The benefit and success of the Bone Anchored Hearing Aid

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Contents

Chapter 1

Introduction

Introduction

Osseointegration is defined as a process of rigid fixation between a titanium fixture (implant) and the surrounding bone.

This concept was first described in clinical use in 1965, when titanium oxide implants were used as a means of providing an anchor for a fixed dental bridge in an edentulous jaw.[1]

In 1977, the application of osseointegration for extra-oral implants in the temporal bone was reported by Tjellström et al.[2] Since then, osseointegration has become increasingly invaluable both in and out of the mouth.

Today the Bone anchored hearing aid (Baha®) is a well established and very popular form of hearing rehabilitation for patients with conductive hearing loss, and is now commercially available worldwide.

Bone anchored hearing aids were introduced to Birmingham UK in 1988. By 1992 it was apparent that bone anchored hearing aid patients required a multi-disciplinary team devoted to their assessment, treatment and long term follow-up. The Birmingham bone anchored hearing aid programme began in earnest in 1992.

Over the past fifteen years the Birmingham team has developed considerable experience with the Baha® both in adults and children and the Birmingham programme is now one of the largest in the United Kingdom (UK).

The initiating team in Gothenberg and the renowned Baha® team in Nijmegen have an enviable record of publications on all aspects of Baha®.

In 2002, the Birmingham Baha® team reported their results of more than 300 adult patients with Baha® and this resulted in a PhD thesis at the Radboud University Nijmegen Medical Centre. This thesis was titled “The Birmingham Bone Anchored Hearing Aid Programme. Some Audiological and Quality of Life outcomes”.[3]

After fifteen years of the Baha programme, it is now time for the Birmingham Baha® team to assess the overall benefit and success of the Baha® in their patients with particular reference to children.

The present PhD thesis describes the overall paediatric experience of the Birmingham team. It also defines the benefit of Baha® in children with Down Syndrome and those in younger age groups which has always been a topic for discussion.

This thesis gives a comprehensive assessment of patient satisfaction for adults and children alike and aims to provide a measure of both benefit and success of Baha®.

Finally, although the literature emphasises a minimal risk of complications, for those clinicians who are involved with the provision of Baha® they must remember that unusual and unexpected complications although rare, do happen and this is discussed in Chapter 4.1.
Before embarking on the evaluation of our patients it is important to understand the basic concepts that surround bone conduction and the evolution of bone conduction hearing habilitation.

Bone conduction physiology.
The phenomenon of bone conduction has really only been understood during the past century.[4,5] Many mechanisms have been proposed over the years however it was Von Bekesy who first discovered that the mode of cochlear hair cell excitation was identical whether the sound wave pathway was via air or bone conduction.[6]
In 1966, Tonndorf postulated that bone conduction was the result of contributions from not one but three major mechanisms.[4]

1.Bone compression mechanism
Vibratory energy reaches the cochlea and results in alternate compression and expansion of the cochlea superstructure. The fluid within the cochlea can not be compressed and therefore has to yield to the forces applied.
The scalae have different dimensions; the total surface of the vestibular side being greater than on the tympanic side of the basilar membrane (ratio 3:2).[7] Contraction of the larger vestibular side results in greater displacement of fluid in the scala vestibuli than in the scala tympani. Displacement of fluid is further enhanced by the semicircular canals and vestibule. This results in fluid being forced into the scala vestibuli causing downward deflection of the basilar membrane.
Finally, it is believed that the compliance ratio between the round window and the oval window is 20:1 and so compression would result in more movement at the round window further amplifying movement of the basilar membrane.[8]
The basilar movement is greatest at the basal turn and so sound perception by this bone compression mechanism contributes largely to the high frequencies.[9]

2. Inertia Bone conduction mechanism
Vibration of the skull results in vibration of the ossicles relative to the skull. The malleus and incus vibrate as one unit rather like a pendulum which can vibrate around an axis held in a support which also vibrates.[10] The resultant motions displace the stapes which results in cochlear stimulation as in air conduction

Sound energy of the external ear

Sound energy radiates from the vibrating bone into the bony and cartilaginous walls of the external auditory meatus. These vibrations radiate to the tympanic membrane and then through the middle ear cleft as in air conduction.

Bone conduction hearing aids: Brief historical overview.

In the 1876, the first bone conduction hearing aid was described by Professor Paladino at the University of Naples. It was a metal rod. One end was placed on the speaker's larynx, the other end against the teeth or the mastoid of the listener. This device was called a Fonifero.[11] During the 19th century, the ear trumpets and various speaking tubes were in vogue.

By the 1920s, electric hearing aids became commercially available. 1960s transistor technology made the "behind the ear" hearing aids a reality.

Historically air conduction aids received the most attention. For those patients requiring a bone conduction hearing aid, there was the electromagnetic vibrator which was designed to press against the mastoid by a tight steel spring/headband connected to a body worn power processor. Many patients found this uncomfortable and very unsightly. A more cosmetic alternative were Hearing spectacles.

The Bone anchored Hearing Aid was introduced in the 1980s. This was a hearing aid retained by a percutaneous implant. Few could have predicted the increasing indications and popularity this hearing aid would achieve.

Osseointegration

Osseointegration is defined as "a direct structural and functional connection between ordered, living bone and the surface of a load carrying implant".[12] Today there are many suggested definitions but the important principle is that the bone and metal are in direct contact preventing fibrous tissue from encapsulating the implant.

A Titanium oxide implant surface is highly biocompatible and encourages integration of osteocytes which in turn form the required non fibrous interface so important for implant stability. This process has been shown to take between three weeks and six months to complete. Recently there has been evidence that osseointegration may be quicker than originally believed, reducing the activation time of the implant from twelve weeks to only six with no obvious increase in complication rates.[13]

The Bone Anchored Hearing Aid

The combination of osseointegration and direct bone conduction with a hearing aid was first described by Tjellström and his team.[14,15] The Baha® is a percutaneous (semi-implantable) hearing aid. It secures to the skull by osseo-integration of a titanium oxide coated implant. It is most effective in rehabilitation of patients with single and bilateral conductive hearing loss, mixed hearing loss and in recent years, it has been shown to perform well in those with single sided inner ear deafness.[16]

Long term outcomes from several world renowned centres have shown excellent stability of the implants, significant audiological benefit and improved patient quality of life and patient satisfaction.[17,18]

The Birmingham Baha® Programme

The Birmingham Osseointegration programme (UK) began in 1988.

The programme was based at the University Hospital, Queen Elizabeth under the leadership of Mr David Proops, Consultant Otologist.

Initial help and expertise was received from Professor Tjellström's team in Gothenburg and more locally from the maxillofacial unit who already had experience with dental implantation.[3]

In 1992, a designated Birmingham Paediatric Baha® Programme was set up with a multidisciplinary team comprising of Otolaryngologists, Audiologists, Anaplasto-logist, a Speech Therapist and an Advanced Nurse Practitioner. Since this time, the programme has grown and it is now recognised as one of the largest in the UK.

The provision for bone anchored auricular prosthesis for congenital and acquired ear abnormalities is dealt with by the FAITEC (Facial and Audiological Implantation Technology) programme. Many of the specialists are actively involved in both programmes.

At the time of this research for this thesis, more than 1000 patients including both adults and children have received a Baha® in Birmingham.

Paediatric experience

To date there have been 182 children implanted with a Baha®. The youngest child was 2 years of age at the time of surgery. Until 2002, the general consensus in Birmingham was that provided the audiological and psychosocial criteria were satisfactory, the earlier the child was implanted then the better the outcome.

In 2002, the Baha Softband® was introduced. Since then, in Birmingham, the treatment of choice for children less than 3 years of age is the Softband®

Surgery is reserved until the child is older. This is discussed in detail in chapter concerning Baha in very young children.

Baha®: The evidence of benefit

Evidence of benefit can be obtained from audiological testing and questionnaire feedback[19]

In this climate of evidence based practice, every aspect of Baha® practice has to undergo scrutiny and critical appraisal and reappraisal by peer review. Classification based upon the strengths of study design and robustness of an outcome is essential to create "Levels of Evidence".[20]

Outcome measures

The impact of a disease state has been categorised by the World Health Organisation (WHO) as shown below.[21]

a. Mortality
b. Functional morbidity; hearing impairment
c. Disability; the restrictions on daily living as a direct result of hearing impairment
d. Handicap; limitations on an individual as a result of hearing impairment
e. Distress; the psychological reaction of the hearing impairment

For the purposes of this thesis, hearing impairment will be adopted as the 'disease state'.

1. Subjective outcome measures.

There have been many studies evaluating surgical as well as audiological outcomes of patients with a Baha®, all with significant evidence of benefit.[22,23,24,25,26,27]

In this era of evidence based practice with the added pressure of justifying the financial costs involved in the provision of a Baha®, all aspects of aetiological, epidemiological, diagnostic, and management interventions must be evaluated. Measuring the benefit and the success of the Baha® is absolutely essential.

Outcomes of medical treatments are no longer measured by death, disability and cure but are now measured by means of health related quality of life measures. These may be

a. generic
b. disease specific
c. domain specific.

The ideal health status instrument should measure what exactly it was designed to measure (validity), the results should be reproducible for a given individual (reliability) and it should be sensitive to any change in health.
The research in this thesis uses disease specific instruments. These assess hearing impairment in context and can measure both disability and handicap and are more sensitive to any change in health status.
There is a wide variety of validated disease specific health status instruments to choose from. Table one illustrates the health status instruments used in this PhD thesis.
This thesis also includes questionnaires designed specifically for hearing aids as seen in Chapter 3.4.This additional information is valuable in assisting the evaluation of efficacy of treatment with a Baha®.

Table 1. Health Status Instruments used in this PhD thesis.

Instrument	Chapter	Author	Outcome	Administered
GHABP[28]	3.5	Gatehouse	Disease Specific	Postal (interview)
GBI[29]	3.2 3.6	Browning	Disease specific	Postal
GCBI[30]	2.2 3.1	Kubba	Disease	Postal
Nijmegen group questionnaire[31]	3.3	Mylanus	Disease specific	Postal
Entific Medical Systems[32]	3.4	Entific	Hearing aid specific	Postal

Scope of this Thesis

The use of osseointegrated implants for Baha® retention is now a well established practice since the device became commercially available in 1987.[33] There are a great many reports acknowledging the benefits of the Baha® both in audiological terms as well as its effects on patient well being.[34,35,36,37] The Baha® is a reliable and effective means of hearing rehabilitation.
There are a great many reports of Baha® in adults and recent years have seen more outcomes of paediatric Baha®.[38,39,40]
In Chapters 2.1,2.2, and 3.1, the overall benefit of the Baha® in a large paediatric population in the UK, have been measured both in the form of surgical and disease specific outcome measures. The results indicate a significant benefit® in

children irrespective of the indication for their Baha®. Chapter 2.2 in particular, demonstrates the benefit of Baha® in children with Down Syndrome.

Audiological outcomes are currently in progress in Birmingham. Implants for bone anchored auricular prostheses are not included in the research for this thesis.

Regarding success of Baha® in children, in all our studies Baha® was found to be an overwhelming success with 97% of the paediatric population content to wear their Baha® on a daily basis.

Previous subjective outcome measure instruments used for paediatric Baha® had been initially validated for adult populations. The recent introduction of a paediatric validated and reliable Glasgow Children's Benefit Profile (GCBI) allowed for a more accurate evaluation of our younger patients and was most likely responsible for the current improved paediatric response rate (73%) in comparison to earlier research in Birmingham in 2002 (40%).

Baha® in children presents a unique challenge; trauma. The majority of paediatric Baha® literature describes problems of trauma to the Baha®, often resulting in failure/loss of abutment.

Chapter 4.1 illustrates that although the majority of Baha® complications are not life threatening and serious, unusual and unexpected complications although rare, do happen.

Surgical outcomes for children aged less than 5 years is discussed in chapter 2.3.

The most appropriate age for implantation in very young children many of whom have craniofacial abnormalities, has for many years, been the subject for discussion. The Birmingham Baha® programme has implanted children as young as 2 years.

Our results demonstrate that this cohort of very young children did have an increase in morbidity associated with Baha®. Their fixture failure rate was high as was revision surgery for significant skin reactions.

The Baha Softband® is currently the treatment of choice for children less than 3 years of age in Birmingham (UK) Surgery is reserved until the child is older both physically and developmentally.[33]

For our Adult patients, Bilateral Baha® is now an accepted and regularly offered intervention. Our early results with subjective and audiological outcomes are presented in Chapter 3.6.

Regarding disease specific outcome measures in the adult population, the Glasgow Benefit Inventory (GBI) and the Glasgow hearing Aid Benefit and Difference Profile (GHABP) were the instruments of choice. They are both validated and reliable outcome tools. They were both administered as postal

questionnaires. The multiple divisions and stems of certain complex questionnaire such as the GHABP resulted in difficulties that are discussed in Chapter 3.5
Finally, a general discussion is presented in Chapter 5.

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Part 2

Bone-Anchored Hearing Aid system in Children

2.1

The Birmingham Paediatric Bone Anchored Hearing Aid programme: A 15 year experience

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Abstract

Objective: To evaluate the complication rates and outcomes of children who were fitted with a bone anchored hearing aid on the Birmingham BAHA programme.

Study design: Retrospective case analysis of clinical records of all children implanted at Birmingham Children's Hospital since the beginning of the programme in 1992 until February 2007.

Patients: A total of 182 children below the age of 16 years fitted with a bone anchored hearing aid. (Baha®) 107 of these children had a significant medical history.

Results: Surgery was performed as a two-stage procedure in 174 children. The healing time was between 3 to 4 months in 112 (64 %) of cases.
Single stage surgery was performed in 8 cases.
Implant failures were 14% of 230 loaded fixtures. (32 fixtures lost in total) Multiple fixture failures (18 fixture failures) occurred in 7 patients. Adverse skin reactions appeared in 34 (17%) patients over a 15-year follow-up period.
Revision surgery was undertaken in 14 (8 %) cases because of skin overgrowth around the abutment. Five of these cases required multiple surgical skin reductions.

Conclusions: The Birmingham Programme has a high proportion of syndromic patients with complex medical problems. The fixture failure rate was found to be 14%. This included the multiple fixture failures in children below 3 years of age.
There was one serious complication. The bone anchored hearing aid is a reliable and effective treatment for selected patients.
Our programme currently has 97% of its children wearing their Baha® on a daily basis with continuing audiological benefit.

Introduction

The use of osseointegrated implants for Baha® retention is now a well established practice since the device became commercially available in 1987.[1] There are a great many reports acknowledging the benefits of the Baha® both in audiological terms as well as its effects on patient well being.[2,3,4,5] The Baha® is a reliable and effective means of hearing rehabilitation.

In the adult population, the Baha® has been used primarily for chronic suppurative otitis media, chronic otitis externa and failure with conventional aids. In the paediatric population, the Baha® has in addition to the above, proven to be enormously useful in cases of congenital aural atresia, and an alternative to canal and middle ear reconstructive surgery.[6,7]

In Birmingham, the first osseointegrated fixture for a Bone Anchored Hearing (Baha®) was implanted on the 23rd of August 1988 in the Birmingham Children's Hospital. The patient was a 15 year old boy who had previously undergone bilateral mastoid surgery. It was almost twelve months before a second patient was implanted. This slow start was due to a combination of difficulties forming a multidisciplinary team with all the necessary specialities, in particular audiology. The period between 1988 and 1992 saw sporadic Baha® surgery. Then in 1992 a designated Birmingham Paediatric BAHA Programme was set up with a multidisciplinary team comprising of Otolaryngologists, Audiologists, Anaplasto-logist, a Speech Therapist and an Advanced Nurse Practitioner. Since this time, the programme has grown and it is now recognised as one of the largest in the UK.

The aim of this study was to evaluate the complication rates and outcomes of children who were fitted with a Baha® on the Birmingham Paediatric Bone Anchored Hearing Aid programme since it began in 1992 until February 2007.

Methods

This was a retrospective case analysis of all children aged 16 and under, who received an osseointegrated fixture for a Baha® at the Birmingham Children's Hospital since 1992.

A total of 182 records were analysed by two clinicians. Outcomes included indication for a Baha®, medical history, surgery, complications and post operative follow up.

All fixtures placed for auricular prosthesis were excluded from this patient cohort.

A small number of children had bilateral Baha and outcomes for the second side were also evaluated.

Results

There have been a total of 182 children under the age of 16 years, who have been implanted and fitted with a Baha® on the Birmingham programme over the past 15 years. There were 102 female and 80 male patients.

Medical History: 107 (59%) children had a significant medical history: There were 28 cases with Goldenhar, 26 children had Treacher Collins, 17 had unusual chromosomal deletions, 15 had Down Syndrome, 4 cases of Pierre-Robin Sequence, The others included cases with Turners syndrome, CHARGE syndrome, Branchio-Oto-renal syndrome.

Table 1. Significant medical history.

Syndrome	Numbers
Goldenhar Syndrome	28
Treacher Collins Syndrome	24
Down Syndrome	16
Unusual Chromosomal deletions	12
Pierre-Robin Sequence	3
Turner Syndrome	3
Crouzon Syndrome	2
CHARGE Association	2
Branchio-Oto-Renal Syndrome	2
Foetal-Alcohol-syndrome	2
Asymetrical Crying face	1
Pfeiffer Syndrome	1
Kabuki Syndrome	1
Dubowitz Syndrome	1
Klippel-Feil	1
Nagar Syndrome	1
Alagilles Syndrome	1
Marfans Syndrome	1
Hunters Syndrome	1
Cornelia de Lange	1
Smith Magennis Syndrome	1
Di George Syndrome	1
Winter Tsukahara Syndrome	1

Indications for Baha®

107 children had a conductive or mixed hearing loss as a result of an underlying syndrome or abnormality. Of the remaining 75 cases with no significant medical history, 38 children had chronic middle ear disease.

Finally, there were 22 children who had isolated congenital atresia not associated with a recognized syndrome (Table 2). All cases had tried conventional air and or bone conduction aids.

Two cases had traumatic injuries to the external ear; 1 burn accident and 1 road traffic accident. Both were unable to wear conventional aids.

Since 2002, all patients undergoing Baha assessment irrespective of the underlying aetiology, had worn a Baha softband prior to surgery with good results. (A total of 94 patients)

Table 2. Indication for BAHA.

Syndrome	Number
Congenital Aural atresia	89
Congenital Microtia	44
Chronic Suppurative Otitis Media	38
Chronic Otitis Externa	6
Failure with conventional Aids	3
Trauma to external ear	2

Side of Implant: The side of implantation was generally dictated by the cochlear function, patient and surgeon preference. There were 97 on the right and 51 on the left.
17 children had bilateral Baha®. Of these children, 4 had bilateral simultaneous implantation (Table 3).

Table 3. Side of fixture

	Number of cases
Right	107
Left	54
Bilateral (staged)	13
Bilateral (simultaneous)	4
No record	4

Age: The age at implantation ranged from 2.0 to 15.1 years. The mean age was 6.8 years. 39 children aged under 5 years had implants between 1992 and 2004.

Procedure: 176 children had two-stage surgery.
There were two senior Otologists responsible for all the implant surgery on the Birmingham Bone Anchored Hearing Aid Programme.
Over the 15 years of the study slight variations in the surgical technique as well as post-operative dressings were noted, however the basis principles were unchanged.
The first procedure involved incision and elevation of the soft tissues including the skin, subcutaneous tissues and periosteum and insertion of two fixtures. In cases

with thin bone or significant surgical concern a third fixture was used. No skin reduction was included in this stage. Both 3 and 4 mm fixtures were used. (Table 4).

Table 4. Surgical considerations.

	Number of Cases
3mm fixtures	115
4mm fixtures	67
Bone augmentation	34
Dura identified	67
Sigmoid sinus identified	11
Mastoid air cell identified	5
No operation notes	5

The second stage was performed between 12 to 51 weeks later (mean 20 weeks)
The standard healing time between the first and second stage procedure was 3 months in 112 children (64%). This time period was increased to 5-6 months in 53 cases (30%) at the surgeons' discretion as a result of operative findings of "inadequate bone thickness".
Social/family reasons resulted in a delay in second stage surgery in 9 cases (5%)
The favoured method of soft tissue management in Birmingham has always been either a local free split thickness graft taken from the post auricular area or a thinned pedicled split thickness flap.
The subcutaneous tissues were reduced and a standard abutment (no larger than 5.5mm) was placed on one chosen fixture.
The implant was placed in contact with the dura in 67 cases, and contact with the sigmoid sinus was reported in 11 cases. Implants in contact with mastoid air cells were noted in 5 cases. The dura was not breached in any case
A one stage surgical procedure was performed for eight patients, all others had standard two stage surgery.
A total of 411 fixtures were implanted during the 15 years of the paediatric programme.

Fixture failures: A total of 32 fixtures were lost over the 15 year period giving a failure rate of 14% of the loaded fixtures.
25 of these failures were in the under 5 age group and all these fixtures were lost within the first two years. There were only 7 fixture failures in children over the age of 5 years. (Table 5).

Table 5. Age and fixture failure

Age (yrs)	No. Cases	Loaded fixtures	Fixtures lost	Fisture Failure rate
<3	14	23	9	40%
3-5	25	40	15	38%
5-10	75	88	7	8%
>10	68	79	1	1%

25 of the failed fixtures were 3mm (78%). Of the remaining 7 failures, 4 (13%) were 4mm. The remaining three cases did not have satisfactory documentation.
19 fixture failures were associated with wound breakdown and significant skin reaction. 5 children lost their fixtures as a result of trauma. There were incomplete records for the remaining case.
No association was identified between cases of fixture failure, with the exception of age.

Skin reactions: Holgers classification of skin reaction was first used in the documentation of post-operative skin reactions in 2001. Prior to this it was a subjective record.
Adverse skin reactions appeared in 34 (17%) patients over a 15-year follow-up period. 'Adverse' was standardised as; a soft tissue problem requiring repeated visits to clinic for wound care, repeated silver nitrate cautery or antibiotic therapy. Complete graft failure occurred in 7 cases, however no further surgery was necessary and healing occurred by secondary intention.
14 further cases required surgical skin revision. In this particular cohort, two children had three surgical reductions each over a three year period.
An 8.5 mm abutment was used in 15 cases.
One case of skin reaction was found to be the result of a rupture of an epidermoid cyst.

Follow-up: The length of follow-up varied from 4 to 13 years.
The first post-operative visit was between days 4-8. (Table 6). Further follow-up was at three months was carried out by the audiological team. Medical review was at twelve months post completion of surgery. An open follow-up appointment with the Advanced Nurse Practitioner was available to all patients. In the formative years of the Programme there were more follow up appointments for each patient than in the latter years. 80 children (44%) had been discharged to either their own local Baha® programme or transferred to the Birmingham adult programme at the time of the study.

Table 6. Postoperative follow-up.

First visit	
Day 4	37
Day 5	71
Day 6	45
Day 7	20
Day 8	9

Baha® wearers (success rate): 176 (97%) patients are still wearing their Baha® on a regular daily basis.

There were 4 non-users. Two of these children had abandoned their Baha® as a result of peer pressure and cosmesis issues. One child had repeated difficulties with the sound processor and opted to return to conventional aids and the final child complained of pain and tenderness of the skin around the abutment when wearing the Baha® however clinical and radiologicalexamination revealed the abutment site to be healthy. Two cases remain unknown.

Discussion

This study was a retrospective case analysis. Retrospective studies raises certain problems. Firstly, the availability and quality of medical records over a 15 year period were not always ideal. Although all 182 records were analysed, four cases had no record of implantation side and five cases had missing operation data. In all nine cases, the records were pre-1996.

The rationale for the management of many cases has not always been clear from the patient records. Availability of audiological data was a particular problem in this study. Cross referencing the operative procedures and dates with the operating ledgers was often necessary.

In the early years of the programme many children were referred from other regions within the UK, however since more regional programmes now have experience with Baha®, many of these children have continued their follow-up nearer their homes. This raised particular issues with long term follow up of the children. The record of late complications that may occur after discharge and the assessment of the current use of Baha® in patients now cared for in other Baha centres was considered. These issues were dealt with by direct contact with the patient/carers by our Advanced Nurse Practition who has kept in contact with the patient and family over the years.

Auricular prostheses require more than one fixture and the site of implantation varies greatly. Also these children tend to have their prosthesis at an older age

and so their surgical considerations may vary considerably from those children having implantation for a Baha® alone. All fixtures for prosthetic prostheses were excluded from the study

The Birmingham Children's Hospital is a tertiary referral Hospital and this is reflected in the high proportion and diversity of the medical conditions noted in our 182 cases.

The multidisciplinary team (MDT) is crucial in the management of these patients. The addition of a Plastic surgeon has recently complimented the Birmingham programme. The anaesthetist also has a vital role which is often underestimated. These children require two general anaesthetics. Many of them may pose intubation difficulties.[8]

In our study, the most common difficulty encountered during fixture insertion was thin calvarial bone. This was not just the result of the child's age but also on the fact that many had craniofacial abnormalities.

Developmental delay of the skull bones including the mastoid has been reported in Treacher Collins syndrome and to a lesser extent in Goldenhar syndrome, the two most common conditions in our series.[9,10]

In two cases the implantation was abandoned. One of these children now wears a Baha®, however the second child has still not been successfully implanted. This child has Dubowitz Syndrome, a rare autosomal recessive condition known to be associated with delayed bone maturation.

The surgical technique has been well described by Tjellström in 1990[11]. All children were under the care of two senior Otologists. The majority of children had a two staged procedure. The techniques of local split skin graft or pedicled split skin graft were used in all patients. The main operative finding was thin calvarial bone. No records of actual bone depth were formally documented. Significant bleeding was encountered in 11 cases but all were successfully managed by insertion of the fixture.

67 children had documented dural exposure in our study. The dura was not breached in any case. Dura and sigmoid sinus exposure during Baha® surgery have been reported to be as high as 70% in the paediatric population[12,13.]

Depressing the exposed dura did appear to restrict the length of the fixture to 3mm as has been reported by Papsin et al in 1997[14.] However, those children who had exposed dura were implanted without any complications and osseointegration did not appear to be compromised.

A one stage surgical procedure was performed in just eight patients. Comparison of results between one and two stage procedures in children, have not shown a significant difference in overall fixture failure rates. However some of the data from

these studies includes adult patients.[15] There is evidence that a two stage procedure is associated with a lower rate of adverse skin reaction than single stage surgery[1.]

Some authors believe that a one stage procedure is successful if a 4mm fixture is used.[1]

It has been suggested that 2mm of cortical bone thickness is necessary for implantation for Baha®[16]. In our series predominantly 3mm fixtures were used. Fixture failure rates have been reported as higher in the paediatric population as compared to the adults.[15.] Our study demonstrated an overall fixture failure rate of loaded fixtures of 14%. However, only 7 fixture failures were identified in children between the age of 5 and 15 years.

78% of the lost fixtures in our series were 3mm. It is interesting that some previous studies have reported an increased failure rate with the shorter fixtures[17]

The lower failure rates in older children together with the apparent success of longer fixtures, raises the interesting question of whether these children should have a sleeper fixture especially if a 4mm fixture can be implanted without difficulty. This raises cost implications.

The Birmingham Bone Anchored Hearing Aid programme has previously implanted very young children.[7] The youngest child was 2 years old at the time of implantation.

In total, there were 39 children implanted prior to their fifth birthday. The fixture failure rate was high in this group.(40%)[18]

Since 2002 no child under the age of 3 years has been implanted on the programme. This is a direct result of the introduction of the BAHA Softband®. The child can wear the Softband® until sufficient growth has occurred. Studies to-date have shown the BAHA Softband® to be a valuable means of aural rehabilitation in this very young group.[19]

In our series the overall fixture failure rate of loaded fixtures was 14% reflecting a loss of 32 fixtures over the 15 year period. This is slightly higher than some similar studies in the literature.[1,13,19,20,21.] This may be a reflection of the large numbers in our study, the many syndromes complicating the fixture itself and its placement and most importantly, the 39 children below the age of 5 years. The paediatric Bone Anchored Hearing Aid team at Great Ormond Street have recently reported a similar adverse outcome rate in younger children.[22]

Our fixture failure rate was 40% in the under 5 year olds. These findings were consistent with other authors who included very young children.[21] Interestingly, more recent reports in under 5 year old children in Toronto, have shown implantation success rates to be comparable with older children.[23]

Many studies reported complications from abutments used for a Baha® and auricular prostheses. It would appear that the fixture failure rate is higher for the Baha®.[24,25]

It has been speculated that the loading of a single implant is less favourable than multiple implants where all are connected to distribute the load more evenly[26]

19 of the 32 fixtures that failed in our series were associated with significant skin reactions. Increased soft tissue complications are well recognised in children[25] As the child grows the fixture and abutment may become buried by new cortical bone. This occurred in one of our patients. The literature suggests that the rate of skin growth is equal in children and adults[27] However, children rely upon their family/carers for help with abutment hygiene. Perhaps this increases the child's risk of soft tissue complications. Furthermore, many of these children have a significant medical condition, many of which are associated with underlying behavioural and developmental delay. This would make maintenance of their Baha® more challenging.

Lastly, older children have an increased risk of acne. They have an increased number of active hypertrophied sebaceous glands making them more at risk of skin complications than the adult Baha® wearer.

Unfortunately in the formative years of the Birmingham programme, no objective classification was used until the introduction the Holgers classification in 2001.[28] Prior to this, the documentation of skin reaction was very subjective and this made exact calculations of skin reaction unclear.

Since the beginning of the Birmingham Paediatric programme the Advanced Nurse Practitioner has had a leading role in the management of the 'wound' and today is largely responsible for the excellent skin results achieved. The follow-up and wound care is tailored to the individual need of the child. The first review is standard between post-operative day 4 and day 9.

Only 17 % of the children had an adverse skin reaction over the 15 year period. "Adverse" related to a wound requiring more than three visits for redressing, repeated application of silver nitrate or the need for systemic antibiotics. This would most likely equate to what is now termed Holgers Grade 3 or above.

A non-standard longer abutment of 8.5mm was necessary in 15 children. This appeared to reduced soft tissue reaction and it overcame the problem of bony overgrowth which is seen in the paediatric population[20]

In the seven cases of complete graft failure, no further surgery was necessary. (Figure 1). All seven wounds healed with secondary intention and the end result was an excellent skin site around the abutment. (Figure 2)

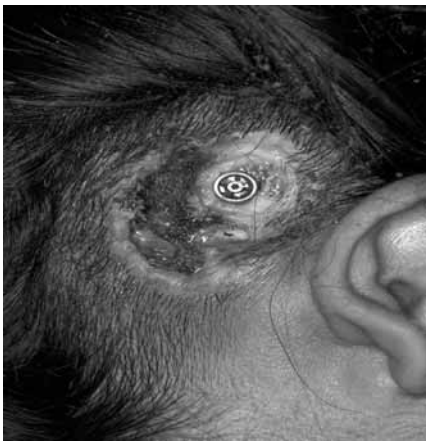

Figure 1. Colour photograph illustrating the complete breakdown of the skin graft surrounding the abutment.

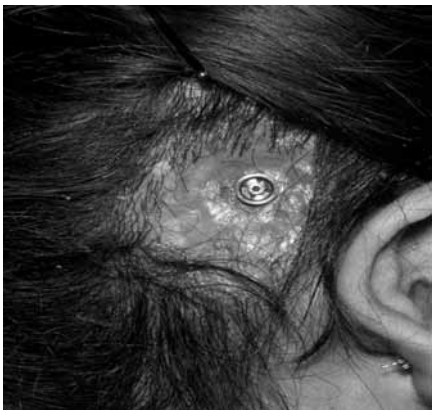

Figure 2. 14 weeks later. The same abutment site illustrating the healing by secondary intention.

Although the potential for increased skin reactions and excess bone formation has traditionally been considered higher in children, in our study we found it was comparable with other recent paediatric studies [1,29,30] and actually less than some previous adult reports.[30]

There has been interesting debate regarding the time to load the abutment. A limitation in paediatric Baha® practice is the long interval between surgery and loading of the sound processor. A recent study of 26 adult patients demonstrated no significant increase in osseointegration failure with a healing time of just 6.5 weeks before the abutment was loaded[30].

The length of time before the second stage was performed in our series varied depending on the operative findings and social/geographical issues. The range was 12-51 weeks (mean 20). Many children have travelled from southern Ireland and distant regions of the UK for their Baha®.One child had the second stage of his Baha® surgery 51 weeks later. The child and his parents had moved to Pakistan for twelve months.

There is concern regarding trauma in the paediatric Baha® population. There is no doubt trauma was important in our series; damage to the device and /or the abutment was common. There were five traumatic fixture failures and one more recent traumatic intra-cranial intrusion injury of the fixture.[31]

Finally, direct comparison of our outcome measures with other published series from different institutions, is difficult because of the great variation in the different study populations. In view of this, we concur with the rationale proposed by the Great Ormond Street Baha® Team in that, the measure of success of any bone anchored hearing aid programme should be a reflection of the number of successful Baha® wearers.[14] In our programme there are currently 176 (97%) patients currently wearing their Baha® on a daily basis.

Conclusions

The Baha® is an effective means of aural rehabilitation that has also been shown to improve the overall quality of life of the child.

Although often described as “safe” and “simple” the procedure is not without risk as shown in this study. However, despite what may be for a minority of children, a prolonged and perhaps difficult process, our programme currently has 97% of its children wearing their Baha® on a daily basis. We feel this excellent success rate is a reflection of the multidisciplinary team; all members play such an active role in managing and supporting these children and their carers to minimise complications.

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2.2

The role of Bone Anchored Hearing Aids in children with Down syndrome

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Abstract

Objectives: To evaluate complication rates and outcomes of children with Down syndrome fitted with a Bone Anchored Hearing Aid (Baha®).
To evaluate whether the Bone Anchored Hearing Aid is a successful form of aural rehabilitation in children with Down syndrome from a patients' perspective

Study Design: Retrospective case analysis and postal questionnaire study

Setting: The Birmingham Children's Hospital, UK

Methods: A total of 15 children were fitted with a Baha® between February 1992 and February 2007. The age range was 2-15 years.
A postal questionnaire was sent to each family. The Glasgow Children's Benefit Inventory (GCBI) was used in this study

Outcome measures: Implantation results, skin reactions and other complications were recorded. Quality of life after receiving a Baha® was assessed with the GCBI.

Results: All 15 patients are using their Baha® seven days a week for more than 8 hrs a day after a follow up of 14 months with continuing audiological benefit.
No fixtures were lost, and skin problems were encountered in 3 (20%)
Regarding quality of life, all 15 patients had improved social and physical functioning as a result of better hearing.

Conclusions: Baha® has an important role in the overall management of individuals with Down syndrome after conventional hearing aids and/or ventilation tubes have been considered or already failed.
This study has shown a 20% rate of soft tissue reaction and there were no fixture losses in this group. No significant increase in complication rates was identified in children with Down syndrome.
Finally, there was a significantly improved quality of life in children with Down syndrome after receiving their Baha®. There was a high patient/carer satisfaction with Baha®.
Two of our series had bilateral two stage fixture procedures without any complications
More consideration should be given to bilateral bone anchored hearing aids in this group.

Introduction

The Bone Anchored Hearing Aid has been successfully used as a method of aural rehabilitation in adults with primarily chronic suppurative otitis media or difficulties with conventional aids. In the paediatric population, in addition to the above indications, the Baha® has been successful with the management of hearing loss as a result of congenital abnormalities.

Pictures from 1505 have been found showing children with Down syndrome. It was formally recognised as a specific entity by an English physician, Dr John Down. The syndrome now bears his name.[1]

Down syndrome is the most common congenital condition affecting around 1in 600 to 1 in 900 live births worldwide. The rate varies according to contraception and termination attitudes in different communities and countries.[1] It is currently estimated that there are 2 million people with Down syndrome world wide and 50,000 of them are in the United Kingdom (U.K).[2]

Hearing loss is a recognised problem in this group of patients, and this is most commonly otitis media with effusion (OME). If untreated, this may affect language and behaviour and so treatment should be instigated early for them to achieve their best potential.[3]

Aim

The aim of this study was firstly, to evaluate complication rates and outcomes of children with Down syndrome fitted with a Baha® and secondly, to evaluate whether the bone anchored hearing aid is a successful form of aural rehabilitation in these children from a patient/carer perspective

Methods

A retrospective case analysis of all children with Down syndrome fitted with a Baha® on the Birmingham Paediatric bone anchored hearing aid programme was undertaken. Records were available from February 1992 to February 2007. The outcome data included medical history, surgery, complications and post-operative follow-up

A postal questionnaire was sent to each patient/family. The Glasgow Children's Benefit Inventory (GCBI) was the tool used in this study. A linear analogue scale was added to the questionnaire. The aim of this addition was to evaluate any change in health status following the Baha®.

Results

Outcomes

A total of 15 children with Down syndrome were fitted with a Baha® between 1992 and 2007.

Age: The age range was 2-15 years. The mean age at implantation was 7 years and 4 months. There were 8 female and 7 males.

Indication: The most common indication for Baha® provision was chronic suppurative otitis media (CSOM) (Table 1).

Table 1. Indication for Baha®

Indication	Number of cases n=15
CSOM	5
OME	4
Hearing aid problems	3
Otitis externa	2
Canal stenosis	1

Previous interventions: 11 children had had previous Ventilation tubes. Seven of this group had more than one set. The remaining 4 children had extremely narrow ear canals.

Of the group that had Ventilation tubes, 7 suffered from persistent otorrhoea post-operatively and had limited improvement in hearing.

Side of implant: 8 children had implants inserted on the right side and 4 on the left. Two cases had bilateral implantation. One boy had bilateral implantation performed simultaneously.

Surgical procedures: All cases had a two stage procedure with a healing time of 12-17 weeks. Six cases had 3mm fixtures, the remaining 9 cases were successfully implanted with 4mm fixtures.

Fixture failures: The total number of fixtures implanted was 36. No child with Down syndrome had a fixture failure.

Skin Reactions: Two cases (13%) had a mild skin reaction (Holgers grade 2) One child (6.7%) had skin overgrowth requiring surgical skin reduction.

One child in this group eventually required an 8.5mm abutment and the skin problem resolved.

Audiology: The range of hearing loss in this group of children was 25-65 dB, the average hearing loss was 34dB. 10 children had a bilateral conductive hearing loss and the remaining five had a mixed conductive and sensorineural loss.

Complications: All were identified within two years of implantation. Skin reaction was the only post-operative problem encountered.
One young boy became a 'temporary' non-user two years after wearing his baha. There were no late complications.
Currently all 15 cases wear their Baha® on a daily basis with continuing audiological benefit.

Glasgow Children's Benefit Inventory Questionnaire.
All 15 questionnaires were returned giving a 100% response rate. The analysis of all 15 questionnaires demonstrated a significant benefit from the Baha®. (Table 2).

Table 2. The Results of the Glasgow Children's Benefit Questionnaire

Question	Median	IQR	5	4	3	2	1
1. Overall life better or worse	5	(5.0, 5.0)	15	0	0	0	0
2. Baha affected daily activity	5	(5.0, 5.0)	13	1	1	0	0
3. Behaviour better/worse	4	(3.0, 5.0)	5	5	5	0	0
4. Development	5	(4.0, 5.0)	9	4	2	0	0
5. Lively	5	(3.0, 5.0)	8	2	5	0	0
6. Sleep	3	(3.0, 4.0)	3	4	8	0	0
7. Appetite	3	(3.0, 3.0)	2	1	12	0	0
8. Self-Conscious	5	(3.0, 5.0)	8	2	4	1	0
9. Social with family	4	(3.0, 5.0)	6	4	5	0	0
10. Social with friends	4	(4.0, 5.0)	6	7	2	0	0
11. Embarrassment	4	(4.0, 5.0)	4	6	5	0	0
12. Distraction	4	(3.0, 4.0)	8	3	2	0	0
13. Learning	4	(4.0, 5.0)	7	7	1	0	0
14. Absence from education	3	(3.0, 5.0)	4	3	8	0	0
15. Concentration	4	(3.0, 5.0)	4	6	5	0	0
16. Frustration	4	(3.0, 5.0)	4	7	3	1	0
17. Self-esteem	4	(3.0, 5.0)	5	5	5	0	0
18. Happiness	4	(4.0, 5.0)	7	6	2	0	0
19. Confidence	4	(3.0, 5.0)	7	4	4	0	0
20. Self Care	5	(3.0, 5.0)	8	2	5	0	0
21. Leisure activities	5	(3.0, 5.0)	8	2	5	0	0
22. Illness	4	(3.0, 5.0)	4	5	5	1	0
23. Visits to Dr.	3	(3.0, 4.0)	1	5	9	0	0
24. Medication	3	(3.0, 4.0)	1	5	9	0	0

IQR: Inter-quartile range

The Box plot in Figure 1 illustrates the overall benefit of Baha® in children with Down syndrome. The median benefit score was +58.

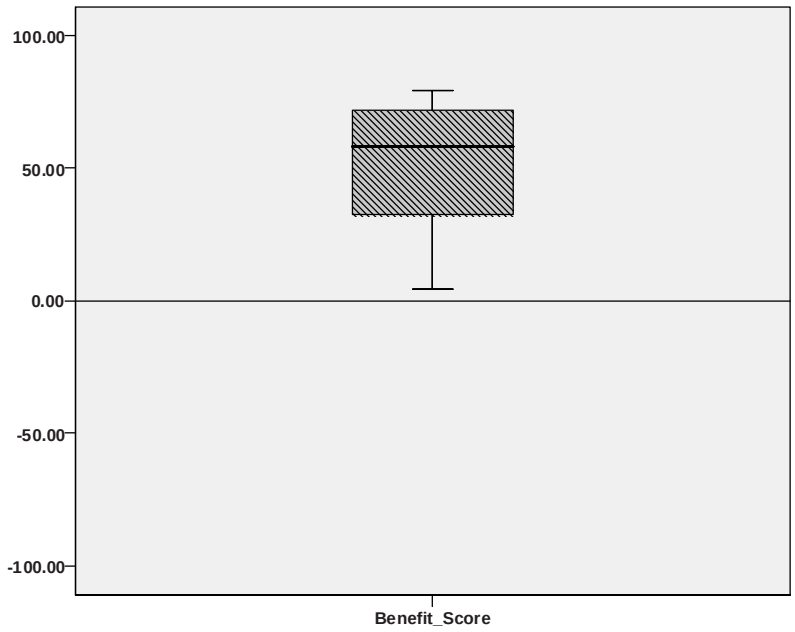

Figure 1. Box plot demonstrating the overall benefit score for children with Down syndrome wearing a Baha®.

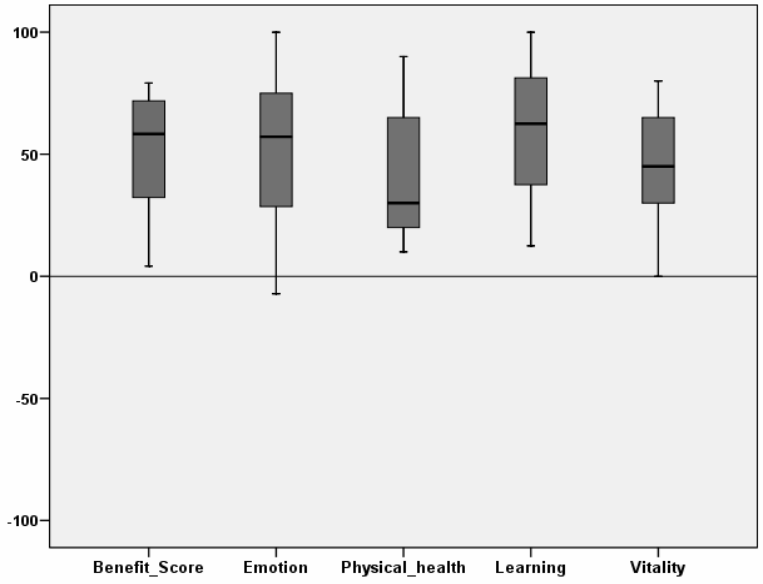

Figure 2. Box plot illustrating the GCBI results for children with Down syndrome who were fitted with a Baha®. Emotion and Learning can be seen to contribute more to the overall benefit score than the other factors.

Figure 2 represents the four factors that relate to emotion, physical health, learning and vitality. Emotion and Learning were found to contribute most to overall benefit.

The linear analogue scale (Appendix 2) was analysed using a Wilcoxen signed ranks test. This demonstrated the perceived improved state of health of the children following their Baha® to be highly significant. $p<0.001$.

Finally, regarding the change in health status before and after their Baha®, all 15 patients had a significant improvement (Figure 3).

As health status improved a similar improvement was noted in benefit score (Figure 4).

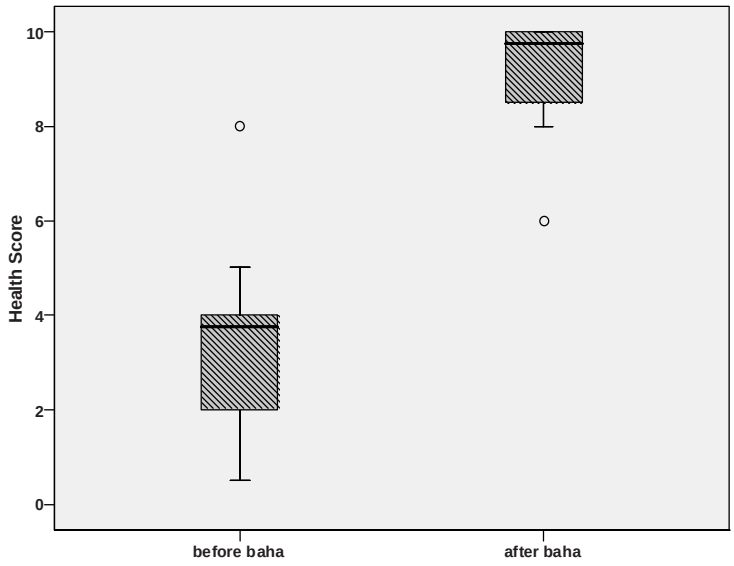

Figure 3. Box plot illustrating the change in health status before and after Baha® in children with Down syndrome.

Discussion

There is now considerable experience with the use of the Baha® and there is no doubt it is an extremely valuable means of aural rehabilitation. Until recently, very little was reported about the use of the Baha® in this group of children.

In children with Down syndrome hearing loss is a recognised problem. The incidence of hearing loss in this group has been reported to be as high as 78%. It is predominantly OME.

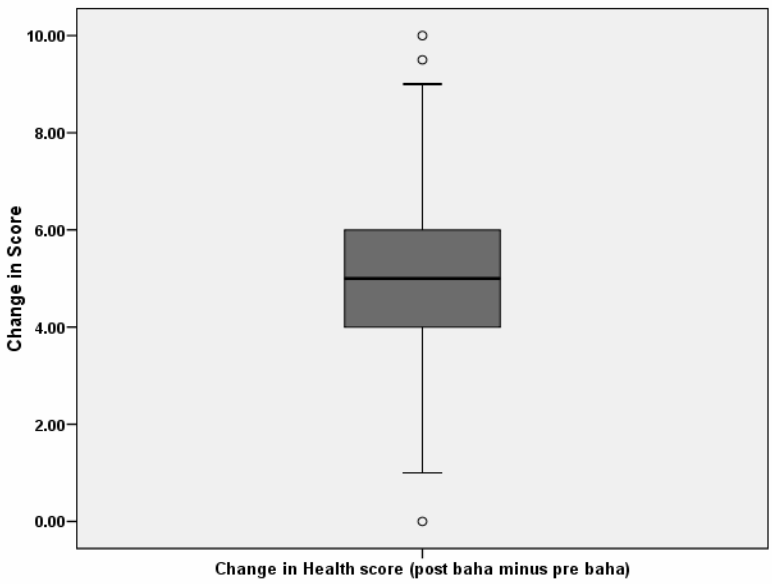

Figure 4. Box plot illustrating the change in benefit score in relation to the improvement in health status score before and after their Baha®.

This is thought to result from a combination of a short, narrow and easily collapsible eustachian tube, and a small, narrow nasopharynx. Children with Down syndrome typically have a general hypotonia which affects the palatal musculature. The overall combined effects compromise eustachian tube function. The conventional treatment with ventilation tubes (VT) is complicated by small narrow ear canals.[2]

Furthermore, there is a high incidence of persistent otorrhoea in those who do have VT inserted. This is believed to be a consequence of children with Down syndrome having a slower development of their immune system.[5] The use of conventional hearing aids is complicated by the fact many of these children have learning difficulties and will not co-operate with a device they can feel in their ear, and these conventional aids can aggravate existing otitis externa and/or otitis media. A recent paper by Sheehan et al discusses the problems with hearing loss in Down Syndrome.[2]

So when is the right time to fit a Baha® in a child with Down syndrome?

It is important to treat the hearing loss as soon as possible in order for the child to develop hearing and language skills. In the Birmingham Programme, there is now an increased use of the Baha Softband® and it is very successful in this group of children.

Sheehan et al reported the UK and Ireland experience of children with Down syndrome with Baha®.[2] They reported 43 cases in all, 24 of which were children. This was a relatively small number when compared to the estimated 50,000 Down syndrome patients in the UK. Only two children were aged under 5 years at the time of their Baha® fitting. Sheehan et al recommended a Baha® as an alternative if conventional aids were unsuccessful.

In our series the average age of implantation was 7 years. This was consistent with other studies.[2] This late age was most likely a reflection of the trials of ventilation tubes and conventional forms of hearing aids used as a first line treatment.

In total, there were 3 (20%) children in our study group with complications as a result of implantation for Baha®. All complications were soft tissue reactions around the abutment. This was comparable with children without Down syndrome.[6,7.]

Sheehan et al published the largest series of Down syndrome patients and they found the soft tissue complication rate to be 50% in children. Results from the renowned Nijmegen Baha team demonstrated the Baha® to be well tolerated in patients with Down syndrome. They did not find an increased complication rate in this group. This was particularly interesting since many of these children have a degree of learning difficulty as part of their syndrome. They suggested extending the indications for BaHa to include patients with learning difficulties.[7]

The lower soft tissue complication seen in our study likely represents the smaller case numbers and less variability between the surgical procedure since only one centre was involved.

Regarding fixture failures, there have been none to date in children with Down syndrome on the Birmingham programme. We have not found any evidence of osseointegration difficulties in this particular group of patients.

We currently have all 15 children wearing their Baha® on a daily basis with continued audiological benefit.

The Glasgow Children's Benefit Inventory was designed and validated as a retrospective questionnaire to assess benefit after a surgical intervention.[9] We used this questionnaire to assess the benefit of Baha® in our children with Down syndrome. As with any paediatric questionnaire especially when used in a group known to have varying degrees of learning disability, the results reflect the patient and the carers opinion.

100% of the questionnaires were returned. This reflects very motivated families and carers. Previous Questionnaire studies of paediatric Baha® wearers had a 72% non-responder rate.[10]

The Glasgow Children's Benefit Inventory has 24 questions. Appendix 1. Each question has 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 was calculated from the individual question scores Table 3**.** This score was then divided by the number of questions (24). This score was then multiplied by 50 to produce a score from -100 to +100. The overall benefit score for Down syndrome children wearing a Baha® was +58. Figure 1.

Table 3. Example of a question used in the GCBI.

Has your child's operation affected how happy and content he/she is?		
a.	much better	(score +2)
b.	a little better	(score +1)
c.	no change	(score 0)
d.	a little worse	(score -1)
e.	much worse	(score -2)

All 15 children (and their carers) believed their overall life was much better since wearing their Baha®. Furthermore, a significant number of this group found that there was an improvement in their daily activities. The majority of children made better progress with their education and learning; better concentration and listening skills developed and they were less easily distracted. This subjective benefit in quality of life In children with learning difficulties was also demonstrated in a recent study from Nijmegen.[11]

In their general health, only one child had a change for the worse following his Baha®. This young man had skin reaction around his abutment requiring surgical reduction. He then became a temporary non-user. He was later diagnosed with Autistic Spectrum Disorder, and after commencing behavioural therapy he once again wore his Baha® successfully and is still an active wearer to date.

The visual analogue scale was added to show the change in health status after the Baha®.

In all 15 cases there was a positive change in health status post Baha®.

Finally, the use of a Baha® in this group of children has been shown provide a significant benefit and improved state of health. It is readily acceptable to the vast majority of these children.

We have found no significant increase in post operative complications in this group of children. The Baha Softband is an excellent means of rehabilitationand avoids the need for surgery in the very young children with Down syndrome.

The GCBI has proved to be a valuable tool for measuring patient benefit and quality of life after their Baha®

Conclusions

Bone anchored hearing aids have been successfully used in the UK for more than 20 years, yet it is only in recent years that the role of the Baha® in Down Syndrome has been evaluated.[1,3-6]

Baha® has an important role in the overall management of individuals with Down syndrome after conventional hearing aids and/or ventilation tubes have been considered or already failed. This study has shown no significant increase in complication rates in children with Down syndrome. Their parents/carers are well motivated to maintain the implants. Finally, there was a significantly improved quality of life (benefit and improved health status) in children with Down syndrome after receiving their Baha®. There was a high patient satisfaction with Baha®.

The success of a Baha® programme should be based on the patient use of the Baha®. In Birmingham, all 15 children are still using their Baha® on a daily basis with continued audiological benefit.

Two of our series had bilateral two stage fixture procedures without any complications. More consideration should be given to bilateral bone anchored hearing aids in this group.

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Appendix 1

The Glasgow Children's Benefit Inventory.

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 & 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 on a task?
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?

2.3

Bone Anchored Hearing Aids in very young children

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Abstract

Setting: The Birmingham Children's Hospital, Birmingham, UK

Objective: To evaluate the outcome of Bone Anchored Hearing Aids in children below 5 years of age.

Study design: Retrospective case analysis of all children below the age of 5 years who received a Bone Anchored Hearing Aid. 1992-2007

Patients: 39 patients aged less than 5 years at the time of implantation. The age range was 2 years to 4years11 months (mean 3years4 months).
25 (64%) cases had a diagnosed syndrome.

Interventions: All patients had a planned two stage procedure for their Bone Anchored Hearing Aid. Two fixtures were implanted in each case.

Results: A total of 63 (loaded) fixtures were implanted in this group. There were a total of 25 (40%) fixture failures in this young patient group.
Multiple fixture failures were identified:
4 (10%) patients had 3 fixture failures each. Two patients had 2 fixture failures. 9 (23%) patients had single failures. One case was a failure to implant fixture.
Mean age of the fixture failure group was 3.5 years.
Significant skin reactions were encountered in 17(44%) cases.

Conclusions: The use of the Baha® in children under 5 has previously been controversial.
In the Birmingham series, there was an increase in morbidity in this young patient group. Fixture failure rate was high as was revision surgery for skin reactions.
In 2002, the Baha Softband® was introduced.
In Birmingham, the treatment of choice for children under 3 years of age is the Softband® until the child is older and more ready for surgery.

Introduction

In 1965, Branemark first introduced osseointegrated titanium dental implants.[1] These proved to be a great success. In 1977 Tjellström and his team reported the first bone-anchored hearing aids[2]. These Bone Anchored Hearing Aids are now known as a Baha®

Today, the Baha® is a well described and accepted form of auditory rehabilitation. In the adult population, the technique is a relatively uncomplicated, one stage procedure that can be performed under local anaesthesia with few complications.

In the paediatric population however, it is not so simple. Firstly, general anaesthesia is preferred and two-staged surgery is necessary. Since many children who need a Baha® often have a significant medical and /or syndromic history the procedure may carry more risk[3]. Secondly, there are issues of soft tissue and skull thickness which vary greatly in young children and may significantly affect the surgical procedure itself as well as any subsequent complication rates.

Finally, when is the best time to implant children?

Obviously, the aim is to restore hearing as soon as possible in order for the child to achieve his/her full potential.

In Birmingham, the paediatric Baha® programme began in 1992 and children as young as 2 years of age were included. This study evaluates the outcomes of these very young children with a Baha®.

Aims

Our aim was to evaluate the outcome of Bone Anchored Hearing Aids in children under 5 years of age at the time of implantation.

Patient and Methods

This was a retrospective case analysis of 39 children who were below 5 years of age when implanted with an osseointegrated fixture for a Bone Anchored Hearing Aid. All records between February 1992 and February 2007 were evaluated by two clinicians. The outcome measures included patient demographics, indication for Baha®, surgical procedures, complications and finally current Baha® wearers.

There were a total of 39 children aged 5 years or under at the time of implantation. The age range of our study group was 2 to 4 years11 months (mean 3yrs, 4mths). There were 20 males and 19 females. 25 (64%) of the cases had a significant medical history. (Table 1).

The indication for Baha® is illustrated in Table 2.

No child under the age of 5 years had an aural prosthesis and so all the children in this study were implanted for a Baha® only. Figure 1 illustrates the age distribution at implantation.

Table 1. Syndromes identified in children below the age of 5 years who were fitted with a Baha®

Syndrome	No. of cases
Treacher-Collins Syndrome	11
Various Chromosomal abnormalities	4
Goldenhars	4
Nagar	1
Branchio-Oto-Renal Syndrome	1
Dubowitz syndrome	1
Pierre-Robin Sequence	1
Antley Bixley syndrome	1
Bindars syndrome	1

Table 2. Indication for Baha® Insertion.

External ear malformation	No. of cases
Treacher Collins	9
Isolated Bilateral atresia	9
Various chromosomal abnormalities	4
Microtia- non syndromic	3
Goldenhars	4
Nagar	1
Dubowitz syndrome	1
Pierre-Robin Sequence	1
Antley Bixley syndrome	1
Bindars syndrome	1
Chronic Suppurative Otitis Media	**No. of cases**
Treacher Collins	2
Isolated Bilateral atresia	2
Branchio-Oto-Renal Syndrome	1

Figure 1. Age distribution at the time of implantation

Results

Surgical procedure

All the children underwent a two stage procedure under general anaesthesia. The side of implantation depended upon the patient and surgeon's preference as well as cochlear function.

23 children had left sided fixture placement and 16 had right sided placements.

A minimum of two fixtures (one sleeper) were used in all cases. Two 3 mm fixtures were used in 38 children. One child aged 2years 4 months had both a 3mm and a 4mm fixture.

In 26 children, multiple attempts were made to find suitable thickness of bone.

Other common operative findings included thin calvarial bone and exposed dura. Table 3.

Table 3. Operative findings

	Number of cases
Thin Calvarial Bone	11
Exposed Dura	10
Gortex membrane used	2
Sigmoid sinus bleeding	1
Emissary vein bleeding	1
Failure to implant	1

In cases of thin bone, the intact dura was depressed with a 3mm fixture.

A Gortex membrane was placed under the fixture flange to promote osseo-integration in two cases, a technique described by Granström in 1998.[2]

The time between the first and second stage varied and appeared to be based on the operative findings. The healing time ranged from 12 to 51 weeks (mean 20 weeks).

Fixtures

A total of 63 loaded fixtures were identified in this group of 39 children. There were sixteen fixture failures in just six children. Table 4.

Table 4. Fixture failures

4 patients	3 fixture failures each
2 patients	2 fixture failures
9 patients	1 fixture failure
1 patient	surgical failure to implant
Total 88 fixtures implanted (59 loaded)	

Table 5 illustrates the fixture failure group in more detail.
There was one failure to implant a fixture in a three year old girl with Dubowitz Syndrome. This patient was included in the fixture failure category.
Five failures were as a direct result of trauma. The remaining were failure to osseointegrate.
The overall fixture failure rate in children below the age of 5 years was 40%.

Table 5. Fixture failure group

Case	Age (y, m)	Sex	Fixture loss	Medical history
1	3.7	M	3	Isolated bilateral atresia
2	3.11	F	3	Isolated bilateral atresia
3	2.8	M	3	Isolated bilateral atresia
4	4.2	F	3	Brachio-Oto-Renal Syndrome
5	4.11	F	2	Isolated bilateral atresia
6	2.9	M	2	Treacher Collins
7	3.8	M	1	Chromosomal deletion 18
8	2.2	F	1	Treacher Collins
9	4.3	M	1	Goldenhar
10	4.11	F	1	Isolated bilateral atresia
12	3.9	F	1	Isolated bilateral atresia
13	4.11	F	1	Dubowitz
14	2.3	F	1	Treacher Collins
15	2.5	F	1	Isolated bilateral atresia
16	2.8	M	1	Isolated bilateral atresia

Soft Tissue
Seventeen children (44%) had a significant skin reaction around the abutment following the second stage of surgery requiring more than three visits to the out patient department for wound care.
Two of these cases had complete graft failure. Both these wounds healed by secondary intention and did not require any further surgery.
Four children required surgical skin reduction and at the time of surgery, excess new bone was identified and removed in one case. Two of these children had two skin reduction procedures each and one young boy aged 2 years8 months, required three skin revision procedures in total. (Table 6).

Follow-up
All 39 children had their first post-operative visit on day 5 or 6. The follow-up regime was tailored to the individual needs of each patient based on their clinical need.

Table 6. Significant Soft tissue complications in children under the age of 5 years.

No.	Age	Medical history	Soft tissue problem	Complication
1	4.8	Goldenhar	Graft infection/overgrowth	delayed healing
2	4.3	Antley Bixley	Graft infection	delayed healing
3	3.7	Bilateral atresia	Graft infection/overgrowth	skin reduction x2. FF
4	2.2	Treacher Collins	Graft infection	FFx2
5	2.1	Treacher Collins	Graft infection	delayed healing
6	4.11	Bilateral atresia	Skin overgrowth	FF
7	3.11	Bilateral atresia	Graft infection/overgrowth	skin reduction
8	2.5	Bindars	Complete graft loss	delayed healing
9	3.9	Bilateral atresia	Skin overgrowth	FF
10	4.6	Bilateral atresia	Skin overgrowth	unknown
11	4.2	B-O-R	Infection/overgrowth	skin reduction x2. FF
12	2.8	Bilateral atresia	Wound haematoma	FF
13	2.5	Bilateral atresia	Graft breakdown	delayed healing. FF
14	4.0	Treacher Collins	Complete graft loss	delayed healing
15	2.3	Trisomy 18	Skin overgrowth/infection	delayed healing
16	2.3	Treacher Collins	Graft infection	FF
17	2.4	Bilateral atresia	Skin overgrowth	Skin reduction x3. FF

FF= Fixture failure

Table 7. Healing time between stage one and stage two of Baha surgery.

Number cases	Time in months	Indication
4	> 6 months	Social/geographical issues
18	4-6 months	Operative findings
17	3 months	Standard practice

The healing time ranged 12-51 weeks Table 7. Families and carers appeared very motivated and appointments were all well attended.
All the fixture failures and significant soft tissue problems were encountered with the first two years.

Baha® wearers
Currently 38 (97%) children from this study are active Baha® wearers The other case has only recently lost her fixture.

Discussion

Baha® is a well described and accepted form of auditory rehabilitation. It is an excellent alternative to middle ear reconstruction and conventional bone conductor hearing aids. This makes it ideal for children with bilateral ear

malformations or persistent otitis media with effusion (OME) that is resistant to more conventional treatments.

In Birmingham, all children in this study had previously worn conventional hearing aids. Eighteen children (46%) had under gone insertion of ventilation tubes with little success. No child under the age of one year was implanted in Birmingham.

Parents and carers need time for consideration of all the treatment options available. In our study group, the parents of the younger children especially those below the age of 3 years, had needed a minimum of two out-patient clinic appointments (at least six months) for further discussion about the Baha® before consenting for surgery.

Earlier studies have shown that children implanted at 1 year of age, were in fact children of parents who themselves were Baha® wearers[3]. These parents obviously required less time for their decision making.

In our programme, no preoperative imaging was undertaken to assess skull thickness in this young group. Since the skull contour primarily determines the position of the Baha®, the authors felt that this was not appreciated by either conventional radiographs or Computerised Tomography (CT). Furthermore, CT in this age group requires sedation /general anaesthesia and exposes the child to a large radiation dose and further risk.[4]

The records for this study were taken from February1992 to February 2007. As for all retrospective case studies, the availability of old records and their contents were not always ideal. 39 records were analysed. Of these, one set had no operative data, and two cases had been destroyed and our data was then taken from correspondence and operating room ledgers.

The indications for Baha® in our young group of patients were predominantly Treacher Collins and isolated aural atresia.

The large numbers of unusual and rare medical conditions seen in our series reflects the fact that the Birmingham Children's Hospital is a tertiary referral hospital. This is similar to those studies from other large specialist Children's hospitals.[5,6,7]

There has been debate regarding the best time to implant children and much of the paediatric Baha® literature reports children aged 4 years and above. It was recommended that age 3 years and above is ideal since the child should then have suitable skull thickness[8]

The surgical technique has been described extensively by Tjellström[9].

Over the fifteen year study period, the surgical technique underwent some modifications however, all the children without exception underwent a two stage procedure under general anaesthesia under the care of two senior Otologists. Our

programme still employs this two stage technique in young children because of the increased risk of trauma, and the increase risk of failure of primary osseointegration.

Our technique of skin graft for Stage II Baha® surgery has always been either a local split thickness free graft or a pedicled split thickness graft at the fixture site. Wolfe grafts were not used in the Birmingham programme. All children had a minimum of two fixtures inserted at the first stage. It is interesting that recent studies have shown that local split thickness grafts were less likely to develop graft hypertrophy than the Wolfe grafts[5].

Difficulties encountered at the time of surgery were mostly thin calvarial bone.

Many operative records unfortunately mentioned neither the skull thickness nor the exposure of dura. This would account for the low numbers of operative findings seen in table 3, particularly as 14 (36%) of the study group were aged below 3 years. One case had no operative records available before 1995. Dura and sigmoid sinus exposure during Baha® surgery have been reported to be as high as 70% in the paediatric population[2].

In 16 children (76%), adequate bone thickness was identified by exploring multiple sites on the temporal bone. In the latter years, this problem of inadequate bone thickness has been overcome by the use of an augmentation technique which has been well described[3]. The use of a Gortex membrane under the fixture flange was documented in two of the children in our study.

Davids et al[6] recently described the placement of a 3mm fixture flush with the outer bone table (dura depressed by the fixture) then a longer period of healing time before Stage II. They found this reduced the need for multiple pilot holes. Their osseointegration rate was 90% in a similar group of very young children.

The recent literature to date describes conflicting results about complications in young children however comparing these results from each centre is difficult because of the very different population groups.

The overall fixture failure rate in our group of young children was 40%. This is higher than that reported in adults[10,11,12] and is in keeping with recent literature from the Great Ormond Street Baha® team[5]. Their fixture failure rate was 26% and their soft tissue reaction rate was 37% with 9% lasting more than 6 months. They identified young age at implantation to be associated with an adverse outcome[5].

All the lost fixtures in our series were 3mm. It is interesting that some previous studies have reported an increased failure rate with the shorter fixtures[13].

In our study, failure to implant a fixture was encountered in one young girl. This child had Dubowitz Syndrome, a rare autosomal recessive condition known to be

associated with delayed bone maturation, low birth weight, growth retardation, short stature, high sloping forehead with a broad nasal bridge, and sometimes eczema[14]. She had behavioural and learning difficulties which are also reported to be associated with this syndrome[15].

This child was successfully implanted two years later.

Very young children aged 3 years and below, did not demonstrate any further significant increase in fixture failures. Of the group that experienced 3 failures each, only one child was less than 3 years old. Similarly, 50% of the groups with two and one fixture failures were below the age of 3 years.

In our experience, skin reaction in young children with Baha® was 42%. This is similar to other reports in the paediatric Baha® literature.[11,16]

The Holgers Classification[17] was not used in Birmingham until after 2001.(Table 8).

Table 8. The classification of skin reaction around the abutment described by Holger KM[12]

Score	Soft tissue description
0	No irritation
1	Slight redness
2	Red, slightly moist. No granulations
3	Red, moist with granulations
4	Loss/removal of skin penetrating implant. Revision required.

Early records pertaining to soft tissue complications were very subjective and difficult to standardise. Fortunately many wounds had photographic documentation.

The soft tissue assessment was carried out by one specialist Baha® nurse who had many years of experience. We felt that any wound that required more than three return visits to the out-patient clinic, repeated silver nitrate application, or surgical reduction were ‘significant’ and we estimate they would likely equate to a Holgers Score 3 or above.

A recent study from The Hospital for Sick Children in Toronto evaluated a group of twenty young children aged less than five years[6]. They identified a low fixture failure rate of 10% which were as a result of trauma. They also reported low soft tissue complication rates, of which only 15% required revision skin surgery. This was in comparison to our revision rate of 21% in a similar group of children.

The timing for osseointegration is currently an exciting issue. The long interval between surgery and loading of the sound processor has been a limitation in paediatric Baha® practice. A recent study of 26 adult patients demonstrated no

significant increase in osseointegration failure with a healing time of just 6.5 weeks before the abutment was loaded[18]. This earlier activation enhanced patient satisfaction.

Research from the dental literature has shown successful osseointegration with a loading time ranging from the immediate post-operative period to 8 weeks[19,20]

Since our study concurs with many other paediatric studies demonstrating a significantly higher rate of soft tissue reaction and fixture failure, longer inter-stage healing times should continue.

Interestingly the Toronto group[6] did have a longer healing time for osseo-integration with a mean interval of 7.7 months between the first and second stage of surgery compared to our mean inter-stage healing time of 20 weeks (5 months). No single stage surgery was performed in the under 5 age group in Birmingham.

The increased morbidity of Baha® in these very young children has to be balanced against the effects of delaying maximum auditory habilitation. There is evidence that a mild conductive hearing loss can affect language acquisition and development in children with no co existing learning difficulties.[7]

In 2002, the Baha Softband® was introduced[21]. Hol et al demonstrated the Baha Softband® (attachment of the Baha® to an elastic head band) provided improved audiological benefit when compared to conventional bone conduction aids in children with congenital bilateral aural atresia; thus providing a valid treatment option for young children. It has also been demonstrated to provide a well tolerated and non-invasive method of managing conductive hearing loss as a result of otitis media with effusion in young children.[22]

The Baha Softband® is currently the treatment of choice for children under 3 years of age in Birmingham. This provides all the benefits of Baha® delivered in an acceptable and well tolerated form for these children without compromising their speech, language and general cognitive development. It also allows time for physical growth especially skull thickness. In our experience, the Baha Softband® has been so popular with very young children that families/carers are keen to proceed to surgery as soon as the child reaches the age of three years.

For children aged between 3 and 5 years, the treatment decision is made after discussion between the patient, family and the Baha® MDT.

Finally trauma is a challenge to any paediatric Baha® team. In our study 5 children lost their fixtures as a direct result of a traumatic injury. One case sustained an intracranial intrusion of both the fixture and abutment.[23] The majority of soft tissue and fixture complications in our study occurred within two years of the surgery however, trauma occurred at any time.

The Baha® multidisciplinary (MDT) team have a role in the care of their patients long after the surgical procedure is complete.

Conclusions

The use of the Baha® in children under 5 has previously been controversial.

In the Birmingham series, there was an increase in morbidity in this young patient group. Fixture failure rate was high as was revision surgery for significant skin reactions.

In 2002, the Baha Softband® was introduced. Since then, in Birmingham, the treatment of choice for children under 3 years of age is the Softband® . It is safe, non-invasive and well accepted by young children allowing development of speech and language. Since there is a recognized increase in morbidity associated with Baha in very young children, our policy is to reserve surgery until the child is older. For children aged between 3 and 5 years, the treatment decision is made after discussion between the patient, family and the Baha® MDT.

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Part 3

Quality of life: Patients opinions and issues

3.1

Quality of life in children fitted with a Bone Anchored Hearing Aid

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D.W. Proops

Abstract

Objectives: To evaluate the self-rated quality of life and benefits associated with the use of a Baha®. To assess any change in health status after a Baha®.

Study Design: This was a retrospective postal questionnaire study. The Glasgow Children's Benefit Inventory (GCBI) was the validated tool used.
Children with a Baha® on the Birmingham paediatric bone anchored hearing aid programme from February 1992 to February 2007 were included.

Patients: 115 children were sent a postal questionnaire. 84 were returned giving a response rate of 73%.
All children had worn their Baha® for more than six months. Children with an implant retained auricular prosthesis were excluded from the study, as were children who were older than 16 years at the time of the questionnaire.
Patients with bilateral Baha® were advised to answer the questionnaire with reference to their first Baha®.

Results: The Baha® was a success in the paediatric population. All 84 children reported a positive benefit with their Baha®. The median benefit score was +54
No child demonstrated deterioration in health status following their Baha®.

Conclusion: The use of a Baha® significantly enhanced general well being, improved patient state of health (quality of life) and finally was considered a success by patients and their families. This study demonstrates a significant benefit from Baha® as measured by the GCBI.

Introduction

There are a great many studies that show the bone anchored hearing aid to be a very safe and effective form of aural rehabilitation.[1-3] These hearing aids are very well established and they have now been in clinical paediatric use in Birmingham since 1992.
The Birmingham Paediatric bone-anchored hearing aid programme has implanted more than 180 children in the past 15 years. Our philosophy is a programme of integrated evaluation and rehabilitation that is ably executed by our multi-disciplinary team.
The adult programme in Birmingham has shown the bone anchored hearing aid to be extremely well tolerated by patients.[4] However; the quality of life in our

paediatric bone-anchored hearing aid wearers has not been formally evaluated until now.

Aim

To evaluate the self-rated quality of life and benefits associated with the use of a bone-anchored hearing aid in children and identify any change in health status following a Baha®

Patients

115 children were enrolled in the study.

The children's age range was 2-15 years at the time of operation (mean 6years 3 months). There were 72 females and 43 males. 8 children had bilateral Baha®. 4 of these children had bilateral simultaneous implantation. This small cohort of children wearing bilateral Baha®, were instructed to answer the questionnaire with reference to their first Baha®.

Children who had worn their Baha® for less than six months were excluded. Also all children who had simultaneous implants for a prosthetic ear were eliminated from the study.

All the children who had now moved to the adult programme were not included in this study.

Finally since many of the children were less than 5 years of age it is probable that many of the questionnaire results the subjective views of the adult carers.

Inclusion criteria: Children who had worn a Baha® for more than six months on the Birmingham paediatric programme.

Methods

This was a postal questionnaire study.

115 children were sent a questionnaire along with a pre-paid envelope for return and a two month waiting time was allowed for response.

The tool chosen for this study was the validated Glasgow Children's Benefit Inventory (GCBI), which is a subjective child orientated post-interventional questionnaire especially developed to evaluate any paediatric otorhinolaryngological surgery and therapy.

This questionnaire was described by Kubba et al in 2004[5] and was designed for patient completion, either at interview or in their own home.

Statistical analysis:

The GCBI (Table 1) has 24 questions based on a five point Likert scale. (Table 2). A score of +2 shows a maximum change for the better whilst a -2 score corresponds to a maximum change for the worse. A summary score was then calculated. This summary score was then divided by 24 (the number of questions) and finally multiplied by 50. This final step produced a score between -100 (maximum change for the worst-harm) and +100 (maximum change for the best-benefit). An addition was made to the questionnaire: A 10cm linear analogue scale designed to reflect a change in health status after the Baha®[4]. Correlation between benefit score and change in health status was performed using a statistical package. SPSS version 10.

Table 1. The Glasgow Children's Benefit Inventory.

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 & 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 on a task?
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?

Table 2. Example of question and scoring system used in the Glasgow Children's Benefit Inventory

Please circle the most appropriate answer		
Has your child's Baha® made his/her life overall better or worse?		
A	much better	(+2)
B	a little better	(+1)
C	no change	(0)
D	a little worse	(-1)
E	much worse	(-2)

Results

115 postal questionnaires were sent to patients who had been fitted with a Baha® between 1992 and February 2007. A total of 84 were returned following the initial letter, giving a response rate of 73%. One further letter was sent to the non responders after a period of 2 months. No telephone contacts were used. There were no responses to the second letter.

There were 31 non-responders. The majority of children in this group (74%) had bilateral chronic suppurative otitis media (CSOM). The remaining 8 children (26%) had an atresia with an associated syndrome.

In 74 questionnaires, extra written comments were added by the children and their families about their general satisfaction with their Baha®. Figure 1.

These were mostly positive comments however, the most disappointing issues involved sound processor failures.

A summary of the 84 questionnaire responses is illustrated in Table 3**.**

The overall benefit score for paediatric Baha® wearers was +54. Figure 2

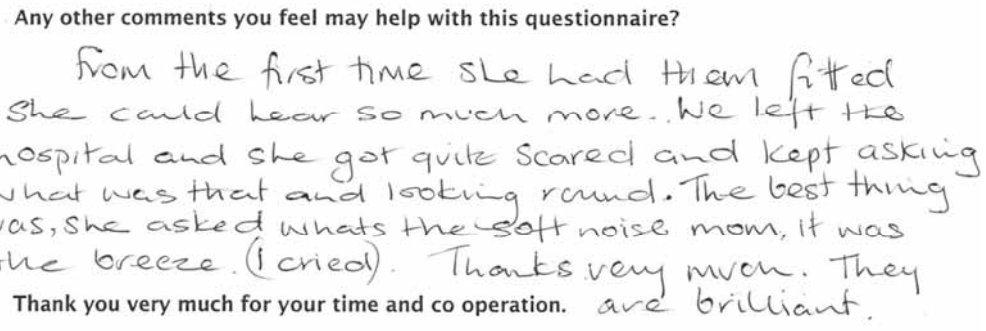

Figure 1. Example of written comments from patients / families

Table 3. Results of all 115 GCBI questionnaires

Summary of All GCBI responses						
Question		+2	+1	0	-1	-2
1.	Overall life	75	9	0	0	0
2.	Affect things he does	62	12	9	1	0
3.	Behaviour	39	19	26	0	0
4.	Development	52	17	15	0	0
5.	Lively	34	20	30	0	0
6.	Sleep pattern	20	14	50	0	0
7.	Food enjoyment	30	11	43	0	0
8.	Self conscious	36	15	22	11	0
9.	Family harmony	43	15	26	0	0
10.	Fun with friends	44	21	18	1	0
11.	Embarrassment	22	24	27	11	0
12.	Easily distracted	27	28	20	9	0
13.	Learning	41	29	14	0	0
14.	Time off	23	18	38	5	0
15.	Concentration	40	24	18	2	0
16.	Frustration	31	28	21	4	0
17.	Self esteem	33	25	22	4	0
18.	Happiness	47	21	15	1	0
19.	Confidence	36	29	17	2	0
20.	Self-care	29	20	34	1	0
21.	Leisure activities	25	23	35	1	0
22.	Dr. visits	10	21	45	6	0
23.	Colds/illness	8	18	56	2	0
24.	Medication	10	13	60	1	0

The data is displayed as 'Box and Whisker' plots .In each figure the 25th and 75th percentiles are illustrated. The patients were grouped according to their underlying pathology.

In this study, the most common conditions were Congenital Aural Atresia, Chronic Suppurative Otitis Media (CSOM), Down Syndrome, Goldenhar Syndrome and Treacher-Collins Syndrome. There was a positive benefit in all conditions. Figure 3. The median scores were 45,44,58,57 and 54 respectively.

In the original GCBI questionnaire, four factors were identified; emotion, vitality, learning and physical health. Figure 4 shows these individual factor scores and the overall benefit score.

Correlation between physical health, emotion, learning and vitality were analysed and a significant result was found between emotion and learning (r=0.65) and emotion and vitality (r=0.73). There was little correlation with physical health. Emotion clearly contributed the most. Figure 4.

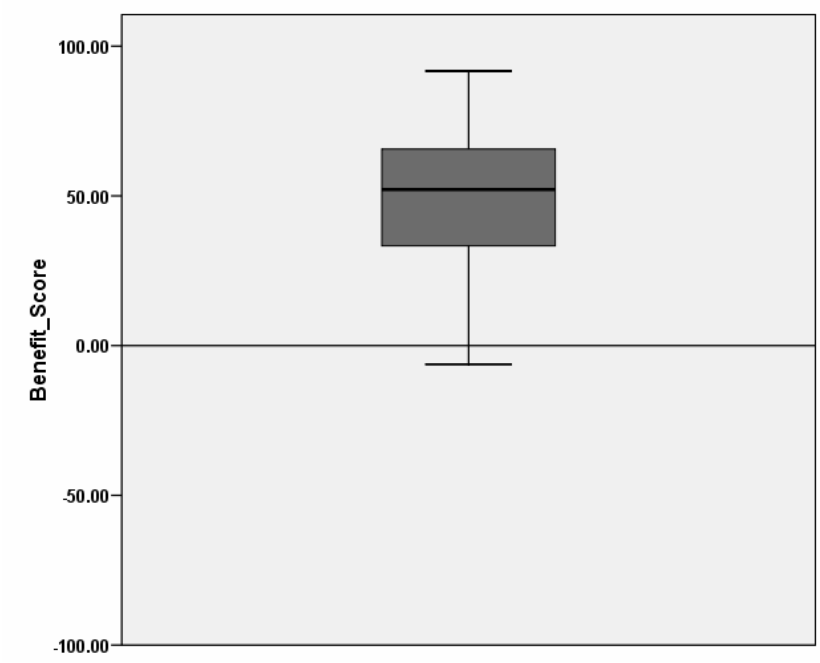

Figure 2. The bone anchored hearing aid benefit score

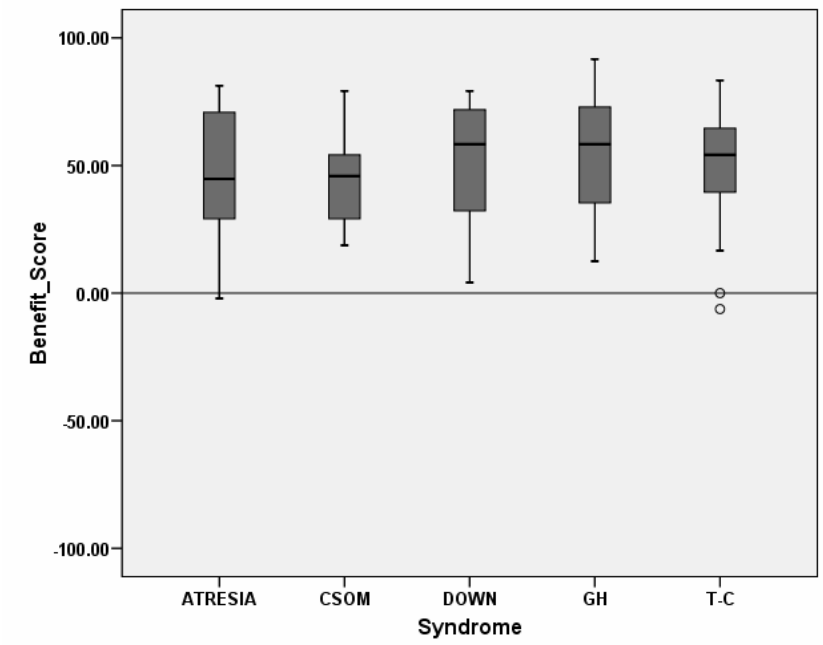

Figure 3. Baha® benefit scores for the major patient groups
Isolated Atresia: n=16; Chronic Suppurative Otitis Media: n=13; Down syndrome: n=12; Goldenhar: n=18; Treacher Collins: n=25

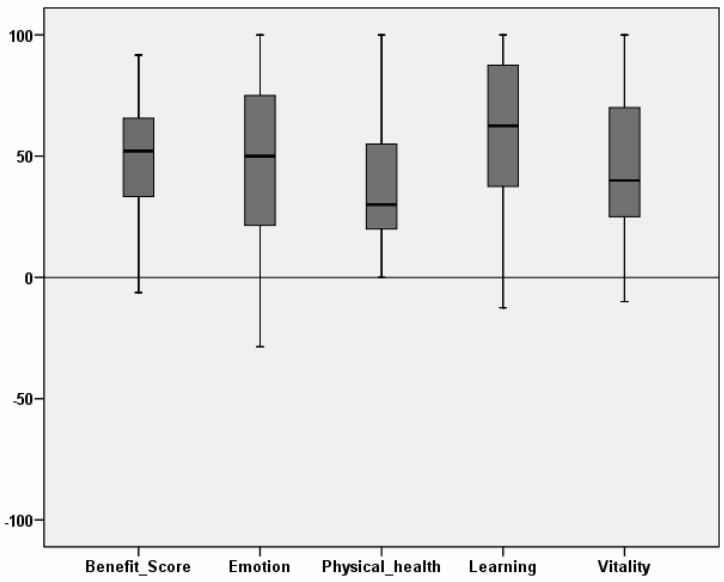

Figure 4. Factor analysis for Baha® in children
Correlation between physical health, emotion, learning and vitality were analysed and a significant result was found between emotion and learning (r=0.65) and emotion and vitality (r=0.73). There was little correlation with physical health.

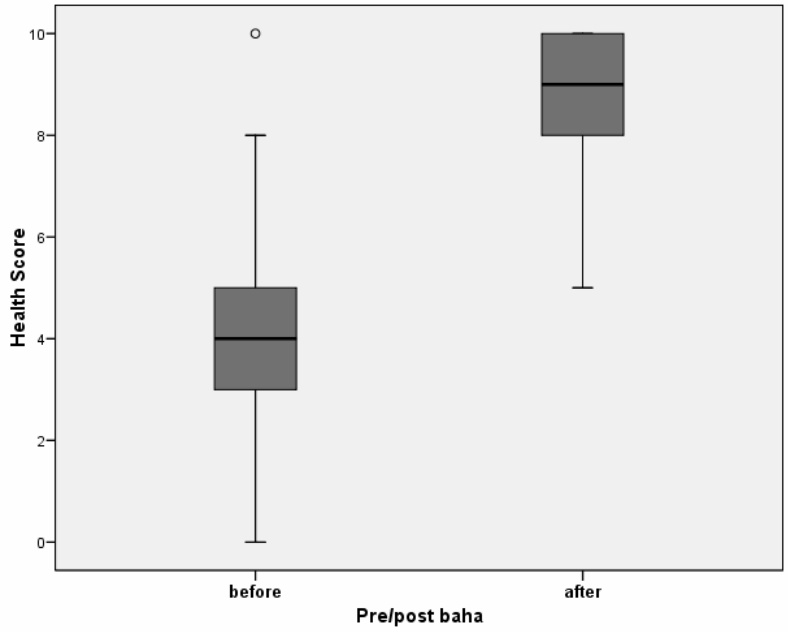

Figure 5. Change in health status before and after Baha®
There was a significant correlation between the change in health status and benefit score. p=0.001

The GCBI is a tool designed to measure benefit. The addition of the linear analogue scale provided a measure of change in health status: A positive change in health status in all 84 patients is seen in this study after the Baha®. Figure 5.
There was a significant correlation between the change in health status and benefit score **(**p=0.001) Figure 6.

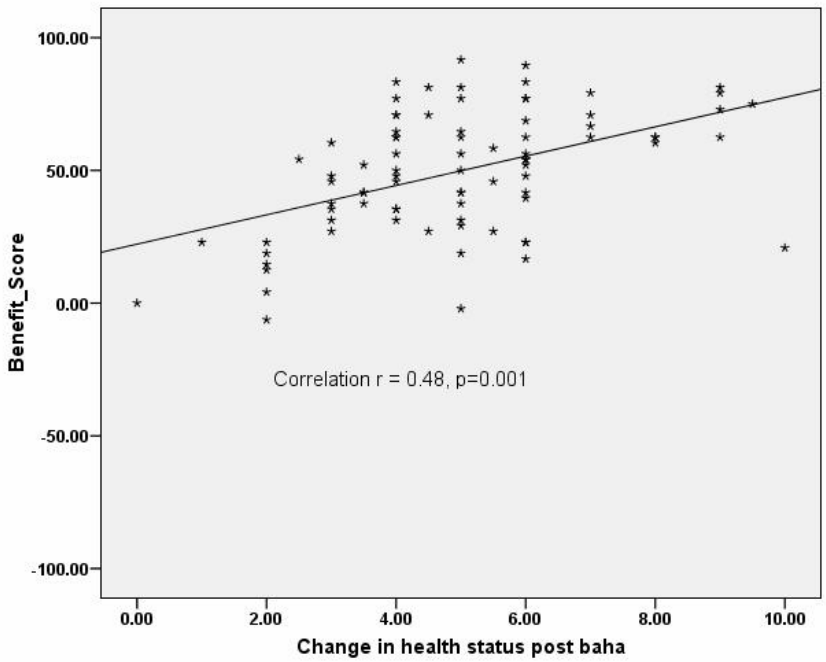

Figure 6. Correlation between benefit score and change in health status

Discussion.

Previous paediatric Baha® satisfaction studies have shown very positive results.[7, 8,9,10,11]

Priwin and Granström[8] used a general 24 question based questionnaire and found that the children favoured their Baha® over conventional hearing aids despite the recognized surgical complications. More recently the team from great Ormond Street Hospital measured quality of life in their children with Baha and found similar results.[12]

In our study we chose the validated Glasgow Children's Benefit Questionnaire. This is a subjective child orientated post-interventional questionnaire. It was developed to evaluate any paediatric otorhinolaryngological surgery and therapy. We did not aim to compare different interventions, but to simply evaluate the self-

rated quality of life and benefits associated with the use of a Baha®. As with any paediatric questionnaire, care must be taken when evaluating the answers since they may reflect the views of the parent/guardian as well as the child. In this study some children were as young as 2 years of age and so it must be assumed that some of the questionnaire results are adult proxy subjective results.

The GCBI (Table 1) has 24 questions based on a five point Likert scale. (Table 2). A score of +2 to -2 was recorded for each question. The overall benefit score median was +54 in our study group.

89% of responders reported a maximum overall benefit from their Baha®. (Table 3).

The benefit of the 27% of non-responders is unknown but we feel that is not an indication to assume they necessarily had a change for the worse.

We do not understand why 31 children failed to respond to the questionnaire. We speculate that language may have been a contributing factor. Our programme has a high proportion of children who do not speak English as a first language and a failing of our study design was a lack of questionnaires in other appropriate languages. The option of an interpreter was considered but was believed to introduce further bias into our study. Translation of this questionnaire into the common languages encountered in children on our programme will be performed for any future studies.

The pathology of the non-responder group was predominantly CSOM. We believe that those children with ongoing complex medical issues such as craniofacial syndromes or syndromes associated with hearing loss were more motivated to reply to their questionnaires than those who attended periodically with otological symptoms only.

Finally, many of our patients come from a poor social class background and they and their families have literacy issues.

In his publication, Kubba et al[5] performed factor analysis: Four factors were identified within the GCBI. These were Emotion, Physical health, Learning and Vitality.

Emotion questions were taken as those relating to self–consciousness, self esteem, family harmony, embarrassment, confidence, ease of distraction and self care.

Physical health involved questions regarding overall life, illness, visits to doctor and medication. Learning related questions included progress, development, concentration and distraction and lastly, vitality involved questions concerning sleep, happiness, fun with friends, leisure activities and enjoyment of food.

Our results indicated that general well being, illness, time off, visits to the doctor and medications were mainly unaffected by a Baha®, however, behaviour, concentration, learning and development showed an improvement following Baha®.

Self consciousness and embarrassment were worsened by a Baha® in 11 cases (13%). In no case did a provision of a Baha® result in a worsening of overall life.

The GCBI is not sensitive to a change in health status. It is more of a benefit score. To evaluate health status, a linear analogue scale as described by Dutt et al in 2002.[4] was incorporated.

In all 84 questionnaires, no child reported a deterioration in health status following their Baha®; health status being defined as the general perception of well being[13].

We report a large number of paediatric patients with significant benefit and improved health status as a result of their Baha®.

Similar studies have used the GCBI to examine quality of life in children with a Baha®. The Great Ormond Street Baha® team recently reported a smaller study group of 71 children. A total of 13 GCBI questionnaires were returned giving a response rate was 18%. Of those who did reply, the Baha® was reported as beneficial.[12] Specific outcomes from the quality of life questionnaires were not detailed in this paper.

The Nijmegen Baha team also reported the use of the GCBI in the assessment of Baha patients with moderate mental retardation. They studied 22 cases both adult and children and found that these patients had a subjective benefit compared to their control group.[14]

Previously the Glasgow Benefit Inventory (GBI) was used to assess quality of life/satisfaction with Baha both in adults and children.

Arunachalam et al reported on 61 Baha patients[15]. This group had an 85% response rate. They demonstrated significant quality of life benefit however it was not clear how many of their cases were children and furthermore, the GBI was never validated specifically for use with paediatric cases.

Since this was a retrospective postal questionnaire study, awareness of bias is important.

All children who had a Baha® and an auricular prosthesis were excluded. This group of children had a significantly different ‘work up’ to surgery, their surgery was at an older age, the procedure differed from those having only a Baha® and finally the aftercare and follow-up was longer.

Children who had worn their Baha® for less than six months were excluded. This was to allow for memory bias. It was felt these children needed more time to adjust to their new Baha®.

Regarding bilateral Baha®, 4 children underwent simultaneous bilateral Baha® thus their experience was no different than the others in the study. A further 4 children had worn their first Baha® for no longer than 2 years before being implanted with the second. These four children were instructed to answer the questionnaire from their first Baha®.

Similarly it was decided to exclude all those children who were now older than 16 years and on the adult programme. Many of these children had worn their Baha® for more than 10 years. Their memories of their quality of life and difficulties prior to Baha® may have diminished.

The length of follow up between the fitting of the Baha® and the questionnaire was very varied. This is a recognised weakness of retrospective studies over long periods of time. When the length of follow up was analysed, 52 children had worn their Baha® for less than 5 years and 32 children had been a Baha® wearer for more than 5 years. No significant differences were identified in benefit. The higher number of Baha® wearers in the first five years was a result of the increasing workload of the programme.

Of the 182 children in the programme, 115 satisfied the inclusion criteria.

We made no attempt to cleave the data in accordance to the model of Baha® used. Over a 15 year period various models had been used with upgrades when appropriate.

All 84 responders were still wearing their Baha® with continuing audiological benefit.

In a recent audit of all children on the programme it was found that 176 (97%) patients were currently wearing their Baha® on a daily basis[15].

Conclusions

The GCBI is a patient orientated questionnaire that provides a measure of change in patient benefit from otorhinological procedures. The addition of the linear analogue scale has provided details of health status before and after provision of a Baha®.

This study did not compare different interventions; it simply established the effect of the Baha® on patient health status. Our study was on a large paediatric population and the results were overwhelmingly supportive for the use of the Baha® in these children. There is no doubt that the provision of a Baha® significantly improved the child's health status and has a positive benefit on their quality of life.

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3.2

The Glasgow Benefit Inventory in the evaluation of patient satisfaction with bone- anchored hearing aids: Quality of life issues

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Abstract

The Birmingham osseointegration programme began in 1988 and during the following ten years there were a total of 351 Bone Anchored Hearing Aid (BAHA) implantees. In the Summer of 2000, a postal questionnaire study was undertaken to establish the impact of the bone-anchored hearing aid on all aspects of patients' lives.

We used the Glasgow Benefit Inventory (GBI), which is a subjective patient orientated post-interventional questionnaire especially developed to evaluate any otorhinolaryngological surgery and therapy. It is maximally sensitive to any change in health status brought about by a specific event: in this case the provision of a BAHA.

A total of 312 bone anchored hearing aid patients, who had used their aids for a minimum period of six months, were sent GBI questionnaires. Two hundred and twenty-seven questionnaires were returned and utilised in the study. The results revealed that the use of a bone-anchored hearing aid significantly enhanced general well being (patient benefit), improved the patient's state of health (quality of life) and finally was considered a success by patients and their families.

Introduction

The Bone Anchored Hearing Aid has provided an alternative to conventional air and bone conduction hearing aids particularly in situations of chronic middle-ear infections, congenital aural atresia and chronic otitis externa.[1]

Since 1977 osseointegrated implants have been shown to provide excellent retention for the bone-anchored hearing aid. During the past 24 years these alternative hearing aids have become increasingly popular. The hearing aid component has recently been manufactured as a more compact device, thus improving its aesthetic appearance.

In a minor surgical procedure performed under local anaesthesia for the majority of patients, a titanium fixture is implanted into the temporal bone. The periosteum of this implant site is removed and the surrounding subcutaneous tissue trimmed. A percutaneous abutment is then attached to the fixture. Three months later, the bone-anchored hearing aid is connected to the abutment. This simple implant technique has made the provision of these bone-anchored hearing aids less traumatic for the patient and overall, more cost-effective.

The Birmingham BAHA programme has implanted both paediatric and adult patients. An evaluation of patient satisfaction and quality of life after BAHA implantation was undertaken.

Patients and Methods

The GBI questionnaire along with a pre-paid envelope was sent to each patient, irrespective of their age, for completion in their own homes. This questionnaire was described by Robinson *et al* in 1996[2] and consisted of 18 questions (Appendix 1). The questionnaire was designed to be completed either at interview or by the patient in their own home.

These18 questions were based on a five-point Likert scale. Half of the questions ranged from a large deterioration in health status to a large improvement in health status. The design of the other half of the questions was reversed. This was to control response bias. The original 18 question GBI was first scored into a total score. It was then scored into the three subscales:

a. Twelve questions relating to general factors
b. Three questions relating to social support issues
c. Three questions concerning physical health

Two additions were made to our questionnaire: Four questions relating to the success of the BAHA (Appendix 2) and a 10 cm linear analogue scale reflecting state of health before and after BAHA (Appendix 3). Neither of these modifications was described in the original GBI strategy.

The total score for each patient was calculated and then averaged to give equal weight to each question. Three (no change) was subtracted from the total and the result multiplied by 50 to produce a benefit score. All these scores ranged from –100 to +100. The same analysis was used for each of the subscales.

The Wilcoxon signed ranks test was used to evaluate the linear analogue scale since it took into account not only the signs of the differences but also their magnitude.

This study was a retrospective postal questionnaire with a four months waiting time for responses from the 312 patients. Subjects who had worn their BAHA for more than six months were included in the study. This was to avoid initial 'enthusiasm bias', allow a gradual learning process with the BAHA and to obviate initial difficulties with fitting and maintenance. A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

Results

In 1988 the Birmingham Bone Anchored Hearing Aid programme was started and during the following decade a total of 351 patients were implanted.

This study group consisted of 242 adults and 109 paediatric patients. The adult age range was 17 to 67 years (median age 45 years) and the paediatric range was 2 to 16 years (median age 9 years). One hundred and eighty-seven patients were male and 164 were female.

Thirty-nine bone anchored hearing aid patients had worn their hearing aid for less than six months and so they were excluded from the study. Three hundred and twelve GBI questionnaires were issued and 227 were completed and returned (72 per cent). Of the 85 non-respondents, 61/85 (72 per cent) were children. The patients that returned the questionnaire had used their BAHA for a period of 6 months to 11 years (mean 5.8 years). Table 1 illustrates the response rate of the study group.

This GBI questionnaire was initially shown to measure the change in health status (benefit) from various otolaryngological interventions.[3-6] In our study, the benefit of wearing a bone anchored hearing aid (quality of life), the success of wearing such a hearing aid and a measure of the health status both prior to and after wearing their bone anchored hearing aid was evaluated.

Table 1: Distribution of response rates

Total numbers of implantees	351	242 adults and 109 children
Total included in the study	312	6 months or more of BAHA use
Number excluded	39	less than 6 months of BAHA use 31 adults and 8 children
Total respondents	227	72% response rate
Total non-respondents	85	
Adults (211)	187 24	respondents (89%) non-respondents (11%)
Children (101) under 16 years	40 61	respondents (40%) non-respondents (60%)

The GBI questionnaire comprised of 18 questions each consisting of five-answer stems known as a five-point Likert scale ranging from a large change for the worse to a large change for the better (Table 2). In the original paper describing the GBI, the score from the Likert scale was then transposed onto a benefit scale ranging from +100 to –100. The same analysis was utilized for the data in this study. In scoring the GBI, all responses to individual questions were averaged so that each question carried equal weight. The data was not distributed normally and so median values were calculated.

Table 3 shows the results of the questionnaire. Patient benefit was found to be significantly improved following implantation with a bone anchored hearing aid. In

no situation did provision of a bone anchored hearing aid result in a deterioration of health.

Table 2. Example of a question used in the Glasgow Benefit Inventory Questionnaire

How successful do you think your BAHA is?	
A Great or moderate failure	score 1
B Partial failure	score 2
C No change	score 3
D Partial success	score 4
E Great or moderate success	score 5

Table 3. Results of GBI questions

Question		Median	Interquartile Range	No. of each answer				
				5	4	3	2	1
a	Effect on life	5	(4.0,5.0)	131	51	40	3	2
b	Overall effect on life	5	(4.0,5.0)	137	60	23	2	3
c	Optimism about future	4	(4.0,5.0)	102	62	56	3	1
d	Embarrassment with BAHA	4	(3.0,5.0)	108	64	42	6	3
e	Self confidence with BAHA	4	(4.0,5.0)	101	70	47	5	1
f	Dealing with company	4	(4.0,5.0)	95	85	38	4	2
g	Support from friends	3	(3.0,4.0)	29	39	136	15	5
h	Visits to GP	3	(3.0,4.0)	32	46	136	7	2
i	Confidence- Job opportunities	3	(3.0,4.0)	44	62	96	11	7
j	Self consciousness	4	(3.0,4.0)	52	75	72	15	10
k	People who care	3	(3.0,3.0)	19	24	174	3	4
l	Frequency of illness	3	(3.0,4.0)	23	54	140	3	4
m	Frequency of medication	3	(3.0,3.0)	17	37	152	14	5
n	Self-opinion	4	(3.0,5.0)	75	94	47	6	2
o	Family support	3	(3.0,4.0)	24	44	147	9	1
p	Inconvenience	4	(4.0,5.0)	84	88	38	11	2
q	Social activities	4	(3.0,4.0)	30	86	95	12	2
r	Social situations	4	(3.0,5.0)	63	65	77	14	6

Table 4. Success of BAHA

Question		Median	Interquartile Range	No of each answer				
				5	4	3	2	1
a	Success of BAHA	5	(4.0,5.0)	170	45	3	3	4
b	Pleased/disappointed	5	(4.0,5.0)	187	24	2	6	6
c	Family opinion	5	(4.0,5.0)	159	48	9	4	5
d	BAHA recommendation	5	(4.0,5.0)	168	43	7	3	3

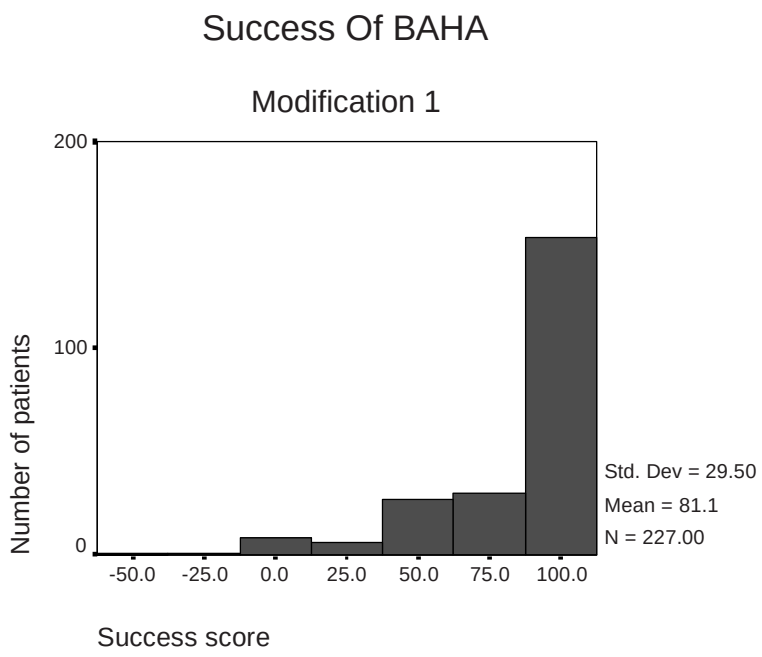

Figure 1. Success of BAHA.

When asked about the success of their bone anchored hearing aid, the overwhelming response was extremely positive (Table 4 and Figure 1).
A remarkable 167 (74%) would encourage others with a similar condition to wear a bone-anchored hearing aid.
Figure 2 represents the summary of the results of the 18 question GBI. It shows the results of each of the three individual subscales. The data are displayed as 'Box and Whisker' plots. In each group the median and 25th and 75th percentiles are displayed. In all three groups the results were very encouraging.
The 10 cm linear analogue scale was included in the questionnaire to directly address the state of health both before and after obtaining a bone anchored hearing aid (Appendix 3). For analysis of this linear analogue scale the (non-parametric) Wilcoxon signed ranks test was used. This showed that the improved state of health of the patients following the use of a bone anchored hearing aid to be highly significant (Table 5).

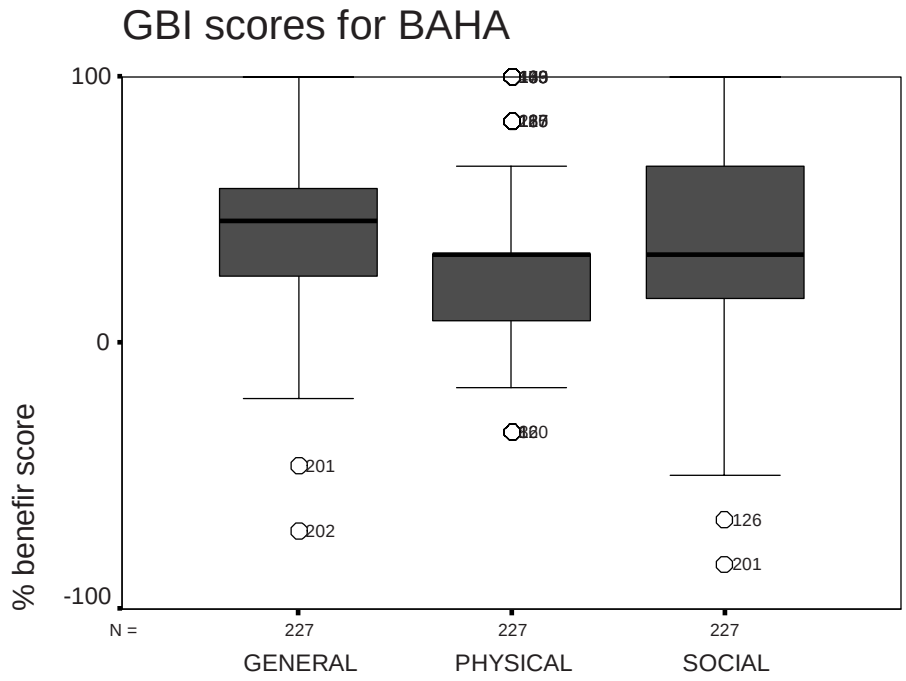

Figure 2. Benefit scores of BAHA using the GBI (Questions a-l were about general benefit, m-o were about the physical benefit and finally p-r pertained to the social benefit)

Table 5. Visual analogue scale regarding State of Health before and after BAHA

	State of health pre BAHA	State of health post BAHA	Difference
Median	56	85	15
Inter-quartile range	(45,76)	(72,91)	(0,30)

Wilcoxon signed ranks test (p < 0.001)

Discussion

The GBI questionnaire is a patient orientated questionnaire designed initially to consist of 18 post-intervention questions. It provides a measure of patient benefit (change in health status) from otorhinolaryngological procedures. It was first developed in 1996 by Robinson et al.[2] The GBI allows a comparison of benefit across different interventions.[3-6] It is designed to measure change in health status, where health status is defined as the general perception of well-being. This includes total psychological, social as well as physical well-being.[7]

In this study the modified GBI questionnaire consisted of 22 questions and a linear analogue scale. A response rate of 72 per cent was achieved. This included both adult and paediatric patients (Table 1).

In response to the modification of the GBI (Appendix 2), these four additional questions regarded the success of the bone-anchored hearing aid. Patients recorded a maximum change for the better (Figure 1). The bone-anchored hearing aid was a success. There appeared to be no change with regards to the number of visits to the GP, support of family and friends and confidence with regards job opportunities. Interestingly, many patients reported annoyance at being asked such questions (Appendix 4). They felt fully supported and cared for by their family and friends irrespective of the type of hearing aid worn. All remaining questions revealed the bone-anchored hearing aid to have a positive effect on their health status. This was supported by the very significant results of the linear analogue scale $p<0.001$ (Appendix 3 and Table 5).

This study did not compare different otolaryngological procedures; it was simply used to establish the effect of the bone-anchored hearing aid on patient health status. In the validation study by Robinson et al cochlear implantation was one of the interventions evaluated.[2] The GBI was found to be responsive to cochlear implantation. Its use for evaluating hearing aid devices was recommended. Only one other study in the literature discusses the use of the GBI following the provision of the bone-anchored hearing aid.[8] Our study is on a large group of patients using the BAHA and the results were overwhelmingly supportive for the use of the bone-anchored hearing aid.

This study was a retrospective postal questionnaire. Some of the patients in the study had worn their bone-anchored hearing aid for ten years. Memories of problems prior to their bone-anchored hearing aid may have faded with time and this of course may be reflected in the results. The GBI is not very sensitive to changes in health status following provision of the bone-anchored hearing aid; it is designed as a benefit questionnaire. The addition of the linear analogue scale has provided details of the health status both before, and after, provision of the hearing aid.

An attempt to cleave data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. However, 72 per cent of the non-repondents were children. Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e., BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in

figures and tables). The data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

Finally, patient benefit was found to be improved by wearing the bone-anchored hearing aid and it significantly improved patient health. The study shows the bone-anchored hearing aid to be a success. Since the provision of such an aid involves a minor surgical procedure that can be performed with local anaesthesia, the authors suggest it should be considered more often for patients with chronic otorrhoea and otosclerosis.

Conclusions

An overwhelming majority of the patients that included both adults and children reported a high degree of satisfaction with the bone anchored hearing aid. Improved self confidence, better job opportunities and better participation in social activities were some of the 'quality of life' issues that were highlighted. The GBI proved to be a valuable instrument in evaluating patient satisfaction and quality of life after BAHA implantation.

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Appendix 1

The Glasgow Benefit Inventory (GBI) Questionnaire

This questionnaire asks how things have changed since you received your BAHA

a) Has getting a BAHA affected the things you do?
Option 1 Much worse
Option 2 A little or somewhat worse
Option 3 No change
Option 4 A little or somewhat better
Option 5 Much better

b) Has getting a BAHA made your overall life better or worse?
Option 1 Much better
Option 2 A little or somewhat better
Option 3 No change
Option 4 A little or somewhat worse
Option 5 Much worse

c) Since you received your BAHA, have you felt more or less optimistic about the future?
Option 1 Much more optimistic
Option 2 More optimistic
Option 3 No change
Option 4 Less optimistic
Option 5 Much less optimisitic

d) Since you received your BAHA, do you feel more or less embarrassed with a group of people?
Option 1 Much more embarrassed
Option 2 More embarrassed
Option 3 No change
Option 4 Less embarrassed
Option 5 Much less embarrassed

e) Since you received your BAHA, do you have more or less self-confidence?
Option 1 Much more self-confidence
Option 2 More self-confidence
Option 3 No change
Option 4 Less self-confidence
Option 5 Much less self-confidence

f) Since you received your BAHA, have you found it easier or harder to deal with company?
Option 1 Much easier
Option 2 Easier
Option 3 No change
Option 4 Harder
Option 5 Much harder

g) With your BAHA, do you feel that you have more or less support from your friends?
Option 1 Much more support
Option 2 More support
Option 3 No change
Option 4 Less support
Option 5 Much less support

h) With your BAHA, have you been to your family doctor for any reason, more or less often?
Option 1 Much more often
Option 2 More often
Option 3 No change
Option 4 Less often
Option 5 Much less often

i) Since you received your BAHA, do you feel more or less confident about job opportunities?
Option 1 Much more confident
Option 2 More confident
Option 3 No change
Option 4 Less confident
Option 5 Much less confident

j) Since you received your BAHA, do you feel more or less self-conscious?
Option 1 Much more self-conscious
Option 2 More self-conscious
Option 3 No change
Option 4 Less self-conscious
Option 5 Much less self-conscious

k) Since you received your BAHA, are there more or fewer people who really care about you?
Option 1 Many more people
Option 2 More people
Option 3 No change
Option 4 Fewer people
Option 5 Much fewer people

l) Since you received your BAHA, do you catch colds or infections more or less often?
Option 1 Much more often
Option 2 More often
Option 3 No change
Option 4 Less often
Option 5 Much less often

m) Since you received your BAHA, have you had to take more or less medicine for any reason?
Option 1 Much more medicine
Option 2 More medicine
Option 3 No change
Option 4 Less medicine
Option 5 Much less medicine

n) Since you received your BAHA, do you feel better or worse about yourself?
Option 1 Much better
Option 2 Better
Option 3 No change
Option 4 Worse
Option 5 Much worse

o) Since your BAHA, do you feel that you have more or less support from your family?
Option 1 Much more support
Option 2 More support
Option 3 No change
Option 4 Less support
Option 5 Much less support

p) Since your BAHA, are you more or less inconvenienced by your hearing problem?
Option 1 Much more inconvenienced
Option 2 More inconvenienced
Option 3 No change
Option 4 Less inconvenienced
Option 5 Much less inconvenienced

q) Since your BAHA, have you been able to participate in more or fewer social activities?
Option 1 Many more activities
Option 2 More activities
Option 3 No change
Option 4 Fewer activities
Option 5 Many fewer activities

r) Since your BAHA, have you been more or less inclined to withdraw from social situations?
Option 1 Much more inclined
Option 2 More inclined
Option 3 No change
Option 4 Less inclined
Option 5 Much less inclined

Appendix 2

Modifications: Subjective opinions regarding success of BAHA

a) How successful do you think your BAHA is?
Option 1 Great or moderate failure/1
Option 2 Partial failure/2
Option 3 No change/3
Option 4 Partial success/4
Option 5 Great or moderate success/5

b) Do you feel pleased or disappointed about getting a BAHA?
Option 1 Greatly or moderately pleased/5
Option 2 A little or somewhat pleased/4
Option 3 No change/3
Option 4 A little or somewhat disappointed/2
Option 5 Greatly or moderately disappointed/1

c) How successful do members of your family and close friends think your BAHA is?
Option 1 Great or moderate success/1
Option 2 Partial success/2
Option 3 No change/3
Option 4 Partial failure/2
Option 5 Great or moderate failure/1

d) If you knew that someone else in your family or a close friend had a similar condition to yours, would you encourage them to get a similar BAHA?
Option 1 Definitely not/1
Option 2 Probably not/2
Option 3 Can't decide/3
Option 4 Probably yes/4
Option 5 Definitely yes/5

Appendix 3

Modification : State of health before and after BAHA

We would like you to indicate your state of health. To help you, we would like you to imagine a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Think about how your health affects:

- Your general well-being
- Your independence and ability to take care of yourself
- Your ability to take care of others
- How you feel about yourself
- Your ability to get around and communicate
- Your ability to socialise
- Your performance at work

Your state of health today with your BAHA

We would like you to choose a point on the scale that indicates how good or bad you consider your state of health is today with your BAHA

Worst----------Best

Your state of health before you received your BAHA
Worst----------Best

Appendix 4

Interesting responses

- *I cannot tell you how this BAHA has changed my life. I wish we had this device years ago, as I have had to rely on lip reading all my life.*

- *Since the BAHA, I have got more into social activities to make up for all the years I missed out.*

- ***Q: Since your BAHA, are you 'more' or 'less' optimistic about the future?***
- *A: I have always been optimistic about the future and cannot see the relevance of this question.*
- ***Q: Since the BAHA, are you 'more' or 'less' embarassed when with a group of people?***
- *A: I have never felt embarassed about wearing any kind of hearing aid. I find this question upsetting.*
- ***Q: Since the BAHA, are there 'more' or 'fewer' people who really care about you?***
- *A: My hearing aid makes no difference. My friends and family have always cared for me. I find this question very upsetting.*

- *My daughter and I filled these forms together; some of the questions were rather difficult for a 9 year old to answer. However, the details in the questions did actually focus her mind on how well (or not) she hears in some situations.*

- *I am very happy and grateful to you for the BAHA and so is my husband. I must have been a miserable person to live with before the BAHA.*

- ***Q: Your State of Health before you received your BAHA and today with your BAHA.***
- *A: I was not mentally retarded before the BAHA. Somehow there is such an implication in this question.*

3.3

An intra-individual comparison of the previous conventional hearing aid with the Bone Anchored Hearing Aid: The Nijmegen group questionnaire

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Abstract

By Spring 2000, a total of 351 patients were implanted on the Birmingham bone anchored hearing aid (BAHA) programme. This group consisted of 242 adults and 109 children. The aim of this retrospective questionnaire study was to directly assess patient satisfaction with their current bone-anchored hearing aid in comparison with their previous conventional air and/or bone-conduction hearing aids.

The Nijmegen group questionnaire was sent by post to 312 patients who used their BAHA for 6 months or longer. The questionnaire used was first described by Mylanus et al (Nijmegen group) in 1998. The total response rate was 72 per cent (227 of 312 patients). The bone-anchored hearing aid was found to be significantly superior to prior conventional hearing aids in all respects.

Introduction

The percutaneous bone conduction hearing aid was first developed by Hakansson in 1985.[1] The bone anchored hearing aid (BAHA) connects directly to an osseointegrated titanium percutaneous implant anchored within the temporal bone. In a minor surgical procedure this implant is fitted under local anaesthetic. Sound vibration is then transferred from the transducer directly to the skull base thus giving direct bone conduction.

Sensorineural hearing loss is the most common form of hearing impairment. Conductive hearing loss is a second, less common, type of hearing deficit that may be suitable for surgical correction. If not, these patients are usually fitted with either conventional air or bone conduction hearing aids. Difficulties arise when hearing loss is further complicated by chronic otitis media, otitis externa and congenital aural atresia. In these particular situations, an ear mould is difficult or impossible to use. In such patients the introduction of the bone anchored hearing aid has proved to be invaluable.[2,3] Conventional bone conduction hearing aids are a less popular option because of their poor aesthetic appearance, comfort, frequency response and inadequate gain.[2]

In this study patients were asked to compare their current bone anchored hearing aid with their previous conventional hearing aid.

Patients and Methods

The questionnaire used in this study was first designed, validated and used by Mylanus et al in 1998 (Appendix 1).[4]

Table 1. Distribution of response rates

Total numbers of implantees	351	
Total included in the study	312	6 months or more of BAHA use
Number excluded	39	less than 6 months of BAHA use 31 adults and 8 children
Total respondents	227	72% response rate
Total non-respondents	85	
Adults (211)	187 24	respondents (89%) non-respondents (11%)
Children (101) under 16 years	40 61	respondents (40%) non-respondents (60%)

The Nijmegen group compared the BAHA to the patients' previous air-conduction hearing aids. However, our study uses the same questionnaire to compare the BAHA to the previous conventional air-conduction (AC) or bone-conductor (BC) aid.

To avoid “enthusiasm” bias and initial difficulties with fitting and maintenance of their bone anchored hearing aid, only those subjects who had worn a bone anchored hearing aid for six months or more were included in this study. A total of 312 patients were sent the postal questionnaire. A waiting period of four months was allowed for return of completed questionnaires. A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

The binomial test (data in non-parametric scales) was applied to the results for statistical analysis.

Results

Three hundred and fifty-one patients were implanted in the BAHA programme. There were 187 males and 164 females. The age range was 2 to 67 years. A total of 312 patients were included in the study and 227 (72 per cent) questionnaires were completed and returned. Of the 85 non-respondents, 61/85 (72 per cent) were children. Patients that returned completed questionnaires had worn their BAHA for a period of six months to 11 years (mean 5.8 years). Table 1 illustrates the distribution of the response rates.

Patients found the bone-anchored hearing aid to be significantly superior in all respects when compared to their previous conventional hearing aids (air-conduction or bone-conductor) as depicted in Table 2. Fifty-eight patients out of

227 patients (25 per cent) had used a bone-conductor (BC aid) at some stage of hearing rehabilitation.

Table 2. Which hearing ais is better with regard to:

Parameter	BAHA	AC/BC Aid	Significance (binomial test)
a. Occurrence of ear infections (reduced)	72.8%	2.4%	*p*=<0.001
b. Speech recognition – Quiet	79.3%	4.7%	*p* =<0.001
c. Speech recognition – Noise	59.2%	6.5%	*p* =<0.005
d. Sound quality	78.7%	8.3%	*p* =<0.001
e. Visibility	70.4%	7.7%	*p* =<0.001
f. Handling	81.8%	4.7%	*p* =<0.001
g. Feedback problems	75.1%	4.7%	*p* =<0.001
h. ENT visits	70.4%	3%	*p* =<0.001

BAHA – Bone-anchored hearing aid; AC aid – Air-conduction aid; BC aid – Bone-conductor aid

Fourteen per cent of respondents found no difference with regards speech recognition in noisy surroundings and 12 per cent found handling of the BAHA to be similar to their previous aids.

When asked to identify the most positive distinguishing feature of their BAHA, 179 (79per cent) of 227 respondents believed sound quality to be the most outstanding feature (*p*=<0.001). One hundred and sixty three (72 per cent) respondents were pleased with the reduced number of ear infections (*p*=<0.001). One hundred and seventy-nine (79 per cent) felt speech in quiet surroundings was improved, and 133 (59 per cent) had similar feelings regarding speech in a noisy environment (Figure 1).

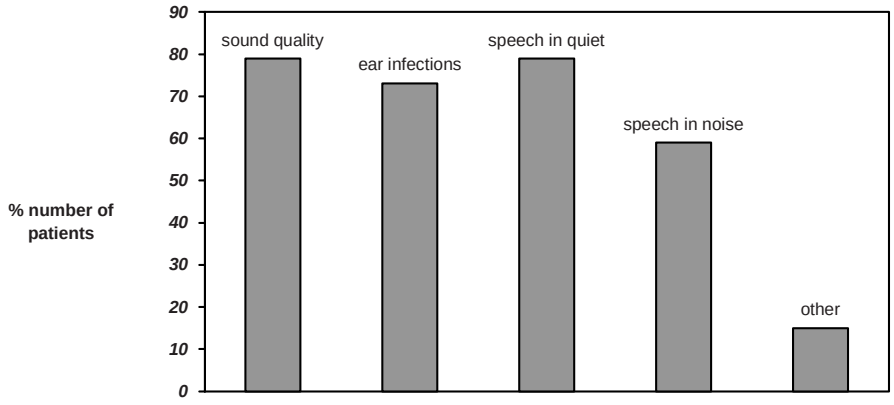

Figure 1. Hearing aid related aspects with which BAHA distinguishes itself in a positive sense.

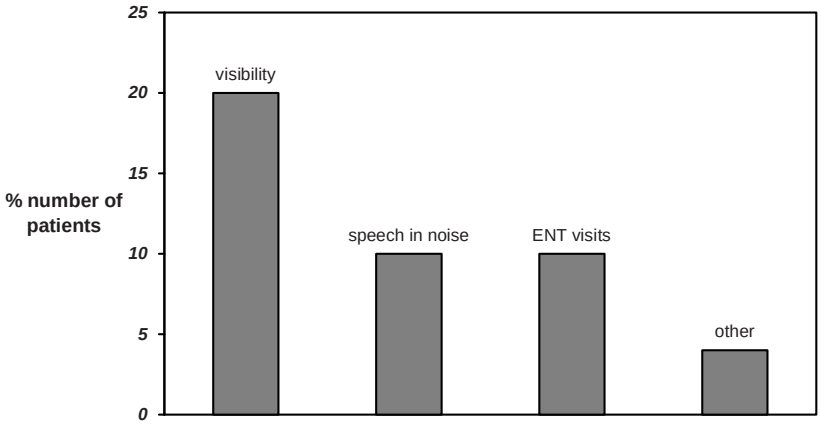

Figure 2. Hearing aid related aspects in which the BAHA distinguishes itself in a negative sense.

Forty-five (20 per cent) of respondents felt that visibility was the most negative finding. Twenty-three (10 per cent) believed speech in noise and the number of visits to the ENT department to be the most negative aspects of the BAHA (Figure 2).

The health of the titanium implant and the ultimate success of the BAHA depend heavily upon the meticulous care and cleaning of the abutment. The cleaning of the BAHA was not really regarded as a problem by 146 (64 per cent) of respondents (p =<0.001) (Figure 3). Finally, the overwhelming majority of patients189 (83 per cent) preferred the BAHA (p=<0.001) (Figure 4).

Discussion

Bone conduction hearing aids were first described in the 18th Century.[5] Today a conventional bone anchored hearing aid consists of a transducer and amplifier attached to a headband or spectacle frame. It is designed to press firmly against the skull vault. These hearing aids have remained unpopular due to their poor aesthetics, discomfort due to constant pressure from the transducer, and poor sound quality at higher frequencies. The alternative bone-anchored hearing aid was first described by Hakansson in 1985 [1] and became commercially available in 1987. The introduction of this titanium implant system by Branemark represented an important breakthrough in establishing both excellent device retention and also reaction-free penetration of the skin.

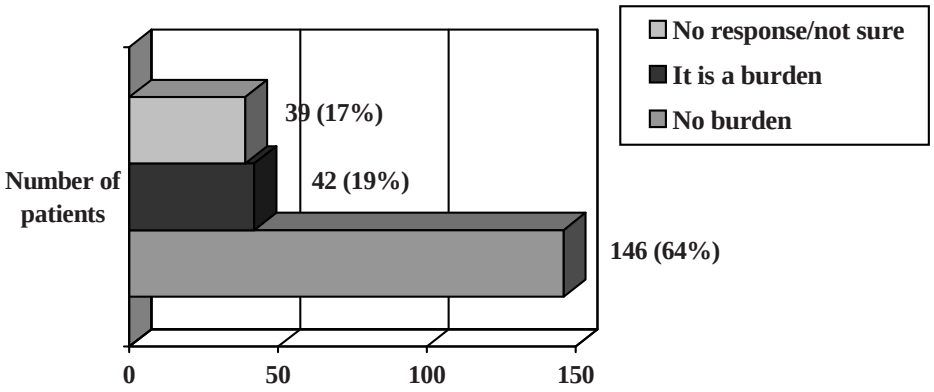

Figure 3. Cleansing and care of the implant site and surrounding skin

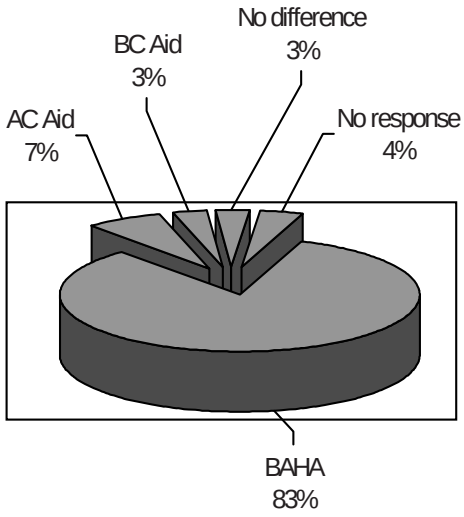

Figure 4. The hearing aid that is preferred the most
BAHA - Bone anchored hearing aid; AC aid - Air conduction aid (conventional); BC aid -Bone conductor aid (conventional)

Today audiological testing is utilized to evaluate hearing aid performance, however these results do not always correlate to the patient's own perception of their hearing aid. This study presents the subjective results of an intra-individual comparison between the bone-anchored hearing aid and previously worn

conventional hearing aids (air conduction - AC, or bone-conductor - BC) of patients in the largest BAHA programme in the UK.

Each patient included in the study had worn a bone-anchored hearing aid for a period of six months to 11 years (mean 5.8 years). Some bias was expected from patients who had worn their bone-anchored hearing aid for many years. Memories of previous hearing aids fade with time and may affect the response to the questionnaire. The underlying otological conditions included congenital aural atresia, chronic otitis media, chronic otitis externa, large mastoid cavities, otosclerosis and an intolerance to alternative hearing aids. The model of bone-anchored hearing aid used by each patient was not identified in this study.

Of the 85 non-respondents, 61/85 (72 per cent) were paediatric patients. The questionnaire does appear to be primarily aimed at the adult patient and questions such as sound quality were difficult for paediatric subjects to both interpret and answer even with help from parents. An attempt to cleave data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e., BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in figures and tables). The data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

The BAHA was found to be better than both the air and bone conduction hearing aids in all aspects. However, the main advantages appeared to be sound quality and reduced ear infections. Speech in quiet surroundings was also considered to be greatly improved with the use of the bone-anchored aid. These findings are in keeping with published literature.[2,6-8] Visibility of the BAHA was found to be the most negative finding. The number of visits to the out-patient clinic and the quality of speech in noise were also believed to be negative factors. Additional patient comments stated that the frequency of out-patient visits was only a problem in the early post-operative period.

Cleansing of the BAHA abutment is vitally important if osseointegration is to be maintained. Patients about to undergo implantation are routinely informed of the need of partner co-operation with cleaning the fixture especially in the early post-operative weeks. In this study, cleaning was not found to be a problem to 64 per cent of respondents.

Finally, the overall preference was overwhelmingly found to be for the BAHA over other hearing aid types.

Conclusions

Seventy-three per cent of patients with previous discharging ears had fewer ear infections with the BAHA. Seventy-nine per cent of the respondents perceived better speech in quiet and 59 per cent better speech in noise with the BAHA.
Seventy-eight per cent of BAHA users liked the quality of sound with the BAHA. Sixty-four per cent of the users did not perceive care of the implant site as a burden. An overwhelming 83 per cent of the respondents preferred BAHA to their previous hearing aids.

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Appendix 1

The Nijmegen Questionnaire

An intra-individual comparison of the bone-anchored hearing aid and previous air conduction hearing aids

1. Which hearing aid is better with regard to:-

A	Occurrence of ear infections	AC aid	BAHA	No difference
B	Speech recognition in quiet places	AC aid	BAHA	No difference
C.	Speech recognition in noisy surroundings	AC aid	BAHA	No difference
D.	Sound quality	AC aid	BAHA	No difference
E.	Visibility	AC aid	BAHA	No difference
F.	Handling	AC aid	BAHA	No difference
G.	Feedback problems	AC aid	BAHA	No difference
H.	ENT visits	AC aid	BAHA	No difference

2. On which of these hearing aid related aspects A to H does the BAHA distinguish itself most from the previous hearing aid in a positive sense?

3. On which of these hearing aid related aspects A to H does the BAHA distinguish itself most from the previous hearing aid in a negative sense?

4. Do you regard cleansing of the implant and the surrounding skin as a burden?

5. In general, which hearing aid do you prefer?

AC hearing aid BAHA No difference

Comments:

3.4

Day to day use and service related issues with Bone Anchored Hearing Aids: the Entific medical systems questionnaire

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Abstract

Over a 12-year period, the Birmingham implantation otology unit has implanted more than 300 patients with bone anchored hearing aids (BAHA).

The Entific Medical Systems questionnaire was administered to these patients to evaluate the day to day use of the BAHA, professional needs, after-care, wear and tear concerns and service related issues. Data analysis revealed that most patients used their BAHA for more than eight hours a day (90 per cent of BAHA users) and every day of the week (93 per cent of BAHA users). A high degree of satisfaction was expressed as regards sound amplification, listening to radio or television news, listening to music, speech perception in quiet conditions, during conversation with one person in noisy surroundings and conversation with family at home. Some degree of difficulty was expressed with the use of the BAHA during conversation with two or more people in noisy surroundings. A slow process of perceptual acclimatization was noticed with the majority of the patients. The majority of patients were pleased with the service as regards care of the wound, BAHA nursing clinics, device repairs and other service-related issues.

Introduction

As part of the Birmingham osseo-integration programme, bone anchored hearing aids (BAHA) have been been implanted in more than 300 patients including adults and children. The overall philosophy of the programme is an integrated evaluation and rehabilitation package that is ably executed by its multi-disciplinary team.[1,2] Bone anchored aids are now more widely used with extended applications. This is in addition to the congenital deafness cases for which BAHA has become the first treatment of choice.[3]

After more than a decade's experience with the BAHA, the Birmingham team applied instruments of patient satisfaction in the form of questionnaires to all its patient population. One such questionnaire study was the Entific Medical Systems (Nobel Biocare) questionnaire that was modified and administered to the patients to evaluate specific issues such as:

1. Daily usage of the BAHA.
2. Wear and tear concerns including device failures, repairs and replacements.
3. Service related issues including nursing care and out-patient clinic visits.

The objective of this study was to ascertain the usefulness of the BAHA as a hearing habilitation device. With this questionnaire, no comparisons were made with the previous conventional air conduction or bone conduction aid or even to a no-aid situation.

Patients and Methods

The Entific Medical Systems (Nobel Biocare) questionnaire was previously used by the Birmingham team in evaluating a small group of paediatric patients.[1]

A modified version of this instrument was used as a retrospective postal questionnaire survey on 312 of the 351 patients who had used their BAHA for more than six months' duration. This was to allow a period of learning with the use of the BAHA and to avoid beginner's enthusiasm and obviate initial difficulties with fitting and maintenance. A period of four months was allowed for return of the questionnaire to the BAHA office.

A small cohort of the patients (15 in number) used bilateral BAHA implants. These patients were instructed to fill in the questionnaires with reference to the use of their first BAHA (longest worn).

Results

Of the 351 patients implanted between 1988 and 1999, 312 were included in the study. A period of six months' use and familiarity with the BAHA was considered essential for learning and acclimatization. It was also hoped that this eliminated any enthusiasm bias. There was a 72 per cent response rate with 227 completed questionnaires being returned. Of the 227 respondents, 187 were adults and the rest children as shown in Table 1. The study addressed three specific areas, viz., day to day use, wear and tear concerns and service issues.

Day to day usage:

The BAHA was most often used all day long by 147 of the 227 (65 per cent) patients. The rest of the patients used the aid for variable periods during the day and some for work only.

Table 1. Distribution of response rates.

Total numbers of implantees	351	242 adults and 109 children
Total included in the study	312	6 months or more of BAHA use
Number excluded	39	less than 6 months of BAHA use 31 adults and 8 children
Total respondents	227	72% response rate
Total non-respondents	85	
Adults (211)	187 24	respondents (89%) non-respondents (11%)
Children (101) under 16 years	40 61	respondents (40%) non-respondents (60%)

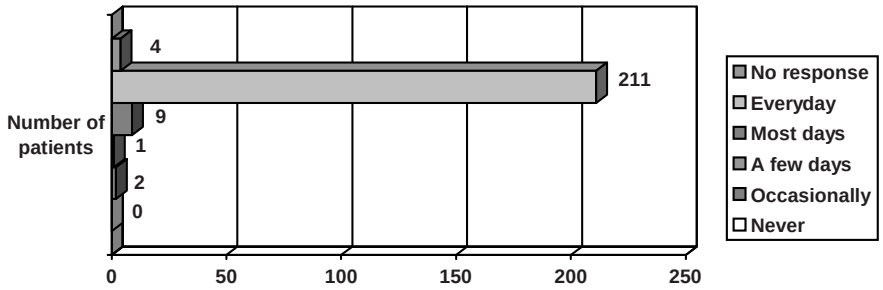

Figure 1. Number of days per week the BAHA is used.

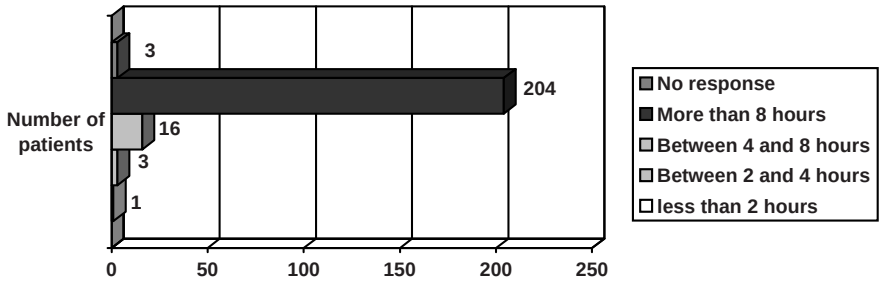

Figure 2. Number of hours of BAHA use per day.

Eleven of 227 (4.8 per cent) of the patients used their previous aids (air or bone conduction aids) as a temporary measure. These included seven patients with fixture failures (six paediatric, one adult), three patients with wound problems and one awaiting hearing aid replacement. Figure 1 illustrates the number of days per week the BAHA was used and Figure 2 shows the number of hours per day with BAHA use. It is reassuring to note that the majority of them found the BAHA useful for more than eight hours a day (90 per cent of 227) and for every day of the week (93 per cent of 227).

One hundred and eighty-five of the users (81 per cent) were satisfied with the degree of amplification that the BAHA produced (Figure 3). One hundred and seventy-two (76 per cent) patients reported that the BAHA was 'quite satisfactory' to 'very satisfactory' when listening to radio and television news (Figure 4). Seventy-four per cent (74+95) of the respondents were pleased with the BAHA when listening to music (Figure 5).

With ‘speech in quiet surroundings’ (Figures 6 and 7), a high degree of satisfaction was expressed by 84 per cent (147+44) of candidates as regards 'conversation

with one person in quiet' and by 67 per cent (86+65) of candidates for 'conversation with two or three people in quiet surroundings'.

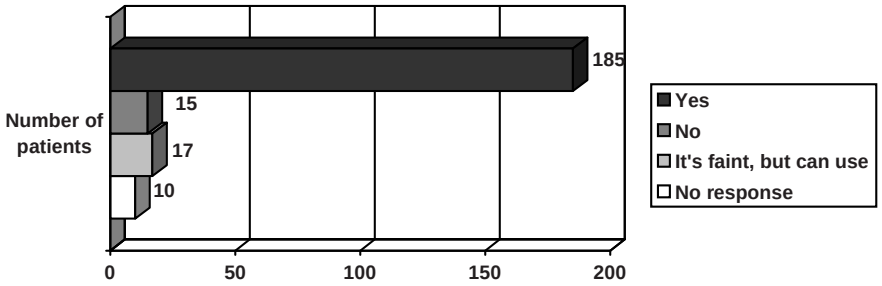

Figure 3. Sound amplification by the BAHA.

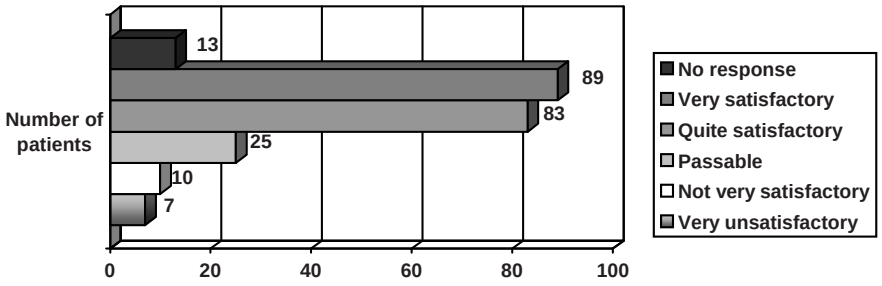

Figure 4. BAHA rating when listening to the radio or television news.

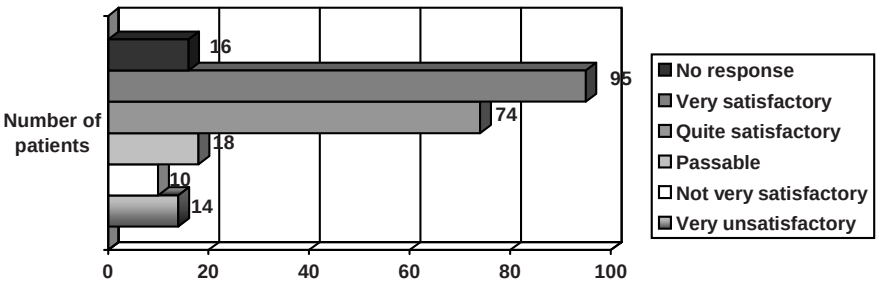

Figure 5. BAHA rating when listening to music.

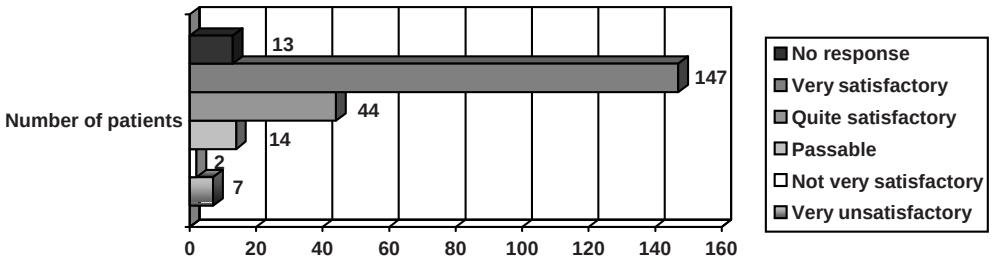

Figure 6. BAHA rating during conversation with 1 person in quiet surroundings.

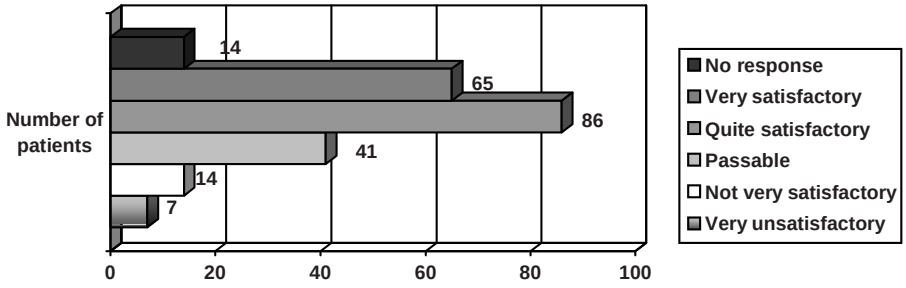

Figure 7. BAHA rating during conversation with 2 or 3 people in quiet surroundings.

The results with speech in noise (Figures 8 and 9) were not that encouraging. Twenty-five per cent and 18 per cent of the patients rated their BAHA as 'passable' with regard to conversation with 'one person in noise' and 'with a group of people in noise' respectively. Only 38 per cent (60+27) were satisifed with the BAHA during conversation with one person in a noisy environment. About 50 per cent of the respondents (72+42) rated the BAHA unsatisfactory as regards speech in noise with a group of people (Figure 9). It was interesting to note that most of these 'unsatisfied' patients had used their BAHAs for less than 3 years. However, speech in noise in a more familiar environment such as 'family and friends at home' elicited a higher degree of satisfaction (69 per cent) with the BAHA (Figure 10).

Sixty-nine per cent of the respondents perceived no difference with the quality of their own voice with the use of the BAHA (Figure 11). A small percentage (5 per cent) perceived their own voices as 'resonant' or 'robotic' with the BAHA.

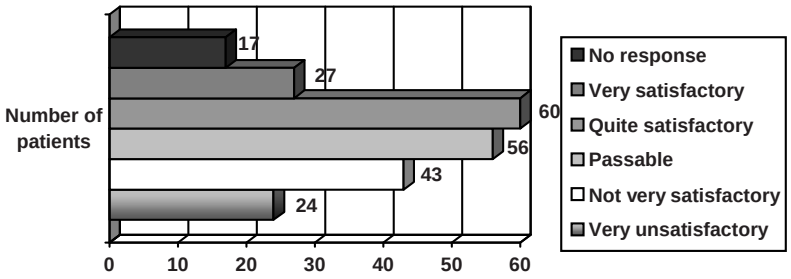

Figure 8. BAHA rating during conversation with 1 person in noisy surroundings.

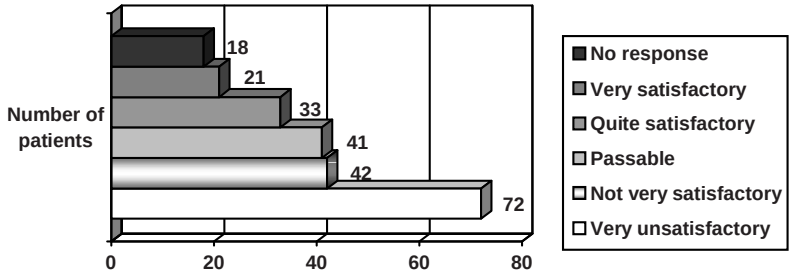

Figure 9. BAHA rating during conversation with a group of people in noisy surroundings.

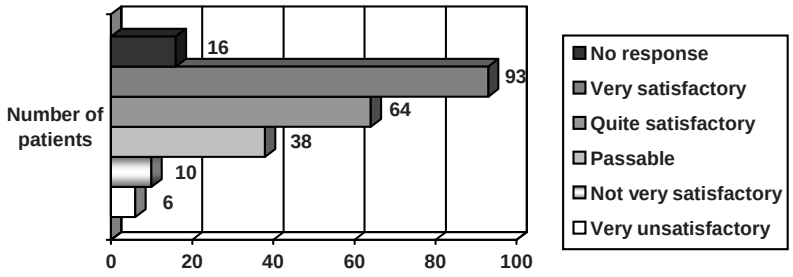

Figure 10. BAHA rating being with family or friends at home.

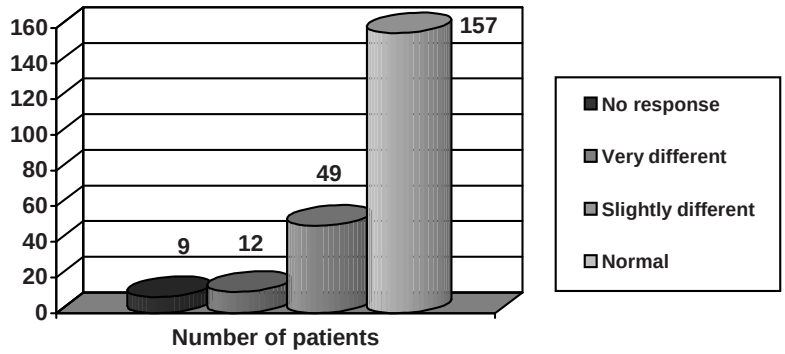

Figure 11. How does your own voice sound when you are using the BAHA?

Patients who had used their BAHA for more than 3 years (143 of 227) were satisfied with the amplification, sound quality and situational uses than those who had been implanted more recently (less than 3years).

Wear and tear concerns

Tables 2 and 3 list the subjective feelings of the patients with the use of the BAHA and the sound produced by the aid respectively. On a satisfaction scale of 1 to 10, the majority of the patients scored in the range of 7 to 10.

Eighty-nine per cent of the patients were pleased with the repairs and replacement service by the audiological team and the company.

Manual dexterity was an issue with some of the patients (four per cent) but the majority of them had a helping hand (question 2) in their environment.

Care of the wound, the fixture-abutment assembly and the BAHA was a problem with a minority of patients (nine per cent) and these were mostly children.

Ninety-two per cent of the patients required battery changes once a month or longer. Questions on telecoil use and the use of the Bicros produced variable responses. Fifteen per cent used the telecoil system and 20 per cent used the Bicros in public places and social gatherings.

Service related issues

A small percentage (three per cent) of patients were dissatisfied with the surgical aspects. These were patients who presented with wound problems and fixture failures. An overwhelming 94 per cent of the respondents were satisfied with the nursing care and the ward staff. Two per cent of the patients were dissatisfied with the waiting times in the specialist out-patient clinics and at the audiology services.

Table 2. Word or phrase that best describes your present feelings about your BAHA and its use (one or more options possible)

Difficult to put in	26	Unnecessary	10
Conspicuous	44	A very great help	152
Tiring	12	Reduces stress	102
Makes me feel awkward	19	Easy to use	156
Not very helpful	7	Very useful in company	116
Noisy	10	Invaluable	142
Difficult to use	3	Wish I had obtained one earlier	160
Uncomfortable	6		

Table 3. Word or phrase that best describes your present feelings about the sound produced by your BAHA (one or more options possible)

Soft/pleasant	63	High/thin	5
Hard/sharp/blaring	29	Deep/dull	3
Natural/clear/pure	113	Muffled	18
Impure	10	Echoing	18
Uncomfortably loud	8	Cracking	18
Far too weak	21	Others	14

Discussion

The selection protocol, referral practice and rehabilitation regimens for both adult and paediatric groups of patients on the Birmingham BAHA programme have been extensively discussed earlier.[1,2] Two other pioneering centres of BAHA implantation i.e. Gothenburg and Nijmegen have published their long-term results with encouraging outcomes.[3,4]

The questionnaire used is a modification of the one previously produced by the Nobel Biocare company and evaluated by the Birmingham team.[1]

A 72 per cent response rate is significant and adds value to the results. Individual questions in the questionnaire have a small 'no response' rate and these were attributed to

1. question not applicable to the candidate and
2. some of the paediatric group who perhaps did not seek help from their parents in completing the questionnaire.

Cleaving data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme. In general, the responses of both adult and paediatric groups were comparable. However, 72 per cent of the non-repondents were children (Table 1). Similarly, comparison of the patient satisfaction with respect to the model of the BAHA used, i.e. BAHA Classic (all generations) and the BAHA Cordelle produced comparable results (data not in figures and tables). The data was again complicated by the fact that a significant number of patients had used various models for variable periods of time, with the company (Entific Medical Systems, Nobel Biocare, Nobel Pharma) upgrading the devices at various stages.

A high degree of satisfaction was expressed by most patients using the BAHA. These results are comparable to published literature from other centres.[5-8]

In many of the day-to-day situations, the candidates perceived a certain degree of learning process. Some patients who were extremely dissatisfied with their previous conventional aids were overwhelmed by the benefits of the BAHA soon after fitting. To obviate this enthusiasm bias and allow a natural trial and learning process, the team chose to test and question only those patients who had used their BAHA for longer than six months. As mentioned, it appeared that patients who had used the BAHA for more than three years were more satisfied with the amplification, sound quality and situational uses as above than those who had been implanted more recently. This was the gradual process of perceptual acclimatization that was expected.

The Birmingham BAHA team includes two specialist BAHA nurses in the adult programme and an advanced nurse practitioner in the paediatric service. They have been involved in the management of dressings, wound care and care of the fixture-abutment assembly. Ninety-four per cent of the respondents were extremely pleased with this service and the nursing care they received during their recovery from surgery. With surgery, a one stage complete procedure under local anaesthetic for adults and a two stage procedure under general anaesthetic for children is the norm as described previously.[3]

Most of the patients were pleased with the care and time allocated for them in the multidisciplinary specialist BAHA and FAITEC (Facial and Audiological Implantation Technology) clinics. Outpatient attendance for suction clearance of draining ears was understandably reduced in a number of patients whose mastoid cavities and perforated ears were rendered dry.[9,10]

Audiological services include a robust pre-assessment protocol, post-implantation periodic evaluation and liaison for repairs, battery changes, replacements with the Entific Medical Systems. The service of specialist speech and language therapists is also available on both the adult and paediatric teams.[11] Most patients were quite satisfied with these services, however there were a few less satisfied individuals. Some of the interesting responses are listed in Appendix 2.

Conclusion

In summary, a high degree of satisfaction was expressed by most of the respondents with the use of the BAHA in their day to day activities at home and at work.

The majority of the respondents were pleased with the care and service provided by the multidisciplinary teams involved.

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Appendix 1

The Entific Medical Systems (Nobel Biocare) Questionnaire

1. The hearing aid most often used - previous AC/BC aid BAHA

2. At home, do you often have someone in your immediate vicinity, e.g.: husband/wife/children/mother/father/sister/brother etc Yes/ No

3. How many days per week do you use your hearing aid?
   1. Every day ---
   2. Most days ---
   3. A few days ---
   4. Only occasionally ---
   5. Never ---

4. How many hours would you say that you use your hearing aid during the course of a normal day?
   1. Less than two hours ---
   2. Between two and four hours ---
   3. Between four and eight hours ---
   4. More than eight hours ---

5. How often do you change the battery? (Type of battery: Zinc/Mercury/Other)
   1. Once a week ---
   2. Twice a month ---
   3. Every three weeks ---
   4. Once a month ---

6. Does your hearing aid amplify sound sufficiently?
   1. Yes ---
   2. No ---
   3. It's faint but I can use it ---

7. How would you rate your hearing aid in the following situations?
   1. Very satisfactory Score 5
   2. Quite satisfactory Score 4
   3. Passable Score 3
   4. Not very satisfactory 2
   5. Very unsatisfactory 1

   a) When listening to the radio or TV news ---
   b) When listening to music ---
   c) Conversation with 1 person in quiet surroundings ---
   d) Conversation with 1 person in noisy surroundings ---
   e) Conversation with 2 or 3 people in quiet surroundings ---
   f) Being with family or friends at home ---
   g) Being with a group of people in noisy surroundings ---

8. How does your own voice sound when you are using your hearing aid?

1. Normal ---
2. Slightly different ---
3. Very different ---

9. Please tick the word or phrase, which best describes your present feelings about your hearing aid and its use (you may tick more than one)

1. Difficult to put in ---
2. Conspicuous ---
3. Tiring ---
4. Makes me feel awkward ---
5. Not very helpful ---
6. Noisy ---
7. Difficult to use ---
8. Uncomfortable ---
9. Unnecessary ---
10. A very great help ---
11. Reduces stress ---
12. Easy to use ---
13. Very useful in company ---
14. Invaluable ---
15. Wish I'd obtained one earlier ---

Remarks

---

10. Please tick the word or phrase, which best describes your present feelings about the sound produced by your hearing aid

1. Soft/pleasant ---
2. Hard/sharp/blaring ---
3. Natural/clear/pure ---
4. Impure ---
5. Uncomfortably loud ---
6. Far too weak ---
7. High/thin ---
8. Deep/dull ---
9. Muffled ---
10. Echoing ---
11. Crackling ---
12. Others (please describe) ---

Remarks

---

11. Please try to indicate how satisfied you are with your present hearing aid by giving it a mark out of 10

1 = very dissatisfied 10 = very satisfied -----

12. Please give your views whether positive or negative on your present hearing aid and the service that has been provided

Audiology service and advice

Battery replacements

Device repairs and replacements

Surgical procedure

Nursing service

Ward care

Outpatient clinic visits and care
---

13. Do you have a Bicros? Yes/No
If yes,

Do you use the additional microphone? Yes/No
Situations used in and reasons for not using

---
14. Do you use the telecoil function? Yes/No
Situations used in or reasons for not using

---

15. Does the BAHA satisfy your professional needs? Yes/ No/ Not applicable

Appendix 2

Interesting Responses

- *The surgeons and the nursing staff are a wonderful team. I offer my sincere thanks to all the members of the team.*

- *Another odd bit of information about my aids (I use binaural BAHAs) is to do with walking in a strong wind. I find that the noise of the wind blocks out the sound of traffic. So I find that I cope better if the aid that faces the wind is switched off and I can hear with the other one which is on the sheltered side, and I just reverse the procedure on the walk back.*

- *I would be very interested in helping to trial an updated BAHA that incorporates an FM receiver that will operate like cordless headphones. I can see the benefits in having the transmitter connected to audio outputs from HiFi, TV, telephone or simply having a microphone input. Having a BAHA that only contains an FM receiver (rather than a microphone) would probably be worthwhile.*

- *We are very sorry that our son broke his BAHA and the abutment accidentally when a ball hit the side of his head.*

- *I lost my BAHA when I was at a concert and was carried by the crowd above their heads and thrown around.*

- *Now this BAHA is very, very good only when it works, which is never. I seem to have problems with it all the time.*

- *I must congratulate the company that produces the BAHA and all the members of the surgical and audiological teams for their splendid service. All the problems I had with the device were readily repaired.*

3.5

Disability, handicap and benefit analysis with the Bone Anchored Hearing Aid: The Glasgow hearing aid benefit and difference profiles

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Abstract

The Birmingham bone-anchored hearing aid programme began in 1988 and by autumn 2000 a total of 351 patients had been fitted with such an aid. The aim of this study was to assess the effectiveness of hearing rehabilitation with the bone-anchored hearing aid. This was a prospective interview-based questionnaire study carried out in the autumn 2000. A total of 84 adult patients were interviewed. Each patient had worn their BAHA for more than one year.

The questionnaire used during these interviews was the Glasgow hearing aid benefit profile (GHABP) and the Glasgow hearing aid difference profile (GHADP). This was first derived and validated by Gatehouse in 1999. The use of bone-anchored hearing aids was found to reduce the level of disability and handicap and provided the most patient benefit and satisfaction.

Introduction

The rehabilitation of patients with hearing loss aims to reduce the level of disability and handicap that occurs as a consequence. Various hearing aids are used to provide amplification and each of these has its own individual problems. Since the advent of the bone-anchored hearing aid (BAHA), it has been shown to be a highly effective hearing aid for patients particularly those with aural atresia, chronic otitis media or externa and more recently otosclerosis.[1-3] It has proved to be extremely well tolerated by patients.

The BAHA was first described in the early 1980s and since then the operative techniques employed have evolved along with the hearing aid device itself. It is currently a single stage procedure in adults that can be performed under local anaesthesia. More recently, the advent of the compact BAHA has further improved the aesthetics of wearing such a device.

A series of postal questionnaire studies were undertaken to evaluate patient satisfaction and quality of life with the BAHA.[4-6] However, a prospective interview based questionnaire was necessary to quantify the BAHA use, the residual hearing disability and handicap, overall benefit and patient satisfaction.

Patients and methods

This was a prospective interview-based study using the GHABP and GHADP. It was designed by Gatehouse in 1999, to evaluate hearing disability, handicap, hearing aid use and benefit, residual disability and patient satisfaction with their hearing aids. [7]

The initial questionnaire provided four predetermined environments and allowed the opportunity for patients to choose a further four situations in which they had hearing difficulties (Appendix 1). The four pre-determined situations assessed were the following:

1. Listening to the television with other family and friends when the volume is adjusted to suit other people;
2. Having a conversation with one other person when there is no background noise;
3. Carrying on a conversation in a busy street or shop;
4. Having a conversation with several people in a group.

The first four questions addressed the benefit of a no hearing aid situation with conventional hearing aids i.e. GHABP. The second questionnaire used the same four situations except these questions were designed to address the difference between conventional aids and BAHA i.e. GHADP (Appendix 2).

The GHABP covered initial disability, handicap, hearing aid use, hearing aid benefit, residual disability and satisfaction. This prospective interview-based questionnaire study was carried out in autumn 2000 at the Queen Elizabeth Hospital, Birmingham.

A total of 84 adult patients who attended the routine follow-up clinics were interviewed. Each patient had worn their BAHA for more than one year. This was to reduce enthusiasm bias when first issued with their hearing aid.

These patients were all randomly selected on the basis of their regular review appointment during a six months' period. No paediatric patients were interviewed for this study. The same clinician interviewed all subjects included in the study.

Scoring of the GHABP and GHADP questionnaires was carried out as recommended in the GHABP - information package.[7] The scores from each of the four situations were added for each patient and the mean calculated for each set of data. The values were then scaled to lie between 0 and 100 by subtracting 1 from each of them and then multiplying by 25.

The results were computed using the SPSS package. These have been represented in `Box and Whisker' plots with median values, interquartile ranges (within the box) and highest and lowest data scores (within whiskers) with outliers, if any.

Results

A total of 84 adult patients were interviewed using the GHABP and GHADP. Patients involved in the study were all interviewed following a routine outpatient

review. The age range was 31 to 58 years (mean 46 years). The gender distribution was equal. In all cases, patients volunteered many of their own situations (data not in tables and figures) but most felt the four pre-specified situations encompassed their main difficulties.

The first part of the questionnaire addressed the issue of a no hearing aid situation compared with their conventional air-conduction (AC) or bone-conductor (BC) hearing aid. In each situation there was considerable disability and handicap but with full time use of a conventional hearing aid, the residual disability was reduced and derived benefit was improved (Tables 1-4).

Table 1. Distribution of scores from Question 1 of the GHABP interview: No hearing aid versus Conventional aid. *Listening to the television with other family or friends when the volume is adjusted to suit other people.*

Percentile	Initial disability	Initial handicap	Reported aid use	Reported benefit	Residual disability	Patient Satisfaction
25th	4.0	4.0	5.0	2.0	3.0	2.25
75th	5.0	5.0	5.0	3.0	4.0	3.0
Median	5.0	4.5	5.0	2.0	3.0	3.0

Table 2. Distribution of scores from question 2 of the GHABP interview: No hearing aid versus Conventional aid. *Having a conversation with one person when there is no background noise.*

Percentile	Initial disability	Initial handicap	Reported aid use	Reported benefit	Residual disability	Patient Satisfaction
25th	3.0	3.0	5.0	2.0	2.0	2.0
75th	4.75	5.0	5.0	4.0	3.0	4.0
Median	3.0	4.0	5.0	2.0	3.0	3.0

Table 3. Distribution of scores from question 3 of the GHABP interview: No hearing aid versus Conventional aid. *Carrying on a conversation in a busy street or shop.*

Percentile	Initial disability	Initial handicap	Reported aid use	Reported benefit	Residual disability	Patient Satisfaction
25th	3.0	3.0	5.0	1.0	3.0	1.0
75th	5.0	5.0	5.0	2.75	5.0	3.0
Median	4.0	4.0	5.0	2.0	4.0	2.0

Table 4. Distribution of scores from question 4 of the GHABP interview: No hearing aid versus Conventional aid. *Having a conversation with several people in a group.*

Percentile	Initial disability	Initial handicap	Reported aid use	Reported benefit	Residual disability	Patient Satisfaction
25th	4.0	4.0	5.0	1.0	4.0	1.0
75th	5.0	5.0	5.0	3.0	5.0	2.0
Median	4.0	4.0	5.0	2.0	4.0	2.0

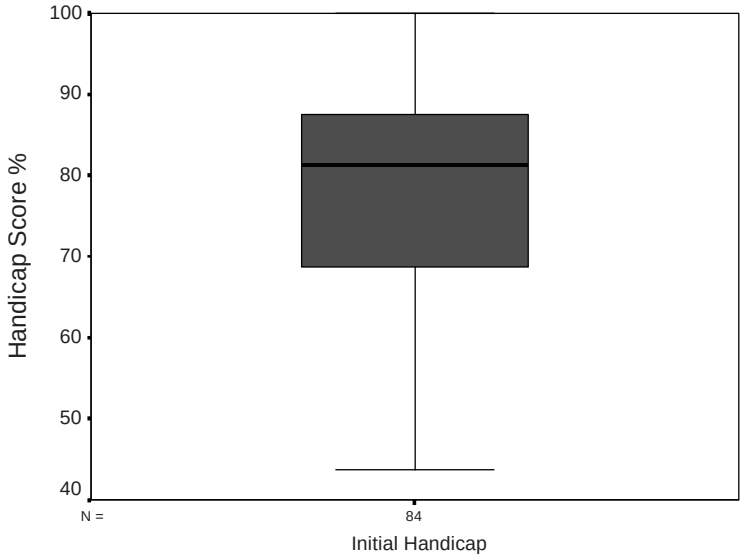

Figure 1. Hearing handicap reported by patients when not using any hearing aid (Box and Whiskers Plot).

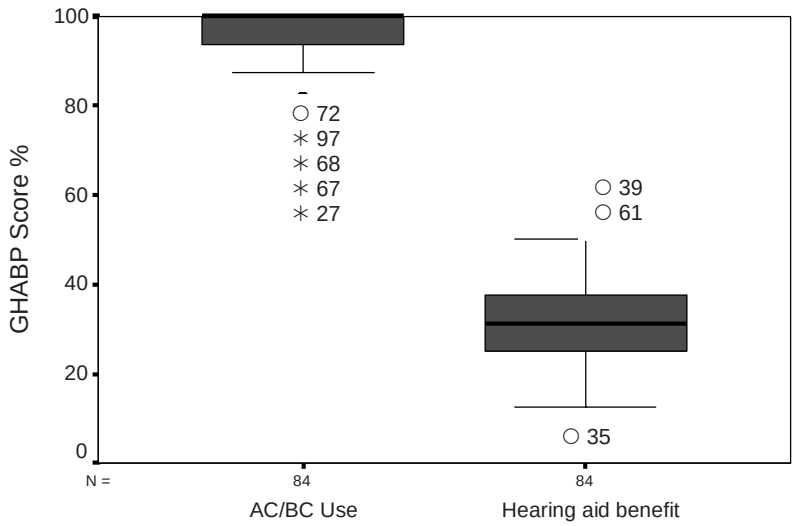

Figure 2. GHABP scores showing the use of conventional hearing aids and the benefit these hearing aids provide.

The initial hearing disability and handicap was considered to be very significant. A GHABP score ranged from 44 to 100 per cent handicap (Figure 1, Whisker plot). The majority (interquartile range) described a no-hearing aid handicap score of 68 to 88 per cent (Figure 1, Box plot). When asked about the amount of

time these conventional hearing aids were used it appeared the vast majority wore their aids all of the time (Figure 2). Only five patients reported wear for less than three quarters of the time. Despite this use, the hearing benefit was surprisingly poor, with a GHABP benefit score range of 28 to 38 per cent (Figure 2). It was found that overall, the hearing disability was less with conventional aids compared to the initial disability (Figure 3).

The second part of the study compared conventional air or bone conduction hearing aids with the BAHA (GHADP). Compliance with BAHA use was excellent and the benefit, reduced hearing disability and overall satisfaction was significantly improved when compared to other aids (Tables 5-8).

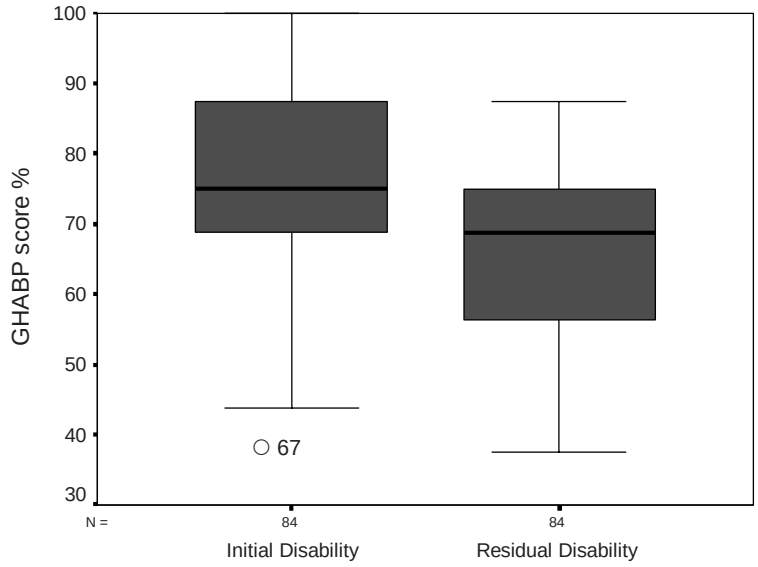

Figure 3. Hearing disability before and after wearing conventional hearing aids.

Table 5. Distribution of scores from question 1 of the GHADP profile: Conventional aid versus BAHA. *Listening to the television with other family or friends when the volume is adjusted to suit other people.*

Percentile	Initial disability with previous aid	Reported previous aid use	Reported BAHA use	Reported benefit with BAHA	Residual disability with BAHA	Patient Satisfaction with BAHA
25th	3.0	4.0	5.0	5.0	1.0	4.0
75th	4.0	5.0	5.0	5.0	1.0	5.0
Median	3.0	4.0	5.0	5.0	1.0	5.0

Table 6. Distribution of scores from question 2 of the GHADP profile: Conventional aid versus BAHA. *Having a conversation with one person when there is no background noise.*

Percentile	Initial disability with previous aid	Reported previous aid use	Reported BAHA use	Reported benefit with BAHA	Residual disability with BAHA	Patient Satisfaction with BAHA
25th	3.0	4.0	5.0	5.0	1.0	5.0
75th	5.0	5.0	5.0	5.0	1.0	5.0
Median	4.0	5.0	5.0	5.0	1.0	5.0

Table 7. Distribution of scores from question 2 of the GHADP profile: Conventional aid versus BAHA. *Carrying on a conversation in a busy street or shop.*

Percentile	Initial disability with previous aid	Reported previous aid use	Reported BAHA use	Reported benefit with BAHA	Residual disability with BAHA	Patient Satisfaction with BAHA
25th	4.0	5.0	5.0	3.0	2.0	4.0
75th	5.0	5.0	5.0	4.0	3.0	5.0
Median	4.5	5.0	5.0	3.0	3.0	4.0

Table 8. Distribution of scores from question 2 of the GHADP profile: Conventional aid versus BAHA. *Having a conversation with several people in a group.*

Percentile	Initial disability with previous aid	Reported previous aid use	Reported BAHA use	Reported benefit with BAHA	Residual disability with BAHA	Patient Satisfaction with BAHA
25th	4.0	4.0	5.0	3.0	2.0	4.0
75th	5.0	5.0	5.0	5.0	3.0	5.0
Median	4.0	5.0	5.0	4.0	2.0	4.0

Firstly, the day to day usage of each type of hearing aid was similar with the majority of patient wearing their aids all of the time (Figure 4). The residual hearing disability was markedly reduced with the use of a BAHA and this was found to be significant (Figure 5).

The benefit of BAHA use was greater than conventional aids (Figure 6), and patient satisfaction was significantly better with the use of BAHA compared to conventional aids (Figure 7). BAHA use was encouraging and the benefit was significantly better than that of prior aids (Figure 8). Finally, the regular use of a BAHA significantly reduced the level of hearing disability compared to both conventional aid use and a no-aid situation (Figure 9).

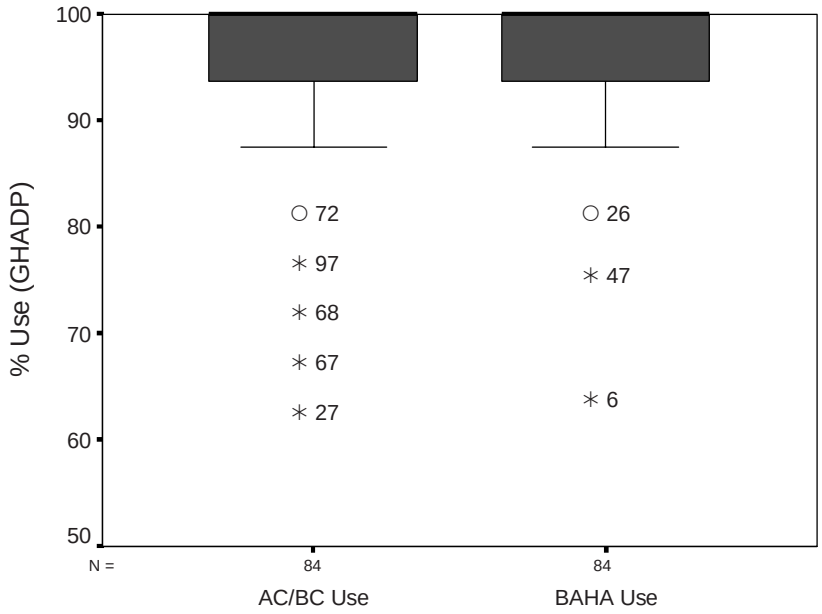

Figure 4. Day-to-day use of hearing aids - the current BAHA and previous conventional hearing aid .

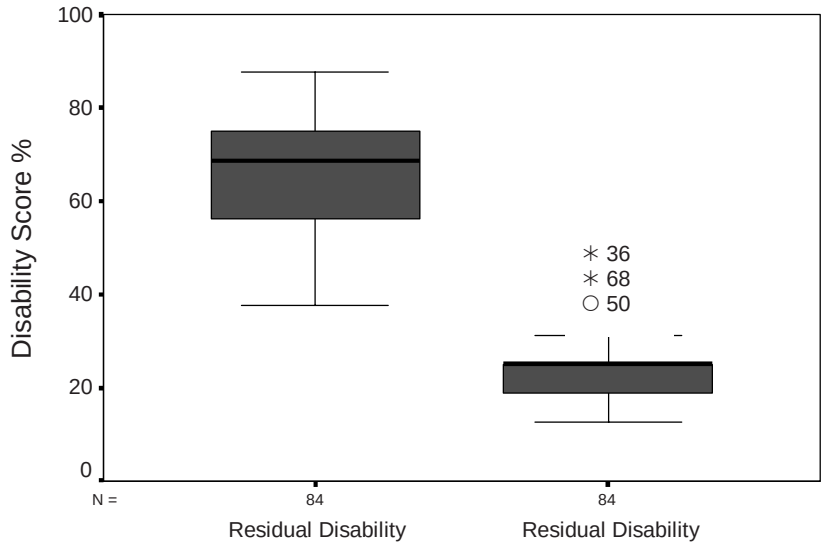

Figure 5. Residual disability after conventional hearing aid compared with the use of a BAHA.

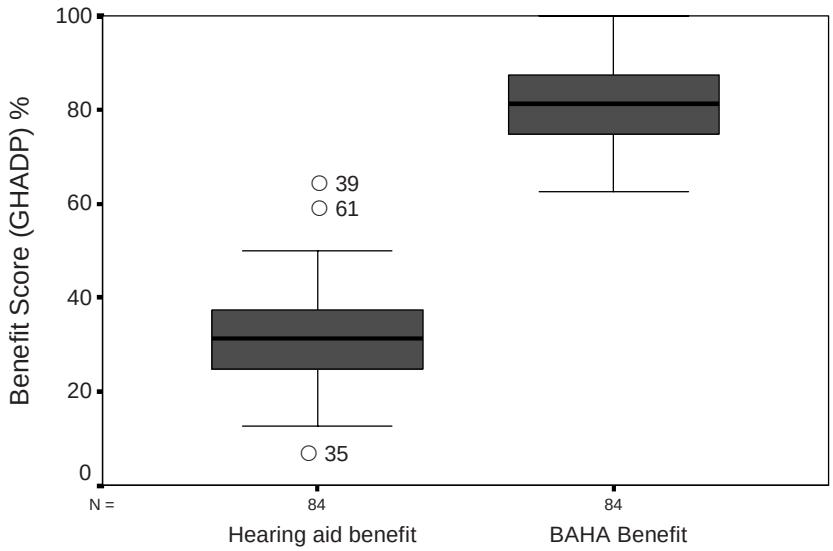

Figure 6. Differences in the benefit obtained by conventional aid and BAHA use.

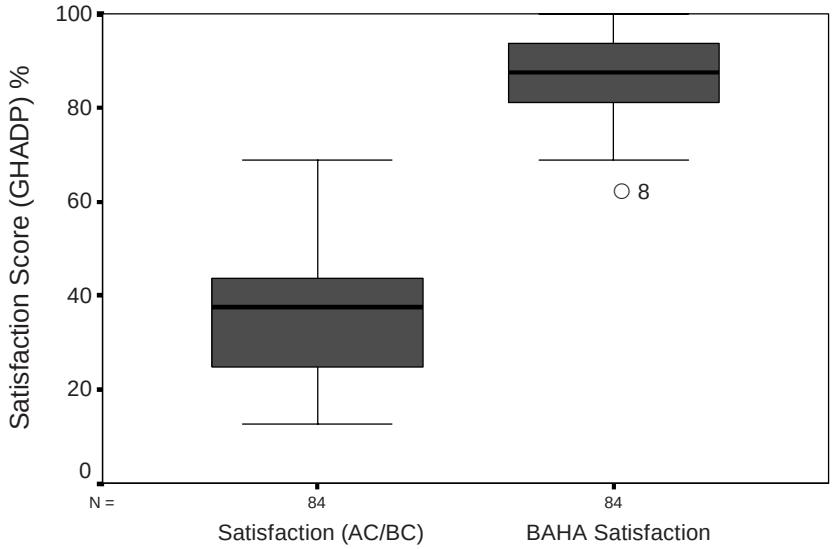

Figure 7. Patient satisfaction with the conventional aid compared with the BAHA.

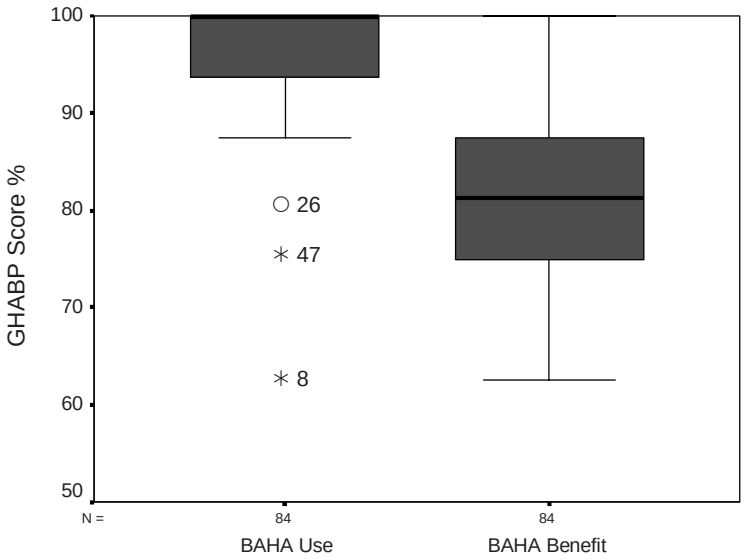

Figure 8. Compliance with BAHA use and perceived benefit.

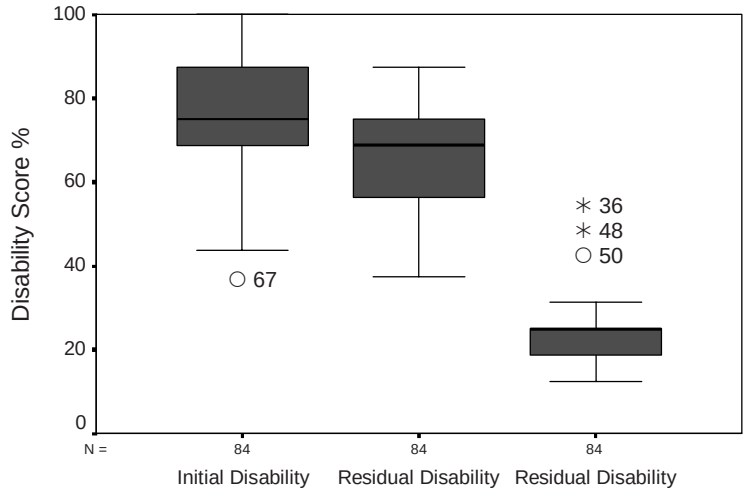

Figure 9. Disability without aid, with conventional hearing aid with the BAHA.

Discussion

Hearing aid services may be configured in a variety of ways but always contain elements associated with the technical performance of the device and the extent to which it helps the listener overcome the deficits and disadvantages experienced in everyday life. In the context of optimizing services, there is a growing

requirement to provide measures of outcome that are appropriate and sensitive to the various options for intervention. It is essential to demonstrate these measures of outcome to bodies or individuals responsible for funding services and to the hearing-impaired listeners.[7]

Performance measures cannot adequately characterize disability and handicap and therefore such instruments have stayed in the self-reporting domain. This has led to the development of a variety of questionnaires and inventories for the characterization of disability and handicap and its subsequent change following intervention.[8-10]

The GHABP is one such client-centred questionnaire. It has been derived, optimized and verified as an instrument suitable for application in the context of evaluation of efficacy and effectiveness of rehabilitation services for hearing-impaired adults. The GHABP firstly assesses four pre-specified listening circumstances which commonly occur in the lives of the hearing-impaired (Appendix 1). These are separately assessed as to

(i) their occurrence,
(ii) their degree of difficulty experienced by the listener (initial disability),
(iii) the effect or impact on the hearing-impaired listener's life (handicap),
(iv) the extent to which the hearing aid is used in that listening circumstance (reported hearing aid use),
(v) the extent to which hearing is improved in that listening circumstance (hearing aid benefit),
(vi) the hearing difficulty experienced by the listener after the fitting of the hearing aid (residual disability) and
(vii) the client's satisfaction with their hearing aid for that listening circumstance.

Another page (not shown in appendix) on the GHABP allows the listener to specify up to four additional listening circumstances of importance and relevance to their everyday communication circumstances, for example, listening to music, having a conversation on the telephone and following a lecture or service in church. Some of the patients in our series (14 per cent of 84) chose to discuss listener-specified situations as mentioned above. However, all 84 of them agreed that the four pre-specified situations reflected the disabilities and benefits quite satisfactorily.

This is then followed by the difference profile (GHADP; Appendix 2) that compares the previous hearing aid with a new hearing aid with respect to the previously described domains.

The GHABP has been optimized and validated previously. Our study is the first to evaluate the use of bone anchored hearing aids using GHABP. Needless to say

the questionnaire is designed to be completed by an independent observer in an office-setting and is not suitable for postal surveys. The GHABP and the GHADP proved to be valuable tools (prospective interview based questionnaires) in the evaluation of our hearing aid services. It is envisaged that the instrument will be applied to all the patients on the Birmingham BAHA programme who are on regular audiological follow-up.

Conclusions

Eighty-four BAHA users were evaluated using the GHABP and the hearing disability was significantly reduced with the BAHA compared to their previous conventional hearing aids. The reported hearing aid benefit and patient satisfaction were higher with the BAHA compared with the previous aids.

This prospective study on 84 BAHA users demonstrates that the GHABP is a suitable candidate for a routine service-monitoring indicator as part of a programme of quality assurance and standards.

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Appendix 1:

The Glasgow Hearing Aid Benefit Profile (GHABP)

GLASGOW HEARING AID BENEFIT PROFILE

Date of Assessment ……

Date of Review ……

Hospital Number.....

Name .....

Address .....

Does this situation happen in your life? 0 ___ No 1 ___ Yes **LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE**					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not at all 2_Only a little 3_A moderate amount 4_Quite a lot 5_Very much indeed	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_Hearing aid no use at all 2_Hearing aid is some help 3_Hearing aid is quite helpful 4_Hearing aid is a great help 5_Hearing is perfect with aid	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not satisfied at all 2_A little satisfied 3_Reasonably satisfied 4_Very satisfied 5_Delighted with aid
Does this situation happen in your life? 0 ___ No 1 ___ Yes **HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE**					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not at all 2_Only a little 3_A moderate amount 4_Quite a lot 5_Very much indeed	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_Hearing aid no use at all 2_Hearing aid is some help 3_Hearing aid is quite helpful 4_Hearing aid is a great help 5_Hearing is perfect with aid	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not satisfied at all 2_A little satisfied 3_Reasonably satisfied 4_Very satisfied 5_Delighted with aid
Does this situation happen in your life? 0 ___ No 1 ___ Yes **CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP**					
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not at all 2_Only a little 3_A moderate amount 4_Quite a lot 5_Very much indeed	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_Hearing aid no use at all 2_Hearing aid is some help 3_Hearing aid is quite helpful 4_Hearing aid is a great help 5_Hearing is perfect with aid	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not satisfied at all 2_A little satisfied 3_Reasonably satisfied 4_Very satisfied 5_Delighted with aid

Does this situation happen in your life? 0 ___ No 1 ___ Yes		**HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP**			
How much difficulty do you have in this situation?	How much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, with your hearing aid, how much difficulty do you now have?	For this situation, how satisfied are you with your hearing aid?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not at all 2_Only a little 3_A moderate amount 4_Quite a lot 5_Very much indeed	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_Hearing aid no use at all 2_Hearing aid is some help 3_Hearing aid is quite helpful 4_Hearing aid is a great help 5_Hearing is perfect with aid	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Not satisfied at all 2_A little satisfied 3_Reasonably satisfied 4_Very satisfied 5_Delighted with aid

Appendix 2:

The Glasgow Hearing Aid Difference Profile (GHADP)

GLASGOW HEARING AID DIFFERENCE PROFILE

Date of Assessment ……

Date of Review ……

Hospital Number.....

Name .....

Address .....

Does this situation happen in your life? 0 ___ No 1 ___ Yes		**LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE**			
With your current hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your current hearing aid?	In this situation, with your new hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your new hearing aid?	In this situation, how much more does your new hearing aid help compared to your previous one?	For this situation, how much more satisfied are you with your new aid than with your previous one?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_New aid much worse 2_New aid worse 3_New aid the same 4_New aid better 5_New aid much better	0_N/A 1_Much less satisfied 2_Less satisfied 3_Equally satisfied 4_More satisfied 5_Much more satisfied
Does this situation happen in your life? 0 ___ No 1 ___ Yes		**HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE**			
With your current hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your current hearing aid?	In this situation, with your new hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your new hearing aid?	In this situation, how much more does your new hearing aid help compared to your previous one?	For this situation, how much more satisfied are you with your new aid than with your previous one?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_New aid much worse 2_New aid worse 3_New aid the same 4_New aid better 5_New aid much better	0_N/A 1_Much less satisfied 2_Less satisfied 3_Equally satisfied 4_More satisfied 5_Much more satisfied
Does this situation happen in your life? 0 ___ No 1 ___ Yes		**CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP**			
With your current hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your current hearing aid?	In this situation, with your new hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your new hearing aid?	In this situation, how much more does your new hearing aid help compared to your previous one?	For this situation, how much more satisfied are you with your new aid than with your previous one?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_New aid much worse 2_New aid worse 3_New aid the same 4_New aid better 5_New aid much better	0_N/A 1_Much less satisfied 2_Less satisfied 3_Equally satisfied 4_More satisfied 5_Much more satisfied

Does this situation happen in your life? 0 ___ No 1 ___ Yes		**HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP**			
With your <u>current</u> hearing aid, how much difficulty do you have in this situation?	In this situation what proportion of the time do you wear your <u>current</u> hearing aid?	In this situation, with your <u>new</u> hearing aid, how much difficulty do you now have?	In this situation, what proportion of the time do you wear your <u>new</u> hearing aid?	In this situation, how much <u>more</u> does your <u>new</u> hearing aid help compared to your previous one?	For this situation, how much <u>more</u> satisfied are you with your <u>new</u> aid than with your previous one?
0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_No difficulty 2_Only slight difficulty 3_Moderate difficulty 4_Great difficulty 5_Cannot manage at all	0_N/A 1_Never/Not at all 2_About ¼ of the time 3_About ½ of the time 4_About ¾ of the time 5_All the time	0_N/A 1_New aid much worse 2_New aid worse 3_New aid the same 4_New aid better 5_New aid much better	0_N/A 1_Much less satisfied 2_Less satisfied 3_Equally satisfied 4_More satisfied 5_Much more satisfied

3.6

Patient satisfaction with bilateral BAHA-the Birmingham Experience

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Journal of Laryngology and Otology 2002; 116: 37-46

Abstract

The Birmingham Bone Anchored Hearing Aid (BAHA) programme has fitted more than 300 patients with unilateral bone anchored aids since 1988. Some of the patients who benefited well with unilateral aids and who had used bilateral conventional aids previously applied for bilateral amplification. To date fifteen patients have been fitted with bilateral BAHAs. The benefits of bilateral amplification have been compared to unilateral amplification in 11 of these patients.

Subjective analysis in the form of validated comprehensive questionnaires was undertaken.

The Glasgow Benefit Inventory (GBI), which is a subjective patient orientated post-interventional questionnaire developed to evaluate any otorhinolaryngological surgery and therapy was administered. The results revealed that the use of bilateral bone-anchored hearing aids significantly enhanced general well being (patient benefit) and improved the patient's state of health (quality of life). The Chung and Stephens questionnaire which addresses specific issues related to binaural hearing was used. Our preliminary results are encouraging and are comparable to the experience of the Nijmegen BAHA group.

Introduction

The Birmingham BAHA programme since 1988 has implanted both paediatric and adult patients. An evaluation of patient satisfaction and quality of life after BAHA implantation was undertaken.[1-3] In addition to a high degree of patient satisfaction, a significant improvement in the quality of life has been reported amongst BAHA users. Recently, some of the patients who had previous experience with binaural hearing applied for a second side BAHA. Encouraged by the experience of the Nijmegen BAHA group,[4-6] the Bilateral BAHA Implantation programme was started in Birmingham in 1995. The practice of bilateral prescription of conventional hearing aids in the United Kingdom is variable and in most centres unsatisfactory.[7] Financial constraints on the National Health Service (NHS) and perhaps ignorance of benefit account for the poor practice of bilateral fitting.[7]

15 patients have been implanted with a second side BAHA to date. In this pilot study, 11 of these patients who had used their second side BAHA for longer than 12 months have been evaluated. Patient benefit and specific issues of binaural hearing have been studied.

Patients and Methods

Since 1995, 15 patients have received a second side BAHA. The criteria that were used in selecting these patients were as follows:

1. Bilaterally symmetrical hearing loss
   (interaural threshold difference of less than 15 dB four-tone-average).
2. Previous knowledge and experience with binaural hearing (conventionally aided bilaterally or unaided).
3. Professional needs of the users: all the patients that have been implanted are in professions that would require the benefits of binaural hearing, e,g., businessmen, teachers and nurses.
4. Motivation - all the patients voluntarily applied for a second side BAHA.
5. Age - the bilateral implant programme has not been extended to the paediatric (under 18 years) population as yet.

12 of these patients who had used their bilateral BAHAs for longer than 12 months were included in the evaluation (Table 1). The 12-month-period was to allow acclimatisation with the bilateral aids and obviate any bias due to initial enthusiasm. The subjective evaluation strategy included two postal questionnaires that were previously validated.

Table 1. Age and sex distribution with diagnosis and duration of BAHA use

Patient number	Age (in years)	Gender	Diagnosis	I BAHA	II BAHA
P.1	31	F	Treacher Collins syndrome	10 years	5 years
P.2	53	M	Bilateral mastoid cavities	10 years	3 years
P.3	31	F	Bilateral congenital hearing loss	4 years	3 years
P.4	22	F	Treacher Collins syndrome	10 years	30 months
P.5	54	F	Bilateral chronic otitis media	5 years	30 months
P.6	42	M	Bilateral mastoid cavities	12 years	2 years
P.7	39	M	Goldenhar's syndrome	4 years	2 years
P.8	45	F	Bilateral microtia	4 years	2 years
P.9	48	F	Bilateral chronic otitis media	3 years	18 months
P.10	42	F	Bilateral acquired otosclerosis	4 years	16 months
P.11	47	F	Bilateral chronic otitis media	5 years	12 months
P.12	53	F	Bilateral mastoid cavities	5 years	12 months

The Glasgow Benefit Inventory (GBI) questionnaire was sent to each patient. This tool was described by Robinson *et al* in 1996 and consists of 18 questions (Appendix 1).[8] Two additions were made to our questionnaire: Four questions relating to the success of the BAHA (Appendix 2) and a 10 cm linear analogue scale reflecting state of health before and after first BAHA and the second BAHA (Appendix 3). Neither of these modifications was described in the original GBI strategy. All the questions in this modified questionnaire were based on a five point Likert scale. An example of the questions and the scoring system has been described in Table 2. Score 1 is a poor satisfaction score and score 5 reflects highest satisfaction. BAHA users were advised to complete separate questionnaires for their first BAHA and their second BAHA.

Table 2. Example of questions used in the modified Glasgow Benefit Inventory questionnaire.

Since you received your second BAHA, have you found it easier or harder to deal with company?		
A	Much harder	score 1
B	Harder	score 2
C	No change	score 3
D	Easier	score 4
E	Much easier	score 5

The Chung and Stephens Binaural Hearing Aid questionnaire was proposed to determine how certain audiological, physical and social factors influence the use of bilateral hearing aids.[9] Selected questions from the four sections of this questionnaire were used with the study group (Appendix 4). Specific issues addressing binaural hearing were studied.

No analytical statistical package has been applied to the results as the number of patients in the study group is small (n=11) and would make the power of such analysis insignificant. However descriptive data in the form of bar charts, cumulative scores and percentages are presented.

Results

15 patients have been implanted with bilateral BAHA to date. 12 of the patients had used their second BAHA for 12 months or longer (Table 1). One of these patients (p.10) did not choose to answer the questionnaires or attend the audiological evaluation for personal reasons. However, it was learnt during a clinic

visit that the patient used her second BAHA for special situations only that included social gatherings and supermarkets.

Of the 12 patients, 6 had chronic suppurative otitis media or discharging mastoid cavities. 4 of them reported dry ears following BAHA use in both ears and 2 reported occasional otorrhoea. 2 patients suffered from Treacher Collins syndrome, one from Goldenhar's syndrome and one other patient had bilateral nonsyndromic microtia. All four benefited with bilateral BAHA and bilateral bone-anchored auricular prostheses, implanted at various stages. One patient suffered from congenital bilateral conductive loss, perhaps congenital otosclerosis and another patient had features strongly suggestive of bilateral acquired otosclerosis. Both these patients chose the option of bilateral BAHA.

Glasgow Benefit Inventory

The original GBI questionnaire with its eighteen questions and the additional four questions from our group consisted of five-answer options (five-point Likert scale) ranging from a large change for the worse to a large change for the better (Table 2).

The question on success of their bone anchored hearing aids received an interesting response, the second BAHA being more successful than the first (Figure 1). More patients were pleased with the second BAHA (10 patients scored 5, greatly or moderately pleased) than they were with the first (6 patients scored 5). Members of the family of most patients believed that the second BAHA was more successful than the first implant. All eleven patients agreed that they would encourage others with a similar condition to wear bilateral bone anchored hearing aids.

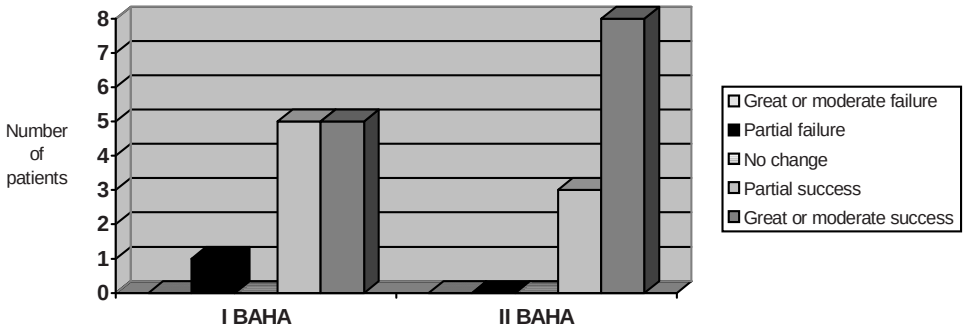

Figure 1. How successful do you think your BAHA is?

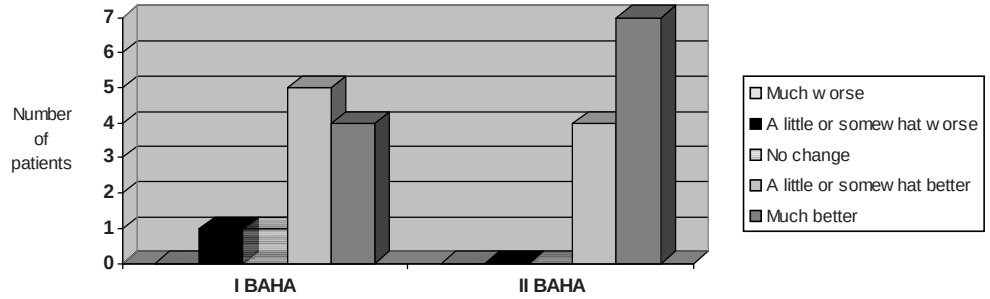

Figure 2. Has getting a BAHA made your overall life better or worse?

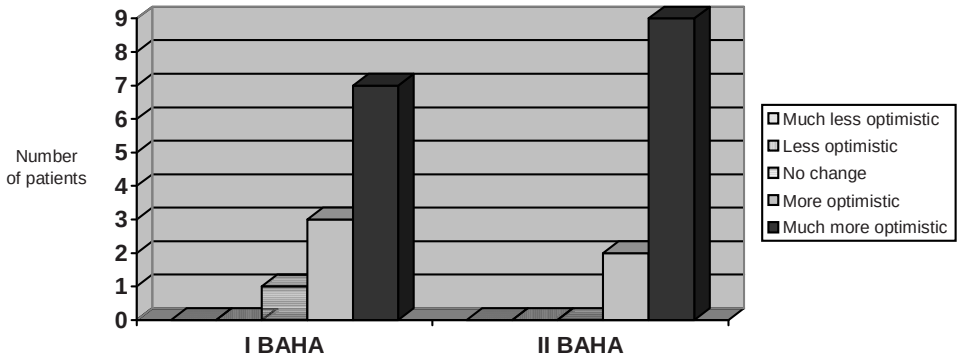

Figure 3. Since you received your BAHA, have you felt MORE or LESS optimistic about the future?

Most patients believed the second BAHA made a remarkable difference to the things they did, made their overall lives much better and hence felt more optimistic about their futures (Figures 2 and 3). There was little embarrassment with the first aid and none with the second and the second BAHA was a great self-confidence booster (Figure 4). Most BAHA users found it easier to deal with company with two implants than with the one (Figure 5). Equivocal responses were obtained to the questions on support from friends and visits to the family doctor (questions g and h, GBI, appendix 1). The majority of them were confident of better job opportunities with bilateral aids than with unilateral aids (Figure 6). Questions on self-consciousness and 'number of people that care' received equivocal responses (questions j and k, GBI). However, it was interesting to note that all six patients with discharging ears reported dry ears or less discharge with bilateral BAHAs than unilateral and hence minimised the need for medications in the form of ear drops and antibiotics (questions l and m, GBI).

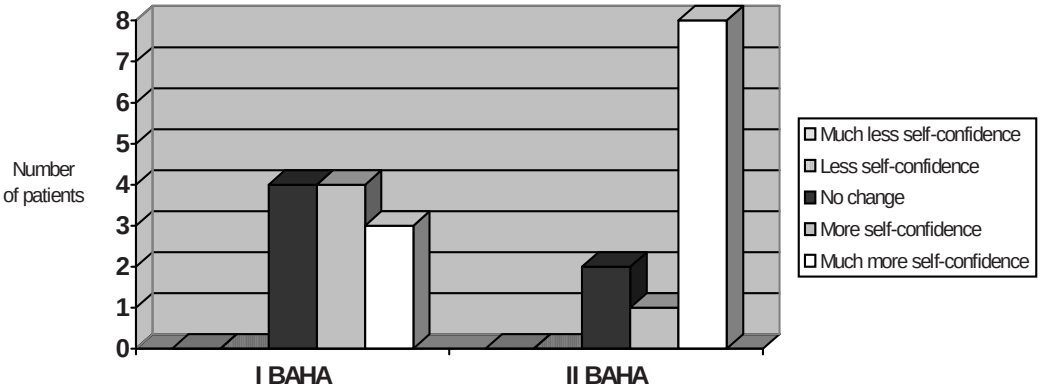

Figure 4. Since getting the BAHA, do you have MORE or LESS self-confidence?

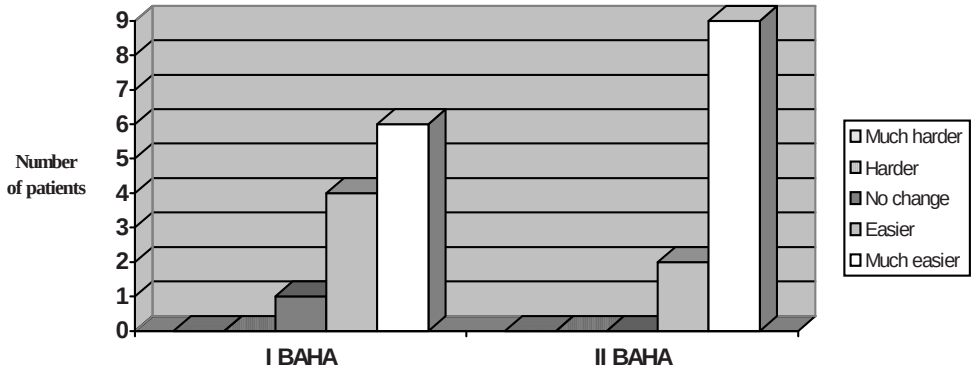

Figure 5. Since you received your BAHA, have you found it easier or harder to deal with company?

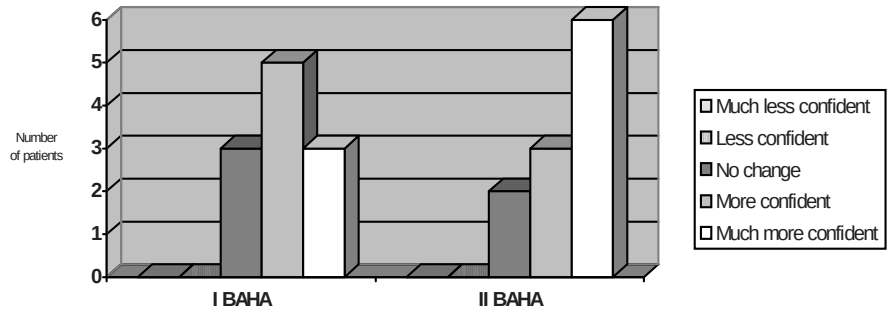

Figure 6. Since you received your BAHA, do you feel MORE or LESS confident about job opportunities?

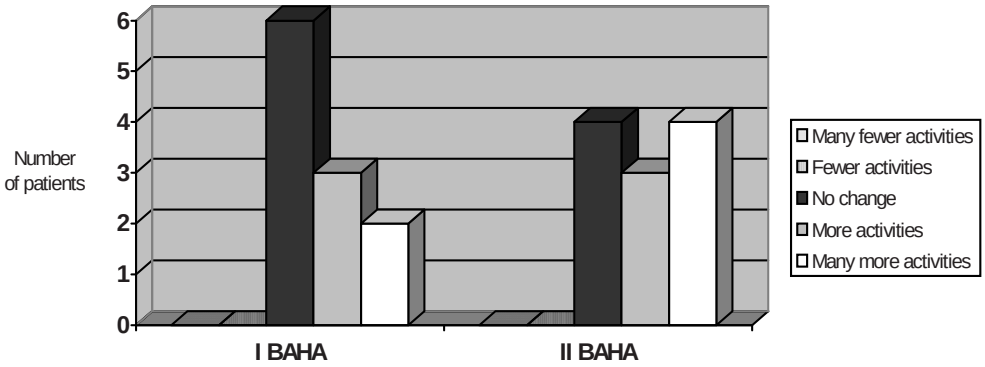

Figure 7. Since getting the BAHA, do you participate in more or fewer social activities?

Table 3. State of health before an after FIRST and SECOND BAHA implants.

Patient number	Before BAHA	After FIRST BAHA	After SECOND BAHA
p.1	80	80	85
p.2	35	70	80
p.3	70	88	100
p.4	50	70	80
p.5	60	80	85
p.6	25	85	85
p.7	80	90	90
p.8	80	90	94
p.9	63	80	90
p.10	-	-	-
p.11	48	83	98
p.12	65	80	90

The majority of them felt better about themselves (10 scoring 5 with second BAHA compared to 6 with the first), received better support from family members (7 scoring 5 with two BAHAs compared to 4 with one) and were less inconvenienced by their hearing problem (11 scoring 5 with two aids compared to 6 with one) with bilateral BAHA implants (questions n, o and p, GBI). And finally, most of the BAHA users were able to take part in social activities to a greater extent with both BAHAs than they could with one BAHA (Figure 7).

Visual Analogue Scale

The ten centimetre linear analogue scale was introduced as a modification in the GBI questionnaire to directly address the state of health both before and after obtaining the first and then the second bone anchored hearing aid (Appendix 3). Improvement in the state of health of the patients following the use of a bone anchored hearing aid was observed to be significant with the first BAHA and this was even better with the second (Table 3).

Chung and Stephens questionnaire

Selected questions from the original Chung and Stephens questionnaire were administered to the bilateral BAHA users (Appendix 4). All the eleven patients were very satisfied with the two BAHAs. 7 of them used the two aids all the time and 4 used them most of the time (questions 1 and 2, Appendix 4). All of them used the two aids for 8 to 12 hours or more everyday and seven days a week (questions 3 and 4). For speech in quiet situations involving 1 or 2 persons, 8 of them preferred two aids to one and two of them did not perceive any difference with one or two aids (Figure 8). Listening to radio, television and records necessitated the use of two BAHAs as did attending meetings, church, pictures or the theatre (Figures 9 and 11). For listening in noisy surroundings, 8 of the BAHA users switched on both aids compared to 3 using one aid only (Figure 10). The majority of them used both the aids for listening to conversation from a distance of 20 feet or more (Figure 12). 9 of them utilised inputs from both the BAHA implants for localisation of sounds whilst two patients did not find any difference with one or two aids (Figure 13). Most of them were comfortable and more relaxed using both the bone anchored aids than one most of the time (Figure 14).

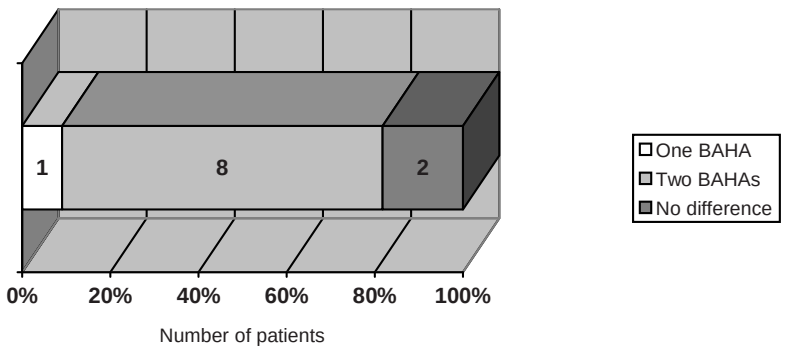

Figure 8. Speech in quiet situations involving 1 or 2 persons

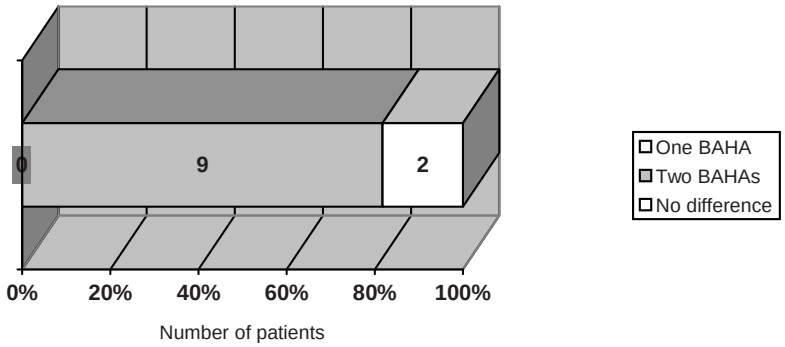

Figure 9. Listening to Radio, Television or Records

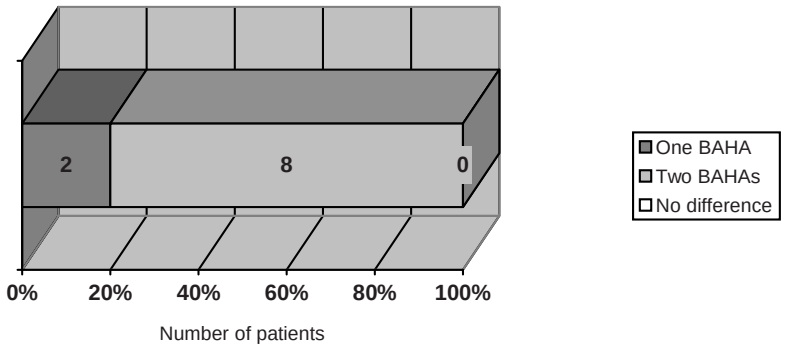

Figure 10. Speech in noisy situations

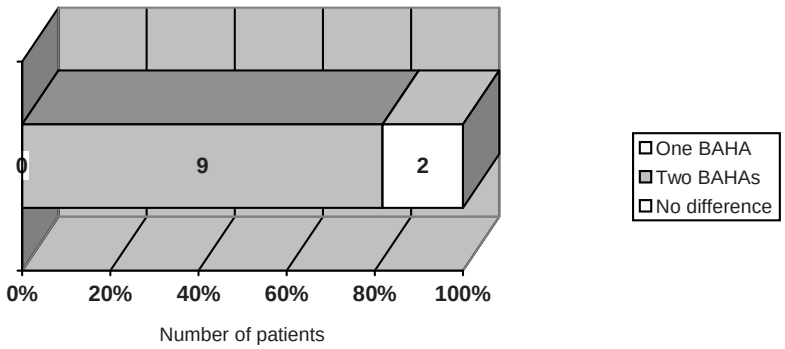

Figure 11. Meetings, Church, Pictures and Theatre

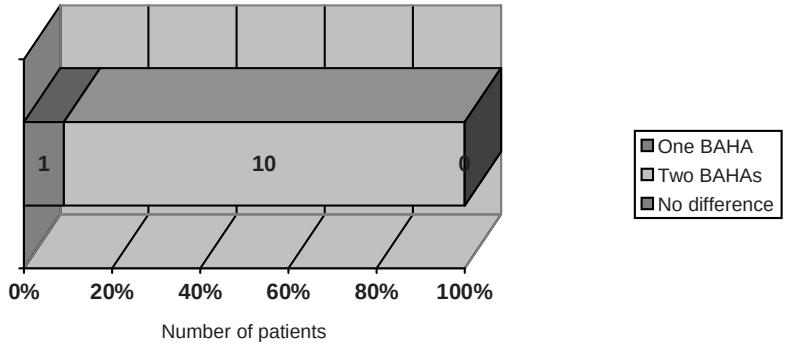

Figure 12: istening to conversation from a distance (over 20 feet)

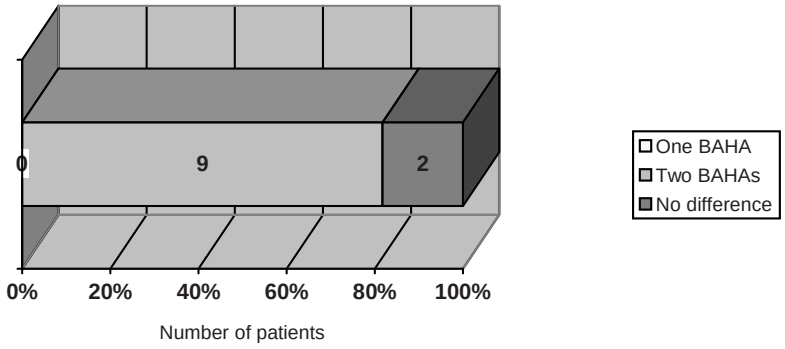

Figure 13. Localisation of sounds

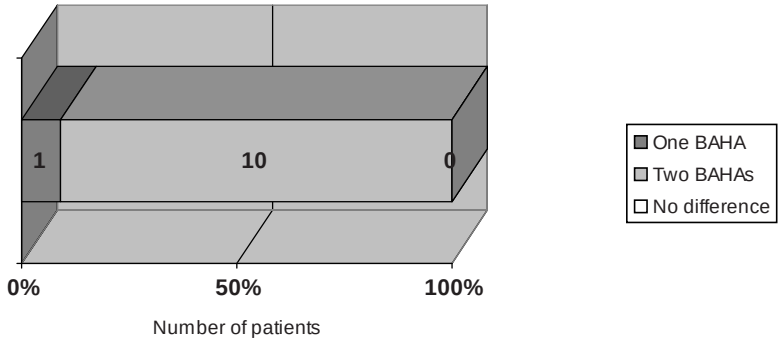

Figure 14. When listening, are you more comfortable (more relaxed) with one or two BAHAs?

Discussion

Binaural hearing may be considered as important to an individual as binocular vision.[7] Bilateral fitting of hearing aids is a practice that appears to be dictated by the knowledge, attitudes of local otolaryngology and audiology teams and most certainly by cost issues.[7] It has been demonstrated that there is improved sound localisation ability and better speech-in-noise perception with bilateral air conduction aids.[10,11] However, binaural hearing with bone conduction is a subject of controversy as it is well known that sound amplification by bone conduction stimulates both the cochleae. It has been clearly shown by Stenfelt *et al* that interaural attenuation of bone conducted sounds may vary between -15 and +40 decibels and in the lower frequencies, stimulation via bone conduction may result in higher stimulus levels at the contralateral cochlea.[12] Many patients with symmetrical hearing loss prefer bilateral amplification to unilateral amplification when fitted with the air-conduction hearing aids. Bilateral amplification may be successful in restoring binaural hearing depending on the hearing configuration and the integrity of the peripheral auditory system.[13]

In the Netherlands, the majority of bone conduction hearing aids is prescribed bilaterally with transducers incorporated in the bows of eyeglasses.[13] The Nijmegen BAHA team has been the first group to evaluate the benefits of bilateral BAHA. The authors have clearly shown that bilateral fitting of BAHA produces binaural hearing.[4-6,13] The Gothenburg BAHA group has implanted 12 patients with bilateral BAHA and these patients are presently being evaluated (Anders Tjellström, personal communication, 2001).

The Birmingham BAHA group started bilateral implantation in 1995. The preliminary results of the case series were presented at the British Academic Conference in Otolaryngology, Cambridge, 1999.[14] Encouraged by our initial results and the Nijmegen experience, more patients are being implanted with bilateral BAHA. The first 11 of the bilateral BAHA users underwent both subjective and objective evaluation.[15]

The Glasgow Benefit Inventory questionnaire is a patient orientated questionnaire and consists of eighteen post-intervention questions (Appendix 1). It provides a measure of patient benefit from ENT procedures. The GBI allows a comparison of benefit across different therapeutic or surgical interventions and is designed to measure change in health status. Health status is defined as the general perception of well-being that includes total physical, social and psychological well-being.[8] Our study included four additional questions and a linear analogue scale of health status (Appendix 2 and 3). In response to the questions from the GBI

and its modifications, all eleven patients who responded believed that the second BAHA was a greater success than the first (Figures 1 to 7).

Chung and Stephens in 1986, produced the results of their questionnaire survey on two hundred patients fitted with bilateral hearing aids.[9] The questionnaire was divided into four sections and addressed patient satisfaction and the amount of use of their bilateral hearing aid fitting (Section A), mode of amplification for listening under various situations (Section B), patients' ability to localise sounds (Section C) and finally, problems encountered in using two hearing aids (Section D). Some of the questions from this questionnaire were used in our study on bilateral BAHAs (Appendix 4). The majority of the patients used both aids for specific situations as illustrated in Figures 8 to 14. It was interesting to note that patients who had used the second BAHA for less than two years appeared to perceive no difference with the use of one or two BAHAs in some of these situations. A gradual process of perceptual acclimatisation was acknowledged by patients who had used both their BAHAs for longer periods. In general, a high degree of patient satisfaction with bilateral BAHAs was reported comparable to the Nijmegen studies.

Conclusions

Eleven patients who had used bilateral bone anchored hearing aids reported a high degree of satisfaction with the two aids with respect to speech perception in quiet, speech recognition in noise and localisation of sounds. A greater improvement in the state of health and hence quality of life was perceived with bilateral BAHAs than with unilateral BAHA.

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Appendix 1

The Glasgow Benefit Inventory (GBI) Questionnaire

This questionnaire asks how things have changed since you received your second BAHA

a) Has getting the *second BAHA* affected the things you do?
Option 1 Much worse
Option 2 A little or somewhat worse
Option 3 No change
Option 4 A little or somewhat better
Option 5 Much better

b) Has getting the *second BAHA* made your overall life better or worse?
Option 1 Much better
Option 2 A little or somewhat better
Option 3 No change
Option 4 A little or somewhat worse
Option 5 Much worse

c) Since you received your *second BAHA*, have you felt more or less optimistic about the future?
Option 1 Much more optimistic
Option 2 More optimistic
Option 3 No change
Option 4 Less optimistic
Option 5 Much less optimisitic

h) Since you received your *second BAHA*, do you feel more or less embarrassed with a group of people?
Option 1 Much more embarrassed
Option 2 More embarrassed
Option 3 No change
Option 4 Less embarrassed
Option 5 Much less embarrassed

i) Since you received your *second BAHA*, do you have more or less self-confidence?
Option 1 Much more self-confidence
Option 2 More self-confidence
Option 3 No change
Option 4 Less self-confidence
Option 5 Much less self-confidence

j) Since you received your *second BAHA*, have you found it easier or harder to deal with company?
Option 1 Much easier
Option 2 Easier
Option 3 No change
Option 4 Harder
Option 5 Much harder

k) With your *second BAHA*, do you feel that you have more or less support from your friends?
Option 1 Much more support
Option 2 More support
Option 3 No change
Option 4 Less support
Option 5 Much less support

h) With your *second BAHA*, have you been to your family doctor for any reason, more or less often?
Option 1 Much more often
Option 2 More often
Option 3 No change
Option 4 Less often
Option 5 Much less often

i) Since you received your *second BAHA*, do you feel more or less confident about job opportunities?
Option 1 Much more confident
Option 2 More confident
Option 3 No change
Option 4 Less confident
Option 5 Much less confident

j) Since you received your *second BAHA*, do you feel more or less self-conscious?
Option 1 Much more self-conscious
Option 2 More self-conscious
Option 3 No change
Option 4 Less self-conscious
Option 5 Much less self-conscious

k) Since you received your *second BAHA*, are there more or fewer people who really care about you?
Option 1 Many more people
Option 2 More people
Option 3 No change
Option 4 Fewer people
Option 5 Much fewer people

l) Since you received your *second BAHA*, do you catch colds or infections more or less often?
Option 1 Much more often
Option 2 More often
Option 3 No change
Option 4 Less often
Option 5 Much less often

m) Since you received your *second BAHA*, have you had to take more or less medicine for any reason?
Option 1 Much more medicine
Option 2 More medicine
Option 3 No change
Option 4 Less medicine
Option 5 Much less medicine

n) Since you received your *second BAHA*, do you feel better or worse about yourself?
Option 1 Much better
Option 2 Better
Option 3 No change
Option 4 Worse
Option 5 Much worse

p) Since your *second BAHA*, do you feel that you have more or less support from your family?
Option 1 Much more support
Option 2 More support
Option 3 No change
Option 4 Less support
Option 5 Much less support

p) Since your *second BAHA*, are you more or less inconvenienced by your hearing problem?
Option 1 Much more inconvenienced
Option 2 More inconvenienced
Option 3 No change
Option 4 Less inconvenienced
Option 5 Much less inconvenienced

q) Since your *second BAHA*, have you been able to participate in more or fewer social activities?
Option 1 Many more activities
Option 2 More activities
Option 3 No change
Option 4 Fewer activities
Option 5 Many fewer activities

r) Since your *second BAHA*, have you been more or less inclined to withdraw from social situations?
Option 1 Much more inclined
Option 2 More inclined
Option 3 No change
Option 4 Less inclined
Option 5 Much less inclined

Appendix 2

Modifications: Subjective opinions regarding success of BAHA

a) How successful do you think your *second BAHA* is?
Option 1 Great or moderate failure/1
Option 2 Partial failure/2
Option 3 No change/3
Option 4 Partial success/4
Option 5 Great or moderate success/5

c) Do you feel pleased or disappointed about getting a *second BAHA*?
Option 1 Greatly or moderately pleased/5
Option 2 A little or somewhat pleased/4
Option 3 No change/3
Option 4 A little or somewhat disappointed/2
Option 5 Greatly or moderately disappointed/1

c) How successful do members of your family and close friends think your *second BAHA* is?
Option 1 Great or moderate success/1
Option 2 Partial success/2
Option 3 No change/3
Option 4 Partial failure/2
Option 5 Great or moderate failure/1

d) If you knew that someone else in your family or a close friend had a similar condition to yours, would you encourage them to get a similar *second BAHA*?
Option 1 Definitely not/1
Option 2 Probably not/2
Option 3 Can't decide/3
Option 4 Probably yes/4
Option 5 Definitely yes/5

Appendix 3

Modification : State of health before and after BAHA

We would like you to indicate your state of health. To help you, we would like you to imagine a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Think about how your health affects:

- Your general well-being
- Your independence and ability to take care of yourself
- Your ability to take care of others
- How you feel about yourself
- Your ability to get around and communicate
- Your ability to socialise
- Your performance at work

YOUR STATE OF HEALTH TODAY WITH YOUR *SECOND BAHA*

We would like you to choose a point on the scale that indicates how good or bad you consider your state of health is today with your BAHA

Worst ---------- Best

YOUR STATE OF HEALTH WITH YOUR *FIRST BAHA*

Worst ---------- Best

YOUR STATE OF HEALTH *BEFORE* YOU RECEIVED YOUR *FIRST BAHA*

Worst ---------- Best

Appendix 4

Chung and Stephens questionnaire (Modified)

1. Are your present hearing aids:
   a. very satisfactory
   b. satisfactory
   c. unsatisfactory
   d. very unsatisfactory

2. Do you wear two hearing aids:
   a. all the time
   b. most of the time
   c. often (for some time everyday)
   d. never

3. On average, how many hours a day do you use two hearing aids?
   a. 0
   b. less than 1
   c. 1-4
   d. 4-8
   e. 8-12
   f. over 12

4. On average, how many days a week do you use two hearing aids?
   a. 0 e. 4
   b. 1 f. 5
   c. 2 g. 6
   d. 3 h. 7

5. When you are listening to speech in quiet situations involving 1 or 2 persons, do you find listening easier using:
   a. 1 hearing aid
   b. 2 hearing aids
   c. no difference

6. When you are listening to TV, radio or records, do you find listening easier using:
   a. 1 hearing aid
   b. 2 hearing aids
   c. no difference

7. When you are listening to speech in noisy situations, do you find listening easier using:
   a. 1 hearing aid
   b. 2 hearing aids
   c. no difference

8. When you are at a meeting, church, pictures or theatre, do you find listening easier using:
   a. 1 hearing aid
   b. 2 hearing aids
   c. no difference

9. When you are listening to conversation from a distance (over 20 feet), do you find listening easier using:

a. 1 hearing aid
b. 2 hearing aids
c. no difference

10. When you have to locate sounds, do you find listening easier using:

a. 1 hearing aid
b. 2 hearing aids
c. no difference

11. When you are listening, do you find it more comfortable (more relaxed and easier) using:

a. 1 hearing aid
b. 2 hearing aids
c. no difference

Part 4

Unusual complications associated with Bone-Anchored Hearing Aids

4.1

Trauma, unusual complications and findings with Bone Anchored Hearing Aids: Report of a case and review of the literature

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Abstract

Objective: We report the second child with a serious traumatic injury involving the fixture and abutment of their bone anchored hearing aid (Baha®).

Method: case reports and review of the world literature concerning trauma, unusual complications and findings with bone anchored hearing aids are presented.

Results: A nine year old girl with Dubowitz syndrome who sustained an intrusion injury of her fixture and abutment following a fall. No other injury was sustained and there was no neurological complication. She underwent immediate removal of the implant and subsequently made a full recovery. Such serious and unusual complications are fortunately very rare.
On review of the literature four unusual and serious complications were identified. Only one involved a traumatic injury in a child.

Conclusion: The role of this case report is to remind the many clinicians who are involved with the provision of Baha® that they must monitor their patients carefully and remember that unusual and unexpected complications although rare, do happen. The care of the patient continues long after the surgery is complete.

Introduction

The use of osseointegrated implants for Baha® retention is now a well established practice since the device became commercially available in 1987.[1] There are a great many reports acknowledging the benefits of the Baha® both in audiological terms as well as its effects on patient well being and the paediatric population, the Baha® has also proven to be enormously useful in cases of congenital aural atresia, and an alternative to canal and middle ear reconstructive surgery. [2,3,4,5]
Currently it has been estimated that more than 30,000 fixtures have been implanted worldwide[6] to date and there are four unusual and serious complications and findings reported.
Although rare, clinicians should remember that unusual and unexpected complications do occur. The care of the patient continues long after the surgery is complete.

Case report

A 9 year old girl was fitted with a Baha® for her moderate bilateral conductive hearing loss. She had been diagnosed with Dubowitz Syndrome at birth; a rare autosomal recessive condition characterised by low birth weight, growth retardation and delayed bone maturation, short stature, high sloping forehead with a broad nasal bridge, and sometimes eczema[7]. She had behavioural and learning difficulties which are also reported to be associated with this syndrome[8].

A left sided Baha® was fitted when she was 4 years of age. This was performed in the well described fashion[9]; two stages with a healing time of 16 weeks for osseointegration.

There were some initial problems with wound infections but these settled with conservative management.

Over a five year period she made excellent progress and managed her Baha® well without complications.

She fell and sustained a blow to the side of her head. The injury was initially thought to be minor and the patient experienced no immediate problems. Later that day, the Baha® abutment was noticed to be embedded deep into the scalp.

Examination revealed an intra-cranial intrusion of both the fixture and the entire abutment. Plain radiographs confirmed the intra-cranial position of the abutment. (Figure 1 and Figure 2).

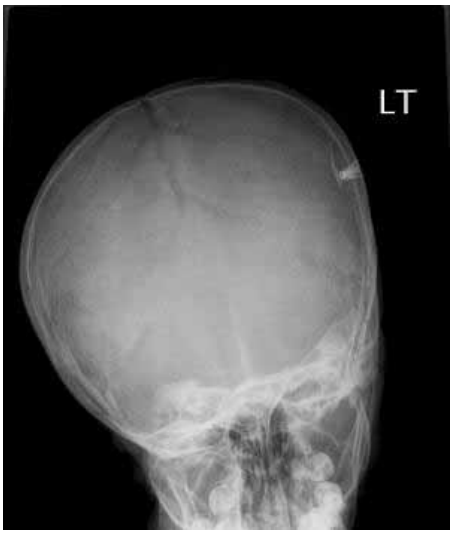

Figure 1. Plain radiograph demonstrating intrusion of the abutment and associated skull fracture.

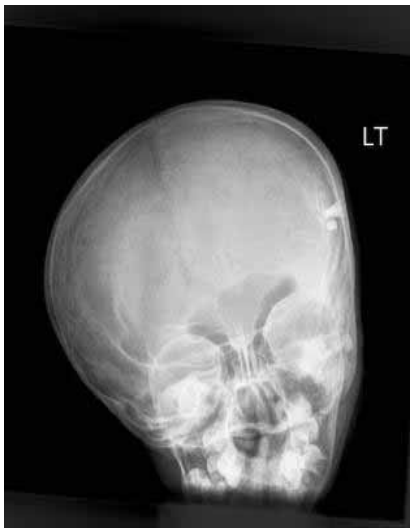

Figure 2. Plain radiograph illustrating a left sided, complete intracranial intrusion of both the fixture and the abutment. The ‘sleeper’ fixture is also noted.

Surgical removal of the implant was undertaken. At the time of surgery, all bony fragments were removed and the dura was found to be intact.
She made an uneventful recovery but is subsequently have difficulty with her conventional hearing aids. She is keen for another Baha®.

Discussion

There has been considerable data collected about patients who wear a Baha®. Almost unique to the paediatric population, is the significant number of patients who have traumatic injuries to the site of their Baha®. Institutions that have a Baha® programme involving children require a good team to support these children long after the surgical procedure has finished. In many cases trauma results in repeated damage to the sound processor rather than the abutment and/or fixture. It is not uncommon for families to request a spare Baha® sound processor in case of such an injury.
The vast majority of studies that report outcomes from paediatric Baha®, describe fixture loss as a direct result of trauma [10,11,12,13] Despite this complication, Baha® in children remains very successful.
Serious and unusual complications are fortunately, very rare. We report one serious complication with a Baha®. This is the only such injury experienced in both the Birmingham adult and paediatric Baha® programme since it began in the late 1980's.
On review of the literature four unusual and serious complications were identified. Only one involved a traumatic injury in a child.
Dietmer et al[14] reported the first case of intrusion injury to the Baha®. This case involved a young girl who had a fall and sustained a blow to the head on the side of her Baha®. As in our case, there was no haematoma, nor intracranial complications. The fixture and abutment were surgically removed immediately and the child made a full recovery and was re-implanted at a later date. This child was not reported to have any significant underlying medical condition.
The young girl in our case had Dubowitz syndrome which is know to be associated with growth retardation with reports of delayed bone maturation. Perhaps this increased her risk of intrusion type injury following trauma.
In November 1993, the first report of an intracerebral abscess after a Baha® abutment change was published by Dietmer et al.[14] Their patient had a significant soft tissue reaction around the abutment and the abutment was removed leaving the well osseointegrated fixture in place. The wound was reported to be almost completely healed when the patient developed the intracranial abscess.

Scholz et al[15] reported the second case of an intracranial abscess after an abutment change. In this latter case, the abscess was diagnosed three months following the procedure.

The interesting points from this second case were firstly, the change of the abutment was reported to be “long lasting” and “complicated” and it would appear the abutment was not actually replaced at the end of the procedure. As discussed by Tjellström et al 2005,[16] abutment change is usually a simple procedure lasting just a few minutes and often performed in the out-patient setting.

Scholz[15] describes the successful drainage of the abscess via the screw hole once the fixture has been removed. Unfortunately the first patient required formal neurosurgical drainage

Both these patients were adults and both made a full recovery after appropriate drainage of the abscess and antibiotic therapy.

It has been reported that 8.5%[17] of fixtures in adults and 21% [18]of fixtures in children, are placed in contact with the dura. It is therefore surprising, there are not more reports of intrusion injury and intracranial infection, especially as many centres are now implanting younger children.

In Birmingham, there have been more than 3000 fixtures implanted between the adult and paediatric programme over the past 15 years; with one significant complication in our 9 year old girl. This rarity is reflected in the world literature. It has been estimated that more than 30,000 fixtures have been implanted worldwide[6] to date and there are four unusual /serious complication reported.

Finally, we have previously described a case of metastasis of a bronchogenic neoplasm to the soft tissue surrounding the Baha® abutment in a 68 year old female[19.] Although in reality it is not a complication, it is significantly rare to warrant a mention along with this group of unusual complications.

Conclusion

Baha is used worldwide with very few serious complications.

The role of this case report is to remind all those clinicians who are involved with the provision of Baha® that they must monitor their patients carefully and remember that unusual and unexpected complications although rare, do happen.

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4.2

Occult bronchogenic carcinoma presenting as metastasis to the site of a Bone Anchored Hearing Aid

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Abstract

The first report of a patient with metastatic bronchogenic carcinoma of the skin surrounding the abutment of a bone-anchored hearing aid (BAHA) is presented. Complications of bone-anchored hearing implantation have been well documented to date. We present a 68-year-old lady who presented with an unusual skin lesion surrounding the abutment of her BAHA. This was the first presentation of her bronchogenic tumour. We also review the literature regarding cutaneous metastasis and complications of BAHA.

Case report

The patient, a 68-year-old female, had suffered from bilateral progressive hearing loss for more than 30 years. She had been diagnosed as suffering from otoscterosis and had undergone a right stapedectomy and a left fenestration procedure in the 1970s. Unfortunately she had not managed well with conventional hearing aids and so she had been fitted with a right-sided BAHA five years previously.

She presented to the ENT clinic with a discharge from the site of her right BAHA abutment. Immediately prior to this she had been taking antibiotics from her General Practitioner to treat presumed infection for one week with no resolution of her symptoms. Her past medical history was otherwise unremarkable.

On examination, the skin at the abutment site was irregularly raised and indurated and the abutment was buried under a centrally placed dry punctum (Figure 1). Swabs of the lesion were taken for culture and sensitivity and an incisional biopsy was also performed. The antibiotic regime was reassessed.

Histopathological examination showed invasive, poorly differentiated carcinoma with a heterogeneous admixture of glandular structures and fewer, highly pleomorphic dispersed cells, some of bizarre giant cell morphology (Figures 2, 3). It was considered that these appearances most likely represented metastatic disease and a bronch-opulmonary origin was suggested for this.

A subsequent chest radiograph revealed a 4 cm diameter lesion at the lower pole of the left hilum, that led to the suspicion of a primary bronchogenic neoplasm. Interestingly, there was also the suspicion of another lesion involving the right fifth rib (Figure 4). An urgent referral was made to the chest physicians.

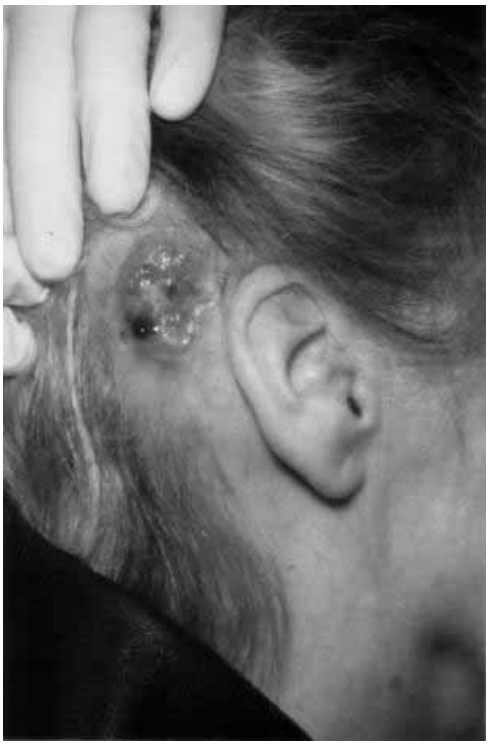

Figure 1. Clinical photograph demonstrating the raised irregular skin completely obscuring the BAHA abutment.

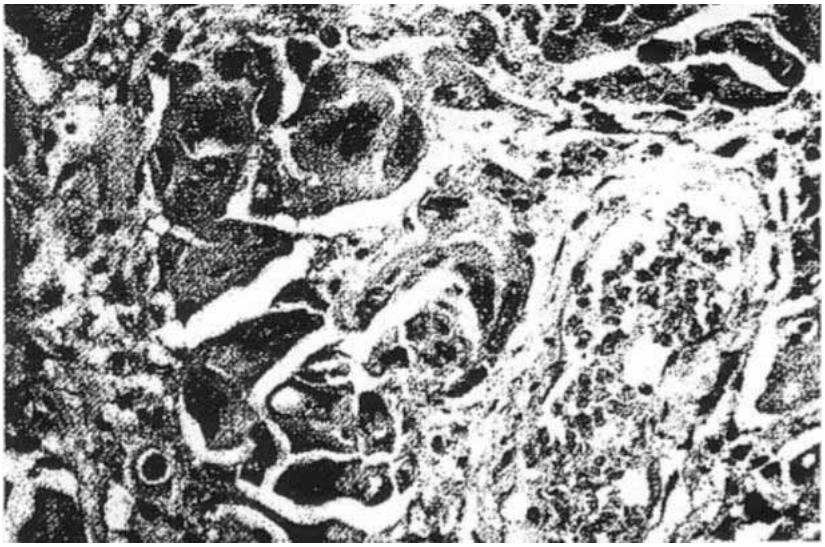

Figure 2. High power photomicrograph illustrating invasive, moderately differentiated adenocarcinomatous glands amidst desmorplastic stroma (H&E: x 100).

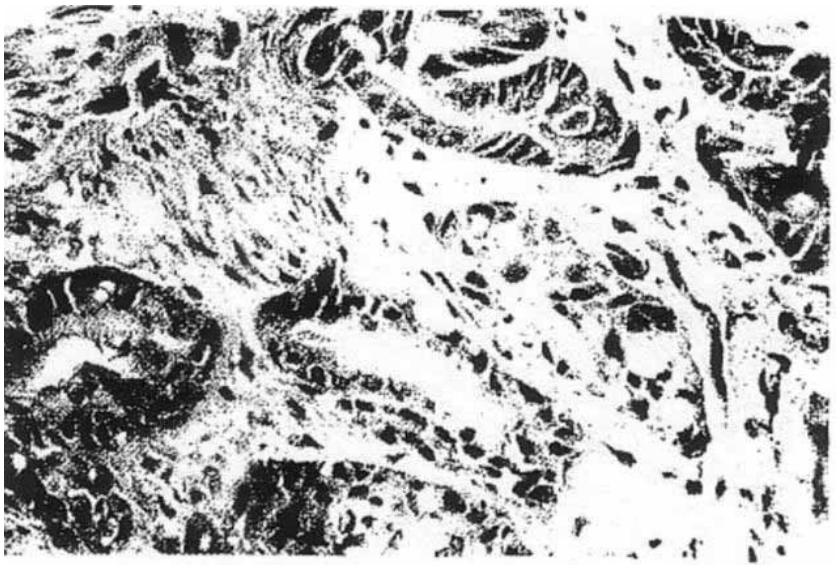

Figure 3. High power photomicrograph demonstrating a field of more poorly differentiated elements including bizarre giant cell transformation (H&E; x'100).

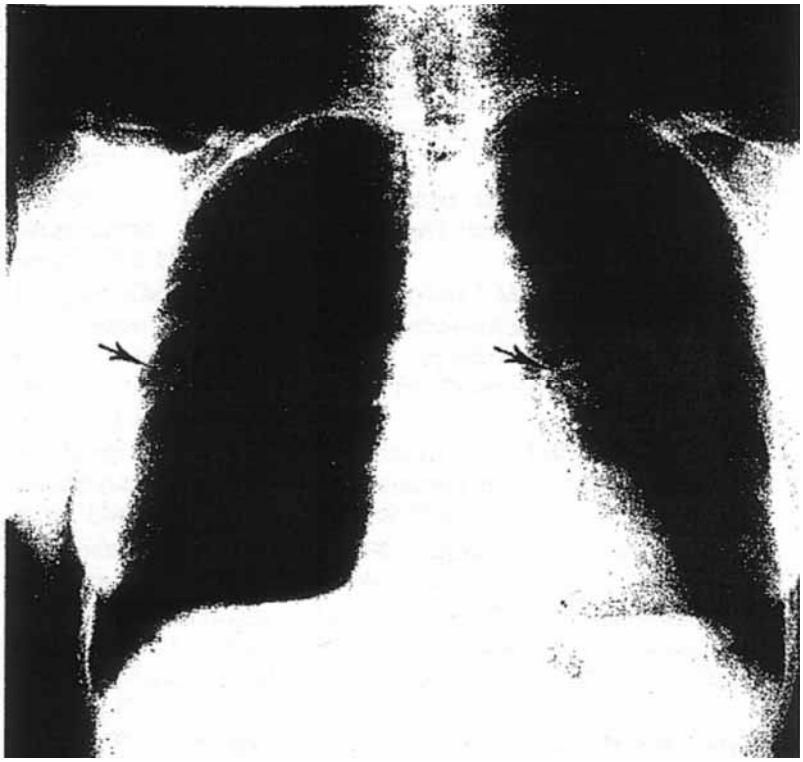

Figure 4. Chest radiograph (anteroposterior) demonstrating a 4 cm mass projected over the lower pole of the left hilum and a lesion of the anterior end of the 5th rib.

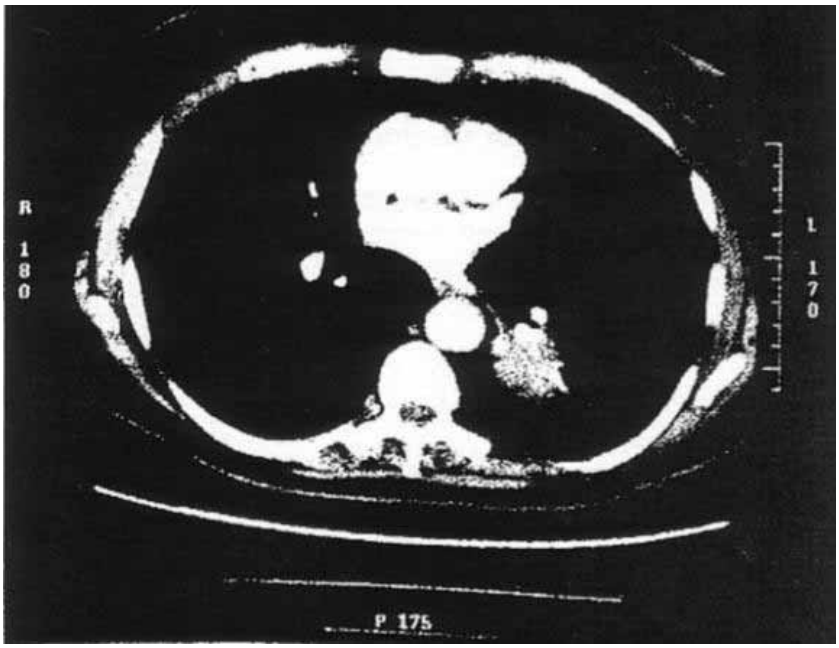

Figure 5. Chest CT scan demonstrating a lesion in the left hilum consistent with bronchogenic carcinoma.

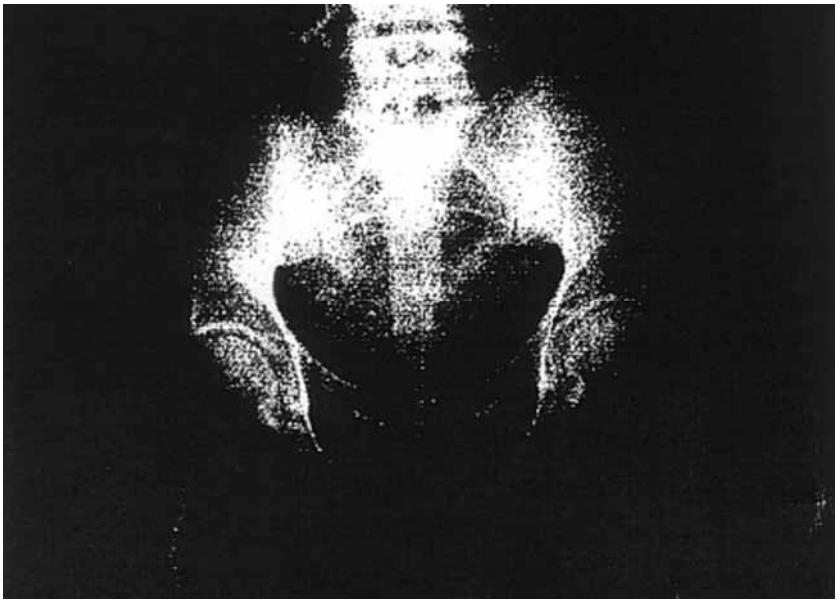

Figure 6. Pelvic CT scan showing an extensive area of abnormal bone texture in the left iliac wing, which has a mixed lytic/sclerotic appearance and a pathological fracture through it.

Needle core biopsy of the chest lesion confirmed a primary, poorly differentiated large cell bronchogenic carcinoma of comparable heterogeneous appearance to the BAHA site tumour. Subsequent computerized tomography (CT) images of tile chest and pelvis confirmed widespread metastatic disease (Figures 5 and 6).

The patient was referred for palliative radiotherapy and died from pneumonia three months after presentation.

Discussion

Osseo-integrated implants were first described in 1965 by Branemark. Their initial application was for dental implants and it was not until the late 1970s that they were first placed in the temporal bone as an attachment for BAHAs.

Complications of BAHAs can be considered in two categories: intra-operative and post-operative complications. Loss of the osseointegrated fixture from its placement in the skull is a serious complication. Many cases of fixture loss have been reported as a result of trauma, especially in paediatric patients and those with poor hygiene.' Soft tissue reactions around the abutment have also been reported and are classified using the Gothenborg scale.[3] Inadvertent penetration of the lateral venous sinus as a result of inadequate thickness of the temporal bone is another documented but rare complication. To date, there have been no reported cases of metastatic disease presenting at the site of a BAHA fixture/abutment.

Skin metastasis from bronchogenic tumours are a well recognized sign of' already disseminated and usually poor prognosis disease.[4] It can be the primary manifestation of occult disease as in this case report, where the primary lesion remains quiescent.[4,5] It is estimated that one to 12 per cent of patients with lung cancer develop cutaneous metastases. "This in turn influences clinical prognosis. Their recognition is, therefore, important. Bronchogenic carcinoma is responsible for the majority of skin metastases in men and is second only to breast cancer in women. [5]

Such cutaneous metastases can occur at any site in the body but typically, they are described on the chest wall, scalp and abdomen. Rarer sites include the extremities.[6,8,9] Any area of the skin may he involved, but usually metastases occur near the primary tumour.[9]

Of the various histological subtypes of lung carcinoma, there is broad consensus that adenocarcinomas and large cell carcinomas as a group show the greatest propensity for cutaneous metastasis [5,6] and that squamous cell

carcinomas, small-cell anaplastic carcinomas, carcinoid tumours, mucoepidermoid carcinomas and sarcomas show the least proclivity to metastasize from lung to skin.[9-11] This, however, is complicated by the well-recognized phenomenon of intratumoural multidirectional differentiation within many lung carcinomas, all elements of which may not be adequately sampled in small biopsies. Distant skin metastasis from lung cancer has been shown to be lymphatogenous and haematogenous, but certain tumours such as pulmonary mesotheliomas reach the skin by direct extension and can appear in surgical scars and needle biopsy tracks.[12,13]

Clinically, cutaneous metastases can appear as nodular, inflammatory and sclerodermoid metastatic lesions.[9,14] The nodular type is generally the commonest type encountered and may be multiple.

The prognosis of patients with lung cancer and skin metastases is very poor because this reflects advanced disease and there is invariably simultaneous involvement of other organs at presentation." The average survival after diagnosis is three to five months. However, in certain cases it can be the solitary manifestation of metastatic disease and can be prognostically crucial.

Our case demonstrates the first report of metastatic bronchogenic carcinoma at a BAHA site. Our patient had been receiving treatment over a three-week period for a presumed skin infection. The lack of response to conventional treatment prompted a biopsy, which established the malignant nature of the problem. This case demonstrates the importance of maintaining a high index of suspicion for cutaneous complications at a BAHA site.

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Part 5

General discussion
Summary and Conclusions
Acknowledgements
Curriculum vitae
Publications

General Discussion

Otology is currently a very exciting speciality. Over the past three decades huge advances have been seen with all types of implantable 'hearing aids.'

The technology and surgical skills have become more advanced and now the new subspecialty of 'Implantation Otology' includes many semi-implantable hearing aids including brain stem and midbrain implants.

With the emergence of all these new techniques and hearing aids, detailed evaluation of aetiological, epidemiological, diagnostic, and management interventions must be performed. Measurements of benefit and success are absolutely essential.

Many health status instruments are available, which aim to evaluate the success and benefit of an intervention. Furthermore these are now well accepted tools and allow standardisation and thus comparison between results.

In the UK, financial considerations are very important in the delivery of any intervention and the Bone Anchored Hearing aid is no exception. Any intervention with proven cost benefit advantages, high patient satisfaction and proven overall benefit in terms of quality of life, is more likely to be made available on the National Health Service (NHS).

The Glasgow Benefit Inventory studies on both the adult and paediatric Baha® populations in Birmingham have demonstrated overwhelming evidence that the Baha® results in a significant improvement in both quality of life and also health status. Furthermore, detailed evaluation of individual groups of children such as those with Down Syndrome and those with other conductive hearing loss has shown similar results. Our findings are reflected in the results of recent studies of Baha® in children with moderate learning difficulties.

Part 2

Chapter 2.1 Baha®

This chapter evaluated the Baha® Baha® Bone Anchored hearing Aid system in Children. In Birmingham, the paediatric programme has been very active for more than 15 years and we believe the Birmingham experience of paediatric Baha® is comparable with that of other internationally renowned Baha® teams such as those in Gothenburg and Nijmegen. *Chapter 2.1* reflects our experience of Baha® in children during this 15 year period.

The findings revealed the majority of our paediatric patients had craniofacial and/or syndromic abnormalities quite often complicated by complex medical conditions. A two stage procedure and predominant use of 3mm fixtures in our centre did not appear to increase morbidity, and overall the fixture failure and soft

tissue results were comparable to other centres. An overall success rate of 97% was a pleasing result.

Chapter 2.2

This paper concentrates specifically on those children with Down Syndrome and both the clinical results and the quality of life scores for this particular group of children demonstrate excellent outcomes. Patient and carer satisfaction was high in this group of patients.

'Quality of life' was evaluated using the Glasgow Children's Benefit Inventory. This was sent as a postal questionnaire to patients/carers. 100% response rate was achieved.

This instrument displayed very dramatically, the hearing benefit from Baha®. A simple linear analogue scale of health status both before and after Baha® demonstrated dramatic improvement with a Baha®.

This raises the issue of considering a Baha earlier in the management of children with Down Syndrome, rather than the rather prolonged pathway of conventional hearing aids and ventilation tubes.

Chapter 2.3

There has been much debate over the past decade regarding the age of implantation for Baha®. In this chapter the children under the age of 5 at implantation were studied. There was no doubt that our results revealed a significant increase in morbidity from Baha® compared to older children. Interestingly not all centres have experienced similar results.

However, since the introduction of the Baha® Softband, an effective and acceptable non-invasive alternative of auditory habilitation is now available thus surgery in this group can be delayed without significant compromise to hearing, speech and language development.

Part 3

Chapter 3.1

This paper evaluated the use of a validated paediatric questionnaire. The Glasgow Children's Benefit Inventory (GCBI) in measuring patient satisfaction with the Baha®.

A high degree of satisfaction was demonstrated. The GCBI is not sensitive to a change in health status. It is more of a benefit score. To evaluate health status, the addition of a simple linear analogue scale was used to demonstrate the health status both pre and post Baha® and a significant improvement in health status

was noted. No child experienced deterioration in health status following their Baha®.
Although the benefit of the 27% of non-responders is unknown this is not necessarily an indication to assume they had a change for the worse. Our study was on a large paediatric population and the results were overwhelmingly supportive for the use of the Baha® in these children

Chapters 3.2, 3.3 and 3.4
Chapter 3.2 demonstrates the high patient satisfaction with Baha® seen in the Birmingham adult Baha® programme. In this study, the Glasgow Benefit Inventory (GBI) was the instrument used to measure hearing benefit from the Baha®. In this study, there was a very poor response rate from the paediatric patients most likely as a result of the design of the questionnaire which was validated for adults. Thus the study results represent predominantly the adult population. The Glasgow Children's Benefit Inventory has since proved to be extremely effective in paediatric Baha® evaluation as seen in *Chapters 2.2* and *3.1*.

In *Chapter 3.3*, the Nijmegen Baha® group questionnaire was used to compare conventional hearing aids with the Baha®. The Baha® demonstrated a significantly higher satisfaction score than the previously used conventional aid in the majority of patients.
The day to day use and service related issues involved with Baha® use were evaluated in *Chapter 3.4* using the Entific medical systems questionnaire. Again the results revealed that the majority of patients were satisfied with the service.

Chapter 3.5
This paper demonstrates very dramatically, the hearing aid benefit with Baha® and the reduction in residual disability. Two instruments were used; Glasgow Hearing Aid Benefit Profile and the Glasgow Hearing Aid Difference Profile. (GHABP, GHADP) These questionnaires required a prospective interview with adult patients attending follow-up clinics.

Chapter 3.6
At the time of this study, the Birmingham experience of bilateral application of Baha® was modest. Bilateral Baha® in 11 patients was evaluated subjectively demonstrating positive results.

Part 4

Chapter 4.1and 4.2

Although the Baha® literature emphasises the low risk nature of both the procedure and the daily management of the hearing aid, complications do occur albeit rarely. The final chapters raise the awareness of the fact that complications may occur long after the surgeons work is done and so surveillance of these Baha® patients is important.

Finally, when the surgical alternative to Baha® is considered, the unpredictability of success rates for improved hearing coupled with risks and complications of an otological procedure may be perceived as too great a risk.

The Baha® is a low risk procedure, well accepted and a proven method of auditory rehabilitation. Bilateral application has been shown to be of benefit particularly with sound localisation.

Previous objective evaluation has demonstrated improved speech intelligibility with bilateral Baha®. Currently, bilateral Baha® implantation is offered in both the adult and paediatric population in Birmingham.

Finally, the role of a Multidisciplinary team is essential especially for the long term support and management of these patients.

Summary

The concept of a Bone anchored hearing aid (Baha®) followed on from the success of osseointegration first described in clinical use in 1965, when titanium oxide implants were used as a means of providing an anchor for a fixed dental bridge in an edentulous jaw.

In 1977, the application of osseointegration for extra-oral implants in the temporal bone was reported by Tjellström. Today the Baha® is a well established and very popular form of hearing rehabilitation for patients with conductive hearing loss, and is now commercially available worldwide.

The Baha® overcomes the problems of conventional bone conduction hearing aids and is currently indicated for use in patients with chronic ear disease not managed with conventional aids, otosclerosis, congenital aural atresia, single sided deafness (conductive or sensorineural). In the paediatric population, the Baha softband has enabled auditory habiliataion to be achieved years before implantation, thus avoiding the increased morbidity of surgical procedures in this young group. Recent evidence supports the use of Baha® in children with learning difficulties.

This thesis concentrates on the evidence of benefit and success of the Baha®. Some of the difficulties encountered were related to the questionnaires and clinical records. All the questionnaires used in this study were validated and have been used for many different otolaryngological assessments.

Postal questionnaires: Previous studies from Birmingham had a high non-responder rate. This was mainly attributable to the questionnaires at that time, being designed and validated for adult patients and relating in a small way to the concerns and aspects of a child's life. By using the Glasgow Children's Benefit Inventory we obtained an excellent response rate in the recent studies.

Retrospective study: Obtaining records from a 15 year period was fraught with difficulty and was not always possible. The research was labour intensive and confounded by record keeping errors. Regarding the response to the questionnaires, there was a response bias since some patients had 15 years of Baha® experience whilst others only had 6 months at the time of the questionnaire.

Long term follow-up: Many of the children were transferred to the adult programme at the age of 16 years. Increasing availability of Baha® has resulted in many patients moving their care nearer to their home and follow-up has been provided elsewhere. Furthermore, over the 15 year period, many of the patients on both the adult and paediatric programmes underwent differing surgical

procedures with differing wound care. Many had used various models of Baha® for variable periods of time.

Despite all of the above, our series of papers from both the adult and paediatric patients demonstrate a significant improvement in quality of life and health status, a dramatic reduction in residual disability and overall reduced visits to both ENT departments and general practitioners with the Baha®.

Finally, the measure of success of any bone anchored hearing aid programme should be a reflection of the number of successful Baha® wearers. In our paediatric programme there are currently 176 (97%) patients currently wearing their Baha® on a daily basis with continuing audiological benefit.

Samenvatting

Het concept van het in het schedelbeen verankerde beengeleiderhoortoestel (BAHA) ontstond nadat in 1965 voor het eerst het succes van osteointegratie in de klinische praktijk beschreven werd. Toen werden titaniumoxide implantaten toegepast voor de fixatie van een prothese met tanden in een tandenloze kaak.

In 1977 berichtte Tjellström over de extra-orale percutane toepassing van titaniumoxide implantaten in het rotsbeen voor aanpassing van een beengeleider-hoortoestel. Nu 30 jaar later is de BAHA een algemeen geaccepteerde en gewenste vorm van gehoorrevalidatie vooral bij patiënten met aanzienlijke gehoorverliezen in het middenoor. Het BAHA-systeem is nu wereldwijd commercieel verkrijgbaar.

Het BAHA systeem is een oplossing voor de problemen die gezien werden bij de toepassing van conventionele beengeleiderhoortoestellen en is momenteel geïndiceerd voor toepassing bij patiënten met een chronische otitis media waar andere conventionele hoortoestellen niet voldoen. Andere oorheelkundige indicaties kunnen zijn bij otosclerose, dubbelzijdige congenitale gehoorgang-atresie en eenzijdige binnenoor doofheid of eenzijdige maximale geleidings-verliezen. De introductie van de BAHA-softband heeft het mogelijk gemaakt in de eerste levensjaren voordat een percutane titaniumschroef geïmplanteerd kan worden met het BAHA systeem een gehoorrevalidatie tot stand te brengen. Hiermee kunnen complicaties die met een vroege implantatie van een percutane titaniumschroef optreden ontlopen worden. Recente klinische waarnemingen geven steun aan de opvatting dat door toepassing van de BAHA en daarmee met herstel van een tweeorigheid leerproblemen op school bestreden kunnen worden.

Deze proefschriftstudie is erop gericht om het succes van de toepassing van het BAHA-systeem met maat een getal te onderbouwen. Bij deze retrospectieve evaluatie ontstonden soms problemen op basis van het ontbreken van een goede klinische documentatie. Bij de kwaliteit van levenstudies is doorslaggevend de kwaliteit van de gebruikte vragenlijsten. Alle vragenlijsten die in deze proefschrift-studie gebruikt werden, waren eerder gevalideerd voor vele verschillende oorheel-kundige evaluaties.

Vragenlijsten per post te versturen: Eerdere BAHA studies vanuit Birmingham hadden last van een hoog percentage non-responders. Dit was vooral een gevolg van de toen gebruikte vragenlijsten, die opgesteld en gevalideerd waren voor

toepassing bij volwassen patiënten, en die maar in een heel beperkte mate gericht waren op aspecten van het kind. Door de Glasgow Children's Benefit Inventory toe te passen werd in onze meer recente studies een hoog percentage responders bereikt.

Retrospectieve studies: Het bleek soms problematisch om alle benodigde klinische gegevens te verkrijgen uit medische statussen met BAHA behandelingen over een periode van 15 jaar. Het bleek een arbeidsintensieve aangelegenheid en het werd bemoeilijkt door het niet eenduidig noteren van klinische bevindingen in het bijzonder van de huidreacties rondom het percutane implantaat. Voor wat betreft de vragenlijsten kan meespelen dat de antwoorden komen van patiënten die maximaal 15 jaar en minimaal pas 6 maanden een BAHA gebruiker zijn.

Lange termijn vervolg controles: Veel kinderen uit het BAHA kinderprogramma zijn op termijn op grond van hun oplopende leeftijd overgegaan naar het BAHA vervolg programma voor volwassenen dat op 16-jarige leeftijd start. Verder is met het in de loop der tijd beschikbaar komen van meerdere BAHA centra met daarmee een betere geografische spreiding voor BAHA patiënten de mogelijkheid ontstaan hun klinische vervolgcontroles dichter bij huis in een ander BAHA centrum te verkrijgen, wat voor de eenduidige vervolgstudies een verlies van gegevens betekent. Verder geldt voor de toegepaste chirurgische technieken, dat die gedurende de laatste 15 jaar aan veranderingen onderhevig zijn geweest wat ook betekenis had voor de snelheid van de wondgenezing. Daarnaast zijn de BAHA hoortoestellen over die 15 jarige periode met elkaar opvolgende modellen steeds wat krachtiger geworden, wat de kwaliteit van gehoorrevalidatie over de tijd heeft verbeterd.

Ondanks al deze variabelen tonen onze publicaties over de toepassing van de BAHA bij volwassenen en kinderen een opmerkelijke verbetering in de kwaliteit van leven en de gezondheid. Daarnaast is er een opmerkelijke afname in de resterende mate van gehandicapt zijn en is het aantal poliklinische controle-bezoeken aan de kno-arts en de huisarts sterk afgenomen.

Een belangrijke methode om het succes van de BAHA toepassing te beoordelen is te bepalen welk percentage van de BAHA patiënten in een BAHA programma daadwerkelijk de BAHA ook gebruikt. In ons BAHA kinderprogramma is het percentage dat de BAHA dagelijks draagt met een aanhoudende goede gehoor-revalidatie thans 97% (n=178).

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Curriculum Vitae

The author of this thesis was born on 22nd September 1966.

After completing pre university education in Birmingham UK in 1986 she entered Dental School at the University of Wales College of Medicine and Dentistry in Cardiff. During her dental training she was awarded a total of 3 distinctions, one gold medal and a travelling bursary for a three month period at the Hadassah Hospital, Jerusalem, Israel (April -July 1990).

After graduating from Dental School with BDS in 1991, she worked in the department of Maxillofacial surgery for two years during which time she obtained her FDS, RCS from the Royal College of Surgeons of England.

In August 1993 she entered the University of Birmingham, Medical School and in the following three years she received three distinctions and two gold medals for medicine. In August 1996 she was awarded MBChB.

During the following four years Dr McDermott worked as a House Officer and Senior House Officer in General Surgery, Neurosurgery, Trauma and Orthopaedic Surgery and Otolaryngology. She obtained her fellowship in Otolaryngology (FRCS) from the Royal College of Surgeons of Edinburgh in June 2000.

In October 2000, she obtained a six year training post as a Specialist Registrar in Otolaryngology, Head and Neck Surgery in the West Midlands. During these years she has published many papers on Bone anchored hearing aids and presented many more papers in academic meetings and international conferences. She has been awarded a number of prizes and travel bursaries.

In 2006 she passed her Intercollegiate Speciality examination in Otolaryngology and was awarded FRCS (ORL-HNS) from the Royal College of Surgeons of Edinburgh. In her senior training years she pursued her interest in Paediatric Otolaryngology.

In July 2007 she was awarded her certificate of Completion of Training in Otolaryngology, Head and Neck Surgery and obtained a place on the Specialist Register in the UK.

Whilst working as a Senior House Officer and later as a Specialist Registrar, Ann-Louise was involved with the work of the Birmingham Baha® team. She travelled to Nijmegen in 2002 with her colleague Mr Sunil Dutt when he defended his thesis on the Birmingham Bone Anchored Hearing Programme. With the support of Professor C Cremers, Mr D Proops and Mr A Reid she has completed this thesis of all her work on bone anchored hearing aids from the Birmingham Baha® Programme.

Ann-Louise McDermott has just been appointed Consultant in Paediatric Otolaryngology Head and Neck Surgery, at the Birmingham Children's Hospital NHS Foundation Trust, Birmingham UK. She is currently studying for the degree of LLM (Legal aspects of medical law) at the University of Wales, College, Cardiff. This is due for completion in 2008.
She is married to Dr Mark Sterry and has twin boys Huw and Luke who have just celebrated their 5th Birthday!

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