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Bone Anchored Hearing Aid

An Evidence-Based Analysis

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practicing medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

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Abbreviations

BAHA	Bone anchored hearing aid
BCHA	Bone conduction hearing aid
CBHA	Conventional bone conduction hearing aid.
dB	Decibel
Hz	Hertz
KHz	KiloHertz
HL	Hearing Level
PTA	Pure tone average
MPS	Maximum Phoneme score

Executive Summary

Objective

The objective of this health technology policy assessment was to determine the effectiveness and cost-effectiveness of bone-anchored hearing aid (BAHA) in improving the hearing of people with conduction or mixed hearing loss.

The Technology

The (BAHA) is a bone conduction hearing device that includes a titanium fixture permanently implanted into the mastoid bone of the skull and an external percutaneous sound processor. The sound processor is attached to the fixture by means of a skin penetrating abutment. Because the device bypasses the middle ear and directly stimulates the cochlea, it has been recommended for individuals with conduction hearing loss or discharging middle ear infection.

The titanium implant is expected to last a lifetime while the external sound processor is expected to last 5 years. The total initial device cost is approximately $5,300 and the external sound processor costs approximately $3,500.

Review of BAHA by the Medical Advisory Secretariat

The Medical Advisory Secretariat's review is a descriptive synthesis of findings from 36 research articles published between January 1990 and May 2002.

Summary of Findings

No randomized controlled studies were found. The evidence was derived from level 4 case series with relative small sample sizes (ranging from 30-188). The majority of the studies have follow-up periods of eight years or longer. All except one study were based on monaural BAHA implant on the side with the best bone conduction threshold.

Safety

Level 4 evidence showed that BAHA has been be implanted safely in adults and children with success rates of 90% or higher in most studies. No mortality or life threatening morbidity has been reported. Revision rates for tissue reduction or resiting were generally under 10% for adults but have been reported to be as high as 25% in pediatric studies.

Adverse skin reaction around the skin penetration site was the most common complication reported. Most of these conditions were successfully treated with antibiotics, and only 1% to 2% required surgical revision. Less than 1% required removal of the fixture.

Other complications included failure to osseointegrate and loss of fixture and/or abutment due to trauma or infection.

Effectiveness

Studies showed that BAHAs were implanted in people who have conduction or mixed hearing loss, congenital atresia or suppurative otitis media who were not candidates for surgical repair, and who cannot use conventional bone conduction hearing aids. The need for BAHA is not age- related.
Objective audiometric measures and subjective patient satisfaction surveys showed that BAHA significantly improved the unaided and aided free field and sound field thresholds as well as speech discrimination in quiet and in noise for former users of conventional bone conduction hearing aids. The outcomes were ambiguous for former users of air conduction hearing aids.

BAHA has been shown to reduce the frequency of ear infection and reduce the discharge particularly among patients with suppurative otitis media.

Patients have reported that BAHA improved their quality of life. Reported benefits were improved speech intelligibility, better sound comfort, less pressure on the head, less skin irritation, greater cosmetic acceptance and increase in confidence. Main reported shortcomings were wind noise, feedback and difficulty in using the telephone.

Experts and the BAHA manufacturer recommended that recipients of a BAHA implant be at least 5 years old. Challenges associated with the implantation of BAHA in pediatric patients include thin bone, soft bone, higher rates of fixture loss due to trauma, psychological problems, and higher revision rates due to rapid bone growth. The overall outcomes are comparable to adult BAHA. The benefits of pediatric BAHA (e.g. on speech development) appear to outweigh the disadvantages.

Screening according to strict eligibility criteria, preoperative counselling, close monitoring by a physician with BAHA expertise and on-going follow-up were identified as critical factors for long-term implant survival. Examples of eligibility criteria were provided.

Cost-effectiveness

No literature on cost-effectiveness of BAHA was found.

Objective

The purpose of this review is to assess the effectiveness and cost-effectiveness of bone-anchored hearing aid in improving the hearing of people with conduction or mixed hearing loss.

Background

Clinical need

People who have hearing loss are usually fitted with an air conduction hearing aid (ACHA). However, an ACHA is not likely to be of help to individuals with conduction or mixed hearing loss resulting from conditions such as otosclerosis or congenital/acquired malformation of the auditory canal. In addition, congenital or acquired atresia may make it impossible to fit a patient with an ACHA. For those with chronic otitis media, the ear mould of the ACHA may provoke or aggravate the infection by occluding the ear canal, resulting in otorrhea that may cause cochlear damage in the long-term. (1) Newer devices such as middle ear implants (MEI or soundbridges) require a well functioning ossicular chain and would not be useful for individuals with middle ear abnormality or chronic otitis media.

Surgical and/or medical treatment of the underlying conditions to achieve satisfactory hearing has been performed with increasing success but it has not been feasible or successful in all cases. (2) For patients who are in need of sound amplification but who cannot undergo surgery or use an ACHA, a bone conduction hearing aid may be the only viable solution.

Bone Conduction Hearing Devices

With bone conduction hearing devices, the sound is transmitted to the cochlea, bypassing the impaired or diseased external or middle ear. These devices include:

Conventional Bone Conduction Hearing Aid

A conventional bone conduction hearing aid (CBHA) transmit sound vibrations to the skull through a transducer element (vibrator) that is continuously pressed against the skin over the temporal bone by pressure exerted by a headband or the temples of a pair of glasses (**Figure 1, Appendix 1**). CBHAs have been shown to stimulate both cochleas.

The following undesirable side effects of conventional bone conduction hearing aids have been reported (1):

- Speech recognition further hampered by sound attenuating tissue layers between the vibrator and the skull.
- Discomfort because of the constant pressure needed to apply the tranducer.
- Poor aesthetics.
- Insecure positioning or shifting of the transducer affecting speech recognition.

Temporal Bone Stimulator

A temporal bone stimulator (TBS) is a transcutaneous bone-conduction device developed by Hough et al. (3) In this device, a permanent magnet, hermetically sealed in a laser-welded, titanium-aluminum-

vanadium can, is implanted in the temporal bone with an orthopedic screw and covered by a thin layer of skin. The magnet is driven by a coil in the external sound processor that also contains the signal processing component. The electromagnetic coil is held in place by permanent magnets housed in the sound processor coil assembly and the implant portion. Sound waves are converted to an electromagnetic field from the coil and travel transcutaneously to the internal magnetic implant. When current flows through the external sound processor, alternating electromagnetic fields cause the magnetic implant to vibrate the skull into which the implant has osseointegrated. The skull vibration initiates movement of the fluids in the otic capsule for sound reception. (3)

TBS may be less vulnerable to trauma and infection since there is no skin penetrating implant. However, there is a relatively wide distance between the implanted magnet and the driving coil that may result in loss of power. (4)

The only temporal bone stimulator that was available is no longer being produced by its manufacturer, and there is no known comparable product in the market.

Bone Anchored Hearing Aid is the subject of this review.

New Technology Being Reviewed

The Bone anchored hearing aid (BAHA) uses direct bone conduction to transmit sound transmission without involving the skin and soft tissue as being part of the vibration transmission path between the transducer and the skull bone.

The BAHA is made up of a titanium fixture that is permanently implanted into the mastoid bone of the skull, a permanent skin penetrating titanium abutment, and an external percutaneous sound processor (transducer) that is attached to the abutment by means of a bayonet coupling **(Figures 2-4, Appendix 1)**. The air-filled gap of the transducer is adjusted to an appropriate length and the resonance frequency and damping are chosen to fit the amplification needed for the typical hearing loss among patients. (5)

Implant Procedure

To surgically create a reaction-free implant- cutaneous junction, two preconditions must be met:

- The skin penetrated by the implant must be hairless in order to help keep the implant site clean.
- The subcutaneous tissue should be aggressively thinned to minimize skin mobility in relation to the implant. This allows the dermal layer to heal directly on the mastoid periosteum, creating a solid immobile foundation for the implant. (6)

For adults, the surgery for the implantation of BAHA is usually performed under local anesthesia on an outpatient basis. General anesthesia is usually used for implants for children. The implant may be performed in a 30-minute 1-stage procedure or a 2-stage procedure with each stage lasting approximately 30 minutes. A skin flap (about 25 mm in diameter & less than 1 mm thick) is remove behind the ear leaving the periosteum in situ. A hole is drilled in the periosteum and the titanium fixture (screw) is inserted. A thin skin graft free of hair follicles, often taken from the fold behind the ear, is sutured in place to cover the exposed periosteum. A hole is made on the skin graft with a dermatology punch to expose the fixture. In a 1-stage process, the titanium abutment is immediately secured to the fixture with a gold screw. A plastic healing cap is snapped onto the coupling. The area is covered with gauze soaked in

antibiotic ointment, an ordinary mastoid dressing and a bandage. The dressing is changed and the surgical area kept clean during the healing. The fitting of the transducer takes place 6 to 10 weeks after the procedure to allow time for osseointegration to take place. (5)

The 2-stage procedure, which was the initial approach and is still used in pediatric cases, requires a 3- to 4-month delay between the implanting of the fixture and the attachment of the abutment. Healing is allowed to take place after the second procedure and the transducer is fitted approximately four weeks later. (7)

The titanium implant is expected to last a lifetime while the external transducer has a warranty for 2 years and is expected to last 5 years.

Regulatory Status

To date, Health Canada has approved only the Branemark System BAHA ®(Entific Medical System AB, Gothanburg, Sweden) which is licensed as a class 3 medical device (License 11960). Three models of BAHA are available:

- BAHA Classic HC 300® (ear-level device replacing HC 200): This device is designed for individuals whose pure tone average bone conduction threshold is equal to or better than 45 decibels (dB) hearing level (HL).

- BAHA Compact®: This device is a miniaturized model similar to HC 300 and is more cosmetically acceptable. It also has a new snap on coupling, replacing the bayonet coupling on Classic 300, making it easier for patients to attach it to the abutment. (8)

- BAHA Cordelle®: This is a stronger device driven by a processor worn on the body, and is intended for individuals whose pure tone average bone-conduction threshold is equal to or better than 70 dB HL (Based on information supplied by Entific Medical Systems).

Literature Review

Objective

The objective of this literature review is to determine the safety, clinical effectiveness and cost-effectiveness of BAHA compared to other bone conduction hearing aids through a systematic review of research studies on effectiveness and cost-effectiveness.

Questions to be answered

- What are the short-term and long-term success rates of BAHA implantation?
- What are the extrusion rates of BAHA?
- What are the survival rates of the implants and external component of BAHA?
- Does BAHA provide better hearing compared to the individuals' former hearing aids and other bone conduction hearing aids?
- What are the negative outcomes/complications of BAHA?
- What are the indications and contraindications for BAHA?
- What are the impacts of BAHA on individuals' quality of life?
- What are the cost components of BAHA?
- What is the cost-effectiveness ratio of BAHA compared to other bone conduction hearing aids?

Method

Search Strategy

Due to time constraints, it was not feasible to conduct a formal systematic review. Instead, a comprehensive review of the literature on BAHA was conducted.

Key words and phrases used included: Bone anchored hearing aid, tissue-integrated implants, effectiveness, cost effectiveness, and quality of life. The search was limit to human studies.

Databases Searched
Published literature was obtained through a search of the following databases for the period of January 1990 to May 2002.

- Cochrane (Systematic Reviews, Abstracts of Reviews of Effectiveness),
- MEDLINE (Health Planning and Administration);
- EMBASE
- CCOHTA (Canadian Coordinating Office for Health Technology Assessment) reports;
- Database of members of the International Agency for Health Technology Assessment [INAHTA]
- Websites of Health Canada, Food and Drug Administration (US), and manufacturers of hearing aids
- Agency for Healthcare Research and Quality [AHRQ]
- Other clinical guidelines clearinghouses

Inclusion and Exclusion Criteria

The following are the inclusion and exclusion criteria used for the selection of articles.

Inclusion Criteria

- English language journal articles reporting primary data on the effectiveness or cost effectiveness of BAHA obtained in a clinical setting or analysis of primary data maintained in registries or institutional databases meeting the following criteria.
  - The study was a systematic reviews, a randomized controlled trial, a non-randomized controlled study, or a case series
  - The study has at least 20 subjects. (Canadian studies regardless of sample size)
  - The study design and methods were clearly described.
  - The data had not been published before or since unless it addresses different outcomes.
- English language articles on other forms of bone conduction devices were also included to provide a basis for comparison.

Inclusion criteria for studies

Subjects in the studies: individuals with conduction or mixed hearing loss or other hearing loss who were not eligible for air conduction hearing aid or surgical correction.

Intervention
Unilateral or bilateral implant of BAHA.

Outcome measures
Information on the safety, effectiveness, patient acceptance and cost-effectiveness of BAHA in comparison to former hearing aids worn by the patients or to other forms of bone conduction hearing aids including the following:

- Outcomes of the studies include a combination of the following:
- Success or failure rates
- % implants/abutment loss/removal.
- % of patients with implants who continued to wear BAHA
- Number of hours that the patients wore BAHA per day.
- Change in hearing thresholds with BAHA compared with unaided hearing and/or with previous hearing aids or with other bone conduction hearing aids.
- Change in speech discrimination in quiet and noise (speech/noise S/N ratio, maximum phenome score MPS) with BAHA compared with previous hearing aids or with other bone conduction hearing aids.
- % of patients that experienced negative outcomes including adverse skin reaction, pain, headache
- Patients' perception of BAHA' s impact on hearing compared to previous hearing aid or compared to unaided (subjective).
- Patients satisfaction with BAHA regarding comfort, infection/discharge, ease of handling and esthetics (subjective).
- Patients' preference for BAHA over other hearing aids.(subjective) and hours of usage/day

Exclusion criteria

Studies with less than 20 subjects were excluded. Studies that solely focused on technical procedure without information on patient outcomes were also excluded. Some review articles were included to provide an understanding of the subject matter but were excluded from the analysis

Results of the Literature Search

The search yielded 141 citations articles. One researcher reviewed the abstract of each citation and determined whether the article has met the inclusion criteria and exclusion criteria. The full texts of eligible studies were reviewed to confirm eligibility. The Level of evidence was assigned according to the following scale that is based on the hierarchy by Goodman. (9) An additional designation "g" was added for preliminary reports of studies that have been presented to international scientific meetings.

Thirty-six articles met the inclusion criteria. One hundred and five articles were excluded for the following reasons:

Foreign language articles	25	
Less than 20 subjects	36	
Not focussed on BAHA	16	
Not clinical study or has more current report	28	Total
excluded	105	

The selected articles are classified in Table 1.

Table 1: Levels of Evidence

Type of Study (Design)	Level of Evidence	Number of Eligible Studies Analyzed
Large randomized controlled trial, Systematic reviews of RCTs	1	
Large randomized controlled trial unpublished but reported to an international scientific meeting	1(g)	
Small randomized controlled trial	2	
Small randomized controlled trial unpublished but reported to an international scientific meeting	2(g)	
Nonrandomized controlled trial with contemporaneous controls	3 a	
Nonrandomized controlled trial with historical controls	3 b	
Nonrandomized controlled trial unpublished but reported at an international scientific meeting	3g	
Surveillance (database or register)	4a	
Case series, multi-site	4b	6
Case series, single-site	4c	30
Case series unpublished but presented at an international scientific meeting	4g	
TOTAL		36

Seven review articles, one consensus guideline and one reference on level of evidence were also used for background information or methodology bringing the total bibliography to 45.

Data extraction and synthesis

A tool (Appendix 6) was used to extract data from the selected articles. Common end points (success rates, extrusion rates, adverse skin reactions and audiometric measures were summarized in Appendices 2 and 3. Pediatric studies were summarized in Appendix 4. Studies that focus on a specific aspect of BAHA were not included in the Appendices but were summarized in the text of this report. A complete list of references is included in the bibliography.

This report presents a descriptive synthesis of the available evidence. No meta-analysis was conducted.

Summary of Studies

Most of the studies were conducted in Goteborg (Sweden), Nijmegen (Netherlands) and Birmingham (The United Kingdom). No randomized controlled trials were found. The studies consisted entirely of level 4 case series and non-randomized comparative studies in which the subjects acted as their own controls. Most of the studies had small samples (less than 200), but generally involved lengthy follow-up.

There was heterogeneity among the studies. The procedures for achieving a stable skin-periosteum interface varied among and within the studies. Some studies compared the performance of BAHA with that of the patients' former hearing aids, whereas others used conventional bone conduction hearing aid or transcutaneous bone conduction hearing aid for comparison. Subjective data on patient satisfaction regarding BAHA was the focus or part of many studies. The major findings were summarized in Appendices 2, 3, and 4 and discussed below.

Success Rates

Success is defined as the achievement of a stable implant without loss of fixture due to trauma or failed osseointegration. The success rates reported by the studies ranged from 88% to 99.3% with a median of 97%. (Appendix 2)

The highest success rate of 99.3% was reported by Hakansson et al. (2) in a series of 147 patients followed over a period of up to 8 years. Proops et al. (10) reported a success rate of 90% in a series of 188 patients. Van Der Pouw et al. (11) reported a success rate of 94.5% during an 8 to 84 month follow-up of 155 patients with BAHA implanted in a one- stage procedure. Snik et al. (12) reported a series of 64 patients who had a success rate of 94% during a maximum follow-up of 68 months. In a case series of 31, Bonding et al. (13) applied life table analysis and reported a cumulative success rate of 100% for the first two years that dropped to 85% after 3 to4 years and to 75% after 7 years.

No significant difference was found in fixture survival rates with either the one-stage or two-stage procedure. (5)

Extrusion Rate

Extrusion is defined as the loss or removal of the implanted fixture. The extrusion rates of the major studies were summarized in Appendix 2.

A wide range of total extrusion rates was reported. In a 1995 series, Tjellstrom et al. (5) reported a total extrusion rate of 11% that comprised 3.4% loss and 7.4% removal. Proops (10) reported a total extrusion rate of 10.1%. Reyes et al. (14) reported an extrusion rate of 17.4%. Despite a relatively short follow-up period, Bonding (13) found a total extrusion rate of 25%, more than twice as high as that found by Tjellstrom et al. (15) and Proops. (10) In addition, in a series of 69 patients, MacNamara et al. (16) reported a 4.3% rate of late fixture loss and 4.3% rate of loose abutment.

The reported rate of fixture loss as a result of failed osseointegration ranged from 0.7% to 5.4% with a median of 2.5%. Failed osseointegration has been partly attributed to bone resorption around the implanted fixture. Bolind et al. (17) observed this particularly among patients who later lost their implants. Higher failed osseointegration rates have been reported for pediatric patients. This will be discussed in greater detail later.

In addition to bone resorption, frequent causes for the loss of fixtures included trauma, infection,

malignant diseases, and poor hygiene. Reported causes for the removal of implants were poor hearing, psycho-cosmetic reasons, discomfort and mechanical failure. (2); (5); (10); (13)–(15); (18)

Mortality Rates

No BAHA-related mortality has been reported.

Adverse Skin Reactions

One of the major complications in BAHA is adverse skin reaction around the penetration site that may necessitate the removal of the implant. In the studies, the tissues surrounding the penetration sites were closely monitored, usually at three-month intervals for the first year and every six months thereafter.

The percentage of patients who did not have any episode of adverse skin reactions varied among studies. Tjellstrom et al. (15) reported in 1994 that 68% of 100 patients were reaction-free during a follow-up period of 8 to16 years. Over the years, improvement in reaction-free penetration of BAHA implant has been observed probably due to improved technique. The reported rates of patients who were free of adverse skin reactions included 70% (14), 79% (10); (18), 90% (19), and 92.5%. (6) Tjellstrom et al. (5) found no difference in the frequency of adverse skin reactions between 1-stage and 2-stage procedures among 149 patients.

Holgers et al. (18) developed the following system for classifying the severity of tissue reactions and medical response (Table 2). This system has been widely adopted by other researchers of BAHA.

Table 2: Grading System for Adverse Skin Reactions

Grade	Skin Reaction
0	No irritation; Epithelial debris removed if necessary
1	Slightly redness. Epithelial debris removed if necessary
2	Red and slightly moist tissue; no granulation formation. Local treatment; extra controls
3	Reddish, moist and granulation tissue. Revision surgery is indicated.
4	Removal of skin-penetrating implant necessary due to infection.

The reported percentage of skin assessments (observations) that showed no adverse skin reactions (grade 0) ranged from 91% to 97%. (11), (5), (14) Reyes et al. (14) observed that the reaction-free assessment rates improved from 64.3% for the first four years of follow-up to 97.2% for the last four years. Grade 2 and 3 skin reactions together ranged from 1.4 % to 2.6%. Grade 4 skin reactions that required removal of the fixture were reported to be less than 1%. (2); (5); (11)

Holgers et al. (20) analyzed tissue biopsies from implant sites and found that, even in the absence of clinical evidence of inflammation, there was an accumulation of T lymphocytes and macrophages in the tissue-implant interface indicating a chronic inflammatory response. It was postulated that these cells form a protective cellular defense barrier in the site of the skin "breach" to the implant. The study also showed the presence of large numbers of polymorphonuclear positive cells, B lymphocytes and plasma cells when clinically apparent graft reaction occurred, indicating bacterial infection superimposed on chronic inflammatory process.(20)

Microbial adhesion is a prerequisite for an infection. Holgers and Ljungh (21) analyzed the bacterial isolates taken from the skin surrounding the BAHA implants of 26 patients. Aerobic and anaerobic bacteria were isolated from patients with and without clinical signs of infection. There were more anaerobic isolates in the group with skin irritation. The most commonly isolated species is coagulase negative staphylococcus. For patients without any sign of infection, the bacterial flora contained a higher variety of species than in the group with signs of infection. Holgers and Ljungh (21) also studied the cell surface hydrophobicity and the binding of immobilized fibronectin, vitronectin and collagen of the isolated bacteria because this could mediate adhesion. Expression of protein binding was found to be similar in strains isolated from the 2 groups. No strain expressed a hydrophobic cell surface. It was concluded that the microenvironment around a titanium implant promotes expression of a hydrophilic rather than a hydrophobic cell surface. This, in turn, makes many infections around the titanium implant curable by local treatment. (21)

Since any mobility or thickening of the skin adjacent to the implant inevitably results in inflammatory process, much effort has been made to develop a surgical technique that will minimize soft tissue reaction and promote implant stability. These included the following:

- Tjellstrom method (22) that uses a free post-auricular skin graft.
- The Browning method (23) that uses transpositional flaps for grafting.
- The Cremers method (24) that uses a straight-line incision and no grafting.
- The Proops method (10) method that uses a thinned pedicle flap.
- The Rothera method (10) that uses a free local skin graft harvested from the transplant site.

Audiometric Results

Free field and sound field BAHA- aided thresholds have been compared with unaided thresholds and aided thesholds achieved with subjects' former hearing aids. The results were summarized in Appendix 3.

Change in hearing thresholds

Bone Anchored Hearing Aid Thresholds Compared to Unaided Thresholds

The BAHA has been shown to produce highly significant ($P < 0.001$) improvement over unaided warble tone thresholds. The mean improvements reported in 2 studies were 29.4 dB (25) and 32 dB. (6)

It is unclear whether the gain in BAHA- aided thresholds is affected by the etiology of the hearing loss. Cooper et al. (26) reported that similar improvements in BAHA-aided mean free field warble tone thresholds were observed for patients with chronic suppurative otitis media and patients with congenital conductive hearing loss. In a retrospective, multicenter series of 41 patients, patients with ostosclersosis or congenital conductive hearing loss had the greatest average improvement in sound field threshold (42dB) over unaided patients. Patients with combined otitis media and otorrhea or cholesteatoma had an average improvement of 33dB. Patients with congenital auditory canal atresia or stenosis showed the lowest average improvement of 22 dB. (6) These results have low generalizability because of the small sample size.

Bone Anchored Hearing Aid Compared to Conventional Bone Conduction Hearing Aid

When BAHA was compared with the conventional bone conduction hearing aid (CBHA), BAHA yielded better sound field warble tone at all frequencies except 0.5 kHz. (25)

Significant differences in free field (quiet environment) thresholds between the BAHA and CBHA were not expected because the patients usually adjust their hearing aids to the most comfortable level. However, Snik et al. (27) reported significantly better aided free field thresholds with BAHA than with CBHA at 0.5, 1, 2 and 4 kHz. Cooper et al. (26) also reported significantly improved aided mean free-field warble tone threshold with BAHA than pervious hearing aids.

It was postulated (12) that aided thresholds were found to be better with BAHA than with CBHAs mainly because the sound quality of BAHA remains acceptable at higher volume settings. As sound vibrations are transmitted to the skull more efficiently, the amplifier is less readily saturated by loud sounds, and a higher volume setting can be used. This is supported by the finding (12) that BAHAs were worn at a relatively higher gain level than CBHAs.

Bone Anchored Hearing Aid Compared to Air Conduction Hearing Aid

Some of the patients who previously used ACHAs, showed improved aided thresholds with BAHA, whereas others did better with ACHA. In a series of 34 patients, Mylanus et al. (28) reported a mean gain in BAHA aided free-field threshold of 6 dB at 1 kHz and 12 dB at 8 kHz compared to ACHAs. Other studies (12); (13); (26); (29) showed that, as a group, former ACHA users showed no improvement in aided thresholds. Browning and Gatehouse (29) showed that of 23 patients that were former users of ACHA, 11 continued to use BAHA and showed superior benefits, while the other five non-users did not. In a series of 62 subjects, Snik et al. (27) found no significant improvement in aided free field thresholds at any frequencies with BAHA compared with ACHA.

Change in Speech Recognition in quiet and in noise

Bone Conduction Hearing Aid Compared to Conventional Bone Conduction Hearing Aid

Snik et al. (12) reported significant improvement in speech recognition in quiet among BAHA users who were former CBHA users. Cooper et al. (26) also reported an improvement, but it was not statistically significant.

Significant improvement in speech recognition in noise has been reported for BAHA compared with conventional hearing aids. These included:

- Hakanssan et al. (2) demonstrated that BAHA users had significant improvement in synthetic sentence recognition and a significant average improvement of 6.2% in word discrimination score over CBHA users.
- Carlsson et al. (30) showed an average improvement of 3.3%.
- Mylanus et al. (31) reported an improvement of 9% for those who preferred BAHA and 4% for those who preferred their former hearing aids.
- Snik et al. (12); (27) reported significant improvement in speech recognition scores with the BAHA for former users of CBHA.

The speech in noise score is, in principle, independent of the volume setting. Nevertheless, better results were found with BAHA. The better scores were ascribed to less distortion as a result of BAHA's better performance, predominantly in the frequency range above 1 kHz, which is the most important frequency range for speech recognition. (1)

Bone Anchored Hearing Aid Compared to Air Conduction Hearing Aid

Former ACHA users did not experience consistent improvement in speech discrimination in noise when they used BAHA. Snik et al. (27) found that the improvement in speech recognition in quiet was not significant for former users of ACHAs. The same investigators (4) reported ambiguous results in speech discrimination in noise for former ACHA users. In 1995, Mylanus et al.(31) reported that the change in scores for hearing in quiet and noise was not statistically different for the ACHA group compared to the BAHA group. In a later study, Mylanus et al (28) reported a small but significant improvement in the speech in noise ratio with BAHA than ACHA. Of the 34 patients studied in this series, 44% improved their scores with the BAHA, whereas 15% performed significantly worse with BAHA.

The ambiguous audiometric results (1); (28) for former ACHA users could be explained by the significant association between the change in speech recognition and the size of the air-bone gap. In their 1998 publication, Mylanus et al (28) provided the following explanation. Hearing by bone conduction is far less effective than by air conduction. Therefore, in case of a pure sensorineural hearing loss, the performance of even a powerful bone conduction device may be poorer than that of an air conduction hearing aid. Conversely, if an air–bone gap is present, the amplification of an air conduction hearing aid needs to be increased substantially to compensate for this gap, and the increased amplification might lead to problems such as feedback and saturation of the amplifier. Such compensation is not necessary for BAHA. Thus with an increasing air–bone gap, the results with the BAHA will remain the same, but those with the air conduction hearing aid will deteriorate. This is consistent with the finding by Cooper et al. (26) that exchanging air conduction hearing aids for BAHAs gave best results in patients with a wide air–bone gap. A breakeven point was found at an air–bone gap of 25 dB to 30 dB. (28)

Patient Satisfaction

Through patient questionnaires, researchers have assessed patients' opinions about the BAHA compared with to their former hearing aids. The results were summarized in Appendix 3**.**

Tellestrom and Granstrom (32) reported that questionnaires completed by 127 patients who had a BAHA implant through a 1-stage procedure provided an average overall satisfaction score of 8.7 on a scale of 1 (very poor) to 10 (excellent). Eighty-seven per cent (87%) of the subjects reported using BAHA for more than 8 hours per day, and 86% of former users of air conduction hearing aids reported a general improvement of their ear infection after switching to BAHA. Eighty-two percent (82%) of former BCHA users reported significant improvement with BAHA in comparison with their former bone conduction device. Important advantages of BAHA (32) reported by the subjects included improved speech intelligibility, better sound comfort, less pressure on the head, less skin irritation, easy handling and greater cosmetic acceptance.

Mylanus et al. (31) used a questionnaire to determine the perception of 65 patients fitted with BAHA including 75% with congenital atresia who were former users of CBHA and 25% with chronic otitis media that were former users of ACHA. The most frequently reported advantage was speech recognition (72%), sound quality (38%), and reduced ear infection (32%). The results also showed that former BCHA users predominantly preferred BAHA with statistically significant improvement in scores for hearing in quiet and noise and sound quality. The improvement in scores for hearing in quiet, hearing in noise, and for comfort were not statistically significant for former users of ACHA. These findings (31) for the ACHA group agreed with the ambiguous audiologic results of the same study.

Forty-one patients using the BAHA and 17 patients using temporal bone stimulator (TBS) completed a questionnaire in a study by Snik et al. (4) All BAHA subjects chose to continue using BAHA. Most (70%) of BAHA subjects who were former users of CBHA preferred BAHA and 12% preferred their

former CBHA. Only 50% of former ACHA users preferred BAHA while slightly less than 50% preferred ACHA. This does not mean that an air-conduction hearing aid is the first choice for these former ACHA users, because they have been advised not to use their ACHA any longer owing to chronic draining of the ears. For such patients, Snik et al. (4) recommended good counselling and a thorough audiological evaluation including the use of a power CROS (contralateral routing of signals) ACHA with a vented ear-mould prior to making a decision to change to BAHA.

In a multicenter study, Stephens et al. (33) asked 39 BAHA patients to list benefits and problems associated with BAHA. One hundred and sixty-five (165) benefits and 105 problems were listed and classified. The main reported benefits were similar to those found by Tjellestrom and Hakansson. (5) In addition, the patients also reported psychological benefits including increase in confidence and feeling safer in traffic. Main acoustic shortcomings included wind noise, speech in noise, and feedback. Patients also found it difficult to use the phone with BAHA, and that the tranducer was easily dislodged. There were no major agreement on medical and psychological shortcomings that included sore scar tissue and difficulty in keeping the abutment free from infection. (33)

MacNamara et al. (16) conducted a questionnaire survey through telephone interviews with 69 BAHA users who had chronic suppurative otitis media. The results showed that 84% of the patients reported significant reduction in discharge, 16% reported no change, and no one reported worsening of discharge. The subjects who reported no change had previously dry or slightly moist ear. Of the 69 patients, 58 % were more satisfied with BAHA than their previous hearing aid and 73% continued to use BAHA for more than 8 hours per day.

Arunachalam et al. (34) used the Glasgow Benefit Inventory with 60 patients to determine their perception of BAHA's impact on their quality of life. The questionnaire was administered before and after the fitting of BAHA. The average improvement in scores with BAHA included +31 for total benefit, +37 for general benefit, +24 for social benefit and +14 for physical benefit. This pattern was found to be similar to findings of studies on other ear interventions. Improvement in quality of life was greater than that achieved with middle ear surgery, but slightly less than that achieved with cochlear implant. Patients with discharge otitis media showed the greatest improvement in the physical domain.

Long-term results were also studied with questionnaires. It was reported that 10 to13 years after receiving a BAHA fitting, almost all patients continued to use the BAHA, and were still satisfied with the results. On a scale of 1 to 5 (with 5 as the best), 24 patients gave an average score of 2.9 for clarity and a score of 2.7 for sound localization with noise in the background. (35)

Experience of Canadian BAHA Programs

Wade et al. (8) reported on a retrospective review of 76 patients implanted with BAHA in Ontario, Canada with a follow-up period of 3 to10 years. About 84% of the patients had chronic ear disease, and the remainder had congenital abnormalities. Complications included 4% implant extrusions that were successfully reimplanted, and skin reactions around the abutment that were mainly mild. Four patients (5%) required regrafting. Forty-eight patients (64%) were still wearing BAHA in excess of 8 hours per day at the time of the report. Fourteen patients (18%) were lost to follow-up and 14 (18%) stopped wearing BAHA. Of the 14 patients who stopped wearing BAHA, three had died and 11 stopped because the device was not powerful enough, was too easily dislodged, or too expensive to repair. Revision surgery was successful in two patients whose ears dried up completely after wearing BAHA for a number of years. A telephone survey showed that 89% of 47 BAHA users gave a rating of 8 or higher on a scale of 1-10 (with 1 for dissatisfied and 10 for extremely satisfied). The authors noted that experience in the implant technique is needed to handle frequent surgical problem, and that well-trained nurses are

mandatory to avoid expensive mistakes in handling the equipment.

Tietze and Papsin (36) reported on a retrospective study of 19 pediatric patients with BAHA implant at an Ontario pediatric hospital. The mean age of the patients was 11.2 years. One stage procedure was used when there was sufficient bone to allow placement of a 4mm fixture. Over a 2-year period, 95% of the patients retained their osseointegrated fixture. There were significant improvements in the post-implantation BAHA-aided thresholds at 0.5, 1, and 4 kHz compared to the preimplantation bone conduction thresholds. Eighty-four per cent of the patients had no irritation at the implant site during follow-up. The remaining patients adverse skin reactions around the implant of grade 1 or higher. The rate of reaction-free skin penetration was 43% for patients who had 1-stage implantation and 88% for 2-stage implantation.

BAHA in Pediatric Patients

Children who have bilateral deformities of the external and middle ears require early amplification with a bone conduction hearing aid for proper speech development. (37) Traditionally, conventional bone-conduction hearing aids were used at an early age. The limitations of conventional bone conduction hearing aids have been discussed. Later in life, these children may undergo re-constructive surgery to try to restore a cosmetically acceptable auricle and/or a functioning ossicular chain. However, the results of these surgical techniques have been shown to be less than satisfactory except for treatment of minor deformities. (37) It has been recommended (37); (38) that children for whom surgical repair is not an option should be helped with bone-anchored hearing aids. The results of the studies on pediatric BAHA are summarized below.

Pediatric Studies

Jacobsson et al. (39) reported on a series of 30 children with a total of 59 titanium fixtures inserted in the temporal bone for anchoring auricular BAHA (16 cases) and epitheses (14 cases). Two-stage procedures were performed and involved extremely gentle handling of the soft tissue and the bone. The patients were followed for an average of 40 months after the fitting of the hearing aid or the prosthesis. The mean fixture survival rate for the whole group was 96.6%. BAHA had a reaction-free skin penetration in 91.6% of the postoperative observations.

In a Swedish study (40) of 76 children with a mean age of 8.4 years, 170 titanium fixtures were implanted for BAHA and prosthesis. Ten implants (5.8%) were lost yielding a success rate of 94.2%. Ninety percent of the losses occurred in the first three years following implant. Of all observations of the skin surrounding the penetration site, 91% were reaction-free. Of the 9% observations that showed adverse skin reaction, 5.1% was grade 1, 2.5% grade 2, and 1.5% grade 3. There were no grade 4 skin reactions. Twenty-two percent of the patients required revision surgery mainly because of the appositional growth of the temporal bone. (40) This revision rate is much higher than those reported for adults.

In the United Kingdom, 32 children were fitted with BAHA in a series by Papsin et al. (41) In this series, a higher failure rate (15%) and higher failed osseointegration rate (9%) were reported. Twenty-five percent (25%) required minor revision surgery for lost abutment, trauma, or chronic skin problems. This revision rate is consistent with that reported by Granstrom et al. (40) in another pediatric series. There were no differences between preimplantation and postimplantation bone or air conduction thresholds. The study found significantly higher adverse skin reaction rates in comparison to other adult or pediatric studies. Eighty-two percent of the patients had at least one episode of skin reaction of grade 1 or higher. Fifty-nine percent of the patients had a skin reaction of grade 3 at some point, and 12.5% went on to lose their BAHA temporarily. A questionnaire completed by 66% of the subjects showed that the majority

reported improvements similar to those of the adult series. In addition, the most also reported improved speech and school performance. Ninety-one percent of the patients continued to use BAHA at the time of the study.

A 1996 report (42) on the Birmingham BAHA pediatric program that included 21 subjects followed over 5 years showed that all subjects obtained better free-field warble tone thresholds with BAHA. All of those in the group with congenital causes of hearing loss who were former ACHA users obtained better free field warble tone thresholds with the BAHA. Seventy-one per cent (71%) of this group obtained better speech discrimination, whereas 29% showed no change. Of the former BCHA users in this group, only 50% showed better speech discrimination with BAHA than their former hearing aids, and the other 50% showed no change. The poor air conduction thresholds of these patients explained the difference in audiometric results. Hearing in quiet and noise were reported by patients to be significantly improved with BAHA, but no significant benefits were reported for hearing the television. All but 1 of the patients gave higher marks to BAHA for overall satisfaction compared with their former hearing aids. A follow-up retrospective review (37) of the program reported the results of the first 107 titanium implants for 31 BAHA and 23 auricular prosthesis. For the BAHA group, the mean age was 7.6 years (2–10 years). Multiple attempts to seat a fixture were necessary in at least 45% of the children. A total of 11.2% of the fixtures was lost during a mean follow up of 3.2 years. Failed integration and trauma accounted for 67% of the loss. In 3 of the cases, a sleeper (spare fixture) was used successfully. Two hundred and fourteen observations of the skin at the penetration site were made. Ninety-two percent of the observations were reaction-free (type 0), and approximately 2% for type 3 and type 4. Seven children required psychological counselling. All children continued to use BAHA during follow-up.

A 7-year audit (43) of anesthesia procedure for BAHA implants in the Birmingham program showed that 71% of the patients received the implant as day surgery. Of 102 surgical procedures, 44% of the procedures were performed with intubation, and 52% had laryngeal mask airway, and 2% had long-term tracheotomies. The overall incidence of intra-operative complications was 5.9%, all related to the airway. The incidence of postoperative morbidity was 17.6%, with nausea and vomiting being the most common at 16%.

Challenges of BAHA Implantation in the Pediatric Population

Unlike adults, the most common indication for the BAHA for children has been bilateral ear malformation. (7) The Birmingham pediatric series reported that 93% of the subjects had congenital syndromes that involved the head and neck, including Goldenhar's Syndrome (occuloauriculovertebral dysplasia) and Treacher Collin's Syndrome (mandibular dysostosis). Only 7% of the children required BAHA as a result of suppurative otitis media. (43)

Specific challenges encountered in BAHA implantation in the younger age group (under 17 years old) included airway management, thin bones, softer and more immature bone, appositional growth of the temporal bone, skin overgrowth of the abutments, and cleaning problems in adolescence. (40); (43)

One of the main difficulties in pediatric BAHA implantation is inadequate skull thickness as a result of age, craniofacial abnormalities, and underdevelopment of the skull and the mastoid bone. The thickness of the temporal bone is critical for implant integration. Thin bones may result in incomplete insertion of the fixture. To overcome this problem, Granstrom et al. (40) recommended using bone augmentation to ensure proper installation of the implant in younger children. They also extended the time between the first and second stage of the procedure for children under 3 years old. Although BAHA has been implanted in children of BAHA users as (36)young as 1 year, operating in such an early age poses additional surgical risks because of the short distance to the dura, sigmoid sinus, and air cells. Pediatric implant surgery also required careful handling of the bone because, with the low mineral content and high

water content, the bone of young children is soft. Researchers concurred that implantation in the very young should be restricted. Granstrom et al. (40) believe that the most suitable period for BAHA implantation would be 2 to 4 years old. Most of the studies (37); (41) have restricted implants to children five years or older. This is also the minimum age for implant recommended by the BAHA manufacturer.

Osseointegration in children has been shown to be marginally less successful than in adults. The Birmingham series (37) and another series in the United Kingdom (41) reported overall failure rates of 11.2% and 15% respectively. Other series (40), (41) reported implant failure rates (4% - 6%) among children that are comparable or lower than those reported for adults. The most common causes for fixture loss among children were incomplete insertion and trauma.

The relatively high rate of failed osseointegration in children has been managed prophylactically in some programs (36), (37), (41), (43) by banking 1 to 2 additional fixtures (sleepers) at the initial operation as spares for future use if needed. Papsin et al. (41) indicated that a fixture makes up approximately 10% of the cost of the operative procedure to implant it, and stated that it is of clear financial benefit to implant two fixtures routinely, considering the failed osseointegration rate of 15%.

Because many of the pediatric BAHA candidates suffered from malformation of the head and neck and about19% also had a history of congenital heart disease, airway management in general, and intubation in particular could be problematic. As the surgical times for BAHA became shorter, the laryngeal mask airway was considered an adequate alternative to intubation. (43)

Compared with adults, children demonstrated a higher rate of bone healing resulting in excessive bony growth around BAHA fixtures, often threatening the abutment and requiring revision surgery. (41) This exuberant bone growth accounted for the higher revision rates reported for children.

With the exception of the significantly higher skin reaction rate reported by Papsin et al. (41), adverse skin reaction rates among children were comparable to those of adults in frequency and severity.

Zeitoun et al. (37) reported that a considerable number of adolescents with implants had psychological problems that required psychiatric counselling, and concluded that a pediatric osseointegration program requires significant investment and a multidisciplinary approach. The investigator further concluded that although implants in children are associated with difficulties, the benefits of the use of BAHA (e.g. on speech development) outweigh their disadvantages.

Biaural versus Monaural BAHA

In almost all the studies, BAHA was implanted monaurally on the side of the ear with the best bone conduction threshold. An exception is a study in which Bosman et al. (44) evaluated biaural fitting of BAHA in 25 patients with at least 3 months follow-up. In the study, sound localization and speech recognition in quiet and in noise were measured for all subjects. Release from masking for pure-tone stimuli in noise with interaural phase difference was also measured in nine of the subjects. The results showed that directional hearing and speech recognition in quiet and in noise improved significantly with two BAHA than with one. Biaural masking level difference measurements showed a significant release from masking of 6.1, 6.0 & 6.6 dB for 125 Hz, 250 Hz and 500 Hz stimuli. The authors concluded that bilateral fitting of BAHA would, to some extent, lead to biaural hearing and that prolonged periods of monaural hearing due to unilateral fitting do not preclude biaural hearing with bilateral fitting at some later stage.

Indications and contraindications for use of BAHA

No clinical guidelines for the use of BAHA were found. However, the inclusion and exclusion criteria for patient selection in the BAHA studies shed light on which patients may achieve optimal benefits from BAHA.

Patient selection criteria of the Nijmegen BAHA program (12) indicates that the patients

- Be at least 6 years old
- Have bilateral conductive or mixed hearing loss but still can benefit from sound amplification.
- May have a sensorineural hearing loss component that did not exceed 65 dB hearing level.
- Are not eligible for reconstructive surgery of the middle ear to improve hearing because of ear canal atresia or a chronically draining ear;
- Have already tried a conventional bone conductor and rejected it because of pain or skin irritation owing to the pressure of the bone conduction transducer or because of serious problems with the appearance of this often disfiguring device.

The audiological criteria of the Birmingham BAHA program (26) were that patients have the following:

- Average bone conduction thresholds (0.5-4 kHz) less than 40 dB HL (ear level) and less 60 dB HL (body worn)
- Speech discrimination score greater than 60%
- Realistic expectations about BAHA.
- Reasonable social support.

The Canadian Program (8) used the following selection criteria :

Surgical Indications
Patients are prioritized from 1 to 4 in decreasing order of urgency:

1. Bilateral congenital atresia
2. Bilateral chronic ear disease resistant to medical and surgical therapy and failed conventional hearing management.
3. Unilateral congenital atresia.
4. Unilateral chronic ear disease.

Patients should be over 5 years old.

Audiological Criteria (As recommended by manufacturer)

- Patients have conduction or mixed hearing loss with a bone conduction pure-tone average (0.5, 1, and 2 kHz) threshold up to 45 dB HL for the Classic 300 or BAHA Compact, and 70 dB for Cordelle II (Body Processor).
- Patients should have air conduction pure-tone averages that are not less than 40 dB
- Patients should have a maximum speech discrimination score better than 60% when using a phonetically balanced word list.

<u>Contraindications for BAHA</u>

Hakassan et al. (2) recommended that, for optimal results, the following limitations should be taken into consideration, although they should not be considered as absolute contraindications:

- PTA BC thresholds (0.5 – 3.0 kHz) worse than 45 dB HL (adjusted to approximately 60 dB HL for HC 220);

- Emotional instability, developmental delay or drug/alcohol abuse (inability to follow instructions, participate in follow-up or maintain adequate hygiene);
- Age less than 5 years.

Economic Analysis

Cost of the BAHA Device

The device cost of the initial implant is approximately $5,324 comprising $4,485 of the fixture and abutment, $3,500 for the external sound processor, and $339 for the disposable surgical components. The transducer is expected to last about 5 years and hence there will be a replacement cost of about $3,500. (Information provided by the manufacturer)

Cost-effectiveness

No literature on the cost-effectiveness of BAHA was found.

Synopsis of Research Findings

Although numerous papers have been published demonstrating the benefits of BAHA, no evidence on the effectiveness of BAHA has been derived via randomized controlled trials. The following is a synopsis of the level 4 evidence on BAHA,

Procedure

Nearly all the studies were based on monaural BAHA implanted behind the ear with the best bone-conduction threshold. Both one-stage and two-stage procedures have been used for adults with good results, whereas the two-stage procedure has been generally used for pediatric implants.

Safety

BAHA appears to be safe. No mortality or life threatening morbidity has been reported.

Success Rates

BAHA implant success rates are high. Most studies reported success rates at 90% or higher. Implant loss or removal resulted mainly from failed osseointegration, trauma and infection. One researcher has reported an implant survival rate of 100% for the first two years following implant and 75% implant survival after 7 years.

Revision rates for tissue reduction or resiting were generally under 10% for adults but have been reported to be as high as 25% in pediatric studies.

To achieve stable, reaction-free implant, the implant must be surrounded by thin, hairless and immobile skin. Hence, the surgical technique used and the experience and skills of surgeons and nursing staff are critical factors to implant survival.

Adverse Skin Reaction Rates

Adverse skin reaction is a major complication of BAHA that impacts on implant survival. The proportion of patients that experienced adverse skin reactions ranged from 8 to 30%. Most of the reactions were mild and responded to treatment with antibiotic ointment. About 1% to 2% of adverse skin reactions required

revision surgery, and less than 1 % required removal of the fixture. Personal hygiene, care of the abutment, and careful follow-up by surgeons informed in the care of these patients make critical impact on adverse skin reaction rates.

Effectiveness of Bone Anchored Hearing Aid

- For former users of conventional bone conduction hearing aids, BAHA was shown to significantly improve unaided and aided free field and sound field thresholds as well as speech discrimination (in quiet and in noise). These findings were based on audiometric tests as well as on questionnaires.

- The benefit of BAHA in hearing thresholds and speech discrimination for former users of air conduction hearing aids is ambiguous. It has been suggested that the effectiveness of BAHA for these patients depends more on the size of the air–bone gap.

- Most former users of bone conduction aid preferred BAHA to their former hearing aids whereas almost half of the former air conduction users preferred their former hearing aids.

- The BAHA does not occlude the ear canal, and allows better ventilation that results in a dryer ear. It has been found to be effective in reducing the frequency of ear infection and discharge particularly in patients with suppurative otitis media.

- Patients reported that BAHA has improved their quality of life in all domains. Major reported advantages of BAHA included better sound quality, less ear infection, greater comfort, less pressure and skin irritation, better conversation and improved esthetics. Major problems reported were difficulty to use the phone, difficulty to clean the abutment and trauma to the tranducer.

- A high percentage of patients continued to use BAHA even after lengthy follow-ups.

- BAHA have been performed safely in children. Generally, BAHA has been performed in children five years of age or older.

- Although there are specific challenges for using BAHA for children, such thin bone, soft bone, more failed osseointegration, psychological problems and higher revision rates due to more rapid bone growth, the overall outcomes are comparable to those of the other non-pediatric studies.

- There were few studies relating to bilateral fitting of BAHA.

- Studies showed that patient screening using strict eligibility criteria is critical for success in implantation and use of BAHA. The eligibility criteria used by all the studies stipulated minimum average bone conduction thresholds, minimum speech discrimination and minimum air conduction thresholds. Speech audiometry has been found to be valuable tool in assessing borderline cases.

- Close follow-up and monitoring particularly regarding the skin condition surrounding the penetration site are critical to implant survival.

- Preoperative counselling to set realistic patient expectation has been found to be useful.

Economic Analysis

No study was found on the cost-effectiveness of BAHA.

Conclusion

- Level 4 evidence suggests that BAHA would be beneficial for a very small subset of patients.
- BAHA is safe.
- Good outcomes can be achieved for a small subset of patients with conduction or mixed hearing loss that cannot undergo surgical repair or wear a conventional bone-conduction hearing aid.
- For those people with chronic discharging middle ear infection or congenital conduction hearing loss, BAHA is likely the only available alternative to the conventional bone conduction hearing aid and would improve hearing without aggravating the ear infection.

Glossary

Air-bone gap	The difference between air conduction threshold and bone conduction thresholds. Air conduction thresholds are obtained when testing hearing via the eardrum and middle ear to the cochlea, as compared to bone conduction thresholds determined by bone oscillator on the mastoid which directly measure neurologic hearing in the cochlea.
Air conduction	The conduction of sound to the inner ear through the external ear canal and middle ear.
Aural atresia	Absence or obstruction of the external acoustic meatus (ear canal). It may be congenital or acquired through trauma or disease.
Cochlea	A spirally wound tube-like structure that forms part of the inner ear and is essential for hearing.
Cochlear implant	A device that electrically stimulates the hearing nerve in the cochlea (inner ear).
Decibel (dB)	A unit of measuring and describing sound intensity or loudness.
Earmould	An impression of the ear canal used to mold the shell of the hearing aid. It is made of silicone or other impression material.
Hertz (Hz)	Cycles per second, a measure of the frequency of sound (number of complete oscillations per unit of time).
KHz	Kilohertz
Gain	The difference between the input signal and the output of the hearing aid. The amount of amplification provided by the hearing aid.
Hearing level (HL)	A measured value of an individual's threshold of hearing expressed in Decibels relative to a specified audiometric standard.
Maximum Phoneme score (MPS)	A measure of free-field speech recognition function
Microtia	Gross hypoplasia or aplasia of the auricle (pinna) of the ear, with a blind or absent external acoustic meatus.
Osseointegration	Direct anchorage of an implant by the formation of bone tissue around it without growth of fibrous tissue at the bone-implant interface.
Otic	Pertaining to the ear.

Otitis Media	Inflammation of the middle ear
Otorrhea	A discharge from the ear, especially a purulent one.
Otosclerosis	Formation of spongy bone in the bony labyrinth of the ear.
Periosteum	A specialized connective tissue covering all bones of the body and possessing bone-forming potentialities.
Pure tone threshold	A measure of hearing sensitivity. It indicates the softest sound audible to an individual at least 50% of the time and is measured as a function of frequency.
Pure-tone average (PTA)	Is usually the average of hearing sensitivity at 500, 1000, and 2000 Hz. This average nearly should match the speech-reception threshold (SRT) (within 5 dB) and also nearly should match the speech-detection threshold (SDT) (within 6-8 dB)
Pure tone air test	This test is performed by placing head phones over the ears and playing different tones. The person is told to indicate when he or she can hear a tone. This test will determine how well a person hears at different frequencies.
Speech detection threshold (SDT)	Also called the "speech-awareness threshold" is the lowest-intensity speech stimulus that an individual can detect at least 50% of the time.
Speech reception threshold or speech recognition threshold (SRT)	The softest intensity spondee word (bi-syllabic words equally emphasizing both syllables) that an individual may correctly repeat 50% of the time. The SRT indicates the level of sound that an individual needs before he or she can hear and understand words.
Speech discrimination or word recognition	The ability to repeat correctly an open set of monosyllabic words at supra threshold intensity. Word lists are phonetically balanced meaning that the speech sounds they use occur with the same frequency as in the whole language.
Suppurative	Producing pus or associated with supperation.
Transcutaneous	Entering through the skin.

Appendices

Appendix 1: Bone Conduction Hearing Aids

Figure 1*
Sound Processor of BAHA

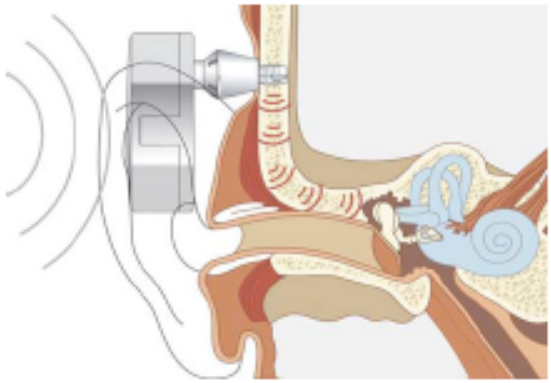

Figure 2*
How BAHA works

†Image retrieved from http://www.pde.com/~kazemir/HearingAids.htm
**Reprinted with permission from Entific Medical Systems, Sweden*

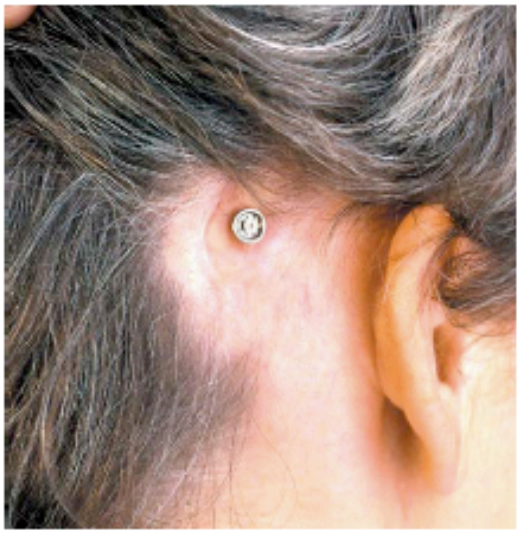

Figure 3*
Skin penetrating abutment of BAHA

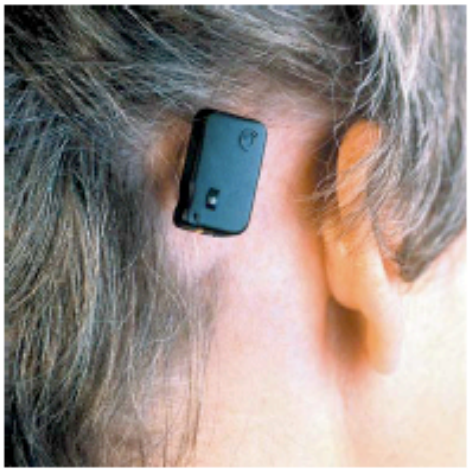

Figure 4*
Sound Processor of BAHA attached.

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Appendix 2: Summary of Clinical Outcomes of Bone Anchored Hearing Aid Implants

	Hakassan B 1990 (2) Sweden	Tjellstrom 1995 (5) Sweden	Reyes 2000 (14) Sweden	MacNamara 1996 (16) UK	Proops 1996 (10) UK	Van Der Pouw 1999 (11) Netherlands	Bonding 2000 (13) Denmark	Lustig L 2001 (6) USA	Jacobsson 1992 (39) (Pediatrics)	Papsin 1997 (41) Pediatrics)	Granstrom 2001 (40) (Pediatrics)	Tietze L 2001 (36) (Pediatrics)	Zeitoun 2002 (37) (Pediatrics)
Type of study	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4b)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)	Case series (Level 4c)
No. of patients (No. of Implants)	147 (167)	149	149	69 chronic suppurative Otitis	188	155 (163)	31	40	30 (16 BAHA)	32	76 (170)	19	31 (56)
Mean age (range) Years	50.8 (SD 17.4)		(3–88)	58 (47–59)	-	48 (9–80)	Median 58 (36–80)	49 (13-83)		5.8 (4.1–16.9)	8.3 (1–16)	11.2 (6.4–16) years	7.6 (2–10)
Follow-up Period Months (mean)	1month–11.5 years		0–8 years	24		8 – 84	42		40	0–4.5 years	7.8 (1–21) years	18	3.2 (0.5–7) years
Success Rate %	99.3	96.6	94.6	98.5	89.9	94.5	100 first 2 yrs	97.5	96.6	91	94.2	95	88.8
Failed osseointegrate % **Loss of Implant %** **Removal of Implant %**	0.7 16 abutments	 3.4 7.4	5.4 7.4	1.5 4.3 (late) 4.3 loose abutment	10.1	 6% fixture & abutment 8% abutment	19.4	2.5		9 15 9% resited	 5.8	5% 	4.7 6.5
Cumulative Success rate % **1 year** **3–4 year** **5 year** **After 7 year**		 94.3 - 95.4					 100 85 75						
Reaction-free skin penetration (% patient)		81	70	78	79			92.5		18			
Reaction-free skin penetration (% of observations)	93 (n=1,236)	96.4	64.3 (1st 4 years) 97.2% (last 4 years)			91			91.7 (for BAHA)		91	84	
Skin Reaction by grade %													
Grade 1	4	1.8	94–97	22 (mild)		6.2			16 (=/> grade 1)	82 (=/> grade 1)	5.1	16 (=/> grade 1)	4.2
2	1.3	1.0	2.4–3.3			1.9					2.5		1.9
3	1.3	0.4	0.5–1.8			1.7					1.5		1.9
4	0.1	0.4	0			0.2							0
Soft tissue revision surgery %					3.2 (episodes)						22	11	

Appendix 3: Summary of Audiometric tests and subjective response to Bone Anchored Hearing Aid

Study/Type	No. of Subjects &Type of Study	Hearing threshold	Speech Recognition &/or Word discrimination	Subjective response to BAHA (questionnaires)
Arunachalam P 2001 (34) New Castle, UK	N = 60 mean age: 45 years Case series (Level 4c)			Glasgow Benefit Inventory (QOL) Total Benefit = +31 General Benefit = +37 Social Benefit = +24 Physical Benefit = +14; Pattern similar to other ear interventions Improvement in QOL greater than middle ear surgery but lightly less than cochlear implant. Patients with discharge otitis media show greatest improvement in the physical domain.
Browning GG 1994 (29) Scotland	N = 23 Mean age: 41 years Case series (Level 4c)	In free field audiometry, the 11 users (69%) gained superior benefit from BAHA compared to AC hearing aid and non-users did not show this gain.		-All previous users of BCHA considered BAHA superior in method of attachment, comfort, convenience -11 (69%) were happy with BAHA (users) -5f these 11 continued to use ACHC along with BAHA 31% (5) reverted to solely using ACHA (non-users)
Coopers HR 1996 (26) Birmingham UK (Adult patients)	N = 68 Mean age Congenital: about 30 years Chronic supperative otitis media: about 60 years Case series (Single centre) (Level 4c) 6-month results analyzed	-No significant difference in air conduction thresholds for patients with chronic supperative otitis media (CSOM)* and congenital conductive hearing loss (CON) † -Pure tone bone conduction averages significantly better in CON group than CSOM group. -Aided mean free-field warble tone thresholds significantly better with BAHA than with previous aids. Similar improvement for CSOM & CON groups	-No significant change in free-field speech discrimination score @ 63 dB between BAHA & previous aids. For CON subjects who were former ACHA†† users, significant improvement in free-filed speech discrimination with BAHA. -CSOM patients who were former ACHA users had greatest proportions with worse speech discrimination using BAHA. *Etiology of hearing loss & type of previous hearing aid have an effect on results from BAHA.	-95.5% used BAHA for more than 8 hrs/day -89.7% of these found sufficient sound amplification by BAHA. -reported significant improvement in hearing in quiet surrounding with BAHA among former users of BCHA. -Significant improvement in hearing in noise reported by all CSOM patientss. CSOM patients who were former BCHA users derived greatest overall benefits in the three hearing situations with BAHA. -More patients checked off positive attributes of sound quality for BAHA. -Overall, patients reported significantly more satisfied with BAHA. 10.3% rated BAHA lower than former hearing aid.

*CSOM Congenital suppurative otitis media ** CBCHA Conventional bone conduction hearing aid
†CON Congenital conductive hearing loss
††ACHA Air conduction hearing aid

Study/Type	No. of Subjects &Type of Study	Hearing threshold	Speech Recognition &/or Word discrimination	Subjective response to BAHA (questionnaires)
Lustig L 2001 (6) John Hopkins U USA	N = 41 Retrospective multicenter case series (Level 4B)	-Average improvement in soundfield threshold = 32+/-19 dB -Closure of air-bone gap: 80% within 10 dB of pre-op bone conduction threshold, -60% within 5 dB, 30% showed over closure. -Average improvement in threshold for subgroups: -Otitis media/otorrhea or cholesteatoma: 33 dB. -congenital auditory canal atresia or stenosis: 22 dB Otosclerosis or congenital conductive hearing: 42 dB. -Post skull surgery canal closure if only operated ear taken into account: 34 dB.		39 patients (95%) continued to wear the implant and report subjectively good hearing & improved sound quality.
Hough D 1997 (3) Okalhoma City, USA	BAHA N = 35 TBS N = 35 (Audiant) retrospective matched comparison of BAHA & Audiant (Level 4c)	-mean threshold of both devices was elevated above their PTA. -No significant difference in mean bone-conduction scores of the two devices -No statistically significant difference between the performance of HC 200 & Audiant for warble tones in the sound field. -The Audiant yielded more gain to near preoperative bone threshold at 250 Hz. The BAHA HC 200 provided greater gain at 2000 Hz. -Both devices produced approximately the same amount of gain at 500, 1000 and 4000 Hz.		
Hakassan B 1990 (2) Sweden	N = 147 (167 implants) mean age 50.8 yrs Case series Single center Goteborg, Sweden	All subjects studied: -Average functional gain for free field warble tone threshold showed significant gain in both BAHA & former hearing aids over unaided. Similarities between the hearing aids. -Improvement showed at every frequency. -Old BC hearing aid had lower sensitivity at higher frequencies. <u>Based on 49 subjects</u>, there is a great spread in functional gains that probably reflect a great spread in conductive hearing loss. -Strong relationship between PTA bone thresholds & successful rehab. -Max. allowable PTA change from 60 dB to 45 dB, the % of patients reported improved hearing changed from 81% to 89% and those reported improved comfort changed from 88% to 95%. Reported worse hearing changed from 12% to 7% & reported worse comfort	Speech discrimination tests (47 patients) Average sound field speech discrimination score (phonetically balanced words) : Unaided = 14%, (@ speech level of 63 dB SPL HC200 = 81% (significant) Old BCHA = 80% Old ACHA = 67% No statistical significance among aided conditions. Synthetic sentence identification (45 patients) BCHA gp (20) improved from 50% to 70% with BAHA ACHA gp (25) improved from 50% to 60% with BAHA	<u>Ear infection</u>: ACHA: 22/24 (92%) reported improvement. BCHA;12/27 reported improvement. Significant improvement reported by former users of ACHA with ear mold. No significant improvement for former BCHA users. 90% reported using BAHA for > 8 hrs/day. None reported not using BAHA at all. -Reported better sound quality, easier to use and more comfortable to wear. -The positive psychoacoustic test results concerning sound quality of HC200 compared to old hearing aids were confirmed by the subject's own opinions. - All most all patients reported considerable improvement in quality of life (greater than 9 out of a scale of 10)

Study/Type	No. of Subjects &Type of Study	Hearing threshold	Speech Recognition &/or Word discrimination	Subjective response to BAHA (questionnaires)
Hakansson B 1994 (25) Sweden	N = 122 Mean age 53.5 yrs 62 M, 60F 84% COM 16% CM Pure Tone Average (PTA) 25.0dB (1-45 dB) Multicenter (9) case series for premarket approval application to FDA Average follow up year=5.6 yrs (4 – 14 yrs)	Sound field warble tone thresholds -All 122 subjects showed improvement using HC200 compared to unaided at 0.5, 1, 2 &3 kHz. (mean improvement 29.4 dB HL, highly significant). -HC200 showed improvement at each frequency when compared with bone conduction HA except for 0.5 kHz). Difference at 0.5, 1 & 3 kHz statistically significant.	Speech Reception threshold (the speech level at which 50% of the words in a word list are correctly identified.) -Mean improvement in SRT between HC2000 & unaided is 26.5 dB HL. All subjects improved. Improvement statistically significant. No significant difference between HC200 & BCHA. Word discrimination Word discrimination at 63 dB HL (conversation level) with a background noise @57 dB SPL. Showed average improvements of 41.6% (HC200 vs unaided. Statistically significant. -Average improvement compared to BCHA = 6.2% , statistically significant. (-25 –58%)	Questionnaire -Average patient satisfaction = 8.7/10 +/- 1.72 -86.6% of patients reported using BAHA >8 hrs/D -Important reported advantages included: improved speech intelligibility, better sound comfort, less pressure on the head, less skin irritation, easy handling, less skin irritation and cosmetically more acceptable. -Of the patients who previously used an ACHA, 44/51 (86% reported a general improvement of their ear infection with BAHA. (possible reason – no ear mould was used, provide better condition for the infection to heal.) -55/67 (82% reported improvement in wearing comfort with HC 200 vs former BCHA. Conclusion: 1. HC200 is superior to the unaided condition in all tests 2. HC200 perform statistically significantly better than BCHA with respect to word discrimination in a noisy situation.
Mylanus E 1998 (28) The Netherlands	N = 34 Retrospective clinical trial Compare audiometric & questionnaire results of BAHA with ACHA	Significant improvement in mean free-field threshold for BAHA of 6 dB @ 1 kH & 12 dB @ 8 kH over ACHA.	-MPS is equal to or better with BAHA than ACHA for patients with air-bone gap > 30 dB -Small but significant improvement in S/N ration with BAHA than ACHA. -No significant correlation between change in S/N and air conduction or bone conduction threshold. - Significant correlation between the change in S/N ratio and the air-bone gap.	Questionnaire response rate = 97% -60% preferred BAHA re less occurrence of ear infection, speech recognition in quiet, quality of sound feedback & frequency of outpatient visits to ENT clinic -majority of BAHA patients had fewer infections - Overall 82% preferred BAHA -27% found taking care of skin around implant a burden 15% preferred former ACHA 3% regard BAHA & ACHA equal -did not express preference in terms of speech recognition. 4/5 preferred monaural BAHA to biaural ACHA.
Mylanus E 1994 (45) Netherlands	N = 62 Multicenter (3) Audiological measurements of BAHA200	Aided Free Field Thresholds Significantly better thresholds were obtained at 0.5, 1, 2 and 4 kHz for conventional BCHA group BAHA did not produce a significantly better threshold at any frequencies for ACHA group. Greater closure of the air-bone gap by BAHA than CBCHA. ** On an individual level, the speech recognition in quiet, in noise, or in both conditions with BAHA HC200 improved in the majority of CBCHA patients and in half of the patients in the ACHA group.	Speech Recognition in quiet The majority of patients had similar results with BAHA & conventional HA in agreement with previous studies. Patients who had maximum phenome score MPS of 100%, difficult to differentiate between the performance of BAHA & conventional hearing aids. Speech Recognition in noise The mean improvement with BAHA was significant in the CBCHA (average of 39%) group but not significant in the ACHA group. Patients with a lower PTA bone conduction threshold (<45dBHL)had better speech recognition in noise results. All patients benefited to a comparable extent irrespective or their hearing loss.	

Study/Type	No. of Subjects &Type of Study	Hearing threshold	Speech Recognition &/or Word discrimination	Subjective response to BAHA (questionnaires)
Mylanus E, 1995 (31) The Netherlands	N = 65 Single center case 75% con. BCHA users 25% former ACHA users (BAHA 200& BAHA220) Compare questionnaire of BAHA & former hearing aids Case series		Audiologic data Speech recognition in noise 62% preferred BAHA for speech in noise and had an average improvement of –2.5+/- 2.2dB (greater) 11% preferred previous hearing aid and had an average improvement of –0.5+/- 2.2 dB (less than that of the group that preferred BAHA) Speech recognition in quiet 73% of patients with MPS<100% preferred BAHA for speech recognition in quiet (average improvement in MPS 9%) 11.4% preferred former hearing aid for speech recognition in quiet (improvement in MPS 4%) Conclusion: statistically significant improvements in the scores with BAHA compared with conventional BCHA for speech recognition in quiet & in noise, quality of sound & comfort). This finding agreed with audiologic scores for speech recognition in quiet & noise reported.	Questionnaire results : Former conventional BCHA users Group 100% used BAHA for more than 8 hrs per day Patients preferred BAHA to the conventional BCHA on all aspects (speech recognition, quality of sound, and skin irritation. No clear difference between HC200 and HC220 46% of patients with former biaural conventional BCHA preferred biaural aid for directional hearing, 39% preferred BAHA & 15% had no preference. Former ACHA Group 94% used BAHA for more than 8 hrs per day, 6% used it for 2-8 hrs/day Change in scores for hearing in quiet & noise not statistically different. Half of former ACHA users reported improved speech recognition & sound quality with BAHA.
MacNamara M 1996 (16) Birmingham UK	N = 69 With chronic suppurative otitis media 24M, 45F mean age 58 years 56% BAHA 200/300 44% BAHA 220 Retrospective Case series (Level 4c)			Questionnaire through telephone Interview: **Discharge** Worse 0% Significantly reduced 84% Unchanged 16% The unchanged either had previously dry ear or remained to be slightly moist. 73% continued to use BAHA for more than 8 hrs per day 58% were more satisfied with BAHA than with previous hearing aid.
Snik AF 1994 (27) The Netherlands	N = 62 BAHA HC 200 Multicenter case series (Level 4b)	-Significantly better aided free field thresholds with BAHA than CBHA Q 0.5, 1, 2 & 4 kHz, but no significant improvement compared to ACHA at any frequencies. - greater closure of air-bone gap with the BAHA than with CBHA. -Patients with a lower PTA bc threshold had better speech recognition in noise results.	-Similar speech recognition in quiet for the majority of with BAHA and the conventional hearing aids. -The mean improvement in speech recognition in noise with the BAHA was significant in the CBHA group (average improvement of 39%), but not significant in the ACHA group -The mean improvement in the S/N ratio in the CBHA group was –2.3+/- 2.4 dB). -The average speech recognition scores were better with BAHA and conventional hearing aid in the subgroups with the smaller sensorineural hearing loss.	

Study/Type	No. of Subjects &Type of Study	Hearing threshold	Speech Recognition &/or Word discrimination	Subjective response to BAHA (questionnaires)
Snik AF 1995 (12) The Netherlands	N = 64 Previous hearing aid BCHA 75% ACHA 25% BAHA: 46 HC 200 18 HC 220 Single centre case series (Level 4c) Follow up 18-68 months	Mean change in aided threshold: HC200 former CBHA: -5dB +/-5.6 HC200 former ACHA: -17+/-5.4 dB HC220 former CBHA: 6.2+/-8.8 dB HC220 former ACHA: -5.1 dB	**With BAHA** Speech Recognition in quiet: Mean change in Phoneme score @ 60 dB (PS60) *Former BCHA* *Former ACHA* 15+/-16 6+/-15 52% improved 19% improved 0% worse 0% worse Mean change in MPS* *Former BCHA* *Former ACHA* 5+/-8 4+/-12 30% improved 13% improved 0% worse 13% worse *Mean change in S/N † score* *Former BCHA* *Former ACHA* 41+/-31 31+/-44 64% improved 54% improved 0% worse 8% worse	**With BAHA** Speech recognition in quiet *Former BCHA* Former ACHA 74% improved 50% improved 10% worse 31% worse Speech Recognition in noise *Former BCHA* *Former ACHA* 76% improved 44% improved 8% worse 38% worse Conclusion Majority of patients who previously used conventional BCHA showed significantly improved speech recognition scores with BAHA & the majority preferred BAHA. Former users of ACHA –results ambiguous, speech recognition poorer than ACHA. BAHA uni-aural compared to bi-aural ACHA.
Snik AF 1998 (4) The Netherlands	BAHA N = 41 TBS†† N = 17 Case series (Level 4c) Mean follow up >4.5 yearss	Speech reception threshold Both BAHA & TBS produced improvement in mean SRT in former users of a conventional BCHA. Only significant in BAHA. -Mean SRT deteriorated significantly for BAHA subjects who were former users of ACHA.	Speech discrimination S/N ratio improved significantly (1.6) with BAHA for former users of conventional BCHA. The results for former users of ACHA were ambiguous. -No significant improvement in TBS subjects.	BAHA subjects who were former users of conventional BCHA: 70% preferred BAHA, 12% preferred CBCHA. BAHA subjects who were former ACHA users: 50% preferred BAHA, slightly less than 50% preferred ACHA. TBS subjects who were former CBCHA users: 50% preferred TBS, no one preferred CBCHA. TBS subjects who were former ACHA users: 30% preferred ACHA, the others had no preference. All BAHA subjects chose to use BAHA.

* MPS Maximum Phenome
† score S/N Speech-to-noise ratio
†† TBS Temporal bone stimulator

Stephens D, 1996 (33) Birmingham UK	N = 39 Multicenter observational (Level 4 b) Benefit/problem questionnaire 24 months after fitting of BAHA		8 BAHA patients from Cardiff & 31 from Birmingham asked to list benefits & problems associated with BAHA. 165 benefits & 105 problems were listed & classified. Congenitally deaf GP listed significantly more benefits than problems than the acquired hearing loss GP; There is no significant difference in the benefits & problems listed by the two grips.	**Benefits:** Main Acoustic: Hearing improved 46%,.Hearing clearer 33%, group conversation possible 10%, ,TV not so loud 10%. Main practical: Easier to put in/use 38%, less noticeable 31%, more comfortable 21%, no headband 15%, volume control easy 10% Main psychological: more confident 28%, don't know it's there 13%, fee safer in traffic 5% Main **Shortcomings:** Main acoustic: Wind noise 21%, speech in noise 21%, feedback 8%. Main practical Difficult to use the phone 23%, easily dislodged 21%, too big 15%, Difficult to clean abutment 10% No major agreement on medical & psychological shortcomings. Listed included sore scar tissue, difficult to keep abutment free from infection. Loss of independence because need someone to fit the O-ring.
Wazen JJ 1998 (35) Columbia University, USA	N = 24 Mean age = 50.5 yearss Multicenter case series (Level 4b) 5/24 prev AC 2/10 prev BC Follow-up 10-13 yearss		Audiology Data (for 9 patients): Mean pre-op bone conduction average = 20 dB Mean speech reception threshold improved from 52 dB to 27 dB (48%) post op.	Perception (questionnaire) scale of 1-5 with 5 being totally satisfied Sound quality in quiet: 4.6+/-0.85 Volume: 4.4 +/- 0.77 Sound quality with music 4+/-1.8 Clarity with background noise 2.9 Sound localization in noise 2.7
Wade P 1992 (19) Canada	N = 24 Audiant TBS N = 11 BAHA Comparative non randomized (Level 4 c)	P5/7 of patients wearing audiant were patients with congenital conductive hearing problems. The overriding patient complaint was that they had to wear their body processor and not the at the ear processor that they had expected to do. Similar findings reported by Browning 1990. wearing Audiant BC permanently Follow-up of 2 patients implanted with the new, larger magnet revealed that only one of the patients was wearing the at the ear processor successfully. That patient has completely normal bone conduction.	-11 patients fitted with percutaneous BAHA for over 18 months were all wearing them successfully with the exception of 1 patients. Audiologic comparison Neither device was able to provide sufficient gain in the lower frequencies to close the air-bone gap. -To do so, the transcutaneous device will need 45 dB more gain & the percutaneous device will need 40dB ,	Conclusion: Otologist must have the flexibility to implant either device. Most patients, cosmetically, seem to prefer the transcutaneious device. If patients have any sensorineural hearing loss at all, up to 45 dB PTA, author suggested that they try the percutaneous device.

Appendix 4 – Summary of Pediatric Studies on Bone Anchored Hearing Aid

Study	No of subjects/Type of Study	Success Rates of Implants	Device Loss and/or Removal	Adverse skin reaction of Implant Site	Hearing Threshold	Speech Recognition &/or Word Discrimination	Subjective Response to BAHA (Questionnaire)
Granstrom G 2001 (40) Sweden	N = 76 Mean age 8.4 years A total of 170 implants for BAHA & prosthesis Case series	94.2%	10 (5.8%) of implants were lost. Better survival with longer fixtures. General early losses. Only 1 lost after 3 years Revision surgery in 22% of patients to reduce excessive tissue under the skin surface due to continuous subcutaneous skin formation.	91% completely reaction free (grade 0). -adverse reactions seen in 9%. 5.1% grade 1, 2.5% grade 2 and 1.5 % grade 3.			Conclusion: -BAHA highly advantageous compared to conventional BCHA. -Fixture survival rate equivalent to those in the adult population. -Significant improvements seen in aided thresholds with BAHA demonstrate the safety & efficacy of BAHA. With close follow-up, successful hearing and cosmetic rehabilitation can be achieved with reduced rehabilitation time and lowered surgical costs.
Jacobsson M 1992 (39) Sweden	N = 30 16:BAHA 14: auricular prosthesis Single center case series Mean follow-up=40 months	96.6% (2 stage-procedure)		BAHA had a 91.6% of skin-reaction-free post-op observations.			
Papsin B 1997 (41) Great Ormond St Hosp for Children UK	N = 32 Mean age 8.9 yearss (4.1 – 16.9) Retrospective analysis review.		15% of fixture loss 9% failed to achieve osseointegration within first 6 months. -9% had fixture re-sited despite full osseointegration 25% required minor revision surgery to thin skin or revise the abutment 29/32 (91%) still wearing BAHA.	-239 skin assessments were made during follow-up. -18% of patients never had only grade o (normal skin) -82% of patients had a skin reaction around the implant of grade 1 or worse. (44% x1, 19% x2, and 9% x3).			

Study	No of subjects/Type of Study	Success Rates of Implants	Device Loss and/or Removal	Adverse skin reaction of Implant Site	Hearing Threshold	Speech Recognition &/or Word Discrimination	
Powell RH 1996 (42) Birmingham UK	N=21 Age:2.5 – 17 yearss 44% Treacher Collins syndrome, 28% bilateral microtia, 16% Goldenhaar'' syndrome, 8% chronic suppurative otitis Case series		100%		Patients generally had a purely conductive hearing loss with large air-bone gap. -The congenital AC group all obtained better free-field warble tone thresholds with their BAHA and 71% obtained better speech discrimination while 29% had the same results with their BAHA compared to their previous aid. -The congenital BC group obtained better free-field warble tone thresholds with their BAHA. 50% showed better speech discrimination with BAHA over previous aid while 50% showed no change.	Subjective data: Hearing in quiet and in noise was significantly improved with BAHA while no significant benefit was obtained with BAHA for hearing the television.	Every patient felt that BAHA was better and each gave BAHA more positive points than were given to their previous aid. When asked about their overall satisfaction with their BAHA compared to their previous aid, only one patient in the congenital AC group gave BAHA a lower mark than their previous aid. These results were similar to those reported for adult patients. Concluded that BAHA is an effective hearing aid for children with congenital hearing loss regardless their previous hearing aids.
Tietze L 2001 Ontario, Canada	N= 19 Mean age 11.2 years (range 6.4–16 years) 18 microtia 2 craniofacial anaomalies	95%	5% (1 patient) lost initial ossointegrated fixture due to head trauma	Reaction free skin penetration site (of 74 follow-up visits) Overall 84% 1-stage process 73% 2-stage process 88%	-No statistical difference in pre- & post- implantation bone or air conduction thresholds -Mean preimplant bone conduction aided tone thresholds were 30, 15, and 28 for 0.5, 1, and 4 KHz respectively. -Mean post-implant BAHA tone thresholds were 25, 10, & 17 for 0.5, 1, & 4 KHz. Statistically better.		
Zeitoun H 2002 (37) Birmingham UK	BAHA N=31 patients= (51 implants)) Mean age for BAHA(7.6 yearss, range) Single center Case series	88.8%	Total 12%, All related to BAHA Failed integration 4.7% Trauma 2.8% New bone formation 0.9% No obvious cause 2.8% Successful use of sleeper fixture = 3	Total of 214 skin observations Type 0 (normal) 92% Adverse skin reactions: Type 1 4.2% Type 2 1.9% Type 3 1.9 % Type 4 0	Problems encountered: -thin bones -incomplete insertion -multiple attempatients to seat fixtures -7 children need counselling for psychological problems.		BAHA highly advantageous compared to conventional BCHA. -Fixture survival rate equivalent to those in the adult population. -Significant improvements seen in aided thresholds with BAHA demonstrate the safety & efficacy of BAHA. With close follow-up, successful hearing and cosmetic rehabilitation can be achieved with reduced rehabilitation time and lowered surgical costs

Appendix 5 - Data Extraction Form (Bone Anchored Hearing Aid)

<table>
<tr><td colspan="2">Author:
Title:</td></tr>
<tr><td colspan="2">Type of Study: RCT ____ , Non-random. Compar._____ , control: no___, contemporaneous _____, Historical _____

Case Series _____ Single centre _____, multicenter _____, system. Review _____, meta-analysis_____

Retrospective review _____, Subjective (questionnaire) _____</td></tr>
<tr><td>Randomization: Yes _____</td><td>No_____</td></tr>
<tr><td>Controlled: Yes _____
Concurrent _____ or Historical _____</td><td>No _____</td></tr>
<tr><td>Sample Size: Study group _____</td><td>Control group _____</td></tr>
<tr><td colspan="2">Blinding: Yes _____ No _____</td></tr>
<tr><td colspan="2">Loss to follow-up: Yes_____ No_____ Unclear _____</td></tr>
<tr><td>Account for loss to follow-up: Yes _____</td><td>No _____</td></tr>
<tr><td>Subject (Study)

Mean age: _____

Male _____, Female _____

COM___, Con. Atresia ___, Chronic disch _____

Others _____

Previous hearing aids

Pre study hearing threshold:</td><td>Subjects (control)

Mean age: _____

Male _____, Female _____

COM___, Con. Atresia ___, Chronic disch _____

Others _____

Previous hearing aids

Pre study hearing threshold:</td></tr>
<tr><td>Compared to: Previous hearing aid _____

Air conduction HA _____

Conventional BCHA_____

T. Bone stimulator _____</td><td>Method:

Hearing threshold:

Speech recognition/discrimination

S/N ratio

Questionnaire (tool)</td></tr>
</table>

Implant success rate _____% **Adverse Skin reaction:** **% with no episode** Grade 0 ____ Grade 3 _____ Grade 1 ____ Grade 4 _____ Grade 2 ____ % of total observations with no adverse skin reaction =	Device loss _____ Device removal _____ **Questionnaire** % prefer BAHA _____ % prefer comparative hearing aid _____ Improved Quality of Life _____ % satisfied with BAHA _____ Perceived hearing _____ % continue to use BAHA _____ for _____ days/wk
Hearing Threshold (BAHA): Mean Sound field warble tone threshold: _____ Free field thresholds _____ Speech reception threshold _____ Conduction threshold _____ Sound quality _____	**Hearing Threshold ( )** Hearing Threshold (BAHA): Mean Sound field warble tone threshold: _____ Free field thresholds _____ Speech reception threshold _____ Conduction threshold _____ Sound quality _____
Speech Recognition/word discrimination (BAHA) Free field speech discrimination _____ Speech discrimination/intelligibility in quiet _____ Speech discrimination/intelligibility in noise _____ S/N ratio	**Speech Recognition/word discrimination ( )** Free field speech discrimination _____ Speech discrimination/intelligibility in quiet _____ Speech discrimination/intelligibility in noise _____ S/N ratio
Other findings	

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