

THE BONE-ANCHORED HEARING AID: AN ALTERNATIVE FORM OF HEARING RESTORATION

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INTRODUCTION

Improved hearing rehabilitation of patients with chronic middle and external ear diseases and atresias is now possible using the bone-anchored hearing aid system. Sound vibrations are directly transmitted via the skull to the cochlea by means of a skin-penetrating titanium implant, bypassing the middle ear. The improved quality of life reported by patients is a combination of increased quality of sound, better comfort, and relief from the irritation of the canal wall skin of the meatus occasioned by conventional air conduction hearing aids.

My intention in writing this article is to increase the awareness amongst the general practitioners in the Morecambe Bay and Lancaster area of an alternative form of hearing rehabilitation utilising the bone-anchored hearing aid.

THE PROBLEMS

Patients with a diagnosis of chronic otitis media and with persistent otorrhoea are not uncommon in clinical otological practice. Surgical and/or medical treatment of middle ear disease and the conductive hearing loss to produce a disease-free ear with satisfactory hearing has been performed for 30 years with increasingly successful results. It is not, however, successful in all cases and a sound amplification device is required to rehabilitate the patient. Persistently discharging ears, often associated with inflammation and irritation of the meatal skin, precludes the wearing of an air conduction (AC) hearing aid because the mould insert to the ear meatus tends to exacerbate both the otorrhoea and the inflammation of the external meatal and canal wall skin.

A more unusual condition is where there is no formation of the external canal wall due to a congenital atresia which may occur as an isolated condition or be part of a syndrome such as Treacher Collins. Complete stenosis of the external auditory canal can also arise as a complication of severe otitis externa. Patients with otitis externa who have sensorineural hearing loss when fitted with an in-the-ear canal mould for hearing aid rehabilitation, often experience an exacerbation of the otitis externa which prevents them wearing the aid.

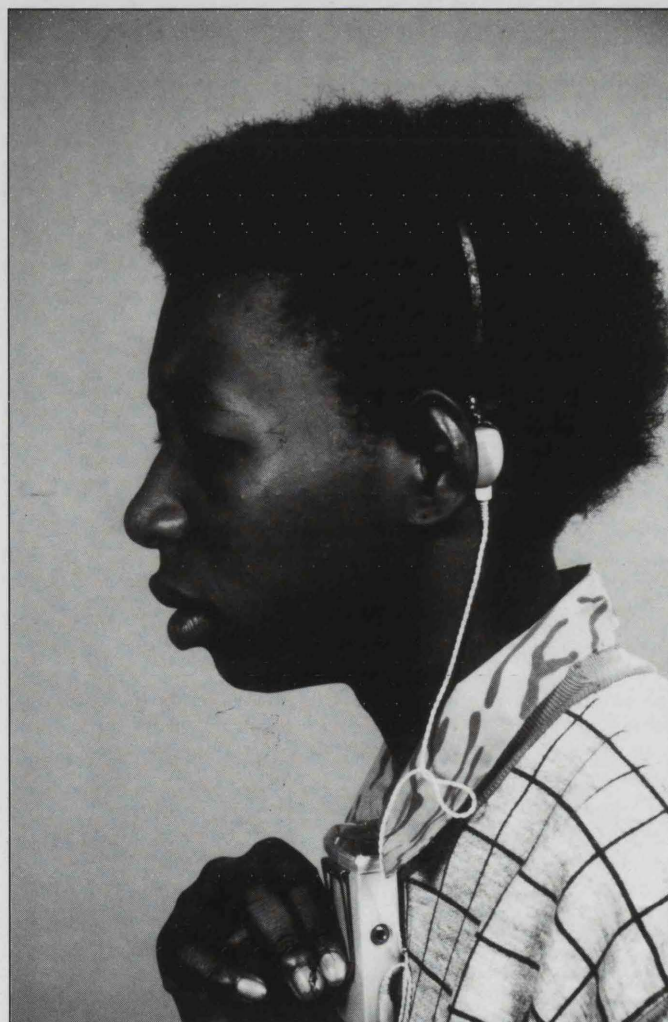
Patients who cannot wear an AC hearing aid but still need sound amplification may be helped by a conventional bone conduction (BC) hearing aid. The principal otological indications for such a device are:

- chronic otitis media, usually with otorrhoea and/or secondary otitis externa
- acquired meatal stenosis

- congenital malformation of the middle or external ear that cannot be surgically corrected.

Other acquired forms of conductive hearing loss such as otosclerosis which results in fixation of the stapedial footplate, or extensive tympanosclerosis which results in ossicular fixation, can be treated by surgical intervention, the alternative being a hearing aid, either AC or BC type.

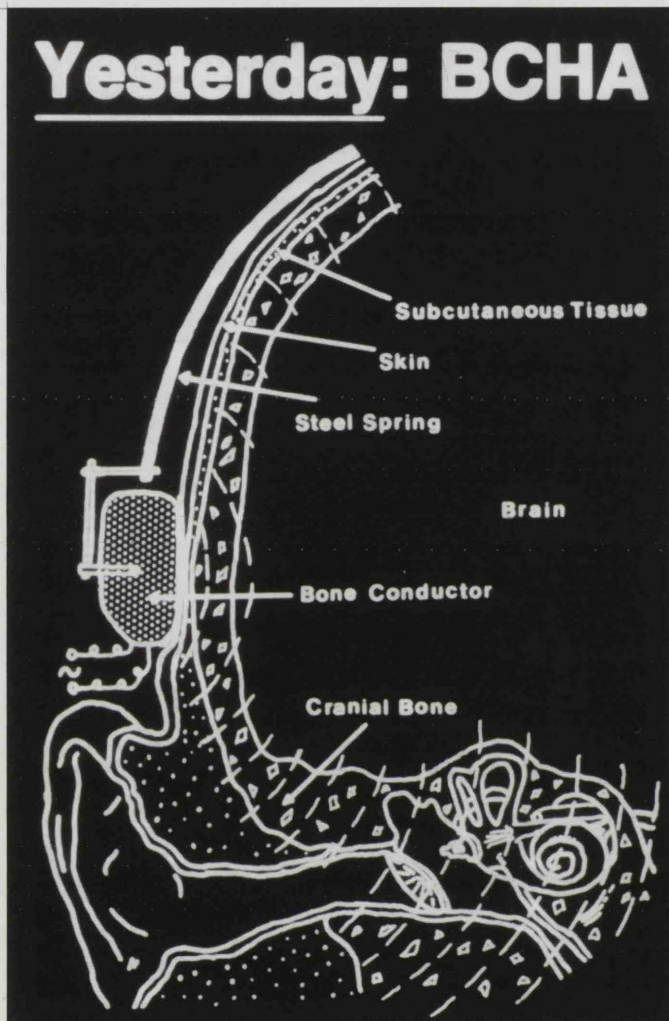
Patients who wear a conventional BC are uniformly unhappy and commonly express complaints, including discomfort, poor sound quality, skin irritation at the site of the BC together with an intense dislike for the actual appearance of the conventional BC aid itself. These complaints are explained in more detail below.



Conventional bone conduction hearing aid (BCHA). Note Alice band, battery box and wire

PATIENT DISCOMFORT

A BC must be applied with a steady pressure to the mastoid region of the temporal bone. This force causes pain, headache, irritation of the skin and eczema. The fitting of the BC with a steel spring or headband (Alice band) is often experienced as uncomfortable and unsightly. In order to reduce acoustic feedback from the BC to the microphone, the two devices have to be separated. The device is cumbersome, and in addition, because a power supply is required, an external battery box and wire must also be worn.



BCHA sound transmission to cochlea

POOR SOUND QUALITY

The quality of the transmitted sound has relatively low fidelity, due to an effect of soft tissue attenuation. Variations in the quality of the transmitted sound occur as the BC is not applied at exactly the same place every time. The BC may also be attached to or mounted in spectacle frames to position it against the mastoid process of the temporal bone with constant pressure. In this situation, the acoustic performance of the aid tends to deteriorate with increased operation time because of the inherent flaccidity of the spectacle frames.

Some patients with middle ear disease use an AC hearing aid despite a draining ear. It is well known that the occlusive effect of an AC aid ear mould, together with the continual presence of an ear mould covered with bacteria and discharge from the middle ear infection, militates against the cure of otorrhoea.

NOBELPHARMA AUDITORY SYSTEM

The Swedish Bone Anchored Hearing System (BAHA),

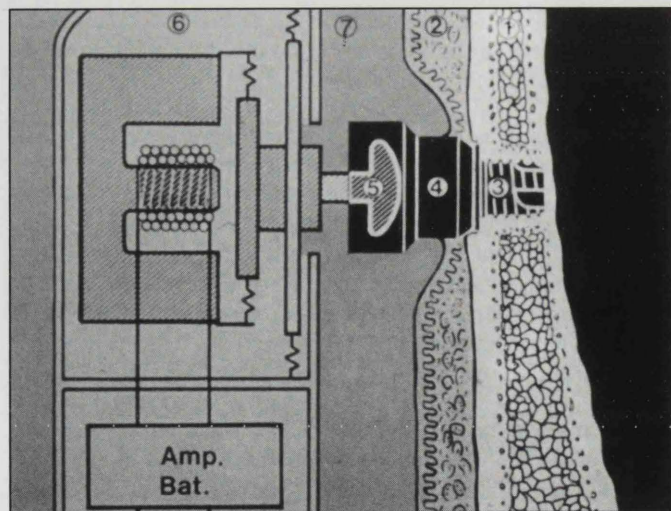
commercially available from Nobelpharma UK Ltd, was developed by the departments of otology and applied electronics at the University of Gotoborg in Sweden in 1977. The system consists of two parts, an external part referred to as the sound processor bone conduction transducer, which is attached via a skin-penetrating titanium abutment onto the



BAHA abutment - cf BCHA band

internal part, an implanted titanium bone fixture. With the BAHA, sound transmission to the skull is direct. In this way it is possible to achieve the same hearing thresholds as transcutaneous conventional bone conduction, but with a lower output of the transducer and considerably less sound distortion.

The titanium bone implant consists of a threaded cylindrical fixture, made of pure titanium, with a perforated flange at the top of it. Dimensions are 3.75mm diameter and 3mm or 4mm in depth. As illustrated below, the skin-penetrating abutment is firmly fixed to the bone implant with the connection screw. Inside, it is fitted with a plastic insert, which is circumscribed by a silicone 'O' ring holding the insert in place and serving as a safety release if the external sound processor is exposed to external forces. The vibrating piston of the sound processor fits into a slot in the plastic insert and is locked in place by a 90° turning motion. To prevent the total avulsion of the planted fixture, the vibrating piston is designed to shatter when an external force is applied to the sound processor.



BAHA attached via piston to abutment from osseointegrated fixture

SUITABLE PATIENT SELECTION

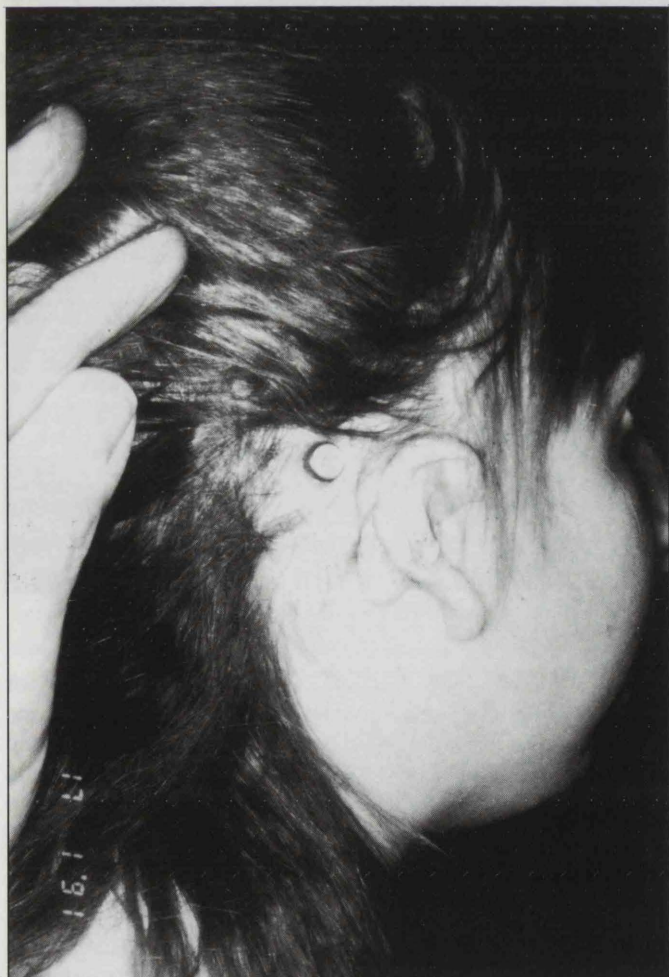
The minimum mean bone conduction threshold across the frequencies of 500hz to 4hz must exceed 40dB for the

conventional BAHA device. Those with a poorer sensorineural reserve to 60dB can wear a super base BAHA with a body-worn transducer. Speech discrimination must be greater than 60%. Thickness of the temporal bone of the skull itself precludes implantation below the age of three or four years. The patient must have a realistic expectation of what the BAHA can achieve in terms of improved hearing ability. Using a bite test bar which is held between the teeth with a BAHA attached, pre-operative patients are able to gain an impression of the eventual hearing result they will achieve with the device. Since there is a skin-penetrating abutment on the scalp which requires daily maintenance hygiene, it is important that patients selected for implantation could reasonably be expected to look after the implant site, after suitable instruction, on a lifelong basis.

SURGICAL PRINCIPLES OF IMPLANTATIONS

The phenomenon of osseointegration where healthy living bone unites with the extremely thin covering of titanium oxide present on the surface of pure titanium implants to produce a rigid, permanent union, was first identified by Branemark and his team at Gotoborg in Sweden in the 1960's. Over half a million dental implants have been used world-wide in the treatment of edentulous patients. Titanium implants attached with a bone-anchored hearing device have been in clinical use in Sweden since 1977.

The site for the titanium abutment can be anywhere on the skull but, conventionally, is placed behind the right ear in a right-handed person within the scalp, thus facilitating easy cleaning, and insertion and removal of the BAHA from the



The abutment site

abutment. Under local or general anaesthesia, a 2cm scalp incision is made, the periosteum incised and a small hole drilled into the temporal bone. In order to maximise the viability of the bone margin surrounding the hole, slow drill speeds are used together with copious cooling to prevent overheating and death of the bone. The hole is then tapped to create a threaded surface to allow the screwing of a titanium fixture into the viable bone. The periosteum is then replaced and the scalp flap closed. The patient is allowed home later the same day. Over the next three months osseointegration occurs and produces a firm union between the titanium fixture and the skull.

The second stage procedure is also carried out on a day-case basis, usually under general anaesthesia. A 2cm disc of scalp is excised and the underlying scalp margins are thinned considerably. A very thin, hairless skin graft is taken from the postauricular area and sutured in position over the defect in the hairbearing scalp. The skin graft is punctured and an external abutment is applied to the osseointegrated titanium fixture. Thereafter, a healing cap is applied and the skin graft is held in place by gauze soaked in antibiotic ointment. After the skin graft has firmly adhered to the underlying periosteum and margins of the external abutment, the patient is ready to be fitted with the bone-anchored hearing aid.



BAHA in place

A useful analogy for the idea of permanent skin penetration by an external abutment is that of a tooth and the periodontal membrane. The gingiva is firmly attached to the periodontal membrane and movement does not occur. Similarly, the split skin graft is firmly adherent to the periosteum and movement does not occur around the abutment. If this were not the case, flexion and loosening would produce gingivitis and loss of the tooth: similarly, granulations lead to loosening of the fixture. Just as the patient must continue to brush his teeth to maintain a healthy gingiva, he must also clean the abutment site where it meets the split skin graft, to prevent loosening.

ADVANTAGES OF A BAHA

Since the external canal is not occluded by an ear mould and any mastoid cavities are aerated, the incidence of persistent otorrhoea is considerably diminished. As a consequence of reduced otorrhoea and lack of direct contact with ear mould material, otitis externa is abolished. The patient is unaware that he is wearing a hearing aid as, to all intents and purposes, it is weightless as it is firmly attached to the skull. Except with the shortest of haircuts, the hearing aid is unseen. The sound reproduction qualities are excellent. The most grateful

patients of all are those adults who have worn conventional BC aids for many years and for the first time can hear "the leaves rustling in the trees". Patients in the past who might have undergone complicated surgery for meatal atresias and stenosis of the inner ear with many potential risks can have their hearing restored with no risk whatsoever to their cochlea. The same argument applies to the treatment of otosclerosis, especially in young patients, as unlike stapedectomy surgery, there is absolutely no risk to the cochlea.

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| <ol style="list-style-type: none"> 1 Any patient who uses a conventional BC hearing aid 2 Any patient who uses an AC aid, despite draining ears 3 Any patient who needs amplification in whom an AC aid cannot be used: congenital atresia where reconstructive surgery is contraindicated operated congenital atresia with draining if mould is used some patients with chronic ear disease patients with radical cavities experiencing acoustic feedback otosclerosis. |
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Table 1 - Indications for bone-anchored hearing aid

NOBELPHARMA CLASSIC 300 BHA

Like all new technologies, there is a financial cost which I feel is money well spent, given the dramatic improvement in the recipient's hearing abilities and overall quality of life. The costings involved for the Classic 300 BAHA supplied by Nobelpharma are:

	£
Nobelpharma Classic 300 BAHA hearing aid device	975
titanium implants and external attachments	690
hospital stay and surgery	335
TOTAL £2000 inc VAT	

The hearing aid itself has a five year unconditional warranty - even if it were run over by a bus, it would be replaced. Extra-contractual referral to the Queen Elizabeth Hospital in Birmingham for this procedure costs about £7,000, though a lower figure is quoted by the ENT unit at Salford Royal Hospital.

The bone-anchored hearing aid programme in the UK was established at the Radcliffe Infirmary in Oxford in the 1980's and prior to my appointment to Furness and Westmorland General Hospitals in 1991, I spent a year as clinical lecturer in ENT at the Radcliffe and performed fifteen first and second stage procedures and ran the BAHA clinic. Although the population base of Morecambe Bay is relatively small, I feel that there are considerable numbers of suitable patients who would gain significant benefit from this alternative form of hearing rehabilitation and I am seeking to establish a BAHA unit at Furness General Hospital. The cost to the Health Authority for treatment locally would be considerably less than it is for extra-contractual referral. Patients would benefit by not having to travel long distances and stay overnight in hospital, which they must at present as there are two surgical procedures. A local BAHA unit would also cut out the need for long-distance outpatient visits for follow-up audiological and surgical assessment. The aim would be to treat adult patients, as the number of children with congenital atresia born in our district in a given year would be too low to maintain an adequate level of expertise, which is in any case available at the Royal Manchester Children's Hospital

Implant Centre under the charge of Mr Michael Rothera. Paediatric atresias should all be referred to this centre of excellence. The children's parents can then be fully informed of all aspects of the child's problem and receive all the necessary support, whether it is genetic counselling, referral to the cranio-facial unit or simply being put in touch with other families who have the same condition. "There is no doubt", says Mr Rothera, "that detailed information and support are vital to help the parents to come to terms with their child's disability. There is always an element of guilt and if this can be dispelled at an early stage, children are brought up in a more confident manner which seems to influence their decision about cosmetic surgery in later life. Once the parents realise that there is a variety of procedures that can help their child in the future, much of their anxiety disappears."

Bone-anchored hearing aids are not usually considered before the age of five but there are some excellent conventional bone-conduction hearing aids which can be fitted at a very early age to allow normal hearing and language development. The small number of children living in the Furness peninsula who have undergone successful implantation at Manchester Children's Hospital have benefitted from shared care in that the surgical dressings and care of the implant site and hearing aid is carried out at Furness General Hospital.

I am told that Morecambe Bay would consider funding and establishing a unit if it can be demonstrated to them that there are sufficient patients with an unmet need for hearing rehabilitation within the catchment population.

The principle of osseointegration implants can also be used to provide fixed sites for abutments to allow secure fixation for rehabilitation prostheses at various sites on the head and neck, in particular loss of an auricle from congenital



Note two fixtures and bar for fixation of auricular prosthesis

absence, trauma or following excision for malignancy, or fixation of orbital and nasal prostheses to cover defects following ablative surgery. The principles of the first and second stage surgical procedures with an intervening period of osseointegration are the same as for the BAHA, but multiple fixtures and abutments are often used with an external bar between the abutments to allow both pieces to be clipped securely into place. The technical and cosmetic expertise required to produce a convincing prosthesis are in short supply in the UK and Queen Elizabeth Hospital in Birmingham, rightly receives the majority of the referrals from the whole of the UK.

FURTHER INFORMATION

Nobelpharma would be happy to provide any patient-orientated literature concerning BAHA for any GP who may have patients suitable for this device.

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For interested readers there is an excellent article on the subject:

Ten years of experience with the Swedish Bone-Anchored Hearing Aid *Annals of Otology, Rhinology and Laryngology* 1990;99(2):910

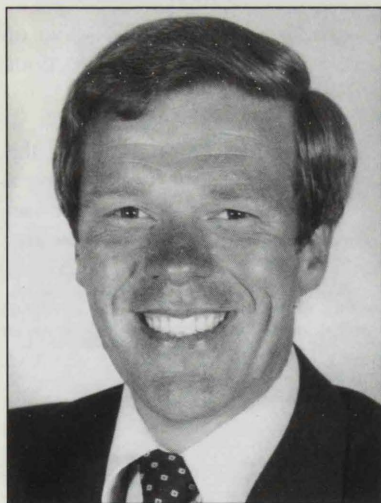
ACKNOWLEDGEMENT

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PHILIP ROY ALLEN MB, CHB, FRCA

Consultant Anaesthetist, Lancaster and Kendal Hospitals 1981–1995



Phil Allen was appointed a consultant anaesthetist to the Lancaster and Kendal hospitals in 1981 where he worked until his untimely death on April 23rd 1995 aged 47. He had been a senior registrar on the Plymouth/Bristol rotation and quickly settled into this area.

Phil was a dedicated colleague who demonstrated in his daily work a profound love of his profession. He was a skilled anaesthetist, equally at home in the routine theatre lists as the serious and difficult emergency cases. He was utterly dependable in a tight spot, knowledgeable, eagle-eyed, confident of his skills and proud of his ability. He transmitted all this to the many trainee anaesthetists whom he loved to teach. Teaching was, for him, an affirmation of his love of anaesthetics. It was never a chore and many anaesthetists have cause to be thankful to Phil for his instruction.

One facet of his work which has become widely known was the development of a chronic pain relief service. He saw the need and acted to improve matters. Not only did he provide the service itself, but he lobbied at local and regional level for improvements throughout the region. Together with Andy Vickers, he set up the North West Acute Pain Group, the first of six groups in England which followed his example. He organised the

first National Pain Conference in February this year and would have arranged another meeting in 1997. Alongside this, he was the Clinical Director of Theatres, a demanding post calling for tact and diplomacy, attributes he had in plenty. It is not hard to be successful when you are so well respected by your colleagues and any number of patients will attest to his kindness, his concern for their wellbeing and his dedication to their needs.

Phil was good fun at all times, especially at the end of a working day when it was time for a pint. He laughed at himself and his weaknesses, especially his occasional outbursts of temper. He loved to talk but he never delayed committee work with unnecessary matters. He held his opinions strongly, was forthright in stating them but was always flexible in his approach to problems, a natural and able leader.

We are truly lucky to have known Phil, to have had the benefit of his company and of his professional skills for the past fourteen years. We extend our deepest sympathy to his wife Gill and his three sons Alex, Tim and David, and to his mother, and in doing so, hope that they will know how highly we regarded Phil and his work. He was a fine man, a cherished colleague and an exemplary doctor.