Manuscript title

Bone-anchored hearing aids for people with bilateral hearing impairment: a systematic review

Short title

Bone-anchored hearing aids for bilateral hearing impairment

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Abstract

Background: Bone-anchored hearing aids (BAHAs) are indicated for people with conductive or mixed hearing loss who can benefit from amplification of sound. In resource limited health care systems it is important that evidence regarding benefit of BAHAs is critically appraised to aid decision making.

Objective of review: To assess the clinical effectiveness of BAHAs for people with bilateral hearing impairment.

Type of review: Systematic review.

Search strategy: Nineteen electronic resources were searched from inception to November 2009. Additional studies were sought from reference lists, clinical experts and BAHA manufacturers.

Evaluation method: Inclusion criteria were applied by two reviewers independently. Data extraction and quality assessment of full papers were undertaken by one reviewer and checked by a second. Studies were synthesised through narrative review with tabulation of results.

Results: Twelve studies were included. Studies suggested audiological benefits of BAHAs when compared with bone conduction hearing aids or no aiding. A mixed pattern of results was seen when BAHAs were compared to air conduction hearing aids. Improvements in quality of life with BAHAs were found by a hearing-specific instrument but not generic quality of life measures. Issues such as improvement of discharging ears and length of time the aid can be worn were not adequately addressed by the studies. Studies demonstrated some benefits of bilateral BAHAs. Adverse events data were limited. The quality of studies was low.

Conclusions: The available evidence is weak. As such, caution is indicated in the interpretation of presently available data. However, based on the available evidence BAHAs appear to be a reasonable treatment option for people with bilateral conductive or mixed hearing loss. Further research into the benefits of BAHAs, including quality of life, is required to reduce uncertainty.

Keypoints

- Twelve studies were included; these were either one group before-and-after studies or cross sectional ‘audiological comparison’ studies.
- The weak methodological quality of the studies means their results should be viewed with caution.
- The included studies focused on hearing capacity. There is an absence of good quality evidence on the effects of BAHAs on quality of life, adverse events and issues such as improvement of discharging ears.
- Research designed to have a low risk of bias is required to underpin clinical decision making. Studies should focus on cost benefits, efficacy regarding audiometric measures, efficacy regarding disease control (e.g. reduced need for Otolaryngology input), and efficacy regarding patient perceived benefits of BAHA.

Background

Bone-anchored hearing aids (BAHAs) are indicated for people with conductive or mixed hearing loss who can benefit from amplification of sound, but are unable to use conventional air-conduction hearing aids. BAHAs are more expensive than air-conduction hearing aids, as they require surgery to fit the abutment and the amplification devices are more costly. Until recently, the hearing aid sound processing technology used was essentially a single channel analog design. Newer devices utilise multiple channels of sound processing, directional microphones, non-linear compression, feedback cancellation and noise reduction strategies, and these features are manipulated using fitting software.[1] However, the candidacy criteria for BAHAs have not altered as a result of the introduction of new sound processing technology.

Formal records of the number of BAHAs in use do not exist. It is thought that there are about 6000 to 7000 BAHAs in current use in the UK (David Proops, Birmingham Children's Hospital NHS Trust, March 2010) and suggestions that as many as 50,000 people have been fitted with a BAHA worldwide,[2] which includes people with single-sided as well as bilateral hearing loss. The number of people who could potentially benefit from a BAHA is uncertain as prevalence data focusing on conductive or mixed hearing loss are not readily available. Access to BAHA provision is variable throughout the developed world and funding is not universally available. Moreover, the clinical effectiveness of the BAHA is unclear.

People with bilateral hearing loss are most commonly fitted with a unilateral BAHA. However, it has been suggested that those with bilateral BAHAs benefit in terms of greater stimulation levels at the cochlea, better directional hearing and space perception, and better speech recognition in noise.[3-7] In a consensus statement from international (Europe and US) BAHA experts in 2005, bilateral application with thorough counselling was advocated in young children with severe congenital conductive hearing impairment.[8] The clinical efficacy of bilateral BAHAs, however, is still debatable.

Objective of review

Given the uncertainty surrounding the use of BAHAs, a synthesis of the available evidence on the benefits and harms of unilateral and bilateral BAHAs in bilateral hearing loss was undertaken to provide more direction to both providers of health care and people with hearing loss. We aimed to synthesise the highest quality evidence available to determine:

1) What is the clinical effectiveness of BAHAs compared with conventional air- and bone-conduction hearing aids, ear surgery and unaided hearing in bilateral hearing loss?
2) What is the clinical effectiveness of bilateral BAHAs compared with unilateral BAHAs in bilateral hearing loss?

This paper summarises the results of the systematic review of clinical effectiveness conducted as part of a project commissioned by the UK National Institute for Health Research Health Technology Assessment programme.[9]

Methods

Search strategy

Nineteen electronic databases, including MEDLINE, EMBASE and The Cochrane Library, were searched from their inception to November 2009 for published and ongoing studies, with no language restrictions (full details of the search strategy are available elsewhere [9]). Additional references were identified from bibliographies of retrieved articles, experts and BAHA manufacturers.

Evaluation method

Two reviewers independently screened studies for inclusion according to predefined criteria:

- *Population:* children or adults with bilateral hearing impairment;
- *Intervention:* BAHA (fitted unilaterally or bilaterally);
- *Comparisons:* BAHA versus bone-conduction hearing aids, air-conduction hearing aids, unaided hearing or ear surgery; unilateral BAHAs versus bilateral BAHAs;
- *Outcomes:* audiometric thresholds, aided audiometric thresholds (pure-tone and warble tone), speech recognition scores, validated measures of quality of life and patient satisfaction, adverse events;
- *Study design:* Prospective controlled studies, prospective one group before-and-after studies, cross-sectional 'audiological comparison' studies, prospective case series (no comparator condition). Only studies with the most rigorous designs were included for each comparison. Where higher level evidence was limited to BAHA models no longer in current use, lower level evidence for models in current use was considered.

Data extraction and quality assessment were undertaken by one reviewer and checked by a second reviewer. Where necessary, data were estimated from figures and/or means and standard deviations were calculated. Methodological quality and quality of reporting were assessed using standard criteria,[10] which were modified to accommodate the types of studies included in this review. During study selection, data extraction and quality assessment, any differences in opinion were resolved by consensus or a third reviewer.

A meta-analysis was inappropriate due to differences in outcome measures and patient populations. Studies were synthesised through a narrative review with full tabulation of results.[9] In reporting the results of studies the original terminology used in the papers has been used. Where this is obscure or unclear, a note of explanation has been inserted if possible.

Results

Quantity and quality of research

A flowchart showing the number of references excluded at each stage of screening is shown in Figure 1. Twelve studies (reported in 15 publications) were included in the systematic review. The included studies were either one group cohort before-and-after studies or cross sectional 'audiological comparison' studies. Only two studies included BAHA models that are in current use.[11,12] No eligible studies comparing BAHAs with ear surgery were identified.

Twenty-eight potentially relevant non-English language papers were identified (list available elsewhere[9]). Examination of the titles and English abstracts (where available) suggested none had a concurrent control group and it was unclear whether any of the studies met the inclusion criteria. Due to the limited value it was anticipated these studies would add to the review and in view of limited resources, these studies were not assessed further.

Characteristics of included studies are presented in Table 1. All 12 included studies were rated overall as 'weak' for their methodological quality and quality of reporting, providing the opportunity for bias (see Table S1 for a summary of methodological quality). The types of biases apparent in some of the studies include selection bias (participants may not be representative of the target population); performance bias (bias in the care provided); measurement or detection bias (how outcomes are assessed); and attrition bias (bias in withdrawals and dropouts). Any observed treatment effects could be due to bias, or a treatment effect could be obscured by bias. These biases could lead to overestimation or underestimation of the true effect.

BAHAs versus bone-conduction hearing aids

Four cohort before-and-after studies[13-18] included a comparison of BAHAs and bone-conduction hearing aids (Table 2). Improvements in the average sound field pure-tone or warble tone thresholds were found with a BAHA by two studies,[13,14] but statistical analysis was reported by only one of these ($p<0.01$).[14] A third study did not report thresholds averaged across frequencies, but found improved thresholds with the bone-conduction hearing aid at 0.25 kHz and 0.5 kHz, and with the BAHA at higher frequencies.[16] No statistical analysis was undertaken.

Speech discrimination tests varied between the studies (Table 2). A statistically significant improvement in speech reception threshold in quiet was found in people with a sensorineural loss of less than 30 dB HL.[18] Another study found no statistically significant difference in sound field speech discrimination scores.[14] Statistical analyses were not reported for other results from the included studies (Table 2).

Two studies reported using a validated measure of quality of life,[13,15] although limited data were presented by one of the studies[13] (see Table S2 for a summary of quality of life scores). The second study found no statistically significant differences between bone-conduction hearing aids and BAHAs using the 36-Item Short-Form Health Survey (SF-36) and European Quality of Life-5 Dimensions (EQ-5D), however a statistically significant improvement with a large clinical impact was found for handicap and disability with the Hearing Handicap and Disability Index.[15]

The number of otolaryngology visits over the preceding six months for draining ears was reported by one study, which found these to reduce from a mean of 5.4 (SD 4.19, range 0 to 20) visits with a bone-conduction hearing aid to a mean of 1.5 (SD 2.1, range 0 to 6) visits with a BAHA (statistical significance not reported).[15]

Four studies reported the results of subjective questionnaires on patient preference,[13,15,18] satisfaction,[14] comfort[16] and self-report of speech recognition in noise and quiet.[14,16-18] None of these questionnaires appeared to have been validated. The data from these studies can be viewed elsewhere,[9] however care should be taken when interpreting results due to the issues associated with non-validated questionnaires.

BAHAs versus air-conduction hearing aids

Five cohort before-and-after studies[14-20] and one cross-sectional study[11] included a comparison of BAHAs and air-conduction hearing aids (Table 3). The direction of effect for sound-field pure tone or warble tone thresholds was inconsistent between the five studies reporting hearing threshold data. Two studies reported a statistically significant improvement in mean sound field warble tone thresholds,[11,14] whilst another study described their data on average warble tone thresholds (0.2 to 4 kHz) as ‘comparable’ between BAHAs and air-conduction hearing aids, but did not provide statistical analysis.[19] Three studies presented thresholds at each frequency individually, but there was no clear pattern as to the comparative benefits of air-conduction hearing aids and BAHAs.[11,16,20]

The direction of the effect was also unclear for speech audiometry, with some studies finding better outcomes with the air-conduction hearing aid and some with the BAHA. A variety of different test protocols were used by the studies. Two studies reported better outcomes with the air-conduction hearing aid for mean sound field speech discrimination scores,[19] or for maximum phoneme score and speech recognition threshold.[16] However, statistical analysis was not conducted (Table 3). A later publication with a different patient group (less severe hearing loss), found a statistically significant decrement in mean speech reception threshold in quiet with the BAHA ($p<0.05$), but a statistically significant improvement in discrimination of speech in background noise (as measured by speech to noise ratio, $p<0.05$).[18] One study found no statistically significant difference in the maximum phoneme score, but a statistically significant improvement in speech in noise ratio with the BAHA.[20] Speech discrimination scores were statistically significantly better with the BAHA in the congenital aetiology group, but not the chronic suppurative otitis media group in one study.[14] The final study reported an improvement with the BAHA in speech understanding in noise described as ‘large and clinically significant’ in participants with mixed hearing loss.[11]

One study reported using a validated measure of quality of life, which was assessed using an air-conduction hearing aid prior to BAHA surgery and again after six months experience with a BAHA[15] (see Table S3 for a summary of quality of life scores). A statistically significant increase in anxiety/depression with BAHAs was found by the EQ-5D, but the clinical effect was small. No other statistically significant differences were found between air-conduction hearing aids and BAHAs by the EQ-5D or the SF-36, however a statistically significant improvement with a large clinical impact was found for handicap and disability with the Hearing Handicap and Disability Index.[15]

The number of otolaryngology visits over the preceding six months for draining ears was reported by one study, which found a reduction with BAHAs compared with air-conduction hearing aids [mean visits 12.7 (SD 10.5) versus 3.3 (SD 4.8)], however statistical analysis was not undertaken.[15]

Five studies reported the results of subjective questionnaires on patient preference,[15,18-20] satisfaction,[14] comfort [16,19] and opinions on speech recognition in noise and quiet.[14,16-18] None of these questionnaires appeared to have been validated. The data from these studies can be viewed elsewhere,[9] but as previously stated, care should be taken when interpreting the results.

BAHAs versus unaided hearing

Four cohort before-and-after studies[12-14,19] included a comparison of BAHAs with unaided hearing (Table 4). All four studies found improvements in sound field thresholds (pure-tone or warble tone) with the BAHA compared with unaided hearing thresholds, and these improvements were statistically significant in the two studies that conducted analysis.[12,14]

Improvements were found in sound field speech discrimination scores,[14,19] speech recognition scores,[12] speech recognition threshold in quiet[12] and speech recognition in noise.[12] However, statistical analysis was not undertaken (Table 4). No self-report measures were reported by these four studies.

Unilateral versus bilateral BAHAs

Four cross sectional studies[3,5,21-23] compared performance on audiological measures with unilateral versus bilateral BAHAs (Table 5). The participants in the included studies all underwent sequential (separate operations) implantation of the bilateral BAHAs.

Two studies reported data on hearing thresholds. Sound-field average tone thresholds were improved with bilateral BAHAs compared with unilateral BAHAs in adults[23] and a small group (n=3) of children[3] with previous experience of bilateral BAHAs, but statistical analysis was not undertaken (Table 5).

Two studies found speech recognition thresholds in quiet were statistically significantly better with bilateral BAHAs[5,23] (Table 5). Another study found all 11 participants scored 100% with right, left and bilateral BAHAs for sound field speech in quiet.[22]

Different tests of speech in noise demonstrated that bilateral BAHAs produced better results than one BAHA when noise was presented from baffle/better hearing side (the side with the BAHA in the unilateral condition), but not when noise was presented from the shadow side (the side opposite to the BAHA in the unilateral condition).[5,22,23]

Three studies demonstrated that sound localisation abilities were improved with bilateral BAHAs.[3,5,23] Correct localisation, localisation within 30˚ and lateralisation measured at 0.5 kHz and 2 kHz were significantly better than chance with bilateral BAHAs, but not with unilateral BAHAs, in the study by Bosman and colleagues. Bilateral BAHAs performed statistically significantly better than unilateral BAHAs.[5,21] (Table 5).

Priwin and colleagues found similar results in their studies of twelve adults[23] and nine children,[3] although no statistical analyses were undertaken. In the first study, accuracy of sound localisation with a unilateral BAHA on the best or shadow side were close to the chance level, while with a bilateral BAHA the accuracy improved. Similarly, the second study found an improvement in sound localisation and sound lateralisation abilities with bilateral BAHAs, while with unilateral BAHAs the results were close to chance levels[3] (Table 5). Two studies used the binaural masking level difference test to suggest that BAHAs give binaural hearing.[5,23] However, it has been argued that the interpretation of some listening tests with bilateral BAHAs is complex, due to effects arising from cross hearing, and is currently incomplete (see Rowan & Gray 2008[24] for background on these issues).

One study[3] described self-report measures using validated tools to assess hearing skills in 'meaningful, real world situations' and hearing aid outcomes (see Table S4). Scores appeared similar between unilateral and bilateral BAHA users for most items, however given the very small sample sizes (n=2 to n=6), these results should be interpreted with caution.

Adverse events

Only three of the included studies reported minimal data on adverse events[13,18,20] (Table 6), therefore additional data from prospective case series were sought. It should be noted that these studies did not undergo the same process of data extraction and quality assessment. Five prospective case series were identified[25-29] (see Table S5 for a summary of these studies) and reported loss of implants between 6.1% (9 to 25 months follow-up)[28] and 19.4% (median 6 years follow-up).[25] The vast majority of participants in the prospective case series experienced no or minor skin reactions.

Discussion

Clinical applicability of the study

Whilst the evidence base is not strong, it appears that when applied to bilateral conductive or mixed hearing loss, audiometric outcomes from BAHA are good and adverse events are rarely reported. Based on the available evidence BAHAs are a reasonable treatment option for consideration by health care commissioners, clinicians and patients, however further research would reduce the uncertainties regarding BAHAs.

Synopsis of key findings

The findings of this review suggest that hearing is improved with BAHAs compared with unaided hearing, and while there appear to be some audiological benefits of BAHAs when compared with conventional bone-conduction hearing aids, the limited evidence base does not provide a reliable estimate of the degree of benefit. The audiological benefits of BAHAs when compared with air-conduction hearing aids are less clear. Limited data suggest an improvement in quality of life with BAHAs when compared with conventional aids, but this was identified by the hearing-specific instrument and not generic quality of life measures. There is an absence of reliable evidence regarding other potential benefits, such as length of time the aid is able to be worn and improvement of discharging ears. The evidence suggests there are some benefits of bilateral BAHAs compared with unilateral BAHAs in many, but not all, situations, and the presence of binaural hearing with bilateral BAHAs remains uncertain.

Comparisons with other studies

These findings are broadly in line with those of a previous systematic review,[30] which assessed the nonacoustic (self-report generic and disease-specific quality of life) benefits of BAHAs. The authors of the previous review concluded that there is limited statistically supported, empirically controlled evidence supporting the nonacoustic benefits of BAHAs relative to more conventional hearing aids or no hearing aids at all. However, the previous review was limited to nonacoustic outcomes and no other systematic reviews of BAHAs for bilateral hearing loss were identified.

Strengths and limitations of the systematic review

This systematic review brings together the evidence for the clinical effectiveness of BAHAs for people with bilateral hearing impairment. This evidence has been critically appraised and presented in a consistent and transparent manor following the principles for conducting as systematic review. The methods were set out in a research protocol which defined the research question, inclusion criteria, data extraction and quality assessment process and methods to be employed at different stages of the review. The conclusions drawn from the present systematic review are constrained by the limitations of the available evidence. Despite a wide ranging and systematic search, no prospective trial with a concurrent control group was identified. There is a high risk of bias in the included studies. Synthesis of the included studies was through narrative review as differences in participants, comparator and outcome measures meant that meta-analysis was inappropriate. No prospective study comparing BAHAs with ear surgery was identified, therefore no conclusions could be drawn. The non-English language references identified by the searches were not translated and screened. However, none of these papers appeared to present higher level evidence and it is unlikely that the inclusion of additional lower level evidence would change the conclusions of this review.

The studies reviewed date from the inception of BAHAs to November 2009 (date of the literature searches). During that time period the hearing aid sound processing technology used was essentially a single channel analog design; however devices that utilise new sound processing technology have recently been released to market by different manufacturers. Research reports indicating improved audibility with such technology are beginning to appear in the conference literature, but whilst these devices are more adaptable, and that may bring some incremental improvement in performance in some users, the candidacy criteria for BAHAs have not altered. As such the results of the analysis undertaken in this systematic review can be brought to bear on current decisions about the commissioning of BAHA services, and the applicability in an individual patient.

To assess whether any new studies have been published since the complete literature searches were undertaken in November 2009, we updated the Medline search (May 2011). Of 78 references identified by the search strategy, two studies were found to meet the inclusion criteria of the systematic review.[31,32] It should be noted that these studies did not undergo the process of data extraction and quality assessment specified a priori in the systematic review protocol. One study[31] compared BAHA with unaided hearing, although the BAHA devices used by participants (n=17) included those no longer manufactured as well as those in current use. The study found an improvement in outcomes with BAHA versus without BAHA. The second study[32] compared a relatively new digital BAHA device versus a powerful behind-the-ear device with feedback cancellation in 16 selected participants with chronic middle ear problems and dry ears. The authors concluded that speech recognition seemed to be better with the BAHA than with the behind-the-ear device in patients with mixed hearing loss when the air-bone gap exceeded approximately 35 dB. Whilst it is important to acknowledge these studies, formal inclusion of their results in the systematic review would not have altered our conclusions.

The outcome measures reported by the included studies have limitations, and it is not always clear what is clinically significant or meaningful to the individual. Audiological measures such as hearing threshold levels or speech reception levels in quiet have often been applied, but may not be sufficiently sensitive to capture the benefit delivered to the individual. We acknowledge that this review has somewhat simplified the interpretation of outcomes, where we have assumed that lower hearing thresholds are better than higher thresholds throughout the review. The review used the study authors' descriptions such as 'improvement' or 'deterioration' where available, however no interpretations were offered by many of the included studies. Data were often presented only in figures and several studies did not report summary statistics such as means and measures of variance.

Although the air-conduction hearing aid may produce better audiometric results in some situations, it should be noted that the most appropriate hearing aid may not necessarily be the one with the best sound processing performance. Other factors such as comfort, the ability to wear the aid and reduced susceptibility to infections need to be considered, but these issues have not been adequately addressed by the included studies. Some included studies reported patient preference, however the tools used were not validated and likely to be biased, especially considering evidence that suggests individuals report preferring the second hearing aid tested, even if it is in fact an identical aid.[33]

Some data were available on the impact of BAHAs on quality of life. One study reported improvements with the Hearing Handicap and Disability Index but not the SF-36 or EQ-5D. The Hearing Handicap and Disability Index is specific to hearing loss, while the SF-36 and EQ-5D are generic measures that do not have a hearing dimension, which may explain the difference in outcomes between the different instruments. Important issues related to comfort, discharge and pain are also not adequately addressed by the instruments. It is therefore difficult to judge the impact of a BAHA on quality of life from these results.

Conclusions

In conclusion, the available evidence is methodologically weak and the results have a high risk of bias. As such, caution is indicated in the interpretation of results. However, based on the available evidence BAHAs appear to be a reasonable treatment option for people with bilateral conductive or mixed hearing loss. Further research into the benefits of BAHAs, including quality of life, is required. Whilst the BAHA intervention does not lend itself to randomised controlled trial study designs, waiting list control studies would be feasible. Further, a comprehensive approach to a number of issues would be beneficial, including: cost benefits, efficacy regarding audiometric measures, efficacy regarding disease control (e.g. reduced need for Otolaryngology input), and efficacy regarding patient perceived benefits.

Sources of support

This project was funded by the NIHR Health Technology Assessment programme (project number 08/25/02) and will be published in full in *Health Technology Assessment*. See the HTA programme website (www.hta.ac.uk) for further project information. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Department of Health.

Acknowldegements

We would like to thank the anonymous peer reviewers for their helpful suggestions. We also would like to thank the advisory group for advice and peer review of a draft of the original report for the National Institute for Health Research Health Technology Assessment programme: Mark Lutman, Professor of Audiology, Institute of Sound and Vibration Research, University of Southampton; Stephen Palmer, Professor in Health Economics, University of York; and Lyn Kolsteron, Service User and Chairperson of BAHA Users Support

(Kent) (BUSK). In addition we acknowledge advice or information provided by Daniel Rowan (Institute of Sound and Vibration Research, University of Southampton), Mark Flynn (Cochlear Limited) and Dianne Darbyshire (Oticon Medical).

Conflicts of Interest

DWP has been an occasional advisor to the Nucleus™ Corporation (parent company of Entific® Medical Systems/Cochlear™), has had several research grants from the Nucleus Corporation, and runs a surgical training course annually for the company for which he is paid a fee.

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Figure 1 Flowchart of identification of studies

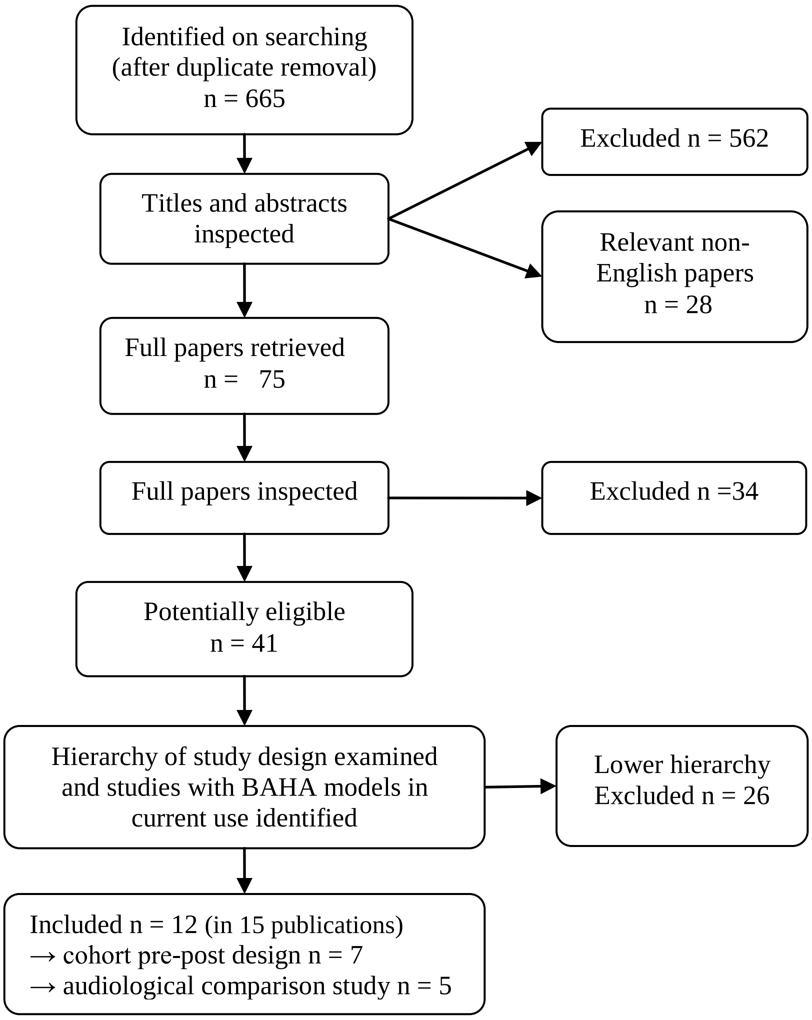

Table 1 Characteristics of included studies

Study	Design	Intervention (timing of audiology)	N	Sex	Age mean years (range)	Participants indication
Unilateral: BAHA vs bone-conduction hearing aid						
Béjar-Solar et al. [13] Mexico	CPP	1. Unaided (pre-op) 1. BCHA (pre-op) 2. BAHA Classic 300 (at 6 months)	11	7M 4F	10 (5-7)	Inoperable bilateral congenital microtia atresia. BC PTA better than 45 dB HL with 100% speech discrimination
Unilateral: BAHA vs air-conduction hearing aid						
[a]Burrell et al. [19] UK	CPP	1. ACHA (pre-op) 2. Unaided (unclear if pre- or post-op)[b] 3. BAHA Superbass or ear level BAHA (NR)	9	NR	NR	Otosclerosis. Average BC thresholds (0.5-4 kHz) < 40 dB HL for ear level BAHA, < 60 dB HL for body worn Superbass
Flynn et al.[11] Sweden	ACS	1. BAHA Intenso 2. ACHA Oticon Sumo DM, digital superpower hearing aid (same session)	10	5M 5F	59 (32-75)	Mixed hearing loss, no further details. Sensorineural hearing loss component ≥ 25 dB HL plus air-bone gap > 30 dB
[c]Mylanus et al.[20] The Netherlands	CPP	1. ACHA (pre-op) 2. BAHA, model NR (4 to 6 weeks)	34	12M 22F	48 (26-72)	Bilateral conductive or mixed hearing loss with chronic otitis.
Unilateral: BAHA versus bone-conduction hearing aid and air-conduction hearing aid, in separate subgroups						
[a]Cooper et al.[14] UK	CPP	Four subgroups: previous aid AC or BC, aetiology CON or CSOM 1. Unaided[b] 2. Previous aid (pre-op) 3. BAHA HC 200, 300 or 220 (at 6 months)	AC 33 BC 35	NR	CSOM/AC 58 CSOM/BC 61 CON/AC 30 CON/BC 24	Chronic suppurative otitis media or congenital aetiology. Average BC thresholds (0.5-4 kHz) <40 dB HL (ear level) or <60 dB HL (bodyworn), speech discrimination score ≥ 60%.
[c]Hol et al.[15] The Netherlands	CPP	Two subgroups: previous aid AC or BC 1. Previous aid (pre-op) 2. BAHA Classic or Cordelle (at 6 months)	AC 36 BC 20	AC 12M 24F BC 9M 11F	AC 47.9 (24-73) BC 62.0 (42-82)	Acquired conductive or mixed hearing loss, no further details.
[c]Snik et al.[16] [17,18] The Netherlands	CPP	Two subgroups (previous aid AC or BC):[16] 1. Previous aid (pre-op) 2. BAHA HC220 (at least 4 weeks)	AC 5 BC 7	NR	AC 60.6 (34-84) BC 62 (46-78)	Recurrent otorrhoea. Severe mixed hearing loss with sensorineural components of 45 to 60 dB HL.[16]
		Four subgroups: previous aid AC or BC, current BAHA HC200 or HC220 [17] 1. Previous aid (pre-op)	AC 14 BC 44	NR	NR (10-77)	Chronic otitis media/externa, aural atresia. Both normal to moderate and more severe sensorineural hearing loss. [17]

		2. BAHA HC200 or HC220 (≥ 4 weeks)				
		Two subgroups: previous aid AC or BC: [18] 1. Previous aid (pre-op) 2. BAHA HC 200 (at least 6 weeks)	AC 8 BC 33	NR	43 (10-70)	Conductive or mixed binaural hearing loss, sensorineural hearing loss of ≤ 30 dB HL. No details of aetiology.[18]
Unilateral BAHA versus unaided hearing, see also three studies above[13,14,19]						
Kompis et al.[12] Switzerland	CPP	1. Unaided (at baseline) 2. BAHA Divino (at 3 months)	7	3M 4F	49 (19-66)	Bilateral conductive hearing loss, some mild to moderate sensorineural hearing loss.
Unilateral BAHA versus bilateral BAHAs (all assessed at same session)						
Bosman et al.[5,21] The Netherlands	ACS	BAHA HC 200 or Classic 300 1. Unilateral, first implant side 2. Bilateral	25	14M 11F	44.3 (12-74)	Recurrent otorrhoea, otitis externa, congenital atresia.
Dutt et al.[22] UK	ACS	BAHA Compact 1. Unilateral, best response, or right and left 2. Bilateral	11	3M [d] 9F	42.3 (22-54)	Treacher Collins syndrome, Goldenhar's syndrome, bilateral: mastoid cavities, congenital hearing loss, chronic otitis media, microtia, acquired otosclerosis.
Priwin et al.[23] Sweden	ACS	BAHA Compact or Classic 300 1. Unilateral, best and shadow side 2. Bilateral	12	3M 9F	51.7 (27-68)	Chronic otitis, otosclerosis, congenital ear canal atresia.
Priwin et al.[3] Sweden	ACS	BAHA Compact or Classic. Two groups: 1. Unilateral - unaided and 1 BAHA 2. Bilateral – unaided, 1 and 2 BAHAs	Unilateral 3 Bilateral 6	3M 6F	11.3 (6-17)	Majority had symmetrical maximal or near-maximal conductive bilateral hearing loss.

AC = air conduction; ACHA = air-conduction hearing aid; ACS = cross-sectional 'audiological comparison study'; BC = bone conduction; BCHA = bone-conduction hearing aid; CON= congenital aetiology, CPP = cohort pre and post study (one group before-and-after study); CSOM = chronic suppurative otitis media; F = female; M = male; NR = not reported; PTA = pure tone average.

[a] There may be overlap of participants between these studies conducted in the UK.

[b] Unaided condition was assessed pre and post-operatively and it is not clear which of these data are presented.

[c] There may by overlap of participants between these studies conducted in The Netherlands.

[d] 1 patient chose not to participate.

Table 2 Audiologic measures: BAHA versus bone conduction hearing aid

Study and outcomes	BCHA	BAHA model	Comparison	Comment
Béjar-Solar et al.[13] (n=11)	**BCHA**	**Classic 300**	**Difference**	
Sound field pure-tone average (0.125-3 kHz), dB HL	30	19	-11 (37% improvement)	Standard deviations not reported
Mean intensity (dB HL) at which 100% speech discrimination achieved in background noise at 65 dB	62	48	-14 (23 % improvement)	Non standard speech test material used: "colloquial language common to Mexico City"
Accurate directional identification of location of a sound source (% of cases)	0	80		"Ability to pinpoint the position of natural vocal speech in an area with high background nose at a distance of 3m"
Cooper et al.[14] CSOM (n=19), CON (n=16)	**BCHA**	**HC 200, 300, 220**	**P value**	
Mean sound field warble tone thresholds, dBA (0.5-4 kHz)	CSOM 42 CON 31	CSOM 35 CON 26	p<0.01 p<0.01	Student's t-test
Mean sound field speech discrimination score (at 63 dB), % correct	CSOM 65 CON 86	CSOM 72 CON 85	p=ns p=ns	Boothroyd word list material used Student's t-test
Snik et al.[16-18]	**BCHA**	**HC 200, 220**	**P value**	
Snik et al. 1992 [16] (n=7)	*BCHA*	*HC220*		"Standard Dutch phonetically balanced word lists consisting of 10 monosyllables"
Maximum phoneme score, %, mean (SD), range	36.1 (28.9), 0 to 85	48.7 (31.7), 0 to 100	NR	
Speech recognition threshold, dB(A), mean (SD), range[b]	(n=2) 40 (7.1), 35 to 45	(n=4) 38.8 (11.1), 25 to 50	NR	
Average difference between the sound field warble thresholds (BCHA minus BAHA), dB 0.25 kHz 0.5 kHz 1 kHz 2 kHz 4 kHz 8 kHz	 2 3 -2 -10 -14 NR			
Snik et al. 1994 [17] (n=44)	*HC 220, HC 200*			"Phonetically balanced monosyllable" material used
Patients with a statistically significant change in: - speech recognition in quiet score with BAHA	*HC 220 (n=11)* Improved: 6 of 11 (54%); Deteriorated: 0 of 11			

- speech to noise ratio score with BAHA - speech recognition in quiet score with BAHA - speech to noise ratio score with BAHA	Improved: 5 of 11 (44%); Deteriorated: 0 of 11 *HC 200 (n=33)* Improved: 4 of 33 (12%); Deteriorated: 0 of 33 Improved: 20 of 33 (60 %); Deteriorated: 0 of 33	
Snik et al. 1998 [18] *(n=33)*	*HC 200*	“Sentence Recognition in Noise” test used
Change in speech reception threshold in quiet (BCHA minus BAHA), mean dB (SD)	2.7 (4.4), improvement $p<0.05$	
Change in speech to noise ratio, mean dB (SD)	2.5 (2.2), improvement $p<0.05$	

Note: study authors’ original terminology retained. BCHA = bone-conduction hearing aid; CON = aetiology congenital; CSOM = aetiology chronic suppurative otitis media; NR = not reported; SD = standard deviation.

Table 3 Audiologic measures: BAHA versus air-conduction hearing aid

Study and outcomes	**ACHA**	**BAHA model**	**Comparison**	**Comments**
Burrell et al.[19] (n=9)	**ACHA**	**model NR**		
Average sound field warble tone thresholds (0.5 to 4 kHz), mean (SD), range, dBA	33 (5.4), 28 to 40	30.6 (8.1), 22 to 43	NR	
Sound field speech discrimination at 63 dBA, % correct, mean (SD), range	91.6 (14.7), 60 to 100	84 (22.3), 30 to 100	NR	Boothroyd wordlist material used
Cooper et al.[14] **CSOM (n=24), CON (n=6)**	**ACHA**	**HC 200, 300, 220**	**P value**	
Mean sound field warble tone thresholds, (dBA, 0.5-4 kHz)	CSOM 40 CON 41	CSOM 33 CON 28	p<0.01 p<0.01	Student's t-test
Mean sound field speech discrimination score (at 63 dB), % correct	CSOM 69 CON 57	CSOM 72 CON 82	p=ns p<0.05	Boothroyd word list material used Student's t-test
Flynn et al.[11] (n=10)	**ACHA**	**Intenso**	**Difference**	
Average aided warble tone thresholds (dB SPL) 0.25 kHz 0.5 kHz 1 kHz 2 kHz 3 kHz 4 kHz 6 kHz 8 kHz	 39 42 37 43 46 50 75 68	 47 39 30 [a] 31 [a] 39 [a] 41 [a] 53 55	p<0.01 overall	Statistical test not reported
Speech-in-noise ratio, dB	3.44	0.88	2.56	"Swedish version of Hearing in Noise test" used
Mylanus et al.[20] (n=34)	**ACHA**	**model NR**	**Difference**	
Mean sound field threshold, dB HL (SD[b]) 0.25 kHz 0.50 kHz 1 kHz 2 kHz 4 kHz 8 kHz	 40 36 28 22 (SD 11.9) 37 55 (SD 21.3)	 39 36 22 (SD 8.3) 25 33 43 (SD 22.3)	 p=ns p=ns p<0.01 p=ns p=ns p<0.001	Two tailed student t-test
Maximum phoneme score (mean ± SD)	Data NR	Data NR	1.0% ± 5.4%, p=ns	Two tailed student t-test

Speech in noise ratio improvement	Data NR	Data NR	1.1 ± 2.1 dB p<0.01	Two tailed student t-test
Snik et al.[16-18]	**ACHA**	**HC 200, 220**		
Snik et al. 1992 [16] (n=5)	*ACHA*	*HC 220*		"Standard Dutch phonetically balanced word lists consisting of 10 monosyllables"
Maximum phoneme score, %, mean (SD) range	81.6 (8.7), 70 to 90	67.6 (22.2), 43 to 90		
Speech recognition threshold, dB(A), mean (SD) range	39 (10.8), 20 to 45	(n=3) 45 (5), 40 to 50		
Average difference between the sound field warble thresholds, dB (ACHA minus BAHA) 0.25 kHz 0.5 kHz 1 kHz 2 kHz 4 kHz 8 kHz	 -6 -5 3 4 15 0			
Snik et al. 1994 [17] (n=14)	*HC 220, HC 200*			"Phonetically balanced monosyllable" material used
Patients with a statistically significant change in: - speech recognition in quiet score with BAHA - speech to noise ratio score with BAHA - speech recognition in quiet score with BAHA - speech to noise ratio score with BAHA	 HC 220 (n=5) Improved: 3 of 5 (40%); Deteriorated: 1 of 5 (20%) No results for HC 220 HC 200 (n=9) Improved: 0 of 9; Deteriorated: 1 of 9 (11%) Improved: 5 of 9 (55%); Deteriorated: 1 of 9 (11%)			
Snik et al. 1998 [18] (n=8)	*HC 200*			"Sentence Recognition in Noise" test used
Change in speech reception threshold in quiet (ACHA minus BAHA), mean dB (SD)	-6.4 (3.7), p<0.05 significant deterioration			
Change in speech to noise ratio, mean dB (SD)	1.6 (1.0), p<0.05 significant improvement			

Note: study authors' original terminology retained. ACHA = air-conduction hearing aid; CON = aetiology congenital; CSOM = aetiology chronic suppurative otitis media; NR = not reported; SD = standard deviation; dB SPL (sound pressure level)

[a] States that clinically, audibility improved by 5-15 dB at these frequencies (although figure does not seem to show that for 0.5 kHz)

[b] SDs for each frequency not reported. States that the SD varied between 11.9 dB at 2 kHz and 21.3 dB at 8 kHz for ACHA, and between 8.3 dB at 1 kHz and 22.3 dB at 8 kHz for BAHA.

Table 4 Audiologic measures: BAHA versus unaided hearing

Study and outcomes	Unaided	BAHA model	Comparison	Comment
Béjar-Solar et al. [13] (n=11)	**Unaided**	**BAHA Classic 300**		
Sound field pure tone average threshold (1.25 to 3 kHz), dB HL	64	19		
[a] Burrell et al. [19] (n=9)	**Unaided**	**model NR**		
Average sound field warble tone thresholds (0.5 to 4 kHz), mean (SD), range, dBA	49.4 (11.9), 40 to 78	30.6 (8.1), 22 to 43		
Sound field speech discrimination at 63 dBA, % correct, mean (SD), range	74 (19.5), 50 to 98[b]	84 (22.3), 30 to 100		
[a] Cooper et al. [14] **Previous aid BC; CSOM (n=19), CON (n=16)** **Previous aid AC; CSOM (n=24), CON (n=9)**	**Unaided**	**HC200, 300, 220**	**P value**	
Mean sound field warble tone thresholds, dB (dBA, 0.5-4 kHz)	**Previous aid BC** CSOM 63 CON 62 **Previous aid AC** CSOM 60 CON 68	**Previous aid BC** CSOM 35 CON 26 **Previous aid AC** CSOM 33 CON 28	 p<0.01 p<0.01 p<0.01 p<0.01	Student's t-test
Mean sound field speech discrimination score (at 63 dB), % correct	**Previous aid BC** CSOM 17 CON 3 **Previous aid AC** CSOM 19 CON 17	**Previous aid BC** CSOM 72 CON 85 **Previous aid AC** CSOM 72 CON 82	 p=NR p=NR p=NR p=NR	Boothroyd word list material used Student's t-test
Kompis et al.[12] (n=7)	**Unaided**	**Divino**	**P value**	
Average improvement in sound-field thresholds over all frequencies compared with unaided, dB		28.0	p<0.0001	Wilcoxon matched pairs signed rank test
Speech recognition thresholds in quiet using two-digit numbers, dB (assume value is mean)	54	23	p=NR	Freiburger numbers material
Speech recognition scores for monosyllabic words in quiet, % correct (assume mean) 50 dB SPL 65 dB SPL 80 dB SPL	 5 15 50	 45 90 95	 p=NR	Freiburger monosyllabic words material

Speech recognition threshold in noise (noise presented from front or back), dB Front Back	 12 9	omnidirectional / directional mode 3 / 4 3 / 1		Basler sentence test material

Note: study authors' original terminology retained. AC = air-conduction; BC = bone-conduction; CON = aetiology congenital; CSOM = aetiology chronic suppurative otitis media; NR = not reported; SD = standard deviation.

[a] Burrell 1996 and Cooper 1996: BAHA data are also presented in Table 2 and Table 3 for the comparisons with bone-conduction hearing aids and air-conduction hearing aids, respectively.

[b] Data missing for two participants

Table 5 Audiologic measures: unilateral BAHA versus bilateral BAHAs

Study and outcomes	Unilateral	Bilateral		Comparison	Comment
Bosman et al. [5,21] **(n=25)**	**Unilateral**	**Bilateral**		**P value**	"Standardised sentence material" used. Repeated measures ANOVA applied.
Speech reception threshold in quiet (dBA)	41.5	37.5		p<0.001	
SNR (dBA), noise from the baffle side	-0.7	-3.2		p<0.001	
SNR (dBA), noise from shadow side	-3.4	-4.0		p>0.05	
Directional hearing at 0.5 kHz, % - Correct localisation - Localisation within 30° - Lateralisation Directional hearing at 2 kHz, % - Correct localisation - Localisation within 30° - Lateralisation	 23 56 54 24 58 64	 42 [a] 90 [a] 85 [a] 45 [a] 89 [a] 87 [a]		p<0.001 across all observations	
Proportion of responses corresponding to the fitted BAHA side at: 0.5 kHz 2 kHz	 75.3% 70.3%	 45.7% 48.8%			
Binaural masking level difference signal to noise ratio	*Bilateral BAHAs (n=9)*				
	S_0N_0	$S_\pi N_0$	S_0N_π		
0.125 kHz	2.2	3.8	-3.7	p<0.001	
0.25 kHz	0.1	-6.0	-5.1	p<0.001	
0.5 kHz	0.4	-5.9	-3.9	p<0.001	
1 kHz	0.4 -	-3.3	-4.9	p>0.05 (ns)	
Dutt et al. [22] **(n=11)**	**Unilateral**	**Bilateral**			
Speech in quiet (Boothroyd word list cumulative scores, 30 words) at:	*Best response*				
30 dB intensity levels	1	5			
40 dB intensity levels	13	19			
50 dB intensity levels	20	24			
60 dB intensity levels	25	28			
70 dB intensity levels	27	29			
80 dB intensity levels	30	30			
Speech in quiet (Bamford-Kowal-Bench sentences)	All 11 patients scored 100% with right, left and bilateral BAHAs.				
Speech in noise (Bamford-Kowal-Bench cumulative	*Best response*				

sentence scores) at: plus 10 SNR zero SNR minus 10 SNR	 99 80 0	 100 81 1		
Plomp test, % correct score (mean (SD), range) - sound front, noise front	*Left side:* 76 (11.7), 56-93 *Right side:* 77.3 (11.7), 58-90	82.4 (13.3), 60-97		
- sound front, noise left	*Left side:* 40.1 (25.3), 2-71 *Right side:* 84.1 (11.2), 55-97	71.1 (14.9), 44-95		
- sound front, noise right	*Left side:* 88.2 (9.0), 72-100 *Right side:* 45.8 (22.1), 13-88	79.5 (11.6), 58-93		
Priwin et al.[23] (n=12)	**Unilateral**	**Bilateral**	**P Value**	
Average difference in sound field tone thresholds (at 0.25 to 8 kHz), dB - sound presented in front, at best side and from behind patients - sound presented at shadow side	 2 to 7 dB improvement with bilateral 5 to 15 dB improvement with bilateral			
Speech recognition in quiet, average threshold, dB HL	*Best side* 38.7	 33.3	 p=0.001	"Phonetically balanced three-word sentences, extracted from five-word sentence tests". Student's paired t-test.
Speech in noise (change in SNR with bilateral BAHA), masking noise presented: - at best side - at shadow side - as surrounding noise	 3.1 dB improvement 1.0 dB deterioration 2.8 dB improvement			
Directional hearing % of correct answers[b] 0.5 kHz 2.0 kHz % of answers within 30° of correct response[b]	*Best/Shadow side* 12 / 11 8 / 10	 25 23		

0.5 kHz 2.0 kHz	23 / 30 28 / 27	53 51		
Binaural masking level difference[c]: 0.25 kHz: - SπN0 - S0Nπ 0.5 kHz: - SπN0 - S0Nπ 1 kHz: - SπN0 - S0Nπ	*Bilateral BAHAs (n=12)* - threshold changes within 3 dB except for 2 patients. - threshold changes between -18 to 3 dB, mean -5 dB. - average threshold change 2 dB - average threshold change -4 dB - average threshold change 3 dB - average threshold change -3 dB			
Priwin et al.[3] (Unilateral BAHA users n=6, Bilateral BAHA users n=3)	**One BAHA (Unilateral n=6 / Bilateral n=3)**	**Two BAHAs (Bilateral n=3)**		
Sound field average tone thresholds, dB HL Mean (SD, range)	24 (5, 20 to 32) / 30 (5, 25 to 35)	25 (5, 20 to 30)		
Speech recognition in noise, median score (%) SNR 0 dB SNR 4 dB SNR 6 dB	 87 / 69 92 / 79 98 / 97	 88 93 90		"Phonetically balanced three-word sentences, extracted from five-word sentence tests"
Localisation of sound at 0.5 kHz, mean % Correct score [d] - 50 dB - 60 dB Lateralisations score [d] - 50 dB - 60 dB	 20 / 20 28 / 20 68 / 60 70 / 68	 50 50 86 94		
Localisation of sound at 3 kHz, mean % Correct score[d] - 50 dB - 60 dB Lateralisations score[d] - 50 dB - 60 dB	 28 / 16 37 / 18 60 / 68 72 / 56	 50 57 80 96		

Note: study authors' original terminology retained. SNR = signal-to-noise ratio; S_0N_0 = in-phase tone stimuli and in-phase noise bands; $S_\pi N_0$ = 180˚ out-of-phase tone stimuli and in-phase noise bands; S_0N_π = in-phase tone stimuli and 180˚ out-of-phase noise bands.

[a] p<0.05 versus the chance level for that outcome. For correct localisation the chance level is 14.3%, (95% CI 32), for localisation within 30° the chance level is 42.9% (95% CI 64) and for lateralisation the chance level is 50% (95% CI 32).

[b] For correct score, the chance level is 8.3%, for answers within 30° the chance level is 25%.

[c] Relative threshold change in dB from the condition 'signal and noise in phase at both sides'.

[d] For correct localisation score, the chance level is 20%, for lateralization score, the chance level is 68%.

Table 6 Adverse effects reported in included studies

Béjar-Solar et al.[13] (n=11)	
Major complications	0/11
Unable to obtain osseointegration (following impact to mastoid area 24 hrs after discharge from first stage)	1/11
Types of skin reactions, n of observations (%)	Total observations: 82
- no irritation	71/82 (87)
- slight erythema	7/82 (8)
- erythema and moisture	3/82 (4)
- red and moist with granulation tissue	1/82 (1)
- infection leading to loss of implant	0
Mylanus et al.[20] (n=34)	
Surgery uneventful in all patients. 2 stopped using their BAHA (after 3 months and 2.5 years) due to pain, no explanation found.	
Snik et al.[18] (n=39)	
Total re-operations: 6/39 (15.4%) [loss due to inflammation (1) or trauma (2), removal due to pain (1), reduction of subcutaneous layer (2)]	