

Paediatric Percutaneous Bone Anchored Hearing Devices Advantages and Challenges

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Paediatric Percutaneous Bone Anchored Hearing Devices Advantages and Challenges

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Chapter 1-1

General Introduction

History

A bone anchored hearing device (BAHD) is a method of auditory rehabilitation where sound is transmitted through bone via an implant direct to the inner ear (cochlea).

The BAHD became commercially available in 1984.¹ Approximately 100,000 people worldwide (adults & children) have had a BAHD. The indications for a BAHD can be broadly classified into patients with a conductive hearing loss, a mixed hearing loss and single sided deafness (SSD) who cannot wear traditional “behind the ear” or “in the ear” air conduction hearing aids.²

Air conduction hearing aids have a mould which either partially or completely fill the external auditory canal therefore may not be suitable for a variety of reasons. These include chronic ear infections and congenital external auditory canal conditions such as microtia/atresia.

Early prototypes of bone conduction hearing devices were developed as far back as the 17th century in the form of hearing rods that were placed against teeth or mastoid part of the temporal bone.³

In the 19th century, the carbon-electric hearing device was developed. This consisted of two parts.

1. A microphone and amplifier worn at ear or body level;
2. A transcutaneous vibrating transducer held against the mastoid bone with a steel headband.

In the early devices, a wire connected the two components, which resulted in unnatural listening conditions until later models encased both components in one housing.

In the 1950's, a bone conductor device was mounted in the arms of a spectacle frame and these were widely used.

These bone conduction hearing devices had a number of drawbacks.

1. To provide sufficient gain, the vibrating device needed to be held relatively tightly against the mastoid bone, which was often uncomfortable and sometimes lead to skin irritation and pressure necrosis. Sound attenuation occurred at the skin interface between the transducer and skull bone especially at the frequencies above 2kHz.⁴
2. The bone conduction spectacles were often cumbersome and aesthetically poor in appearance leading to poor user compliance.

In cases of single sided deafness, a CROS (Contralateral Routing Of Signal) aid has been traditionally used. It consists of two parts – a microphone (transmitter) and a hearing aid (receiver). Systems comprise of two behind-the-ear units

connected to each other by wire or by wireless transmission; they can also be incorporated into spectacles. Sound is transmitted from the deaf ear to the “hearing ear” however the hearing ear will be occluded by the receiver.

To overcome these problems in the outer and middle ear, an implantable BAHD was developed in the 1980s by Hakansson, Tjellstrom and co-workers in Gothenburg, Sweden.¹ It transmitted sound through bone conduction directly to the inner ear. This was called a percutaneous bone-anchored hearing aid (BAHA). Early results showed that the BAHA improved audiometric results and quality of life scores in appropriately selected patients.^{5,6}

Nobelpharma, Nobelbiocare and later Entific Medical System TM were over time the original companies that produced the BAHA; they were subsequently taken over in 2005 by Cochlear TM. In 2009, Oticon Medical also started producing a percutaneous bone anchored hearing device.⁷ Consequently, the term “BAHA” became a trademark by the original manufacturer therefore we use the term “BAHD” in this thesis to encompass both devices.

Hearing physiology

Air conduction hearing

Sound is transmitted through the outer, middle and inner ear. Sound waves traverse the external auditory canal causing mechanical vibrations of the tympanic membrane. This, in turn, is transmitted through to the inner ear via the ossicular chain in the middle ear cleft. Displacement of the inner ear fluid compartments results in basilar membrane stimulation leading to sensory cells excitation in the organ of Corti. The generated action potentials are transmitted through the auditory nerve to the brain leading to sound perception.

Bone conduction hearing

In 1960, Von Békésy discovered that cochlear hair cell excitation was identical regardless of whether the sound wave arrived at the cochlea via air conduction or bone conduction.⁸ This finding was confirmed in 2007 by an extended method of the original experiment described by Von Békésy.⁹ Animal models suggested 7 possible mechanisms of bone conduction¹⁰ although only four of these are significant for the normal and impaired human ear.¹¹

1. Inertia of cochlear fluids
2. Middle ear ossicle inertia
3. Compression of cochlear walls

4. Sound energy of the external ear

Inertia of cochlear fluids

As the fluid within the cochlear compartments cannot be compressed, the vibration of bone around the cochlea causes a pressure gradient across the basilar membrane that forms a travelling wave. The inertia of cochlear fluids is thought to be the dominant contributor to bone conduction particularly below 4kHz.

Middle ear ossicle inertia

When the bones of the skull vibrate as a whole, the vibration of the ossicles in the middle ear is delayed because of the inertia caused by their suspensory elastic ligaments. At low frequencies, the ossicles vibrate in phase with the skull and do not produce any relative motion. At approximately the resonant frequencies of the ossicles themselves (1.5-3.1kHz) the malleus and incus vibrate as one unit, which consequently displaces the stapes that results in cochlear stimulation.

Compression of cochlear walls

The vibrating bone causes compression and expansion of the cochlear walls. This causes displacement of the cochlear fluid compartments, which is greater in the scala vestibuli compared to the scala tympani. This is thought to be attributable to two reasons. Firstly, there is a difference in compliance between the oval and round window because oval window mobility is limited by the stapes footplate.¹² Secondly, although the scala vestibuli has a smaller relative volume than the scala tympani¹³, the scala vestibuli is connected to the perilymphatic chamber of the vestibular system therefore the resulting mass of fluid moving secondary to alternate compression and expansion of the cochlear walls is larger than in scala tympani. This mechanism occurs predominately at frequencies above 4kHz.

Sound energy of the external ear

Skull vibration from bone conduction causes the bony and cartilaginous walls of the external auditory canal to vibrate. These vibrations are transmitted through the tympanic membrane to the middle ear cleft akin to the method of air conduction transmission of sound. This occurs at low frequencies (400-1200Hz).

Osseointegration

Osseointegration is defined as “a direct structural and functional connection between ordered, living bone and surface of a load carrying implant”.¹⁴ The origins of osseointegration lie within dentistry¹⁵, however, Tjellstrom et al were the first to

combine the principles of osseointegration with the concept of bone conduction hearing aids.¹⁶ The first three patients were fitted with a percutaneous titanium implant for a bone conduction hearing device in 1977.¹⁷

A titanium oxide implant is highly biocompatible and promotes osseointegration of osteocytes with the implant. Histological studies have shown that osseointegration of a titanium implant comprises of both soft tissue/implant integration as well as direct bone/implant integration; the latter having ultrastructural features of filiform- and podocyte-like processes of osteocytes attached to the implant when viewed with electronmicroscopy.^{18,19}

The time taken for complete osseointegration to produce a stable implant was originally thought to take at least 3 months. However, in recent years, modifications in implant design and technology has resulted in implant loading as early as 6 weeks with no increase in skin reaction or implant loss rate.²⁰ Indeed, there is now evidence that implant loading as early as 3 weeks in adults with good quality bone is safe allowing hearing rehabilitation at an earlier stage.²¹

Percutaneous Devices

Advantages of Percutaneous Devices

In contrast to a traditional transcutaneous BCHD, sound transmission via a percutaneous device results in a gain of 5-15dB at frequencies above 1kHz as no sound is lost in the skin, muscle tissue and hair.²²

Audiological and subjective benefit of percutaneous BCHDs compared to traditional BCHDs have been shown in several studies²³⁻²⁵, however the results compared to air conduction devices are ambiguous²⁶. The BAHD improves speech recognition in noise compared to convention air conduction aids, the benefit being greater with a larger air-bone gap²⁷. The audiological benefit seems to occur when the air-bone gap is greater than 35dB with the patient reporting better preference with the BAHD compared with the air conduction aid above 45dB²⁸.

Disadvantages of Percutaneous Devices

Implanting a percutaneous hearing device requires surgery, which can be performed under general or local anaesthetic. Complications are predominately related to soft tissue reactions around the device abutment.

Soft tissue reactions

Skin changes around the implanted abutment are common. These can be graded using the Holgers classification (table 1) however this grading system is subjective and therefore prone to inter-observational variation²⁹

Table 1.

Holgers grading	Description
Grade 0	No reaction
Grade 1	Reddish discoloration of the skin around the implant
Grade 2	Red and moist surface of the skin around the implant
Grade 3	Formation of granulation tissue around the implant
Grade 4	Extensive soft tissue reaction that requires implant removal or leads to implant loss

Skin around the abutment can hypertrophy and this may respond to local treatment (topical steroids) or may require soft-tissue revision surgery in severe cases³⁰ Changing to a longer length abutment is an alternative option and can be done in the outpatient setting.^{31,32}

The cause of the soft tissue reaction is unclear. Theories include a foreign body reaction to keratin at the titanium-bone interface³³, micro-leakage of bacteria in the connection between the implant and abutment³⁴⁻³⁶ and biofilm formation on the threads of the abutment screw.³⁷

Children & BAHDs: The Challenges

Aetiology

The aetiology of paediatric hearing loss is very diverse and identifying the cause can be a great challenge. In our experience, one of the most common reasons for a BAHD in children is a congenital conductive hearing loss associated with atresia of the external auditory canal. Atresia is often associated with malformation of the middle ear and pinna and in most cases the cochlea is (almost) normal. Children with congenital atresia tend to have a large air-bone gap often between 50-60dB.³⁸ The BAHD has been shown to provide better speech recognition compared to traditional hearing aids when the air-bone gap is greater than 35dB.³⁹

The incidence of atresia is estimated to be 1 in 10,000 births with approximately 25% of cases being bilateral.⁴⁰ The majority occurs in isolation, but may be part of

a syndrome such as Treacher-Collins, Crouzons or Goldenhar syndrome.⁴¹ Therefore these children often have significant co-morbidities (e.g. neurological conditions, facial-cranial anomalies) that need to be considered when considering a BAHD. A retrospective review of a large series of children who had a BAHD in our institution over a 15-year period showed a high proportion of syndromic patients with complex medical problems – over 50% had a significant medical history.⁴²

Other indications for a BAHD include chronic outer/middle ear conditions where a traditional air conduction aid may exacerbate infection by decreasing ventilation and increasing moisture from the hearing aid mould causing excessive feedback (e.g. in a mastoid cavity).

Co-morbidity

When considering BAHD in children, their co morbidity plays a much greater influence on the treatment planning than in the adult population. The vast majority of children require a general anaesthetic for BAHD implantation however many of these children may have complex medical and developmental conditions that increase the risks of surgery. Our anaesthetic colleagues in our institution reviewed the case notes of 43 BAHD children who had surgery between 1992-1999; one hundred and two anaesthetics were given in total (this figure includes the initial one or two stage surgery plus any other general anesthetics required related to the BAHD e.g. skin reduction, revision surgery etc). Mean age at operation was 6 years and 2 months with a range from 1 year and 11 months to 14 years. Over a third of the children had a difficult view of the larynx at intubation (Cormack and Lehane grade 3 or 4 view of their larynx as graded by an experienced paediatric anaesthetic consultant) and the overall incidence of airway complications was 5.9%.⁴³ A more recent review in our institution (134 children who had BAHD surgery between 2008-2011), showed that just under half of the children had a recognized syndrome or dysmorphism and just under a fifth had a congenital cardiac anomaly (Personnel communication with R Banga, 2013).

Audiological testing in children

Careful assessment of the child's hearing by experienced paediatric audiologists is important in selecting children who will benefit from a BAHD. Indications for a BAHD include conductive hearing loss, mixed hearing loss and single sided deafness.

Audiological assessment can have particular challenges. Many children who require a BAHD have learning difficulties; the spectrum of which may vary e.g. in Down's syndrome.

The trial of a bone conductor on a headband, typically the BAHD Softband, is very useful and can be used to predict BAHD benefit.^{44,45} It is also an option for children too young for surgery or at high anaesthetic risk.

However, some children may also have behavioural issues which preclude any sort of preoperative audiological assessment including a trial of a headband device. Our institution reviewed 4 such children where a BAHD assessment was not possible due to severe behavioural/mental/sensory disorders.⁴⁶ All four children currently wear their BAHD for more than 8h a day. Parents reported a positive impact of the BAHD on the behaviour and mood of their children; the BAHD showed a positive benefit when assessed using the Glasgow Children's Benefit Inventory and showed a positive change in health status. There was no surgical morbidity in this group although a more intensive postoperative follow up was required.

Naturally parental/carer counseling is even more important in these cases as there is an element of "blind faith" - they must have realistic expectations of the potential benefits, the need for intensive postoperative care and potential complications if the final outcome is not as anticipated.

Unilateral hearing loss and effects on development and education

Until recent years a child with normal hearing in one ear was deemed to be "normal" and no intervention was offered for the unilateral hearing loss. In more recent years, evidence has emerged that children with a unilateral or bilateral conductive hearing loss and unilateral sensorineural hearing loss are at a higher risk for academic, speech-language, and social-emotional difficulties than their normal hearing peers.⁴⁷ The exact reasons for this are complex and may not be solely due to their hearing loss, however it is reasonable to assume that hearing loss will play some role.⁴⁸

Bilateral hearing loss and effects on development and education

Bilateral BAHDS in adults with bilateral hearing loss have proven to be superior to unilateral fitting, in both audiological measurements and in overall patient satisfaction.⁴⁹ There is increasing evidence that this is also the case in the paediatric population - fitting of bilateral BAHDS in children with bilateral conductive hearing loss has audiological benefits (sound localization & sound perception in noise) and also renders high patient satisfaction.^{28,50-53} In children

with bilateral conductive hearing loss, the improvement has been shown to be in the speech frequencies.⁵⁴

Unlike adults, many children are not good historians and they depend on the teachers and parents/carers to identify their problems. Therefore teachers/parents/carers as well as other allied educational and health care professionals play a very large role in ensuring that these children are not overlooked and are given the best opportunity to achieve their potential.

Surgical techniques

The goal in BAHD surgery is to achieve osseointegration of the implant with minimal surrounding skin reaction.

Length of screw

Skull thickness is important, as there must be sufficient depth of bone for the implant to osseointegrate. The United States Food and Drug Administration (FDA) medical product guidelines states the minimum age for a bone anchored hearing device is 5 years old (US Food Drug Agency K984162) and this generally equates with sufficient bone thickness.⁵⁵ Ideally a 4mm length screw is used otherwise a 3mm length screw is used in cases of reduced skull bone thickness.

However, in practice, BAHD is performed at ages less than 5 years old and it is generally accepted that complications such as skin reactions/implant loss are more common in this younger patient cohort^{56,57} and in certain other subgroups e.g. children with behavioural problems⁵⁸. Goretex® has previously been used to try to gain extra length. If there was insufficient bone thickness, the fixture was inserted slightly proud to the bone and Goretex® was placed in the gap. A bone conductor on a headband (such as the BAHA® Softband) is an alternative to early surgery and can be useful whilst waiting for the child to grow older prior to surgical intervention.^{44,45}

Sleeper

The traditional approach in children has been to insert a second ipsilateral (or contralateral) sleeper fixture at the initial surgery which could be used in cases of implant extrusion.⁵⁹ However refinements of implant design have shown improved implant stability as early as 6 weeks²⁰ and some BAHD units no longer use a sleeper fixture and perform BAHD surgery in children as a single stage⁶⁰⁻⁶²

One/Two stage surgery

In the traditional two-stage surgery, the fixture was inserted into the skull at the first stage. After a period of time for osseointegration to occur, the second stage comprised of a skin graft (free or pedicled), soft tissue reduction and abutment placement.⁶³

In the 1990s, the linear incision technique was developed with the aim of simplifying the surgical technique by removing the need for a skin flap and therefore avoiding the risk of flap necrosis^{64,65} however skin and soft tissue reduction was still required.

The Nijmegen group reported favorable outcomes using this technique; skin reaction and fixture loss rates were comparable to paediatric BAHD surgical techniques using a skin flap.⁶⁶ In general, one stage surgery was performed in children over the age of 10 and two-stage surgery in children below the age of 10.

Skin thickness & length of abutment

Traditionally, a short abutment (5.5mm) is used at primary surgery and the longer 8.5mm abutment is used in cases of peri-abutment skin hypertrophy; our institution has reported positive outcomes on the use of a long abutment on both 3 and 4mm fixtures in cases of skin hypertrophy.⁶⁷ It has also been suggested that a long abutment could be used at the time of primary surgery if a patient is found to have significant soft tissue thickness.³²

There is individual variation in the amount of soft tissue in each patient; increasing age and male gender are predictive of a thicker soft tissue measurement on ultrasound studies.⁶⁸ This study suggested that pre-operative evaluation of skin thickness could influence the surgical technique used. However, the need for soft tissue reduction has also been questioned. A recent study in 34 children where no soft tissue reduction was performed showed fewer complications, shorter surgical time, no numbness and improved cosmetic appeal in comparison with the group that underwent the traditional skin thinning procedure.⁶⁹

Post op challenges

Postoperative wound care is important in all patients with a BAHD - the paediatric population are no exception and have their own unique challenges.

Many studies have shown the most common problem is soft tissue reactions around the abutment, which if not dealt with, can lead to skin hypertrophy, infection or even implant extrusion. A large retrospective review of 970 adult and paediatric patients (1132 implants) showed that 94 implants (8.3%) were lost; most of these were spontaneous and occurred in the first year after surgery.⁵⁸ When the

results were analyzed by age, the rate of implant loss in children (<16years old) was 15.2% versus 7.3% in adults which was statistically significant. A similar implant loss rate of 16.3% was reported in a series of 93 children (21/129 fixtures); again most occurred in the first year after surgery and there was no difference in extrusion between the standard 4mm fixtures and the smaller 3mm fixture.⁷⁰

Regular postoperative dressings play an important role. Although no standardized dressing is used in all BAHD units, the type of dressing used and frequency of change is important.⁷¹

In adults, postoperative skin complications can often be treated on an outpatient basis. This may involve peri-abutment steroids (cream or injection) or even reduction of skin under local anaesthetic. Naturally, this may be more difficult in a young, non-cooperative child and any more invasive intervention will require sedation or a general anaesthetic.

Carers/parents play a pivotal role. They need to know how to care for the BAHD site both in the postoperative period as well as in the long term. It has also been shown that socioeconomic factors appear to contribute to a higher risk for complications with a statistically significant increased risk in children from deprived backgrounds.⁷² In addition, certain groups of children such as those with behavioural problems, require a more intensive postoperative follow up for peri-abutment skin care.⁷³

Device usage and compliance have specific issues in children. Parents & teachers play an important role in encouraging usage; the child's own perception of self-image is also important and in some cases bullying & poor self-image can lead to non-usage of the device.⁴⁶

Trauma

Trauma following BAHD implantation is well documented in both adults and children although the latter group is more frequently affected.⁴²

Trauma may result in damage to the external sound processor, abutment and/or fixture. It is our institutions experience that it is not uncommon for families to request a spare BAHD sound processor.

Most fixture losses in the paediatric group are a result of direct trauma^{56,74-76} therefore appropriate child and parent/carer counseling is essential to minimize this risk. Implant intrusion^{57,77} and epidural haematoma⁷⁸ following trauma have been reported; other rare complications include intracerebral abscess and epidural haematoma in the postoperative period.^{79,80}

Assessing benefit

Assessing the benefit of a BAHD in children has its own unique challenges.

Audiological testing

This can comprise of measurements of hearing thresholds, speech understanding in quiet & noise and auditory orientation tests. This can be performed with and without the BAHD in a variety of scenarios e.g. Hearing in Noise Test (HINT)⁸¹ During the HINT, the patient is required to repeat sentences both in a quiet environment and with competing noise being presented from different directions. Compliance in the paediatric population will depend on the child's age, maturity and comprehension to understand and follow instructions without losing interest during the course of the test.

Questionnaires

Another method to assess benefit is by using questionnaires. As with all questionnaires this relies on the respondent's literacy skills and understanding of the questions. Responses may be influenced by background, ethnicity and culture and, in the case of children, the responses may reflect patient and/or carer opinion.

The Children's Home Inventory for Listening Difficulties (CHILD) questionnaire has been used to determine BAHD benefit.⁸¹ The parent/child scores 15 situations that mirrors typical home communication scenarios at different distances, background noise, and varying child interest levels. The parent can complete it when their child is typically at a developmental age of about 3-12 years. The minimum age for a child to complete the questionnaire is 7-8 years. The parent reads each question and then determines how well the child appears to be able to hear and understand under different listening situations (typically over a period of time). An 8-point scale has been provided for the parent to choose from as they estimate their child's listening abilities.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) has 24 items divided into four 6-item subscales. The subscales include "ease of communication", "reverberation", "background noise" addressing speech understanding in various everyday environments and "aversiveness of sounds" which quantifies negative reactions to environmental sounds.⁸² The Health Utilities Index Mark 3 (HUI3) questionnaire assesses 8 attributes – Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition and Pain – each with 5 or 6 levels of ability/disability.

It is used to describe health status and to obtain utility scores which consequently are used to estimate health-related quality of life and quality-adjusted life years.⁸³

De Wolf et al used both the APHAB and HUI3; the BAHD showed benefit in children with both unilateral and bilateral hearing loss with the magnitude of benefit being greater in the latter group. Overall mean health utility scores and disability index scores on the HUI3 were similar.²⁸

The Speech, Spatial and Qualities (SSQ) of hearing scale for children is an adaptation of the original SSQ.⁸⁴ The questionnaire evaluates hearing abilities across 3 domains: “speech perception”, “spatial hearing” and “other qualities”. Dun et al used only the “spatial hearing” component of the questionnaire because their aim was to assess the benefit of using bilateral BAHDs; they found a trend towards better spatial hearing with the child had bilateral aids at a younger age.⁵¹

The most commonly used method to assess BAHD outcome is the Glasgow Children’s Benefit Inventory.⁸⁵ It was designed and validated as a retrospective questionnaire to assess benefit after a surgical intervention. It consists of 24 questions with each question having five-answer options (five-point Likert scale ranging from a large change from the worst to a large change for the better). A summary score is calculated from all the questions, then divided by 24 and multiplied by 50 to produce a score from -100 to +100. A positive score indicates surgical benefit from the procedure, a negative score indicates the opposite and a score of zero indicates no change.

Future of the BAHD & potential implications

Recent developments in bone conduction hearing systems have seen the introduction of transcutaneous devices such as the Alpha 1 (Sophono™) and Bonebridge™ (Medel)⁸⁶, although the latter device is not currently approved for children. Its main advantage is that it has no skin-penetrating abutment and therefore eliminates the risk of abutment skin reactions. Aesthetically there is no visible external abutment and also less risk of trauma. The external sound processor is held in place by magnet which is transcutaneously coupled to another magnet on an internal osseointegrated component beneath the skin.

Early experience with the Sophono has been positive showing minimal skin reaction rates and audiological benefit in both adults & children.^{87,88} However, one study compared the Sophono with a traditional percutaneous BAHD (6 children in each group). It showed similar skin reaction results but the percutaneous BAHD showed slightly better audiological results in sound field thresholds, speech recognition threshold, and speech comprehension at 65 dB. A skull simulator was

used to compare both systems and it showed the percutaneous BAHD had an output 10 to 15 dB higher compared with the Sophono device.⁸⁹

As shown already, it is not unusual for paediatric candidates for a bone anchored hearing implant to have other co-morbidities such as neurological conditions. These conditions often require magnetic resonance imaging for diagnosis and/or monitoring. Therefore the presence of magnetic components in these transcutaneous devices may be problematic. Theoretically the internal magnetic component of these transcutaneous devices could be removed if a MRI scan was essential however this would be invasive and require a general anaesthetic. No such MRI compatibility issues exist with the more traditional, percutaneous bone anchored hearing devices as these have an osseointegrated titanium implant.

Thesis Prelude

The paediatric BAHD was introduced to the Birmingham Children's Hospital, UK in 1988. The Birmingham paediatric BAHD programme began in earnest in 1992 and has developed into one of the largest in the United Kingdom over the last 20 years and provides a fully comprehensive, multi-disciplinary approach for children. This PhD thesis, the second from the Birmingham Paediatric BAHD group, focuses on recent advances and extended applications of Bone Anchored Hearing Devices in children.

This thesis begins with a review paper describing the role of the BAHD in children. It describes the indications for a BAHD in a child and also focuses on particular surgical challenges applicable to the paediatric population. It also provides a summary of recent trends and advances in paediatric BAHD surgery.

The thesis continues with individual papers looking at extended applications of the BAHD in children.

Children with behavioural problems

Previously reported papers of children in this group have been on the mild to moderate end of the spectrum of behavioural problems^{73,90}; the numbers were small (22 patients) but all these patients were able to have a trial of a bone conductor on a headband. We report our experience with 4 children at the severe end of the spectrum where no formal trial of a hearing aid was possible.

Use of 8.5mm abutment in children

The use of the 8.5mm abutment and its long-term outcome in the paediatric population has not been reported in the medical literature. We describe our experience with the use of the 8.5mm abutment in a series of 16 children who have required a long abutment.

Quality of life in children treated with a BAHD for single sided sensorineural deafness

Compared to the adult population, there is less experience of the outcome of using a BAHD in children with single sided deafness. The aim of this paper is to report our experience in a series of children with single sided sensorineural deafness where a BAHD was used for auditory rehabilitation.

The quality of life in children with unilateral conductive hearing loss: a patient carer perspective

The aim of this paper was to evaluate the impact that a BAHD has on the quality of life in children with symptomatic unilateral conductive hearing loss (UCLH).

Magnetic Resonance Imaging - implications for children with a BAHD

Recent developments in bone conduction hearing systems have seen the introduction of transcutaneous devices comprising of magnetic components. Our aim was to identify the number of children implanted with a traditional, non-magnetic percutaneous BAHD who would not have been eligible for a transcutaneous implant based on magnetic resonance imaging (MRI) need.

BAHD Dressings & Infection rates

In addition, an observational study of BAHD infection rates using different post-operative dressings is included in this thesis. Although the subject population comprised of adults, this study reinforces the need for meticulous postoperative care of the abutment site by the medical team and the patient, which is of even more importance in the paediatric population.

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Chapter 1-2

Bone anchored hearing devices in children: an update

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Abstract

Objective: Over recent years, there have been a significant number of publications reporting evolving bone anchored hearing device (BAHD) indications and modifications in surgical techniques. We aim to present a review of recent trends in paediatric BAHD surgery and also discuss alternative treatment options available.

Methods: All papers referring to paediatric BAHD surgery (English language) were identified from Medline, Pubmed, Cochrane library and Embase search in May 2011. Abstracts were read and relevant papers were obtained.

Results: BAHDs have evolved over recent years as technology has advanced. New bone conduction hearing devices have recently been launched such as the Ponto system [Oticon™], Alpha 1 (M) hearing system [Sophono™], Soundbite system [Sonitus™] and the Vibrant Soundbridge system [Medel™]. Modifications to existing implant systems have significantly altered BAHD practice with earlier loading of the sound processor now a positive step forward.

Conclusions: The latest generation of percutaneous devices have been designed to reduce skin complications, promote better osseointegration and earlier loading of the sound processor. Alternative devices without a skin-penetrating abutment are now available and have shown promising results in the paediatric population.

Introduction

Bone anchored hearing devices (BAHDs) have been commercially available since 1987.¹ They work on the principle of sound conduction through bone via a percutaneous osseointegrated implant. Over recent years, there have been a large number of publications reporting evolving indications for these devices and modifications in surgical techniques. The aim of this paper is to present a review of recent trends in paediatric BAHD practice and also discuss the alternative devices available.

Indications

The indications for a BAHD in the paediatric population include²

1. congenital aural atresia
2. congenital microtia
3. chronic suppurative otitis media
4. persistent otitis media with effusion
5. chronic otitis externa
6. unilateral profound hearing loss
7. unilateral mixed hearing loss
8. failure with conventional aids
9. trauma to ear (e.g. traumatic ossicular disruption)

The benefits of a BAHD in congenital aural atresia and microtia in children are well documented.^{3,4} The BAHD provides a method for acoustic input and has shown to improve quality of life. The BAHD does not preclude reconstructive surgery at a future date providing the implant is appropriately placed. The BAHD has also been shown to be beneficial in children with bilateral and unilateral conductive or mixed hearing loss.⁵ Subjective benefit was reported to be greater in children with bilateral BAHDs in terms of better sound localisation and speech recognition in noise.^{5,6,7}

There is increasing evidence that a BAHD can be of benefit in children with profound unilateral sensorineural hearing loss.^{8,9} Christensen et al reviewed 23 children (age range 6-19) that had a BAHD for single sided deafness.⁸ They assessed outcome using two questionnaires - Hearing in Noise Test (HINT) and Children's Home Inventory for Listening Difficulties (CHILD). Scores before and after surgery showed noticeable improvements in hearing in noise and listening difficulties scores.

Certain subgroups of children have been shown to benefit from a BAHD. In particular, children with Down's syndrome¹⁰ and children with learning or behavioural difficulties who find conventional behind-the-ear aids difficult to tolerate have shown very positive results when assessed with the GCBI^{11,12,13} and have no reported increase in complication rates.¹⁰

Bone anchored hearing aid surgery is best provided by a multidisciplinary team. The audiologist is a key member of this team. Initial assessment is aimed at correctly identifying those children who fit the audiological criteria for a BAHD. A suitable trial of a BAHD on a headband is essential to predict both subjective and

objective benefit from the device. Debate remains regarding the appropriate length of this trial but the authors suggest three months. In some children with severe behavioural problems, where BAHD assessment and trial is not possible, BAHD surgery can be undertaken with good outcomes.¹³ A multidisciplinary team approach is important when working with these children and their families.

What age to implant?

The United States Food and Drug Administration (FDA) medical product guidelines states the minimum age for a bone anchored hearing device is 5 years old.¹⁴ However, the age of implantation continues to cause debate – there is no currently accepted clinical consensus for a minimal age for surgery.¹⁵ Traditionally, emphasis was placed at implanting when a child was old enough to have adequate skull thickness. This was thought to be above the age of three thus allowing the fixture (3 or 4mm) to be inserted to the optimal depth for osseointegration.¹⁶ Complication rates have been quoted to be higher in children implanted at a very young age^{17,18} however BAHD surgery has been performed successfully and with no reported complications as young as 14 months old.¹⁹

Single stage surgery and sleeper fixtures

BAHD surgery in children has traditionally been performed as a two-stage procedure with placement of a second, ipsilateral “sleeper” fixture for use in cases of implant extrusion. Placement of a sleeper fixture on the contralateral side has been described in children with bilateral hearing loss who may wish bilateral implantation at a later date. It has been suggested that this approach is a more cost-effective use of the “sleeper device” and reduces the total number of procedures needed.²⁰

The attraction of single stage surgery is that it only requires one general anaesthetic. Single stage BAHD surgery has been reported in children as young as 3 years old^{15,21-23} and the benefit of a sleeper fixture has been questioned in view of refinements in implant design which have reduced the chances of osseointegration failure.²⁴ The Nijmegen group with experience of a 1000 patients (145 were children) found that those children over the age of 10 years were most suitable for single stage surgery [Personal communication, Professor Cremers Sept 2011].

Surgical procedure

The goal in BAHD surgery is to achieve osseointegration of the implant with minimal surrounding skin reaction. Over the years, there have been a number of modifications of the original technique first described by Tjellstrom.²⁵ In the traditional two-stage surgery, the fixture was inserted into the skull at the first stage. After a period of time to allow for osseointegration, the second stage comprised of a skin graft (free or pedicle), soft tissue reduction and abutment placement.

A variety of skin graft techniques have been described and the introduction of a powered dermatome (BAHA ® Dermatome) provided a reproducible method of providing suitable thin skin around the abutment.²⁶

Soft tissue reduction at the first stage has also been reported in the older child.²⁷ At the second stage, the abutment can be placed onto the fixture following a “skin punch” under local anaesthetic in the outpatient setting.

The linear incision technique was developed in the early 1990s with the aim of simplifying the surgical technique by removing the need for a skin flap and therefore avoiding the risk of flap necrosis.²⁸ Other reported advantages include minimal disturbance of the skin at the implant site and a reduction of surgery time to approximately 20 minutes in experienced hands.

The Nijmegen group reported favorable outcomes using this technique in 129 paediatric cases. The majority were performed as a two-stage procedure (71%) and skin reaction and fixture loss rates were comparable to paediatric BAHD surgical techniques using a skin flap.²⁹

Ideally, it would be beneficial to assess the skull thickness prior to drilling, as in practice several burr holes may be necessary intra-operatively in order to find adequate calvarium bone thickness to accommodate the fixture and abutment. Federspil et al reported a cadaveric study that used a handheld ultrasound probe to measure skull thickness and found it to be comparable to computerized tomography (CT) measurements.³⁰ Ultrasound imaging may also prove useful to find the implant for stage 2 BAHD surgery. Ultrasound machines are available in most operating theatres as anaesthetists commonly use them for central line placement. The ultrasound probe could be used before draping the patient to locate the fixture and mark the site of surgery.

Complications

Paediatric BAHa practice is not without its challenges and complications including trauma are well reported.¹⁸ The most common complication in paediatric BAHd practice is a peri-abutment soft tissue reaction. Holger's skin reaction classification ranges from skin irritation and erythema to an overt infection causing implant extrusion.³¹ A variety of postoperative dressings have also been described which may influence skin reaction rates.^{32,33} However, in our clinical experience, one of the most important factors to minimize any postoperative skin problems is careful wound care and skin hygiene around the abutment; the child and their carers play an important role in this regard.

Problems with skin hypertrophy and/or abutment skin overgrowth can occur several years after the original BAHd operation and is typically reported at the time of puberty.³⁴ This can be treated using topical steroids cream and injections although the latter may be poorly tolerated in children.³⁵⁻³⁷ Abutment skin overgrowth may require skin reduction surgery. There is increasing evidence that changing to a longer 8.5mm abutment can be useful in these cases; this abutment change may be changed in the outpatient setting in older children thus avoiding a surgical skin reduction.^{34,38}

The pathogenesis of the skin reactions is unclear. A study by Khwaja et al suggested keratin as the causative factor; a foreign body reaction was demonstrated to keratin and keratinocytes at the titanium bone interface.³⁹ A more recent study by Grant et al has demonstrated significantly elevated levels of key biomarkers of inflammation (e.g. tumour necrosis factor, interleukin 1 etc) from fluid exudate around inflamed abutments compared to non-inflamed abutments.⁴⁰ Studies from dental implants suggest that micro-leakage of bacteria in the connection between the implant and abutment may contribute to abutment skin reactions.⁴¹⁻⁴³ Biofilm formation on the threads of the abutment screw has also been demonstrated on BAHd implants that failed to osseointegrate.⁴⁴ In practice, the skin reaction is likely to be due to a combination of the above factors.

Updates in BAHD design/processors/new manufacturers

The design of the BAHD has evolved over the past two decades – the latest generation of Cochlear™ BAHA® implant design (series BI300) has new characteristics:

1. Wider diameter implant (4.5mm versus 3.75mm) to increase implant stability
2. A smaller sized thread at the implant neck which improves optimum load distribution
3. A roughened surface (Tioblast™ coat) on the intraosseous part of the implant that increases the rate and strength of osseointegration.

These design changes have been shown in pre-clinical models to be superior in terms of osseointegration and implant stability when measured using resonance frequency analysis.^{45,46} A randomized, prospective multi-centre clinical study of 77 adult patients comparing the new design with the previous generation has showed that adequate osseointegration occurs as early as 6weeks (when measured with resonance frequency analysis (RFA)⁴⁷; this provides promising data which may eventually lead to loading of sound processors at an earlier stage in children. The latest Cochlear™ Baha® 3 System sound processor portfolio have both technological and practical advances for children with a wide range of hearing loss. Automated bidirectional hearing and noise reduction systems improve sound quality and clarity; the processors are also available in various child friendly aesthetic colours and have been designed to allow the parents, carers or child to easily identify if the hearing aid is functionally correctly.^{48,49}

Ponto system

In 2009, Oticon Medical™ introduced the Ponto® bone-anchored hearing aid system. Similar to the system from Cochlear™, it consists of an implant, percutaneous abutment and an external sound processor. Recent clinical studies with this device have been very encouraging and the Ponto® is now another well-accepted choice in the field of BAHDs.⁵⁰

The Oticon™ abutment is available at a 10-degree inclination if needed for patients with abutment skin problems. The latest generation of processor (Ponto Pro series) contains features such as automatic adaptive multiband directionality, noise reduction and learning volume control which have been shown to perform better than the first generation of Cochlear BP-100 processors in a small series of 9 patients.^{51,52}

Recent experience of the longer 12mm abutment have been positive [Personal communication, A Childs to AL McDermott & P Sheehan to AL McDermott]

Transcutaneous bone anchored hearing device

The development of a BAHD without a percutaneous abutment is now available.⁵³ The Alpha 1 (M) hearing device by Sophono™ comprises of a surgically implanted internal plate that houses two magnets hermetically sealed in a titanium case. The external sound processor houses a bone oscillator and uses a metal disc and spacer shim to magnetically couple to the internal component and deliver auditory stimulation through the closed skin. This has been used in over a series of 100 patients (adults and children above the age of 5 with bone conducting thresholds better than or equal to 45 dB HL).⁵⁴ Its main advantage is that it has no skin-penetrating abutment and therefore eliminates the risk of abutment skin reactions. The sound conduction principle for this device is identical to the bone conduction hearing aid on a headband. This device may be particularly useful in children for a number of reasons. There is no percutaneous abutment therefore no peri-abutment skin problems and less risk of trauma. Aesthetically, there is no visible external abutment although an external sound processor is still necessary.

Many of the children seen on BAHD programmes may require autologous ear reconstruction at a later date. Autologous reconstruction can be compromised by any surgical incision in the area behind where the neo-auricle is to be placed. Soft tissue reduction is not required for a transcutaneous implant and the skin incisions may be placed distal to the proposed surgery site for autologous reconstruction. However, a major disadvantage is that the magnetic component within the device may prevent the use of magnetic resonance imaging (MRI).

The BAHD on a headband continues to be a valuable method of providing aural rehabilitation to very young children who are too young for surgery or may have other medical concerns.^{55,56} The bone anchored hearing device on a headband is the gold standard for pre-operative assessment in children and can be used to predict the potential benefit of an implanted BAHD. The final hearing result with the bone-anchored device after implantation is usually better than with the sound processor attached to the headband⁵⁷; the difference has been reported as much as 18dB.⁵⁸

Intra-oral bone conduction device

The SoundBite Hearing System (Sonitus [™]) is a removable, non-surgical hearing aid system that transmits sound through bone conduction to the cochlea via the teeth. It is currently licensed for adults with a conductive hearing loss and single sided deafness.⁵⁹ A recent study has shown the device to be beneficial in 22 adults with single sided deafness who used it for 6months; there were no reported adverse events.⁶⁰

It has two components: a removable “in the mouth” hearing device and an external behind the ear microphone unit worn on the impaired ear. Both components have rechargeable batteries. No dental work or modifications to the teeth are required; the intraoral device is hermetically sealed inside a dental grade acrylic and sits behind the back upper molars. The microphone picks up the sound at the ear and transmits the signal wirelessly to the intra-oral device. A small actuator converts the signals into vibratory energy, which is transmitted through bone to the cochlea.⁶¹

In the future of paediatric hearing rehabilitation, this device may be prove to be a viable hearing rehabilitation option particularly for older teenagers; it would offer a much more acceptable cosmetic alternative to the current bone conduction headband for this image conscious age group.

Vibrant Soundbridge

The Vibrant Soundbridge (Medel[™]) indications for adults include conductive, sensorineural and mixed hearing loss. In June 2009, the Vibrant Soundbridge received approval for patients younger than 18 years of age in the European Union. Reports to date have shown it to be another treatment option in paediatric patients with ear canal atresia and ossicular anomalies by placing the floating mass transducer (FMT) on the long process of the incus, mobile stapes remnants, round or oval window.⁶² However, a pre-operative computerized tomography (CT) scan is needed and there is no option of a preoperative headband trial. Magnetic resonance scanning can also cause dislocation of the FMT.⁶³ Therefore these factors, in addition to cost, may limit its use in the paediatric population.

Conclusion

The bone-anchored hearing devices are important hearing rehabilitation tools. There have been significant advances in the past few years, which have improved the stability of the implant and shortened the time to loading of the processor. There have been also advancements of the processors, which are now all digital and have improved sound quality. New techniques and devices which deploy bone conduction have been introduced which will make surgical rehabilitation of conductive and mixed hearing loss an expanding sub-specialty area of auditory rehabilitation.

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Chapter 2

The use of a bone-anchored hearing device (BAHD) in children with severe behavioural problems – the Birmingham programme experience

Jayesh Doshi, Ann-Louise McDermott, Andrew Reid, David Proops

Abstract

Objective: A trial of a bone conductor is traditionally used to determine whether a bone anchored hearing device (BAHD) will be beneficial to a child. However there is a subgroup of children where a BAHD assessment is not possible due to severe behavioural/mental/sensory disorders. We describe our experience in a small series of such children.

Method: Retrospective case series review of four children at the severe end of the spectrum of behavioural difficulties who underwent BAHD implantation where no formal preoperative hearing aid assessment was possible. The Glasgow Children's Benefit Inventory and a visual analogue scale assessing health status were used to determine the benefit of BAHD implantation in this group.

Results: There was no surgical morbidity in this group although a more intensive postoperative follow up was required. All four children wore their hearing aids at least 8 hours a day. Parents reported a positive impact of the BAHD on the behaviour and mood of their children. The BAHD showed a positive benefit when assessed using the Glasgow Children's Benefit Inventory and showed a positive change in health status.

Conclusions: We feel that our early experience with BAHD in children with severe behavioral difficulties has been positive to date. Multidisciplinary teams should not dismiss these children even if a trial of a bone conductor is not possible. We feel that the bone-anchored hearing aid has been successful in our cases because the children do not physically feel the presence of the hearing aid.

Introduction

The decision to use a bone-anchored hearing device (BAHD) in a child traditionally depends upon

1. determining hearing thresholds using age-appropriate hearing tests
2. trial of a bone conductor or softband device
3. counseling of the child and parents/guardians

However there is a subgroup of children with severe behavioural problems where this full assessment is not possible. Hearing thresholds may have to be obtained under a general anaesthetic and a trial of a bone conductor softband device may

not be possible because of the child's extreme behaviour. The aim of this paper is to describe our experience with four such children with severe behavioural problems and discuss the problems we faced when assessing whether a BAHD would be suitable.

Methods

Case 1

A five-year-old male was referred to our department for a right external auditory canal agenesis and right pinna aplasia. The left external auditory canal was narrow with a normal pinna. Past medical history included hemi-facial microsomia, developmental delay, visual impairment and behavioural difficulties. His behaviour prevented any awake audiometry testing; auditory brainstem response under general anaesthesia demonstrated air conduction thresholds of 60dB HL in the right ear and 30dB HL in the left ear. Bone conduction thresholds were between 10-20dB. Attempts of using a right bone conductor (BC) aid and a left behind the ear (BTE) hearing aid had been unsuccessful; he removed the hearing aids within minutes and it was difficult to ascertain if he was receiving any significant benefit from them. He underwent a two-staged right-sided BAHD implantation in 2008.

Case 2

A six-year-old male presented to our department with a long-standing history of otitis media with effusion. Past medical history included craniosynostosis, developmental delay, visual impairment secondary to optic nerve hypoplasia, chromosomal abnormalities, congenital hypothyroidism and behavioural difficulties. His external auditory canals were very narrow which prevented grommet insertion. He would not tolerate wearing any hearing aids or his spectacles; interestingly he even found it difficult to tolerate the sensation of his own clothing. As a consequence of his behavioural difficulties, hearing thresholds were obtained under a general anaesthetic. Left and right air conduction thresholds were 60 and 50 dB HL respectively; bone conduction thresholds were between 30-40dB HL. He underwent bilateral BAHD implantation in 2008.

Case 3

An eight-year old girl presented to our department with a long-standing history of otitis media with effusion. She had multiple sets of previous ventilation tubes however these had to be removed because of recurrent infections. Past medical

history included hemi-facial microsomia, developmental delay, visual impairment and severe behavioural problems. Pure tone audiometry thresholds could only be obtained for one frequency at each visit because her behavioural problems. Her left and right air conduction thresholds were 50dB HL (four frequency average) and bone conduction thresholds were 10dB HL; it took approximately six months to complete the assessment.

Case 4

A five-year-old boy presented to our department with a long-standing history of a bilateral mixed conductive hearing loss. Past medical history included global developmental delay, Fallot's tetralogy, Arnold-Chiari malformation, bipolar mood disorder, Tourette's syndrome, dysmorphism and challenging behaviour. Brainstem responses showed left and right air conduction thresholds of 60dB HL with bone conduction thresholds of 30 dB HL. Trials of hearing aids had been unsuccessful as he violently threw them away every few minutes. He underwent a right and left BAHD implantation in 2004 and 2008 respectively.

The demographics and indications of using a BAHD in each of the children are summarized in table 1.

Table 1. Demographics and indications for BAHD

Patient	Indication for BAHD	Treatment	Age (years)when BAHD fitted	Other problems
1	Right external auditory canal agenesis	Right BAHD	5	Developmental delay Visual impairment Hemifacial microsomia
2	Mixed hearing loss	Bilateral BAHD	6	Craniosynostosis Visual impairment Multiple chromosomal abnormalities Developmental delay
3	Glue ear – recurrent otorrhoea with previous grommets	Bilateral BAHD	8	Hemi facial microsomia Visual impairment Developmental delay
4	Mixed hearing loss	Bilateral BAHD	5	Dysmorphism Severe learning difficulties Abnormal electrophysiological brain activity – unknown cause Fallot's tetralogy

A questionnaire was sent retrospectively to the parents/guardians of all four children. The questionnaire consisted of the validated Glasgow Children's Benefit Inventory (GCBI) and a 10 cm visual analogue scale to assess any change in health status. The GCBI is a subjective child orientated post-interventional questionnaire especially developed to evaluate any paediatric otolaryngology surgery and therapy.¹ The GCBI consists of 24 questions based upon a five point Likert scale (ranging from +2 to -2). A score of +2 shows a maximum change for the better whereas a score of -2 corresponds to a maximum change for the worse. All the scores are added together, divided by 24 and multiplied by 50. This gives score between +100 (maximum change for the best i.e. benefit) and -100 (maximum change for the worst- i.e. harm). The 10cm visual analogue scale was also included to directly assess health status of the child before and after the BAHD. A positive change in health status (i.e. score greater than zero) implies benefit to the overall health of the child whereas a negative change in health status (i.e. score less than zero) implies deterioration in the overall health of the child.

Results

Postoperative Care

The immediate postoperative care was more challenging for both parent and surgeon. The children would not tolerate a postoperative compression head bandage – all dressings had been completely removed by the child before leaving the operating suite.

Following the second stage procedure, an intensive postoperative care regime was required with more frequent visits to the outpatient department to check the site of the BAHD. There was no surgical morbidity. The patients who had bilateral BAHDs were done sequentially.

Postoperative Assessment

Follow up ranged from 6 months to 4 years. All patients wore their BAHD for more than 8 hours per day. No formal postoperative audiology was possible in the early postoperative months. Since they had a good clinical result following their BAHD, testing under general anaesthesia was not deemed appropriate. Two children began to vocalize within 6 weeks of their BAHD (case 1 and 2) and all four cases were noted to have improved behaviour and reduced frustration. It was interesting that two guardians noted music to now be a very successful method of managing

difficult behavioural issues (cases 2 and 4). All parents reported a very positive impact following the BAHD. This was reflected in the GCBI and visual analogue scores (figures 1 and 2)

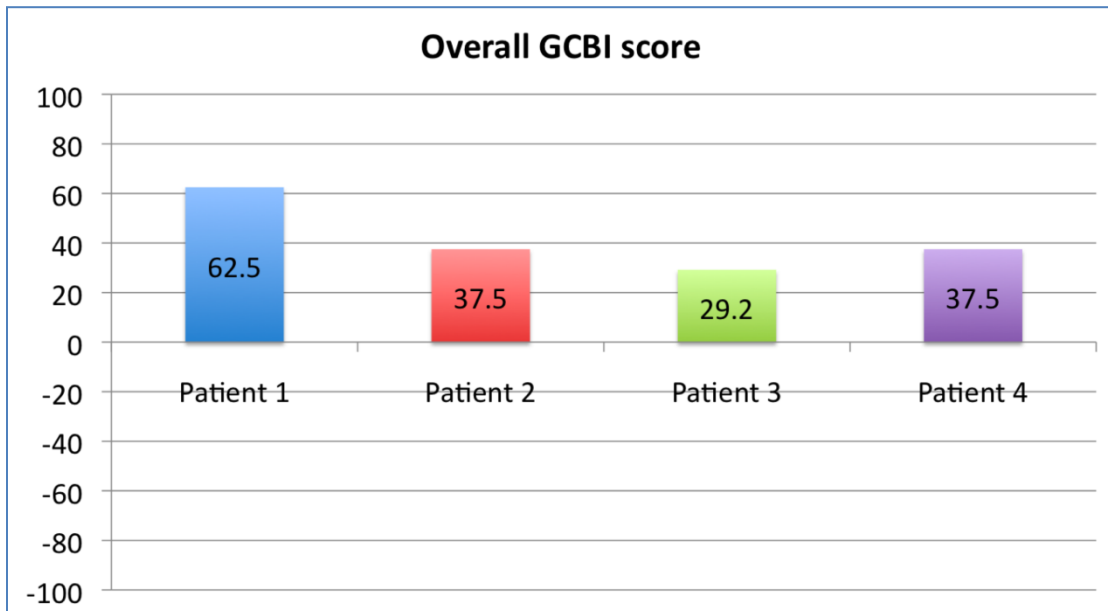


Figure 1. GCBI score for each patient

N.B. Patient 1 had a unilateral right BAHD (normal hearing in left ear). The remaining patients had bilateral BAHDs.

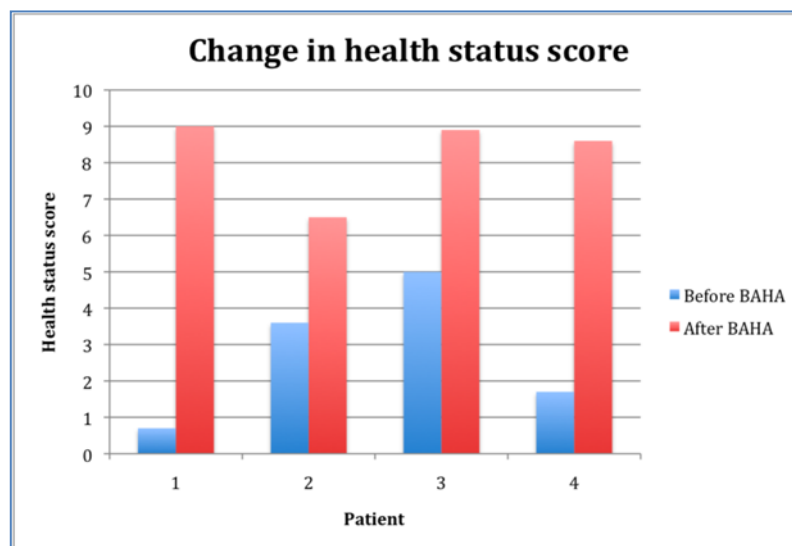


Figure 2. Change in visual analogue score for health status.

Discussion

Previous studies have found a BAHD to be useful in specific patient subgroups. This includes patients with Down's syndrome who may also have learning and behavioural difficulties.² BAHD has also been shown to be useful in patients with mild mental retardation.^{3,4} However all of these patients had been able to have a trial of a bone conductor/soft band preoperatively to assess whether a BAHD would be beneficial.

Our group of children represented the extreme end of the spectrum of behavioural disorders and so the trial of conventional aids, bone conductor aids and a softband was not possible. The hearing thresholds (ABR or pure-tone) for these children confirmed a BAHD would be beneficial from an audiological perspective. The decision to perform the surgery was made without the trial of a bone conductor/soft band. The parents and guardians were fully informed and made the final decision to proceed after a thorough consultation from our BAHD team.

Why do these children tolerate a BAHD when they have sensory intolerance to glasses, clothes and conventional hearing aids?

A potential advantage of a BAHD is the lack of contact between the sound processor and the skin. Due to the lack of detailed communication with these children, we can only speculate that these children were less aware of the BAHD simply because the sound processor sits on an abutment and is not in contact with the skin. There may also be some skin numbness around the abutment site as this has been reported in some cases.⁵ The sound processor could have easily been removed from the abutment by the child however parents/guardians reported that these children did not interfere with the BAHD.

The fitting of the BAHD was an emotionally traumatic procedure for each child however all the guardians/parents reported a complete acceptance of the BAHD within the first 3 days.

Our experience with children with significant learning difficulties, suggest that they benefit both from an audiological and quality of life perspective following a BAHD. There have been no traumatic episodes and no fixture loss or skin problems in any of these children.

Finally, all children with such severe learning disabilities should be assessed very carefully and managed by a BAHD multidisciplinary team. Families and guardians should be fully informed of the options including any potential difficulties and problems that may occur with the provision of a BAHD.

The options of BAHD should not be dismissed purely on the grounds of the severity of their behavioural problems. Each case should be considered on its own

merits. Parents and surgeons need to be prepared for a more challenging post-operative period, however our results in this small cohort of children has been very rewarding. Parents /guardians have reported an improved quality of life for each child.

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Chapter 3

The 8.5 millimetre abutment in children – the Birmingham Bone Anchored Hearing Device programme experience

Jayesh Doshi, Ann-Louise McDermott, Andrew Reid, David Proops

Abstract

Objective: To the best of our knowledge, the use of the 8.5 millimetre (mm) abutment and its long-term outcome in the paediatric population has not been reported in the medical literature. We describe our experience with the use of the 8.5mm abutment in a series of 16 children who have required a long abutment.

Study Design: Retrospective case series review

Setting: Tertiary hospital

Patients: Patients less than sixteen years of age who had a 8.5mm bone anchored hearing device abutment fitted.

Intervention: Use of a 8.5mm bone anchored hearing device abutment.

Main Outcome Measures: Indications and complications with using the 8.5mm abutment.

Results: We have used the longer abutment on both 3mm and 4mm fixtures. We have found the need to use it particularly around the time of puberty when we observed soft tissue problems develop. Follow up after insertion of the long abutment ranged from 6 months to 6 years. There was one fixture extrusion 2years after a long abutment had been fitted.

Conclusion: Overall, we have found the long abutment to be useful in a selected paediatric population.

Introduction

In the adult population, a 5.5mm abutment is usually inserted onto a 4mm fixture at the time of primary bone anchored hearing device (BAHD) surgery. Soft tissue overgrowth around the abutment is a recognized problem – it may be treated topically with steroids preparations or may require surgical soft tissue reduction.^{1,2,3} In patients who do not respond to this treatment, the standard 5mm abutment may need to be changed to the longer 8.5mm abutment and this has shown to be beneficial in the adult population.⁴

Paediatric BAHD patients can differ from adults in the following ways

- 1) The surgery is often two staged rather than single stage;
- 2) A 3mm fixture may be used instead of a 4mm fixture due to thinner cortical bone;
- 3) It is performed under a general anaesthetic rather than local anaesthetic;
- 4) The indication for a BAHD may be related to a syndromic condition. These children often have multiple co-morbidities that may affect the healing process and ideally the number of general anaesthetics should be minimized.

To the best of our knowledge, the use of the 8.5mm abutment and the long-term outcome in the paediatric population has not been reported in the medical literature.

The aim of this paper is to discuss

- 1) Our indications for using the longer abutment
- 2) Complications we encountered using the longer abutment

Methods & Patients

Sixteen patients (six female and ten male) who had a 8.5mm abutment fitted were identified from our departmental database. The age of when the BAHD was fitted ranged from 3 to 15 years of age (mean 9.6 years old).

BAHD placement was a single stage operation in 3 patients and the remaining 13 patients had a two-stage operation.

Nine patients had a 3mm fixture inserted at the primary surgery due to thin cortical bone thickness; the remaining seven patients had a 4mm fixture inserted. All patients had a 5.5mm abutment placed initially at either their single or second stage operation.

Indications for using the BAHD are shown in table 1.

Method of changing abutment

The BAHA® torque rench set was used in conjunction with the counter torque rench to remove the 5.5mm abutment. The 8.5mm abutment is then secured using the same instruments. No local anaesthesia is required; the process of changing

to a longer abutment took only a few minutes to perform. Figure 1 demonstrates the difference in the length of the abutments.

Table 1. Indications for using a bone anchored hearing device

Indication	Number of patients
Persistent otitis media with effusion associated with Downs syndrome	4
Conductive hearing loss secondary to aural atresia/microtia	3
Conductive hearing loss associated with syndromic middle ear/external ear atresia/microtia	5
Unable to use "behind the ear" hearing aids due to recurrent ear infections refractory to medical treatment	4



Figure 1. 5.5mm and 8.5mm abutment (Figure courtesy of Cochlear®)

Results

Reasons for requiring a longer 8.5mm abutment included thickened skin round the original 5.5mm abutment preventing the BAHD to be attached (12 patients) and skin growth over the 5.5mm abutment (4 patients). Examples are shown in figures 2a and 2b. These latter four patients had skin reduction under a general anaesthetic and a longer abutment inserted whereas the former 12 patients had their abutment changed in the outpatient department without the need of an anaesthetic. All the histology results from the patients who had skin reduction around the original 5.5mm abutment showed a foreign body giant cell reaction secondary to keratin.

The mean age of our patients when they required the use of a long abutment ranged from 7-16 years of age (mean 14.2 years old).

Follow up after insertion of the long abutment ranged from 6 months to 6 years.



Figure 2a:
Skin flush against the 5.5mm
abutment



Figure 2b.
Skin growth over a 5.5mm
abutment

Only one patient had a complication after a long abutment was used. A patient with Treacher Collins syndrome had the initial two-stage BAHD surgery performed at the age of 7 when a 5.5mm fixture was placed on a 3mm fixture. At the age of 14, overgrowth of skin around the abutment required a skin reduction and insertion of a 8.5mm abutment. Two years later, the fixture and longer abutment became loose and fell out spontaneously. A 5.5mm fixture was subsequently placed on a sleeper fixture that had been inserted at the primary surgery.

Discussion

The Birmingham BAHD programme has implanted 182 children (less than 16years old) between 1992 and Feb 2007; a large proportion of these patients are syndromic and have complex medical problems.⁵ In addition, behavioural problems are not uncommon and consequently treatment of skin problems around the abutment can be challenging for both the surgeon and the parents.

The most common reason we found for using the longer abutment was soft tissue overgrowth that prevented the BAHD from attaching to the abutment. One of the causes of skin overgrowth is due to failure of adequate soft tissue reduction at the primary operation⁶; it has also been suggested that the technique of soft tissue reduction may also play a role⁷. However, we found that in our cohort of patients that the majority had a trouble free period for many years and it was not until puberty that skin problems developed. Puberty involves hormonal fluctuations and this is known to have effects of the structure and physiological activity of the skin.^{8,9}

We found that the 5.5mm abutment could be easily removed and changed to the longer 8.5mm abutment in the outpatient setting avoiding the need for an anaesthetic, which was preferable in view of the co-morbidities of our paediatric population.

Our 4 patients who had growth of skin over the abutment naturally prevented changing to a long abutment in the outpatient setting; they underwent surgical reduction of the excess skin with a change in abutment length in theatre.

We had one extrusion of a 3mm fixture two years after a long abutment was placed on it. It was not related to trauma or infection therefore the cause of this

was unknown. One could postulate this may be due to a change in physical forces on the fixture itself. However there is currently no evidence in the literature of the ability of the fixture to withstand an increase in mechanical forces secondary to the longer abutment and the effect this may have on osseointegration - further studies are required to investigate this.

However, we have also had experience of using a 8.5mm abutments on 4mm (69 patients) and 3mm fixtures (30 patients) in our adult BAHD programme with no fixture extrusions⁵ (follow up 6 months to 5 years after changing to the longer abutment). The cohort of patients in the paediatric and adult BAHD programme are naturally very different and the osseointegration process may differ in the paediatric and adult skull.

In summary, we have found the long abutment useful in a selected paediatric population on both 3mm and 4mm fixtures. We have found the need to use it particularly around the time of puberty when we observed soft tissue problems develop. The long term outcomes of using a long abutment is still to be fully evaluated but our initial experience has shown promising results.

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Chapter 4-1

Quality-of-Life Outcomes After Bone-Anchored Hearing Device Surgery in Children With Single-Sided Sensorineural Deafness

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David Proops, Ann-Louise McDermott

Abstract

Objective: To report our experience in a series of children with single sided sensorineural deafness where a bone-anchored hearing device (BAHD) was used for auditory rehabilitation.

Study Design: Retrospective case review.

Setting: Tertiary referral centre.

Patients: Eight children (4 male & 4 female) who had BAHD surgery for single sided sensorineural deafness between 2007-2010.

Intervention(s): Bone-anchored hearing device was used for auditory rehabilitation.

Main Outcome Measure(s): Glasgow Children's Benefit Inventory (GCBI), Single sided Deafness (SSD) Questionnaire and change in health benefit scores (visual analogue scale).

Results: All but one of the children showed a positive GCBI score; the child that reported a negative score was due to low self-confidence and self-esteem issues secondary to bullying at school. The results of the SSD questionnaire were generally positive with a mean satisfaction score of the BAHD as 9/10. All the children had an improvement in health benefit.

Conclusions: Our findings add further evidence to support patient perceived benefit of a BAHD in single sided sensorineural deafness in the paediatric population.

Introduction

Single sided deafness (unilateral profound sensorineural hearing loss) has been reported to have an incidence between 0.1 to 3% in the paediatric population.^{1,2}

The cause of the hearing loss may be congenital or acquired. Historically, treatment options ranged from no intervention (especially if the contralateral ear had normal hearing thresholds) to FM amplification systems and contralateral

routing of signal (CROS) aids; these latter devices having limited user compliance.^{3,4}

In adults with single sided deafness, studies have shown both objective and subjective improvement in audiologic metrics with a bone anchored hearing device (BAHD) when compared to unaided conditions.^{5,6,7} Studies have shown that adults with single sided deafness treated with a BAHD do have an improved quality of life^{5,8} however this benefit may not be as great as other patient groups (e.g. conductive or mixed hearing loss).⁹ Compared to the adult population, there is less experience of the outcome of using a BAHD in children with single sided deafness.

The aim of this paper is to report our experience in a series of children with single sided sensorineural deafness where a BAHD was used for auditory rehabilitation.

Material and Methods

Eight children (4 male & 4 female) had BAHD surgery for single sided sensorineural deafness between 2007-2010.

All the children had been assessed by a community paediatrician and been fully investigated for the aetiology of the hearing loss.

The paediatric audiology department had referred these children to the otolaryngology department on the request of parents reflecting educational concerns resulting from their child's hearing.

All the children were assessed in the multi-disciplinary BAHD clinic and underwent a trial of using a bone conductor on a headband for a minimum of 3 months.

The parents/carers of the children were asked to complete a Glasgow Children's Benefit Index (GCBI) and a Single Sided Deafness (SSD) Questionnaire after a minimum of 6 months of BAHD usage.

The GCBI is a subjective child orientated post-interventional questionnaire especially developed to evaluate any paediatric otolaryngology surgery and therapy.¹⁰ The SSD questionnaire was specifically designed to be administered after BAHD implantation for single sided deafness; the questionnaire was first used in clinical study in 2003¹¹. It is based upon a questionnaire developed by Entific Medical Systems, which was published in the product's audiology manual.¹² We also asked the parents to mark on a 10cm visual analogue scale their child's health status before and after the BAHD.

Results

Clinical data

Four children had congenital hearing loss and four children had an acquired hearing loss. Patient 5 had sustained a skull base fracture following trauma at the age of 9 years old. Patient 6 had meningitis aged 3months old. In the remaining group of children, no aetiology for the hearing loss had been identified.

The age at which surgery was performed ranged from 7.5 years old to 12.2 years old. The patient demographics are summarised in table 1.

Table 1: Patient Demographics

Patient	Cause of unilateral hearing loss	Ear with single sided deafness	Age of referral for BAHD	Age of BAHD surgery	Year of surgery	Length of follow up (months)
1	Congenital - unknown	Left	5	9.5	2009	27
2	Congenital - unknown	Left	9.8	10.7	2007	56
3	Congenital - unknown	Left	6.2	7.5	2010	16
4	Congenital - unknown	Right	10.4	11	2009	30
5	Acquired - skull base fracture	Right	9	12.2	2007	52
6	Acquired - meningitis	Left	9.6	10.1	2008	41
7	Acquired - unknown	Left	8.2	8.9	2009	30
8	Acquired - unknown	Right	6.6	8.3	2010	21

None of the children had any significant co-morbidities. They all had normal or near normal air conduction hearing thresholds in the contralateral ear (table 2). Patient 6 had the worst air conduction thresholds in the contralateral ear [mean air conduction threshold of 23.3dB (0.5, 1 and 2KHz)] which may have been related to the episode of meningitis that caused SSD in the contralateral ear.

All the children underwent a two-stage procedure with a minimum period of 3months between the first and second stages of surgery. A “skin dermatome” technique was used in all cases. A 5.5mm abutment was used on 4mm fixture in

all the children. There were no postoperative skin complications with no cases of implant extrusion (follow up 16-56 months). All the children used a BAHD Intenso processor on their abutment.

Table 2. Air conduction thresholds (dB) in the better hearing ear

Pt	250Hz	500Hz	1kHz	2kHz	4kHz	8kHz
1	25	20	5	-5	-5	0
2	10	5	5	-5	0	-10
3	-	20	20	5	10	-
4	-	5	0	0	0	-
5	20	20	15	15	5	25
6	35	25	25	20	20	10
7	15	15	5	5	5	-
8	5	5	5	-5	-10	-

All patients had a profound sensorineural hearing loss in the poorer hearing ear

Questionnaire results

GCBI

The GCBI scores ranged from -6.3 to 68 (figure 1) with a median of +47.5. All patients but one child (patient 5) showed an improvement in GCBI results. An analysis of the subcomponents making up the GCBI score of patient 5 showed that the negative scores were within the “emotional” subcomponent of the GCBI whereas the “health”, “learning” and “vitality” subcomponents were neutral or positive. On further questioning, patient 5 had confidence and self-image issues secondary to bullying at school.

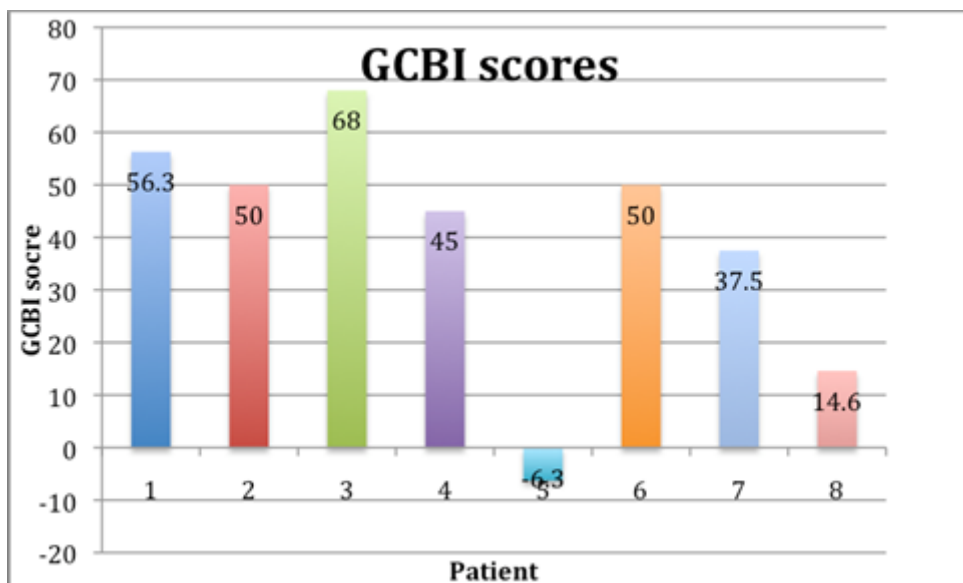
SSD questionnaire results.

The majority of children (6/8) used their BAHD for 7days/week and 7/8 children used the BAHD for more than eight hours a day (figures 2 and 3).

The average satisfaction score was 9/10 with the BAHD; 5/8 thought the quality of life had improved.

There was a subjective benefit whilst using the device one-to-one in half the children; the other half did not report a difference.

Using the device within a group, all but one of the children felt the BAHD was beneficial. There was perceived benefit by the majority of children when using the device to listen to music, TV or radio. There was also a perceived benefit of the BAHD by the vast majority of children when someone spoke to them on their deaf side in a daily commonplace scenario (at the dinner table). Results are summarised in figure 4.



GCBI - Glasgow Children's Benefit Inventory

Figure 1. Glasgow Children's Benefit Inventory Scores

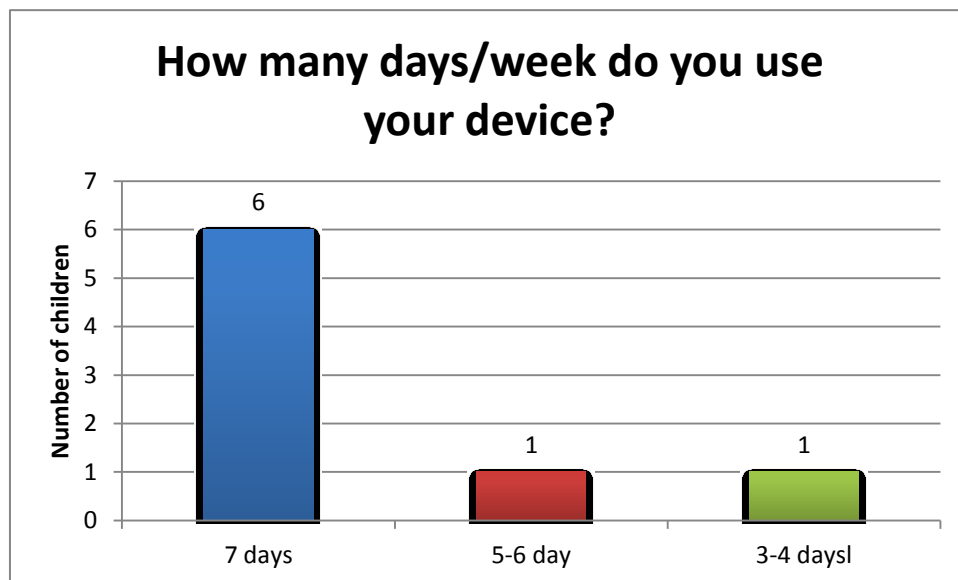


Figure 2. Frequency of device usage

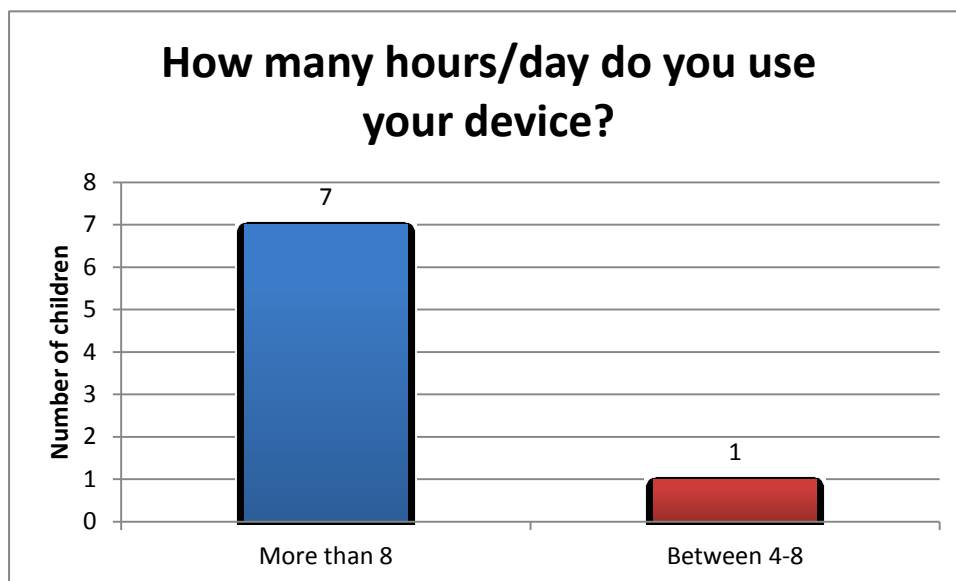


Figure 3. Intensity of device usage

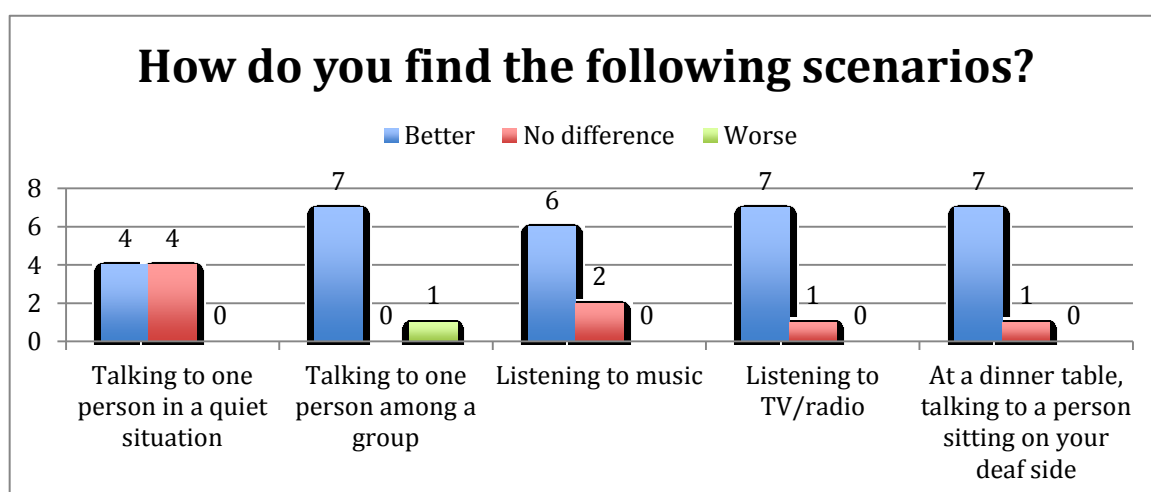


Figure 4. Practical benefit of the device

Change in health status

For all the children, parents reported an improvement in health status following surgery (figure 5). The median change in health status following BAHD surgery was +4 (range 3-4.9)

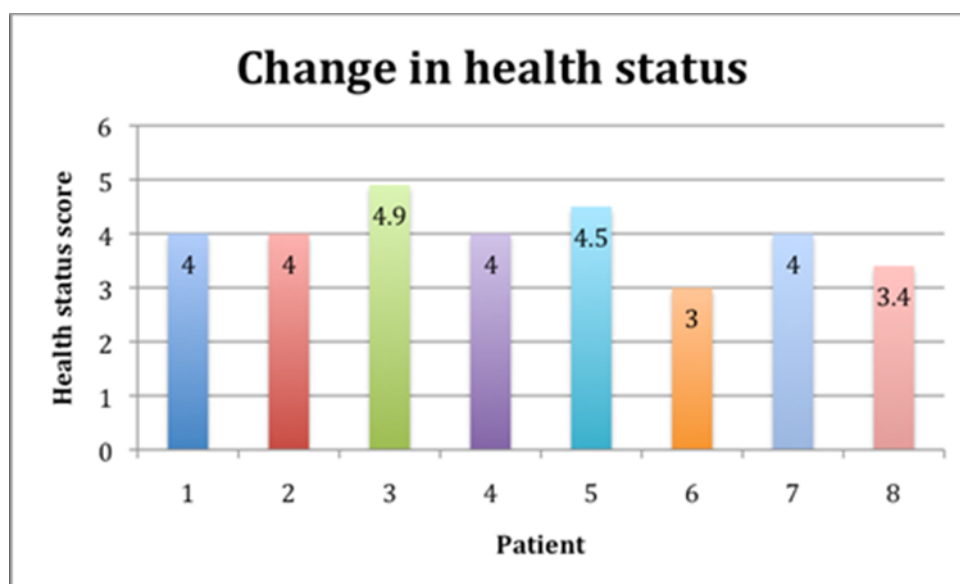


Figure 5. Change in health status

Discussion

Our paper suggests that an BAHD does improve the quality of life in children with SSD and adds to the sparse literature on this topic.

Christensen et al reviewed 23 children (age range 6-19) that had an BAHD for single sided deafness at their institution.¹³ They assessed outcome using two questionnaires - Hearing in Noise Test (HINT) and Children's Home Inventory for Listening Difficulties (CHILD). Scores, before and after surgery, showed noticeable improvements in both these outcome measures with the BAHD. The authors had previously shown similar results in a pilot study of three teenagers with single sided deafness.¹⁴ Gluth et al also demonstrated improvement in HINT and CHILD scores post BAHD surgery in a series of three teenagers with single sided deafness.⁸

In our series of 8 children, we used the GCBI and SSD questionnaire to assess benefit. All but one of the children showed a positive GCBI score; the child that reported a negative score was due to low self-confidence and self-esteem issues secondary to bullying at school.

Compared to adults with SSD treated with an BAHD, the results in our paediatric population are more favourable. The median GCBI score in our cohort of children

was +47.5. Martin et al reported a median GBI score of +11 in 42 SSD BAHD adult users.⁹

The GCBI scores from this study are also comparable to the benefit obtained by adults with bilateral devices for conductive hearing loss. Ho et al reported GBI score of +38 with the use of bilateral BAHDs.¹⁵

Over half of the children in this paper had a GCBI score equal or above +50. The magnitude of the positive GCBI scores reflects comparably to other paediatric BAHD indications. A series of 84 children from our institution showed a mean GCBI score of +54 following BAHD surgery for chronic suppurative otitis media, atresia or syndrome-related conductive hearing loss (Down's/Treacher Collins/Goldenhar syndrome).¹⁶

The results of the SSD questionnaire were generally positive with a mean satisfaction score of the BAHD as 9/10.

Admittedly, our series of 8 children is relatively small. They had all been referred because of parental concern with their children's educational development therefore it could be argued that selection bias was introduced as the questionnaire results were from a "motivated" parent/child population. In addition, the GCBI and SSD questionnaires assess subject satisfaction therefore they explore whether the device meets or exceeds expectations; the results can be affected by positive bias particularly if respondents feel grateful for intervention even if it is not technically or objectively successful.¹⁷

A recent study has also found there is a wide variation between individuals (both adults and children) in the transcranial attenuation of bone-conducted sound therefore this may also influence subjective benefit of a BAHD.¹⁸

In summary, our findings add further evidence to support patient perceived benefit of a BAHD in single sided sensorineural deafness in the paediatric population. The magnitude of benefit can be comparable to the more established indications for a paediatric BAHD. Further work is required in a larger series of children to investigate if this benefit is statistically significant.

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Chapter 4-2

Bone anchored hearing devices in children with unilateral conductive hearing loss: A patient/ carer perspective

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Abstract

Objective: To determine the outcome of a bone anchored hearing device in children with a unilateral conductive hearing loss.

Methods: A retrospective case note analysis in a tertiary referral paediatric hospital. A total of 17 consecutive paediatric patients with a unilateral conductive hearing loss were fitted with a bone anchored hearing device between 2005 and 2010.

Results: The average age of bone anchored hearing device fitting ranged from 6 years, 3 months to 16 years. Average age at fitting was 10 years, 6 months.

Qualitative subjective outcome measures demonstrated benefit.

The vast majority of patients reported improved social and physical functioning as well as improved quality of life.

All 17 patients are currently using their bone anchored hearing device on a daily basis after a follow up of 6 months.

Conclusions: This study has shown improved quality of life in children with unilateral hearing loss after receiving their bone anchored hearing device. There was a high patient satisfaction and improvement in health status reported by children/carers. Bone anchored hearing devices have an important role in the management of children with symptomatic unilateral hearing loss. Perhaps earlier consideration of a bone anchored hearing device would be appropriate in selected cases.

Introduction

In 1987, the first semi-implantable bone conduction devices became commercially available.¹⁻³ Initially when bone anchored hearing devices (BAHD) were first introduced, they were used primarily for those patients in whom it was not possible to wear conventional air conduction aids. This typically included patients with chronic middle and external ear disease, congenital malformations of the external auditory meatus and pinna. Recent years has seen the indications for a BAHD expand.^{4,5}

The percutaneous BAHD is currently a well-recognized and very effective method of rehabilitation for patients with both unilateral and bilateral conductive and mixed hearing loss.^{6,7}

It is well known that a bilateral hearing loss in children can cause problems with speech and language development, and if not recognized early can ultimately affect educational achievements and have an impact on the child's behaviour.

The magnitude of morbidity imposed upon a child with a unilateral hearing loss is much less understood. Some children appear to perform well and have no apparent disadvantage from their unilateral hearing loss (UHL), yet others are more handicapped by their UHL. In 2004 Lieu et al⁸ showed that there was a significant proportion of children with a UHL that had educational or behavioural problems at school when compared to their normal hearing peers. Christensen et al have shown that children with UHL find benefit with BAHD both on audiological testing and patient satisfaction questionnaire⁹ and Priwin et al has shown that the fitting of a BAHD in children with unilateral conductive hearing loss (UHL) leads to improved speech recognition in noise, but less favorable improvement in sound localization.¹⁰ In addition to this, Kunst et al found that some patients with a UHL had such good unaided directional hearing and speech in noise scores that aided testing with the BAHD did not confer significant overall improvement. Despite this the compliance with BAHD use was very high in this group of patients suggesting patient benefit.¹¹

Are there any risk factors to predict the children that will struggle? How should these children be treated? Should they be ignored until there is an evident educational need, should they all be aided or is there a compromise?

This paper aims to evaluate the impact that BAHD has on the quality of life in children with symptomatic unilateral conductive hearing loss (UHL).

Patients and methods

All children fitted with a BAHD for UHL between 2005 and 2010 were identified from a departmental database. There were 17 in total. A retrospective case note review was undertaken. As part of their on going follow up, all these children and/or carers completed a Glasgow Children's Hearing Aid Benefit Profile (GCBI) and a Single Sided Deafness (SSD) Questionnaire. They also used a visual analogue scale to indicate their perceived health status before and after their BAHD which

has been used in other published quality of life papers and has been shown to correlate with GCBI score.^{5,12,14}

The GCBI is a validated subjective child orientated post-interventional questionnaire designed to evaluate any paediatric otolaryngology intervention.¹⁵ It consists of 24 questions based upon a five point Likert scale. A score of +2 shows a maximal positive change and a score of -2 a maximal negative change. The sum total score is divided by 24 and multiplied by 50 to give a score ranging from +100 to -100 depicting a positive or negative change. Specific questions in the inventory relate to emotion, physical health, learning and vitality (see Appendix 1).

The SSD questionnaire was specifically designed to be administered after BAHD implantation for single sided deafness. It is designed to evaluate the number of hours and days that the BAHD is used and also to evaluate the benefit in various social situations. The questionnaire was first used in clinical study in 2003¹⁶ and it is based upon a questionnaire developed by Entific Medical Systems, which was published in the product's audiology manual¹⁷ (see Appendix 2).

The 10cm visual analogue scale was used to determine the change in health status before and after the BAHD where a positive change represents benefit to the overall health of the child and negative change represents deterioration.

Results

Age at referral

A total of 17 consecutive paediatric patients with UCHL were fitted with a BAHD between 2005 and 2010. The age at referral ranged from 3 months to 14 years with an average of 7 years and 6 months. The age at BAHD fitting ranged from 6 years, 3 months to 16 years, with an average age of 10 years, 6 months. The average age of referral for the children with congenital and acquired UCHL was 7 years, 2 months and 8 years, 2 months respectively. There was one child with a congenital UCHL that was fitted 8 years after the first referral to the otolaryngology clinic. She was seen in the audiology clinic six months prior to fitting but it was not clear in the records why there was such a long delay between the appointments. It was apparent from many of the records that the families had sought help from audiology because they firmly believed that their child had educational or speech and language difficulties as a result of their hearing impairment.

Aetiology of hearing loss

Congenital abnormalities accounted for 12/17 (71%) of the cases. The remaining 5/17 (29%) were acquired. See Tables 1 and 2.

Table 1. Congenital unilateral conductive hearing loss cases

Case	Aetiology	Affected side	Age of onset of deafness	Age at referral	4 tone average (0.5,1,2,4 kHz)		Age at BAHD fitting	Year of BAHD fitting
					L	R		
1	Microtia and atresia	L	Birth	7y	70	10	15y	2009
2	Hemifacial microsomia	L	Birth	3m	80	15	6y 3m	2008
3	Isolated unilateral bony ear canal atresia	R	Birth	7y	20	55	8y	2009
4	Hemifacial microsomia	L	Birth	10y	80	5	12y 5m	2009
5	Microtia and atresia	R	Birth	2y	20	70	7y 6m	2008
6	Hemifacial microsomia	L	Birth	10y	65	10	11y 9m	2006
7	Isolated unilateral bony ear canal atresia	L	Birth	8y	70	15	10y 3m	2008
8	Microtia and atresia	R	Birth	7y	0	65	9y 2m	2009
9	Microtia and atresia	L	Birth	9y	55	0	9y 3m	2003
10	Congenital ossicular malformation	R	Birth	7y	20	65	10y	2009
11	Microtia with atresia	R	Birth	11y	10	70	12y 8m	2006
12	Microtia with atresia	R	Birth	8y 2m	5	70	9y 8m	2010

Table 2. Acquired unilateral conductive hearing loss cases

Case	Aetiology	Affected Side	Age of Onset	Age at referral	4 tone average (0.5,1,2,4 kHz)		Age at BAHD fitting	Year of BAHD fitting
					L	R		
1	Chronic Suppurative Otitis media	L	4y	4y	60	20	9y 6m	2009
2	Chronic Suppurative Otitis media	R	8y	9y	5	50	13y 3m	2009
3	Chronic Suppurative Otitis media	L	?	5y	80	25	8y 3m	2008
4	Chronic Suppurative Otitis media	R	6y	9y 3m	10	45	10y 3m	2010
5	Chronic Suppurative Otitis media	R	?	14y	10	60	16y	2010

GCBI results

All but one child reported a positive change on the GCBI after having a BAHD for their UCHL. See Figure 1.

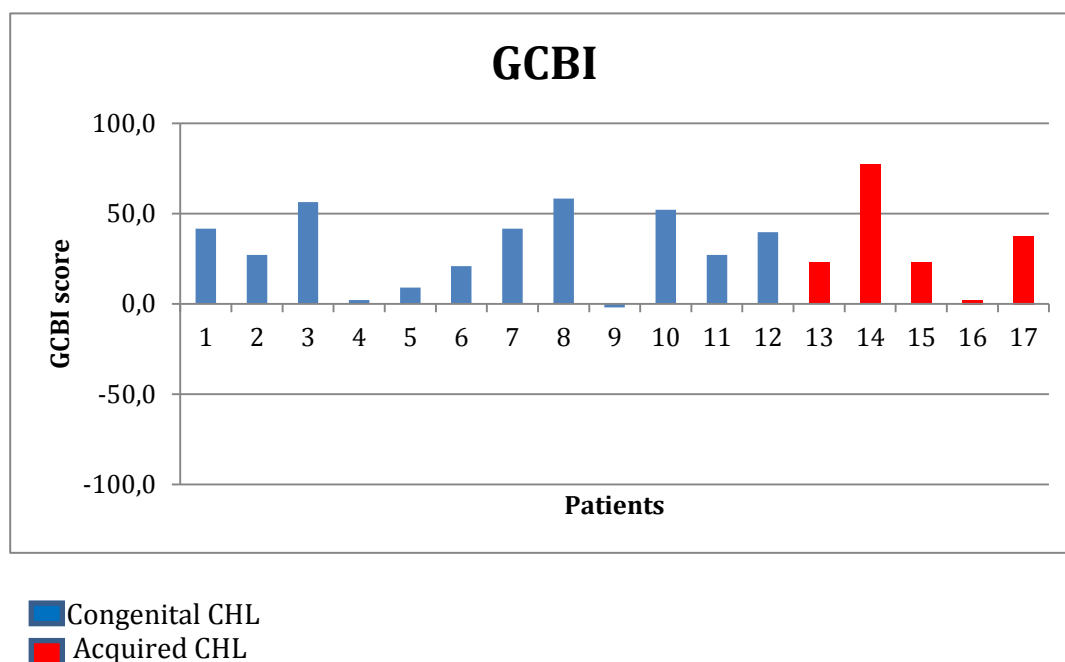


Figure 1. GCBI results

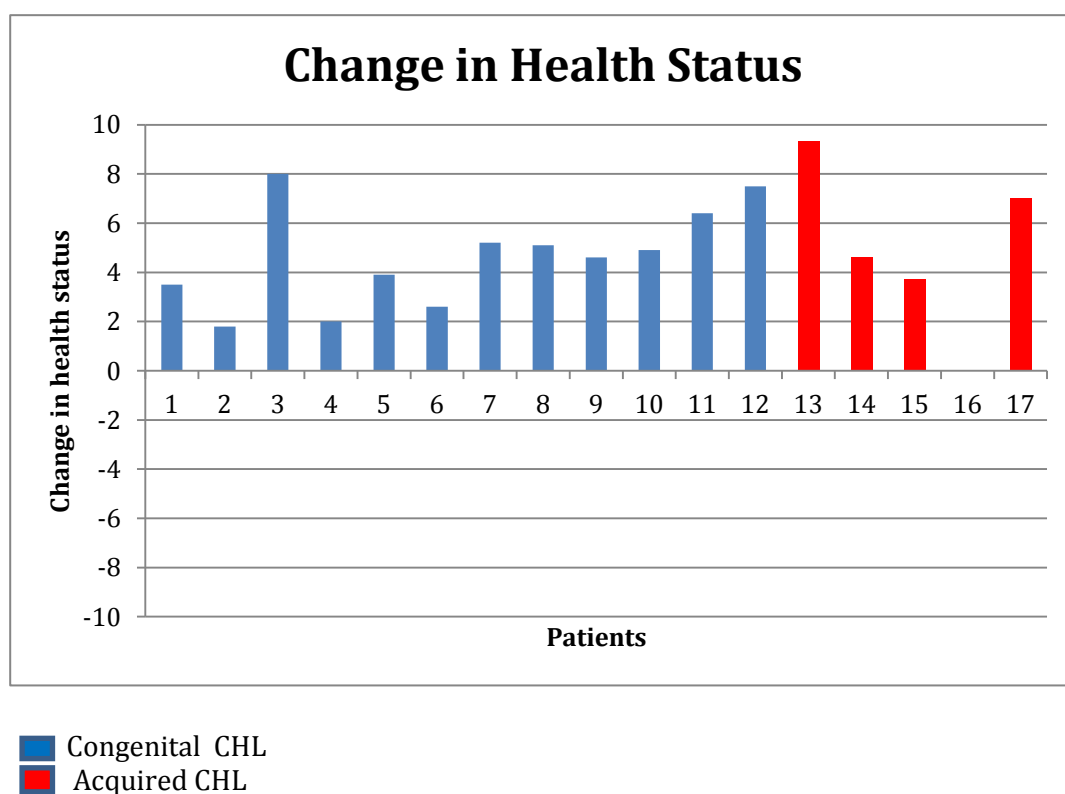


Figure 2. Change in health status

Change in health status

The visual analogue scale for the change in health status showed that all but one patient reported a positive improvement in health status after their BAHD for UCHL. One child reported no change. See figure 2.

Device usage

When looking at the number of days the BAHD was used by the children, in both the congenital and acquired groups, the majority were using their device 5-6 days a week.

When looking at the number of hours of usage a day, the majority of children were using the BAHD for at least four hours a day, in fact most of them were wearing it for more than eight hours a day. There was one child in the acquired CHL group that was using the BAHD for less than two hours a day.

Finally, 100% of children used their BAHD.

Satisfaction and Quality of life

None of the children were dissatisfied with the BAHD, in fact 16/17 (94%) were satisfied to a degree and only one child 1/17 (6%) felt that the BAHD made no difference. When questioned about how they perceived the BAHD had affected their quality of life, 13/17 (76%) children felt that it made a significant improvement. See figure 3.

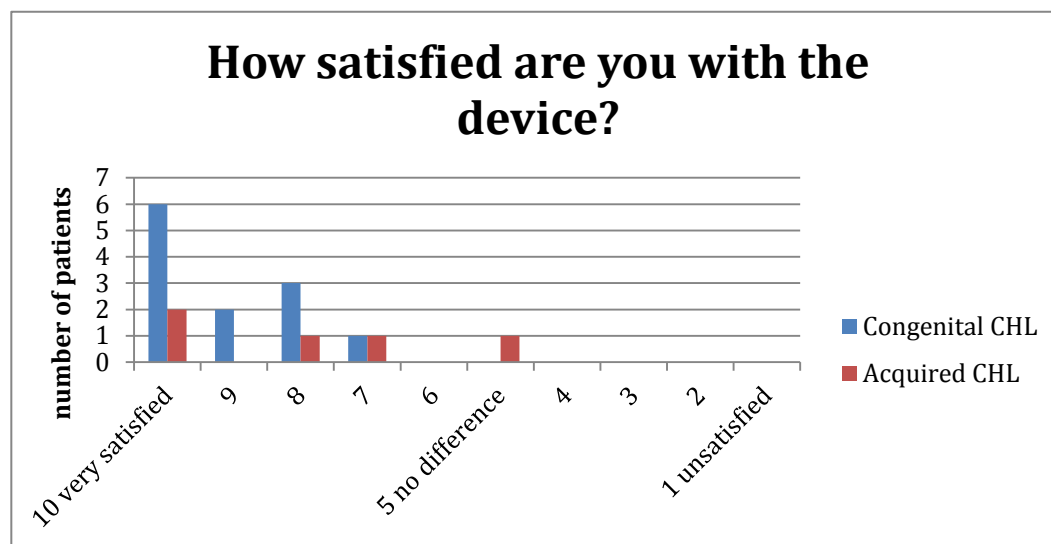


Figure 3. Satisfaction

The results from the SSD questionnaire reflected the value of BAHD in five specific situations: Talking to one person in a quiet situation, talking to one person in a group, listening to music, watching the television or radio and at the dinner table talking to a person on the deaf side. All of the children reported that their BAHD was of value in at least one of these conditions, with most of the children finding value in four or five of the specified situations. Looking at the situations in isolation, the BAHD was deemed most useful in a group situation and least useful talking to one person in a quiet background. The BAHD did not have a negative impact for any child in any of these specific situations. See Figures 4-6.

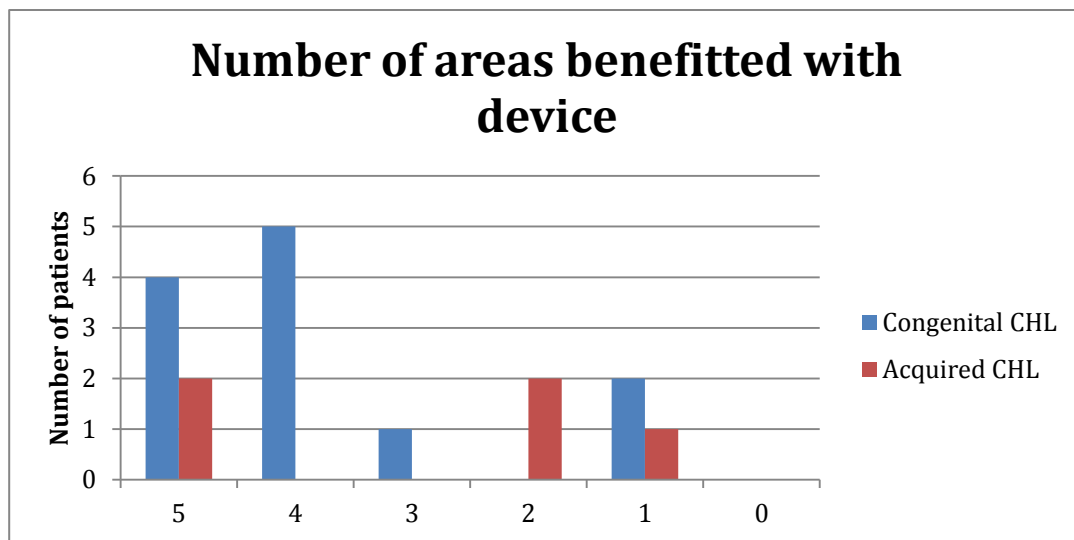


Figure 4. Number of areas benefitted with device

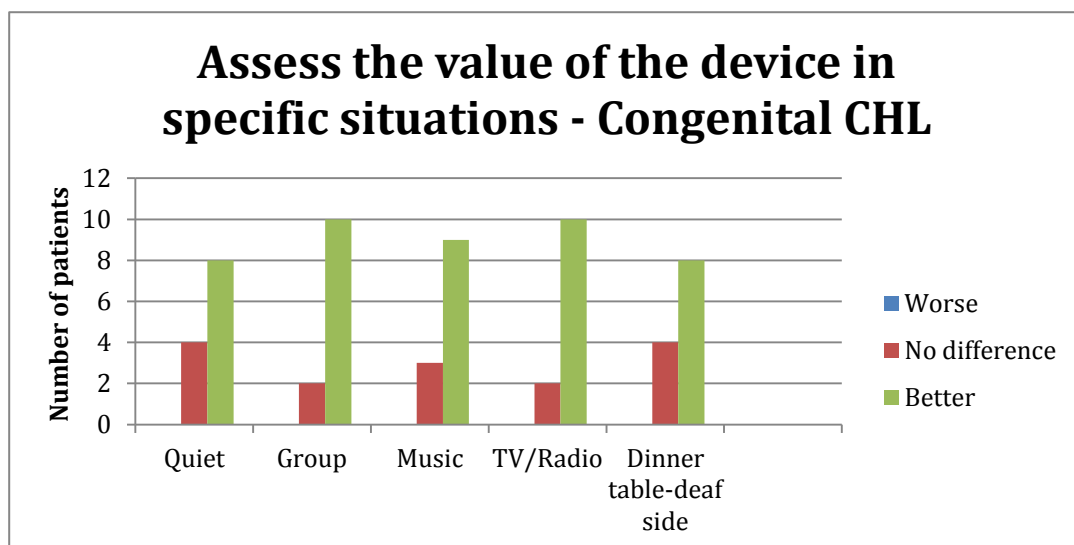


Figure 5. Value of device in specific situations - congenital CHL

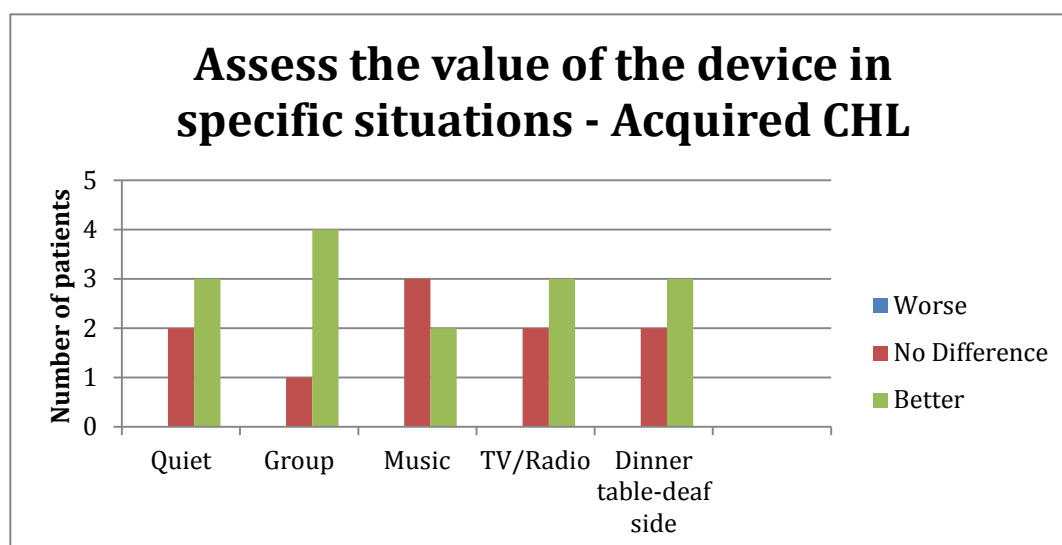


Figure 6. Value of device in specific situations – acquired CHL

Discussion

Any study using a patient questionnaire for results is subject to recall bias.

Carers are usually asked to help complete the questionnaires if the child is not old enough to do so themselves. It must be remembered that the results may reflect the carer's views and perceptions. When working with children the role of the parent/carers is hugely important and so their views and perceptions should be considered an important part of outcome results.

Evidence from studies using the GCBI have shown a prior expectation to the intervention and the perceived benefit from the intervention may deteriorate with time.¹⁵

The cohort of children in this study were 'a selected group' who had been referred for a specific hearing problem. All of the children were referred with significant speech and language difficulties, and/or significant educational and behavioural issues compared with their siblings or peers. The older children were noted to be having difficulties at school and were already having additional educational measures implemented.

Interestingly, 12 of the children had a clearly recognizable congenital UCHL with external ear abnormalities. The nature of their hearing loss was identified very early yet the age of referral for audiological assessment/ help was late (average age at referral being 7 years and 3 months).

All the children in this study had either a congenital or acquired CHL.

Only two children had additional learning difficulties (associated with co-existing medical conditions) that may have influenced their outcomes. When reviewing literature about children with any UHL, social backgrounds, medical co-morbidity and educational assessments all vary from cohort to cohort and so comparison of any of their outcomes is difficult. Another variable is the degree of support provided by different schools in different geographical areas. Some institutions cater for such children using many techniques including radio aids, individual class assistant's help and input from the visiting teachers of the deaf.

Further controversy surrounds the learning and behavioural problems. Have these arisen as a consequence of the long-standing hearing difficulties?

The educational potential of any child is dependant on many factors not just their hearing. Hence it is very difficult to interpret the actual benefit of the BAHD in any child with a UHL.

GCBI

The majority of the GCBI results were positive. One child had a negative score and two further children had small positive scores.

The child reporting a negative score was a teenager. This particular child had a number of obvious congenital abnormalities and had a long-standing tracheostomy in situ. Unusual chromosomal abnormalities had been identified but no formal syndrome or association had been diagnosed. Bullying had been a recurrent problem despite changing schools on a number of occasions. A significant self-image issue had resulted. Despite all of the above, this child reported an improved health status from their BAHD on the visual analogue scale. Furthermore, this child continues to wear their BAHD every day.

Two children reported a small positive score on the GCBI: A teenage female with hemifacial microsomia who has concerns regarding her appearance and self-esteem. Again, despite her low self-esteem and issues with her image, she is a good user and reports hearing benefit with her BAHD. The second young man was also a teenager with similar issues regarding bullying and self-image although his UHL was acquired. Chronic ear discharge was the constant concern for him.

All three children scored poorly on the questions relating to emotion. They had issues with self-esteem and appearance. It would appear that for this group, the BAHD added to their negative self-image issues. Despite finding the BAHD of benefit, they were concerned about the appearance of the BAHD. This is a common problem in teenagers and adolescents. There is evidence in the literature that children, (particularly boys) have issues regarding self-image when it comes

to bone conduction aids and BAHD¹⁸ which may adversely affect their questionnaire results.

The visual analogue results were interesting. Three of the children showed a small positive change on the GCBI. When compared to the corresponding visual analogue score, these three children showed a very large increase in health status. There was some subjective evidence from comments made in the free text that the BAHD had made a positive difference.

In the current health climate evidence supporting BAHD is crucial. Demonstration of positive self reported patient benefit resulting from a BAHD will be increasingly more important in the evaluation of a cost benefit analysis.

In the paediatric literature, de Wolf¹⁹ et al found that in children with congenital unilateral conductive hearing loss, the BAHD was of particular benefit in educational settings, but does not reliably lead to a significant benefit in all domains. It is re-iterated that in these children it is vital to perform a pre-operative trial with a headband in order to predict benefit.

In the adult literature Snik et al found that those patients with a longstanding or congenital hearing loss reported a smaller benefit than those with an acquired hearing loss.²⁰ Martin et al found that the BAHD was less beneficial in adults that had hearing loss for more than ten years.²¹

Not all children with a UHL need aiding, yet those with a significant hearing handicap do well with a BAHD. It is often very difficult for the BAHD clinician to decide what and when any treatment should be offered. Historically children presenting with a UHL were reassured if normal hearing thresholds were demonstrated in the contralateral ear.

Failure to identify those children with difficulties may likely result in a proportion of children who will not realize their full educational potential and be a burden to society.

In our institution, children referred with a UCHL are assessed audilogically with directional age appropriate hearing tests. They are fitted with a BAHD softband™ for a trial period of up to 3 months. They are advised to wear it both at school and in the home. At the child's school, the visiting peripatetic teacher is asked to report on their progress during this period along with other staff involved. In conjunction with this, the children or their carers fill in subjective quality of life questionnaires regarding their experiences with the BAHD softband™.

A BAHD is then offered if the trial period shows a significant improvement.

Carers/ parents of children presenting with a congenital CHL and congenital ear malformation are counseled regarding the possible long-term sequelae of unilateral hearing loss. Regular audiological assessment is arranged at age 9-12 months, 18 months, and yearly thereafter. Early intervention with a Baha® softband™ is offered if there are any concerns regarding hearing or speech development. Genetic counseling and discussion regarding cosmetic appearance of any congenital deformity of the ear are other aspects of the consultation.

Conclusions

The BAHD has an important role in the overall management of children with UCHL who are struggling with speech and language skills and have behavioural and educational issues. This study has shown a significantly improved quality of life in our cohort of children with symptomatic UCHL after receiving their BAHD. There was a high patient satisfaction and improvement in health status reported by children and carers. Qualitative subjective outcome measures demonstrated significant benefit. The vast majority of children had improved social and physical functioning as a result of better hearing and both carers and children reported an improved quality of life. Increased awareness of the potential consequences of a UCHL should be highlighted to healthcare professionals. An early opinion should be sought for any such child with difficulties that fail to respond to usual treatments.

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Appendix 1. The GCBI Questionnaire

1	Has your child's BAHA made his/her life overall better or worse?
2	Has your child's BAHA affected the things he/she does?
3	Has your child's BAHA made his/her behaviour better or worse?
4	Has your child's BAHA affected his/her progress or development?
5	Has your child's BAHA affected how lively he/she is during the day?
6	Has your child's BAHA affected how well he/she sleeps at night?
7	Has your child's BAHA affected his/her enjoyment of food?
8	Has your child's BAHA affected how self-conscious he/she is with others?
9	Has your child's BAHA affected how well he/she gets on with the rest of the family?
10	Has your child's BAHA affected his/her ability to spend time and have fun with friends?
11	Has your child's BAHA affected how embarrassed he/she is with other people?
12	Has your child's BAHA affected how easily distracted he/she has been?
13	Has your child's BAHA affected his/her learning?
14	Has your child's BAHA affected the amount of time he/she has had to be off nursery, playgroup or school?
15	Has your child's BAHA affected his/her ability to concentrate?
16	Has your child's BAHA affected how frustrated and irritable he/she is?
17	Has your child's BAHA affected how he/she feels about him/herself?
18	Has your child's BAHA affected how happy and content he/she is?
19	Has your child's BAHA affected his/her confidence?
20	Has your child's BAHA affected his/her ability to care for him/herself as well as you think they should, such as washing, dressing and using the toilet?
21	Has your child's BAHA affected his/her ability to enjoy leisure activities such as swimming and sports and general play?
22	Has your child's BAHA affected how often he/she needs to visit a doctor?
23	Has your child's BAHA affected how prone he/she is to catch colds or infection?
24	Has your child's BAHA affected how much medication he/she needed to take?

Appendix 2. The SSD Questionnaire

Question Number	Question	Possible responses
1	How many days/week do you use your device?	7days/week
		5-6 days/week
		3-4 days/week
2	How many hours/day do you use your device?	More than 8
		Between 4 and 8
3	Has your quality of life improved due to the device?	Yes
		No
4	Try to determine your satisfaction....(10 point rating scale)	Score from 0-10
5.1	Talking to one person in a quiet situation?	Better
		No difference
		Worse
5.2	Talking to one person among a group?	Better
		No difference
		Worse
5.3	Listening to music?	Better
		No difference
		Worse
5.4	Listening to TV/radio?	Better
		No difference
		Worse
5.5	At a dinner table, talking to a person sitting on your deaf side?	Better
		No difference
		Worse

Chapter 5

Magnetic Resonance Imaging and Bone Anchored Hearing Devices: Paediatric considerations

Jayesh Doshi, Sara Schneiders, Katherine Foster, Andrew Reid,
Ann Louise McDermott

Abstract

Objective: Recent developments in bone conduction hearing systems have seen the introduction of transcutaneous devices comprising of magnetic components. Our aim was to identify the number of children implanted with a traditional, non-magnetic percutaneous bone anchored hearing device (BAHD) who would not have been eligible for a transcutaneous implant based on magnetic resonance imaging (MRI) need.

Study Design: Retrospective case review

Setting: Tertiary referral centre

Patients: 206 children who had a percutaneous BAHD at the Birmingham Children's Hospital (Jan 2009-Oct 2012).

Intervention(s)

BAHD for auditory rehabilitation

Main Outcome Measure(s)

MRI procedures performed for each child after BAHD implantation

Results: Twenty eight percent (56/206) of children required at least one MRI scan after receiving a BAHD with many patients requiring more than one MRI scan. The main indication for MRI scanning was for neurological co-morbidities; a MRI brain was the most common scan performed

Conclusions: A significant proportion of our cohort of children would not have been eligible to consider these newer devices because of imaging considerations. Clinicians should be mindful of any need for MRI scanning when considering implant choices in the paediatric population.

Introduction

Recent developments in bone conduction hearing systems have seen the introduction of transcutaneous devices such as the Alpha series (Sophono™), Bonebridge™ (Medel), BAHA 4 Attract [Cochlear] and middle ear implants [Vibrant Soundbridge (Medel)]. These devices consist of internal & external magnetic components. It is not unusual for paediatric candidates for a bone

anchored hearing device to have other co-morbidities such as neurological conditions which may require magnetic resonance imaging which, in some cases, may need to be serially repeated.

Our aim was to identify the number of children implanted with a percutaneous BAHD who would not have been eligible for a transcutaneous implant on the basis of MRI scan need.

Methods

We performed a retrospective case review of all children who had a percutaneous BAHD at the Birmingham Children's Hospital (Jan 2009-Oct 2012). All radiological procedures performed for each child after implantation were reviewed.

Results

206 children were identified with a BAHD.

Indications for the BAHD are shown in figure 1. The most common indication was a conductive hearing loss. Patients with Down's syndrome and Treacher Collins syndrome made the majority of this group.

The type of surgery performed is shown in figure 2.

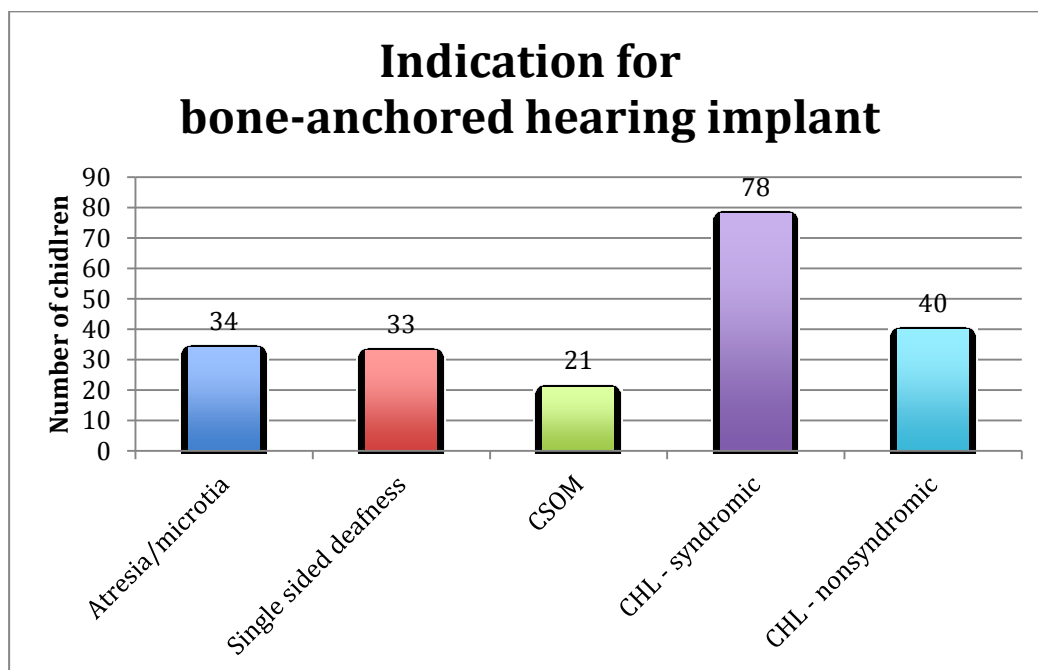


Figure 1: Indication for BAHD

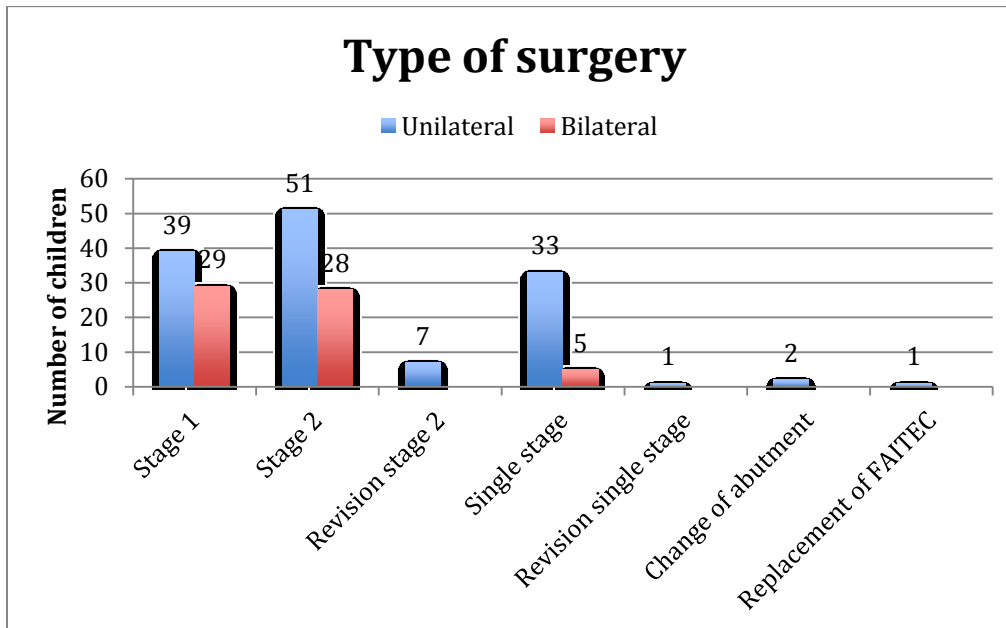


Figure 2: Type of Surgery *

*Incomplete data in 10 children therefore not included in above figure.

Twenty eight percent (56/206) required at least one MRI scan post implantation with many patients requiring more than one MRI scan (figure 3).

The main indication for MRI scanning was for neurological co-morbidities; a MRI brain was the most common scan performed (figure 4).

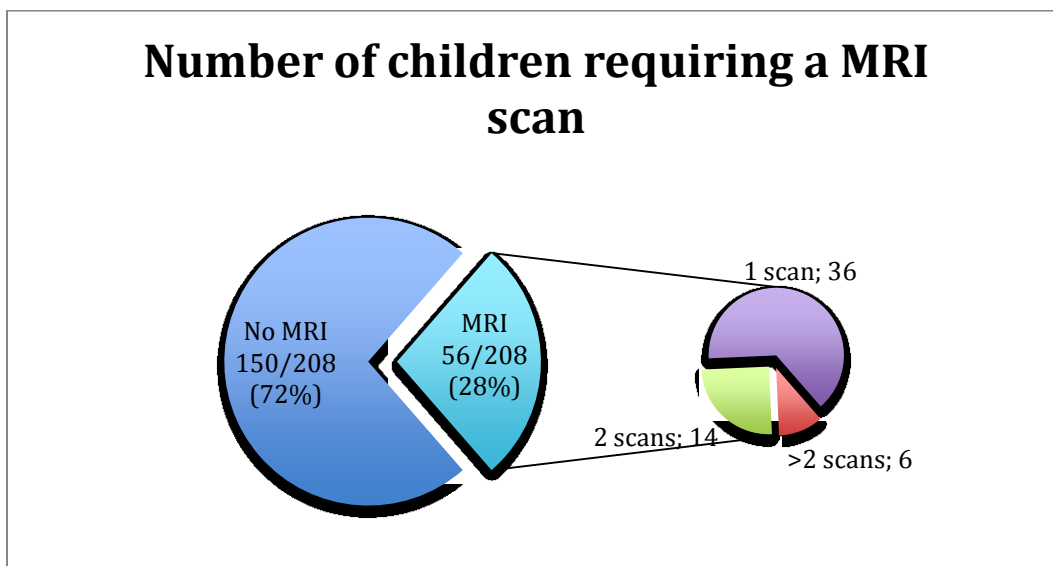


Figure 3: Number of children requiring a MRI scan

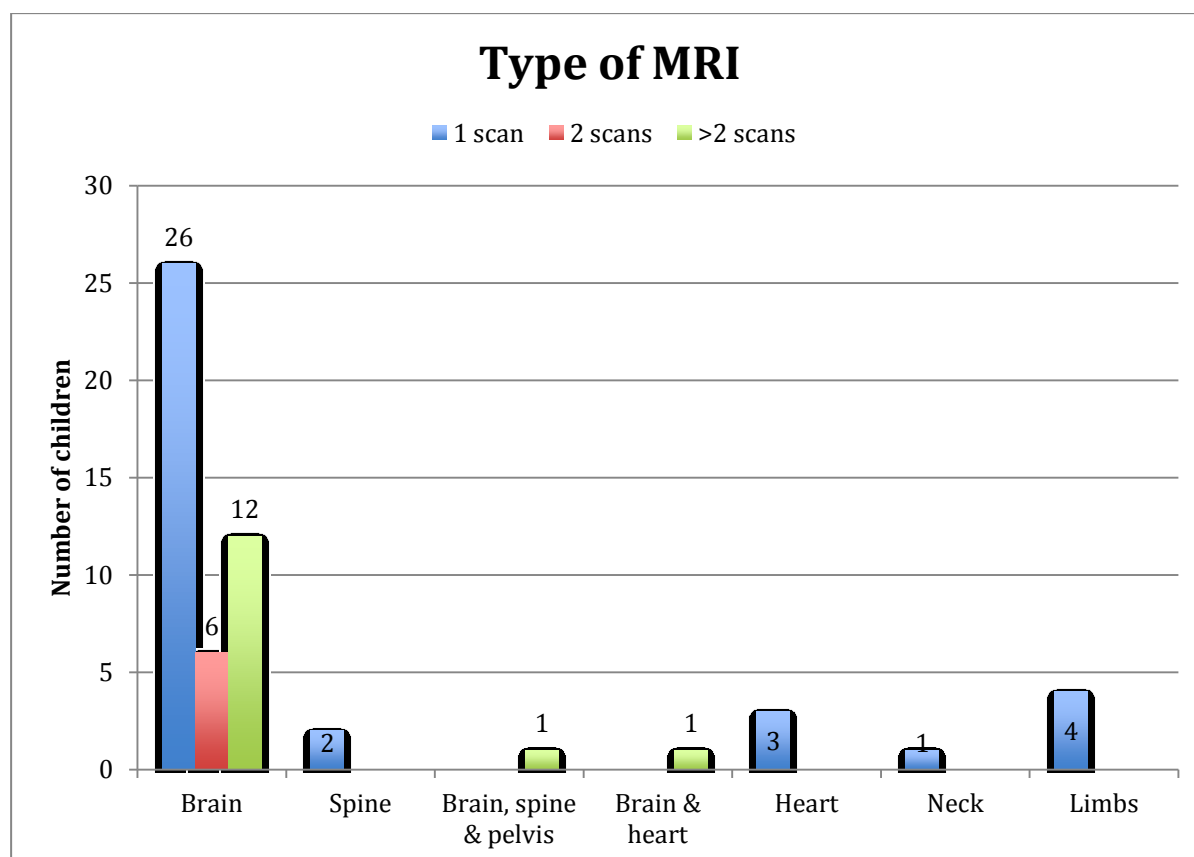


Figure 4: Type of MRI

Discussion

The lifetime likelihood of needing a MRI scan has increased over the last decade. Reasons include greater availability of MRI scanners, reduced cost, the benefit of no radiation exposure and that MRI is often the imaging modality of choice. The Organization for Economic Co-operation and Development (OECD) showed that the incidence of inpatient MRI scan has increased from 12.8/1000 population (in year 2000) to 40.8/1000 population (in year 2010) in the United Kingdom.¹ This data excludes the number of outpatient MRI scans that are requested therefore the actual number of annual MRI requests will be much greater.

Children who require a bone-anchored hearing device often have other significant co-morbidities. These are often neurological conditions where MRI scanning may be of diagnostic use and a method of monitoring disease progression.

MRI compatibility with otological implants have both clinical and practical implications. In the case of bone-anchored hearing devices with a magnetic component, a logical comparison could be made with magnet –containing cochlear implants devices. According to the consensus statement of the National Institutes of Health (1995), MRI should be performed in cochlear-implanted patients only if

there is a strong medical indication and appropriate safety procedures are applied.² Potential problems include heating of the electromagnetic coil, induction of electrical current, image artifact and demagnetization of the internal component. Several authors have conducted in vitro experiments investigating these aspects and cochlear implants remain in proper working order after a single MRI head scan provided the surgical attachment is correct.^{3,4,5,6,7} Of practical note, the shadow artifact occurs approximately 5-6cm around the implant – it is due to the metallic implant itself rather than the magnet. The magnitude of demagnetisation (if it occurs) is approximately 11-15%. However this demagnetization can be overcome by increasing the strength of the magnet in the external component of the hearing device.⁸ Therefore MRI can be performed in cochlear implant patients provided certain precautions are taken although it must be noted that individual manufacturers have their own recommendations of MRI compatibility for each of their individual devices.

Of course in the case of a profoundly deaf child there is little choice for hearing habilitation other than a CI. This is not the case for children with conductive and mild to moderate sensorineural hearing loss. The choice of hearing implant is greater but the implications of such choice is significant.

Bone anchored hearing devices options

Sophono

The Alpha 1 & 2 hearing devices by Sophono™ comprises of a surgically implanted internal plate that houses two magnets hermetically sealed in a titanium case. The external sound processor houses a bone oscillator and uses a metal disc and spacer shim to magnetically couple to the internal component and deliver auditory stimulation through the closed skin. In April 2013, Sophono™ received clearance from the U.S. Food and Drug Administration for Alpha 1 and 2 patients to have a magnetic MRI up to 3T.

Bonebridge

The Bonebridge is a partially implantable hearing system consisting an external audio processor held magnetically over an internal device, which transmit sound through bone directly to the inner ear. The product literature states that MRI is permissible upto 1.5T however an artifact of 15cm around the implant may occur and audible interference may be perceived despite the external processor having been compulsorily removed. It is currently not licensed for use in children.

BAHA Attract

The Baha Attract system is a passive transcutaneous system where sound is transmitted as vibrations from an externally worn sound processor through the skin to a magnet attached to an internal titanium screw fixture. This new system is MRI compatible up to 1.5T however image artifact may be up to 11cm - is not currently CE marked or approved by the FDA (Personnel communication from The 4th International Symposium on Bone Conducting Hearing - Craniofacial Osseointegration Conference 2013).

Vibrant Soundbridge

The Vibrant Soundbridge (Medel™) has a magnetic component in the external/internal fixation components as well as the floating mass transducer (FMT). Indications for this device include adults with conductive, sensorineural and mixed hearing loss.

In June 2009, the Vibrant Soundbridge received approval for patients younger than 18 years of age in the European Union. It has been used in paediatric patients with ear canal atresia and ossicular anomalies by placing the floating mass transducer (FMT) on the long process of the incus, mobile stapes remnants or the round/oval window.⁹ A review of its MRI compatibility & safety showed that imaging up to 1.5T suggested no serious risk of harm to the patient or damage to the VSB, however, the FMT may potentially dislocate depending on transducer position, the security of the transducer to the vibratory structure and the coupling mode used.¹⁰ Currently, Medel state that the Vibrant Soundbridge is not MRI safe (personal communication between Medel & S Schneider).

Percutaneous Devices

No such MRI compatibility issues exist with the more traditional, percutaneous bone anchored hearing devices (Cochlear BAHA and Oticon) as these have an osseointegrated titanium implant although it must be noted that image artefact still occurs (15.1 to 17.4 mm).¹¹

Although transcutaneous hearing devices/middle ear implants have their clear benefits, it may be argued that these relatively more invasive surgical procedures may not be the best option for the child who will require MRI scanning at some point in the future.

Conclusion

A significant proportion of our cohort of children would not have been eligible to consider these newer devices because of imaging considerations. Clinicians should be mindful of any need for MRI scanning when considering implant choices in the paediatric population.

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Chapter 6

Observational study of bone-anchored hearing device infection rates using different post-operative dressings

J. Doshi, Y. Karagama, D. Buckley, I. Johnson

Abstract

Introduction: Avoidance of infection at the implant site is a crucial element to the success of bone-anchored hearing device (BAHD) implantation. However, little evidence exists to suggest the best post-operative wound dressing to use.

Material and methods: We report our experience with 160 consecutive BAHD patients, using four types of post-operative BAHD wound dressing (Tri-adcortyl®, Mepitel®, Allevyn®, and Acticoat 7® with Allevyn). Patients were reviewed at week one and week two post-operatively. Infection was defined as a positive wound swab culture or evidence of cellulitis at the BAHD site.

Results: Post-operative BAHD infection rates were 16 per cent, 50 per cent, 10 per cent and 5 per cent, for each of the four dressings respectively, and the mean number of additional visits to wound care clinic were 1.5, 3.7, one and 0.4, respectively.

Discussion: Acticoat 7 with Allevyn produced the lowest infection rate and thus became the dressing of choice for our BAHD programme.

Introduction

One of the main causes of failure of the bone anchored hearing device (BAHD) is post-operative infection at the implant site. The infection prevents osseointegration of the titanium implant, which eventually leads to extrusion of the device. This negates the previously reported positive quality of life benefits of the BAHD^{1,2} and has significant time and economic implications for the health service. Therefore, avoidance of infection is a crucial element to the success of BAHD implantation, but little evidence exists to suggest the best post-operative wound dressing to use. The Freeman Hospital is a large tertiary centre in the north-east of England and has had an established BAHD programme since 1992. This is currently the largest BAHD programme in the United Kingdom, performing approximately 130 adult BAHD implantations per annum. Our inclusion criteria for BAHD implantation are the standard indications recommended by the manufacturer.³ All patients undergo a one stage surgical approach performed as a day case procedure. Post-operatively, they are reviewed twice in a nurse-led BAHD wound clinic.

The microprocessor is fitted at three months to allow time for osseointegration of the implant to occur.

Materials and methods

Our study population consisted of 160 patients undergoing consecutive BAHD implantations performed between December 2002 and January 2005. All first time BAHDs were included in the study but 'redo' BAHDs were excluded. All the operations were performed by the same surgeon, who had several years' experience of performing BAHD operations prior to this study. We compared the use of four types of post-operative BAHD wound dressing (ribbon gauze soaked in Tri-adcortyl® (TAC) ointment, Mepitel® (silicone), Allevyn® polyurethane), and Acticoat 7® (silver) with Allevyn®) with patients' post-operative infection rate.

Patients were reviewed at week one and week two post-operatively at the nurse-led BAHD wound care clinic. At the first clinic review, the dressings were removed and the BAHD site cleaned with normal saline, using an aseptic technique. The site was redressed with the same type of dressing that had been used at the original operation. At the second post-operative clinic review, the dressing was removed and the sutures cut. The BAHD site was then kept open.

Infection was defined as a positive wound swab culture or evidence of cellulitis at the BAHD site. Patients were followed up if there was evidence of infection, and the number of additional visits to the BAHD wound care clinic was noted.

Statistical analysis was performed using SPSS version 11 software.

Results and analysis

The patients comprised of 82 men and 78 women, with a mean age of 45 years-old (range, 20–80 years).

Figure 1 shows the number of patients and the different dressings used. Figure 2 shows the overall infection rates; Table I gives a breakdown of the infection rates for each type of post-operative dressing. Non-parametric data analysis showed a statistically significant difference in these infection rates ($p < 0.05$).

Figure 3 shows the mean number of additional visits patients required to the wound care clinic.

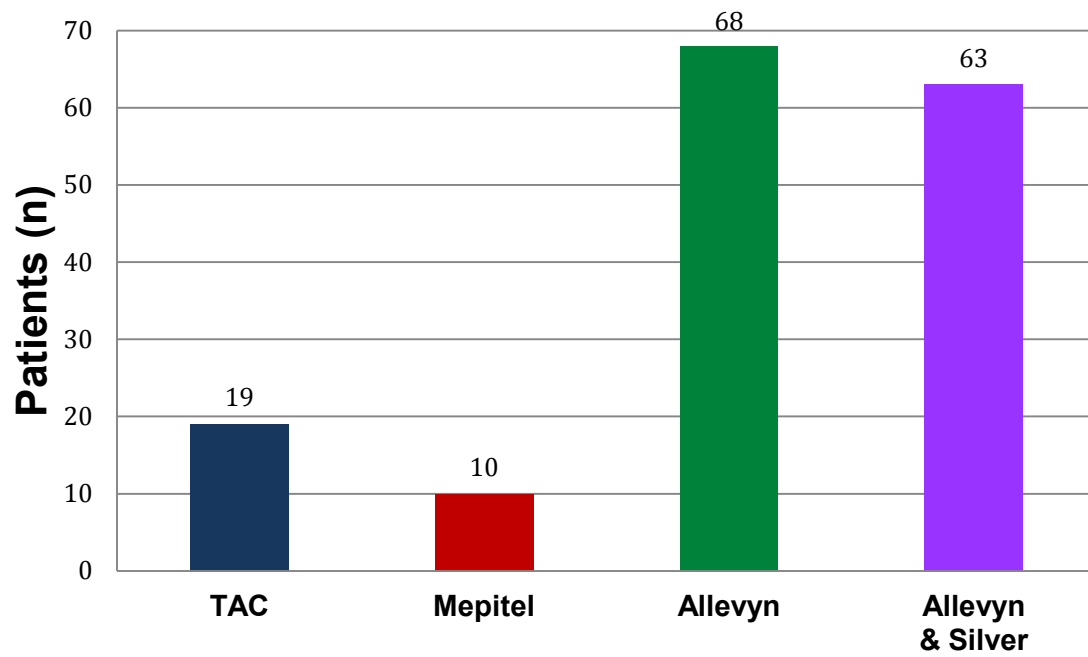


Figure 1. Types of post-operative dressings used. TAC = Tri-adcortyl

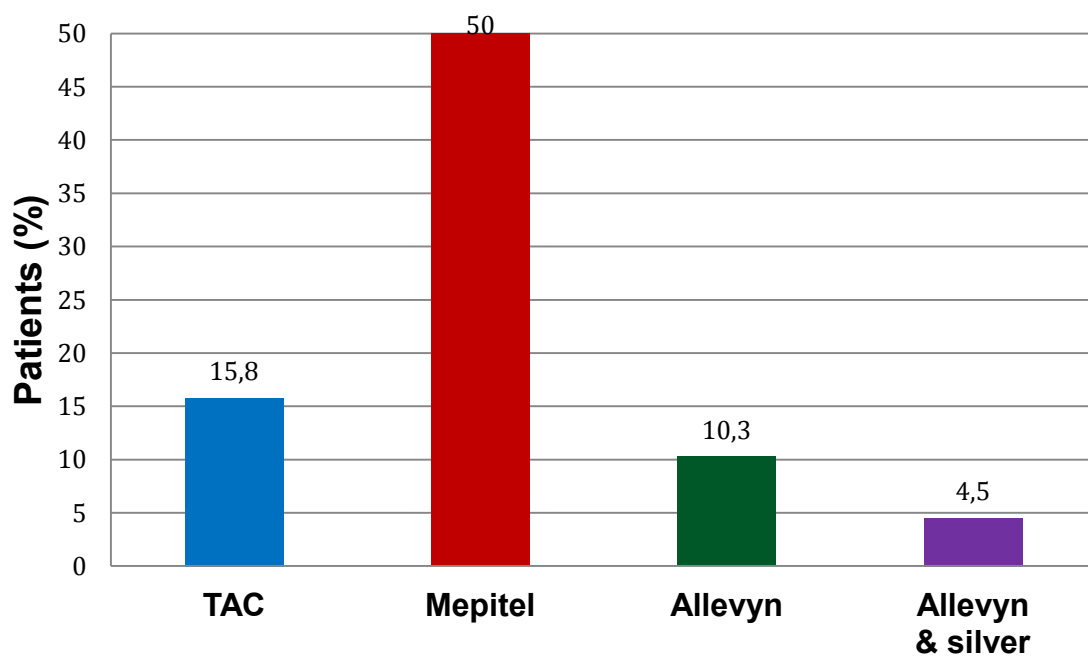


Figure 2 Post-operative infection rate for each dressing. TAC =Tri-adcortyl

Table 1. Infection rates for each type of post-operative dressing

Dressing	Positive microbiology Swab (n)	BAHD site Cellulitis (n)
TAC	2	1
Mepitel	3	2
Allevyn	5	2
Acticoat & Allevyn	2	1

BAHD = Bone Anchored Hearing Device; TAC = Tri-adcortyl

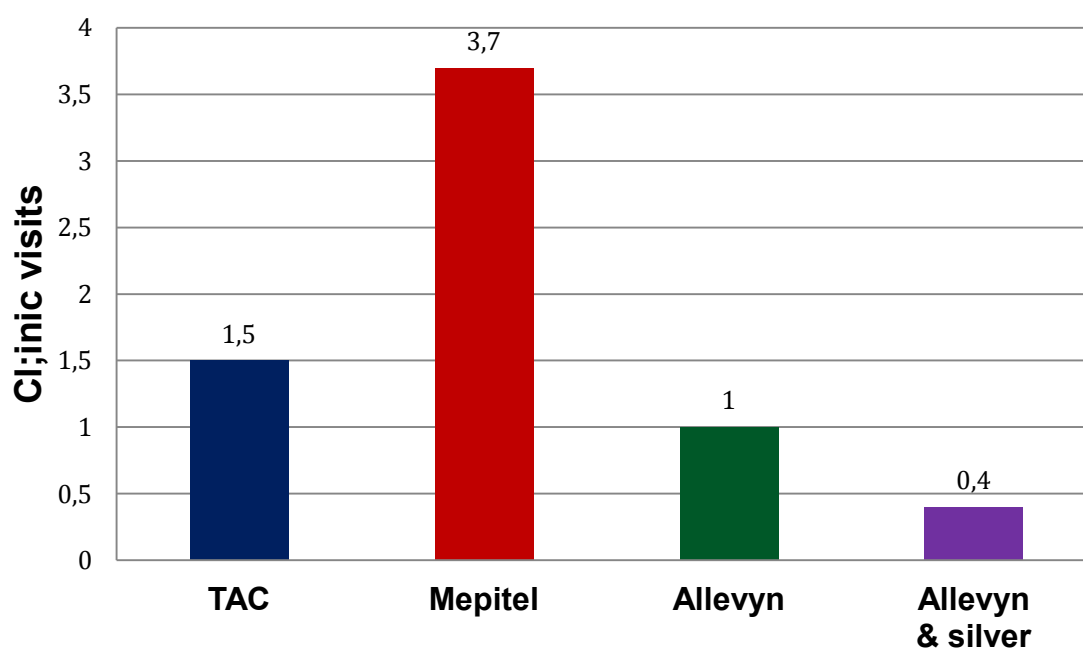


Figure 3. Mean number of additional post-operative visits to the wound care clinic for each dressing. TAC = Tri-adcortyl

Discussion

We have had experience with four types of postoperative wound dressing since our BAHD programme began. The first was ribbon gauze soaked in TAC ointment. This dressing was used because it was recommended at other established BAHD centres.⁴ Allevyn and Mepitel were the suggested dressings named in the BAHD technical operating manual.³ The addition of the silver-impregnated dressing (Acticoat 7) was a departmental decision; this dressing had been used with apparent success in other surgical specialties in which wound care was particularly crucial.

Mepitel was used on only 10 patients because a significant post-operative problem arose: an infection rate of 50 per cent. This was alarmingly high and therefore we

felt it would be inappropriate to continue to use this dressing in the study. We suspect the problems experienced with the Mepitel dressings were due to insufficient pressure on the wound site, which allowed post-operative swelling to occur and thus provided an environment in which infection could occur.

The Allevyn dressing was thicker and seemed to control any post-operative swelling around the abutment site. The infection rate for Allevyn was 10 per cent, which compared favorably with that of the TAC dressing (16 per cent). The addition of the Acticoat 7 dressing around the abutment with Allevyn on top reduced infection rates further, to 5.5 per cent. We hypothesize that this may have been due to the antimicrobial activity of the silver-impregnated dressing.

- This study describes the authors' experience with the use of four types of post-operative dressing for bone-anchored hearing aids .
- Infection rates varied from 50 to 5.5 per cent depending on which dressing was used .
- The type of dressing used resulted in a marked difference in the number of visits patients required to the post-operative wound care clinic.

The infection rates for the different dressings were reflected in the number of additional visits required to the BAHD wound care clinic. The problem experienced with Mepitel resulted in the highest number of additional clinic visits, at 3.7, followed by the TAC dressing, at 1.5 additional visits. Most of the Allevyn patients needed one additional visit to the wound care clinic, whereas the majority of Allevyn and silver patients were discharged after the normal two post-operative clinic visits.

Our study had some limitations. Infection was defined as either a positive microbiology wound swab or the presence of cellulitis at the BAHD site. The latter definition of cellulitis comprised of erythema, pain and swelling, and this was a subjective assessment. However, the infection assessment was made by the same individual BAHD specialist nurse, who had had many years' clinical experience of post-operative BAHD care. Co-morbidities, such as diabetes or the use of steroid medications, were not specifically recorded for all patients. However, a retrospective review of the notes of the 18 patients who had a BAHD infection showed that only one of them had a possible confounding factor (insulin-dependant diabetes). No patients received any prophylactic antibiotics prior to their BAHD operation. Finally, treatment allocation was not randomized; we used the dressings sequentially.

We feel that the choice of post-operative dressing is a crucial element in the success of BAHD implantation.

It is imperative to reduce the risk of infection and thus to provide optimum conditions for osseointegration of the BAHD.

In our experience, we had the lowest infection rate and the least post-operative problems with a combination of Allevyn and Acticoat 7, and we therefore now use this as our preferred post-operative BAHD wound dressing. A randomized controlled trial would be the next step to produce level I evidence.

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Chapter 7

Discussion

General Discussion

Bone anchored hearing device surgery in children has evolved considerably since their original introduction in 1984. This thesis has concentrated on the challenges and important factors that present to clinicians working with children with bone anchored hearing devices. There have been several particular areas in which changes in bone anchored hearing device surgery has evolved the most. These are discussed below:

Indications

Bone anchored hearing device surgery is no longer confined to conductive and /or mixed hearing loss. Significant evidence of benefit has now been demonstrated in children with single sided hearing loss (both sensorineural and conductive) allowing them an additional option from the traditional Contralateral Routing of Signal (CROS) hearing aid. This thesis also provides evidence of excellent bone anchored hearing device compliance in this group of children with a unilateral hearing loss as well as subjective benefit when assessed with Glasgow Children's Benefit Inventory questionnaires and health benefit measurements. As more centres publish their results, this will add to the body of literature regarding audiological and subjective benefits of bilateral or unilateral BAHD surgery in children. Future studies need to correlate this with educational benefit and achievements to provide robust evidence to expand availability and funding for these devices in public healthcare systems where resources may be limited.

Assessment

How do we assess which children will benefit from a BAHD and how much will that benefit be? It is clear from the literature that many factors play a role; no two children are the same. A multi-disciplinary assessment is essential. This includes an accurate audiological assessment by a paediatric audiologist. A trial of a bone conductor on a headband remains paramount in selecting children who may benefit from a bone anchored hearing device. This trial should ideally be several months to allow sufficient time to adapt to the device and use it in a variety of daily scenarios. However we have shown that it is not essential in all cases and this is highlighted in the chapter pertaining to children with severe learning difficulties. This thesis has shown such children gain significant benefit from a bone anchored hearing device despite not being able to trial a bone conductor on a headband. These children would most likely have been excluded for consideration of such a hearing implant in previous years. It is not only the audiological assessment that is important. Parent/child expectations need to be evaluated and addressed. Self-

image is important to children; a BAHD may show benefit in the audiology testing room but it is of little value if the child is self-conscious and will not use the BAHD in the classroom environment when surrounded by their peers. Appropriate counseling is essential to minimize non-usage.

Surgical technique

The introduction of a linear incision technique has eliminated problems of skin graft failure however great care is essential with this technique to ensure the skin preparation and thinning is meticulously performed. The most recent evolution is performing BAHD surgery without any soft tissue/skin reduction but this technique is still in its infancy and long-term outcomes are not yet known. There has been a trend towards single stage surgery in older children which reduces the number of general anaesthetic procedures required. Not all clinicians routinely use a ‘sleeper fixture’ which reduces the cost and time needed for surgery.

Postoperative care

Peri-abutment wound care is essential to minimize soft tissue reactions. The choice of postoperative dressing choice remains controversial and this is reflected by individual units and surgeons having their own preference. There has been a trend to use longer abutments in the cases of skin hypertrophy; it has also been used at primary surgery in children who have a high risk/history of skin hypertrophy or overgrowth. This thesis has shown that the use of a longer abutment can be an extremely useful adjunct in the treatment of peri-abutment skin hypertrophy and overgrowth in children with no long-term problems.

Improved technology

Fixture & abutment design

Changes in the design of the fixtures and the abutments have led to reduced peri-abutment skin reactions and much earlier loading of the sound processors in adult programmes and this practice is increasingly applied to children. Implants have become wider in diameter to improve stability, the thread has become smaller to improve load distribution and coatings have been introduced to increase the rate and strength of osseointegration. The introduction of hand-held resonance frequency equipment to objectively measure implant and abutment stability in the clinical setting has given health care professionals the opportunity and confidence to load implants at an earlier stage.

Processor design

Originally, there was just one manufacturer of a percutaneous bone anchored hearing device however there is now a selection of sound processors available which allows a greater surgeon & patient choice. Changes in digital processing sound technology have improved the directionality of the microphones and output of the sound processors. The processor appearance has improved and this is very important for young patients. They are now available in various child friendly aesthetic colours and have been designed to allow the parents, carers or child to easily identify if the hearing aid is functionally correctly.

Transcutaneous systems

Modern technology in the form of the transcutaneous bone anchored hearing device is still relatively new however it may in the future confer the benefit of a traditional percutaneous implant systems without the problems associated with an abutment. The lack of an abutment is very appealing particularly in the paediatric population however this thesis has shown there remains a practical issue with the latest technology. Clinicians must be mindful that transcutaneous devices may have magnetic resonance imaging compatibility issues that need to be addressed. In addition, there is obvious artifact that may affect the usefulness of the imaging. As experience with these devices improves, long-term outcomes (implant complications/survival and subjective patient quality of life measures) will become available which will allow comparison with the traditional percutaneous devices.

Middle ear implants

Middle ear implants such as the Vibrant Soundbridge (Medel™) can also be an alternative option in children with a conductive and/or mixed hearing loss. In June 2009, the Vibrant Soundbridge received approval for patients younger than 18 years of age in the European Union. In appropriate cases, the floating mass transducer (FMT) can be placed on the long process of the incus, mobile stapes remnants, round or oval window. However, a pre-operative computerised tomography (CT) scan is needed and there is no option of a preoperative headband trial. Magnetic resonance imaging compatibility is also an issue therefore these factors, in addition to cost, may limit its use in the paediatric population.

Corrective surgery

The role of primary corrective surgery should also not be forgotten. However, the anatomy of the middle ear space may not be suitable. In addition, the BAHD has

the advantage of providing acoustic input from an early age (e.g. a BAHD on a headband) and eliminates any risks that may arise from corrective middle ear surgery.

The future

Despite the obvious advances in paediatric bone anchored hearing device surgery, there are still challenges that have to be met.

For the clinicians, the goal is to perform single stage surgery for a child with a reliable and reproducible technique with minimal peri-abutment skin reactions. Peri-abutment skin reactions have long been a problem for both clinicians and children alike.

The sound processor should have an acceptable cosmetic appearance. There is no doubt that peer pressure and self image is important in the success of a bone anchored hearing device for a child / young person. The sound processor should be loaded early to allow acoustic stimulation as soon as possible. The device should not preclude any medical interventions such as MRI scanning. The device should be robust, reliable and require little or no maintenance from a child/parent perspective.

BAHDs are undoubtedly a very valuable resource for hearing rehabilitation in the paediatric population. The expanding indications for their use coupled with the increased evidence of their benefit would suggest the numbers of children treated will continue to grow.

Current technology is rapidly progressing with exciting new innovations to further ensure benefit to children with BAHDs. Recent additions of Wifi streamers to provide wireless sound transfer to the telephone, computer and other electric devices is just such an example.

It is not inconceivable that a fully implantable device may be available in the lifetime of our children.

Chapter 8

**Summary / Samenvatting
Curriculum Vitae
Acknowledgements
List of Publications**

Summary

This thesis has shown there have been a number of advances in paediatric BAHD surgery.

BAHDs have evolved over recent years. New BAHD manufacturers have encouraged competition as well as technological improvements allowing newer devices to be developed. The latest generation of percutaneous devices have been designed to reduce skin complications, promote better osseointegration and earlier loading of the sound processor. The sound processor technology has improved resulting in better sound quality. Transcutaneous BAHDs without a skin-penetrating abutment are now available and have shown promising results in the paediatric population.

Chapter 2

This chapter comprised of a retrospective case series review of four children at the severe end of the spectrum of behavioural difficulties who underwent BAHD implantation where no formal preoperative hearing aid assessment was possible. The BAHD was used daily and parents/carers reported a positive impact of the BAHD on the behaviour and mood of their children. We have shown that the BAHD is now a feasible option for children who may not be able to go through the traditional preoperative BAHD assessment process. Although a more rigorous postoperative regime was required, we have demonstrated that a BAHD can be successful in these children.

Chapter 3

Peri-abutment care remains a challenge - both the surgeon and patient have pivotal roles. Surgical technique and postoperative wound care are important to minimize peri-abutment skin reactions. In this chapter, we described our experience with the use of the 8.5mm abutment in a series of 16 children. We have demonstrated a clear role for long abutment in appropriate cases. We found the need to use it particularly around the time of puberty when we observed soft tissue problems develop. It appears to be a reliable option on both 3 and 4mm

fixtures in cases of skin hypertrophy and can also be used during revision surgery in cases of abutment skin overgrowth.

Chapter 4.1 and 4.2

We have provided more evidence showing the benefits of a BAHD in children a unilateral profound sensorineural hearing loss or a unilateral conductive hearing loss.

In chapter 4.1, we reported our experience in a series of 8 children with single sided sensorineural deafness where a bone-anchored hearing device (BAHD) was used for auditory rehabilitation. The majority of children used their BAHD for more than 8 hours/day for all 7 days of the week. Patient/carer satisfaction was high with the majority reporting an improvement in the quality of life of their children.

In chapter 4.2, we performed a retrospective case note analysis of 17 consecutive paediatric patients who had a BAHD for auditory rehabilitation. Results showed qualitative subjective outcome benefits when measured with GCBI. The BAHD was used on a daily basis and improved social and physical functioning as well as improved quality of life.

Chapter 5

The development of a transcutaneous device introduces an interesting option in the management of children who require a BAHD. The lack of a percutaneous abutment and its associated problems is appealing. In this chapter, we performed a retrospective review of 206 children who had a percutaneous BAHD. However, we have shown that a magnet-containing transcutaneous BAHD may not be a practical device for a proportion of children with significant co-morbidities when a MRI scan is likely to be needed. Twenty eight percent (56/206) of children required at least one MRI scan with some children requiring multiple MRI scans; this would have proved to be of practical issue with the recently introduced transcutaneous BAHDs.

Chapter 6

This chapter comprised of an observational study of 160 consecutive patients reporting bone-anchored hearing device infection rates using different post-operative dressing. The choice of dressing appeared to influence wound problems

and the number of visits required to the nurse-led wound care clinic. Although the results are reported on an adult population, it is highly pertinent to the paediatric population where parents/carers also have a responsibility for maintaining peri-abutment hygiene.

Samenvatting

In 1984 werd voor het eerst gestart met de toepassing van percutaan in het schedelbeen verankerde hoortoestellen. Sedertdien heeft deze toepassing van in het schedelbeen verankerde beengeleider hoortoestellen een enorme ontwikkeling doorgemaakt. Deze proefschriftstudie is beperkt tot de toepassing van deze percutane beengeleider hoortoestellen bij kinderen. In het bijzonder is aandacht besteed aan het uitbreiden van de indicatiestelling en het evalueren van de daarbij verkregen resultaten. Evenzo is er studie van gemaakt in hoeverre belangrijke gegevens, zoals de wijze van de "soft tissue" chirurgie en de lengte van het toegepaste abutment (8.5 ipv 5.5 mm) van invloed zijn op de verkregen resultaten.

Op de volgende 3 terreinen van de toepassing van het in het schedelbeen verankerde hoortoestel zijn in de tijd grote veranderingen ingetreden:

1. De indicatiestelling voor toepassing van het in het schedelbeen verankerde hoortoestellen en welk preoperatief verricht onderzoek benodigd is.

De indicatie voor in het schedelbeen verankerde beengeleider hoortoestel (BAHD) is niet alleen meer beperkt tot de dubbelzijdige gehoorverliezen van het geleidingstype (uitwendige gehoorgang en middenoor) of gemengde gehoorverliezen (geleidingsverlies tezamen met een binnenoorverlies). Eenzijdige conductieve gehoorverliezen alsook eenzijdige binnenoorverliezen behoren inmiddels tot het indicatie gebied voor een behandeling met een BAHD. Voor de nog zeldzame toepassing van een BAHD vanwege een eenzijdige binnenoorverlies bij kinderen worden in dit proefschrift opnieuw belangrijke positieve bevindingen verschaft. De verkregen bevindingen zijn zodanig goed, dat daarmee een goed alternatief voorhanden is gekomen voor de voorheen al beschikbare CROS (Contralateral Routing Of Signal) hoortoestel toepassing.

Deze proefschriftstudie verschaft proefondervindelijk verdere steun voor de toepassing van het in het schedelbeen verankerde beengeleider hoortoestel bij kinderen met een eenzijdig geleidingsverlies. Door gebruik te maken van vragenlijsten als meetinstrument, zoals de Glasgow Children's Benefit Inventory, werden kwaliteit van leven studies verricht.

Een multidisciplinaire team benadering , inbegrepen een proefaanpassing met een Softband Beengeleiderhoortoestel, is aangewezen om de kinderen te selecteren van wie verwacht mag worden dat zij profijt zullen gaan hebben van een in het

schedelbeen verankerde beengeleider hoortoestel toepassing. Toch blijkt er een kleine groep kinderen te bestaan met zowel een ernstige ontwikkelingsstoornis en bovendien een gehoorstoornis, die ook zonder een eerdere Softband beengeleider proefaanpassing als onderdeel van de standaard multidisciplinaire toetsing, succesvol aanvaard kunnen worden voor een behandeling met een percutane beengeleider hoortoestel aanpassing. Deze kinderen bleken eerder een Softband proefaanpassing niet te verdragen. Tot nu toe werd aan dergelijke kinderen de BAHD toepassing nog onthouden.

2. De chirurgische techniek en de behandeling van de huidreacties rondom het percutane implantaat.

Door de invoering van de lineaire incisie techniek is de noodzaak van het toepassen van een vrij huidtransplantaat - met het risico van het teloor gaan van dat transplantaat - verdwenen. Daarentegen blijft het bij de toepassing van het klassiek korte (en lage) 5.5 mm titanium opbouw (abutment) noodzakelijk de subcutane weefsel reductie zeer zorgvuldig te verrichten.

Er is een trend om bij de wat oudere kinderen de operatie niet meer in twee tempi maar in een tempo te verrichten. Dat scheelt dan een extra ziekenhuis opname en een algemene narcose. Omdat bij kinderen het verlies van het titanium implantaat hoger is dan bij volwassenen, kiezen vele chirurgen er voor om als reserve implantaat een extra titanium schroef (een "sleeper") te plaatsen. Anderen laten dit na vanwege de daarmee gemoeide extra kosten en de extra benodigde operatietijd.

Het gebruik van een langer 8.5 mm abutment in plaats van het klassieke 5.5 mm abutment bij kinderen (dit proefschrift) blijkt een belangrijk middel om een hypertrofie/ verdikking van de huid al of niet met overgroei van het abutment te helpen voorkomen.

3. Verbeterde technologie toegepast in het beengeleider hoortoestel

In het verleden was er slechts een firma - en wel onder de elkaar opvolgende benamingen: Nobelpharma, Nobelbiocare, Entific en nu Cochlear BAS - die het percutane beengeleider hoortoestel en het percutane implantaat met de benodigde chirurgische instrumenten en apparatuur leverde. Inmiddels is sinds enige jaren Oticon Medical als tweede firma op dit zelfde terrein werkzaam. Hierdoor is er zo een competitie ontstaan en is er voor de patiënt/arts/audioloog een keuzevrijheid ontstaan. Vernieuwingen in het ontwerp van het titanium implantaat en de percutane titanium bovenbouw - inbegrepen de langere abutments - hebben geleid tot minder huidreacties rond het percutane implantaat.

Tegelijk is er een trend ontstaan om bij volwassenen het implantaat eerder te gaan belasten met het beengeleider hoortoestel. Het is nog onduidelijk of het wel verantwoord is om ook bij kinderen het implantaat eerder dan voorheen te gaan belasten met het beengeleider hoortoestel, ook al is een vroegtijdige gehoorrevalidatie vanwege het gehoorverlies een juist streven.

Veranderingen in de digitale processor van het hoortoestel hebben een aantal verbeteringen bewerkstelligd. De richtinggevoeligheid van de ingebouwde microfoons is verbeterd. Het verstaan te midden van rumoer is al bij herhaling verbeterd. De kracht van het hoortoestel is over de tijd toegenomen. Tevens is de vormgeving aantrekkelijker geworden, wat kinderen zeer weten te waarderen.

Sinds enkele jaren en zeer recent zelfs opnieuw zijn er nu enkele (passieve en aktive) transcutane beengeleider hoortoestellen beschikbaar gekomen. Een belangrijk voordeel is dat het percutane contact, gevoelig voor infecties, zo vermeden kan worden. Echter door een noodzakelijkerwijs nu wel te implanteren magneet - nodig voor de fixatie van het hoortoestel aan het hoofd - ontstaat de kwestie van MRI incompatibiliteit. Tegelijk is vooralsnog de geholpen gehoordrempel na aanpassing van dit beengeleider hoortoestel en vergeleken met de percutane toepassing als gevolg van het transcutane contact ongeveer 10 dB zwakker. De nabije toekomst zal moeten gaan uitwijzen hoe belangrijk deze voordelen en deze nadelen zijn.

Deze proefschriftstudie toont aan dat naast de nu al behaalde resultaten er toch weer andere nieuwe vraagstellingen, als gevolg van wederom gerealiseerde technologisch vernieuwingen, gaan ontstaan. Een van die vele kwesties is in hoeverre de bij de transcutane toepassing te implanteren magneet en de daarmee gepaard gaande MRI incompatibiliteit van betekenis zal zijn. In deze proefschriftstudie wordt aangetoond dat vooral deze populatie kinderen met een BAHD toepassing een grote behoefte kent aan MRI diagnostiek (dit proefschrift). Daarnaast is er het probleem dat de afbeelding van het gebied alwaar de magneet is geïmplanterd niet goed meer is af te beelden met die beeldvormende techniek.

Curriculum Vitae

Jayesh Doshi was born in Rochdale, UK on 23rd September 1977. His childhood was spent in the North-west of England where he attended Bury Grammar School.

Following his undergraduate medical studies at Manchester Medical School, Jayesh graduated with an honours degree in 2001 [MBChB(Hons)].

His pre-registration medical and surgical posts were at Manchester Royal Infirmary and Salford Royal Hospital, Manchester. He then moved to Newcastle-upon-Tyne where he completed his basic surgical training rotation between 2002 and 2005. During this period he successfully passed the MRCS examinations in 2004. (MRCS Edinburgh)

As senior house officer in otolaryngology in Newcastle-upon-Tyne, he decided to pursue a career in ENT. In 2006 Jayesh was successful in obtaining a place on the West Midlands ENT Higher Surgical Training programme.

During this six years of higher surgical training in Otolaryngology, Jayesh gained wide experience in all aspects of ENT surgery. His particular sub-specialty interest is Otology. It was whilst working with Ann Louise McDermott at Birmingham Children's Hospital, that Jayesh first became interested in bone-anchored hearing device surgery and the challenges this surgery held for children and clinicians alike. He took an active interest in the paediatric bone anchored programme of research and audit and continues to be a very active member of the team to date.

Jayesh was successful in obtaining his FRCS (ORL-HNS) in 2010 at the Royal College Surgeons Edinburgh.

Jayesh has just completed an otology/facial plastics fellowship in Dunedin, New Zealand and will be starting a one-year otology/skull base fellowship in Manchester, UK from August 2013.

He has demonstrated a keen interest in research and teaching. He has published 26 peer-review articles in addition to 14 newsletter/correspondence publications. He has 25 oral presentations (14 at international/national meetings) and has presented over 40 posters (27 at international/national meetings). He has won 4 regional presentation prizes. He is a member of the ENT UK subcommittee for medical students since 2008; He also has a Masters (MSc) in Medical Education from the University of Dundee (2011) during which he developed an ENT

educational learning website for medical students and junior doctors (www.enttheatre.com). He has been a faculty member of the West Midlands ENT Course for junior doctors for the last 4 years.

Jayesh is married to Ashvini Menon who has been a constant source of support throughout his training and research. His interests include traveling and his recent year in New Zealand has left him with an insatiable appetite for tramping!

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-



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- * Doshi J, Sheehan P, McDermott AL. Bone anchored hearing aids in children: An update. *Int J Pediatr Otorhinolaryngol*. 2012;76:618-22
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