TITLE: Completely-in-the-Canal and Bone Anchored Hearing Aids: A Review of the Clinical Effectiveness and Cost-Effectiveness

DATE: 4 March 2010

CONTEXT AND POLICY ISSUES:

Hearing loss affects people of all ages.\(^1\) It can be classified as mild, moderate, severe, or profound based on decibels (dB) hearing loss (dBHL).\(^1\) Mild hearing loss is between 26 dBHL and 40 dBHL, moderate is between 41 dBHL and 70 dBHL, severe is between 71 dBHL and 90 dBHL, and profound hearing loss is 91 dBHL or greater.\(^1\)

There are three types of hearing loss: conductive, sensorineural, and mixed.\(^1\) Conductive hearing loss involves the outer and middle ear and sound is mechanically or physically blocked; it is often corrected through medical or surgical intervention.\(^1\) Sensorineural hearing loss is also referred to as nerve hearing loss, involves damage to the cochlea (i.e., inner ear) or the eighth cranial nerve, and can have various etiologies including aging, viral or bacterial infections, trauma, or exposure to loud noises.\(^5\) Sensorineural hearing loss is not normally corrected through medical or surgical methods and is often treated with a hearing aid.\(^3\) Mixed hearing loss refers to conductive hearing loss and sensorineural hearing loss.

Hearing aids are used to amplify and deliver sounds.\(^1\) There are different categories of hearing aids including conventional hearing aids, bone conduction devices, middle-ear implants, and bone-anchored hearing aids (BAHA).\(^1\) Conventional hearing aids can be behind the ear, in the ear, in the ear canal, completely-in–the-canal (CIC), on the body, or contralateral routing of signal. Several factors are considered when determining which type of hearing aid is most appropriate for individuals, including degree of hearing loss, work setting, and acceptance of hearing loss.

CIC hearing aids are hearing aids that fit almost entirely in the canal. They are small in size and are deeply placed, thus, the number of output and response controls are limited and there is no directional microphone.\(^1\) The BAHA are surgically implanted to the inner ear and operate on bone-conducted auditory stimulation.\(^1,3\) A titanium fixture is surgically implanted into the temporal bone of the skull.\(^2,3\) The hearing devices transmit sound directly to the inner ear.

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Completely-in-the-Canal and Bone Anchored Hearing Aids through the temporal bone, bypassing the external auditory canal and middle ear. Both the BAHA and CIC hearing aid have been approved for use by Health Canada.

In some occupations adults are exposed to a higher risk of noise-induced hearing loss. In addition, Canadians may be employed in environments that require special electronic equipment, special uniforms and helmets, and work in areas considered outside of normal day-to-day activities for the regular citizen. This report will review evidence regarding the clinical effectiveness and cost-effectiveness of CIC hearing aids and BAHA for adults less than 60 years of age across a variety of situations.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of completely-in-the-canal and bone anchored hearing aids?

2. What is the cost-effectiveness of completely-in-the-canal and bone anchored hearing aids?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline, PubMed (supplemental search), The Cochrane Library (Issue 1, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2005 and February 2010. No filters were applied to limit the retrieval by study type.

To be considered for inclusion, observational studies were required to be prospective, include a minimum of 10 patients, and have at least 50% of the study sample suffering from sensorineural hearing loss. Outcomes of interest for this report included acoustic benefits, non-acoustic benefits (e.g., quality of life), durability, use in different environments (e.g., international countries), and infection rates.

SUMMARY OF FINDINGS:

One health technology assessment, one systematic review, and three observational studies were identified for BAHA. No RCTs, controlled clinical trials, or economic studies were identified. No relevant studies were identified for CIC hearing aids. No relevant studies were identified for specific occupations that may have unique needs. Definitions for the non-acoustic measures used in the included studies can be found in Appendix 1. Additional information on the included studies is reported in the tables of Appendix 2.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by observational studies.
Health technology assessments

Quebec’s health technology agency (Agence D’Évaluation des Technologies et des Modes D'Intervention en Santé) published a health technology assessment on BAHA in 2006. A summary was available in English.

The authors concluded that patients with BAHA experienced acoustic and non-acoustic benefits, especially for users of bone-conduction hearing aids and users of conventional hearing aids who suffer from chronic middle-ear infections. They also stated that limited evidence was found. The benefits were especially noted for users of BAHA and those with conventional hearing aids with chronic middle-ear infections. Other etiologies of hearing such as unilateral sensorineural hearing loss, bilateral implantation, and tinnitus were considered experimental patient indications. The authors reported that the technology was considered safe with most of the adverse events being skin reactions.

The included studies for the health technology assessment appeared to be three reviews (no statement regarding the methodological rigour of the reviews), including one from the Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care and twenty primary studies published after the Ontario review.

Systematic reviews and meta-analyses

Johnson, et al. conducted a systematic review on the quality of life benefits of BAHA compared to bone-conduction hearing aids, air-conduction hearing aids, or no hearing aids. Non-acoustic benefit was measured through generic health-related quality of life outcomes and disease specific quality of life outcome measures.

Seven observational studies (n = 439) were included. Sample sizes ranged between nine and 227. The studies included a wide range of populations including children and adults, patients with and without prior hearing aid use, and a variety of hearing loss etiologies. Study quality was assessed through seven questions that related to areas such as power calculations, inclusion/exclusion criteria, description of hearing aid fitting processes, and whether measures of hearing aid verification were reported. The data could not be pooled due to the heterogeneity across the studies in outcome measures, inclusion criteria, and inconsistently presented results.

Patients who were new hearing aid users reported statistically significant benefits on two non-acoustic (quality of life) measures, the Visual Analog Scale of the Glasgow Benefit Inventory and the Hearing Handicap Inventory for Adults. While patients also had greater scores on other aspects of the Glasgow Benefit Inventory, no statistical significance numbers were reported. For patients who were previous users of air-conducted hearing aids, there was a statistically significant decline in the Euro QOL-5D; for example, these patients were more depressed and anxious. Statistically significant improvement in disability and handicap scores of the Hearing Handicap Inventory were reported for BAHA patients who previously had air-conducted hearing aids and bone-conducted hearing aids. The Medical Outcome Study SF-36 measure did not show any quality of life benefits for the BAHA; no statistics were reported. Also, previous hearing aid users had better scores on the Glasgow Benefit Inventory, indicating perceived enhanced quality of life; no statistics were reported. The authors reported that the generic measure of quality of life (i.e., Euro QOL-5D and Glasgow Benefit Inventory) may not be...
The authors concluded that there was limited empirical evidence regarding the non-acoustic benefits of BAHA compared to conventional hearing aids or no hearing aids and therefore, physicians should be cautious when advising patients on the non-acoustic benefits of the BAHA.

**Prospective Observational studies**

Linstrom et al. published a study in 2009 that compared seven patients with unilateral complete or near complete deafness with the BAHA to 20 patients with normal hearing.

Patients in the BAHA group had adult-onset deafness and were on average 49.7 years old and patients in the comparator group were on average 33.5 years old. Patients were assessed on acoustic and non-acoustic outcomes at one month, six months, and 12 months. However, scores on the outcome measures were pooled across the time points as time-related changes were not found. Patients were assessed on acoustic outcomes through the Hearing-in-Noise for Speech Recognition test. The authors reported that the BAHA patients’ acoustic performance was not similar to the patients with normal hearing; however, no statistics were reported. When adjusted for baseline performance, the aided BAHA group (BAHA system turned on) did not outperform the non-aided BAHA group (BAHA system turned off) for signal-to-noise speech recognition. Quality of life outcomes were assessed through the Abbreviated Profile of Hearing Aid Benefit tool as well as the Single-Sided Deafness Questionnaire. For the Abbreviated Profile of Hearing Aid Benefit, the aided BAHA group performed statistically significantly better on three of four subscales (background noise, ease of communication, and reverberation sections) as well as the global scale compared with the non-aided BAHA group. No difference was found for the aversiveness subscale. The BAHA median scores for the Single-Sided Deafness were such that the authors stated the BAHA had a positive impact; however, statistics were not reported.

The authors concluded that the BAHA group experienced significant benefits on the Hearing-in-Noise Speech Recognition test up to one year after the BAHA implantation. However, the authors also stated that use of the BAHA did not result in speech recognition in noise comparable to the group with normal hearing. Non-acoustic benefits were also seen in the patients with BAHA. Industry involvement was not reported.

In 2009, Yuen et al. published a study on 21 patients who had successfully undergone BAHA surgery. They compared acoustic and non-acoustic outcomes when the BAHA was turned on and turned off. The included patients had unilateral severe to profound sensorineural hearing loss and speech discrimination score of less than 30%. Various etiologies of hearing loss such as congenital (n = 1), acoustic neuroma (n = 9), idiopathic sudden sensorineural hearing loss (n = 3), and mumps (n = 1) were included. Most of the patients were male (n = 13) and hearing loss duration ranged between four months and 59 years. The ages of the patients ranged between 33 years to 77 years of age.

Non-acoustic outcomes were measured by two surveys, the Abbreviated Profile of Hearing Aid Benefit and the Glasgow Benefit Hearing Aid Benefit Profile. Sixteen of the 21 surveys were returned. No statistical significance testing regarding The Glasgow Benefit Hearing Aid Benefit Profile was reported due to the large standard deviation and highly variable scores. The
Abbreviated Profile of Hearing Aid Benefit scores indicated benefits for the BAHA through statistically significant higher scores for ease of communication, background noise, reverberation, and aversiveness to sound. The acoustic outcomes were measured by a Hearing-in-Noise Test for speech recognition. A benefit was seen for the BAHA when the speakers were placed to the left and right of the patient’s head. The benefit did not exist when the speakers were placed in front and back of the patient’s head. All outcomes were measured three months after the surgery.

The authors concluded that the BAHA system improved speech reception threshold levels and that non-acoustic benefit was also reported. The authors stated that there were no competing interests and no industry funded was reported.

Hol et al.9 published a study in 2005 on the use of BAHA in patients with unilateral inner ear deafness. The objective was to assess acoustic and non-acoustic outcomes.

Each of the 39 patients was fitted with a BAHA contralateral routing of sound hearing aid (CROS) on a headband and evaluated after a minimum of one month. Of the 39 patients, 30 agreed to undergo BAHA surgery. They had the BAHA CROS fitted six to eight weeks after surgery. Each patient was assessed without the hearing aid at the start of the study, at least one month after having the BAHA CROS fitted on a headband, four to six weeks after the CROS was fitted after the BAHA surgery, and lastly, by mail, at one-year following BAHA surgery.

Of the 30 patients who had surgery to implant the BAHA CROS, 29 were included for analyses. One patient was excluded due to the patient’s mental inability to complete the outcome measures. The majority of the patients (n = 19) had undergone acoustic neuroma surgery prior to the study. Acoustic performance was measured through sound localization measurements and speech perception in noise. The authors reported that while the sound localization performance was significantly better than chance, the scores did not approach the same levels of people with normal binaural hearing; no statistics were reported. Non-acoustic outcomes were measured through the Abbreviated Profile of Hearing Aid Benefit; Glasgow Benefit Hearing Aid Benefit Profile; the International Outcome Inventory for Hearing Aids, Single-Sided Deafness Questionnaire. The results for the non-acoustic outcomes were generally positive.

The authors concluded that the BAHA CROS cannot restore binaural hearing in patients with unilateral inner ear deafness and that patients were satisfied with the BAHA CROS one year after surgery.

Limitations

Methodological rigour of the included studies was limited as non-randomized study designs are associated with higher risk of bias. However, RCTs may not be ethically or logistically possible for surgically implanted hearing aids. No studies for the CIC hearing aids were identified.

Outcomes were not measured past one year follow-up thus the acoustic and non-acoustic benefits for longer periods of time are unknown. In addition, the effectiveness of the BAHA under a wide range of environmental conditions (e.g., internationally, with use of helmets, interference with other electronics), durability of the hearing aids, and infection rates were not explored.
CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Limited evidence was identified regarding the acoustic and non-acoustic benefits of BAHA. The relevant included evidence was mainly observational studies which are associated with higher risk of bias. The health technology assessment from 2006 indicated that using BAHA for unilateral sensorineural hearing loss, bilateral implantation, and tinnitus were considered experimental patient indications. The authors of the systematic review indicated that due to the lack of evidence, caution should be used when advising patients on the non-acoustic benefits of the BAHA. None of the identified literature pertained to how BAHA would perform in environments that are not representative of typical day to day activities.

No evidence was identified for the CIC hearing aids. No relevant economic studies were identified for BAHA or CIC hearing aids.

No evidence was found that addressed the environmental demands of specific jobs, and therefore the applicability of the limited identified evidence should be considered when discussing possible treatments options with these patients.

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REFERENCES:


APPENDIX 1: Definitions of Non-Acoustic Measures

**Abbreviated Profile of Hearing Aid Benefit**

The questionnaire has four domains: ease of communication, listening under reverberant conditions, listening in background noise, and aversiveness to sound. There are 24 items and a higher score on specific domains are indicative of hearing problems.

**Euro QOL-5D**

A two-part instrument. The first is a questionnaire that provides measures on the following health domains: usual activities, mobility, self-care, pain/discomfort, utility, and anxiety/depression. The second part is a Visual Analog Scale with 100 being best imaginable health and 0 being worst imaginable health.

**Glasgow Benefit Inventory**

This tool is used to assess a patient’s quality of life after a medical intervention. There are 18 questions each based on a five-point Likert scale. There are twelve questions that address general factors, three questions that address social support, and three questions that address physical health. There are two parts, the first covering four predetermined environments and the second part allows patients to choose four additional situations where they experience hearing difficulties.

**Hearing Handicap Inventory for Adults**

A 25-item questionnaire that identifies problems that hearing loss may be causing for the patient. The two subscales are emotional reaction and perceived social limitations. The maximum score is 100 and the minimum score is 0; with a higher score representing a higher perceived handicap. Patients respond “Yes” (four points), “No” (zero points), or “Sometimes” (two points).

**International Outcome Inventory for Hearing Aids**

A seven–item survey that asks hearing aid users about the hours per day they use the hearing aid, the benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others, and quality of life. Each question is based on a five-point scale with a higher score indicative of a better outcome.

**The Medical Outcome Study SF-36**

This 36-item questionnaire measures health status over eight general health concepts including bodily pain, general health, vitality, social functioning, and mental health.

**Single-Sided Deafness Questionnaire**

The questionnaire consists of 12 items regarding to the use, satisfaction, and benefit of using the hearing aid in different listening situations compared to no hearing aid. Each question is based on either a three-point or four-point scale. In addition, the aesthetics and handling of the hearing aid are also questioned and are answered on a discrete visual analogue scale; with a score of 10 indicating “very satisfied” and a score of 1 indicating “very dissatisfied”.

APPENDIX 2: Additional Information for Included Studies

Table 1: Summary of Health Technology Assessments and Systematic Reviews for Bone-Anchored Hearing Aids

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Patient population, inclusion and exclusion criteria</th>
<th>Interventions compared (number of patients)</th>
<th>Outcomes</th>
<th>Number of included studies</th>
<th>Evaluated study quality?</th>
<th>Summary of main results</th>
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</thead>
</table>
| AETMIS³ (2006)        | All ages, various etiologies of hearing loss         | BAHA (sample sizes not reported)            | Acoustic, non-acoustic             | 3 literature reviews, 20 clinical trials | Not reported             | Benefits, mainly non-acoustic, by users of bone-conduction hearing aids and by users of conventional aids who suffer from chronic middle-ear infections  
  Most complications are skin reactions  
  Use in patients with bilateral implantations, unilateral sensorineural hearing loss, and tinnitus is considered to be experimental |
| Johnson, et al.⁵ (2006)| All ages, various etiologies of hearing loss         | BAHA (n = 439) versus more conventional hearing aids or no hearing aids | Non-acoustic: Generic health-related QOL measure or disease-specific QOL measure | 7 observational            | Yes                      | New users of hearing aids  
  Glasgow Benefit Inventory showed increased quality of life, no statistical significance reported  
  Hearing handicap Inventory for Adults, respondents with BAHA had statistically significant improvement (p = 0.04)  
  Experienced users of hearing aids  
  No differences for the Medical Outcome Study SF-36 questionnaire                                                                                                                                           |
## Study (Year) | Patient population, inclusion and exclusion criteria | Interventions compared (number of patients) | Outcomes | Number of included studies | Evaluated study quality? | Summary of main results
---|---|---|---|---|---|---

Respondents showed a significant decline ($p < 0.01$, effect size = 0.3) in the Euro QOL-5D, a generic quality of life measure, in those who had previous air-conduction hearing aids (e.g., more anxious, more depressed)

Respondents of the Hearing, Handicap and Disability Inventory showed a significant reduction in disability ($p < 0.01$, effect size = 0.79) and handicap ($p < 0.01$, effect size = 0.86) after the BAHA fitting, for previous users of air-conduction hearing aids

Respondents of the Hearing, Handicap and Disability Inventory had a significant reduction in disability ($p < 0.01$, effect size = 1.42) and handicap ($p < 0.01$, effect size = 0.79) after the BAHA fitting, for previous users of bone conduction hearing aids.

AETMIS = Agence D’Evaluation Des Technologies et Des Modes D’Intervention En Santé; BAHA = bone anchored hearing aid; RCT = randomized control trial; QOL = quality of life
### Table 2: Summary of Findings for Included Primary Studies

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<thead>
<tr>
<th>Study (Year)</th>
<th>Patient population, inclusion and exclusion criteria</th>
<th>Interventions compared, Number of patients</th>
<th>Patient traits</th>
<th>Study outcomes, Follow-up</th>
<th>Summary of main results</th>
</tr>
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</table>
| Linstrom, et al7 (2009) | Unilateral complete or near complete deafness (adult-onset), normal or near-normal hearing in the better ear, between 18 years and 75 years | BAHA, n = 7 Comparator (people with normal hearing), n = 20 | Sex  
BAHA  
2 males, 5 females  
Comparator  
5 males, 15 females  
Mean age  
BAHA = 49.7 years (range: 35.3 years to 66.7 years)  
Control = 33.5 years (range: 22.7 years to 70.4 years)  
Length of deafness  
Mean: 7.39 years (range: 2 years to 14 years) | Follow-ups occurred at 1 month, 6 months, 12 months | Acoustic  
There were no statistically significant changes in signal-to-noise speech recognition performances for the BAHA group (aided and unaided), when adjusted for baseline performance  
The BAHA aided and unaided signal-to-noise speech recognition did not approximate the control group  
Non-acoustic  
For the Abbreviated Profile of Hearing Aid Benefit, the aided BAHA group experienced statistically significantly favourable scores on the listening in background noise (p < 0.001), ease of communication (p = 0.0003), listening under reverberant conditions domains (p < 0.0001), and the global scale (p < 0.0001). No difference was found for the aversiveness of sound domain (p = 0.11)  
For the Single-Sided Deafness Questionnaire, BAHA median responses indicated positive impact, no statistics reported. |
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<tr>
<td>Yuen, et al.8 (2009)</td>
<td>Unilateral severe to profound sensorineural hearing loss and speech discrimination score of less than 30 per cent. Etiologies of hearing loss included congenital (n = 1), acoustic neuroma (n = 9), idiopathic sudden sensorineural hearing loss (n = 3), and mumps (n = 1)</td>
<td>n = 21 BAHA turned on and BAHA turned off</td>
<td>Age Range: 33 years to 77 years Sex 8 males 13 females Duration of deafness Range: 4 months to 59 years</td>
<td>Acoustic 3 month follow up: hearing-in-noise test for speech recognition Non-acoustic 3 month follow up: Abbreviated Profile of Hearing Aid Benefit: Glasgow Hearing Aid Benefit Profile</td>
<td>Time over the follow-up periods was not a statistically significant factor in either questionnaire. Mean decrease in signal-to-noise ratio was 5.5 decibels SPL (range: 2 decibels to 11 decibels) when BAHA was turned on, p = 0.00001 for the 90/270 speaker paradigm. Mean increase in single-to-noise ratio was 1.6 decibels SPL (range: 0 to 6 decibels) for the 0/180 speaker paradigm when BAHA turned on (p = 0.01). Abbreviated Profile of Hearing Aid Benefit: when BAHA turned on, ease of communication (change score = 16.2, 95%CI: 7.4 to 2.0), background noise (change score = 18.2, 95%CI: 9. to 26.9), and reverberation (change score = 26.4, 9 CI = 1.8 to 37.0), and aversiveness to sound (change score = 9.5 (95%CI: 0.4 to 18.). Glasgow Benefit Hearing Aid Benefit Profile: Large standard deviations in the scores.</td>
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<td>Study (Year)</td>
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<td>Hol et al.9 (2005)</td>
<td>Unilateral inner ear deafness</td>
<td>n = 30 Unaided</td>
<td>Sex 14 female 15 male</td>
<td>Acoustic Speech Perception</td>
<td>revealed highly variable experiences with the BAHA</td>
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<td>Etiologies of hearing loss: Acoustic neuroma surgery (n = 19); cerebellopontine tumour (n = 2), congenital unilateral deafness (n = 3), stapedotomy surgery (n = 2), Morbus Meniere (n = 1), trauma (n = 1), cholesteatoma surgery (n = 1), unknown origin (n = 1) One patient (acoustic neuroma) later excluded due to inability to complete the outcome questionnaires due to mental abilities</td>
<td>Fitted with CROS hearing aid, evaluated after at least one month BAHA surgery and the BAHA CROS fitted six to eight weeks later, evaluated four to six weeks after the BAHA CROS fitting</td>
<td>Age Range: 29 years to 79 years</td>
<td>Non-acoustic Abbreviated Profile of Hearing Aid Benefit; Glasgow Benefit Hearing Aid Benefit Profile: -unaided, conventional CROS, BAHA CROS at six weeks and one year follow up</td>
<td>Patient with the BAHA CROS were able to localize sounds significantly better than chance, but the scores were not similar to than normal binaural hearing, no statistics reported.</td>
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<td>Time with hearing aid Range: 7 months to 79 years and 3 months</td>
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<td>Abbreviated Profile of Hearing Aid Benefit; Glasgow Benefit Hearing Aid Benefit Profile, at 6 weeks (change from baseline, p value)</td>
<td>Non-acoustic Abbreviated Profile of Hearing Aid Benefit; Glasgow Benefit Hearing Aid Benefit Profile, at 6 weeks</td>
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<td>CROS: ease of communication (-7.2, p = 0.03), background noise (-21.1, p = 0.00), reverberation (-9.6, p = 0.0001), aversiveness to sound (12.7, p = 0.02) BAHA CROS: ease of communication (-13.1, p = 0.001), background noise (-21.1, p = 0.00), reverberation (-19.1, p = 0.00), aversiveness to sound (-3.7, p = 0.52)</td>
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<td>Glasgow Benefit Hearing Aid Benefit Profile, at 6 weeks</td>
<td>Mean Benefit from baseline BAHA CROS: 52% CROS: 39% Mean Residual Benefit from baseline</td>
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<td>Mean follow up = 1 year, 4 months (range: 11 months to 2 years, 1 month</td>
<td>BAHA CROS: 32% CROS: 42% Mean satisfaction from baseline BAHA CROS: 51% CROS: 32% International Outcome Inventory for Hearing Aids, change between 6 weeks and 1 year BAHA CROS: six of seven domain scores did not differ significantly (n = 23); one domain, satisfaction, was statistically significantly poorer (p = 0.0017) Single-Sided Deafness Questionnaire BAHA CROS, quality of life improved in 21 of 24 patients who responded (timepoints not reported)</td>
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BAHA = bone-anchored hearing aid; CI = confidence interval; CROS = contralateral routing of sound