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An evaluation of the quality of evidence available to inform current Bone Conduction Hearing Device national policy

Short title: Evaluating the evidence available to inform current BCHD policy

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Abstract

Objectives

In 2016 NHS England published the commissioning policy on Bone Conducting Hearing Devices (BCHDs). This policy was informed by updated evidence on the clinical and cost effectiveness of BCHDs as well as by the 2013 Bone Anchored Hearing Aid (BAHA) policy. Commissioning policies set the criteria for service delivery and therefore have a major impact on the care received by patients. It is important that stakeholders have a good appreciation of the available evidence informing policy, since this will promote engagement both with the policy as well as with future research leading on from the policy. In this paper, we provide stakeholders with a transparent and pragmatic assessment of the quality of the body of evidence available to inform current BCHD national policy.

Method

1) A systematic review of the literature on BCHDs published since the development of the 2013 policy was performed in September 2016, adhering to PRISMA recommendations. The search terms used were: bone conduction; bone conducting; bone anchor; BAHA; Bone Anchored Hearing Aid; Bone Conducting Hearing Device; BCHD; Bone Conduction Hearing Implant; BCHI; Sophono; Bonebridge; Soundbite; Ponto; Hearing aid; implant; device; hearing device. Publications that could inform current BCHD policy were included. The quality of included articles was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.

2) The quality of evidence referenced by the 2013 BAHA policy was assessed using the GRADE system.

Results

1) Out of the 2576 publications on BCHDs identified by the systematic search, 39 met the inclusion criteria for further analysis. Using the GRADE criteria, the quality of evidence was classified as of 'very low quality.'

2) The 2013 BAHA policy was informed by 14 references. The GRADE system classifies the quality of evidence that informed the policy as of 'very low quality'.

Conclusions

The GRADE system defines the body of evidence available to inform current national BCHD policy as of 'very low quality'. There is an urgent need for high quality research to help make informed policy decisions about the care of patients with hearing loss. An (inter)national registry of BCHDs could address this need.

Introduction

NHS England issues commissioning policies that aim to ensure that the NHS delivers better outcomes for patients within its available resources.¹ Commissioning policies set the criteria for service delivery and therefore have a major impact on the care received by patients. It is important for commissioning policies to be based on strong evidence so that policy decisions are well informed. It is equally important that stakeholders have a good appreciation of the available evidence, since this will promote engagement both with the policy as well as with future research leading on from the policy.

In July 2016 NHS England published the commissioning policy on Bone Conduction Hearing Implants (BCHI) with separate commissioning criteria for Bone Conducting Hearing Devices (BCHDs) and Middle Ear Implants.² Their policy criteria for BCHDs were informed by updated evidence on the clinical and cost effectiveness of these devices,² as well as by the 2013 Bone Anchored Hearing Aid (BAHA) commissioning policy.³ In this paper, we provide stakeholders with a transparent and pragmatic assessment of the quality of the body evidence available to inform current BCHD policy.

Method

This study was conducted in two parts: 1) Systematic review and critical assessment of the body of literature on BCHDs; and 2) Critical assessment of the evidence informing the 2013 BAHA policy.

1) A systematic review of the literature on BCHDs published since 2012, i.e. the year of the search for the 2013 policy, was performed adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations.⁴ An expert librarian designed and conducted a comprehensive search of the Medline and Embase databases on 15th September 2016 using the Ovid portal and taking into account the specific questions and types of BCHDs discussed in the 2016 policy. The search terms used were: bone conduction; bone conducting; bone anchor; BAHA; Bone Anchored Hearing Aid; Bone Conducting Hearing Device; BCHD; Bone Conduction Hearing Implant; BCHI; Sophono; Bonebridge; Soundbite; Ponto; Hearing aid; implant; device; hearing device.

Two authors (R.M and N.H), working independently, screened all titles and abstracts for eligibility; and records considered potentially relevant were retrieved in full text and assessed for eligibility. Reference lists of review articles were also screened to identify additional relevant articles. Any disagreements were discussed with the senior author (A.S) and resolved by consensus. Data were extracted independently by the same authors (R.M and N.H) and disagreements were resolved by discussion and consensus.

Original research articles and review articles that could inform current BCHD policy were included. Specifically, articles were included if they covered:

- Clinical and/or cost effectiveness
- Clinical indications in adults and/or children
- Contraindications in adult and/or children
- Indications for bilateral vs unilateral implantation in adults and/or children
- Additional considerations for implantation in children
- Strategies for service provisioning

Papers were excluded if they were:

- Non-clinical research
- Non-English language
- Conference proceedings

- Letters to journal editor
- Published before 2012

The quality of included evidence was subsequently assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.⁵ GRADE is a systematic and explicit approach to making judgements about the quality of evidence; and is widely accepted as the most effective method of linking evidence-quality evaluations to clinical recommendations.⁶ GRADE rates evidence across studies and classifies quality of evidence (also known as certainty in the evidence) into high, moderate, low, and very low.⁵ Evidence can start high or low and move up or down based on study characteristics.

Evidence from randomised controlled trials (RCTs) start as high-quality evidence but must meet certain criteria to stay at that level whilst evidence from observational studies start as low quality evidence but may move up in certain circumstances. The factors that increase or decrease quality of evidence include: quality of methodology, consistency of results across studies, directness (generalisability) and effect size.⁵

- 2) The articles referenced by the 2013 NHS commissioning policy were obtained. The quality of this body of evidence was assessed using the GRADE system as above.⁵

Results

- 1) The systematic search revealed 3753 publications, removing duplicates left 2576 publications for screening of title and abstract. One hundred and four articles were full text assessed and 39 articles fulfilled the criteria for inclusion. Figure 1 shows the PRISMA flow chart 1.

Table 1 summarises the 39 included articles and their critical assessment. Table 2 provides the GRADE assessment across this evidence. Eighteen articles were retrospective case series; 3 were case reports; 8 were prospective case series; 4 were systematic reviews; 4 were narrative reviews; 1 was a Delphi study, 1 was a consensus document. All were non-RCTs and therefore started with a

'low quality' rating. Further assessment of study quality, consistency, directness and effect size, classified the evidence they generated as of 'very low quality'.

- 2) Table 3 summarises the evidence informing the 2013 commissioning policy and their critical assessment. Table 4 provides the GRADE assessment across this evidence. Of the 15 references cited,³ one was not used to inform the policy, rather it was a fact sheet on BAHAs.⁷ The referenced articles were published between 1996 and 2011 and included personal communications with stakeholders, advice from specialist units, original journal articles, technology assessments, a specialised services definitions set, a statement paper and a quality standards guideline. All references were non-RCTs and therefore started with a 'low quality' rating. Further assessment of study quality, consistency, directness and effect size classified the body of evidence they generated as of 'very low quality'.

Discussion

Our work suggests that the evidence available to inform current BCHD policy is incomplete and needs to be strengthened, as is the case for other hearing loss management strategies.^{3,8-11}

On a European level, concerns over the evidence base for surgical implants in general has been raised by the IDEAL collaborative and the House of Commons Science and Technology committee.^{12,13} Across the UK and EU, implants can enter surgical practice on the basis of equivalence data, meaning that an implant can be used on the basis of similarity to another implant rather than evidence of its own safety and effectiveness.^{12,13} The recall of Poly Implant Prothese (PIP) breast implants and metal on metal hip implants identify the dangers of relying on such data for the evaluation of safety and efficacy.¹⁴⁻¹⁶

Whilst there is a clear need to strengthen the evidence base for BCHDs and other surgical implants, it is important to consider the barriers to high quality research and in particular to RCTs in this field. These relate to resource limitations, equipoise, challenges in patient recruitment, generalisability and loss to long term follow up.¹² Some of these barriers may be overcome by the establishment of

an (inter)national registry of BCHDs. Compared to trials, a registry requires fewer resources, has stronger external validity and allows for data collection on long-term outcomes, which is particularly relevant to implants.¹⁷ With current initiatives to collect data on BCHDs being fragmented and incomplete,^{18,19} an (inter)national registry would provide valuable information on clinical and cost-effectiveness that is essential for policy and guideline development.^{8-10,20,21,22}

We acknowledge that the quality assessment of evidence using GRADE involves some degree of arbitrariness; however advantages of its simplicity and transparency outweigh these limitations.²³

Recognising that the 2016 BCHD commissioning policy was informed by updated evidence on BCHDs as well as by the 2013 BAHA policy, we systematically reviewed and quality assessed the recent literature on BCHDs, and critically assessed the evidence informing the 2013 policy. This approach assures a robust assessment of the available body of evidence to inform current BCHD policy.

Conclusion:

Using the GRADE system, the body of evidence available to inform current national BCHD policy is classified as of 'very low quality'. There is an urgent need for high quality research to help make informed policy decisions about the care of patients with hearing loss. An (inter)national registry of BCHDs could address this need.

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Author	Title	Year	Aim of paper	Study design	Factors which lower quality	Factors which raise quality	Summary of findings
Gerdes et al	Comparison of Audiological Results Between a Transcutaneous and a Percutaneous Bone Conduction Instrument in Conductive Hearing Loss	2016	To compare the hearing performance and QOL outcomes of the Bonebridge transcutaneous bone conduction implant to the percutaneous BAHA device	Retrospective case series	Retrospective, subjective QOL assessment, small sample size of 20 patients (10 in each group)	Presence of a control group	The transcutaneous bone conduction hearing implant is an audiological equivalent alternative to percutaneous bone-anchored devices in patients with conductive hearing loss
Sprinzi and Wolf-Magele	The Bonebridge Bone Conduction Hearing Implant: indication criteria, surgery and a systematic review of the literature	2016	To assess the safety and effectiveness of the Bonebridge for individuals with conductive or mixed hearing loss, and single sided deafness	Systematic review	Study selection, data extraction and study quality assessment were carried out by a single reviewer, majority of included studies were case series with limited sample sizes	Systematic review	The transcutaneous Bonebridge provides audiological benefit to patients suffering from conductive or mixed hearing loss and single sided deafness. It has a lower complication rate to percutaneous systems and higher and more reliable hearing gain compared to other transcutaneous or percutaneous systems
Carr et al	Bone-conduction hearing aids in an elderly population: complications and quality of life assessment	2016	To determine whether an elderly population with hearing impairment can be adequately rehabilitated with a bone conduction hearing aid (BAHA)	Retrospective review	Retrospective, telephone and postal questionnaire, large range of follow up times, risk of recall bias	Sample size of 51 patients	The bone conduction hearing aids are an ideal method of hearing rehabilitation in the elderly for all forms of hearing loss. It provides significant benefit with no increased complication rate
Crowson and Tucci	Mini Review of the Cost-Effectiveness of Unilateral Osseointegrated Implants in Adults: Possibly Cost-Effective for the Correct Indication	2016	To review all cost effectiveness analyses on osseointegrated implants	Narrative review	Not a systematic review	Nil	There are 2 cost-effectiveness analyses published to date. The cost-effectiveness of the BAHA, compared to conventional hearing aid devices remains unclear. The BAHA should not be considered as an alternative to a normal hearing aid, but rather as an effective option for the patient given the correct indication
Bianchin et al	Active Bone Conduction System: Outcomes with the Bonebridge Transcutaneous Device	2015	To report a case series of 4 patients with Bonebridge implantation	Retrospective case series	Four patient case series, different surgical approaches used, large range in follow up	Nil	The Bonebridge appears to be safe and effective for individuals with chronic otitis media, aural atresia and otosclerosis with inadequate benefit from conventional surgery or bone conduction hearing aids

Iseri et al	Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study	2015	To compare the clinical and audiological outcomes as well as patient satisfaction between the percutaneous Dermalock and the transcutaneous Attract systems	Retrospective case series	Retrospective study, unequal group sizes	Multicentre study	Both transcutaneous and percutaneous techniques are effective in the rehabilitation of conductive hearing loss when conventional hearing aids cannot be used. Better hearing results were observed in the percutaneous, bone-conduction group
Zernotti and Sarasty	Active Bone Conduction Prosthesis: Bonebridge™	2015	To systematically review the surgical techniques and outcomes of the Bonebridge	Systematic review	Systematic review not performed as per PRISMA guidance, poor quality of included studies, 20 patients included across all included studies	Nil	Bonebridge appears to be effective for patients with conductive/mixed hearing loss and single sided deafness. Bonebridge has fewer complications than percutaneous bone conduction implants and shows proven benefits in speech discrimination and functional gain
Gavilan et al	Quality standards for bone conduction implants	2015	To establish consensus on the quality standards required for centres willing to create a bone conduction implant program (transcutaneous)	Quality standards established by the HEARRING network	Based on expert opinion. No published formal methodology to achieve consensus	Nil	Bone conduction implants are useful in patients with conductive and mixed hearing loss for whom conventional surgery or hearing aids are no longer an option. They can also be used in patients affected by single-sided deafness
Gurgel et al	A Novel Intraoral Bone Conduction Hearing Prosthesis: One-Year Safety and Efficacy Study	2015	To assess the safety and efficacy of the SoundBite device after 12 months of use	Prospective cohort study	No randomisation, patients received a fee for completing questionnaires, subjective questionnaire, 37 patient loss to follow up	Multisite, prospective cohort study, large sample size	The SoundBite is a safe and effective alternative to percutaneous osseointegrated hearing implants for patients with single sided deafness
Laske et al	Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness	2015	To assess the Bonebridge device in adults with single-sided deafness	Prospective cohort study	Small sample size of 9 patients, subjective hearing questionnaires, different aetiologies of hearing loss	Prospective cohort study	Speech discrimination in noise for patients implanted with the Bonebridge is comparable with patients with other bone conduction hearing aids. QOL improved for patients. The Bonebridge is an effective option for patients with single sided deafness
Denoyelle et al	Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia	2015	To assess the effectiveness of the Sophono Alpha1 implant for unilateral hearing rehabilitation in children with ear atresia, compared to a BAHA on a test band	Prospective case series	Small sample size of 15 children, subjective parental reported quality of life, large range of follow up	Prospective study	The Sophono Alpha1 device should be a treatment option for children with ear atresia
Leterme et al	Contralateral Routing of Signal (CROS) Hearing Aid versus Transcutaneous Bone Conduction in Single-Sided Deafness	2015	To assess the Sophono transcutaneous bone conduction device in single sided deafness, in comparison to a CROS hearing aid in terms of hearing	Prospective cross over study	Small sample size of 18 patients, devices used for different durations (60 days CROS, 7 days Sophono),	Multicentre, prospective study	Both devices improved hearing in noise and the quality of life equally. Transcutaneous devices represent an

			performances, user satisfaction, and quality of life		subjective QOL measure		effective option in SSD
Reinfeldt et al	The bone conduction implant: Clinical results of the first six patients	2015	To investigate audiological and quality of life outcomes for a new active transcutaneous device called the Bone Conduction Implant	Prospective case series	Small sample size of 6 patients, large age range of patients, subjective QOL measure, 6 month follow up	Prospective study	The transcutaneous Bone Conduction Implant provides safe and significant hearing rehabilitation for patients with mild-to-moderate conductive or mixed hearing loss
Briggs et al	Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results From a Prospective, Multicenter, Clinical Investigation	2015	To assess the clinical performance of the BAHA attract system	Prospective case series	Small sample size of 27 patients	Multicentre, prospective study	The BAHA attract system provides good hearing performance in patients with a conductive hearing loss or single-sided sensorineural deafness, with good wearing comfort and minimal soft tissue complications
Mojallal et al	Retrospective audiological analysis of bone conduction versus round window vibratory stimulation in patients with mixed hearing loss	2015	To compare audiological outcomes in patients treated with a BAHA or an active middle-ear implant	Retrospective analysis	Retrospective file review, comparative analysis had small cohort of patients (six patients in each group)	Nil	BAHAs are an effective, simple and reliable option for the treatment of conductive and mixed hearing loss. They are a good option for patients unwilling to undergo complex middle ear implant surgery
Lieu et al	Management of Children with Unilateral Hearing Loss	2015	To provide an overview of the management of children with unilateral hearing loss	Narrative review	All includes studies had small sample sizes, short follow up times, and did not provide long term outcome measures	Nil	For children with conductive unilateral hearing loss such as from aural atresia or ossicular malformation, surgical implantation of a bone conduction hearing device has been shown to improve binaural hearing
Jovankovicová et al	Surgery or implantable hearing devices in children with congenital aural atresia: 25 years of our experience	2015	To compare outcomes of congenital aural atresia reconstruction with those of bilateral hearing implants (BAHAs, Vibrant Soundbridge and Bonebridge) in children	Retrospective review of patients who underwent congenital aural atresia reconstruction. Prospective case series of patients fitted with implants	Only 8 patients underwent BCHD implantation, some patients in the BCHD group underwent previous atresia surgery, unable to differentiate between results of BCHD and Vibrant Soundbridge, insufficient demographic details for implant group	Nil	Implantable hearing devices give patients with congenital aural atresia better and longer lasting functional audiological gain than atresiaplasty
Doshi et al	Bone anchored hearing aids in children	2015	To provide an overview of bone anchored hearing devices in the paediatric population	Narrative review	Narrative review of prospective and retrospective case series	Nil	Children with unilateral conductive hearing loss and unilateral sensorineural hearing loss are at a higher risk for academic, speech-language and social-emotional difficulties than their normal hearing peers. It may be sensible to offer bone anchored hearing devices in such cases. Bilateral BAHAs have proven to be superior to unilateral fitting in adults with bilateral hearing loss

Coutinho et al	Successful bone-anchored hearing aid implantation in a patient with osteogenesis imperfecta	2015	To report a case of successful BAHA implantation in an adult patient with type III osteogenesis imperfecta	Case report	Only 1 case, limited follow up of 14 months	Nil	A 45 year old man with type II osteogenesis imperfecta underwent BAHA implantation. The patient had mixed hearing loss, with a mild sensorineural component in both ears and an air-bone gap of 45-50 dB HL. Following BAHA implantation, implant stability quotient was measured at each visit upto 14 months and was found to be steady. In selected osteogenesis imperfecta cases, osseointegrated implants should be considered in the management of hearing loss
Amonoo-Kuofi	Experience of bone-anchored hearing aid implantation in children younger than 5 years of age	2015	To assess outcomes following BAHA implantation in children younger than 5 years of age	Retrospective chart review.	Retrospective study, only 24 children, subjective measurement of QOL benefit from parents, questionnaires filled by parents - therefore may reflect their opinions - not their child's, recall bias, no outcome data published specific to each child	Senior surgeons performing operations, only 1 child lost to follow up, good average duration of follow up 2.8 years	There was a final mean QOL improvement following BAHA implantation. The BAHA implant appears to be of value to children under age 5 years. 8 of 24 children underwent BAHA implantation under 3 years of age and whilst no specific outcome data for these patients are presented, the authors note that mean QOL improved
Riss et al	Indication criteria and outcome with the Bonebridge transcutaneous bone-conduction implant	2014	To investigate Bonebridge patients concerning their functional gain and speech perception; to be able to select the right patient for this procedure	Retrospective study	Small sample size of 23 patients, heterogeneous patient group	Nil	The Bonebridge provides satisfactory results concerning functional gain and speech perception. It is advisable that preoperative bone conduction is within 45 dB on the ipsilateral ear for combined or conductive loss
Marsella et al	Sophono in Pediatric Patients: The Experience of an Italian Tertiary Care Center	2014	To assess the use of the Sophono device in paediatric patients	Prospective case series	Small sample size of 6 patients, subjective QOL measure filled by parents	Prospective case series	Sophono implants can be an effective alternative to percutaneous implants in patients with bilateral, conductive hearing loss
Al-Qahtani et al	External auditory canal atresia: Surgical correction compared with bone anchored hearing device	2014	To evaluate the hearing results, complication rate and parental satisfaction following BAHA compared to traditional surgery in the treatment of external auditory canal atresia	Retrospective study	Retrospective study, telephone QOL assessment, non-validated QOL measure, heterogeneous patients, unequal study groups, delay between surgery and telephone interview (recall bias)	Nil	For auditory canal atresia, BAHA provides superior hearing results, greater parental satisfaction and fewer complications than surgery
Iseri et al	A new transcutaneous bone anchored hearing device - the Baha Attract System: the first experience in Turkey	2014	To assess the effectiveness of the BAHA Attract system	Prospective case series	Small sample size of 12 patients, heterogeneous patients	Prospective, multicentre study	The BAHA attract system is promising for patients with conductive or mixed hearing loss who are unable to wear conventional hearing aid and is comparable to percutaneous systems

Farnoosh et al	Bone-Anchored Hearing Aid vs. Reconstruction of the External Auditory Canal in Children and Adolescents with Congenital Aural Atresia: A Comparison Study of Outcomes	2014	To compare outcomes in hearing between EACR and BAHA in a pediatric population with congenital aural atresia	Retrospective chart review	Retrospective study design, subjective QOL questionnaire - some completed via telephone, recall bias, uneven numbers in each group (19 in BAHA group and 49 in EACR group), average age was significantly different between groups, bilateral interventions were performed in more children in the BAHA group than in the EACR group	Nil	15% of children underwent BAHA for unilateral hearing loss. In these patients, pure tone average improved post BAHA implantation. QOL and incidence of surgical complications between the two interventions were not significantly different. BAHA implantation provided a better, more reliable audiological outcome than EACR
Dun et al	Bilateral bone conduction devices: improved hearing ability in children with bilateral conductive hearing loss	2013	To assess whether children with bilateral conductive hearing loss benefit from bilateral BAHA fitting	Retrospective case series	Retrospective, small sample size of 10 children, different ages of patients at implantation, different processor used in 1 patient	Nil	The bone conduction device has better hearing outcomes than atresiaplasty in patients with congenital aural atresia
Nicolas et al	Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device	2013	To assess long term satisfaction and sound localisation after implantation with BAHA in patients with single-sided deafness	Retrospective case series	Retrospective, heterogeneity in included patients, subjective QOL score, small sample size of 21 patients	Nil	The BAHA is an effective treatment for single sided deafness with improvement in speech perception and quality of life
Nadaraja et al	Hearing outcomes of atresia surgery versus osseointegrated bone conduction device in patients with congenital aural atresia: a systematic review	2013	To compare hearing outcomes of atresiaplasty versus osseointegrated bone conduction device (OBCD) in congenital aural atresia patients	Systematic review	All included studies were retrospective, considerable heterogeneity in included studies	Systematic review	The bone conduction device has better hearing outcomes than atresiaplasty in patients with congenital aural atresia
Hol et al	Comparison Between a New Implantable Transcutaneous Bone Conductor and Percutaneous Bone-Conduction Hearing Implant	2013	To compare the percutaneous BAHA system with the Sophono Alpha 1 implant	Retrospective analysis	Small sample size of 6 patients that used the BAHA, Retrospective study	Nil	All included children had unilateral hearing loss (secondary to congenital ear canal atresia) and pure tone averages for all children improved following BAHA implantation. Percutaneous BAHA outcomes were slightly better compared with Sophonos in terms of sound field thresholds, speech recognition threshold, and speech comprehension at 65 dB. Skin reactions were comparable between groups
Doshi et al	Quality-of-Life Outcomes After Bone-Anchored Hearing Device Surgery in Children With Single-Sided Sensorineural Deafness	2013	To report outcomes in children with single sided sensorineural deafness treated with BAHA implantation	Retrospective case review	Small sample size of 8 children, retrospective, subjective questionnaire and visual analogue scale assessment, questionnaires filled by parents - therefore may reflect their opinions and not their child's, recall bias, children referred because of parental concern with their child's educational development - possibility of selection bias due to "motivated" parents	Nil	In all but 1 child (7/8 children) with single sided sensorineural deafness, BAHA implantation resulted in a positive Glasgow Children's Benefit Inventory score. Mean satisfaction score of the BAHA was 9/10. All the children had an improved health benefit. In addition, when compared to the literature concerning adults with single sided deafness treated with a BAHA, the results in this paper's pediatric population are more

							favourable
Oliveira et al	Results of the implantation of bone-anchored hearing aids in patients with Treacher-collins syndrome	2013	To present 2 cases of patients with Treacher-Collins syndrome who underwent implantation of BAHA	Case report	Only 2 cases, no validated QOL of measure, time of follow ups not provided	Nil	BAHA resulted in improved audiometric results for both patients with Treacher-Collins syndrome
Banga et al	Bone-anchored hearing devices in children with unilateral conductive hearing loss: a patient-carer perspective	2013	To evaluate the impact of a BAHA on the QOL in children with unilateral conductive hearing loss	Retrospective case note analysis	Small sample size (17 patients), retrospective, subjective written and visual questionnaires, recall bias, large range in ages (6 years to 16 years), large range between patients in terms of age of referral and age of BAHA implantation, large range in the number of hours that children were using the BAHA, questionnaires filled by parents - therefore may reflect their opinions, not their child's	The single sided deafness questionnaire (SSD) was specifically designed for assessment after BAHA implantation for single sided deafness	Implantation of BAHA resulted in improved health status, QOL and patient satisfaction in children with unilateral hearing loss
Bento et al	Bone-anchored hearing aid (BAHA): indications, functional results, and comparison with reconstructive surgery of the ear	2012	To review the main indications for BAHA, and assess the audiological benefits compared with other treatment modalities. Also to compare the data from the literature with the author's sample of 13 patients who underwent this procedure between 2000 and 2009	Narrative review	Not a systematic review, included studies of limited sample size and quality	Nil	BAHA is a better treatment option than reconstructive surgery for patients with bilateral deafness
Marsella et al	Pediatric BAHA in Italy: the "Bambino Gesù" Children's Hospital's experience	2012	To review the centre's experience with paediatric BAHA from 1995-2009	Retrospective review	Retrospective study	Large sample size of 47 children	Children with an indication for BAHA should be referred to specialised centres where they can receive a multidisciplinary approach. In such settings 1 stage surgery and implantation at younger than 5 appears safe
Zeitler et al	Bone-Anchored Implantation for Single-Sided Deafness (SSD) in Patients with Less Than Profound Hearing Loss	2012	To evaluate hearing outcomes in patients undergoing BAHA for single sided deafness with less than profound hearing loss (≤ 90 dB HL)	Retrospective chart review. 2 groups 1) The study group consisted of all SSD subjects with less than profound hearing loss (≤ 90 dB HL PTA) in the affected ear (residual hearing group). The control group comprised all SSD subjects implanted under the standard criteria (>90 dB HL PTA)	Retrospective, subjective outcome measure, different sample sizes between the 2 groups (19 in residual hearing group and 26 in the control group), small sample size, variance in inter-subject GHABP scores, authors are consultants for the main implant company used in study	Presence of a control group	Patients with less than profound unilateral SNHL demonstrated significant benefit in all measures for both fixed and variable signal to noise ratio (SNR) testing. These patients also reported satisfaction and subjective benefit with their BAHA device postoperatively. When the residual hearing group was compared with the control group, no significant objective differences were observed for any of the listening-in noise conditions

Janssen et al	Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review	2012	To compare outcomes following implantation of bilateral BAHAs versus unilateral BAHAs in patients with bilateral permanent conductive hearing loss	Systematic review	Systematic review. All 11 included studies were of low quality (observational studies). Included studies consisted of adults and children. Bias in selection of subjects receiving a second BAHA. Different selection criteria between studies for bilateral BAHA implantation. Limited sample sizes, unable to conduct summation analysis owing to heterogeneity of included studies. Variation between included studies on time of follow up. Included studies had subjective questionnaires	Systematic search. Subjects varied in age, hearing loss etiology, and previous amplification experience - therefore benefit from bilateral BAHA does not appear to be greatly limited by any of these variables	Bilateral BAHA provided superior audiological benefit compared to unilateral BAHA. Bilateral BAHAs also resulted in increased patient perceived benefit
Hill et al	Adult bone anchored hearing aid services in the United Kingdom: Building a consensus for development	2012	To gain consensus for BAHA services in the UK	Delphi technique	Poor response rate for initial round, increased weight of representation from Wrexham and Birmingham	High level of agreement in final consensus statements	A consensus of 33 statements was validated by this Delphi process. There was insufficient agreement on whether 15 patients per year was the minimum number of patients to run a viable BAHA service. 10% felt there was no viable minimum number of patients needed, 2% suggested 5 patients per year, 23% suggested a figure of between 8 and 12, and 65% felt that 15 patients per year was an acceptable minimum. To be included on the final consensus statement there needed to be an agreement of more than 75%
Davies et al	The first reported treatment of Nager syndrome associated hearing loss with bone-anchored hearing aids: case report	2012	To report the first case of treatment of Nager syndrome associated conductive hearing loss with bone- anchored hearing aids, in a three-year-old boy.	Case report	Only 1 case. Short 3 months follow up	Nil	A three-year-old boy with Nager syndrome was successfully treated for conductive hearing loss using bilateral bone-anchored hearing aids
Bouhabel et al	Congenital aural atresia: Bone-anchored hearing aid vs. external auditory canal reconstruction	2012	To compare audiological outcomes between BAHAs and EACR in children with congenital aural atresia	Retrospective chart review. 20 patients underwent EACR, whereas another 20 patients were implanted with a BAHA device	Retrospective review, small sample size (20 patients), large range in patient age (3-18), 3 patients had concurrent cholesteatoma, different preoperative hearing thresholds between the 2 groups	Study conducted over 9 years	19 of the 20 paediatric patients underwent BAHA implantation for unilateral hearing loss secondary to unilateral congenital aural atresia. This resulted in significant improvement in audiological outcome. BAHA implantation was found to be safe and reliable. It also resulted in better audiological outcomes than EACR in children with congenital aural atresia

Table 1. Summary and critical assessment of included studies

QOL quality of life, CSOM chronic suppurative otitis media, BAHA bone anchored hearing aid, EACR External auditory canal reconstruction

Initial score based on type of evidence	Quality of methodology	Consistency of results across studies	Directness	Effect size	Overall score
Low quality (non RCTs)	Significant limitations present	Most studies show similar results	Limited generalisability	Limited	Very low quality

Table 2. GRADE analysis across the 39 included articles

Author	Title	Year	Type of paper	Aim of paper	Methodology	Factors which lower quality	Factors which raise quality	Main findings
Proops	Bone anchored hearing aids. British Association of Otorhinolaryngologists Head & Neck Surgeons. Statements of clinical effectiveness	1998	Statement paper	To provide an overview of BAHAs including indications and evidence base	Narrative review/ consensus statement	Statement paper based on expert opinion and low quality observational studies	Nil	The BAHA is useful for patients with conductive or mixed hearing loss. It is of primary benefit to those who are unable to wear a conventional hearing aid. BAHAs give good audiological and QOL outcomes and are low risk. The service is best delivered by multidisciplinary teams
Health Quality Ontario	Bone anchored hearing aid. An Evidence-Based Analysis	2002	Health technology policy assessment	To determine the effectiveness and cost-effectiveness of BAHAs in improving the hearing of people with conductive or mixed hearing loss	Descriptive synthesis of findings from 36 research articles published between January 1990 and May 2002	All evidence was derived from observational studies (case series and non-randomised comparative studies). Included studies had small sample sizes ranging from 30-188 patients. There was heterogeneity amongst included studies. Many included studies focused on subjective patient satisfaction data	The majority of included studies had follow-up periods of eight years or longer	BAHA implantation is safe. The need for BAHA is not dependent on age. Objective and subjective measures demonstrated significantly improved hearing following BAHA implantation. Recipients of BAHAs should be at least 5 years old. The benefits of paediatric BAHA appear to outweigh the disadvantages. No literature on cost-effectiveness was available
Macnamara et al	The bone anchored hearing aid (BAHA) in chronic suppurative otitis media (CSOM)	1996	Journal article	To assess the outcome of BAHAs in patients with CSOM	Retrospective case review	Retrospective study, large range of follow-up (1 month to 7 years), short mean follow-up of 24 months, some patients received other previous treatments which may be a confounding factor, subjective questionnaire, risk of recall bias	Good sample size (69 patients)	CSOM is an indication for BAHAs. In 84% of cases, patients had significantly reduced discharge. The majority of patients wore their BAHA for more than eight hours per day and 58 per cent were more satisfied with their BAHA than their previous aid
Wazen et al	Results of the bone-anchored hearing aid in unilateral hearing loss	2001	Journal article	To evaluate the effectiveness of the BAHA in patients with unilateral conductive or mixed hearing losses	Prospective case series	Small sample size of 9 patients. Short follow up	Nil	BAHA was successful in improving binaural hearing in patients with unilateral conductive or mixed hearing loss. BAHA is a safe intervention
The National Deaf Children's Society	Quality Standards in Bone Anchored Hearing Aids for Children and Young People	2010	Quality standards guidelines	To provide guidelines for professionals working with deaf children and young people	Narrative review	No published methodology on how this guidance was produced, majority of included studies were observational studies with limited sample sizes and follow-up times	Nil	BAHAs are an effective option for children with chronic middle or outer ear infection, children with congenital abnormality of the ears, children with severe-profound unilateral hearing loss. BAHAs should be offered as soon as clinically appropriate to help develop speech and communication ability. This will be when the multidisciplinary team and the child's parents consider the child to be an appropriate candidate.

Gillett et al	Bone-anchored hearing aids: results of the first eight years of a program in a district general hospital, assessed by the Glasgow benefit inventory	2006	Journal article	To report the clinical results of a BAHA programme in a district general hospital	Retrospective questionnaire study	Retrospective study, subjective questionnaire, poor response rate for questionnaire (69%)	Good sample size (41 patients); long period of data collection (1994-2003)	BAHA implantation significantly improved QOL. The BAHA is a safe, and effective treatment for selected patients. A successful BAHA programme can be run in a district general hospital.
Burrell et al	The bone anchored hearing aid: the third option for otosclerosis.	1996	Journal article	To present their experience of BAHA for patients with otosclerosis	Retrospective case review	Retrospective study, small sample size (19 patients), full set of post operative data only available for 9 patients, subjective outcome measures, discrepancy between objective audiological assessment and patients' subjective responses	Nil	BAHA results in audiological improvements in patients with bilateral otosclerosis. BAHAs may be another option for those unwilling/unable to have stapedectomy or hearing aid
Personal communication	Personal communication. Dr David Selvdurai Consultant Ear Nose and Throat Surgeon, St George's Hospital, Tooting, London	Unknown	Personal communication	N/A	N/A	Personal communication, no transcript	Nil	Nil
NHS Specialised services	Specialised services national definitions set (2nd edition)	2009	Definition set	To identify an activity that should be regarded as specialised services	Narrative review	Included articles were observational studies with small sample sizes and short patient follow up. Some studies had subjective patient outcome measures	Nil	Suitable candidates for BAHA are those who have a conductive hearing loss, mixed hearing loss or single sided deafness and are unable to wear a conventional aid. They can also be suitable for atretic ears, chronic suppurative otitis media. The service requires a multidisciplinary team
Quebec AETMIS	Bone-anchored hearing aids. Summary. Agence d'évaluation des technologies et des modes d'intervention en santé	2006	Technology assessment	This is an assessment of BAHAs by AETMIS (Agence d'évaluation des technologies et des modes d'intervention en santé)	This assessment of BAHAs by AETMIS used the Health Quality Ontario review as a starting point. They then conducted a literature review between 2002 and 2005	AETMIS acknowledge that their assessment is based on limited evidence. Their document mainly used evidence gained from the 2002 Health Quality Ontario Review - where all included studies were of low quality evidence (case series or non randomised comparator studies). In their own literature review, covering the period from 2002 to 2005, none of the included studies were randomised controlled trials. They were observational studies with limited sample sizes	The majority of the studies have follow-up periods of eight years or longer	BAHAs significantly improved users' hearing thresholds and speech. BAHAs also led to subjective improvements in QOL and were deemed safe. BAHAs should be implanted following multidisciplinary team assessment. Centres performing BAHAs should treat at least 15 cases per year. Children should be aged 5 or over

Monksfield et al	Cost-effectiveness Analysis of the Bone-Anchored Hearing Device	2011	Journal article	To establish the cost-effectiveness of BAHAs	A prospective cohort case-control analysis	Costs for treatment were obtained from the Birmingham BAHA program and may not be nationally representative. Self-selection of patients who had been invited to participate may be a source of bias. Subjects acted as their own control rather than a true case-control study. There were limitations in cost collection data: data used were the billing rates to the primary care trust funding the BAHA. Detailed costs were not collected. These included: assessment, operation, post operative care, adverse events, primary care costs, non medical costs. The opportunity cost of a contralateral routing of signal aid was not taken into account for patients in which it may have been appropriate. Nineteen patients did not complete the full study which may affect utility results	Use of the Health Utility Index (HUI) as a measure of health utility because the HUI includes questions on hearing. Good sample size of 89 patients for data analysis.	The BAHA is likely to be cost effective. The ICER was £17,610 per QALY. At a cost-effectiveness threshold of £20,000 per QALY, there is a 56% probability that a BAHA is cost-effective and 69% probability if the threshold is £30,000 per QALY.
House et al	Bone-anchored hearing aids: incidence and management of postoperative complications	2007	Journal article	To investigate the complications of BAHA implantation	Retrospective case review	Retrospective study. Subjective questionnaire. Poor response rate for the questionnaire (69%)	Good sample size (149 patients)	Complications of BAHA are low in incidence and severity. The most common complication was skin overgrowing the BAHA abutment (7.4%)
ARIF	Aggressive Research Intelligence Facility. Bone anchored hearing aids (bilateral): conductive hearing loss deafness	2005	Advice on the evidence on the clinical and cost-effectiveness of BAHAs	To provide advice on the clinical and cost effectiveness of bilateral BAHAs in comparison with unilateral BAHAs	ARIF is a specialist unit based at the University of Birmingham. It incorporates research findings in order to help advise on problems submitted to ARIF	All evidence was derived from five small case series with sample sizes ranging from 3 to 25. No systematic reviews were identified. With no control group in the included studies, they may be a tendency for reporting bias and confounding factors	Nil	The clinical effectiveness of bilateral BAHAs is neither fully supported nor refuted
Personal communication	Personal Communication, Dr Elwina Timehin, Mr David Selvadurai, BAHA Programme, St Georges Healthcare NHS Trust	Unknown	Personal communication	To gain opinions from stakeholders	Personal communication	Personal communication	Nil	"Patients with unilateral sensorineural deafness do benefit from using the device. At present we give them a trial of a CROS (Contralateral Routing of Sound) aid when assessing their suitability for the device. In general if they benefit from its use then they definitely benefit from using the BAHA" and "The total number of patients is small, perhaps only 2-3 per year across all our PCTs"

Table 3. Summary and critical assessment of the evidence base informing the 2013 BAHA Commissioning Policy

QOL quality of life, CSOM chronic suppurative otitis media, BAHA bone anchored hearing aid, ICER incremental cost effectiveness ratio, QALY Quality adjusted life year

Initial score based on type of evidence	Quality of methodology	Consistency of results across studies	Directness	Effect size	Overall score
Low quality (non RCTs)	Significant limitations present	Most studies show similar results	Limited generalisability	Limited	Very low quality

Table 4. GRADE analysis across studies informing the 2013 NHS commissioning policy

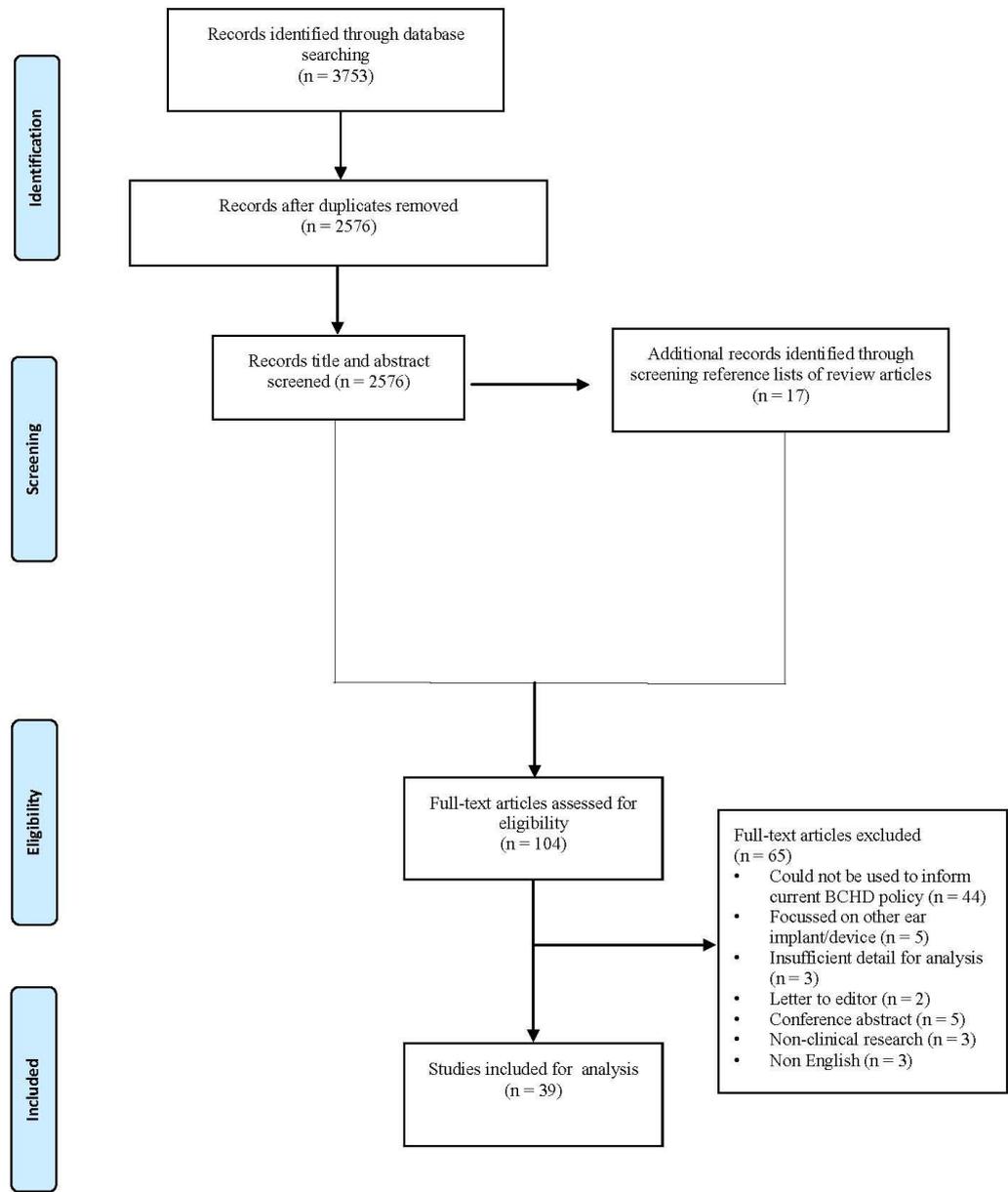


Figure 1. PRISMA Diagram