Implant stability measurements using resonance frequency analysis: biological and biomechanical aspects and clnical implications, Periodontol 47 (2000 2008) 51–66.

36. K.M. Holgers, A. Tjellstro¨m, Bjursten LMet al, Soft tissue reactions around percutaneous implants: a clinical study of soft tissue conditions around skin- penetrating titanium implants for bone-anchored hearing aids, Am J Otol. 1988 Jan;9(1):56-9.

37. M.S. Osborne, E. Hoskison, A. Child-Hymas, J. Gill, A.L. McDermott, Five year clinical outcomes and evaluation following implantation of the Oticon™ wide bone anchored hearing system in 47 children, Int. J. Pediatr. Otorhinolaryngol. 137 (2020 Oct) 110244.

38. J.M. Fussey, E. Harterink, Jet al Gill, Clinical outcomes following Cochlear BIA300 bone anchored hearing aid implantation in children, Int. J. Pediatr. Otorhinolaryngol. 111 (2018) 89–92.

39. S. Ali, L. Hadoura, A. Carmichael, N.K. Geddes, Bone-anchored hearing aid A single-stage procedure in children, Int. J. Pediatr. Otorhinolaryngol. 73 (8) (2009 Aug) 1076–1079.

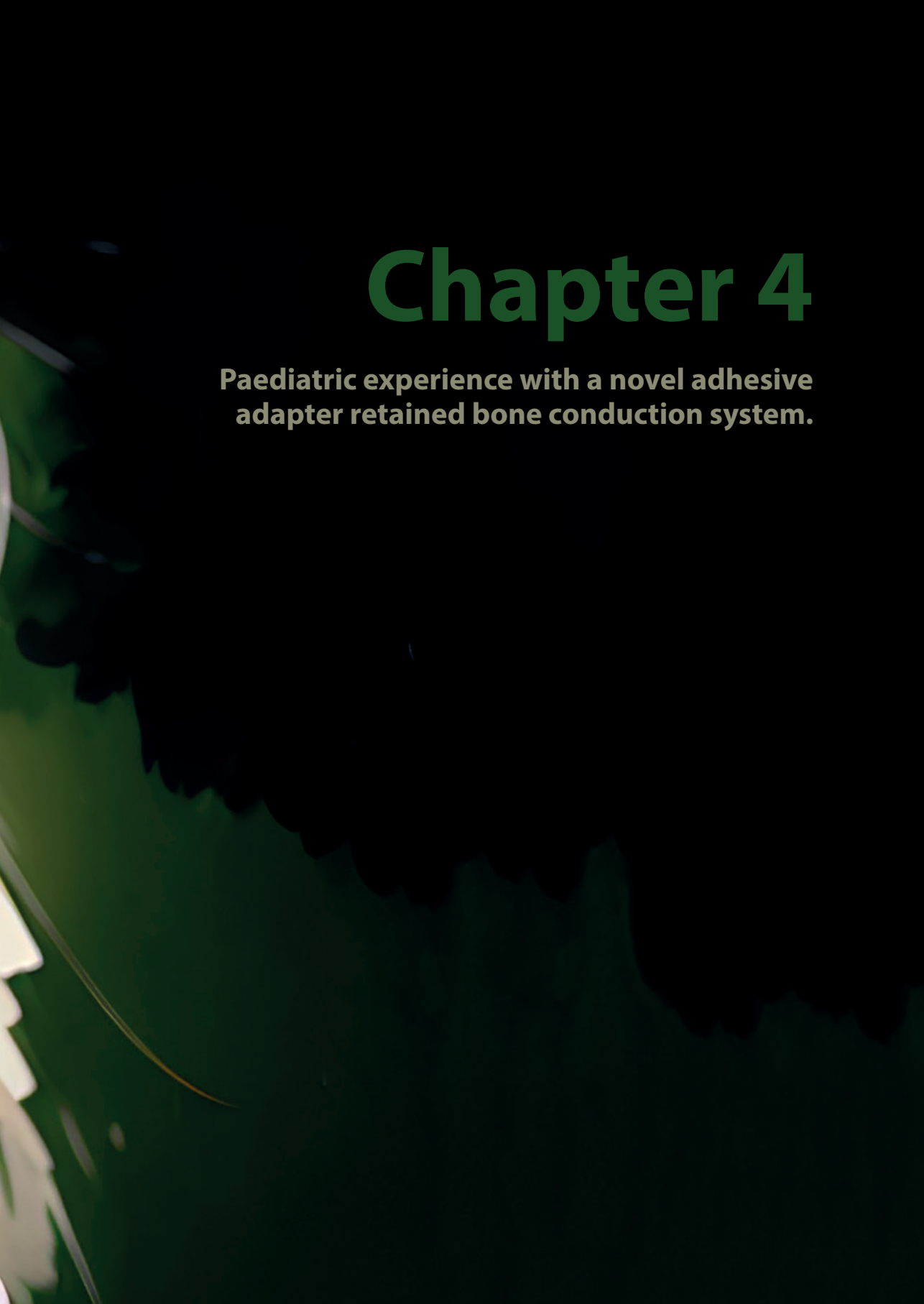
40. C. McLarnon, I. Johnson, T. Davison, J. Hill, B. Henderson, D. Leese, S. Marley, Resonance frequency analysis of osseo-integrated implants for bone conduction in a pediatric population - a novel approach for assessing stability for early loading, Int. J. Pediatr. Otorhinolaryngol. 78 (4) (2014 Apr) 641–644.

41. K. Takanhashi, Y. Morita, S. Ohshima, S. Izumi, Y. Kubota, A. Horii, Bone density development of the temporal bone assessed by computer tomography, Otol. Neurotol. 38 (2017) 1445–1449.

42. Smith K, Politte D, Reiker G, et al. Automated measurement of pediatric cranial bone thickness and density from clinical computed tomography. Conf Proc IEEE Eng Med Biol Soc 2012;2012:4462–4465.

43. T. Nogaki, M.M. Paparella, S. Cureoglu, A structural analysis of tympanic compartments of the middle ear in patients with down's syndrome: a temporal bone study, Otol. Neurotol. 41 (8) (2020 Sep) 1149–1157.

44. R.B. Glass, D.K. Yousefzadeh, N.J. Roizen, Mastoid abnormalities in Down syndrome, Pediatr. Radiol. 19 (5) (1989) 311–312



Chapter 4

Paediatric experience with a novel adhesive adapter retained bone conduction system.

Chapter 4.1

First paediatric experience with a novel, adhesive adapter retained bone conduction hearing aid system.

Osborne MS, Child-Hymas A, Gill J, Lloyd MS, McDermott AL
Otol Neurtol 2019;40:1199-1207
PMID: 31469800

Abstract

Objectives

To assess the audiological outcomes, practicalities, and impact on quality of life of a new, non-implantable, adhesive retained bone conduction hearing aid in children.

Study design

A prospective, single-subject repeat measure, cohort study.

Setting

Community and in pediatric assessment center.

Patients

Twenty-one children aged between 5 and 15 years with a conductive hearing loss of >/=25 dB HL in the better hearing ear.

Intervention: Audiological comparisons were made using pure-tone thresholds; unaided, with a softband aid, and with the new adhesive retained bone conducting system.

Main Outcome Measures

Comparison of hearing threshold levels. Data analysis via paired *t*-testing, significance set at value <0.01. Quality of life was assessed via the Glasgow Children's Benefit Inventory and a 10 cm linear analogue scale. A hearing aid review questionnaire provided insight into practical use.

Results: Statistically significant improvement in thresholds of 7.3 dB HL (p=0.0001) was demonstrated with the adhesive system as compared with softband aids. After 4 weeks of usage, the mean hearing thresholds for the adhesive hearing system improved from 55 dB HL±2.4 to 31 dB HL±7.9 in unaided and aided conditions. Improvements in QOL were demonstrated with LAS and GCBI. Four children reported mild skin reactions. Eighty-six percent reported improved self-confidence.

Conclusion

The adhesive aid produces comparable audiological results to the commercial softband hearing aids. It provides an excellent alternative in the treatment of conductive hearing loss without the possible complications and costs of a surgical intervention. Furthermore, it preserves skin envelope over the mastoid for those who wish to proceed with an autologous pinna reconstruction in the future.

1. Introduction

The positive impact of overcoming conductive hearing loss (CHL) on a child's language acquisition and social development with the use of bone-anchored hearing implants (BAHI) is well documented [1-8]. As hearing technology develops, breakthroughs have been made in both active and passive transcutaneous bone conduction systems with improving audiological outcomes [9-16].

Transcutaneous implant systems reduce potential for skin complications traditionally associated with percutaneous implants. Such implant systems produce excellent audiological outcomes but still require the surgical implantation of either an osseointegrated fixture and/or magnet or a bone conduction floating mass transducer [17-21].

For those children with isolated microtia and canal atresia, the cosmetic considerations are extremely important. Care must be taken in choosing the placementof any implant system in children with pinna deformity to ensure that a skin envelope is maintained over the mastoid for potential future autologous reconstruction. Scaring in this region may compromise the option of reconstruction in later life as coverage of the neoauricle with local tissue might be insufficient [22-24].

Nonsurgical transcutaneous hearing systems provide a simple and effective solution for both a unilateral and bilateral CHL. Although audiologically effective, subjective patient feedback highlights poorer compliance with headbands due to concerns about the aesthetics. This can be a deterrent for many older children with self-perception issues and concerns about integrating with their peers. Additionally, the retention pressure by headbands may produce some complications and limitations in daily usage [25]. Eye glass mounted options can be limited due to the weight of the processor. This is problematic for patients withmicrotia. many of whom may not have sufficient external pinna to hold their eye glasses level with the additional weight. Furthermore, microtia is often asymmetrical making the uses *of* spectacles impractical [26,27].

With the headband options, migration of the sound processor from its optimal position reduces its efficacy [28]. It also increases artifacts by movement over the patient's own hair. Often the position of the processor can "slip" and be far from the mastoid process and therefore the cochlea. This becomes more pronounced for those children requiring glasses or those with an unusual shaped skull.

The transcutaneous adhesive bone conducting (BC) system used in this study was designed for pressure-free sound transmission, prevention of sound processor migration and removes

the requirement for a headband. It is comprised of a lightweight sound processor and an adhesive adapter pad placed onto the hairless postauricular skin directly over the mastoid bone.

Early publications of the outcomes of use of this adhesive BC hearing system in adults with CHL demonstrated high levels of user satisfaction and no skin irritations [29], as well as comparable results to conventional softband devices with regards to speech understanding and sound localization [30].

In this study, we report the results of the first group of pediatric patients with a CHL, to use an adhesive retained BC hearing aid system. The primary objective was to assess its audiological effectiveness when compared with the child's unaided thresholds and those obtained with a BC hearing aid worn on a softband.

Secondary objectives were to assess the quality-of-lifeimpact after using the adhesive hearing system for a minimum of 4 weeks including the evaluation of the day-to-day practicalities of using this novel hearing device.

2. Methods

2.1 Study Design

A prospective, single-subject, repeat measure, cohort study in which each participant served as their own control. Following ethical approval through the NHS Research Authority (Ref 17/ LO/0588, IRAS project ID 217184) participants were recruited from the patient body at Birmingham Children's Hospital.

2.2 Patients

Twenty-one subjects with 22 devices completed the study. Twenty patients had a unilateral CHL and 1 patient was bilateral. Participants were aged between 5 and 15 years with conductive hearing loss greater than or equal to 25 dB HL in the better hearing cochlea. Participants were required to have previous experience using transcutaneous bone conduction hearing systems and to be native English speakers. Patients were excluded from the study if there was evidence of fluctuation of hearing loss over a 2-year period of 15 dB in either direction, nonresponsive active ear infection and/or chronic fluid in or about the ear, retrocochlear or central auditory disorders, masking problems in audiometric free field tests and any physical, psychological, or emotional disorder that would interfere with the ability to perform testing and engage in rehabilitation procedures. Informed written consent was obtained before enrollment.

2.3 Study Device and Setting

Audiological assessment via pure-tone audiometry (PTA) free field testing with warble tones. All children were measured at first visit with the adhesive retained BC hearing system - ADHEAR (MED-EL, Austria) and an Oticon Ponto (Oticon Medical, Askim, Sweden) device on a softband. Both devices were fitted as per default setting and measurements were performed at a comfortable volume for each subject in sound field testing. To remove comparison bias of the two devices no independent fitting strategy was used. The same Oticon Ponto device was used for all base line tests on each subject set to its generic program. The ADHEAR device has four inbuilt software settings which the user can independently select depending on the environment. During testing the same setting was used for each participant and a fitting prescription was therefore not required.

Sound field threshold measurement was performed with warble tones on each participant under four separate conditions with the loudspeaker at 1 m in front of the subject. 1) unaided, 2) when using the softband device, 3) using the ADHEAR device at initial visit (V1), and 4) with the ADHEAR after a minimum of 4 weeks continual use (W4). For those participants with unilateral hearing loss, the normal hearing ear was occluded during testing.

All participants and primary caregivers underwent training on the placement, removal, and use of the new adhesive adaptor and sound processor at the initial appointment. All audiological tests were performed in the identical sound booth by the two named senior audiologist authors of this article.

2.4 Subjective Assessments

Following a minimum of 4 weeks use of the adhesive retained BC aid, each child with the help of their carer was asked to complete a 10 cm Linear Analogue Scale (LAS) relating to their perception of health status both before and after the use of the new system. They were also requested to complete a Glasgow Children's Benefit Inventory Questionnaire (GCBI) to subjectively assess the impact of the adhesive retained BC aid on their quality of life. [Appendix 1, http:// links.lww.com/MAO/A823].

Finally, a manufacturer's hearing aid review questionnaire (HARQ) was completed which was aimed to assess the functionality and ease of use of the new system [Appendix 2, http://links.lww.com/MAO/A824].

2.5 Statistical Analysis

The results *were* analyzed by paired f testing. Significance was set at $p < 0.01$. Sample size and power calculations were based upon 2016 paper Ihler et al. [31]. It compared in a prospective study the audiological preoperative results with a bone conduction hearing device using

a headband with postoperative results with an implantable bone conduction device. In the preop trial with the Headband they measured an improvement in hearing thresholds from 53±13.8 to 37.4±11.3 on average. Using this data an effect size (dz) of 1.3 is measured. Assuming a significance level (α) of 0.05 and a power of 80% for the same subject group a sample size of 6 subjects was calculated. To allow for possible dropouts (approximately 20%) and to provide additional safety and efficacy information, it is recommended that at least eight subjects should be included from a statistical point of view. To draw more powerful conclusions a sample size of 20 was chosen, above the statistically required number.

3. Results

Twenty-four consecutive patients were initially enrolled in the study; three were subsequently excluded; two due to age being outside study criteria at the time of eventual fitting, and one due to the late detection of a mixed hearing loss.

Twenty-one subjects with 22 devices completed the study: 20 patients had a unilateral CHL and 1 patient was bilateral. The gender distribution was very similar with 11 females and 10 males. The mean age was 9 ± 3 years. and the meantime using the adhesive system was 7 ± 2.4 years. Fourteen participants had congenital CHL and 7 acquired CHL (Table 1).

Standard pure-tone audiometry was done during the first visit to confirm CHL. Mean air conductions $PTA_{4(0.5\text{-}4kH.)}$ thresholds of 57 dBHL ±11. Free field pure-tone audiometry using warble tones demonstrated an improvement in thresholds at all frequencies with both the softband aid and the adhesive retained BC aid as compared with unaided. The softband mean PTA_4 was found to be 30 dBHL ±6. The adhesive retained BC system at fitting demonstrated a PTA4 27 ± 6 and at the fourth week 26 ± 3 (Fig. 1).

Figure 2 demonstrates the mean sound field thresholds over the frequency range of 500 Hz to 8 kHz in unaided and aided conditions that the first visit (VI) and after a minimum of 4 weeks of continued use (W4). As the graph demonstrated there is an improvement in thresholds above 1 kHz with adhesive retained BC system as compared to softband at both review points.

Table 2: Participants' demographics, including age at initial fitting, aetiology of hearing loss and hearing loss type. Gender, side of hearing loss and time using the device.

ID	Aetiology	Hearing loss	Age	Gender	Side	Time (weeks)
101	Isolated Atresai	cong CHL	5	F	R	4
102	Isolated Atresai	cong CHL	12	F	L	4
103	CSOM	aqu CHL	11	M	L	5
104	CSOM	aqu CHL	14	M	L	12
107	CSOM	aqu CHL	14	M	Bilat	6
108	Isolated Atresai	cong CHL	7	M	L	5
109	Ossicular fixation	cong CHL	5	F	L	5
110	microtia	cong CHL	6	F	L	5
111	CSOM	aqu CHL	5	M	L	6
112	CSOM	aqu CHL	10	M	R	6
113	microtia	cong CHL	9	M	R	4
114	microtia	cong CHL	11	F	R	6
115	microtia	cong CHL	7	F	R	9
116	CSOM	aqu CHL	9	F	L	8
117	microtia	cong CHL	10	F	R	12
118	Ossicular fixation	cong CHL	7	M	L	8
119	microtia	cong CHL	14	F	R	10
121	microtia	cong CHL	7	M	R	8
122	microtia	cong CHL	6	F	R	6
123	CSOM	aqu CHL	8	M	L	8
124	haemangioma	aqu CHL	10	F	L	8

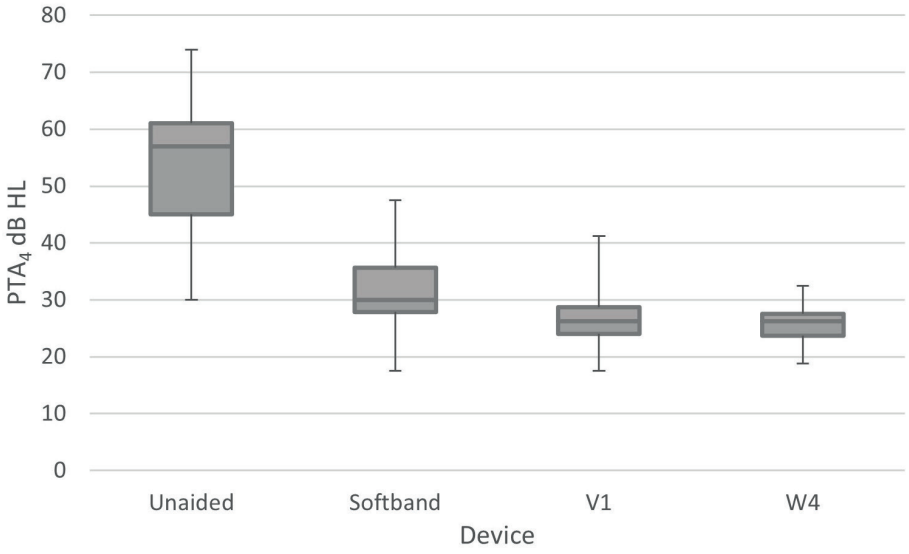
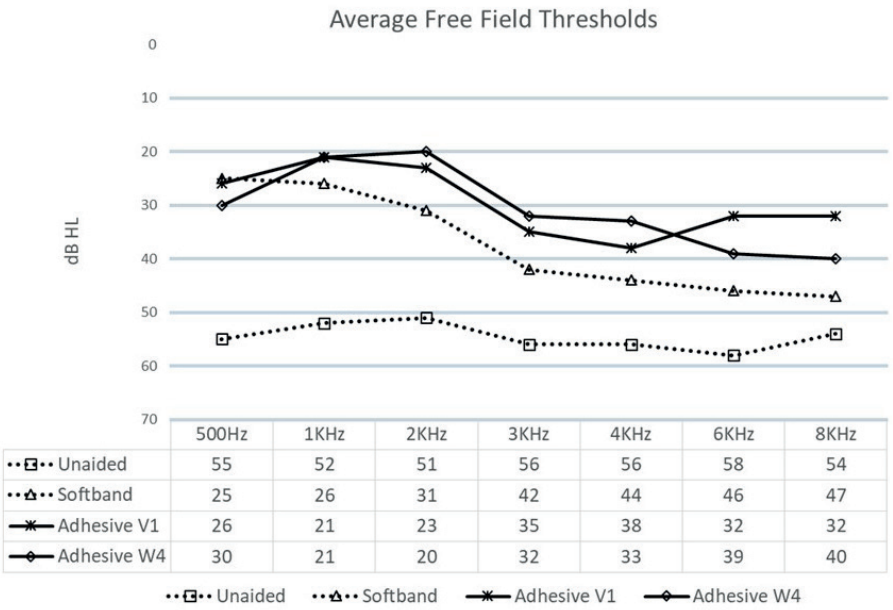


Figure 1: Box plot of PTA4 comparison between each test condition



	500Hz	1KHz	2KHz	3KHz	4KHz	6KHz	8KHz
Unaided	55	52	51	56	56	58	54
Softband	25	26	31	42	44	46	47
Adhesive V1	26	21	23	35	38	32	32
Adhesive W4	30	21	20	32	33	39	40

Figure 2: Mean Free Field Pure tone audiometry results.

Better thresholds are demonstrated with the adhesive aid at fitting (V1) and after 4 weeks of use (W4) in all frequencies about 1KHz, this is more marked in the upper frequencies.

Table 2: Statistical subgroup comparison of mean free field PTA Thresholds between each review point.

	Mean Threshold Difference Between Each Group dB HL	*p* Value	95% CI		Standard Error of Difference
Unaided : Softband	*19.0*	*0.0001*	*15.21*	*22.88*	*1.844*
Unaided : V1	*24.6*	*0.0001*	*20.37*	*28.81*	*2.028*
Unaided : W4	*26.3*	*0.0001*	*21.35*	*31.29*	*2.391*
Softband : V1	*5.6*	*0.0001*	*3.23*	*7.86*	*1.114*
Softband : W4	*7.3*	*0.0001*	*4.15*	*10.39*	*1.501*
V1 : W4	*1.7*	*0.163*	*-0.76*	*4.21*	*1.196*

The results of paired *t* test analysis of the mean sound field hearing threshold (0.5 to 8 kHz) are demonstrated in Table 2. Softband device improved mean thresholds by 19 dB HL and the adhesive retained BC system by 26.3 dB HL after 4 weeks of use as compared to unaided tests. In addition, significant improvements between the adhesive retained BC aid and softband were measured in both visits. The mean improvement compared to softband was 5.6 dB HL at visit 1 (V1) and 7.3 dB at visit 2 (W4). A nonsignificant 1.7 dB improvement between visits was found with the adhesive retained BC system: a possible acclimation effect.

A statistical improvement in thresholds is demonstrated with softband and adhesive aid use when compared with unaided. The adhesive aid improves mean thresholds at fitting (V1) and after 4 weeks of use (W4). There is however no statistically significant difference in the thresholds of the adhesive aid at V1 compared with W4.

Subjective assessments on the impact of quality of life were made using the validated GCBI (32) from which the pattern of responses to the questions can also be split into four dimensions relating to emotion, physical health, learning, and vitality. Table 3 demonstrates the number of responses to each individual question of GCBI.

Overall GCBI response scores increased following the use of the adhesive retained BC system for 4 weeks by 33 ± 25, further analysis shows a positive score in all four dimensions: Emotion 24 ± 27, physical health 20 ± 19, learning 36 ± 33, and vitality 24 ± 26 (Fig. 3). This indicated that there was a perceived benefit to using the adhesive system; however, there is a wide variation in responses with three participants demonstrating a negative overall score of -6, -8, and -17. In one of the participants this was due to whistling when wearing a headscarf.

In addition, the 10 cm LAS was included to evaluate the subjective change in health status perceived by the patient before and after being fitted with the adhesive hearing system. The

mean LAS score increased by 4.5 from 4 ±1.4 to 8.5 ±1.4 $p = 0.0001$ (95% CI 5.23 -3.53) (Fig. 4), this again gives evidence that there was statistically significant perceived health status benefit from the use of the adhesive system *for* pediatric patients.

Table 3: Number of responses to each individual question of GCBI

No	Question	Much better	Little better	No change	Little worse	Much worse
1	Overall life	10	9	1	1	0
2	Things they do	6	6	9	0	0
3	Behaviour	2	8	11	0	0
4	Progress and development	8	7	6	0	0
5	Liveliness	5	4	11	1	0
6	Sleep	2	4	15	0	0
7	Food	0	4	17	0	0
8	Self-consciousness	5	5	8	2	1
9	Family Harmony	4	3	14	0	0
10	Fun with Friends	5	4	12	0	0
11	Embarrassment	3	6	12	0	0
12	Distractibility	3	4	8	6	0
13	Learning	9	5	6	1	0
14	Absences from school	1	3	16	0	0
15	Concentration	3	8	6	4	0
16	Irritability	4	6	9	2	0
17	Self-esteem	5	7	7	2	0
18	Happiness	5	2	13	1	0
19	Confidence	5	6	8	2	0
20	Self-care	2	2	17	0	0
21	Leisure	3	4	13	1	0
22	Colds	1	2	18	0	0
23	Visits to doctor	1	0	20	0	0
24	Need for medications	1	0	20	0	0

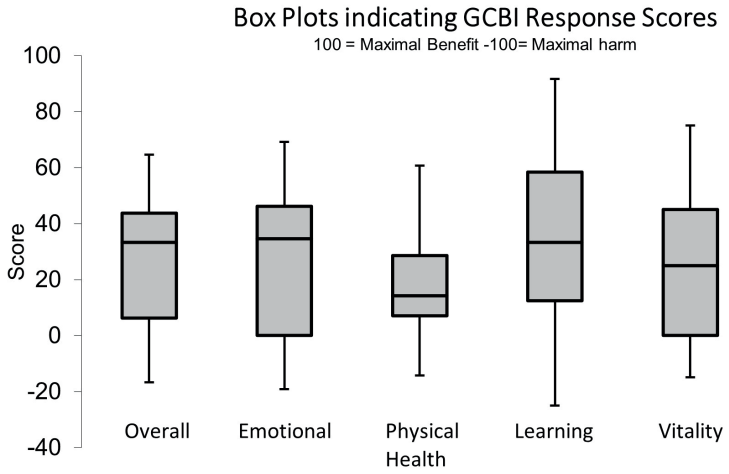


Figure 3: Box Plots of GCBI score, overall and in 4 key dimensions.

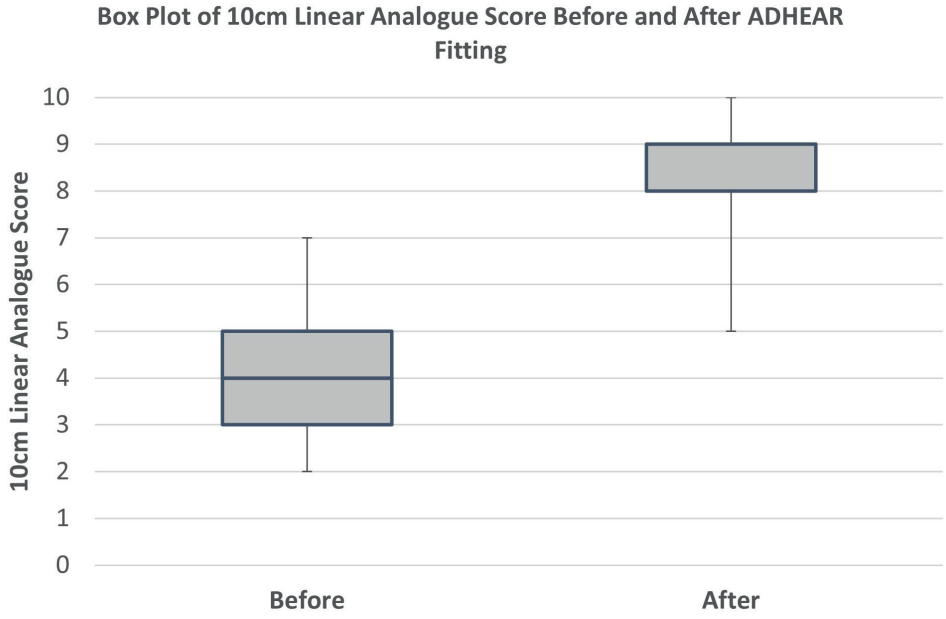


Figure 4: Box Plot of 10cm Linear Analogue Score before and after the adhesive hearing aid fitting demonstrating a significant improvement in score.

The manufacturer's HARQ was completed for each participant to provide an insight into the day-to-day use of this adhesive retained BC hearing system. It comprised of 19 questions that looked at the functionality of using the aid. The overall response was positive in all areas but not all the questions included have an impact with regards to this study. We have therefore focused on the responses to six core questions (Fig. 5). Only four individuals reported minor skin redness, which resolved overnight once the adhesive adapter had been removed. Eighteen of the 21 children (86%) reported feeling more confident when wearing the adhesive system as compared with their previous hearing aid devices. Hearing quality was rated good or very good in 16 participants. The adhesive adaptor was changed at most, every second day and most often fell off only once during the whole period of study, indicating that it maintained its position well in children undertaking normal daily activities. The adhesive BC system was worn a mean of 9 hours per day (±2). At no time during the study did any child request to opt out and return to their previous bone conduction hearing device.

4. Discussion

Literature review of PUBMED, Cochrane Library, and NHS Athens was conducted. To the authors' knowledge there have been no previous published studies comparing the audiological and subjective benefit of an adhesive BC hearing system to softband aids in pediatric patients.

The use of this adhesive retained BC hearing system provided comparable audiological results to the traditional softband BC solutions in children with CHL. The adhesive retained BC system improves thresholds on average, 7.3 dB HL above the softband aid after a minimum *of* 4 weeks use. The improvement was greatest at the higher frequencies which may be a result of the ability to position it with improved contact directly over the mastoid and thus the cochlear.

The adhesive adaptor had to be replaced more often by four children, but this did not discourage them from using it. Three children had microtia with a low hairline, so hair shaving was necessary to ensure sufficient space for adapter placement. The redness of skin was reported in four children which resolved leaving the skin free over the night without any further treatment.

Overall GCBI data indicated that the adhesive retained BC system has a benefit on quality of life with improvements in all but three individuals. The reason for these negative responses was reported as more "distractibility and loss of concentration". This may in part be due to the influence of a new device which the child needs time to become acclimatised to. There was also feedback reported from a headscarf wearer reducing the quality of sound. The dimensions in which the greatest impact was demonstrated were Emotional and Learning.

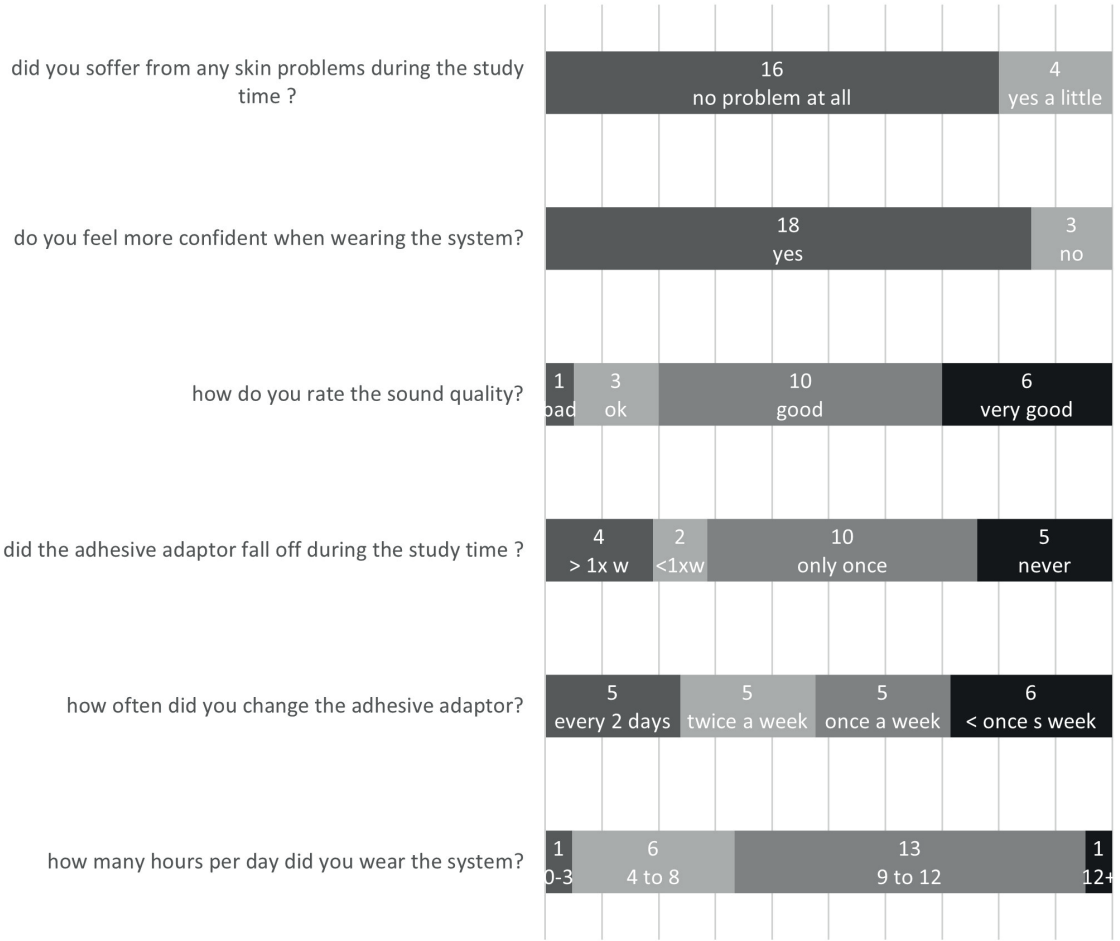


Figure 5: Bar graph showing the number of responses to each question.

The LAS doubled from 4.1 to 8.5 before and after the use of the adhesive retained BC aid.

The responses from the HARQ indicated excellent levels of daily use of the adhesive retained BC system of up to 15 hours per day and there was little or no problems that discouraged the use of the device. Self-confidence in 18 of participants was increased following the use of the adhesive system.

Following the closure of this study, all children requested to continue with the use of the adhesive retained BC system and to date none have returned to their previous bone conduction hearing aids. This is supported by recently published research in adult patients with CHL using the ABC system which reports high patient satisfaction levels and no skin irritation [29], and comparable audiological finding to softband use with regards to speech recognition and sound localization [30].

Many children are concerned with their appearance. The fact that no child in our study chose to cease using their new adhesive retained BC hearing system and return to previous bone conduction hearing aids was encouraging.

The improved quality of life and improved learning most likely reflected the fact that the children were more accepting of the aesthetics of the adhesive adapter and were happy to wear their hearing system for longer periods in more situations than their previous softband, which could be uncomfortable and unsightly. Many children reported softband use only during the time at school.

One concern regarding this transcutaneous adhesive hearing system is the loss of effective sound transmission through the intact skin and subcutaneous tissues. However, this did not appear to be the case in this study. The associated skin morbidities were minimal, whilst the aesthetic concerns were also negligible. The positioning of the adhesive adapter with the sound processor directly over the cochlear is advantageous and this is rarely possible with the softbands [33, 34].

Although we found the positioning with the adhesive adaptor to be stable, the replacement of these does incur additional costs as compared to a softband device. In addition, each patient's requirement for the frequency of replacement is variable and influenced by the patient's own skin, hairline and impacted if wearing eye glasses and head scarves. Some children require hair to be shaved in order for the adhesive adaptors to be optimally positioned.

No child has the same requirement for the pads and therefore this additional cost cannot be simply calculated. On average during this study, we found that the adhesive adaptors were

changed every second day, (three to four times a week) however some individuals require this more frequently. The ADHEAR user kit including processor and attachment costs £2078 (incl. VAT) and the adhesive adaptors cost £35.75 (15pcs) adding £371 -495 a year in additional costs; approximately £2511 (incl. VAT) for the first year. However, pricing is not uniform across Europe so there is fluctuation in these figures. In the Netherlands for example the user kit cost €3531 and the adaptors are €41.65 (15pcs). The impact of this incremental cost is therefore dependant on the frequency of changing the adhesive adaptor and this should be taken into consideration.

In comparison a Oticon soft band mount costs £48.60 and the price of the processor in the UK fluctuates from NHS trust to trust. This ranges between £2097 to £2895 depending on the producer and model used therefore total maximal cost for year 1 £2145- 2944. In the Netherland these costs are equivocal.

For children with long standing acquired conductive hearing loss such as those children with Down syndrome [35], Primary Ciliary dyskinesia (PCD) [36] and those with a cleft palate [37], the NICE guidelines do not recommend ventilation tubes. The authors of this paper feel that the adhesive hearing system could be an appropriate treatment alternative in these high-risk groups of children.

For those children with microtia, the adhesive retained BC system provides a simple non-invasive option especially if they wish to consider autologous ear reconstruction in the future. The skin envelope on the microtia side is thus preserved and remains unscarred [38].

A further advantage of this system is that it avoids the process of estimating the surface area of healthy skin needed for an autologous reconstruction in the future when placing a surgical Bone conducting hearing implant (BAHI). This estimation is difficult for the BAHI surgeon, since often the surgical BAHI is placed at a young age well before the age of cosmetic considerations and the possibility of future autologous ear reconstruction. As the child grows, the distance measured between microtia remnant and BAHI may still not be sufficient to allow for a framework to match the unaffected side. This adhesive retained BC hearing system is a very valuable hearing option for such children providing excellent “cosmetic” hearing until such time as the child and carers decide on their aesthetic pathway.

5. Conclusion

The adhesive retained BC hearing aid system produces comparable audiological results to softband BC aids, with evidence of improved hearing thresholds, possibly due to the direct positioning over the mastoid and thus the cochlea.

This study provides evidence that the adhesive retained BC hearing aid system is an acceptable alternative in the treatment of CHL without potential complications and costs involved with a surgical intervention, thus making it an important addition to the choices for hearing rehabilitation in children.

The resultant impact of its use has shown a significant improvement in patient's QOL with children preferring this form of hearing system to the traditional softbands. Finally, the authors recommend its use in children with microtia thus preserving the skin envelope over the mastoid for future autologous pinna reconstruction.

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References

1. Lin L, Bowditch S, Anderson MJ, May B, Cox KM, Niparko IK. Amplification in the rehabilitation of unilateral deafness; speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otol Neurotol 2006;27:172-82.
2. Priwin C, Jonsson R, Hultcrantz M, Granstrom G. Baha in children and adolescents with unilateral or bilateral conductive hearing loss a study of outcome. Int J Paediatr Otorhinolaryngol 2006;71:135-145.
3. Hol KM, Cremers CW, Coppens-Schellekens W, Snik AF. The BAHA softband. A new treatment for young children with bilateral congenital aural atresia. Int J Pediatr Otorhinolaryngol 2005;69:973-80.
4. Judith E, Cho Lieu. Speech-language and educational consequences of unilateral hearing loss in children. Arch Otolaryngol Head Neck Surg 2004;130:524-30.
5. Liu CC, Livingstone D, Yunker WK. The role of bone conduction hearing aids in congenital unilateral hearing loss: A systematic review. Int J Pediatr Otorhinolaryngol 2017;94:45—51.
6. Banga R, Doshi J, Child A, Pendleton E, Reid A. McDermott AL Bone-anchored hearing devises in children with unilateral conductive hearing loss: A patient-carer perspective. Ann Otol Rhinol Laryngol 2013;122:582-7.
7. Lieu JE, Tye-Murray N, Karzon RK, Piccirillo IF. Unilateral hearing loss is associated with worse speech-language scores in children. Paediatrics 2010; 125:e1348-55.
8. Doshi J, McDermott AL. Bone anchored hearing aids in children. Expert Rev Med Devices 2015;12:73-82.
9. Jovankovicovà A, Stanik R, Kunzo S, Majàkovà L, Profant M. Surgery or implantable hearing devises in children with congenital aurai atresia: 25 years of our: experience. Int J Pediatr Otorhinolaryngol 2015;79:975-9.
10. Giannantonio S, Scorpecci A, Pacifico C, Marsella P. A functional and anatomical comparison between two passive transcutaneous bone conduction implants in children. Int J Pediatr Otorhinolaryngo/ 2018;108:202-7.
11. Bezdjian A, Bruijnzeel H, Daniel SI, Grolman W, Thomeer HGXM. Preliminary audiologic and peri-operative outcomes of the Sophono™ transcutaneous bone conduction device: A systematic review Int J Pediatr Otorhinolaryngol 2017; 101:196-203.
12. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: Results from a prospective, multicentre, clinical investigation. Otol Neurotol 2015;36:834-41.
13. Dimitriadis PA, Hind D, Wright K, et al. Single-centre experience of over a hundred implantations of a transcutaneous bone conduction device. Otol Neurotol 2017;38:1301-7.
14. Polonenko MI, Carinei L, Gordon KA, Papsin BC, Cushing SL. Hearing benefit and rated satisfaction in children with unilateral conductive hearing loss using a transcutaneous magnetic-coupled bone-conduction hearing aid. J Am Acad Audiol 2016;27:790-804.

15. Riss D, Amoldner C, Baumgartner WD, et al. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. Laryngoscope 2014; 124:2802-6.

16. Eeg-Olofsson M1, Håkansson B, Reinfeldt S, et al. The bone conduction implant-first implantation, surgical and audiologic aspects. Otol Neurotol 2014; 35:679-85.

17. McDermott AL, Williams J, Kuo M, Reid A, Proops D. The Birmingham paediatric bone-anchored hearing aid program: A15 year experience. Otol Neurotol 2009;30:178-83.

18. Fussey JM, Harterink E, Gill J Child H mas A, McDermott AL. Clinical outcomes following Cochlear™ BIA300 bone anchored hearing aid implantation in children. Int J Pediatr Otorhinolaryngol 2018;1l 1:89-92.

19. den Besten CA, Nelissen RC, Peer PG, et al. Retrospective cohort study on the influence of comorbidity on soft tissue reactions, revision surgery, and implant loss in bone-anchored hearing implants. Otol Neurotol 2015;36:812-8.

20. Van der Gucht K, Vanderveken O, Hamans E, Claes J, Van Rompaey V, Van de Heyning P. Adverse skin reactions following percutaneous bone conduction implant surgery using the linear incision technique with and without subcutaneous tissue reduction. Acta Otolaryngol 2017;137:149-53.

21. Shapiro S, Ramadan J, Cassis A. BAHA skin complications in the paediatric population: Systematic review with meta-analysis. Otol Neurotol 2018;39:865-73.

22. Storck K, Staudenmaier R, Buchberger M, et al. Total reconstruction of the auricle: Our experiences on indications and recent techniques. Biomed Res lui 2014;2014:. 373286.

23. Bajaj Y, Wyatt ME, Gault D, Bailey CM, Albert DN. How we do it: BAHA positioning in patients with microtia requiring auricular reconstruction. Clin Otolaryngol 2005;30:468-71.

24. Ali K, Mohan K, Lui YC. Otologic and audiology concerns of microtia repair. Semin Plast Surg 2017;31:127-33.

25. Reinfeldt S, Håkansson B, Taghavi H, Eeg-Olofsson M. New developments in bone-conduction hearing implants: A review. Med Devices (Auckl) 2015;8:79-93.

26. Saroul N, Akkari M, Pavier Y, Gilain L, Mom T. Baha-mediated rehabilitation of patients with unilateral deafness: Selection criteria. Audiol Neurootol 2014;19:85-90.

27. Zawawi F, Kabbach G, Lallemand M, Daniel SI. Bone-anchored hearing aid: Why do some patients refuse it? Int J Pediatr Otorhinolaryngol 2014;78:232-4.

28. Dobrev I, Stenfelt S, Rüösli C, et al. Influence of stimulation position on the sensitivity of bone conduction hearing aids without skin penetration. Int J Audiol 2016;55:439-46.

29. Dahm V, Baumgartner WD, Liepins R, Arnoldner C, Riss D. First results with a new, pressure-free, adhesive bone conduction hearing aid. Otol Neurotol 2018;39:748-54.

30. Gawliczek T, Munzinger F, Anschuetz L, Caversaccio M, Kompis M, Wimmer W. Unilateral and bilateral audiological benefit with an adhesively attached, noninvasive bone conduction hearing system. Otol Neurotol 2018;39:1025-30.

31. Ihler F, Blum J, Berger M-U, Weiss BG, Welz C, Canis M. The prediction of speech recognition in noise with a semi-implantable bone conduction hearing system by external bone conduction stimulation with headband: A prospective study. Trends Hearing 2016;20:. 2331216516669330.

32. Kubba H, Swan IR, Gatehouse S. The Glasgow Children's Benefit Inventory: A new instrument for assessing health-related benefit after an intervention. Ann Otol Rhinol Laryngol 2004;113:980-6.

33. Baker AR, Fanelli DG, Kanekar S, Isildak H. A retrospective review of temporal bone imaging with respect to bone anchored hearing aid placement. Otol Neurotol 2017;28:86-8.

34. Purcell PL, Jones-Goodrich R, Wisneski M, Edwards TC, Sie KC. Hearing devices for children with unilateral hearing loss: Patient- and parent-reported perspectives. Int J Pediatr Otorhinolaryngol 2016;90:43-8.

35. Paulson LM, Weaver TS, Macarthur CI. Outcomes of tympanostomy tube placement in children with Down Syndrome: A retrospective review. Int J Pediatr Otorhinolaryngol. 2014 Feb;78(2):223-6

36. Andersen TN, Alainin MC, vonBuchwald C, Nielsen LH. A longitudinal evaluation of hearing and ventilation tube insertion in patients with primary ciliary dyskinesia. Int J pediatr otorhinolaryngol 2016;89:164-8.

37. National Institute for Health and Care Excellance. NICE. Clinical guidance CG60 2008.

38. Purcell PL, Jones-Goodrich R, Wisneski M, Edwards TC, Sie KC. Hearing devices for children with unilateral hearing loss: Patient- and parent-reported perspectives. Int J Pediatr Otorhinolaryngol. 2016 Nov;90:43-48

Chapter 4.2

Longitudinal study of use of the pressure free, adhesive bone conducting hearing system in children at a tertiary centre.

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Abstract

Objectives

To assess the long-term compliance and usability of the non-implantable, adhesive bone conduction hearing aid system in children. Review of patient demographics, compliance and continued use. Identification of factors that impact on future patient selection.

Methods

Retrospective case series review of all children aged 5 and above fitted with the adhesive bone con- duction hearing aid at a paediatric tertiary centre in the UK between 2015 and 2019. Data collected from medical and audiological records. Patient demographics skin complications patient feedback and changes in hearing aid provision were recorded.

Results

82 children (40 female, 42 male) were provided with 89 adhesive hearing devices. To date 72 (87.8%) of the fitted patients continue to use the device daily with minimal reported skin complications. Of the 10 patients that no longer use the adhesive aid, 5 no longer use any hearing device at all and the remaining 5 patients use an alternative hearing system. These include spectacle aids (n = 2) and bone anchored hearing implant (n = 3).

Conclusion

Adhesive aid products are reported to provide comparable audiological results to the commercial softband hearing aids. They provide an excellent alternative in the treatment of conductive hearing loss without the costs and possible complications of a surgical intervention. A compliance rate of 87.8% of all patients fitted with the adhesive system demonstrates a high level of patient satisfaction. The device may also provide an appropriate stepping stone to implanted device once a child reaches the age in which an autonomous decision can be made. The limitations of the device have been the variability in the longevity of the adhesive adaptor and interference with headscarves, hats and glasses with a low frequency of transient minor skin reactions reported.

1. Introduction

The application of the adhesive bone conducting hearing aid device (ADHEAR MED-EL, Austria) has grown in popularity since its intro- duction in 2015. Multiple centres now demonstrate audiological and quality of life indicator improvements as compared to conventional alternative hearing aid options including functional gain in word recognition score by up to 30% [1]. In paediatric studies, statistically significant gains in speech audiometry with babble noise and hearing thresholds were improved as compared to unaided thresholds. This was demonstrated in children with both sensorineural (6.34 dB HL p = 0.027) and conductive hearing loss (13.29 dB HL P = 0.008) [2]. When compared to conventional softband hearing aids, the adhesive device demonstrated a 7.3 dB HL advantage in free field thresholds [3j as well as functional gains of 5.7 dB [4]. Speech understanding in noise and in multiple streams, sound localization and sound quality were rated significantly better with the adhesive device as compared to softband [5].

In the adult population audiological comparisons to implanted passive bone conducting devices (Baha® Attract) [6] demonstrated comparable hearing benefits with the adhesive hearing system where the mean aided thresholds and speech understanding in quiet, and noise were similar. In patients with single sided deafness, a randomized crossover study comparing the application of a contralateral routing of signals (CROS) hearing aids, 70% of included subjects reported that the adhesive hearing system was partially useful or better [7].

Non-surgical transcutaneous hearing systems provide a simple and effective solution for both a unilateral and bilateral CHL. Although audiologically effective, subjective patient feedback particularly in children highlights poorer compliance with headbands due to concerns about the aesthetics. This can be a significant deterrent for older children with self-perception issues and concerns about integrating with their peers. Additionally, the retention pressure by headbands may produce some complications, more discomfort and limitations in daily usage [8]. With the bone conduction headband options, migration of the sound processor from its optimal position reduces its audiological efficacy [9]. It also increases artifacts by movement over the patient's own hair. Often the position of the processor can 'slip' and be far from the mastoid process and therefore the cochlea. This becomes more pronounced for those children requiring glasses or those with an unusual shaped skull as seen with some craniofacial conditions.

The development and application of an adhesive bone conducting aid overcomes many of these issues in the paediatric population due to its lightweight construction, optimal positioning and adhesive "nonpressure" retention. The removal of an obvious headband improves self-confidence which ultimately improves compliance with the device demonstrated by a 53% increase in median daily wearing times from 4.3hrs to 8.1hrs [10].

1.1 Objectives

This study reviews all children at a paediatric tertiary centre who were fitted with an adhesive retained bone conducting hearing device since 2015. It aims to identify compliance rates, usability and factors that will help guide patient selection and application in children with pure conductive hearing losses. It also expresses this center's personal experiences and patient feedback. Audiological outcomes are not considered in this study.

2. Material and methods

2.1 Study design

A retrospective case series of all paediatric patients ages 5-16 years who have been fitted with the adhesive retained bone conducting hearing system - ADHEAR (MED-EL, Austria).

2.2 Patients

82 children (40 female, 42 male) aged 5yrs and above were provided with 89 adhesive hearing systems between 2015-July 2019. All patients had a pure conductive hearing loss greater than or equal to 25 dB HL in the better hearing cochlea.

2.3 Study device end setting

Use of the adhesive retained BC hearing system - ADHEAR (MED-EL, Austria) were followed up for a minimum of 9 months following fitting. Data was retrospectively collected in March 2020 from medical and audiological electronic notes, providing a follow up of 9 months to 4.5 years. Complication, patient feedback and changes in aid preference were noted.

2.4 Subjective assessments

Patient demographics, aetiology of hearing loss, compliance of use of the adhesive device were recorded on an excel spreadsheet for comparison, patient personal experiences recorded. In those patients who were found to be non-users, alternative hearing aids and cause of non- use were recorded.

3. Results

82 children over the age of 5 years were fitted with 89 adhesive retrained bone conducting device. 40 female, 42 males. 7 children (8.5%) were fitted with bilateral hearing systems. The mean age of the study cohort was 11 years.

Table 1 demonstrates the current age distribution of fitted children and the figures of continued usage. 29 (35.4%) had an acquired conductive hearing loss vs 53 (64.6%) with a congenital conductive hearing loss. Table 2 demonstrates the aetiology of the conductive hearing loss which was most commonly atresia/microtia effecting 25 (30.4%) of children.

14.6% (12) children had not had any previous hearing aid experience. All other children had previous experience with other devices including bone conduction headband solutions 51 (62.1%), BC hardband 13 (15.8%), behind the ear aid 3, 'Adjoin' 2 and spectacle aid 1.

Table 1. Total number of patients fitted at each age, number of patients no longer using adhesive aid in each age group. Number not using any aid, and alternative aid provided in each age group.

Current Age	Fitted N	Non-users N	No Aid	Alternative aid chosen	Continued use %
4	2	0			100
6	3	0			100
6	5	0			100
7	5	1	1		80
8	6	0			100
9	7	1		1 BAHI	85.7
10	8	2	1	1 BAHI	75.0
11	7	1	1		85.7
12	4	2	1	1 SA	50.0
13	11	1		1 SA	90.9
14	7	0			100.0
15	5	0			100.0
16	8	1	1		87.5
17+ *Adult*	4	1		1 BAHI	75.0
Total	82	10	5	5	87.8

BAHI - Bone anchored hearing implantation, SA - Spectacle aid.

Table 2: Aetiology of conductive hearing loss. Inherited genetic disorders include CHARGE, Down's, Noonans, xxx, PCD and 22.q.11.

Aetiology	Number of children
Atresia/microtia as part of another condition	25
Isolate microtia or atresia	14
Ventilation disorders	13
CSOM	10
Inherited genetic disorder	10
Cleft	2
Other	8

Ventilation disorders included, chronic perforation, retraction, tympanoplasty, OME. Other diagnosis includes Arthrogryposis, Haemangioma, Blind end ear canal, and unrecorded (n = 4).

72 (87.8%) of all 82 fitted children continue to use the device daily. A total of 10 (12.2%) children are no longer users the aid. Of these, 5 (6.1%) no longer used any hearing aid device and 5 (6.1%) use alternative aids. The alternatives included spectacle aids (n = 2) and implant retained hearing devices (n = 3). Patient preference was the main influencing factor for the 5 children who no longer use any form of hearing device. Feedback from these individuals reported they did not find any hearing aids useful or they were planning to have more advanced hearing reconstructive surgery. Of the 5 individuals who were provided alternative hearing devices, those children who needed to wear spectacles, reported positioning problems with the adhesive device and therefore were successfully fitted with spectacle aids.

Of the three individuals who were subsequently implanted, one aged 10 years old chose the implant retained device due to challenging behavioral issues affecting their compliance with the adhesive aid and softband aids. After extensive discussion and counseling the family decided that an implant would be more suitable and have better daily use. The further 2 individuals who underwent implant retained surgery reported no adverse complication or compliance issues with the adhesive aid. The decision to change was based upon their positive experiences with a bone conducting headband device.

Within our cohort of patients, on average the adhesive pad required replacement every second day keeping in line with the manufacture guidelines. 7 (8.5%) children reported an increased frequency of replacement above the manufacturer's recommendation of three times per week. One child required a change of adhesive pad up to four times per day due to the nature of his skin type whereas other individuals reported 7-day use from a single adhesive pad.

Some children required hair to be shaved in the post auricular region for the adhesive adaptors to be optimally positioned. This was predominantly children with microtia where the hair line was very low. Minor skin redness was reported in 8 individuals which resolved overnight once the adhesive pad had been removed. No stability issues were reported from any patient, however interference with both the adhesive pad and device was reported with headscarf and hat use.

4. Discussion

Literature review of PUBMED, Cochrane Library and NHS Athens was conducted. To the authors' knowledge there have been no previous published longitudinal studies into long term application and continued use of the adhesive bone conducting device, it also provides data on the biggest consecutive cohort published from a single center.

The excellent long-term compliance rate of 87.8% is similar to 80% demonstrated by Neumann et al. [4] when compared to conventional bone conducting systems. This retention rate is likely to represent the high levels of patient satisfaction, substantiated by numerous studies which indicate statistically significant improvements in quality of life indicators when using the adhesive retained hearing aid system. These include system-specific quality of life questionnaire (SSQ12), AQoL-8D [1,5,10,11], LAS and GCBI. Most improvement is demonstrated in learning and emotion dimensions [3].

Improved compliance with the adhesive device may also reflect the improved audiological outcomes compared to the unaided condition [1, 2) and comparable audiological outcomes as compared to softband mounted bone conduction device [3-5,10], passive magnetic devices (Baha® Attract) [6) and CROS aids in single sided deafness [7]. However, is should be noted that these studies were carried out on small sample size (mean 11 patients) with the exception of Osborne et al. [3] who included 21 children and demonstrated an improvement in thresholds of 7.3 dB HL ($p = 0.0001$) over those recorded in soft band aids and Urik et al [2] who demonstrating improved thresholds in both as compared to the unaided condition in 17 patients.

The improved quality of life most likely reflected the fact that the patients are more accepting of the aesthetics of the adhesive adaptor and were happy to wear their hearing system for twice as long [10] and in more situations than their previous softband. Many children report softband use only during their time at school.

Many children are concerned about their appearance and self-perception can cause more difficulties as they reach their teen years. Subjective feedback for our paediatric cohort reflected that children did not want to 'stand out', they wanted control over their appearance and some teenagers would rather manage without a hearing aid than stand out with one.

The introduction of the adhesive device provides a further option for children with conductive hearing loss. The older children/teenagers in our institution made an informed and autonomous choice about the hearing aid they used. This engagement was ultimately thought to be a huge factor that increased compliance and retention of the adhesive hearing aid system.

Although we found the positioning with the adhesive adaptor to be stable, the replacement of these pads does incur additional costs as compared with a softband device. In addition, each patient's requirement for the frequency of replacement is variable and influenced by the patient's own skin, hairline and impacted if wearing eye glasses and head scarves. No child has the same requirement for the pads and on average we found that the adhesive adaptors were changed every second day (three to four times a week); however, some individuals require this more frequently.

This centre's experience with the adhesive retained bone conduction system has been positive, and its application is growing. It is now a first choice for children with microtia and avoids the need for any hearing surgery before a decision on autologous reconstruction has been made. It is also a first choice for many children with long standing conductive hearing loss such as those children long standing otitis media with effusion, as seen in children with Down syndrome, Primary Ciliary Dyskinesia and those with a cleft palate.

Applications for children with transient conductive hearing loss may also be appropriate in the future. These include otitis media with effusion and post-operative patents who may be waiting for second stage ossiculoplasty following mastoid surgery. The adhesive hearing device is also another reliable form of a Bone Conduction trial before planning an implantable hearing solution.

Application in adults in the immediate post-operative period has already been studied to overcome this transient conductive hearing loss created by the tamponade effect from blocking the auditory canal. Speech perception for monosyllables in quiet improved by 46%, compared to the unaided condition after one week and a functional hearing gain improved by 19 dB [11] thus improving the recovery of patients even in short term. Future research into these types of application in the paediatric population is advised.

4.1 Limitation

The current study reports on long term outcomes of consecutive 82 children provided with the adhesive retained bone conduction system between 2015 and July 2019 and although retrospective in its data collection method the quality of information gathered was considered comprehensive as all patients' records were identifiable and complications recording were complete. Retrospective studies, however, are limited to the nature of missing data. In addition, the length of follow-up ranges from 9 months to 4.5 years and it is possible with a longer follow up compliance may decrease.

The absence of uniform standard for review of quality-of-life indicators was also limitation for the current study, with a positive impact being inferred from continued use of the hearing system rather than numerically demonstrated with the application of GCBI or LAS. This is a possible area to include in further research from this centre.

5. Conclusion

The adhesive retained bone conducting aid produces comparable audiological results to other conventional bone conduction hearing aid options. It provides an excellent alternative in the treatment of conductive hearing loss without the possible complications and costs of a surgical intervention. A compliance rate of 87.8% of all children fitted with the adhesive system demonstrated a high level of patient satisfaction. The device may also provide an appropriate steppingstone to implantable options once a child reaches the age in which an autonomous decision can be made regarding permanent implantation. Limitations of the adhesive device include the variability in the longevity of the adhesive adaptor. Interference with head scarves, hats and glasses and low frequency minimal transient skin reactions reported.

Declaration of competing interest

No authors involved with the paper have any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations that could inappropriately influence, or be perceived to influence, their work. The sound processors used in this study were supplied by MED-EL. All research and analysis were undertaken by BCH independently.

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Submission declaration

This work has not been previously published or submitted for journal publication. Preliminary results have been presented at OSSEO 2019 – Miami.

Contributors

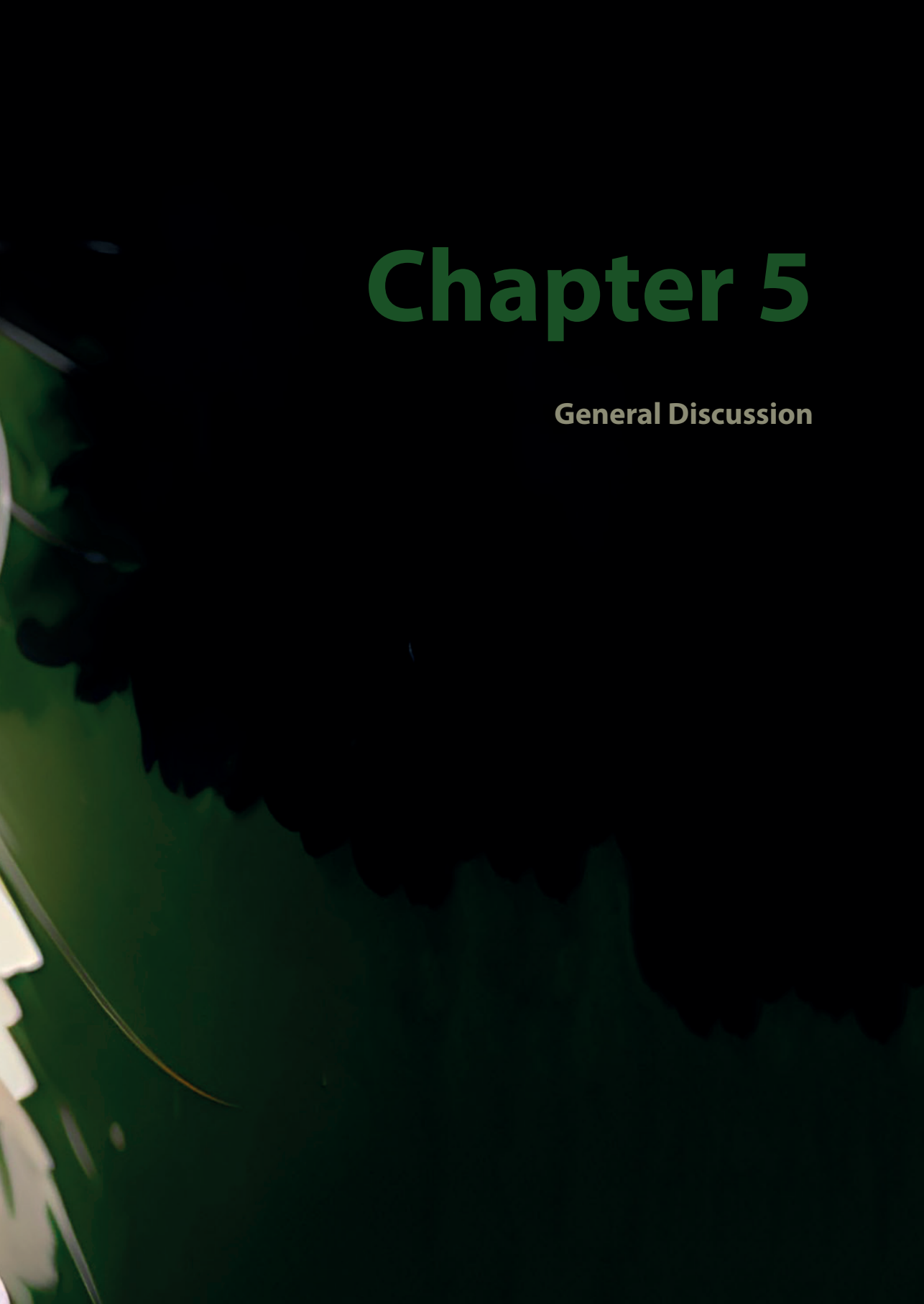
Mr M S Osborne – Study design, literature review, data analysis, preparation editing and submission of article.

Mrs A Child- Hymas - Data collection. Audiological support, final paper review and editing.

Ms A L McDermott - Data collection, Final paper review and editing

References

1. V. Dahm, W.D. Baumgartner, R. Liepins, C. Arnoldner, D. Riss, First results with a new, pressure-free, adhesive bone conduction hearing aid, Otol. Neurotol. 39 (6) (2018 Jul) 748–754
2. M. UriK, D. Hosnova, I. Slapak, J. Jancikova, J. Odstrcilik, J. Jarkovsky, W.D. Baumgartner, First experiences with a new adhesive bone conduction hearing device in children, Int. J. Pediatr. Otorhinolaryngol. 4.26 (204 9 Nov) 4.0964. 4.
3. M.S. Osborne, A. Child Hymas, J. Gill, M.S. Lloyd, A.L. McDermott, First pediatric experience with a novel, adhesive adapter retained, bone conduction hearing aid system, Otol. Neurotol. 40 (9) (2019 Oct) 1199-1207.
4. K. Neumann, J.P. Thomas, C. Voelter, S. Dazert, A new adhesive bone conduction hearing system effectively treats conductive hearing loss in children, Int. J. Pediatr. Otorhinolaryngol. 122 (2019 Jul) 117-125.
5. A. Favoreel, E. Heuninck, A.L. Mansbach, Audiological benefit and subjective satisfaction of children with the ADHEAR audio processor and adhesive adapter, Int. J. Pediatr. Otorhinolaryngol. 4.29 (2020 Feb) 4. 09729.
6. P.H. Skarzynski, A. Ratuszniak, K. Osinska, M. Koziel, B. Krol, K.B. Cywka,H. Skarzynski, A coinporotive study of a novel adhesive bone conduction device and conventional treatment options for conductive hearing loss, Otol. Neurotol. 40 (7) (2019 Aug) 858-864.
7. G. Mertens, A. Gilles, R. Bouzegta, P. Van de Heyning, A prospective randomized crossover study in single sided deafness on the new non-invasive adhesive bone conduction hearing system, Otol. Neurotol. 39 (8) (2018 Sep) 940-949.
8. S. Reinfeldt, B. Håkansson, H. Taghavi, M. Eeg-Olofsson, New developments in bone-conduction hearing implants: a review, Med. Devices (Auckl.) 8 (2015 Jan 16) 79-93.
9. I. Dobrev, S. Stenfelt, C. Röösli, L. Bolt, F. Pfiffner, R. Gerig, A. Huber, J.H. Sim, Influence of stimulation position on the sensitivity of bone conduction hearing aids without skin penetration, Int. J. Audiol. 55 (8) (2016 Aug) 439-446.
10. V. Dahm, A.B. Auinger, R. Liepins, W.D. Baumgartner, D. Riss, C. Arnoldner, A randomized cross-over trial comparing a pressure free, adhesive to a conventional bone conduction hearing device, Otol. Neurotol. 40 (5) (2019 Jun) 571-577.
11. R. Weiss, A. Loth, M. Leinung, S. Balster, D. Hirth, T. Stöver, S. Helbig, S. Kramer, A new adhesive bone conduction hearing system as a treatment option for transient hearing loss after middle ear surgery, Eur Arch Otorhinolaryngol. 2020 Mar;277(3):751-759



Chapter 5

General Discussion

General Discussion

In the 45 years since the initial conception of the bone conduction hearing device (BCHD) there has been significant technological evolutions in both non-surgical and surgical applications. This innovation has created greater choice and can now be tailored to the patients' audiological needs. These options have been evaluated in the wider literature over the past four decades proving that BCHDs are both safe, effective, and very well accepted by patients, both young and old alike.

Chapter 2

The Oticon™ wide implant system was launched in 2009 and used at Birmingham Children's Hospital from 2014. This chapter demonstrates the clinical outcomes of the Oticon™ wide implant (Oticon Medical), with a focus on skin complication rates and fixture loss over a 5-year period in a cohort of complex children, typical of those undergoing treatment in a Tertiary paediatric hospital.

Innovations in Bone Anchored Hearing Implant (BAHI) systems have resulted in more stable implants since their commercial introduction and in 2009 a new implant was introduced. The new implant had a diameter of 4.5mm, from the previous 3.75mm width and the abutment structure had been altered from the previous cone shape to a bell shape. The larger implant diameter provided a larger bone-implant contact surface and was designed to improve osseointegration and the overall stability of the implant. The shape of the abutment aimed to reduce soft tissue complications and skin overgrowth. A systematic review published in 2020 by Kruyt et al [1] supported the finding that wider implants provided a greater stability and a reduction in spontaneous fixture loss in children. It demonstrated a 17.1% loss in small-diameter implants compared to a 5.9% for wide diameter implants irrespective of any other design variation.

This increasing evidence for better stability allowed at this same time, a shift towards utilizing longer abutments at the primary placement [2]. This provided superior soft tissue tolerability, [3,4,5]. Both Cochlear and Oticon increased the range of available abutments lengths which could be attached to their implant. Cochlear provided 6, 9 and 12 mm abutments and Oticon provided 6, 9, 12 and 14 mm abutments respectively.

Chapter 2 presents the review of 47 children who underwent BAHI implantation with the wide Oticon™ implant between January 2014 and December 2015 with a total of 70 implants: 24 (51%) unilateral and 23 (49%) bilateral implantations. The mean age was 9 years 6 months. All were performed with two staged procedures. Of those 70 implants, 49 (56%) had a 3 mm length and 21 (30%) 4 mm length. The length of the applied abutments at second stage surgery was

6 mm (23%), 9 mm (54%), 12 mm (8.6%) and 14 mm (2.9%). Of the 70 implants originally loaded with an abutment, there were seven fixture failures (10%). All occurring following implantation with the 3 mm fixture.

Peri-abutment skin related complications were reported to affect eight implants (11.4%). Four peri-abutments skin problems were successfully treated with replacement with a longer abutment resulting in subsequent resolution of the skin issues. Two peri-abutment skin reactions required topical antibiotic treatment and one peri-abutment skin overgrowth required revision skin reduction surgery (1.4%).

In patients below the age of five years, soft tissue complications, skin revision rates as well as traumatic and spontaneous fixture loss rates were higher [6]. 5 children in this very young age group were included in the study and interestingly, they showed favorable results although the sample size was small.

It is concluded that the Oticon™ wide implant produces comparable results to previous studies with regards peri-abutment skin complications, revision surgery and, overall fixture loss. However, the results of this Birmingham paediatric BAHI series appears superior to previous implant systems used at Birmingham Women's and Children's Hospital (BWCH).

Chapter 3 entitled "Clinical features of a novel laser ablated titanium Bone-Anchored Hearing implant" included two original published articles, one paper in a paediatric population and one paper specific to children with Down syndrome, including resonance frequency analyses.

In **chapter 3.1** a total of 115 consecutive paediatric patients aged 4 to 15 years were implanted with 176 laser ablated titanium bone anchored implants from January 2016 to January 2019. Clinical outcomes, implant failure rates and post implantation stability quotient (ISQ) scores were studied over the first 12-month period. A median 12-months survival of 96.6% was observed. Six implants (3.5%) were lost in total, one (0.6%) was lost due to trauma. Adverse skin reactions (Holger's grade 2-4) were observed in 4.4% of all postoperative visits, occurring in 22 individuals (19.1%).

The ISQ results, irrespective of abutment size, demonstrated an increasing trend from 49.1 to 57 over the 12 months review period. A statistically significant change was only demonstrated from the 3 months follow up assessment onwards. No relationship could be identified between the ISQ result and spontaneous fixture failures.

It was concluded that the use of 4.5 mm wide ablated titanium bone anchored hearing implants resulted in superior survival rates and excellent clinical outcomes compared with previous

implant systems. The absolute ISQ data did not provide an indication of potential fixture failure, however this must be considered with caution as this sample size was small (n=5).

In **Chapter 3.2** a prospective study is presented for 31 consecutive children with Down syndrome, all aged between 5 and 16 years of age. A total of 43 Ponto BHX Oticon™ laser ablated titanium implant systems were used in this study group. 3 children underwent unilateral single stage implantation, whilst the remaining 28 children received a total of 40 implants as two stage procedures.

12 children had bilateral implants, 19 had unilateral implants (implant diameter 4.5 mm: implant length 3 and 4 mm). Manufacturer pre-mounted abutments of lengths 6, 9 and 12 mm were used in the three single stage surgeries (n=3). Individual abutments of the same length choices were applied at all second stage surgeries (N=40 abutments).

A high implant survival rate (95.3%) and low adverse skin reactions rate (3.2%) are presented which are in keeping with those recorded in the published literature. These outcomes are much improved compared to all the previous BAHI systems used at the Birmingham Children's Hospital.

The conclusions regarding the outcomes for the resonance frequency analysis are for this study, in line with chapter 3.1.

Chapter 4 contains two studies that report on the outcomes identified of a novel, non-implantable, adhesive retained bone conduction hearing system in children (ADHEAR) produced by MED-EL.

In **Chapter 4.1** twenty-one children aged between 5 and 15 years with a conductive hearing loss of greater than or equal to 25 dB HL in the better hearing ear were recruited. These children were fitted with the adhesive ADHEAR system. All the children had previous experience with a transcutaneous bone conducting hearing system prior to the study. 21 children had unilateral, and 1 child (4.5%) had bilateral CHL acquired aetiology (CSOM).

All children were provided with a single adhesive ADHEAR device. Audiological comparisons were made using pure-tone thresholds; unaided, with a Ponto softband, and with the adhesive ADHEAR system. Quality of life impact was assessed with two well recognized and validated questionnaires; GCBI and LAS as well as the manufacturer's questionnaire.

Patients were excluded from the study if there was evidence of fluctuation of hearing loss; 15 dB in either direction over the previous 24-month period. Of the 21 children, 8 had acquired

and 13 had congenital causes for the CHL. The commonest aetiologies included microtia (n=8), isolated ear canal atresia (n=3) and ossicular fixation (n=2). The age distribution in both groups were similar (5-14 years), however as expected, the acquired group had more older children: 5 (62%) children were over the age of 10 in the acquired group compared to 4 (30%) in the congenital.

The ADHEAR adhesive system demonstrated a statistically significant improvement in thresholds of 5.6 dB HL (p=0.0001) over and above those found with conventional Ponto softband devices. Following 4 weeks of acclimatisation with the device, the hearing advantage had increased to 7.3 dB HL. Mean thresholds were improved by 19 dB HL with Ponto softband and 26.3 dB HL with the use of the ADHEAR system as compared to the unaided situation. This improvement was demonstrated across all frequencies above 500Hz. Mean PTA_4 during Ponto softband and ADHEAR system use was found to be 30 dB HL ± 6- and 26-dB HL ± 3 respectively.

A quality-of-life review revealed 86% of children had improved self-confidence with the use of the ADHEAR system as compared to their previous transcutaneous device. GCBI response scores increased at the 4-week review by 33 ± 25 although overall GCBI demonstrated negative scores in 3 participants. The LAS score increased by 4.5 after fitting with ADHEAR system.

This initial review of ADHEAR's application provided evidence that this was a comparable alternative to the Ponto softband device and was very well-liked and accepted by the children. Its application in the paediatric population was limited by health and safety concerns surrounding the ease of access to the battery and the risks this posed to young children. There was also variability in quality and longevity of the adhesive. The patient's skin and the manufacture batches of product varied.

At the time of this study the lack of suitable locking mechanism for the battery door prevented the fitting of children under the age of 5 therefore this was the minimum inclusion age. The latest model of the adhesive ADHEAR system now has a lockable battery door.

As central auditory maturation is age dependent and limited by hearing input from only one ear, the impact of both the aetiology and time of onset of conductive hearing loss is not yet fully understood. It is becoming more apparent that hearing in noisy circumstances and lateralisation is improved by bilateral hearing input and therefore the provision of bilateral hearing solutions at an earlier age has the greatest impact [7,8,9]. Although the age at which this effect is most important for central maturation is yet unclear. There may indeed be a difference in those with bilateral losses as compared to unilateral.

For this reason, the adhesive ADHEAR system application may become more an important BC solution that can be easily utilised at an earlier age. Further study into this is advised as is the distinction between bilateral and unilateral losses.

The initial study does not make distinction between congenital or acquired losses when analysing the impact of the ADHEAR system. However, presented below is the mean PTA_4 for those children in all audiological conditions when sub-divided into congenital verses acquire aetiologies.

	Congenital HL	**Acquired HL**
Unaided	59	48
Softband	32	32
ADHEAR V1	27	26
ADHEAR V2	27	24

Although the baseline mean PTA_4 is 11 dB HL lower in the congenital hearing loss group, there is no difference between either group in the aided situations.

In **Chapter 4.2** a clinical study is presented that assessed the long-term compliance and usability of the non-implantable, adhesive ADHEAR bone conduction hearing aid system in children.

A retrospective study of all children aged 5 years and above fitted with the adhesive bone-conduction hearing aid between 2015 and 2019 in BWCH was performed. In total 82 children in a consecutive cohort (40 female, 42 male) aged 5-16 years were provided with 89 adhesive ADHEAR hearing systems. 22 (26%) children had bilateral hearing losses although only 7 children (8.5%) were fitted with bilateral hearing systems. 53 (64%) of the children have congenital hearing loss, 29 (36%) had acquired.

The mean age of the study cohort was 11 years. A total of 10 children became non ADHEAR users. 5 children (6.1%) no longer used any hearing aids system and the remaining 5 (6.1%) used an alternative system including spectacle aid (n=2) and Ponto Bone anchored implant system (n=3). This paper indicated that the ADHEAR system was a viable hearing device alternative and was well tolerated and accepted in the paediatric patient group. It showed that (87.8%) of those 82 children continue to use the ADHEAR device on a regular daily basis thus suggesting a high level of patient satisfaction.

The conclusion of these two presented studies is that the adhesive ADHEAR system provides an excellent alternative to non-surgical bone conduction hearing devices. It should be one of the first-choice options for children with microtia since it avoids the need for any implant surgery prior to any decision on autologous reconstruction. In addition, it can be utilised as an appropriate steppingstone to moving forward to an implantable device once a child reaches the age where they can also be involved in decision making discussions.

The ADHEAR system is limited by the variability in the longevity of the adhesive mount and associated reported skin sensitivity. The addition of a locking door for the battery compartment will improve its application and availability to younger children. Further review and study of this age group is recommended as is long term follow up for ADHEAR users.

As an early adopter of this technology, BWCH has gained a great deal of experience over the last three decades, engaging with regular and rigorous reflection, review, and assessment of developing technological innovations and their applications in the paediatric setting. This foundation of high-quality research created a valuable comparison of new technologies as they were introduced, and from this evaluation many lessons were learnt. A series of 6 core principles have been established because of these 35 years of clinical and patient experience.

Core Principle 1 – In children with bilateral conductive hearing loss: – One sound processor is good, Two sound processors are excellent.

Bone conducting hearing device application is now well established for unilateral rehabilitation of both conductive and mixed hearing loss. Bilateral application is still debated in the literature: This is more established in adult patient groups [9] with improvement in speech perception in noise and sound localisation demonstrated [10].

Bilateral application in children is still controversial but has been demonstrated to be superior to single sided implantation in achieving educational goals over the long-term, as well as having improved sustained quality of life measures. In addition, BCHDs are established for the management of hearing losses picked up at younger ages due to the effectiveness of screening programs and are widely used in audiological rehabilitation programs such as that at BWCH. It is well known that bilateral hearing losses have a direct effect on speech and language development, behaviour and education and therefore early rehabilitation improves outcomes in all these aspects.

In 2013 improvements in spatial recognition were demonstrated in bilaterally aided children, with a reduction in the minimum audible angle to 13 degrees from 57 degrees in monaural aiding [7]. More recently, bilateral application in children with congenital conductive hearing losses has demonstrated improved lateralisation and sound localisation and it was concluded

that binaural cues improved directional hearing, increased safety, feeling of comfort and understanding, particularly important in the paediatric patient group [8].

Systematic reviews of the impact of the use of bilateral BCHDs provide evidence of objective and subjective benefits [11,12] however, the quality on numbers of this type of study are limited especially in the paediatric population. Interestingly similar findings are demonstrated in children and adults with non-surgical BCHDs such as the ADHEAR [13,14,15], softband and Sound arc [16]. Shiraishi et al reported a comprehensive review of bilateral BCHD studies and concluded that bilateral devices improve sound localisation and lateralisation. However, the degree of accuracy in sound localisation by bilateral BCHD varied considerably among patients [17].

Previous research conducted at BWCH by Banga et al concluded that all children with bilateral losses benefit from bilateral aiding especially those under the age of 5 [18]. These principles are reflected in the overall number of patients that ultimately receive bilateral implantation at BWCH being 49% [19] and 53% [20] in the studies presented in this thesis.

Complication rates are reported to be higher in the paediatric population, especially those under the age of 5 years. The introduction of the soft band mounted bone conduction hearing device as well as an adhesive ADHEAR hearing device allow for earlier intervention without concerns of surgical intervention. As demonstrated in the wider literature and from the presented findings of this thesis, skin complication and fixture failure rates have continued to improve over time: This is a direct result of innovations in implant and abutment design as well as surgical techniques that moved away from skin grafts and soft tissue reduction and moved to minimally invasive, tissue sparing techniques.

These improved outcomes both in adults and children, have allowed clinicians the confidence to bilaterally implant without fear of additional complication. There has also been a move towards earlier implantation in younger children with increasing evidence that this is safe and effective.

Core principle 2 – Careful Assessment of all aspects of the Child's history.

Assessment of the paediatric population creates additional challenges as compared to an adult group. In the adult population, audiological testing generates objective thresholds which can be compared and contrasted in both the unaided and aided environments with each hearing aid device. These can then be applied directly to each patient and their personal circumstances and own considerations can be incorporated into the decision making, following appropriate consultation, and counselling. The ultimate decision to provide an implant and choice of implant system is a collaboration between clinicians and the patient, led by a patient centered approach.

Within the paediatric setting there are many challenges in the assessment. Firstly, there are issues with cognitive understanding in many of our patient groups. This is often due to a young age but many of the children have additional educational, emotional, and physical disabilities. Secondly, there is a lack of sufficient patient maturity and autonomy to make independent decisions in the majority of cases. Peer pressure at school, self-perception and self-esteem add another layer of complexity as children reach puberty and their teenage years. A multi-disciplinary assessment is essential for all children which includes specialist paediatric audiological assessments. A trial period of a BAHD on a softband, or ADHEAR, without commitment to surgical intervention, provides invaluable insight for patients, care givers and clinicians. It is this trial period that is the most important in predicting the benefits from providing such an implant retained bone anchored aid device in a child.

These same factors also create additional barriers when attempting to undertake objective audiological assessments and obtain completed feedback questionnaires.

It is experience of BCWH, that the patient reported outcome measures hold far more gravitas when considering the benefit of hearing rehabilitation options than a purely audiological assessment. Assessment of Quality-of-life impact is achieved through the application of validated questionnaires, real world usage time and patient reported concerns. We would consider that the reported use of a hearing device of greater than 8 hours a day 7 days a week with associated improvement in a child's psychosocial development, as a success, irrespective of any audiological benefit that may have been demonstrated during objective tests.

This approach is not without its limitations. In practice, caregivers and parental guardians provide this information as a proxy for their children and so results are affected by engagement with the studies, willingness to respond to questionnaires and attendance for follow-up appointments. Despite following formal research study protocol where caregivers / child sign research agreements to attend pre-set follow up appointments and complete feedback, it has been noted that there has been a pattern of poor response rates because of social and cultural factors as well as the increase burden of research and attendance.

In the UK, school attendance is carefully monitored and there is a reluctance to miss school for follow up visits if the child is well. Furthermore, many of our patients have multiple comorbidities and additional learning needs which require additional attendance at hospital for other medical reviews. Attending the hospital when the carers perceive their child has no concerns regarding their hearing, maybe not be seen as a priority by their caregiver and adds to the burden of care. Indeed, the additional time away from the educational environment in these circumstances may also be seen as a negative impact. Interestingly recent study from Texas Children's hospital concluded that a missed initial ABR appointment was the greatest

limiting factor in delaying or preventing BCHD provision to children [21] resulting in up to half of appropriate patients not receiving a BAHD, underpinning the importance of appropriately and timely assessments. Conversely caregivers may be motivated to over report improvements in children based on previous experiences and expectations.

When making our assessment of the impact of hearing devices, the BWCH team built a relationship with each family offering a direct contact system for any concerns. As a result of this, the BWCH team worked on the foundation that patients or caregivers would report concerns to medical professionals and request urgent review if necessary. The lack of attendance for routine follow-up appointments is therefore interpreted as a lack of complications or concerns. This is only possible due to the ease of the open communication streams between patients and our program team to allow for direct review if requested.

To improve these factors in the future, we continually strive to reduce barriers to attendance, offering telephone consultations, email contact, App based questionnaires and video consultations. In recent years following the impact of the Covid 19 pandemic, remote consultations have become increasingly more common in practice as the infrastructure and IT platforms to support them have become readily available. In addition, patient understanding of these alternative methods of review has become more acceptable to patient groups. Although video consultation is in its infancy in the Birmingham program, this has potential and is likely to improve response rates and compliance in future studies.

Core Principle 3 – Wider fixtures and better Abutment geometry.

It is now well established that the wider diameter implant improves spontaneous implant losses as compared to the previous narrow implants. This in combination with surface modulation and optimisation in fixture design have improved osteointegration. Abutment shape and surface coating developments have improved skin infection, irritation, and overgrowth rates. In 2018, the use of the Cochlear BAI300 implant system demonstrated the impact of abutment and fixture design on clinical outcomes. The wider fixture was more stable with less fixture failures, however the abutment design was problematic resulting in increased peri abutment skin issues [22]. The combination of these factors leads to less medical or surgical interventions following implantation.

Core Principle 4 – Processor Design capable of withstanding the paediatric population.

As discussed earlier in the introduction chapter, there has been dramatic improvement in size, shape, and interconnectivity of BCHD processors. The reduction in the overall footprint, weight and increased mounting options makes the sound processor more cosmetically acceptable. This combined with increased inter-connectivity options to help in classroom setting with

wireless connection as well as facilitate ease of use of modern technology such as mobile phones and computers has made them more attractive to children who can be very self-aware. Improving these aspects of BCHD makes them more desirable to children and helps them to engage with and take ownership of the decision-making process.

Safety is also an important consideration. Battery ingestion is a very significant risk and so battery compartment doors must be lockable to prevent accidental ingestion of button batteries. The adhesive ADHEAR has recently introduced this to the product enabling younger children to benefit from its use however prior to this change there were limitation in providing such aid to young children because of these safety concerns. Rechargeable batteries would resolve this issue entirely as there would be no need for a door and with the associated significant improvement in reducing cost and environmental impact this should be applied across all BAHD's.

As processor and rechargeable battery technology continues to reduce is size and weight over time, the overall footprint of available devices continues to decrease proportionately. From an aesthetic point of view, this will further improve the acceptance of children as they can more easily camouflage their devices should they wish.

Innovations in water resistance options for BCHD are yet unexplored in the medical technology sector but would likely offer a significant positive impact if developed. Currently there are barriers for children with additional hearing needs in undertaking water sports and recreational swimming. It is currently necessary for children to remove their aid completely during this activity. This is not ideal, especially during swimming lessons. Children need to be able to hear clear instruction while undertaking swimming lessons in an acoustically challenging and particularly noisy environment. This has an impact on both learning and safety. Water resistance is now widely available for mobile phones and headphones in the recreational setting and therefore this would be an excellent opportunity for development in the hearing aids of the future.

Core Principle 5 – Direct bone stimulation.

The best audiological outcomes are gained through direct contact of a vibrating processor with the skull, and that the fitting range is determined by the maximum output. Percutaneous and active transcutaneous BCHDs have significant audiological benefit over softband mountings, ADHEAR and passive devices, as they do not need to overcome the attenuation caused by the overlying skin and soft tissues. Overall, the best audiological results are seen in percutaneous and active transcutaneous systems, with the highest maximal output.

Core Principle 6 – Increased Social Awareness.

Social acceptance of any hearing aid, especially in children of teenage years, is important. A particular group that this causes concern for, are those who already have a different appearance such as microtia, hemifacial microsomia, Treacher- Collins syndrome to name just a few. Self-perception is driven largely by appearance and more recently the increasing influence of social media. Fortunately, as of late there has been an active drive to improve awareness and education for those individuals with an additional audiological need, aiming to improve acceptance and understanding of why people need to wear hearing devices.

An excellent example is that of Rose Ayling-Ellis who won UK Strictly Come Dancing in 2021. Following her success, a survey of deaf children and their families by the National Deaf Children's Society found that her increased social visibility in the competition, improved children's confidence to wear hearing devices and encourage them to talk more openly about their own deafness.

In August 2022 Mattel announced that they will be releasing a 'Barbie' wearing a 'behind the ear 'hearing aid as part of its new diversity campaign; a concept that Oticon previously developed with a teddy bear wearing a BAHD many years ago. Indeed, many children's television programs have begun to introduce role model characters with hearing disabilities; examples being Eastenders, and Toy story 4. Programs aimed at younger children on CBBC such as 'Mr Tumble' (Justin Fletcher MBE) utilise Makaton sign language increasing awareness and understanding of hearing challenges for both the children and their care givers, and these programs are enjoyed by all including those children without additional hearing or learning needs. Now Marvel has introduced more than one superhero with hearing impairment, into their universe including 'Echo' and 'Blue ear' the first superhero with a special listening device that gives him super-sonic hearing. This character was created in the likeness of Anthony Smith, a four-year-old boy born with mosaic trisomy 22.

This increased general social awareness of both the need for and the appearance of hearing devices is vital to improve the engagement of patients and normalise their use. Overtime time this approach is likely to reduce or remove the social stigma of wearing such hearing devices.

The recreational use of bone conduction headphones has also increased in popularity. These headphones allow users to remain aware of their surroundings while listening to music. This is particularly important when running, cycling, or undertaking snow sports. As a result, they are the only headphones approved for use in road races under the UK Athletics Rules of Competition. More recent innovations have been brought to the market regularly including waterproof headphone versions, which have the functionality to work as a walkie-talkie, take calls, undertake multiway group chats as well as listening to music.

Frontiers and Future research opportunities

Osia® System (Cochlear, Mölnlycke, Sweden)

At the forefront of current developments is the new Osia® System (Cochlear, Mölnlycke, Sweden), Seen by some, as the panacea for active transcutaneous BCHDs. This transcutaneous device comprises of a piezo power transducer and magnet, implanted under intact skin. The external sound processor sends signals via electromagnetic induction. The Osia® system requires no bony surgical well creation and utilises a single BI300 osseointergated fixture to secure it to the temporal bone. The combination of a minimally invasive procedure along with the absence of significant bony remodeling, makes this an attractive option for children. A recent review of medical device reports in the USA has demonstrated a 2.1% complication rate in more than 1500 implantations [23] which suggests favorable outcomes when compared to other active devices such as the bone bridge, and percutaneous options.

In the paediatric setting, research is currently limited. However, the evidence reported to date report an overall successful, uncomplicated placement with excellent audiologic outcomes [24]. Repeated processor connectivity issues have been reported and represent a potential area for future device development [25]. Further follow-up and comparative studies with other BCHDs are necessary to fully evaluate the effectiveness of the Osia® system in children and this would be an excellent avenue for future study.

Vibrant Soundbridge - MED-EL, Innsbruck, Austria

An alternative rehabilitation option to BCHDs are the exciting developments in middle ear implants. Introduced into the market in 2002, the Vibrant Soundbridge (VSB) (MED-EL, Innsbruck, Austria) provides an alternative method to directly stimulate the inner ear. The Vibrant Soundbridge consists of two primary components: a Vibrating Ossicular Prosthesis (VORP 503) and the SAMBA 2 audio processor which provide electromagnetic, direct-drive amplification. The VORP is surgically implanted under the skin and its floating mass transducer is coupled to the ossicular chain, commonly the long process of incus or placed in contact with the oval window, round window, or stapes head. Signal are passed from the processor via the magnetic coupling, this signal is then converted to movement of the floating mass transducer and directly stimulates the inner ear. It has been designed for people with mild to severe sensorineural hearing loss, as well as for those with conductive or mixed hearing loss.

The VBS performance in adults is well reported and meta-analysis in 2016 highlighted its benefits particularly with regards to mixed hearing loss and failed previous tympanoplasties when classical ossiculoplasty could not provide enough functional gain [26].

The application of middle ear implantation in children is now well established and international consensus was published in 2010 [27]. It has been found to be a safe alternative, with stable improved audiological performance and significantly improved perception of speech in noisy situations with a high sound quality [28,29,30,31]. Further studies highlighted significant speech discrimination improvement from 28.9% (unaided) to 95.5% (Soundbridge-aided) in children between the age of 5-9 and 18.5% to 89% in children between 10-17 years. Interestingly they noted that older children 10-17 showed a faster adaptation to the VSB [32].

When assessing the impact of middle ear implants on quality of life in children using questionnaires, Leinung et al concluded that children with unilateral atresia benefited more from the VSB compared to bone conducting hearing devices. They felt this was a result of the reported increase in the daily usage time, better localisation and audiometry results [33] when compared to other BCHD. The VSB is proving to be a viable option for hearing rehabilitation in children.

Impact of shrinking market Competition

In April 2022, the Cochlear® Group and Demant announced the acquisition of the hearing implant division of Demant: Oticon Medical®. This acquisition underwent a Phase 2 investigation by the Competition and Market Authority (CMA) in the UK led by an independent inquiry group, In June 2023, the CMA published its final findings and prohibited the sale of the Bone-Anchored business of Oticon Medical. The merger was blocked as it may have led to a substantial lessening of competition in bone conduction solutions resulting from a single company holding a 90% market share. They suggested that this would have an direct impact on patients creating less choice, reduced quality, or less innovation, as well as the NHS potentially paying higher prices [34].

Subsequently, Demant and Cochlear announced an amended agreement in which Cochlear would acquire only the cochlear implant division of Oticon Medical®. The review process for this amendment via the CMA, the Australian Competition and Consumer Commission (ACCC) as well as others internationally is still ongoing and Demant / Cochlear expect to close this in the first half of 2024.

It is hoped that the CMA's decision to maintain healthy competition in the bone conductive hearing technology market, will fuel innovation, drive development and lead to innovation and breakthroughs in BAHD technology, delivering better yet unimagined products for the future.

References

1. Kruyt IJ, Bakkum KHE, Caspers CJI, et al. The efficacy of boneanchored hearing implant surgery in children: a systematic review. Int J Pediatr Otorhinolaryngol 2020;132:109906
2. Nelisson R. Bone Conduction Devices. Implant designs long-term use. PhD thesis 2016. Radboud University Nijmegen.
3. Doshi J, McDermott AL, Reid A, Proops D. The 8.5mm abutment in children: the Birmingham bone-anchored hearing aid program experience. Otol Neurotol. 2010 Jun;31(4):612-4.
4. Monksfield P, Ho EC, Reid A, Proops D. Experience with the longer (8.5 mm) abutment for Bone-Anchored Hearing Aid. Otol Neurotol. 2009 Apr;30(3):274-6
5. Dun CA, Hol MK, Mylanus EA, Cremers CW. Fitting of an 8.5-millimeter abutment for bone conduction devices: indications and postintervention course. Ann Otol Rhinol Laryngol. 2011 Jun;120(6):386-90.
6. Amonoo-Kuofi K, Kelly A, Neeff M, Brown CR. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. Int J Pediatr Otorhinolaryngol. 2015 Apr;79(4):474-80.
7. Dun CA, Agterberg MJ, Cremers CW, Hol MK, Snik AF. Bilateral bone conduction devices: improved hearing ability in children with bilateral conductive hearing loss. Ear Hear. 2013 Nov-Dec;34(6):806-8
8. den Besten CA, Vogt K, Bosman AJ, Snik AFM, Hol MKS, Agterberg MJH. The Merits of Bilateral Application of Bone-Conduction Devices in Children With Bilateral Conductive Hearing Loss. Ear Hear. 2020 Sep/Oct;41(5):1327-1332.
9. Caspers CJI, Janssen AM, Agterberg MJH, Cremers CWRJ, Hol MKS, Bosman AJ. Sound localization with bilateral bone conduction devices. Eur Arch Otorhinolaryngol. 2022 Apr;279(4):1751-1764
10. Canale A, Ndrev D, Sapino S, Bianchi C, Bordino V, Albera A. Speech in Noise With Bilateral Active Bone Conduction Implant for Conductive and Mixed Hearing Loss. Otol Neurotol. 2022 Aug 31. doi: 10.1097/MAO.0000000000003671. Epub ahead of print. PMID: 36040056.
11. de Wolf MJ, Shival ML, Hol MK, Mylanus EA, Cremers CW, Snik AF. Benefit and quality of life in older bone-anchored hearing aid users. Otol Neurotol. 2010 Jul;31(5):766-72.
12. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg. 2012 Sep;147(3):412-22.
13. Ren LJ, Duan YS, Yu JC, Xie YZ, Zhang TY. Instant auditory benefit of an adhesive BCHD on children with bilateral congenital microtia. Clin Otolaryngol. 2021 Sep;46(5):1089-1094.
14. Gawliczek T, Munzinger F, Anschuetz L, Caversaccio M, Kompis M, Wimmer W. Unilateral and Bilateral Audiological Benefit With an Adhesively Attached, Noninvasive Bone Conduction Hearing System. Otol Neurotol. 2018 Sep;39(8):1025-1030

15. Snapp H, Vogt K, Agterberg MJH. Bilateral bone conduction stimulation provides reliable binaural cues for localization. Hear Res. 2020 Mar 15;388:107881

16. Gawliczek T, Wimmer W, Munzinger F, Caversaccio M, Kompis M. Speech Understanding and Sound Localization with a New Nonimplantable Wearing Option for Baha. Biomed Res Int. 2018 Sep 25;2018:5264124

17. Shiraishi K. Sound Localization and Lateralization by Bilateral Bone Conduction Devices, Middle Ear Implants, and Cartilage Conduction Hearing Aids. Audiol Res. 2021 Sep 30;11(4):508-523

18. Banga R, Child A, Reid A, McDermott AL Subjective benefit following the addition of a second BP100 softband processor for children with bilateral conductive hearing loss. Chapter 6 pp 129-141 PhD Thesis Banga, 2013 Nijmegen

19. Osborne MS, Hoskison E, Child-Hymas A, Gill J, McDermott AL. Five year clinical outcomes and evaluation following implantation of the Oticon™ wide bone anchored hearing system in 47 children. Int J Pediatr Otorhinolaryngol. 2020 Oct;137:110244

20. Osborne MS, Child-Hymas A, Holmberg M, Thomsen P, Johansson ML, McDermott AL. Clinical Evaluation of a Novel Laser-Ablated Titanium Implant System for Bone Anchored Hearing Systems in a Pediatric Population and the Relationship of Resonance Frequency Analysis With Implant Survival. Otol Neurotol. 2022 Feb 1;43(2):219-226.

21. Alexander NL, Silva RC, Barton G, Liu YC. Acquisition limitations of bone conduction hearing devices in children with unilateral microtia and atresia. Int J Pediatr Otorhinolaryngol. 2020 Jul;134:110040

22. Fussey JM, Harterink E, Gill J, Child-Hymas A, McDermott AL. Clinical outcomes following Cochlear™ BIA300 bone anchored hearing aid implantation in children. Int J Pediatr Otorhinolaryngol. 2018 ;111:89-92

23. Crowder HR, Bestourous DE, Reilly BK. Adverse events associated with Bonebridge and Osia bone conduction implant devices. Am J Otolaryngol. 2021 Jul-Aug;42(4):102968

24. Florentine MM, Virbalas J, Chan DK. Early surgical and audiologic outcomes of active, transcutaneous, osseointegrated bone-conduction hearing device (Osia 2® system) placement. Int J Pediatr Otorhinolaryngol. 2022 May;156:111114

25. You P, Choi A, Drob J, Hunsaker SM, Liu YC, Silva R. Early Outcomes of a New Active Transcutaneous Bone Conduction Implant in Pediatric Patients. Otol Neurotol. 2022 Feb 1;43(2):212-218

26. Ernst A, Todt I, Wagner J. Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: A systematic review. Laryngoscope. 2016 Jun;126(6):1451-7

27. Cremers CW, O'Connor AF, Helms J, Roberson J, Clarós P, Frenzel H, Profant M, Schmerber S, Streitberger C, Baumgartner WD, Orfila D, Pringle M, Cenjor C, Giarbini N, Jiang D, Snik AF. International consensus on Vibrant Soundbridge® implantation in children and adolescents. Int J Pediatr Otorhinolaryngol. 2010 Nov;74(11):1267-9

28. Hempel JM, Sprinzl G, Riechelmann H, Streitberger C, Giarbini N, Stark T, Zorowka P, Koci V, Magele A, Strenger T, Müller J, Wollenberg B, Frenzel H. A Transcutaneous Active Middle Ear

Implant (AMEI) in Children and Adolescents: Long-term, Multicenter Results. Otol Neurotol. 2019 Sep;40(8):1059-1067

29. Bruchhage KL, Leichtle A, Schönweiler R, Todt I, Baumgartner WD, Frenzel H, Wollenberg B. Systematic review to evaluate the safety, efficacy and economical outcomes of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. Eur Arch Otorhinolaryngol. 2017 Apr;274(4):1797-1806

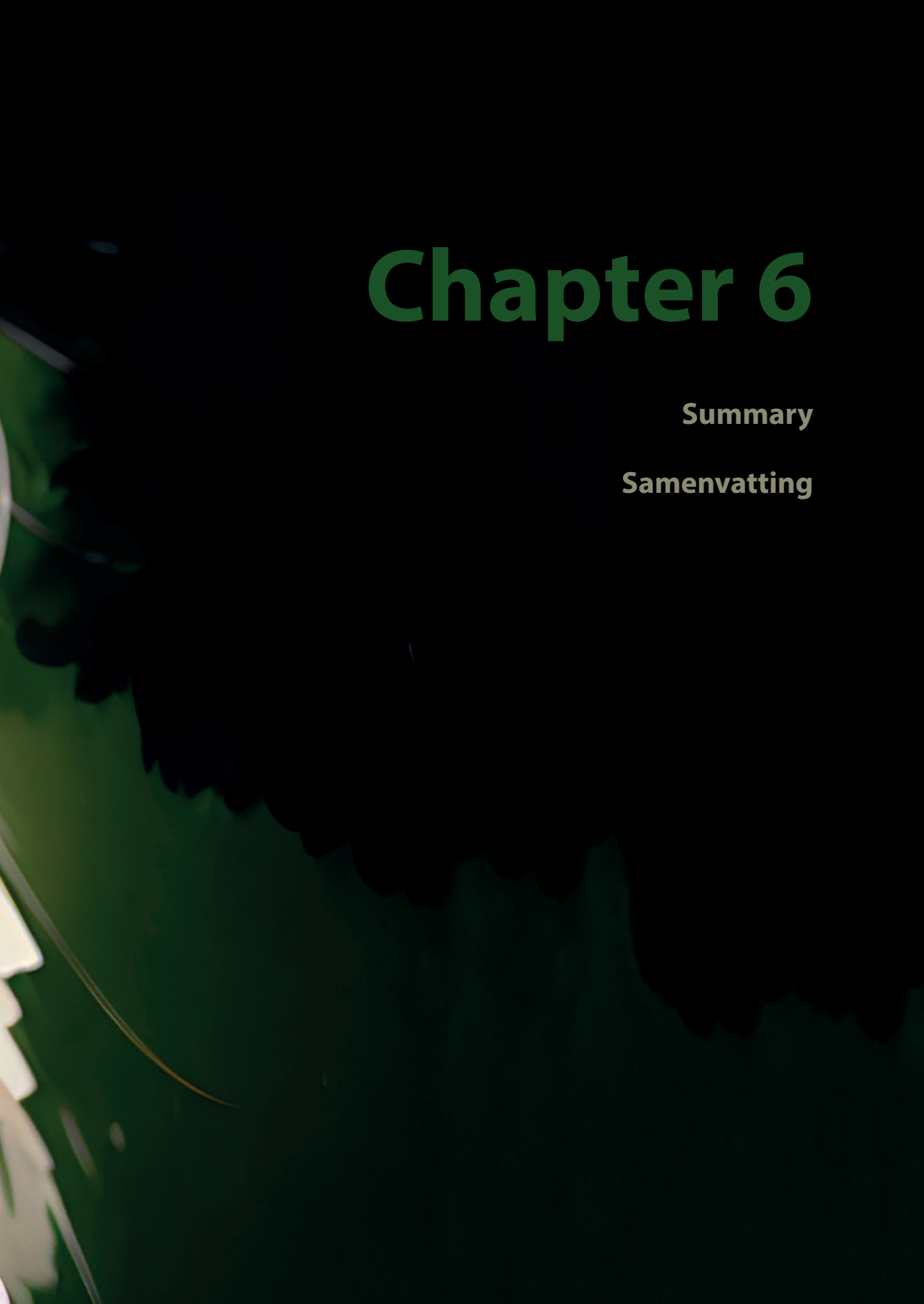
30. Lailach S, Zahnert T, Maurer J, Hempel JM, Koitschev A, Hollfelder D, Frenzel H, Wollenberg B, Arndt S. The vibrating ossicular prosthesis in children and adolescents: a retrospective study. Eur Arch Otorhinolaryngol. 2020 Jan;277(1):55-60

31. Takahashi M, Iwasaki S, Furutate S, Oka S, Oyamada S, Yasumura K. Active middle ear implant (vibrant soundbridge) in children with unilateral congenital aural atresia. Acta Otolaryngol. 2021 Jan;141(1):34-38

32. Frenzel H, Sprinzl G, Streitberger C, Stark T, Wollenberg B, Wolf-Magele A, Giarbini N, Strenger T, Müller J, Hempel JM. The Vibrant Soundbridge in Children and Adolescents: Preliminary European Multicenter Results. Otol Neurotol. 2015 Aug;36(7):1216-22

33. Leinung M, Zaretsky E, Lange BP, Hoffmann V, Stöver T, Hey C. Vibrant Soundbridge® in preschool children with unilateral aural atresia: acceptance and benefit. Eur Arch Otorhinolaryngol. 2017 Jan;274(1):159-165

34. https://www.gov.uk/government/news/cma-action-protects-outcomes-for-hearing-implant-patients



Chapter 6

Summary

Samenvatting

Summary

Research presented in this thesis adds to the increasing body of evidence that the application of wide diameter surface modulated implant in combination with appropriate length abutment minimise the risk of adverse skin reactions, spontaneous losses, and fixture failures. It presents some of the largest single centre, consecutively implanted patient groups in the paediatric setting in the world. It is also the only centre to directly compare the impact of clinical outcomes of fixture design in paediatric Down syndrome patients.

This thesis also explored the audiological improvements of a novel adhesive bone conductive hearing device and its impact of quality of life in the short and medium term. These were the largest studies in the paediatric population at the time of publication.

Chapter 2

Application of a wide diameter implant in paediatric population

This chapter comprises of a retrospective review of the first forty-seven children implanted with 70 4.5mm Oticon wide implants over a 5-year period. The finding of this study demonstrated an improved rate of skin complication that the previously used BAI300 Cochlear fixture 11% vs 77% but a higher fixture loss 10% vs 5% however the mean follows up time for this study was twice as long at the BAI300. The improvement in skin complication was because of better abutment design and the lack of a hydroxyapatite coating found in the BAI300.

Chapter 3

3.1 Impact of laser ablating the surface of a wide diameter implant on clinical outcomes and the application of RFA in the paediatric population

Following the success of the previously studied 4.5mm wide diameter implant, Oticon released an implant with a laser ablated surface. This prospective study analysed 115 paediatric patients with 176 implants with regards to clinical outcomes and application of Resonance frequency analysis in the paediatric population. The findings of this study demonstrated significant improvement in regards to both fixture failure rate and soft tissue complication when compared to all previously utilised implant systems at BCH. An overall fixture loss of 3.4% was reported with a skin complication rate of 4.4% of all post-operative visits.

RFA analysis found an overall increase over time following implantation, however, this increase only became statistically significant at the 3 months review point. No correlation between RFA and fixture loss could be identified. Therefore, utilising RFA an implant outcome predictor could not be verified, and conclusions cannot be drawn based on individual ISQ values alone. Trends can be followed but only in individuals or groups in which variables remain the same, this is challenging in the paediatric setting with a heterogenous patient group.

3.2 Impact of laser ablating the surface of wide diameter implant on clinical outcomes and application of RFA in paediatric patients with Down Syndrome

Paediatric patients with Down syndrome comprised the largest cohort (27%) of paediatric patients implanted with the laser ablated Oticon implant. This prospective study analysed 31 consecutively implanted paediatric patients with Down syndrome. Fixture loss was found to be 4.6%, higher than in the same general implanted paediatric population (4.4%) adverse skin reactions were identified in 8 children 3.2%. Overall mean ISQ increased from 46.2 at loading to 56.7 at 12 months. Although statistical significance varies at each review point, when compared to the baseline statistical significance is seen from the 3- month review point. This study demonstrated a very low morbidity associated with the laser ablated implant system, and good clinical outcomes in children with Down Syndrome. Utilising RFA an implant outcome predictor could not be verified, and conclusions cannot be drawn based on individual ISQ values alone.

Chapter 4

4.1 Audiological impact and quality of life analysis of a novel adhesive bone conductive hearing aid in children over the age of 5.

Review of 22 consecutive patients with conductive hearing losses greater than or equal to 25 dB HL that were fitted with a novel adhesive bone conductor hearing aid. 21 children had unilateral, and 1 child (4.5%) had bilateral CHL. All children were provided a single ADHEAR device.

Free field and PTA_4 analysis show improvement with ADHEAR (26 dB HL) compared to the unaided (55 dB) and comparable results to softband devices (30dB HL). Quality of life analysis via LAS and GCBI showed improvement in all dimensions, with a preference demonstrated towards the adhesive device over soft band. This initial review of ADHEAR's application provided evidence that this was a comparable alternative to softband devices and well-liked by patients. Its application was limited by the absence of a locking battery door and the variability in adhesive quality dependent on the patient's skin.

4.2 Medium term follow up (9-54 months) of the application of adhesive bone conductive hearing aid in children over the age of 5

Review of 82 consecutively fitted children with a novel adhesive bone conductor hearing aid for a minimum of 9 months (SD 9-54). 60 children had unilateral CHL and 22 (26.8%) had bilateral CHL. All children were provided with one device except for 7 children (8.5%) who received bilateral devices.

88% of children continue to use the device indicating a high-level patient satisfaction. At total of 10 children no longer used the adhesive aid. 5 of these (6.1%) no longer used any hearing aids

system and the remaining 5 (6.1%) used an alternative system including spectacle aid (n=2) and BAHD (n=3). This paper indicated that ADHEAR was a viable alternative over short and medium term and was well tolerated and accepted in the paediatric patient group.

Samenvatting

In dit proefschrift wordt beschreven dat de toepassing van titanium implantaten met een wat wijdere diameter en een wat ruwer aangepast oppervlak voor een betere verankering van de beengeleider hoorschroef zorgen en dat met een wat hogere uitwendige opbouw (abutment) op de hoorschroef de ongewenste bijwerkingen van implantatie , zoals huidreacties rondom het percutane implantaat en de afstoting van de hoorschroef, opvallend doen afnemen. Dat zijn bevindingen uit een studie verricht bij een opeenvolgend geïmplanteerde serie kinderen in het kinderziekenhuis in Birmingham (U.K.). Dit kinderziekenhuis is wereldwijd voor de BAHD toepassing een van de grootste zelfstandige centra. Dat geldt ook voor eenzelfde toepassing van de percutane BAHD bij kinderen met het syndroom van Down, welke studie werd uitgevoerd in een directe vergelijking met de eerdere uitkomsten van de toepassing van BAHD bij andere kinderen. Het gaat dan om de klinische uitkomsten van deze nieuwe BAHD toepassing met deze nieuwe titanium implantaten voor de percutane Beengeleider hoorschroef bij kinderen met het Syndroom van Down.

Evenzo worden in dit proefschrift de resultaten voor het gehoor beschreven van de toepassing van een nieuw type beengeleider hoortoestel (ADHEAR®) welk toestel aan de huid achter de oorschelp verkleefd wordt ter fixatie. De uitkomsten van een kwaliteit van levenstudie voor de korte en de middellange termijn worden hier gepresenteerd voor vooral kinderen met een éénzijdig groot geleidingsverlies. Op het moment van deze publicatie betrof het toen opnieuw de grootste serie gekend in de literatuur wereldwijd.

Hoofdstuk 2

De toepassing van een titanium hoorschroef met een wat wijdere diameter bij kinderen

In dit Hoofdstuk worden in een retrospectieve studie de resultaten beschreven zoals die over een periode van 5 jaar verkregen werden bij de eerste 47 kinderen die geïmplanteerd werden met in totaal 70 4,5 brede Oticon "wide implants" titanium hoorschrioeven.

De uitkomsten van deze studie toonden een lager percentage van ongewenste huidreacties in vergelijking met de eerdere uitkomsten van het BAI300 titanium implantaat van de firma Cochlear, namelijk van nu 11% tegen eerder 77%, echter het verlies van implantaten nam in deze nieuwe serie toe van 5% naar 10 %. Hierbij valt de volgende kanttekening te maken namelijk dat de follow up tijd bij deze nieuwe studie twee maal zo lang was dan bij de eerdere BAI 300 studie.

De afname van de huidreacties , als complicatie, worden toegeschreven aan de nieuwere vormgeving van het abutment en aan het nu ontbreken van een hydroxyapatiet oppervlak , zoals dat nog werd toegepast bij het BAI300 implantaat.

Hoofdstuk 3

Hoofdstuk 3.1
Het effect op de klinische uitkomsten van het met een laser verruwde oppervlak van het titanium implantaat met een wijdere diameter en het effect daarvan op de uitkomsten van de Resonantie Frequentie Analyse (RFA)

De firma Oticon lanceerde na hun eerdere succes met het 4,5 mm wijdere titanium implantaat opnieuw een nieuwere versie van hun titanium hoorschrioef met als vernieuwing een door laser wat verruwd oppervlak.

Bij 115 kinderen werden prospectief de toepassingen van dit implantaat voor 174 implantaten bestudeerd en geanalyseerd en wel specifiek voor de verkregen klinische resultaten en voor de resultaten zoals die verkregen werden met Resonantie Frequentie Analyse (RFA).

De uitkomsten van deze nieuwe studie toonden opmerkelijk betere resultaten in vergelijking met alle eerdere studies met deels geïmplanteerde beengeleider hoorschroeven (BCH).

Er werden minder titanium hoorschroeven afgestoten en er waren minder ongewenste huidreacties. Het verlies aan hoorschroeven was 3,4 % en het percentage ongewenste huidreacties was 4,4 %.

De uitkomsten van Resonantie Frequentie Analyse (RFA) over de tijd gemeten na implantatie toonden over de tijd een toename welke toename alleen op het meetpunt 3 maanden na implantatie statistisch significant was. Er werd geen correlatie gevonden tussen verlies van het implantaat en de uitkomsten van de RFA metingen. Daarom kunnen de uitkomsten van RFA metingen niet gebruikt worden als een voorspeller voor een eventueel opkomend verlies van het implantaat. Tevens kunnen op basis van het Implant Stability Quotiënt (ISQ) alleen in individuele gevallen geen conclusies getrokken worden.

Een mogelijke trend in verkregen RFA waarden kan op individuele basis gevolgd worden. Zo mogelijk ook voor bepaalde groepen mits er gelijke variabelen zijn. Dit laatste valt echter moeilijk vooral in een paediatrische patiënten groep, die onderling juist zo verschillend is.

Hoofdstuk 3.2
Effect van een met de laser verruwd oppervlak van het implantaat met de grotere diameter op de klinische resultaten als ook het effect daarvan op de toepassing van RFA bij kinderen met het syndroom van Down.
Deze prospectieve studie analyseerde de uitkomsten bij 31 opeenvolgend met dit implantaat met een verruwd oppervlak geïmplanteerde kinderen met het syndroom van Down.

Verlies van het implantaat werd bij 4,6 % van de geïmplanteerde patiënten met het syndroom van Down gevonden, dus iets hoger (4,4 %) dan voor de gehele paediatrische patiëntgroep is gevonden.

Ongewenste huidreacties werden bij 8 kinderen (3,2 %) opgemerkt. Het gemiddelde Implant Stability Quotiënt (ISQ) nam over de tijd toe van 46.2 bij belasting van het implantaat (dus bij de startmeting) tot 56.7 bij het latere 12 maanden meetpunt.

Alhoewel de mate van statistische significantie verschilt voor elk meet moment, wordt er vanaf 3 maanden vergeleken met de uitgangswaarde steeds een statistische significante hogere ISQ waarde gevonden.

Voor deze BCHD implantaten, met door een laser toepassing verruwd oppervlak, worden opvallend goede resultaten beschreven. Nu hier ook voor de kinderen met het syndroom van Down.

Toepassing van Resonantie Frequwntie Analyse (RFA) van het geplaatste implantaat blijkt nog geen goede voorspeller voor de stabilitiet van het implantaat (c.q. verlies van implantaat) en daarom wordt nu geconcludeerd dat alleen op basis van dergelijke individuele metingen daaruit nog geen conclusies getrokken mogen worden.

Hoofdstuk 4

Hoofdstuk 4.1
De audiologische waarde en de uitkomsten van een kwaliteit van leven analyse voor een nieuw adhaesief type Beengeleider hoortoestel (ADHEAR) zonder een percutane verankering bij kinderen ouder dan 5 jaar.
De uitkomsten van een audiologische evaluatie en van een kwaliteit van leven studie na toepassing van het nieuwe ADHEAR beengeleider hoortoestel bij 22 (waarvan 21 met een éénzijdig geleidingsverlies) opeenvolgende kinderen worden hier gepresenteerd. Vrije veld audiometrie en de gemeten gemiddelde gehoordrempels voor de 4 frequenties (0.5, 1.0, 2.0 en 4.0 = PTA 4) tonen voor ADHEAR een gemiddelde uitkomst van 26 dB Hl. Na toepassing

van de transcutane Softband BCHD is dat 30 dB Hl. en zonder enige gehoorrevalidatie is die uitkomst 55dB Hl.

Kwaliteit van leven metingen met behulp van lineaire analoge schaal (LAS) en met behulp van de Glasgow Children's Benefit Inventory (GCBI) toonden voor alle uitkomsten een verbetering met een duidelijke voorkeur voor een ADHEAR toepassing in vergelijking met de Softband toepassing.

Deze eerste klinische studie over de toepassing van een revalidatie met ADHEAR toont aan dat deze toepassing een vergelijkbaar alternatief is voor de al langer bestaande evenzo transcutane BCDH toepassing en dat deze ADHEAR toepassing door de kinderen meer gewaardeerd wordt.

Beperkingen van de ADHEAR toepassingen zijn nu nog dat de mate van verkleving van het ADHEAR hoortoestel aan de huid nu nog wat variabel is en dat de benodigede batterij in het toestel nog onvoldoende afsluitbaar is en zo dus voor het kind toegankelijk blijft.

Hoofdstuk 4.2
Uitkomsten op de middellange termijn (9-54 maanden) voor de ADHEAR toepassing bij kinderen ouder dan 5 jaar.

Voor 82 opeenvolgende kinderen bij wie een nieuw type adhaesief Beengeleider Hoortoestel (ADHEAR) werd toegepast gedurende minimal een periode van 9 maanden (SD 9-54) worden hier gepresenteerd.

In totaal zijn 72 (88%) van de kinderen met een ADHEAR hoortoestel dit hoortoestel blijven dragen, wat blijk geeft van een hoge patiënt tevredenheid. In totaal 5 kinderen gebruikten nadien geen enkele vorm van gehoorrevalidatie meer en enkele gebruiken thans een alternatieve BCHD zoals een beengeleiderbril of een ander typen in het schedelbeen verankerd hoortoestel.

Deze publicatie laat zien dat de nieuwe ADHEAR toepassing op de korte en de middellange termijn een bruikbaar alternatief blijkt te zijn voor de nu onderzochte patiënten. Een toekomstige retrospectieve vervolg studie staat nu al gepland voor de wat langere termijn.

Chapter 7

List of Publications
Acknowledgements
Curriculum Vitae
PhD portfolio table
Research data management
List of abbreviation

List of Publications

Clinical Evaluation and Resonance Frequency Analysis of Laser-ablated Titanium bone-anchored Hearing Implant System in Children with Down Syndrome.
Osborne MS, Child-Hymas A, McDermott AL
Int J Pediatr Otorhinolaryngol. 2021 Nov 11;151:110981 PMID 34781113

Clinical evaluation of a novel laser-ablated titanium implant system for bone anchored hearing systems in a paediatric population and the relationship of resonance frequency analysis with implant survival.
Osborne MS, Child-Hymas A, Holmberg M, Thomsen P, Johansson ML, McDermott AL
Otol Neurotol. 2022 Feb 1;43(2):219-226. PMID 34816808

Impact of Coronavirus (CoVID-19) on Urgent Referrals to Secondary Care Otolaryngology. A Prospective Case Series
Osborne MS, Bentley E, Farrow A, Chan J, Murphy J
Laryngol Otol. 2020 Sep 28:1-4. PMID 32981533

Longitudinal Study of use of the Pressure free, Adhesive Bone Conducting Hearing System in Children at a Tertiary Centre.
Osborne MS, Child-Hymas A, McDermott AL
Int J Pediatr Otorhinolaryngol. 2020 Nov;138:110307 PMID 32810685

Five year Clinical outcomes and evaluation following implantation of the Oticon™ Wide bone anchored hearing system in 47 children.
Osborne MS, Child-Hymas A, Gill J, McDermott AL.
Int J Pediatr Otorhinolaryngol. 137 (2020) 110244 PMID 32896356

First Pediatric Experience With a Novel, Adhesive Adapter Retained, Bone Conduction Hearing Aid System.
Osborne MS, Child-Hymas A, Gill J, Lloyd MS, McDermott AL.
Otol Neurotol. 2019;40(9):1199-1207 PMID 31469800

Middle ear Pressures in Wind Instrument Musicians.
Osborne MS, Morris S, Clark MPA, Begg P
Otology & Neurotology; July 2018 39 (6):791-796 PMID 29794684

A Helpful technique for increasing the size of a tracheostomy window in patients with calcified or challenging tracheas utilising a Kerrison Punch Forceps
Osborne MS, Krishna S, George A, Costello D, Corbridge R
Clin Otolaryngol. August 2018 PMID 30092614

The Surgical Arrest of Post-Tonsillectomy Haemorrhage: Hospital Episode Statistics 12 years on.
Osborne Ms, Clark MPA
Ann R Col Surg Eng. 2018 May; 100(5):406-408 PMID 29484936

A helpful technique for water precautions following ear surgery; Utilising the anaesthetic air cushion mask.
Osborne M S, Clark MPA
Clin Otolaryngol. 2018 Apr; 43(2):777-778 PMID: 28306201

A helpful Technique in stabilising and Avoiding Fatigue during Microlaryngoscopy.
Osborne M S, Mitchell- Innes A, Costello D
Clin Otolaryngol. 2015 Apr; 40(2):169-70. PMID: 25765811

Picture Quiz - A Man with Absolute dysphagia after eating a steak
Osborne M S, Saunders T, Fuerstenberg F, Costello D, Dhesi B
BMJ 2014 Sep 10; 349:g5462 PMID: 25209933

Co- Author

Provision of bone conduction hearing implants in England in adults and children: a review of Hospital Episode Statistics data 2012-2021.
Conybeare A, Bennett L, Osborne MS
J Laryngol Otol. 2024 Mar 8:1-6. Epub ahead of print. PMID: 38456642

There is a frog in my throat? ' case report of prolapsing lung apex presenting as a neck lump
Ahmed R, Osborne MS, Ahsan F
Ann R Coll Surg Engl. 2021 Sep;103(8):e249-e251 PMID: 34464574

The evolution of sinus surgery in England in the last decade – An observational study
Gupta K, Jolly K, Bhamra N, Osborne MS, Ahmed SK
World J Otorhinolaryngol Head Neck Surg. 2020 Oct 19;7(3):240-246 PMID 34430832

The changing face of rhinology in the NHS: a study of septoplasty, septorhinoplasty and rhinoplasty hospital episode statistics.
Balai E, Jolly K, Bhamra N, Osborne MS, Barraclough J.
Ann R Coll Surg Engl. 2021 Apr;103(4):291-295. PMID 33661043

A Novel Cost-Effective Safety Adjunct to Flexible Nasendoscopy During The COVID-19 Pandemic: The Personal Protective Endoscopy Mask (PPEM)
Jolly K, Darr A, Osborne MS, Bhamra1 N, Barraclough J
Surg Innov. 2021 Apr 27doi: 10.1177/15533506211013158. PMID: 33904365

Experiences in academic publication among ENT trainees in the UK: results from a national survey
S Shahidi, M Osborne, S Bola, M Murphy
J Laryngol Otol. 2021 May;135(5):396-402 PMID: 3385854

Writing clinic letters in head and neck outpatient services – are we doing what patients want?
Gupta K, Balai E, Osborne MS, Ismail S, Murphy M
Int J Clin Pract. 2021 Apr;75(4):e13907. PMID 33280216

Prevalence of patients who return to theatre post adenoidectomy; a review of Hospital Episode Statistics data 2012-2019
Bhamra, N, Osborne MS, Balai E, Jolly K, Barraclough, J.
Cureus. 2021 Mar 18;13(3):e13980. PMID: 33880306

COVIDTrach collaborative. COVIDTrach; the outcomes of mechanically ventilated COVID-19 patients undergoing tracheostomy in the UK: Interim Report.
Br J Surg. 2020 Nov;107(12):e583-e584. PMID 32940347

The diagnostic value of cytology in parotid Warthin's tumours: International multicentre series.
Borsetto D, Fussey JM, Cazzador D, et al.
Head Neck. 2020;42(8):2215-2216 PMID: 32108408

The diagnostic value of cytology in parotid Warthin's tumors: international multicenter series.
Borsetto D, Fussey JM, Cazzador D, et al.
Head Neck. 2020;42(3):522-529 PMID: 31762130

Improving the quality of assessment and management of nasal trauma in a major trauma centre (MTC): Queen Elizabeth Hospital, Birmingham.
Khajuria A, Osborne MS, McClleland L, Ghosh S.
BMJ Open Qual. 2019;8(4):e000632. PMID: 31803851

Neck Swelling and Enlarged Tonsils
Gill C, Osborne MS, McCelland L
BMJ 2019 Jul 25; 366:l4361 PMID: 31345837

Will Children Ever Learn? Removal of Nasal Foreign Bodies: A Study of Hospital Episode Statistics.
Morris S, Osborne MS, McDermott AL
Ann R Coll Surg Engl. 2018 Jul 3:1-3. PMID 29968507

Head and Neck Anatomy: Impact of Focussed Near-Peer Teaching on Anatomical Confidence in 30 Undergraduate Medical Students.
Morris S, Osborne MS, Bowyer D
J Surg Educ. 2018 May 11. pii: S1931-7204(18)30128-4 PMID 29759952

National prospective cohort study of peritonsillar abscess management and outcomes: the Multicentre Audit of Quinsies study
West Midland Research Collaborative
J Laryngol Otol. 2016 Aug;130(8):768-76. PMID 27282632

A rare Complication of nasal retaining loop insertion.
Saunders T, Osborne M S
Austin J Otolaryngol 2(4): id1038 (2015) - Page - 02

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Med-El

Curriculum Vitae

Max Sallis Osborne was born in Worcester, UK on the 11th of July 1983 the youngest of two boys, his mother a biology teacher and his father worked in the cardiac medical technology industry. His childhood was spent in the boarders of Worcestershire and Shropshire where he attended Tenbury High School for his GCSE's and The Royal Grammar School Worcester for his A-levels.

Following this he studied for his undergraduate degree in Physiology at Cardiff University, gaining a 2.1 hons BSc. Prior to starting medical school Max took time to travel and work abroad including 6 months living and working in Dublin, Ireland as a medical sales customer service agent. 6 months in Queenstown New Zealand working in security and snowboarding. He then took part in the prestigious Voluntary Service Overseas (VSO), Global Exchange youth program which aimed to increase social awareness and global citizenship. During this program Max lived and worked within local communities both in Feltham and Hounslow, London, UK, and Piliyandala, Colombo, Sri Lanka on a wide variety of charity and education projects, the single most enlightening experience of his life.

Following this Max returned to the UK to undertake his medical studies, graduating MBChB in 2011 from University of Birmingham Medical School. Junior doctor training was undertaken in the West Midlands before entering an ENT themed core surgical training post in 2013. In 2015 Max successfully obtained a place on the West Midland ENT higher Surgical Training Program.

During his 6 years of higher surgical training in Otolaryngology Max has gained broad experience in all aspects of ENT Surgery, developing a specialty interest in Otology and Paediatrics at an early stage which evolved in to interesting in to developing and designing research projects. While in his second year of higher training while working under the supervision of Ms Ann-Louise McDermott he was introduced to paediatric Bone conductive hearing technologies and took on an active role analysing and publishing research in this area maintaining strong links with Birmingham Children's Hospital throughout the remaining of his training period.

Max built upon his interest in otology and was awarded the MIO course award to attend the Nijmegan Ear Surgery course in 2019 which provided an excellent foundation to build upon in my higher training. He also placed 2nd in the RSM Cambridge Temporal bone competition that same year.

In November 2021 Max successfully obtained his FRCS (ORL-HNS) at the Royal College of Surgeons, England.

Max has recently taken on a consultant role in the Dudley Group NHS Foundation Trust and is enjoying establishing himself for the next stage of his career.

He has demonstrated a keen interest in research and teaching. Published 28 peer reviewed articles and 10 oral presentations at National and international Level. He has received multiple awards for dedication to medical teaching for both undergraduate and postgraduate students and gained a PGDip in Clinical Education which led to being accepted as a Member of the Academy of Medical Educators.

More recently he had focused on the developed a course focused on preparation for the MCQ examination specifically designed to help those trainees with a background of neurodiversity following his own experiences and challenges with this as a trainee. He also volunteers regularly as faculty at PESC, BACO, SPR interview courses and local and regional emergency ENT courses and NPCPO.

Between 2019 and 2022 he was an active member of the British Association for Paediatric Otolaryngology council (BAPO) and co-ordinated their two-day international conference in 2019. In 2023 he joined the council of the Midlands Institute of Otorhinolaryngology.

Max is married to Fiona Osborne who has been the bedrock of support through his training and research. He is the father of two beautiful and strong willed boys, Rufus who is now four and Alexander who is one. Both are a constant source of inspiration and joy and a reminder of why he chose his path in life.

PhD Portfolio

Name of PhD Student	*M S Osborne*		
Department	*Otorhinolaryngology*	**Promotors**	*Prof. Dr. M.K.S. Hol*
			Prof CWRJ Cremers
			Ms AL McDermott
Graduate School	*University of Birmingham, UK*		

Courses and Workshops	Years
Postgraduate Diploma in Clinical Education	2021
Education and Clinical Supervision Course	2021
Managing Trainees in Difficulty	2021
Transition to Consultancy	2021
Research and Critical Appraisal Course	2020
Higher Surgical Courses and Training	
Otology	
54th Nijmegen Ear Surgery Course	2019
Temporal Bone Dissection Course:	
Keele Temporal Bone Course	2021
Cambridge Temporal Bone Competition	2019
Keele Temporal Bone Course	2019
Keele Temporal Bone Course	2018
West Midlands Temporal Bone Dissection Course	2017
Coventry & London Temporal Dissection course	2016
Coventry & London Temporal Dissection Course	2014
Sinus Anatomy and Dissection Course	
FESS Masterclass Dissection course	2021
Live Virtual Sinus Dissection course	2021
Keele FESS course	2017

LASER Safety	
Laser Core Knowledge Programme	2020
CO2, KTP Laser safety course	2017
Head and Neck Surgery Course	
Smith & Nephew Coblation Tonsillotomy Course	2021
Performing Tracheostomies on Patients with Covid 19	2020
Keele University Head and Neck Dissection	2019
West Midlands Head and neck dissection course	2016
UHB Laryngology Course	2016
London MDT Head and Neck Imaging Course	2014
Transnasal Oesophagoscopy Course	2017
Septorhinoplasty and Facial Plastics Surgical Course	
Keele Facial Plastics course	2018
West Midlands Rhinoplasty and Facial Plastics	2017
West Midlands ENT Facial Plastic Course	2016
Research and Critical Appraisal Skills	
Research and Critical Appraisal Skills course	2020
RCS Research Methodology Training Day	2014
Good Clinical Practice (GCP)	
GCP Refresher Course	2018
Good Clinical Practice	2011
Paediatric ENT Skills and Knowledge	
Paediatric Intermediate Life Support PILS	2021
Paediatric Intermediate Life Support PILS	2020
British Paediatric Otolaryngology Course GOSH	2018
Paediatric Intermediate Life Support	2017
UHB Paediatric Life Support course	2013
Safeguarding Children Level 2	2013
ENT Craft Course	
West Midlands Radiology and Ultrasound course	2016
The Sheffield core skills ENT course	2014
Management of ENT Emergencies	2014

25th West Midlands Emergency ENT course	2013
Intercollegiate Basic Surgical Skills	2013
Post Graduate Courses	
Care of the Critically Ill Surgical Patient	2014
Advanced Trauma Life Support	2014
Clinical Radiology for Emergency Medicine	2012
Foundation Course in Clinical Radiology	2012
Advanced Life Support	2011
ALERT	2011
HST Management and Leadership Courses	
Edward Jenner Programme:	2021
Managing Trainees in Difficulty	2021
Education and Clinical Supervision course	2021
Transition to Consultancy	2021
Mastering Shared Decision Making	2021
Essentials of teleconsulting communication	2020
Mastering Adverse Outcomes	2019
Mastering Professional Interactions	2019
Principle Course Organiser	
British Association of Paediatric Otolaryngology - two-day conference	2021
FRCS part 1 Preparation course	2021
Regional Training Day - Swallowing disorders	2019
Core Surgical ENT training day	2019
ENT emergencies for Allied health professionals	2018
Teaching	
National Practical Course in Paediatric Otolaryngology	2022
FRCS part 1 Preparation course	2021
ST3 interview course	2019
BACO SFP Skills Station	2018

(Inter)national Symposia and Congresses	
British Association of Paediatric Otolaryngology - 1 oral presentation	2022
OSSEO Miami 1 oral presentation	2019
IAD - 1 oral presentation	2018
BACO - 3 poster presented - 1x best poster prize	2018
Regional Symposia and Congresses	
Midlands Institute of Otorhinolaryngology - 1 oral presentation	2019
Midlands Institute of Otorhinolaryngology - 1 oral (prize), 1 poster presentation	2018

Prizes and Awards	
RSM Temporal Bone Competition – Second Prize	2019
Joint Forces Command Presentation – First Prize	2019
MIO course award for trainees - £2000	2018
BACO 2018: Innovation in ENT-Poster prize – Scott Brown	2018
MIO Winter meeting Presentation- First Prize - £500	2018

Other	
Junior BAPO council member	2019-2022
Association of Otolaryngologists in Training (AOT) West Midlands trainee Representative	2020-2021

Research Data Management

This thesis is based on the results of human studies, which were conducted according to guidelines for Good Clinical Practice. All studies were granted ethical approval by the research and development committee of the Woman's and Children's Hospital NHS Trust (BWCH). None of the studies were subject to the medical research involving human subjects act (WHO).

Oticon Medical AB (Askim, Sweden) supported the studies in chapter 2 and 3. MED-EL (Innsbruck, Austria) supported those studies in chapter 4. No financial grants were given from either company. Data ownership from all included studies resides with BWCH.

There are no actual or potential conflicts of interest including any financial, personal, or other relationships with other people or organizations that could inappropriately influence, or be perceived to influence, their results of all the published studies in this thesis. All data presented in this research was recorded, analyzed, and interpreted by BCWH independently.
No person or institution provided financial support to conduct or prepare this research. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Prior to patient inclusion, written informed consent was obtained following BWCH protocol. In studies included in chapter 2 and 3, patients demographics, outcome, surgical methodology and RFA data were recorded on paper case report forms. Furthermore, with regards to studies included in chapters 2-4, patient specific paper questionnaires were completed at regular interval defined by the study design, all papers were stored securely within the audiological departments site file for update and reference.

On completion of each study this data was converted to electronic format in Excel and combined with audiological data. This was stored on a secure internal ENT department system and access granted to only those individuals with a role in the project.

The privacy of the participants is this thesis has been preserved by the allocation of individual patient identification numbers which corresponds to all data collected as well as consent documents and questionnaires.

All primary and secondary data that was obtained for the studies described in chapters 2,3 and 4 (including raw data, data analysis, results and manuscripts and all other relevant files) have been stored on secure computers with password encrypted access.

The informed consent forms are archived separately from the questionnaires and patient case report forms in the department archive of the ENT department at BWCH. All data will be saved for 15 years after the termination of the studies as per the research protocol and BWCH research rules. The datasets analyzed during these studies are available from the corresponding author on reasonable request.

List of Abbreviations

AC	Air Conduction
Baha®	Bone Conduction Hearing Aid
BAHD	Bone Anchored Hearing Device
BAHI	Bone Anchored Hearing Implant
BC	Bone Conduction
BCH	Birmingham Children's Hospital*
BCHD	Bone Conduction Hearing Device
BHX	Biohelix
BMI	Body Mass Index
BWCH	Birmingham Women's and Children's Hospital*
CHL	Conductive Hearing Loss
CROS	Contralateral Routing of Signals
CSOM	Chronic Suppurative Otitis Media
CT	Computed Tomography
DS	Down Syndrome
GCBI	Glasgow Children's Benefit Inventory
HARQ	Hearing and Review Questionnaire
ISQ	Implant Stability Quotient
ISQH	Implant Stability Quotient High
ISQL	Implant Stability Quotient Low
LAS	Linear Analogue Scale
MIPS	Minimally Invasive Ponto surgery
NICE	National Institute of Clinical Excellence
OME	Otitis Media with Effusion
PCD	Primary Ciliary Dyskinesia
PTA	Pure Tone Audiometry
PTA_4	Pure Tone Average (average hearing threshold over 4 frequencies 500,1000,2000,4000 Hz)
QOL	Quality of Life
RFA	Resonance Frequency Analysis
SA	Spectacle Aid
SD	Standard Deviation
SNHL	Sensorineural Hearing Loss
ST	Scala Tympani
SV	Scala Vestibuli
VORP	Vibrating Ossicular Prothesis
VSB	Vibrant Soundbridge

*Following an NHS trust merger in 2018/19 BCH became BWCH