

This is a repository copy of *The use of bone anchored hearing aids*.

White Rose Research Online URL for this paper: http://eprints.whiterose.ac.uk/120132/

Version: Published Version

Monograph:

Tomlinson, J., Sutton, J. and Cooper, N.J. (1997) The use of bone anchored hearing aids. Other. Guidance Notes for Purchasers (97/10). Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield, Sheffield. ISSN 1900733080

Reuse

This article is distributed under the terms of the Creative Commons Attribution-NonCommercial (CC BY-NC) licence. This licence allows you to remix, tweak, and build upon this work non-commercially, and any new works must also acknowledge the authors and be non-commercial. You don't have to license any derivative works on the same terms. More information and the full terms of the licence here: https://creativecommons.org/licenses/

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



Trent Development and Evaluation Committee

The purpose of the Trent Development and Evaluation Committee is to help health authority and other purchasers within the Trent Region by commenting on expert reports which evaluate changes in health service provision. The Committee is comprised of members appointed on the basis of their individual knowledge and expertise, and includes non-clinically qualified scientists and lay members. It is chaired by Professor Sir David Hull.

The committee recommends, on the basis of appropriate evidence, priorities for:

- the direct development of innovative services on a pilot basis;
- service developments to be secured by health authorities.

The statement that follows was produced by the Development and Evaluation Committee at its meetings on 22 April 1997 and 21 October 1997 at which this Guidance Note for Purchasers (in a draft form) was considered.

THE USE OF BONE ANCHORED HEARING AIDS

AUTHORS: Tomlinson J, Sutton J and Cooper NJ. Sheffield: Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield 1997. Guidance Note for Purchasers: 97/10.

EXPERT ADVISORS TO TRENT DEC: Dr J Tomlinson, Consultant in Public Health, Leicestershire Health Authority; Dr J Sutton, Senior Research Officer, Leicestershire Health Authority.

DECISION: The Committee agreed there was a place for bone anchored hearing aids in the absence of an auditory canal and chronic suppurative otitis media on a case by case basis. Operations should be undertaken at a specialised centre to enable evidence of effectiveness to be built up. More evidence was required before more widespread use of bone anchored hearing aids could be recommended.

THE USE OF BONE ANCHORED HEARING AIDS

J Tomlinson J Sutton NJ Cooper

Trent Institute for Health Services Research Universities of Leicester, Nottingham and Sheffield

GUIDANCE NOTE FOR PURCHASERS 97/10

Published by the Trent Institute for Health Services Research

© 1997 Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield.

ISBN 1900733080

Referencing information:

Tomlinson J, Sutton JC, Cooper NJ. *The Use of Bone Anchored Hearing Aids* Sheffield: Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield, 1997. (Guidance Note for Purchasers: 97/10.)

Further copies of this document are available (price £10.00) from:-

Suzy Paisley
Senior Information Officer
Trent Institute for Health Services Research
Regent Court
30 Regent Street
SHEFFIELD S1 4DA

Tel 0114 222 5420 Fax 0114 272 4095 E-mail scharrlib@sheffield.ac.uk

Please make cheques payable to "The University of Sheffield"

ACKNOWLEDGEMENTS

Thanks are expressed to Mr D W Proops, Consultant ENT Surgeon, Queen Elizabeth's Hospital, Birmingham and to Professor S Gatehouse, Scientist in charge of the MRC Institute of Hearing Research, Glasgow for their useful contributions to the paper.

ABOUT THE TRENT INSTITUTE FOR HEALTH SERVICES RESEARCH

The Trent Institute for Health Services Research is a collaborative venture between the Universities of Leicester, Nottingham and Sheffield with support from NHS Executive Trent.

The Institute:

- provides advice and support to NHS staff on undertaking Health Services Research (HSR);
- provides a consultancy service to NHS bodies on service problems;
- provides training in HSR for career researchers and for health service professionals;
- provides educational support to NHS staff in the application of the results of research;
- disseminates the results of research to influence the provision of health care.

The Directors of the Institute are:

Professor R L Akehurst (Sheffield);

Professor C E D Chilvers (Nottingham); and

Professor M Clarke (Leicester).

Professor Akehurst currently undertakes the role of Institute Co-ordinator.

A Core Unit, which provides central administrative and co-ordinating services, is located in Regent Court within the University of Sheffield in conjunction with the School of Health and Related Research (ScHARR).

FOREWORD

The Trent Working Group on Acute Purchasing was set up to enable purchasers to share

research knowledge about the effectiveness and cost-effectiveness of acute service

interventions and determine collectively their purchasing policy. The Group is facilitated by

The School of Health and Related Research (ScHARR), part of the Trent Institute for

Health Services Research, the ScHARR Support Team being led by Professor Ron

Akehurst and Dr Nick Payne, Consultant Senior Lecturer in Public Health Medicine.

The process employed operates as follows. A list of topics for consideration by the Group is

recommended by the purchasing authorities in Trent and approved by the Purchasing

Authorities Chief Executives (PACE) and the Trent Development and Evaluation Committee

(DEC). A public health consultant from a purchasing authority leads on each topic assisted

by a support team from ScHARR, which provides help including literature searching, health

economics and modelling. A seminar is led by the public health consultant on the particular

intervention where purchasers and provider clinicians consider research evidence and

agree provisional recommendations on purchasing policy. The guidance emanating from

the seminars is reflected in this series of Guidance Notes which have been reviewed by the

Trent DEC, chaired by Professor Sir David Hull.

Repla

In order to share this work on reviewing the effectiveness and cost-effectiveness of clinical

interventions, The Trent Institute's Working Group on Acute Purchasing has joined a wider

collaboration, InterDEC, with units in other regions. These are: The Wessex Institute for

Health Research and Development, The Scottish Health Purchasing Information Centre

(SHPIC) and The University of Birmingham Institute for Public and Environmental Health.

Professor R L Akehurst,

Chairman, Trent Working Group on Acute Purchasing.

CO	NTENTS		Page
EXI	ECUTIVE S	SUMMARY	1
1,	INTROD	UCTION	2
2.	USE OF	BONE ANCHORED HEARING AIDS :	
	SUMMA	RY OF EVIDENCE OF EFFECTIVENESS	5
	2.1	Main Reported Benefits	6
	2.2	Main Reported Complications	6
	2.3	Bone Anchored Hearing Aids versus Air Conduction Hearing Aids	7
	2.4	Bone Anchored Hearing Aids versus Conventional Bone	
		Conduction Hearing Aids	7
	2.5	Bone Anchored Hearing Aids and Bilateral Otosclerosis	7
	2.6	Bone Anchored Hearing Aids in Children	8
	2.7	The Patients' Views	8
3.	COST A	ND BENEFIT IMPLICATIONS OF ADOPTING	9
	INTERVI	ENTION	
	3.1	Costs	9
	3.2	Opportunities for Cost Saving	10
4.	OPTION	S FOR PURCHASERS AND PROVIDERS	12
	4.1	Effective Clinical Practice	12
	4.2	Competition	13
5.	DISCUS	SION AND CONCLUSION	14
6.	USE OF	BONE ANCHORED HEARING AIDS: SUMMARY MATRIX	16

APPENDIX A: Examples of Questionnaires	used in Birmingham to	17
Ascertain a Patient's Opinion of the BAHA Hearing Aids	compared to Conventional	
REFERENCES		19

LIST OF T	ABLES AND FIGURES	Page
Table 1	Classification of the Quality of Evidence	5
Table 2	Quality of Published Evidence on the Effectiveness of BAHAs	6
Table 3	Costs	10
Figure 1	Bone Anchored Hearing Aid	4

EXECUTIVE SUMMARY

Hearing Aids are categorised according to their method of sound conduction; this can be an air conduction hearing aid (ACHA) or a conventional bone conduction hearing aid (CBHA). A more specialised form of CBHA is the bone anchored hearing aid (BAHA). Both air and bone conduction hearing aids are widely used and are of proven benefit.

Although a good ACHA provides the best results, there are a number of patients for whom this type of hearing aid is not suitable (e.g. patients with atresia of the ear or severe chronic suppurative otitis media (CSOM)). If the CBHA is also unacceptable to the patient (e.g. due to discomfort, cosmetic reasons or poor audiological quality) the BAHA may provide an alternative. In addition, BAHAs are increasingly being viewed as an option for the treatment of otosclerosis, replacing more expensive and difficult procedures such as ossiculoplasty and stapedectomies. The three diagnostic groups of patients most likely to benefit from BAHAs are therefore:

- Congenital anomalies involving the ear;
- Chronic suppurative otitis media (CSOM);
- Otosclerosis.

Although several papers have been published demonstrating the benefits of BAHAs, no evidence on the effectiveness of BAHAs has been derived via randomised controlled trials. 'Moderate' grade evidence indicates that good outcomes can be achieved for certain groups of patients.

Purchasers should press for randomised controlled trials (or an independent evaluation exercise), to establish evidence on the clinical and cost-effectiveness of BAHAs in the three patient groups. Future studies should facilitate improvement in patient selection criteria which would reduce inappropriate referrals and increase compliance after implantation. Further research is also required which compares the BAHA with other interventions for otosclerosis. Meanwhile, purchasers may opt for (a) no BAHAs; (b) BAHAs only within strict patient criteria; or (c) BAHAs freely available.

1. INTRODUCTION

Hearing aids fall into one of two main categories according to their method of sound conduction:-

- Air conduction hearing aids (ACHA);
- Conventional bone conduction hearing aids (CBHA).

Both are widely used and are of proven benefit. A good ACHA gives the best results, but is not suitable for all patients. Some patients would benefit from an ACHA, but are unable to wear one. For example, those patients who have ear canal abnormalities or recurrent discharge can be provided with a CBHA. This type of aid operates through a transducer which is pressed firmly on to the skin over the temporal bone and held in place by a headband. Acoustically, the signal generated by the transducer passes through the skin and subcutaneous tissue to the skull bones. The two major problems with CBHA are, firstly, the pressure on the bone may make the aid uncomfortable to wear and, secondly, the layers of skin and tissue between transducer and bone weaken the acoustic signals¹.

These problems can be overcome with the use of a special type of CBHA, called the Bone Anchored Hearing Aid (BAHA), as shown in Figure 1. This comprises a small titanium screw, implanted into the temporal bone, to which the BAHA is connected, via an abutment.

The patients likely to benefit from a BAHA can be classified into three groups:

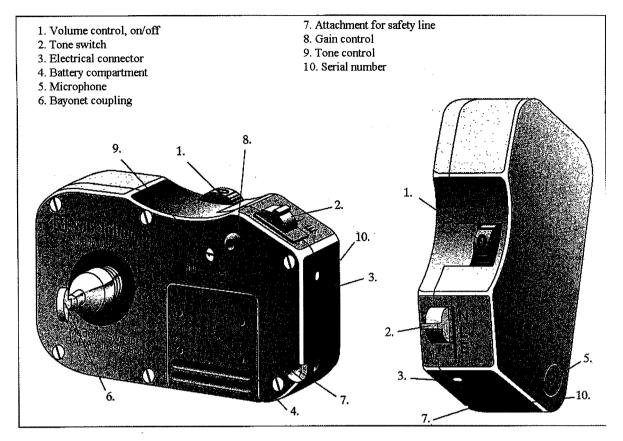
- Congenital abnormality the prevalence of this is uncertain; however, research in Birmingham and Glasgow suggests between 1:4,000 and 1:10,000 live births have such a deformity (Personal Communications from Prof. S. Gatehouse and Mr. D. Proops, respectively). The BAHA offers the benefit of increased comfort and better cosmetic results (over the CBHA with headband) and, for some patients, improved audiology.
- Chronic Suppurative Otitis Media (CSOM) the prevalence of this varies around the country but approximately 10-20 per average sized district (500,000 population) could meet the patient criteria (personal communication from Mr D Proops).
- Otosclerosis approximately 2.1% of the adult population² have this condition, of whom
 95% will be successfully rehabilitated using conventional hearing aids or stapedectomy.

However, there exist diverse opinions amongst otologists concerning the role of surgery and hearing aids in the management of otosclerosis.

BAHAs are implanted through a simple surgical procedure. However, a multi-disciplinary team is required to assess and follow up the patient. The precise team required depends on the BAHA candidate who can be classified into one of two groups:

- Those with chronic otitis media and otosclerosis who require long-term management of hearing impairment. A team similar to the conventional hearing aid management team is needed with the addition of appropriate surgical expertise and back-up.
- Those with congenital abnormalities who require facial prostheses in addition to a BAHA
 implant, who need a team which includes maxillofacial surgeons, speech therapists and
 geneticists, as well as the hearing impairment management team.

Figure 1 Bone Anchored Hearing Aid



Source: Nobel Biocare. Selection criteria and evaluation for the Bone Anchored Hearing Aid: manual for the audiologist.

2. USE OF BONE ANCHORED HEARING AIDS: SUMMARY OF EVIDENCE OF EFFECTIVENESS

Using the classification of the quality of evidence shown in Table 1, the quality of published evidence is summarised in Table 2.

Table 1: Classification of the Quality of Evidence

	Evidence obtained from at least one properly designed randomised controlled trial.
II-1	Evidence obtained from well designed controlled trials without randomisation.
II-2	Evidence obtained from well designed cohort or case controlled analytic studies, preferably from more than
	one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention, or from dramatic results in
	uncontrolled experiments.
III	Opinions of respected authorities based on clinical experience, descriptive studies or reports or expert
	committees.
IV	Evidence inadequate owing to problems of methodology, e.g. sample size, length or comprehensiveness of
	follow-up, or conflict in evidence.

Table 2: Quality of Published Evidence on the Effectiveness of BAHAs.

Reference Paper	Type of Study	Quality of
•	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Evidence
Hakansson B et al. Ten years of experience with the Swedish BAHA system. ³	Summary of outcomes of 147 BAHAs over 10 years.	II-3
Mylanus EAM et al. Audiological results of the BAHA HC200, multicentre results. ⁴	Outcomes of BAHA (HC200) for 62 patients from multicentre study.	II-2
Cooper HR et al. The Birmingham BAHA programme:-referrals, selection, rehabilitation, philosophy and results. ⁵	Questionnaire data on patients' experience following BAHA for comfort and audiology.	111
Macnamara M et al. The BAHA in CSOM. ⁶	Notes review and telephone interviews of 69 CSOM patients' subjective outcomes of BAHA.	III
Burrell SP et al. The BAHA - third option for otosclerosis. ⁷	Outcomes of 10 patients with otosclerosis treated with BAHA as an alternative to stapedectomy or conventional hearing aids.	IV
Cremers CWRJ et al. Hearing with BAHA HC200 compared to a conventional CBHA. ¹	16 patients' performance with BAHA (HC200) and CBHA.	IV
Mylanus et al. Patients' opinions of bone- anchored versus conventional hearing aids. ⁸	Opinions of 65 patients on BAHA versus CBHA.	Ш
Hartland SA et al. BAHA wearers with significant sensorineural hearing loss (borderline candidates) patients' results & opinions. ⁹	Outcomes of 16 'borderline' BAHA cases. Results include; audiological, comfort, reduction in ear discharge.	IV
Powell RH et al. Birmingham BAHA programme: Paediatric experience and results. ¹⁰	Subjective and objective outcomes on 21 BAHA paediatric patients with variety diagnostic criteria for surgery.	III or IV
Mylanus EAM et al. A one stage surgical procedure for placement of percutaneous implants for the BAHA. ¹¹	Outcomes of first 33 one-stage implants of BAHA.	III
Tjellstrom A et al. Long-term follow-up with the BAHA: a review of the first 100 patients between 1977 and 1985. 12	Outcomes of first 100 consecutive patients.	II-3

2.1 Main Reported Benefits

- It has been reported that 90%, or more, of BAHA patients wear their hearing aid for at least 8 hours per day.^{3,8} (There are no comparable data for conventional hearing aids.)
- Patient satisfaction questionnaires produce consistent patient preference for the BAHA,
 based on comfort, quality of sound and cosmetic results.^{1,3,4,5,13}
- Speech-recognition-in-noise is better with a BAHA compared to a CBHA.^{1,5,8} This is thought to be due to the better free field thresholds, the higher frequency range and the lower level of harmonic distortion.
- BAHA surgery for those with a history of CSOM; 84% of patients experienced a significant reduction in ear discharge.⁶
- Improved audiology and patient acceptability of BAHA over CBHA.¹
- There is evidence to suggest that the BAHA can be very helpful for sensorineural loss if the patient is unable to wear a conventional hearing aid.^{9,13}

2.2 Main Reported Complications

- Some patients have been known to suffer from skin reactions following the titanium fixture implant. However, 68% have been reported to remain skin-reaction free. Just 11% of patients have more than 2 episodes of skin reaction. 12
- Another, more serious complication is failure of the implant to osseointegrate; i.e. unstable anchorage resulting in the bone implant remaining loose several months after insertion. However, this complication is rare. In the study by Hakansson et al.,³ just 1 case in 167 bone implants suffered from this problem.

2.3 Bone Anchored Hearing Aids versus Air Conduction Hearing Aids

The results of the BAHA when compared to the ACHA show similarities in audiological terms. However, none of this evidence has been derived from a randomised controlled trial, nor from an independent evaluation exercise. In particular, very little control has been exercised over the quality of the previous/alternative management which the individuals have been offered.

Patients who can wear a conventional ACHA will obtain maximum audiological advantage from this device. However, when a conventional aid cannot be worn, (e.g. with atresia of the ear or severe CSOM) the wearability of the BAHA provides another form of rehabilitation.

2.4 Bone Anchored Hearing Aids versus Conventional Bone Conduction Hearing Aids

The audiological results are better for BAHA as compared to CBHA, due to the more direct conduction of sound, via the titanium fixture and bone. The interposition of the soft tissues with the CBHA¹ results in loss of acoustic quality.

2.5 Bone Anchored Hearing Aids and Bilateral Otosclerosis

Interest in BAHAs, as a third option in the management of bilateral otosclerosis, is increasing. Conventionally, the first treatment is ACHA and the second, unilateral stapedectomy. Both of these have disadvantages:

- ACHAs are often considered unsightly and are less popular amongst younger patients.
 They are sometimes uncomfortable to wear and produce otitis externa in a substantial number of cases.³
- Stapedectomy: this option is suitable for 95% of cases, but 5% of patients have significant morbidity, so the operation is only offered unilaterally in the United Kingdom.
 Therefore, even the best results can only render the patient mono-aural. Patients who have failed stapedectomy or have otosclerosis in their only untreated ear, or those who

cannot or will not wear a conventional hearing aid, can be rehabilitated well by the use of BAHAs.⁷

2.6 Bone Anchored Hearing Aids in Children

The BAHA seems to be safe for use in children as young as two years old, and is especially good for syndromal children with no ear canals or inability for other reasons to wear a conventional hearing aid.¹⁰

2.7 The Patients' Views

A study by Mylanus et al.⁸ used a questionnaire survey (Appendix A) to investigate the patients' opinion of the BAHA, compared to conventional air and bone hearing aids. Patients completed a questionnaire before the surgical procedure with respect to the conventional hearing aid, and five months after surgery with respect to the BAHA. Patients favoured the BAHA compared to the CBHA on all hearing-aid-related aspects, and significant improvement was reported in quiet, noise, quality of sound and comfort.

Of the patients fitted with a BAHA due to unsuitability of a conventional ACHA (e.g. CSOM), many patients reported ACHAs to be better with respect to speech recognition. However, all these patients noted great benefit from the BAHA in the form of reduced or complete elimination of ear infections. These patients had been fitted with a BAHA following recurrent ear infections and an unsuccessful trial period with CBHA. BAHAs are, therefore, advantageous in terms of reduced infections, but patients may experience poorer speech recognition than they have been accustomed to with the ACHA.

3. COST AND BENEFIT IMPLICATIONS OF ADOPTING INTERVENTION

Published evidence to assess cost-effectiveness ratios using conventional measures such as QALYs is largely lacking, but some assessment of costs and potential for savings is given in this section.

3.1 Costs

The cost of BAHAs includes:

- Assessment;
- Single stage day case implant under local anaesthetic;
- Hardware (approx. £1,400). The hardware is expected to last for five years and possibly much longer in adults;
- Maintenance contract which includes approximately two out-patient visits per year and replacement of the hardware after five years (approx. £470 per year).

The table below indicates the costs for local providers within and around the Trent Region:

Table 3: Costs

PROVIDER	ASSESSMENT	IMPLANT AND YEAR 1	FOLLOW UP YEAR 2	TOTAL AT 5 YEARS
QUEEN'S MEDICAL CENTRE, NOTTINGHAM	-	£3,300 includes assessment	£430	£5,020
UNIVERSITY HOSPITAL, BIRMINGHAM	£70/visit (normally 2 visits i.e. £140)	£6,190	£523	£8,422
ADDENBROOKES, CAMBRIDGE				
Child Adult	costs not available	£7,939 £7,639 Hardware & fitting	£184 £184	£8,675 £8,375 excludes assessment
SHEFFIELD	costs not available	£3,611 Hardware, fitting & warranty £44 OP first appointment	£23	£3,747 excludes assessment
BIRMINGHAM CHILDREN'S Stage 1 Stage 2	- .	Hardware, fitting & maintenance £5,755 £5,755 includes assessment	Included in implant costs	£11,510
LEICESTER ROYAL INFIRMARY	-	£3,650 includes assessment	£78.46	£3,963.84

3.2 Opportunities for Cost Saving

The opportunities for cost saving include:

- a) Patients with congenital anomalies (e.g. absence of external meatus) previously required extensive reconstructive surgery. BAHAs avoid the necessity for prior re-constructive surgery;
- b) Patients with CSOM previously required frequent out-patient attendances for aural toilet. Use of BAHAs reduces the need for this.

sclerosis, if stapedectomy to and cost of second stapedect	the other ear

4. OPTIONS FOR PURCHASERS AND PROVIDERS

The following options were discussed during and after a seminar held by the Trent Institute Working Group on Acute Purchasing:

- Option 1 Do not purchase.
- Option 2 Purchase only if patient is included in randomised controlled trial.
- Option 3 Purchase only within strict patient criteria which would vary according to original patient diagnosis:
 - i) Paediatric specified congenital anomalies only;
 - ii) CSOM after ACHA and CBHA have been tried and failed, due to excessive ear discharge;
 - iii) Otosclerosis unilateral BAHA only for 'second' ear after 'first' has undergone failed stapedectomy.

Option 4 Purchase so as to make BAHAs freely available, when requested.

At present, there is little direct evidence on the cost-effectiveness of using BAHAs to treat the three patient groups defined above. Purchasers need to press, therefore, for randomised controlled trials to be performed or, where this is inappropriate, some form of independent evaluation exercise to be carried out.

Purchasers who wish to buy BAHAs should ensure that correct clinical practice is followed.

4.1 Effective Clinical Practice

To improve effectiveness and efficiency:

- BAHA services should consist of a multi-disciplinary team which includes an otologist;
- BAHA services should focus around existing Cochlear Implantation providers to allow easier evaluation and monitoring, especially for children. This argument may not be as strong for adults;
- an adult service should perform a minimum of 10-12 BAHAs per annum to enable the multidisciplinary team to maintain skills (consensus view);

- the paediatric service should be carried out in specialised centres only as numbers are small. Teams should include surgeons skilled in appropriate reconstructive surgery;
- CSOM patients need to be selected according to an agreed protocol.

Further research is required before the BAHA is adopted as the first line treatment for patients with otosclerosis.

4.2 Competition

No competition exists between hardware manufacturers; the Swedish based manufacturer holds a patent and CE marking on the titanium implant which achieves osseointegration.

5. DISCUSSION AND CONCLUSION

The BAHA services are dependent on a large range of multi-professional skills. Without this, the outcomes from BAHA surgery will not be optimised. Paediatric BAHA centres will inevitably be fewer in number and more specialised than adult centres. This is because the numbers of children requiring BAHA surgery are smaller. Also, the diagnostic origins of their hearing problems are usually congenital and require the skills of reconstructive surgeons as part of the team, alongside the BAHA multi-disciplinary team.

At present, there is lack of evidence, based on randomised controlled trials, for the use of the BAHA. However, evidence of a 'moderate' grade indicates that, in certain patient circumstances, the BAHA produces good outcomes for the recipient in terms of reduction in aural discharge, comfort and 'usability'. In addition, for those who cannot wear other types of aid, there is an improvement in audiological quality of life. To date, the strongest evidence for the use of BAHAs is for patients with certain congenital anomalies and for CSOM patients where other methods have failed. It is, therefore, recommended that research should focus on:

- Comparing BAHAs with other interventions for otosclerosis;
- Improved CSOM patient selection; this should help to reduce inappropriate referrals and non-use of BAHA after implantation.

The following patient selection criteria are proposed, until future research indicates how further refinements to the criteria can be made:-

Patient Criteria for BAHA Surgery

a) Congenital Anomaly

- Anomaly of ear or absence of external meatus which precludes use of ACHA for practical reasons.
- Following trial of the CBHA for at least 6 months, which has been unsuccessful for the following reasons:-

- i) poor audiological quality;
- ii) poor level of comfort;
- iii) cosmetically unacceptable;
- iv) poor compliance due to i, ii or iii.

b) CSOM

The process for selection of an appropriate hearing device for patients should be through the following stages:-

- i) ACHA if it offers benefit;
- ii) ACHA tried for at least 6 months with alternation between left and right ears;
- iii) If ACHA alternation is unsuccessful due to continuous or increased severe aural; discharge, CBHA may be suitable;
- iv) If CBHA is unsuitable, due to discomfort, cosmetic problems, or poor audiological quality, BAHA may be a further option.

c) Otosclerosis

Patients with bilateral otosclerosis who have had stapedectomy to one ear, which has failed.

USE OF BONE ANCHORED HEARING AIDS: SUMMARY MATRIX

PATIENT GROUP	PATIENT CRITERIA	ESTIMATED	OPPORTUNITY FOR	AUDIT POINTS	EFFECTS THAT	COST-
	(GUIDELINES NOT	FUTURE ACTIVITY	COST SAVING		COULD BE EXPECTED	EFFECTIVENESS
	PROTOCOLS)				IN RELATION TO	
					STARTING POINT	
Adults and children	Anyone who would benefit from a		1. Concentrate services	1. Structure		No evidence at present.
with agreed patient	conventional hearing aid but		to ensure at least 10 -12	-Composition,		
criteria for treatment.	unable to wear one and has:		patients managed per	experience and training		
	Bilateral congenital	1 - 2.5 per 10,000	team per year.	of team;	-	
	deformities:	live births.		-devices used.		
	-no pinnae;		2. Ensure appropriately	-		
	-canal atresia or stenosis of		trained and experienced	2. Process		
	auditory meatus;		multi-disciplinary team.	-Number of patients		
	-absence of middle ear			already implanted by		
	structure.		3. Fit BAHA to patients	team and number being		
	Bone conduction thresholds		with congenital	implanted annually.		
	not worse than 45 dB PTA or		deformities without prior			
	60 dB for body worn super		re-constructive surgery.	3. Outcomes	-Average length of	
	bass aids.			-Incidence of	wearing > 14 hours.	
	Speech discrimination score		4. Appropriate fitting of	complications.	-Better word recognition	
	not worse than 60%.		BAHA will reduce out-	-Evidence of use of	in noise possibly due to	
	Chronic bilateral middle or	Prevalence of 10-20	patient attendances for	device.	better free field	
	external ear infections	per 0.5 million	aural toilet.	-Audiological measures	thresholds and higher	
	worsened by conventional	population.		of performance.	frequency range and	
	aids despite alternating use of		5. Limit stapedectomy	-Self-reported changes	lower level of harmonic	
	aid between ears.	-	surgery to one	in quality of life.	distortion.	
	Bilateral otosclerosis and the	Otosclerosis 2.1%	procedure per patient by			
	patient works at heights or	population	a recognised otologist.			
	has had unsuccessful surgery	prevalence.				
	on one ear.		6. Encourage			
	(These categories are	-	competition between			
	approximately 5% of all		providers.			
	otosclerosis patients)					

APPENDIX A Examples of Questionnaires used in Birmingham to Ascertain a Patient's Opinion of the BAHA Compared to Conventional Hearing Aids

Questionnaire A

(1)	How many hours per day did you use your previous hearing aid (CHA)?					
	> 8 hours	4 - 8 hours	2 - 4 h	ours	< 2 hours	not at all
	How many hour	s per day do yo	u use your B	AHA?		
	> 8 hours	4 - 8 hours	2 - 4 h	ours	< 2 hours	not at all
(2)	Which hearing a	aid is better with	regard to	.?		
	- A: ear infection	ons	CHA	BAHA	no di	fference
	- B: speech red	cognition	CHA	BAHA	no di	fference
	- C: sound qua	lity	CHA	BAHA	no di	fference
	- D: visibility		CHA	BAHA	no di	fference
	- E: skin irritatio	on	CHA	BAHA	no di	fference
	- F: handling		CHA	BAHA	no di	fference
(3)	On which of the	se hearing-aid-r	elated aspec	ts A to F doe	es the BAHA d	istinguish itself most
from the previous hearing aid in a positive sense?						
	greatest disadv	vantage,		2nd mo	st important di	sadvantage,
	aspect			aspect.		
(4)	On which of the	se hearing-aid-r	elated aspec	ts A to F doe	es the BAHA d	istinguish itself most
	from the previous hearing aid in a negative sense?					
	greatest disadv	vantage,			ost important disadvantage,	
	aspect			aspect.		
(5) How good is your speech recognition in situation with background noise (p						e (party or group
	gathering) with t	the BAHA comp	ared to your	previous hea	aring aid?	
	much better	better	equa	al	worse	much worse
(Caa	a. Mulanua EAM	The Dans Ana	h a al a	- Aid Olivia	-111'-1-	atant a contra

(Source: Mylanus EAM. *The Bone Anchored Hearing Aid. Clinical and audiological aspects*. EAM Mylanus, 1994)

Questionnaire B

(1) Speech recognition in quiet:

When it is quiet, can you understand....

- a) one man? b) one woman? c) one child? d) television e) radio
- (2) Speech recognition in noise:

Can you understand someone who is speaking....

- a) while the radio or television is on? b) at a party or meeting?
- c) in a crowded hall? d) in a restaurant? e) in a street with a lot of traffic?
- f) in a busy shop? g) in a lecture hall? h) on a bus or train?
- I) in a car?
- (3) Quality of sound:

What is your opinion on the quality of sound of....

- a) the voices of men? b) the voices of women? c) the voices of children?
- d) your own voice? e) music? f) a telephone conversation? g) cutlery?
- h) drilling? I) slamming doors? j) passing trains? k) traffic?
- (4) Wearing comfort:
- a) Is your hearing aid comfortable to wear?
 b) Is your hearing aid practical in everyday
 use?
 c) Are you troubled by rustling noises when moving around?
 d) How do you view the hearing aid with regard to feed back?
 e) Do you experience troublesome intrinsic noise from your hearing aid?

Two questions were posed after the patient had been fitted with the BAHA:

Do you experience difficulty with cleaning the skin around the abutment?

yes sometimes no

and for the patients who had previously used a conventional hearing aid binaurally: which hearing aid is better with regard to directional hearing?

CHA BAHA no difference

(Source: Mylanus EAM. *The Bone Anchored Hearing Aid. Clinical and audiological aspects*. EAM Mylanus, 1994)

REFERENCES

- (1) Cremers CWRJ, Snik AFM, Beynon AJ et al. Hearing with the Bone Anchored Hearing Aid (BAHA HC 200) compared to a Conventional Bone-Conduction Hearing Aid (CBHA). Clinical Otolaryngology 1992; 17: 275-79.
- (2) Browning GG, Gatehouse S. The prevalence of middle-ear disease in the adult British population. *Clinical Otolaryngology* 1992; 17(4): 317-21.
- (3) Hakansson B, Liden B, Tjellstrom A, et al. Ten years of experience with the Swedish bone-anchored hearing system. *Annals of Otology Rhinology and Laryngology* 1990; 99(Suppl 151): 1-16.
- (4) Mylanus EAM, Snik AFM, Cremers CWRJ, et al. Audiological results of the Bone Anchored Hearing Aid HC 200, multicentre results. *Annals of Otology, Rhinology and Laryngology* 1994; 103: 368-374.
- (5) Cooper HR, Burrell SP, Powell RH et al. The Birmingham Bone Anchored Hearing Aid Programme:- Referrals, selection, rehabilitation, philosophy and adult results. Journal of Laryngology and Otology -Supplement 21:13-20, 1996.
- (6) Macnamara M, Phillips D, Proops DW. The bone anchored hearing aid (BAHA) in chronic suppurative otitis media (CSOM). Journal of Laryngology and Otology Supplement 21: 38-40,1996.
- (7) Burrell SP, Cooper HC, Proops DW. The Bone Anchored Hearing Aid third option for otosclerosis. Journal of Laryngology and Otology Supplement 21:31-37,1996.
- (8) Mylanus EAM, Snik AFM. Cremers CWRJ. Patients' opinions of Bone-Anchored versus Conventional Hearing Aids. *Archives of Otolaryngology Head & Neck Surgery* 1995; 121(4):421-5,1995 April.
- (9) Hartland SA, Proops DW. Bone Anchored Hearing Aid wearers with significant sansorineural hearing loss (borderline candidates). Patients' results and opinions. Journal of Laryngology and Otology Supplement 21:41-46,1996.

- (10) Powell RH, Burrell SP, Cooper HR, Proops DW. Birmingham Bone Anchored Hearing Aid Programme: Paediatric experience and results. Journal of Laryngology and Otology Supplement 21:21-29, 1996.
- (11) Mylanus EAM, Cremers CWRJ. A one stage surgical procedure for placement of percutaneous implants for the Bone Anchored Hearing Aid. *Journal of Laryngology and Otology* 1994; 108: 1031-5.
- (12) Tjellstrom A, Granstom G. Long-term follow-up with the bone-anchored hearing aid: a review of the first 100 patients between 1977 and 1985. ENT Journal: vol 73(2) 112-4, 1994 Feb.
- (13) Snik AFM, Mylanus EAM, Cremers CWRJ. Bone Anchored Hearing Aids in patients with sensorineural hearing loss and persistent otitis externa. *Clinical Otolaryngology* 1995; 20(1): 31-35, 1995 Feb

Other papers published by the Trent Institute for Health Services Research are listed below:-

Guidance Notes for Purchasers

96/01	Working Group on Acute Purchasing: The use of DNase in Cystic Fibrosis (1996) by JN Payne, S Dixon, NJ Cooper and CJ McCabe.	£6.00
96/02	Working group on Acute Purchasing: Tertiary Cardiology (1996) by J Tomlinson, J Sutton and CJ McCabe.	£6.00
96/03	Working Group on Acute Purchasing: The use of Cochlear Implantation (1996) by Q Summerfield and J Tomlinson.	£6.00
96/04	Working Group on Acute Purchasing: Statin Therapy / HMG Co-A Reductase Inhibitor Treatment in the Prevention of Coronary Heart Disease (1996) by MD Pickin, JN Payne, IU Haq, CJ McCabe, SE Ward, PR Jackson and WW Yeo.	£6.00
97/01	Working Group on Acute Purchasing: The Clinical and Cost-effectiveness of Computed Tomography in the Management of Transient Ischaemic Attack and Stroke (1997) by A Ferguson and CJ McCabe.	£10.00
97/02	Working Group on Acute Purchasing: Prostacyclin in the Treatment of Primary Pulmonary Hypertension (1997) by TW Higenbottam, SE Ward, A Brennan, CJ McCabe, RG Richards and MD Stevenson.	£10.00
97/03	Working Group on Acute Purchasing: The Use of Riluzole in the Treatment of Amyotrophic Lateral Sclerosis (Motor Neurone Disease) (1997) by J Chilcott, P Golightly, D Jefferson, CJ McCabe and S Walters	£10.00
97/04	Working Group on Acute Purchasing: Recombinant Factor VIII Versus Plasma Derived Factor VIII in the Management of Haemophilia A: An Examination of the Costs and Consequences (1997) by C Green and RL Akehurst.	£10.00
97/05	Working Group on Acute Purchasing: The Use of Cisplatin and Paclitaxel as a First Line Treatment in Ovarian Cancer (1997) by SM Beard, R Coleman, J Radford and J Tidy.	£10.00
97/06	Working Group on Acute Purchasing: The Use of Alpha Interferon in the Management of Chronic Myeloid Leukaemia (1997) by RG Richards and CJ McCabe.	£10.00
97/07	Working Group on Acute Purchasing: Spinal Cord Stimulation in the Management of Chronic Pain (1997) by J Tomlinson, CJ McCabe and B Collett.	£10.00
97/08	Working Group on Acute Purchasing: The Use of Growth Hormone in Adults (1997) by JN Payne and RG Richards.	£5.00

97/09 Working Group on Acute Purchasing: A Review of the Use of Donepezil £10.00 in the Treatment of Alzheimer's Disease by FA Pitt, J Chilcott, P Golightly, J Sykes, M Whittingham.

Discussion Papers

No. 1. Patients with Minor Injuries: A Literature Review of Options for their £7.00 Treatment Outside Major Accident and Emergency Departments or Occupational Health Settings (1994) by S Read. 96/01 Working Group on Acute Purchasing: The role of Beta Interferon £7.50 in the Treatment of Multiple Sclerosis (1996) by RG Richards, CJ McCabe, NJ Cooper, SF Paisley, A Brennan and RL Akehurst. 96/02 The Mid-level Practitioner: A Review of the Literature on Nurse £10.00 Practitioner and Physician Assistant Programmes (1996) by P Watson, N Hendey, R Dingwall, E Spencer and P Wilson. 96/03 Evaluation of two Pharmaceutical Care Programmes for People with £10.00 Mental Health Problems Living in the Community (1996) by A Aldridge, R Dingwall and P Watson. 97/01 Working Group on Primary and Community Care Purchasing: Report of £10.00 the Sub-Group on the promotion of Quality in Primary Care - Effective Purchasing of Primary and Community Health Care: Promotion of Quality in the Provision of Primary Care (1997) by S Jennings and M Pringle. 97/02 Working Group on Primary and Community Care Purchasing: Report of £10.00 the Sub-Group on Information Needs for Health Needs Assessment and Resource Allocation (1997) by T Baxter, A Howe, C Kenny, D Meechan, M Pringle, P Redgrave, J Robinson and A Sims.

Copies of these documents are available from:-

Suzy Paisley
Senior Information Officer
Trent Institute for Health Services Research
Regent Court
30 Regent Street
SHEFFIELD S1 4DA

Tel 0114 222 5420 Fax 0114 272 4095

E-mail scharrlib@sheffield.ac.uk

Please make cheques payable to "The University of Sheffield"