

BONE ANCHORED APPLICATIONS

1/05

Entific Medical Systems International Updates

Baha[®] surgery in children



The highs and lows of a paediatric Baha[®] clinic!

Successful bilateral Baha[®] treatment in toddlers



Achieving effective listening in the school environment



Child's
Story

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The views expressed by the authors in this publication do not necessarily reflect those of Entific Medical Systems.

Editorial

Baha® in children

We are delighted to bring you a very special edition of *Bone Anchored Applications* that is entirely devoted to the treatment possibilities and ongoing care of children with the Baha system. It is widely accepted that paediatric Baha treatment requires unique consideration and we are grateful for contributions from some of the most experienced Baha teams from around the world who share their expertise.

Our thanks to Dr Anders Tjellström for providing an overview article that highlights the many and varied issues that must be considered both in the short and long term when it comes to offering Baha to the younger patient. We would also like to thank Dr Tjellström in particular for his overall interest and support with this special paediatric issue.

The surgical aspects of Baha treatment in children will be of interest to many readers and we are grateful to the following contributors for their valued input. Dr Blake Papsin from Toronto Sick Children’s Hospital, shares his tips & tricks for successful paediatric Baha surgery and points out some of the key factors for success. From Naples, Italy, Dr Antonio della Volpe discusses the benefits of utilizing a one-stage surgical protocol for some of their paediatric atresia patients. And from Johannesburg, South Africa, Dr Maurice Hockman highlights the advantages of using a CT scanning technique prior to surgery for optimum results.

Effective listening for the Baha child in school is the focus of an in-depth article by John Briggs, M.Ed. from Cambridge, UK and Dr Arjan Bosman from Nijmegen in The Netherlands presents a case study on the value of combining an FM system with Baha in the school environment. Addressing the needs of the younger child, Myrthe Hol, also from Nijmegen, comments on the issues surrounding bilateral Baha provision for children who are too young for surgery.

Birmingham Children’s Hospital, UK, is the longest standing paediatric Baha clinic in the world. We interviewed key members of the team to find out about the challenges they face on a daily basis and how they provide a service that cares for both the child and the family. And our thanks to the Galloway family from Alabama in the USA for sending us their own personal Baha story, “Through a Father’s Eyes.”

In September 2004, the AAO-HNSF conference in New York was the setting for a mini-seminar focusing on the treatment of children with the Baha system – see our report starting on page 23.

***Bone Anchored Applications* is published by Entific to keep you informed. Your contributions, comments and feedback are always welcome. If you have an article you would like to see published in this magazine, please contact the editor by email: nicki@frithsden.com**

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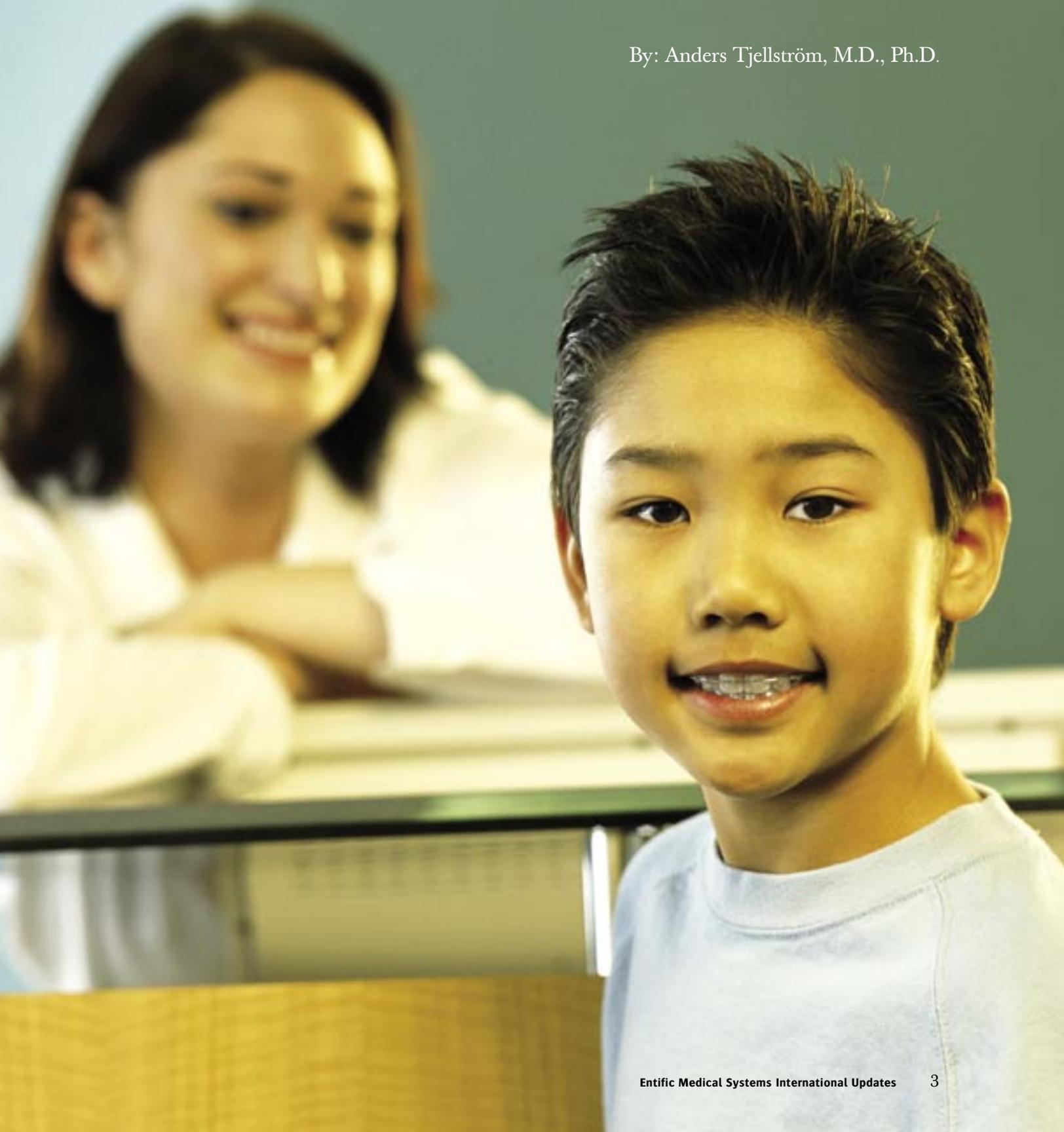
Printed by Geson SkandiaTryckeriet, Göteborg, Sweden

Publisher: Entific Medical Systems, Göteborg, Sweden

Baha® in children

– an overview

By: Anders Tjellström, M.D., Ph.D.





Dr. Anders Tjellström

The ability to communicate is one of the most important issues for members of modern society and hearing is, of course, one of the key functions for communication. It should be remembered that hearing impairment is one of the most common physical handicaps in the industrialised world and is found in all age groups.

During early childhood hearing is crucial for 'normal' development; not only for speech acquisition but also as a prerequisite for normal intellectual development. Over the last few years more and more information has become available demonstrating that even relatively minor hearing problems can be significant. A serous otitis media which stands untreated for more than six months may delay development.¹ Judith E. Cho Lieu, M.D., from the Department of Otolaryngology – Head and Neck Surgery at Washington University School of Medicine, St Louis, has published a fascinating survey of papers on unilateral hearing loss during childhood.² Dr Lieu concludes that there is now evidence that pre school children with unilateral hearing loss run the risk of delayed speech development. She also found it unclear if these children actually “catch up” as they grow older. They often have not only educational

problems but also behavioural problems in school.

It should be pointed out that there are studies where these problems have been found to be of less importance. However, there certainly seems to be a consensus on the importance of awareness of, and attitude to, the risks amongst both parents and teachers. The recognition of the handicap of unilateral hearing loss has resulted in a much more active attitude to children with bilateral conductive hearing loss of other origins. Re-perforation after myringoplasty does occur, often due to poor Eustachian tube function. If the hearing is impaired Baha treatment could be helpful and an advantage with the system is that the procedure is reversible. The tube function might improve, the drum may heal and there may be no need for a hearing device. The same is true for congenital malformations where surgery might be more successful if it could be delayed for some years.

Congenital malformation itself involves two key concerns; the abnormal external ear and the hearing. Due to the time

difference between developments of the various elements of the hearing system during gestation these patients often have normal cochlear function. This makes them ideal candidates for a Baha sound processor. Reconstruction of the external ear canal and the middle ear is difficult and often takes considerable time in surgery. During surgery the facial nerve might be at risk and the cochlea could be exposed to acoustic trauma. The new external ear canal will be lined by a skin graft leaving a scar somewhere on the body. This skin will unfortunately never have the same properties as “original” ear canal skin and has to be cleaned regularly by the otologist. Even in experienced hands the resulting hearing is often modest and the long term outcome is often less successful. On the other hand, Baha surgery can provide the child with good hearing with few associated risks and a high degree of predictability. Atresia surgery can then be delayed until the child is older, more cooperative during the post op treatment and is also able to be involved in the decision making process him/herself. Our experience with Baha in single sided sensorineural



deafness is still limited to adults but in these cases has been very successful.

When the Baha programme was initiated in our department with the first three patients in 1977 we of course selected adults for our first trials. Long standing chronic ear disease was the main indication during these early years. It was not until we had a large group of adult patients that we started to go down in the age range treated. I think it should be stressed that when we are taking up a new surgical technique, the first cases should be adults. Acquiring initial surgical experience on young children is, in my opinion, not in line with ethical principles. The initial two-stage procedure in adults (with three months between implant insertion and skin penetration/fitting of the sound processor) was changed to a one-stage procedure at the end of 1980s. Although one-stage surgery is now routine for adults, in children we still use the two-stage protocol. The rationale for this is that the quality of the bone in the child differs from the adult in several ways.

The mineral content is much lower and the water content higher resulting in soft bone which has to be taken into consideration during surgery. The thickness of the skull is another important factor. We have measured the skull bone at the Baha implant site and found great individual variations even in adolescence. The mean thickness at the age of 5 years was only 2 mm. During surgery we found the dura of the middle cranial fossa at the bottom of the implant site in more than 25 % of cases. This means that surgery has to be carried out very carefully. During initial drilling the hole must be checked



for bone at the bottom; this is made easier by widening the hole throughout drilling to allow for direct inspection. By doing so the risk of damaging the dura or sigmoid sinus is diminished.

Having said this, stability measurements using the RFA technique have shown fairly high ISQ values in children, indicating good stability.³ The failure rate for implants in children below the

age of 16 years treated in our Implant Unit was found to be the same as for adults; 5.8 % as opposed to 6.0 % in a 4–8 year follow up study.⁴ Anecdotal incidence of non-integration and early loss of integration has been reported. This could perhaps be explained by the use

of too high a torque at insertion relative to bone quality/quantity. Professor Brånemark's mantra "minimum tissue violence surgery" is still valid!

An important issue related to implants in children is the question of potential toxicity. An implant that will probably stay in the body for many years to come

must not be toxic or produce allergic reactions. The implant used for the Baha system is made from Cp Titanium with a very high degree of purity. This is in contrast to many other "titanium" implants which are alloys, often with aluminium and vanadium. This Cp Titanium has been used for more than 40 years in humans and for 27 years as part of the Baha system and no toxic effects have been seen or reported. We have studied potential allergic reactions to Cp Titanium itself but have not found any such effect, even in the very allergic individual.⁵

Data on adverse skin reactions associated with permanent skin penetration has been published.^{4,5} Using the grading system according to Holgers, the frequency of mild adverse reaction with just some redness was found to be 3.1 % adults and 5.1 % in children, redness and moisture around the abutment was found to be 2.1 % vs. 2.5 % and reactions involving granulation tissue requiring more active treatment was 0.6 % vs. 1.5 %. Therefore we have seen a slightly higher frequency in children. The reason for this is not clear but it has been suggested that less effective hygiene might be one explanation and also that children have more active skin

***“Professor
Brånemark’s
mantra is
still valid!”***

with more acne and sweat glands etc. Since the introduction of the dermatome in Baha surgery we have a feeling that the frequency of adverse skin reactions has been further reduced. A study on this is ongoing and will be published.

Closely linked to the Baha concept is the use of titanium implants for the retention of external ears and other craniofacial prostheses in children. The most common reason for providing a prosthesis is congenital malformation. However, also in the paediatric group we find defects after trauma and post tumour treatment. In congenital malformation we prefer to wait as long as possible to allow the child to be part of the decision making process. We also work closely with the plastic surgeons, discussing the alternative of autogenous reconstruction, although, in fact, most of our children with facial defects are referred to our unit from plastic surgery.

At the 2004 American Academy of Otolaryngology – Head & Neck Surgery meeting in New York, Baha in children was discussed in a mini-seminar. I had the honour to chair the session with the following panel; Dr Antonio De la Cruz from House Ear Clinic in Los Angeles, Dr John Niparko from Johns Hopkins in Baltimore, Dr Blake Papsin from Toronto Sick Children's Hospital and Dr Jack Wazen from Columbia University in New York. Mr David Proops from Birmingham, UK, was also scheduled to be on the panel but had to cancel his trip to New York at the last minute. In the discussion the panellists agreed on the statement that reconstructive surgery of the atretic ear is a challenge. One of the most experienced surgeons, Dr De la Cruz, stressed the importance of CT scanning with regard to the 3-dimensional relationship between the relevant anatomical structures. Inner ear malformation as well as facial nerve

abnormalities will make surgery more difficult and risky and he recommends Baha in such situations. The other panellists agreed on this. Dr Niparko recommended the Jahrsdoerfer criteria as an aid in the decision making process between ear canal reconstruction or Baha. Dr Papsin mentioned the unique anatomical situations in the young child with an often very thin calvarium. In a written statement Mr Proops pointed out the predictable hearing results that he can achieve with Baha are in contrast to the results after external ear canal reconstruction. He also stressed the overwhelming importance of hearing over the cosmetic aspects.

Dr Wazen emphasized the importance of bilateral hearing for normal development and achievement in school. Dr Wazen uses Baha on the test rod or softband and coined a new expression – the “wow-effect” – as “an immediate reaction, a smile or widening of eyes which opens the door for acceptance to both the device and implantation.” This is something that those of us who have

been evaluating children for Baha have long experienced. Now we have a name for it – the Wazen wow effect!

In conclusion, Baha can be seen as a strong alternative in selected cases with hearing impairment. Baha surgery performed according to given guidelines is safe and gives predictable results. New knowledge regarding the importance of bilateral hearing has extended the indications for Baha. Studies focusing on this are being carried out at several centres and preliminary data is very promising. Research in this area should be encouraged and results should be published. In spite of the data on the benefit of Baha in children available today there is still a need for making colleagues aware of the possibilities. I feel that it is vital to spread this awareness not only amongst the paediatric otological community but also to general paediatricians, general practitioners and other specialists who work together to improve the outcome for children with hearing disabilities.

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Achieving effective listening for the Baha® child: Managing the school environment



By: *John Briggs M.Ed. Aud. B. Ed. (Hons) P.G. Cert. Ed. H. I., Addenbrookes Hospital, Cambridge, UK*

John Briggs trained as a Teacher of the Deaf, working both in mainstream and special schools. After qualifying as an Educational Audiologist at Manchester University, John continued in this capacity working for education authorities as well as acting as an external examiner for

MSc in Educational Audiology and speaking at conferences both at home and abroad on topics ranging from acoustics to cochlear implantation. He now works at the Emmeline Centre, Addenbrookes Hospital, UK as the Paediatric Rehabilitationist for implanted devices.

If all communication were one to one, in the best of acoustic conditions, how much better would the outcome of aiding be for our patients? Unfortunately, life is not so neat and understanding and managing the environment in which a hearing impaired child has to function is an essential part of the total rehabilitation package.

The handicapping impact of a given hearing loss is dependent on environmental and communicative factors. Few acoustic environments are likely to be more challenging than the classroom.¹ All the factors that contribute to poor listening conditions may well be present; long reverberation times due

to hard floor, ceiling and wall surfaces, constantly changing distance and position of the teacher, multiple talkers, unfamiliar vocabulary and topics and many sources of background noise.

The importance of good acoustic conditions to effective learning has long been recognised. Provision of good acoustic conditions for the hearing impaired child is as much a part of providing equal opportunities and access to learning as is the provision of wheelchair access to another child. This need has been recognised by the United Kingdom Department for Education for many years. However their most recent advice, contained in

the government “Building Bulletin” series of publications, has placed greater and clearer requirements on local authorities both to build to a required standard and to have a programme that includes upgrading of existing buildings over time.²

Recognising that acoustic conditions can play a major part in determining the effect of hearing loss is a vital step towards optimising the management of the child with a Baha sound processor. History taking should elicit details of the events, situations and places that cause difficulty. When interviewing children, it is important to modify the way that questions are presented, so that the

child really understands and to make sure that questions are sufficiently open ended to allow the child to volunteer useful information. “Can you hear your teacher properly?” is likely to be greeted with a helpful nod and smile. Questions that provoke reflection such as, “Which is your best room at school for listening?” and “Which is your worst room at school for listening?” can be followed by “Why is your best/worst?”

Care should be taken in interpreting children’s responses. The younger child may not be critically aware of their own difficulties. Some years ago, while evaluating acoustic conditions in a school, a class was surveyed by questionnaire to identify their perceptions of ease of listening in various situations. There were two children from the thirty five sampled who reported no difficulty whatsoever. These were the only two with hearing impairment. While self evaluation questionnaires may not always be appropriate, there are times when they can be very useful, especially for breaking the ice with a teenager, who may not be forthcoming directly, but may well be happy to discuss their answers to a questionnaire.

To take our understanding of the individual child’s situation further, structured observation is often invaluable. This information may preferably be gathered by direct observation or indirectly from teachers. Many such tools are available and each has its strengths, but it is useful to be sure that whichever is used includes items about the level and type of support

that the child receives informally from peers as well as from adults. Many hearing impaired children cope in the classroom only because of the asides and promptings of their neighbours.



Baha® Compact with Phonak Microlink FM receiver

Because of the classroom dynamic, this often goes unnoticed by the teacher, particularly as this kind of support is often given while the teacher is busy. This information may be most easily obtained by the teacher of the deaf or educational audiologist at the same time as the acoustic assessment is completed.

The third part of the picture should be obtained by an audiometric evaluation of the change in speech discrimination abilities between noisy and quiet conditions.³ In this case, testing with signal to noise ratios of 0 and +10 may be found to reveal efficiently a significant decrease in function. Many Baha users, in common with those children with single sided hearing loss, may be receiving sound from one side only. Speech and noise sources should be separated spatially in order to review the impact of relative location of speaker and noise, thus simulating the mobile situation found in daily life. If a decline in performance has been noted that is consistent with reports obtained previously, then it is important to move to the next stage of the management pathway.



Easy Listener fixed soundfield system courtesy of P.C. Werth Ltd.

It is at this stage that the hospital based Baha audiologist is likely to need to call on the services of the educational audiologist or teacher of the deaf working for the local education

authority. (Part of the training of educational audiologists in the UK is in the assessment of acoustic conditions, their modification and their impact on learning.) Armed with the results of the investigation so far, the school needs to be visited. The aim of this visit is to evaluate the acoustic conditions that prevail in the classroom and to observe and discuss classroom management as it affects the hearing impaired child.^{4,5}

This evaluation should consider four major questions. The first relates to good teaching practice, the rest to the acoustic environment:

- Teaching style and classroom management: – are the communication needs of the child being met?
- Distance: – who is the child trying to listen to and where are they relative to the child?
- Background noise: – what noise sources are there, where are they and what are they? What is the level of noise generated? Are the noise sources continuous or intermittent?
- Reverberation time: – is this within acceptable limits? What materials are used in the room/s?

The results of this survey, added to the functional information obtained earlier, should provide the evidence that allows the formulation of a management plan. This will include advice on teaching strategies and on adaptations and modifications to the teaching environment that will have a beneficial effect for the hearing impaired child and, this is worth stressing, will have beneficial effects for all other users of the space.^{6,7}

Within this framework, an important question is being asked. Can the Baha child’s listening difficulty in these situations be addressed by environmental modification, room

based sound systems and management of teaching practice, or is there a need for the child to have a personal FM system, adding to their responsibility for its care and use?

This question becomes equally pertinent when considering the needs of a child with single sided deafness and should be part of the process whereby appropriate intervention is determined. If the reported handicapping situations are limited to those which can be effectively managed without medical intervention, then that option should be explored, knowing that the child's situation will need to be regularly reviewed to ensure that those interventions remain effective as situations and needs change.

A well established way of overcoming many acoustic problems is the use of FM transmission systems.⁸ These are available in three configurations: soundfield, desktop and personal. All systems comprise an FM transmitter and microphone (used in most cases, by the child's teacher or, in the home environment, the parent) and a receiver, which in the case of a personal FM system inputs the transmitted signal directly to the hearing aid/sound processor or, in the case of fixed or desktop soundfield systems, to a receiver and array of speakers. In the desktop system, this is reduced to a single speaker and receiver in a single convenient package about the size of a large paperback book.

In the UK, such systems are funded and maintained by the local education authority. It is their role to jointly identify and provide the necessary equipment. Importantly, they will also provide training and advice to the child's school. Without this liaison and support,

sustained effective use of supplementary equipment is unlikely. Many education authorities employ an educational audiologist who has responsibility for liaising with hospitals over clinical management and will have responsibility for equipment provided by the education authority.

FM systems address the deterioration of signal quality by the simple expedient of placing the transmitter microphone a very short distance from the speaker's mouth. This short microphone distance thereby provides:

- Improved gain of the signal relative to background noise by a factor of around 20 dB for a direct input personal system and around 10 dB for a speaker based system.
- Delivery of the speech signal in the near field, reducing the impact of reverberation.
- A more consistent level of speech signal which is independent of the actual distance from speaker to listener.



Desktop totable FM system courtesy of P.C.Werth Ltd.

Choice of system will depend on several factors. It may be that, in some cases, systems are already in use. A child with difficulties in manipulation may be better served by a desktop than a personal system. The child that moves from

classroom to classroom will not be well served by a permanent installation. It may be, in some instances, that fundamental questions relating to room acoustics need to be met before anything else should be considered. Co-ordination with local services becomes essential in delivering a management package that meets the child's needs in all circumstances. Environmental adaptations may, in some cases be the only measures needed to

alleviate problems caused by a hearing loss.

Whether FM systems are used or not, the principle of considering the child's functioning in daily life in all its variety remains essential in the process of deciding how and when to intervene. Without this, the hospital team work in an abstract environment and the chances of providing effective and appropriate interventions are severely reduced.

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Acknowledgement:

We are grateful to P.C.Werth Ltd. for allowing the use of some of the photographs included in this article.

Baha® and Phonak Microlink FM Receiver

By: Arjan J Bosman, M.Sc., Ph.D.

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Aafke, a young girl with Treacher Collins Syndrome, is bilaterally fitted with two Baha® Compacts. In addition, she uses a Phonak Microlink FM system with receivers directly coupled to the audio-input of her Baha sound processors. At school the FM system provides optimum reception of the teacher's voice; the combination of Baha and Microlink being especially valuable during difficult listening tasks such as dictation or instructions in noisy surroundings.

Aafke was born with various craniofacial disorders corresponding to Treacher Collins Syndrome: microtia of both outer ears, atresia of both ear canals and a palato schisis. Hearing screening at one-month of age with Brainstem Evoked Response Audiometry confirmed the presence of a bilateral conductive hearing loss: 50 dB loss on the right side and 60 dB loss on the left side. Aafke received a conventional bone conductor fitted on a spring when she was 3 months old and at 5 months an informal pre-school training programme was started to stimulate Aafke's speech and language development. From the age of 2 ½ she began to attend a special school for hearing impaired children and children with speech and language disorders.

Three years later, when Aafke was 5 ½ years old, she was fitted with a Baha®

Compact device, replacing the conventional bone conductor. For Aafke, the Baha sound processor meant a great improvement in both wearing comfort and sound quality. She still remembers the new sounds she heard with her Baha device: when returning home after the fitting she noticed for the first time in her life the clicking sound of the indicators in her mother's car!

With the new sound processor Aafke's speech and language development showed great progress and, only 6 months after the Baha fitting, she was able to move to a regular school for mainstream education in her local town. Aafke greatly

enjoys going to her new school where she meets friends from her own neighbourhood. After about a year Aafke received her second Baha device and the Microlink FM system. In the beginning she was a bit confused by the sound



Fig. 1. Lateral view of Aafke with a Baha® Compact fitted with a Phonak Microlink receiver



Dr. Arjan Bosman

of the second Baha, as she could not tell right away where the sounds were coming from. But this quickly improved and now she is very happy with her two sound processors. Both her directional hearing and her speech perception in noise are much better with two Bahas than with one.

The Baha/Phonak Microlink FM system consists of a microphone and an FM transmitter worn by the speaker and a small FM receiver coupled to the external input of the Baha® Compact (Fig. 1). The FM receiver has a small switch for switching between three input modes: Baha microphone alone, FM system alone or the combination of Baha microphone and FM system.

Aafke has an FM receiver on both her Baha devices and a Campus S transmitter for her teacher. This type of transmitter setup is demonstrated in Fig. 2. In the classroom Aafke mainly uses the combined input of the microphone and FM system and with this combination she can hear the teacher well while still maintaining contact with her classmates.

During dictation Aafke switches to FM input alone to minimise disturbing sounds. In the intervals Aafke switches the FM system off for optimum communication with her peers. Practical issues are well taken care of: her mother changes the batteries but if necessary Aafke can also change the batteries at school. The Microlink transmitter is recharged at the end of every school day. Finally, for optimum handling of the Microlink transmitter, Aafke's teachers have received additional instructions.

Apart from her two guinea pigs Aafke has another great hobby: playing the recorder. She receives individual tuition and with her Baha devices she hears clearly what she is playing. Recently, she was involved in a public performance with a group at the local theatre and she had no problem hearing that she was still in tune with the other

players! As her mother proudly stated, "it all went perfectly!"

So, Aafke is now eight years old and is doing very well at her school thanks to Baha and Microlink. She still enjoys going to school and playing the recorder. Her future looks bright! This story of bilaterally fitted Baha sound processors in combination with an FM system clearly demonstrates the added value of a solo system in critical listening situations. Although an FM system involves significant costs, these costs should be valued in the light of a large reduction in educational costs. Keeping in mind that mainstream education is an order of magnitude less costly than



Fig. 2. Aafke and her mother demonstrating the Campus S transmitter

special education, including children like Aafke within mainstream education by using the Baha system and an FM system is highly cost effective, apart of course from the positive effects upon social well being and career prospects later in life!

Entific to hold corporate symposium at the International Otitis Media Congress in Amsterdam

In April 2005, Amsterdam is the host city to the 5th Extraordinary International Symposium on Recent Advances in Otitis Media.

On Tuesday April 26th from 13.00–14.00, Entific Medical Systems will organise a corporate symposium focusing on Baha treatment for hearing impaired people with otitis. Special attention will focus on the care and options for those with mental disabilities and special needs. Entific invites you to visit our corporate symposium and we look forward to welcoming you to Amsterdam.

General Symposium Information : The overall theme of this year's symposium will be "International Insights and Innovations in Otitis Media" and the conference aims for international co-operation and exchange of knowledge between investigators and clinicians, emphasizing a spirit of collaboration. The two and a half day meeting will concentrate on the exchange of recent clinical insights and innovative scientific ideas including

a focus on the state of the art in Otitis Media and its translation to clinical and preventive practice, looking at real innovations in Otitis Media management and research and learning from the diversity of views, practices and research traditions in different countries.

Visit: www.om2005.nl



Baha[®] Surgery in Children

*By: Blake Papsin, M.D.
Toronto Sick Children's Hospital, Canada*

Dr. Blake Papsin and his team have been working with Baha in children since 1997. In this article, Dr. Papsin comments on the key surgical issues that should be considered when treating the paediatric Baha patient.



At the Hospital for Sick Children in Toronto an active paediatric Baha program has been in place since 1997. At our institution, the quality of anesthesia and our dedicated multidisciplinary team (including an audiologist, a social worker, superb OR and post-operative nurses) have allowed us to explore the boundaries of utilizing Baha sound processors for children with conductive hearing loss. Over the years we have reported in press and in presentations some of the tips and tricks for successful Baha application.

We routinely use a two-staged surgical approach up until around age nine after which we find we can usually implant a child in a single stage (usually still with a 3 mm fixture but occasionally with a 4 mm fixture). In children younger than 4 years of age we lengthen the interval between the two stages to allow for osseointegration in children whose calvarial thickness is almost always less than 3 mm. The interval can be up to 1 year if for example an 18 month old undergoes first stage surgery (the child therefore is aided by age 2.75).

In children it is commonplace to encounter dura and/or the sigmoid sinus when placing the fixtures but no injury to these structures is caused if they are handled with respect. We routinely place the fixture directly down onto these surfaces without incident. The new self-tapping fixtures are a little sharper at the tip so extra care must be taken to avoid injury to these delicate structures. I can think of no better method of sealing a leak in a low pressure system (CSF or venous system) than with an osseointegrated fixture and I would recommend placing the fixture to stop a “leak” rather than using bone wax or introducing other foreign material.

If 3 mm bone is encountered in a child the fixture can be inserted fully as in Fig. 1A. In bone less than 3 mm thick, the options of fully inserting the fixture (Fig. 1B) or leaving the fixture extending out

from the calvarial surface are possible (Fig. 1C). Reports of using either bone chips or a biological membrane to augment osseous growth under the fixture flange in cases where the fixture is left protruding from the bone have been published with impressive results (Fig. 2). In our own institution we opt to simply fully insert the fixtures (Fig. 1B) and lengthen the inter-stage interval to allow for additional osseous growth if it is felt to be necessary.

We routinely place two fixtures at stage I surgery in children. The two reasons for this are that we like the security of a banked fixture so that we can reapply the sound processor in the shortest period of time should a failure occur and so that we can train our residents to become comfortable with implant surgery. Although we suggest only placing a second (banked) fixture in cases where only a 3 mm fixture can be inserted we actually always place a second one even if the bone is 4 mm thick (it’s a ritual and I’m a surgeon – need I say more).

The major difference between operating on a child (and especially a young child) and an adult is that the patients commonly have craniofacial anomalies which make establishment and maintenance of their airways challenging. In addition, children almost always require general anesthesia for Baha surgery. The actual surgical procedure (in two separate stages) is very similar in children and adults but in children competent anesthetists with an armamentarium of scopes, airways and experience are additionally required. Baha fixture installation can be successfully accomplished in children as

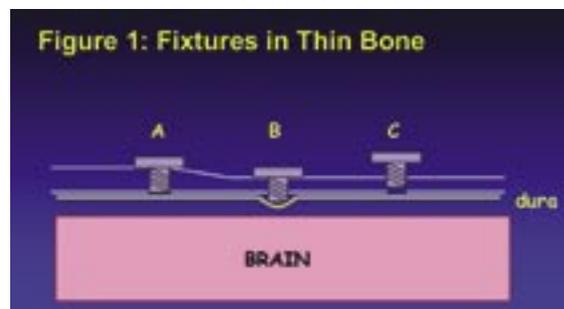


Fig. 1

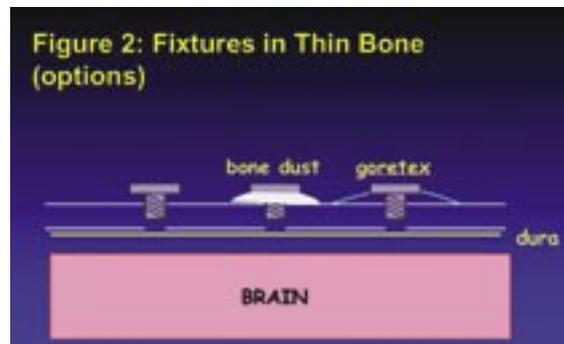


Fig. 2

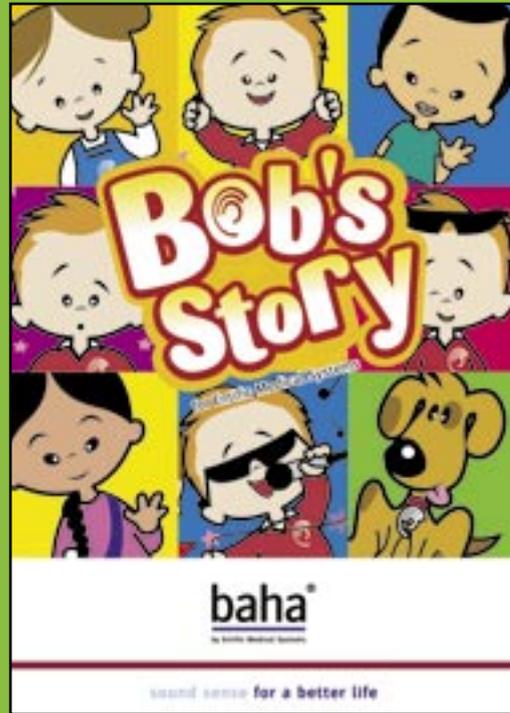
young as 18 months which allows the second stage to be performed in the child’s second year.

We remain enthusiastic about using the Baha system in children and continue to explore the boundaries of safe application in young children. Taking small steps in association with competent audiological and anesthetic colleagues is the best way to ensure good results applying Baha sound processors to young children and those with craniofacial anomalies.



Dr. Blake Papsin

Coming soon.....



Bob is about to find out how the Baha system will help him to hear better!

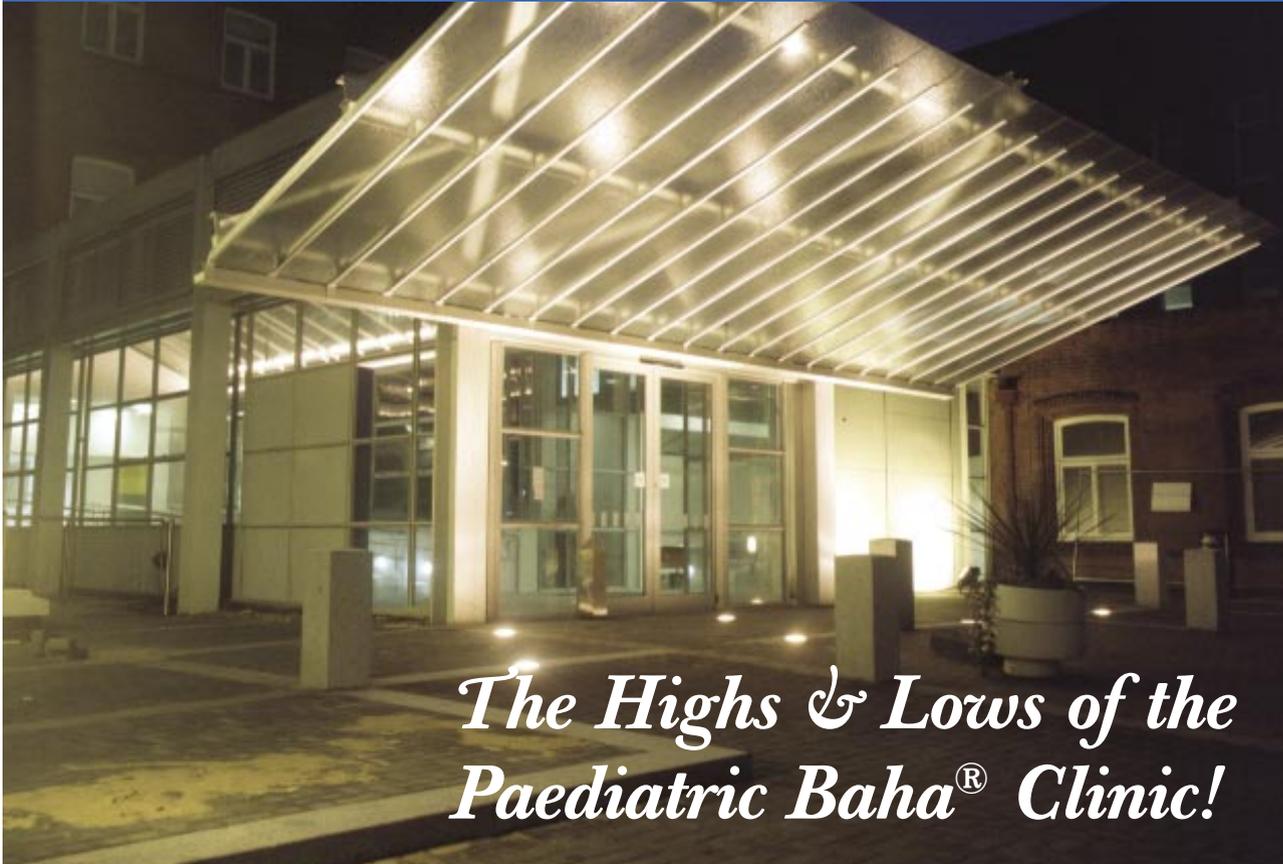
Illustrated with bold cartoons, Bob's Story explains all about Baha treatment in entertaining pictures and child-friendly language. Bob goes to see his doctor, finds out all about Baha and what will happen at the hospital and learns about when he will get his new device and how he can look after it.

Bob's Story is an interactive CD aimed at Baha wearers up to the age of around 7 or 8 and represents the first item in a package of support material that is being developed by Entific especially for children.

We would like to thank all customers who have contributed ideas to the development of this material. Although this project originated in the UK market where the need was first recognised, it

has become apparent that there is an international need for support material for children and their families and the company is now committed to developing suitable items in several languages for both younger children and teenagers (UK English, US English, Dutch and French).

For more information about the Bob's Story interactive CD please contact your local Entific office.



The Highs & Lows of the Paediatric Baha[®] Clinic!

Birmingham Children's Hospital, UK, is home to the longest standing and busiest paediatric Baha clinic in the world. Baha treatment is carried out in Birmingham in two hospitals: adults are referred to the Queen Elizabeth University Hospital and the Children's Hospital takes care of young people up to the age of sixteen. The total number of Baha patients treated in Birmingham since they started in 1988 now stands at more than 1,000; and approximately 250 of them are children! The majority of children and their families will spend most of their time outside of the ENT clinic, and instead with various team members who take them through the various stages of treatment, from the

decision making process through to long term post-fitting follow-up. Sheena Hartland, Chief Audiologist, has been involved in the programme since 1992 and works closely with Snr. Audiologist Anne Child. Jane Moffat, Lead Clinical Speech & Language Therapist, and Jo Williams, Advanced Nurse Practitioner within ENT, have both worked with Baha since the late 1990s. Whilst the Baha programme is only one element of their daily workload, much effort has gone into providing a service that cares for both the child and the family. We spoke to these key members of the team about the challenges of working in a busy paediatric Baha clinic.

What are your roles within the Baha programme?

Sheena Hartland: "Within Audiology, Anne and I are of course responsible for the pre and post operative assessments and fitting. Along with our ENT and nursing colleagues we also see patients for checking the skin hygiene and tightening abutments and report on any problems of this nature. This skill sharing is vital as it allows our patients

to be seen as soon as possible and we can prevent small problems becoming bigger ones! We also put a great deal of effort into what we call 'matching' whereby all children newly referred are 'matched' with a current user in terms of their hearing loss, family situation and so on. This forms an important part of the decision making process for the family. We also have to bear in mind that the children's future hasn't been decided and the impact of their hearing impairment

isn't known, or for that matter, the progress of related disease. So we spend a lot of time in contact with their parents sharing information to enable decisions to be made and in educating anyone involved in the child's local support network. Children go through more changes in a shorter period of time than adults so we need to take this into account and act appropriately as the child moves from pre-school to school and through to adolescence."



Sheena Hartland



Anne Child



Jo Williams



Jane Moffat

Anne Child: “There’s also a lot to look after from a practical point of view as well as coordinating the entire programme! Children with Baha often become new personalities in terms of their ability to communicate and their self-confidence. Some have to be forced by their parents to take it off at night! This is great to see – but they are also a lot more emotionally dependant on their device so if anything goes wrong it’s a ‘big’ problem! They are often very sensitive to faults or small changes in function - as well as to the colour if we have to replace their device. They may be totally dependant on their Baha for school and although we maintain a loan service, we may not always be able to replace their device immediately. Younger children are not always aware whether it is working properly, so mechanisms have to be put in place to pick up on any mechanical problems early. With around 300 Baha out there all of this takes time to administer!”

Jo Williams: “I’ve been working with Baha for around 6 years and my main role is to prepare the children and their families for surgery and admission and overall aftercare including post-op dressings and wound care. The surgical aspect can be a critical one for parents

and I’m around to help them with any problems and concerns. We have to remember that the parents are making a decision for someone else, their child, and there may be constant worries that they are doing the right thing. They are often concerned about anaesthesia for instance and it is helpful for them to have someone to talk to both on the ward and in clinic. Although the operation is a day case and for those of us who work in the ENT field it is seen as a minor procedure, any surgery can still be traumatic for the parents of a young child! And as a regional centre for newborn craniofacial abnormalities, I also liaise in terms of patient care with the Craniofacial, Cleft palate, Respiratory and Anaesthetic teams on a regular basis.”

Jane Moffat: “My overall role is to assess how the hearing loss is impacting on the child’s development; to assess their communication skills and intervene as necessary. For the congenital children, this may take the form of long term liaison with both the parents and the appropriate community services. Although these children may already have good local support, more direct therapy may be required from our Baha team. It’s so important that parents understand the impact that the hearing

loss could have for their child in the long term, to openly discuss other learning needs and that we offer the best advice we can. I see it as helping the parents to have a holistic view of their child – dealing with the hearing impairment is part of the overall management – and this requires a truly team-based approach. Children with chronic otitis have other needs. They may have some learning difficulties in the early years and it’s essential to identify how speech and language therapy can help as well as other health and educational services. For older children, an explanation of the child’s needs via school visits may be sufficient. Again it’s a question of liaison between the child, their parents and community services. Children’s needs are constantly changing and Baha may only be part of the picture!”

What are the main considerations when selecting children for Baha treatment?

Jo: “Around 40% of the children we see have a congenital hearing loss associated with ear malformation. The parents may want ‘the perfect child’ and by concentrating on the aesthetic issues, may underestimate the effect the hearing loss may have on the child’s development

and therefore the importance of finding a solution. Sometimes we see older children with chronic ear infections who understand how the Baha device can help, but the parents may still take a lot of persuading because of the surgery."

Jane: "It can be a complex assessment for some of the children we see and may end up being a series of decisions taken over a period of time. Sometimes, especially with the very young, congenital child, we may be the first team who are clear to the parents about the child's hearing problem as opposed to them focussing on the external abnormality. Of course, the Baha processor isn't going to solve all their problems but less than 5 % of our referrals don't have one in the end!"

Sheena: "From an audiological viewpoint, children are often more straightforward to assess because of the mostly conductive loss, compared to adults where there may be a sensorineural component. But of course, especially for the younger children, it's important to have the appropriate tests and facilities and assessment can be more difficult if the child is not compliant. Above all, we have to make sure that the parents as well as the children have an appropriate level of expectation about the outcome."

What is involved in your 'matching' process?

Sheena: "Matching' is something that we have always held as a principle but over the last 3 years it has become a mandatory part of our Baha programme. It basically involves the child and family having the opportunity to meet another child and family who are already using the Baha system. To enable an open discussion about the pros and cons so that they go into the programme as fully informed as possible. When a child is referred to us we try to match him or her not only in terms of their hearing

impairment, but also taking into account other issues that may involve the whole family. It is especially important for the congenital child where concerns and decisions around the aesthetics may take precedence in the parents' minds over the hearing. The families should match in terms of their expectations and fears as well as 'personal' circumstances. The more boxes we can tick the better!"

Anne: "It is reassuring for the child and the adults to see the device being worn by another child. Our experience over the years has shown that overall expectations become far more realistic. Advice is seen as being impartial and 'correct' if coming from another family and this in turn supports the decisions they make. They can also get practical tips and discuss worries in confidence. Going through this process helps the family to confirm in their own minds how important their child's hearing is and establishes a commitment to their child having surgery, wearing the device and the long term follow-up."

Jane: "Of course, the bigger the programme gets, the harder it is to manage! It can be time-consuming and logistically complicated due to integrating with peoples' busy lives and the geography of where they live. On the other hand, if our patient numbers were a lot smaller it would be even harder to find a 'good fit' between patients."

What about special considerations for particular groups of patients?

Jo: "We are very aware of the needs of congenital children and their families in coming to terms with what may be a myriad of problems that will have to be faced over the coming years. And the importance of good communications with the other specialists involved in their ongoing care."

Sheena: "For children with multiple syndromes, Down syndrome and other learning and educational problems, we also have to be prepared for non-compliance and behavioural issues. The family must be involved in the care and use of the processor and we can't always predict the outcome even though, audilogically, we know it will benefit their hearing. Age is also a factor. The policy is for children to transfer to the adult centre at the age of 16 but for some of these children this is not appropriate."

Jane: "This is an area of our work that is under current review. At 16 they may be changing schools or going to college and a change in their hearing care at the same time may cause difficulties. A programme especially for adolescents would be the ideal as they also have other issues to contend with. The importance of communicating with their peers, a heightened sense of aesthetics and confidence in social situations may cause worries as well as practical things like using a mobile phone or thinking about job opportunities. As their educational setting becomes more formal, their hearing needs may change. Also teenagers who have had fluctuating hearing for years may lack social skills if they haven't had good support. The NDCS runs good life-skills courses for this age group and this can be a great benefit."

So, what are the 'highs' and 'lows' of your work in the clinic?

Jo: "The hardest part is I suppose trying to cope with the emotional needs particularly of the parents when their expectations are understandably high. But seeing the children after treatment is a delight and I enjoy the ongoing relationship with them and their families. The feedback we get really helps me to feel that I've made a difference."



Sharing skills and information is a vital part of the clinic's work

Jane: "You can have all the policies, procedures and systems you like but every day is different! Becoming involved in people's lives is a privilege but also a huge responsibility. But we know that a significant group of children with Baha do exceptionally well – it provides a foundation for them to do well in the future and can have a

massive impact across all aspects of their lives. It's great to see them achieve so much as they grow older. Getting the long term picture is very satisfying and gives us new information that we can pass on to other families."

Anne: "It can be very frustrating if people are non-compliant when we are

trying to match children for their own benefit! The high is knowing, even at the early stages of assessment, that the child will do well with Baha."

Sheena: "Fixture failures are disappointing – though fairly infrequent. Having said that, all children have a 'banked' implant and nobody has ever refused a replacement fitting! I think we all feel that there are still many questions when it comes to treating children. There is definitely a need for further studies and in particular to get a stronger evidence base for areas such as unilateral loss, bilateral fitting and knowing the optimum time to fit the processor depending on the indication. But it is always gratifying when we fit the sound processor to get the almost immediate feedback and it is very rare in any type of rehabilitation to be as sure of the outcome as we are with our Baha children."

Masterclass in Paediatric Baha® Surgery – October 2005

Entific UK are constantly aware of the changing needs of their Baha customers and in particular the demand for increasingly diversified training courses.

At our Manchester training centre we aim to ensure that we offer training courses for all professionals that are involved with Baha at every level of experience, which is why when Mr Patrick Sheehan (ENT Consultant North Manchester) approached us with the suggestion that we run a one-day **Masterclass in Paediatric Baha Surgery**, we were delighted to include this in our selection of courses for this year.

The aim of the day, which will take place in October 2005, is to assist and advise those Surgeons who are already well experienced in adult Baha surgery and are now considering including children in their Baha programme. Some delegates may have already carried out some paediatric cases and have come across different issues that they would like to discuss with other more experienced colleagues.

It is widely accepted that Baha surgery for children requires completely different considerations and techniques so we are bringing together a selection of our most experienced Paediatric Surgeons from around the world to share their expertise, tips and techniques.

For more information and to register your interest please contact the Entific UK office on:

Tel: 00 44 (0) 1625 528214 **Fax:** 00 44 (0) 1625 521930
or **E-mail:** office@entific.co.uk





Through a Father's Eyes

How the Baha[®] system helped one little girl hear her DJ daddy for the first time

Ragan Galloway was born with Treacher Collins Syndrome, a hereditary condition that primarily affects the structures of the head and face. Children and adults with this condition have under-developed ears and many, as in Ragan's case, have some degree of hearing loss, almost always conductive. Here, her father Barry tells the story of his daughter's struggle with her hearing loss and how the Baha system helped enhance her life.



My daughter, Ragan, lived for the first five years of her life struggling to communicate with those around her. The most you could get from her would be a one or two word answer to any question. In fact, you almost had to structure your question so that she could answer with a 'yes' or 'no.'

My wife and I first took Ragan to visit Children's Hospital of Alabama after a friend of the family mentioned hearing about a new surgery that helped those with hearing problems. There, we met with Dr. Audie Woolley, a pediatric otolaryngologist, and told him we wanted to have Ragan's hearing tested to see how severe her loss was before making a decision on what kind of treatment to pursue.

After it was determined that Ragan's hearing loss was significant, Dr. Woolley told us about the Baha system. The only problem was that you had to be five years old for the surgery. At the time, Ragan was only a little over four, so we had to wait.

Dr. Woolley was confident that this was the perfect solution for Ragan. Because

of her narrow ear canals, she couldn't use hearing aids. They would whistle and gave her no boost at all. Dr. Woolley went over every detail about the Baha system and surgery and we were convinced that this treatment could help her.

When Ragan turned five almost a year later we moved forward with the surgery, which was uneventful. Ragan was home by lunch that same day and she was up and running around and playing with no problems. She never once complained of any problems with the surgery.

Six months later, the titanium implant had osseointegrated and Ragan was ready to be fitted with the sound processor – the final phase of the Baha system. Since then, the difference in my daughter is amazing.

Ragan has always been a pleasant child, but before the Baha system surgery she was almost kind of shy. Around the family she was fine, but around strangers she really didn't want to talk or be talked to. After the Baha system surgery she became a totally different child. She now loves being around other people,

especially kids her age. In school she talks to the kids now more than ever.

The greatest moment for me was the day after her sound processor was turned on. I came home from work as a radio announcer and, up until that day, I had always wondered if Ragan really had any idea what I do for a living. But that day I came home...she looked up at me with her eyes shining and said 'Dad, I heard you on the radio today!' At that moment, I knew she probably had heard me talk on the radio for the first time in her life. That was a very special time for me.

The biggest change I have seen in my daughter is her ability to carry on a conversation. Now she is able to answer questions in detail. She is also able to ask you questions and you can understand what she is asking. In the past, it was really difficult to try and understand exactly what she was saying. But her speech is improving each day and it makes her life, and ours, much easier.

We really appreciate Dr. Woolley educating us about this treatment for Ragan. He is the one who suggested the Baha system from the very beginning, but he



Ragan at home with her brother, Reid

also educated us about all the options available to us. He went over every detail step by step. Ragan loved him, and that was unusual. After all our trips to doctors' offices and the hospital, Ragan really did not like to see a doctor or nurse anywhere near her. But she was always comfortable with Dr. Woolley.

Dr. Audie Woolley

Dr. Audie Woolley, of Children's Hospital of Alabama, is a pediatric otolaryngologist with a special interest in pediatric otology, focusing on treating children with hearing impairments and craniofacial needs. He is also the director of the Cochlear Implant Program at the hospital.

Dr. Woolley first learned about the Baha system at the American Academy of Otolaryngology (AAO) Conference three years ago and was immediately interested because it was a unique treatment option for children he was treating with malformed ears and ear canals. "Because



Dr. Audie Woolley

the Baha system does not fit in the ear, I knew this was a viable treatment option for many of the kids I see."

He performed his first Baha surgery two years ago and Children's Hospital has since given 10 children the ability to hear with the Baha system.

"It's wonderful, especially for children

with conditions such as Goldenhars and Treacher Collins because of their complex atresia," says Dr. Woolley. "The Baha system works so much better than hearing aids for these kids and they are all testing in a normal hearing range since receiving it."

Dr. Woolley also offers advice to parents considering the Baha system for their child. "What parents need to know is that this device provides great hearing results, but there can be wound problems, so it's important to take care with good hygiene practices."

Dr. Woolley also thinks the Baha system is a good treatment option for children with atresia because the surgery is simple. "Usually children with complex atresia are poor surgical candidates. There is often a high risk for undergoing the extensive surgeries associated with some treatments, but the Baha system surgery is faster, easier, and produces better hearing results."

Considerations for successful bilateral Baha[®] treatment in toddlers

Myrthe Hol is a member of the Nijmegen Baha team and is currently completing her PhD thesis covering various aspects of Baha treatment, including Quality of life assessment and long-term follow-up, Unilateral and bilateral conductive hearing loss and Baha for Single Sided Deafness. We asked Myrthe to comment on the issues surrounding bilateral Baha provision for children who are too young for surgery.

Hearing is essential for the speech and linguistic development of a child from the very first day of its life. The Baha[®] Softband is a solution for young children with bilateral conductive hearing loss, too young for Baha surgery.

Successful results have been reported with unilateral Baha application in adult patients as well as children with bilateral conductive loss.¹⁻³ However, in patients with bilateral conductive loss, unilateral application of Baha does not provide binaural cues.



Bilaterally fitted Baha[®] Compacts on the Softband

Fortunately, promising results have been reported on the bilateral application of Baha sound processors.⁴ Speech recognition in quiet and in noise is significantly improved as well as a reported improvement in sound localisation.

An immediate advantage of processing information with two ears over listening with one ear is an increase in loudness; louder sound perception will result in better speech recognition. Furthermore, the detection of interaural time and intensity differences might enable sound localization in the horizontal plane. Another benefit is a reduction in deleterious effects of background noise by employing directional hearing.

It is therefore of importance to provide binaural cues to these very young children with bilateral conductive hearing loss by means of bilateral Baha application. Historical research into young animals has suggested that the auditory



Myrthe Hol

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neural structures that enable binaural sound processing only develop normally if binaural hearing is undisturbed. Some authors have suggested that adapting to binaural stimuli is limited to critical periods during development.⁵

Bilateral application of conventional bone conductors in young children is not possible. Typically, a conventional bone conductor comprises a bone vibrator on one side of a steel headband and a hearing aid on the other side. This implies that the microphone is always located at the opposite side of the head to the vibrator. The Baha system is the only bone conductor with the microphone on the same side of the head as the vibrator and is thus applicable for bilateral fitting. The youngest age for percutaneous titanium fixation to skull providing Baha coupling is about three years.

The Baha[®] Softband is an elastic fillet with a Baha sound processor con-



nected to a plastic disk sewn into the band. The band itself is adjustable with Velcro. The sound processor is held against the skin behind the ear, through the pressure from the fillet, and it thus transmits the sound via the skull bone to the cochlea. This application of the Baha system makes use of the conventional transcutaneous coupling of the transducer (sound vibrator) to the skull bone. In unilateral softband application, the sound processor can be placed somewhere on the head, preferably at a location with relatively thin skin. The mastoids and forehead are such locations and the position of the device can be changed during the day. However, in bilateral application the sound processors should be placed on either mastoid requiring special attention to the soft tissue in case of soreness. In addition, regular re-fittings may be necessary because the softband can lose its elasticity over time.

The Baha® Softband was initiated in Nijmegen where the first toddlers worldwide were offered this solution.⁶ One of these children was later fitted bilaterally with the Compact device. Hearing thresholds were assessed with a double visual reinforcement audiom-

etry (VRA) set-up, one on either side of the child. This enabled us to measure aided thresholds and sound lateralisation. The follow-up period was more than 2 years.

Lateralisation of sound was measured using a fragment of a children's song, presented at random at either the right or left side. At three months follow-up good lateralization was observed. Electro-acoustical measurements showed that the frequency responses were comparable between the Baha® Compact and the Baha® Classic, applied in the conventional transcutaneous way, after corrections for the average gain. However, the loudest sounds that could be processed properly were significantly higher for the Classic than for the Compact. This suggests that for the softband application the Baha® Classic is a better choice than the Compact.

The first results of young children fitted with a Baha® Softband show age-appropriate language development. These results urge further investigation in a larger group of children, preferably fitted bilaterally.

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Treating the paediatric Baha® patient

– a report from AAO-HNSF 2004

The 2004 American Academy of Otolaryngology – Head & Neck Surgery Foundation (AAO-HNSF) conference was the venue for a highly attended mini-seminar focusing on the treatment of children with the Baha system. Moderated by Dr. Anders Tjellström, key speakers were invited to talk on a variety of topics that are crucial to the successful management of paediatric patients.



Anders Tjellström opened the meeting, welcoming all participants and introducing the panel of eminent Baha surgeons who had been invited to talk about key aspects of treatment. Dr Tjellström expressed his hope that the subsequent panel discussion and questions from the floor would highlight both the key technical issues and touch on the philosophy behind treating the paediatric patient.



Dr. Anders Tjellström chaired the mini-seminar

Treating the atretic child

The first presentation by Dr Antonio de la Cruz, from the House Ear Institute, Los Angeles focused on treatment options that should be considered for the atretic child. Outlining the problem, he stated that congenital atresia occurs in one in every 10,000–20,000 births, is

more common in males and on the right side, and 1 in 4 cases are bilateral. When considering whether to carry out ear reconstruction as opposed to providing a Baha device, Dr de la Cruz commented that there are two key elements to consider. “Firstly, every surgeon needs to know the level of hearing, which can be difficult to establish in the very young child. Before considering surgery of any kind we need to know objectively whether there is a hearing loss in both ears,” he said. “Secondly, we need to establish from CT scanning the 3 dimensional relationship between the relevant anatomical structures. A child with what I would consider a ‘minor’ malformation would be a candidate for ear reconstruction as would any child presenting with cholesteatoma.” Dr de la Cruz continued by describing the situation when a child is considered inoperable. “Where there is no space to reconstruct the canal, combined with inner ear malfunction and facial nerve abnormality, I would recommend Baha treatment.” His talk concluded with comments regarding optimum age for reconstructive surgery and addressed the, sometimes controversial, question of whether or not to reconstruct the child with a unilateral loss. Comments from the panel included the psychological and educational importance of providing a hearing solution at an early age for

bilateral atresia and of choosing the most predictable solution for the case in question.

Paediatric Baha surgery

The second speaker was Dr Blake Papsin of the Toronto Sick Children’s Hospital. With 8 years of experience with Baha, Dr Papsin originally became familiar with the system at the Great Ormond Street children’s hospital in London, UK. Dr Papsin was asked to discuss considerations for paediatric Baha surgery and in particular to look at aspects of surgical controversy in the very young child. Key issues raised covered the following topics: one-stage versus two-stage surgery in children, the possibility of ‘banking’ a spare fixture, optimum implant size, potential problems related to dura and sigmoid sinus exposure and the options available in terms of membrane techniques. Touching on the issues raised when considering children with craniofacial abnormalities, Blake Papsin stated that the key issue is calvarial thickness. He also highlighted the importance of considering the age and maturity of the child, the attitude of the parents and the distance from care in terms of follow up. Dr Papsin discusses these issues in our more in-depth article on pages 12 & 13.



Unilateral hearing loss in children

Dr Jack Wazen introduced the topic of the impact of unilateral hearing loss (UHL) in children and the applicability of any type of hearing rehabilitation for these children. Based at the Columbia Presbyterian Hospital in New York, Dr Wazen was one of the first clinicians involved in Baha treatment in the US. Jack Wazen began by stating that, “the handicap experienced by those with UHL has long been underestimated. Difficulties include hearing sound from the deaf side, understanding speech in noise and feelings of imbalance. In children these problems often manifest themselves as uncooperative and inattentive behaviour in school.” The prevalence of UHL is estimated to be between 0.04–3.4 % in newborns rising to 0.1–5 % in children generally. “Advantages of binaural hearing include sound localisation, reduction of the head shadow effect, binaural summation, improved speech recognition in noise and improvements in spacial balance and listening ease,” he continued. Describing traditional interventions, Dr Wazen touched on preferential seating in school, parental/teacher education, the use of various amplification systems and the importance of screening for speech and language delays when investigating educational and behavioural difficulties. “Looking for objective evidence of the negative impact of UHL in children, we have reviewed the literature. Cho Lieu et al. reviewed 19 papers on the

effect of UHL on speech, language and education. The results showed a zero to significant incidence of speech and language problems with a significant number of children having considerable difficulty in school. 22–25 % had to repeat at least 1

grade and 12–41 % received additional educational support.” Reviewing two further papers, Jack Wazen described speech development and academic failure in children with UHL compared to their peers. “We now recognise the benefits of binaural hearing. The appropriateness of binaural hearing has become more of a standard in the provision of binaural hearing aids. And we no longer hesitate to provide stapedectomy in unilateral otosclerosis to provide binaural hearing,” he continued.

Discussing the results of several studies carried out by his group, Dr Wazen showed that the results of the hearing handicap inventory carried out in adults with unilateral conductive or mixed loss showed a significant drop in the handicap from pre to post implantation with Baha. “Baha has proved to be a safe and effective device and to have good patient acceptance,” he commented. In addition, a questionnaire on patients with unilateral loss wearing Baha on their deaf side showed that the great majority enjoy use of the Baha device 7 days a week, 8 hours a day. “Whilst it is intuitive to expect better performance with binaural hearing, the lack of reproducible, objective evidence I believe stems from, in part, a deficiency in appropriate scientific methods to prove the point and reproduce real life experiences; to measure improvement when the patient, subjectively, is fairly

convinced of it,” he concluded. At the end of this presentation, Anders Tjellström passed on a comment from Mr David Proops of the Birmingham Children’s Hospital, UK, who could not be present on the panel but had sent some comments for inclusion by email. “We offer Baha for adults with SSD, how can we deny the child?”

Autogenous v. prosthetic reconstruction & Baha

Finally, from John Hopkins, Baltimore, Dr John Niparko spoke in depth about treatment options for children with aural atresia with or without microtia and how to offer guidance to the parents. During his talk, Dr Niparko addressed issues related to both the external ear and the ear canal. He pointed out that, prior to 1990, neither Baha nor implant retained prostheses were an option in the US for regulatory reasons. “In fact,” he said, “any one of the four options now available can interact with the others.” Regarding external ear reconstruction using autogenous cartilage he commented on the importance of the size of the auricular remnant and the difficulties associated with treating children with microsomia and Treacher Collins due to the deficiency of the skull base. Dr Niparko also paid tribute to the outstanding results achieved for microtia repair with autogenous cartilage as represented by the work of Dr Bert Brent and showed successfully reconstructed cases where there had been auricular remnants preoperatively and significant skin, and in some cases soft tissue and a lobule, enabling accommodation of the cartilage skeleton. “If autogenous reconstruction is chosen this will directly affect whether the child will have a Baha device and where it will be placed,” he commented.

However, Dr Niparko also focused on the psychological impact of an

unsuccessful autogenous cartilage reconstruction. "Not only has the child been born with a deficiency in craniofacial anatomy but also they have a reconstruction that's gone bad." He pointed out the importance of being able to predict when one might see a pinna reconstruction that has the proper contours, delicacy and trajectory to achieve a cosmetically pleasing result. "On the other hand," said John Niparko, "in cases of complete anotia prosthetic reconstruction using osseointegrated implants can provide the opportunity for the prosthetic professional to fashion a prosthesis with a fine anterior edge that defies detection." He continued by showing several successful cases with tissue integrated prostheses.

With regard to ear canal reconstruction, and acknowledging the practical and professional work of Dr de la Cruz, Dr Niparko continued, "the Jahrsdorfer criteria capture the anatomy and syndromic considerations that help us to decide whether to go with canal repair and tympanoplasty or with the Baha approach." He also referred to the question of bilateral ear canal reconstructions as opposed to the Baha alternative during the decision making process. "For the family, he said, "the timing is also critical. For microtia repair it has been shown that the first psychological trial comes at the age of 6 or 7 when the child is immersed in a group of peers on a continuous basis. Then in adolescence when 'fitting in' and being 'cool' is the primary concern." Addressing age and timing for prosthetic reconstruction John Niparko discussed the adequacy of cortical bone and the requirement for hygiene and 'taking care' of the abutments and surrounding tissue. For the Baha approach he commented on greater awareness of newborn screening for hearing loss and parental pressure to use the softband at an early age for speech and language input. "It

is quite remarkable to see the delight in the children even when very young," he commented. Finally Dr Niparko discussed the potential to compromise future microtia repair if a Baha implant is placed beforehand. "If there is any possibility of future reconstructive surgery, we would suggest that the implant is placed at least 3 cm from the prospective auricular rim, thus placing the Baha in a more posterior position than usually chosen," he concluded.

The symposium finished with discussion between the panel and the audience covering a wide range of issues including how to predict when a child will be happy with their Baha device. Although many clinics use the headband or softband either at the clinic or in the home situation, Jack Wazen stated that the 'wow' effect was the best indicator, "an immediate reaction, a smile or widening of the eyes opens the door for acceptance to both the device and implantation."



Entific Medical Systems Inc. was pleased to have been part of the American Academy of Otolaryngology – Head & Neck Surgery Foundation (AAO-HNSF) 2004 Annual Meeting and Expo.

The conference took place September 19-22 at the Jacob K. Javits Convention Center in New York. The agenda offered attendees various presentations featuring the Baha system including:

"Incorporating Implantable Hearing Devices in a Private Practice Setting," presented by James S. Atkins, Jr., M.D.; ***"Pointers and Pitfalls in Baha Surgery,"*** presented by Anders Tjellström, M.D., Ph.D.; ***"Baha and Auricular Prostheses in Children,"*** presented by Blake C. Papsin, M.D. and Adrian James, FRCS; ***"Baha: Implantable Bone Conductor,"*** presented by Anders M.R. Tjellström, M.D., Ph.D. and John K. Niparko, M.D.; ***"Implantable Hearing Devices: Indications, Surgery, Outcomes,"*** presented by Jose N. Fayad, M.D., Jaclyn B. Spitzer, Ph.D., and Jack J. Wazen, M.D.; and ***"Management of Sudden and Progressive Sensorineural Hearing Loss,"*** presented by Mitchell K. Schwaber, M.D. and John F. Kveton, M.D.

The 2004 conference welcomed more than 10,000 attendees and the Entific booth experienced high traffic. The conference was a great success and Entific looks forward to participating in 2005!

One-stage Baha® Surgery in Children: *Our Experience*

By: Drs. A. della Volpe, N. Mansi, A.M. Varricchio, Department of Otorhinolaryngology,
Santobono Children's Hospital, Naples, Italy



The ENT team at the Children's Hospital in Naples lead by Dr della Volpe have been treating children with the Baha system since 2002 and to date have 11 paediatric Baha patients in their care. Almost two years ago the team moved to a one-stage surgical approach for their paediatric patients in order to lower the inherent risks associated with general anaesthesia for atretic children.

Front row from left: V. Pastore (Audiology technician), F. Mariosa (Speech therapist), N.Mansi (Head of ENT), T. Cotecchia (Audiology technician), A.M. Varricchio (Fellow in ENT).

Back row from left: A. Bojano (Audiologist), R. Izzo (Head of Audiology), A. della Volpe (Head of Baha & cochlear implant programme).

In paediatric patients with bilateral atresia, Baha treatment represents a valid alternative in the rehabilitation of conductive hearing loss that is inevitably associated with a delay in language development.

Our experience concerns 8 children (5 males and 3 females) with an age range of 2 to 12 years. Of these, 5 were affected by isolated auditory atresia and 3 had auditory atresia associated with Franceschetti syndrome.

Preoperative audiological testing was performed to confirm the eligibility of our patients to receive Baha treatment. To achieve this, an audiogram was used to determine whether the patients

had sufficient bone conducted hearing and word recognition in order to use the device successfully. A bone conducted four frequency (500–1K, 2K, 3K) PTA of less than 45 dB HL and a word recognition score of greater than or equal to 60 % for PB words was preferred. All children had been wearing a traditional bone conduction device prior to their inclusion in the programme.

For all children enrolled in the programme, Baha implantation surgery was performed under general anaesthesia and as day-case surgery. Beforehand all of the children concerned underwent a CT scan of the temporal bone with particular focus on the zone

where the implant was to be inserted. Bilateral implantation was performed in only one child and in this case there was a delay of nine months between fixture placement and abutment connection. Indeed, we usually prefer to install both the fixture and the abutment in a single procedure in order to avoid the children undergoing two interventions with general anaesthesia. One-stage surgery is thus carried out as a single 30 minute procedure instead of two procedures, each lasting 30 minutes.

The surgical technique we use is as follows (see Figs. 1–6):

1. Implant placement (and subsequent positioning of the Baha sound

processor) is based on a standard measurement and direction from the external meatus; 50–55 mm from the ear canal. It is fundamental that the device is positioned so that it does not touch the pinna of the ear.

2. In order to avoid hair re-growth and improve sound quality, we perform a very thin flap (about 25 mm in diameter and < 1 mm thick) and we remove all the subcutaneous tissue and the periosteum only from the small area where we drill the hole. A 3 mm hole for the fixture is drilled in the temporal bone (3 mm implants have been used in all our cases), followed by tapping and then fixture insertion. To date we have not used the new self-tapping system.

3. In the one-stage procedure the titanium abutment is immediately secured to the fixture with a screw.

4. Then we suture the skin and connect the healing cap.

For all patients we wait nine months before connecting the sound processor to ensure good bone integration of the titanium implant. The follow up period ranges from 3 to 18 months.

Interestingly, children treated with the Baha device have clearly reported greater benefits in speech intelligibility – from 106/140 to 132/140 syllables (without masking) and from 100/140 to 120/140 syllables (with masking). Fig. 7 shows vocal audiometric values of children treated with traditional bone conductor (pink line) and with Baha (yellow line).

In our study population to date we have experienced neither problems with osseointegration nor infection of the surgical wound. Thus, we believe that the one-stage Baha surgical procedure can be used successfully for children as well as for adult patients.



Fig. 1 - Thin skin flap



Fig. 4 - The abutment connected to the fixture



Fig. 2 - Removing the periosteum



Fig. 5 - Suturing



Fig. 3 - Drilling the hole for the fixture



Fig. 6 - Nine months after surgery: connecting the sound processor

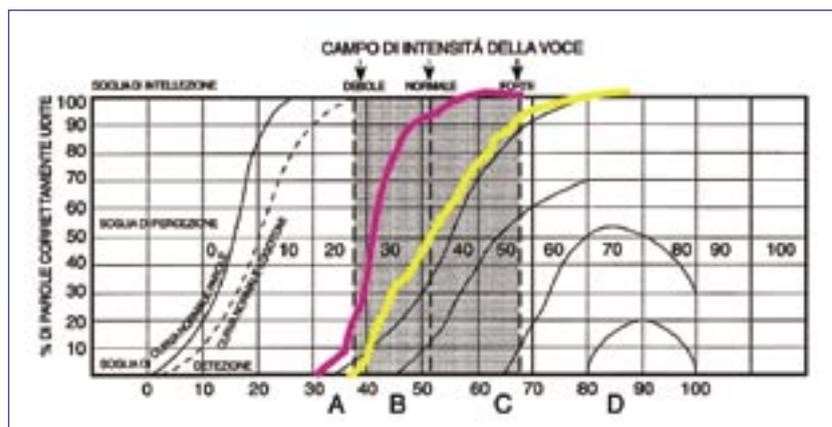


Fig. 7

A Technique for Pre-operative Determination of Fixture Position in Children

By: Dr. Maurice H. Hockman FCS (Otol) SA, Dr. Martin Gill FCS (Otol) SA
& Dr. Charles Sanyika FCRad (Diag) SA
Linksfeld Park Clinic & Olivedale Clinic
Johannesburg, South Africa



Dr. Maurice Hockman

“Our Baha programme, the first in South Africa, was initiated 4 years ago, developing out of the Johannesburg Cochlear Implant Program. To date 24 patients have received a Baha sound processor including 4 children with bilateral aural atresia. Several other Baha centres have since been established in South Africa.”

The thickness of the child’s skull can be a major limiting factor in paediatric Baha placement. If a 3 mm long fixture is to be used a minimum skull thickness of 2.5 mm is required.¹ Due to the variable thickness of the child’s skull it is well known that at surgery a number of “test holes” may have to be drilled before a site with adequate skull thickness is found.² Using Computerized Axial Tomography (CAT) the thickness of the skull can be measured at any specific position. This possibility has enabled us to devise a technique for determining, pre-operatively, the optimal position for fixture placement.

Method

The method involves a Helical CAT scan through the head with 3D soft tissue reconstruction.

CAT Parameters used:

Slice thickness	0.2 cm
KV	120
MA	200
SEC	0.75
FOV	240

Using the lateral view of the 3D soft tissue reconstruction the position for fixture placement is chosen in the following manner (see Fig. 1):

- Line AB is drawn from the lateral canthus of the eye (point A) to the presumed site of the external auditory canal on the pinna remnant (point B).
- Line BC is then drawn on a 50mm arc originating from point B.
- Point C is the potential site for fixture placement.
- An arrow marker is introduced at point C.

By scrolling through the axial cuts of the CAT scan of the head, the arrow may be located and the thickness of the skull is then measured at that point (see Fig. 2).

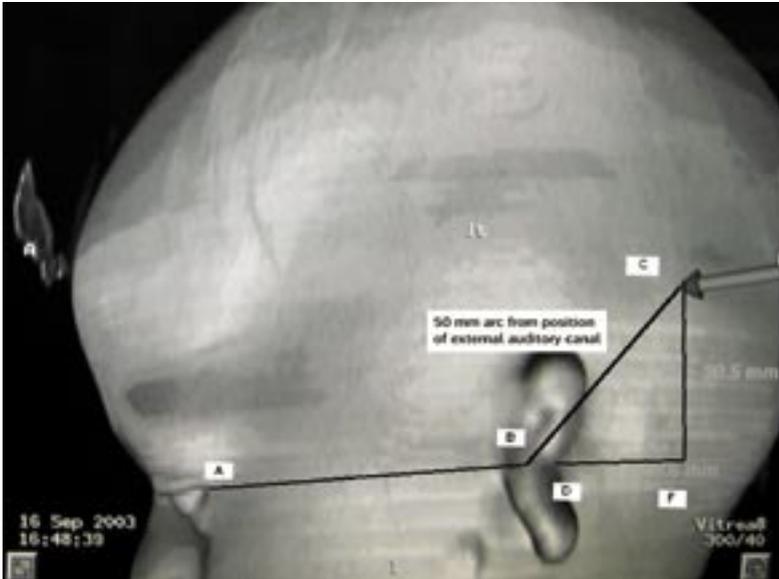


Fig. 1: 3D CAT soft tissue reconstruction of the head, lateral view, with measurements of fixture site at point C

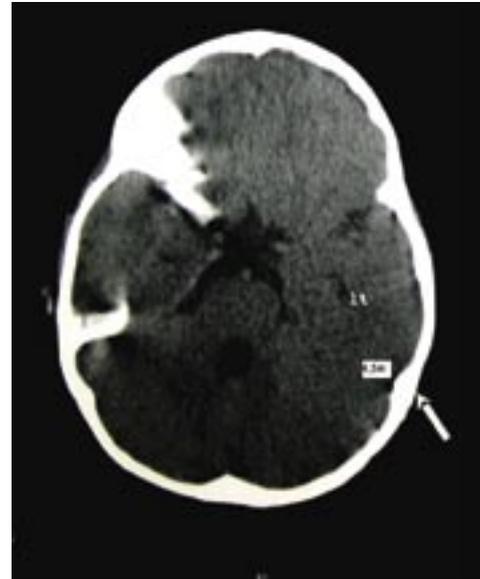


Fig.2: Axial CAT of head at cut showing the marker arrow and skull thickness

It is important that we are then able to locate the site that is likely to be most appropriate for surgery during the surgical procedure. In order to achieve this measurements of the chosen site are determined from landmarks on the pinna remnant that will be identifiable at surgery. For example points D and F (see Fig.1). The lengths of line DF and line FC are noted for use in surgery.

Summary

This technique has been used in 4 cases of bilateral aural atresia in children aged between 3 and 4 years. It has proved to be very accurate in predicting the skull thickness at the chosen site. In none of the cases was it necessary to drill a second hole. The technique can thus significantly shorten operative time and prevent complications that may follow the drilling of multiple sites.

References

- 1 Tjellstrom A., Hakansson B., Granstrom G: Bone-Anchored Hearing Aids Current Status in Adults and Children. *Otolaryngol Clin North Am* 34: 337–364, 2001
- 2 Granstrom G., Tjellstrom A: Guided Tissue Regeneration In The Temporal Bone *Ann of Otol Rhin and Laryngol* 108: 349–354, 1999

Happy Christmas, Oliver!

Oliver is a four year old boy with Alagille's syndrome who cannot wear an air conduction aid due to constant infections. Two days before Christmas 2004 Oliver was fitted with a Baha® Softband and Compact sound processor. "All Oliver wanted was to be able to hear his favourite TV programme, 'Brum'", said Louise McMichael, Entific UK's Sales Training Manager. "He came running into the clinic to see his new softband with Aliens on it. Within minutes Oliver was stomping around as if he had heard his feet for the first time. He could even hear the audiologist whisper to him from behind her hand!"

Oliver is under the care of audiologist and clinical scientist Bernie Twohig at the Hearing Services Dept., St Marks Hospital in Coventry, UK.



In Brief

Entific is constantly working on small product changes to make sure all instrumentation remains compatible
 – ‘In Brief’ keeps you informed!

Longer cords for Baha® Cordelle

Following many requests from our customers we will be replacing the 50 cm Cordelle cord with a longer 75 cm cord. The 75 cm cord is available in beige for beige and grey processors and in black for the black model.

Article number	Denomination
90623	Cordelle Audio Cord, beige, 75 cm
90625	Cordelle Audio Cord, beige, 150 cm
90627	Cordelle Audio Cord, black, 75 cm
90629	Cordelle Audio Cord, black, 150 cm

New article numbers

The following components remain the same but have been allocated new article numbers.

Old article number	Denomination	New article number
SEC 002-0	Flange fixture 4 mm	90493
90206	Fixture 4 mm	90613
SDCB 028-0	Cover Screw Space w. internal hexagon	90620
DIB 037-0	Screwdriver Internal Hexagon long	90480
26672	Machine Screwdriver 20 mm Unigrip	90380
DIC 010-0	Open-end Wrench	29082
DIC 259-0	Abutment Holder Plastic	90640
AS 43-245-36	Raspatorium	PI 010/36
90436	Healing abutment 7 mm Unigrip	90193

New article number for the Safety line

The article number for the Safety line, HCB 282, has been changed to HCB 282-0.

Longer Baha® Softband

The new Baha® Softband Long is especially designed for children with larger heads and for adults who are waiting for Baha surgery. This longer version is 60 cm long and the Velcro® fastening allows flexible fitting. The product will be available from the beginning of March and is delivered in a kit containing two Softbands; one black and one beige. The product number is: 90655.



New packaging for Implanted handpiece tubing

W&H has improved the packaging of the handpiece tubing (both as a spare part and when packaged together with the handpieces). The new plastic bag must be torn apart and it is no longer possible to reseal the package – see photo.



Baha® & Tinnitus Retraining Therapy: Initial Findings

*By: M P Thill, MD & P Lurquin, MA, ENT Department
CHU St Pierre, Brussels, Belgium*

The Baha system is now used for the rehabilitation of a unilateral dead ear and has shown good results. In some patients a dead ear is accompanied by a more or less incapacitating tinnitus, leading to discomfort and depression. In our tinnitus clinic we are very familiar with Tinnitus Retraining Therapy (TRT), combining counselling, emotional management and the fitting of a white noise generator. We apply TRT to very symptomatic patients. To help with the selection of these patients we use various different questionnaires. One of them, the Tinnitus Handicap Inventory (THI), is designed to establish the extent of the emotional, functional and overall distress that the condition is causing the individual. A THI of >40 % has been shown to be a good indication for TRT.

Knowing the concept of using Baha for Single Sided Deafness and given the encouraging results of TRT (80 % improvement in our tinnitus population at 4 months), we wondered if the combination of these two techniques would result in better symptom control. We tested our hypothesis in 2 patients:

Case 1: C.N., a 57-year-old woman, was operated by the translabyrinthine approach for a left vestibular schwannoma, resulting in a left total hearing loss and an enhancement of a pre-existing tinnitus in that ear. The patient couldn't sleep anymore and developed a persistent headache, a gastric ulcer and severe depression. She asked for advice as medical treatment had not given her any relief. We found a low frequency tinnitus and a THI score of 56 %. At work, the patient was also impaired by her unilateral loss. We

suggested the use of a Baha sound processor on the dead side combined with an 'in-house' producer of white noise within a Phonak MLX shoe attached to the Baha device at the audio input. We carried out TRT combining counselling, emotional management and white noise. After 3 months of therapy the THI score fell from 56 % to 12 %, the patient was no longer disabled by her tinnitus and she had already developed better sound localisation.

Case 2: C.H., a 58-old-woman, had one year earlier suffered a sudden total left-sided hearing loss – probably of vascular origin. Her hearing loss did not recover even after multiple medical treatments. The total deafness was accompanied by an incapacitating tinnitus of 6 kHz which badly affected her family and professional life, resulting in tiredness and depression with a THI of 88 %. A Baha device fitted with a white noise generator was used and TRT was carried out. After 3 months of therapy the patient was very satisfied, was no longer depressed or anxious and the THI score dropped from 88 % to 24 %. There was also an improvement in sound localisation.

In conclusion, the combination of Baha and TRT showed very good results in these two patients and greatly improved their quality of life. Further patients are now being selected in our tinnitus clinic to better evaluate this new technique.

N.B. A more detailed study based on these initial findings from St Pierre Hospital will be published in *Bone Anchored Applications* later this year.

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