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MA: IMPLANTABLE BONE CONDUCTION AND BONE ANCHORED HEARING AID

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Description

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC hearing aids may not be suitable for patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear and may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHAs) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or for patients with unilateral single-sided sensorineural hearing loss.

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing device with a percutaneous abutment or a partially implantable bone-anchored hearing device with transcutaneous coupling to the sound processor, the evidence includes observational studies that report pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially implantable bone-anchored devices have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device aided state. No direct comparisons other than within-individual comparisons with external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable bone-anchored hearing device with contralateral routing of signal, the evidence includes 1 randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 145 patients, generally have reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone-anchored devices to hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral hearing assistance devices improve hearing to a greater degree than unilateral devices. BAHAs may be considered an alternative to external devices in patients who are not candidates for external devices. By extension, use of an implantable bone-conduction device with contralateral routing of signal may be considered medically necessary in patients with unilateral sensorineural deafness.

Related Policies
III.179 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

III.199 Cochlear Implant

Policy

I. **Unilateral** fully or partially implantable bone-conduction, percutaneous or transcutaneous (bone-anchored) hearing aid(s) **may be considered medically necessary** as an alternative to an air-conduction hearing aid in patients 5 years of age and older with conductive or mixed sensorineural/conductive hearing loss, when the following criteria is met:

A. Must meet **ONE** of the following medical criteria:

1. Congenital or surgically induced malformations (eg, atresia) of the external ear canal or middle ear; **OR**

2. Chronic external otitis or otitis media; **OR**

3. Tumors of the external canal and/or tympanic cavity; **OR**

4. Dermatitis of the external canal.

AND

B. A pure-tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device), or 65 dB (Cordele II device).

II. For **Bilateral** implantable bone-conduction, percutaneous or transcutanous bone anchored hearing aids for symmetrically conductive or mixed hearing loss **may be considered medically necessary** in patients 5 years of age and older patients meeting the above audiologic criteria (A and B) with loss as defined by a difference between left- and right-side bone-conduction threshold of < 10 dB on average measured at 0.5, 1, 2, and 3 kHz (4 kHz for OBC and Ponto Pro), or < 15 dB at individual frequencies.

III. For **Unilateral Sensorineural deafness** with normal hearing in the other ear an implantable bone-conduction, percutaneous or transcutaneous (bone-anchored) hearing aid **may be considered medically necessary** in patients 5 years of age and older patients when the pure-tone average air-conduction threshold of the normal ear is >20 dB measured at 0.5, 1, 2, and 3 kHz.

IV. Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with **bilateral sensorineural deafness**, are considered **investigational.**

Background

Hearing Loss

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing detects sound at or below 20 dB. The American Speech-Language-Hearing Association has defined degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB). PTA is calculated by averaging hearing sensitivities (ie, the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

Sound amplification using an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an AC hearing aid on the normal or less affected side.

Bone-Conduction Hearing Devices

External bone-conduction hearing devices function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be applied close to the temporal bone, with either a steel spring over the top of the head or a spring-loaded arm on a pair of spectacles. These devices may be associated with pressure headaches or soreness.

A bone-anchored implant system combines a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on osseointegration through which living tissue integrates with titanium in the implant over 3 to 6 months, conducting amplified and processed sound via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids. Implantable boneconduction hearing systems are primarily indicated for people with conductive or mixed sensorineural or conductive hearing loss. They may also be used with CROS as an alternative to an AC hearing aid for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone-conduction hearing systems that connect to bone percutaneously via an abutment. With this magnetic technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Because the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4 to 5 mm over the implant when it is surgically placed.

Regulatory Status

Five Baha® sound processors manufactured by Cochlear Americas (Englewood, CO) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use with the Baha auditory osseointegrated implant system:

* Baha Cordelle II

* Baha Divino

* Baha Intenso (digital signal processing)

* Baha BP100

* Baha 4 (upgraded from the BP100).

FDA cleared the Baha system for use in children ages 5 years and older and adults for the following indications:

* Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;

* Patients with bilaterally symmetric conductive or mixed hearing loss may be implanted bilaterally;

* Patients with sensorineural deafness in 1 ear and normal hearing in the other (ie, single-sided deafness);

* Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

Baha sound processors can be used with the Baha® Softband™. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the

cochlea. In 2002, the Baha® Softband™ was cleared for marketing by FDA for use in children younger than 5 years. Because this application has no implanted components, it is not addressed in this evidence review.

Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas' Baha devices:

* OBC Bone Anchored Hearing Aid System (Oticon Medical, Askim, Sweden). Cleared in November 2008.

* Ponto Bone Anchored Hearing System (Oticon Medical). Cleared in September 2012. A nextgeneration Ponto Pro device can be used with either Oticon or Baha implants.

Two partially implantable magnetic bone-conduction devices cleared by FDA through the 510(k) process are:

* Otomag® Bone Conduction Hearing System (Sophono, Boulder, CO; now Medtronic, Minneapolis, MN),

* Cochlear Baha Attract (Cochlear Americas, Centennial, CO).

The Bonebridge™ (MED-EL, Innsbruck, Austria) is another partially implantable bone-conduction implant that is considered an active transcutaneous device. It has been cleared for marketing in Europe but has not received FDA approval for use in the United States.

The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists of a behind-the-ear microphone and an in-the-mouth hearing device. In 2011, it was cleared for marketing by FDA through the 510(k) process for indications similar to the Baha. As of January 2015, Sonitus Medical is in bankruptcy.

FDA product code (for bone-anchored hearing aid): LXB. FDA product code (for implanted boneconduction hearing aid): MAH.

Rationale

This evidence review was created in December 1995 and has been updated regularly with searches of the MEDLINE database, most recently through December 7, 2015.

The evidence related to the use of implantable bone-conduction devices, also referred to as boneanchored hearing aids (BAHAs), is characterized by observational studies that report pre- and postimplant hearing outcomes for patients treated with these devices. Many of these studies combine patients with different underlying disease states and indications. No randomized controlled trials (RCTs) have compared implantable bone-conduction hearing aids to other hearing augmentation devices or sham devices. However, given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, a within-subjects comparison of hearing before and after device placement may be a reasonable study design. Following is a summary of key findings.

Overall Efficacy of BAHA Devices Systematic Reviews and Meta-Analyses

Two systematic reviews by the Health Technology Assessment Program were published in 2011 on the use of BAHAs for bilateral hearing impairment.1,2 The quality of available studies on the use of BAHAs

was weak. No studies with control groups were identified. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional boneconduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs were greater than with air-conduction (AC) hearing aids was uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but that evidence, too, was uncertain. Implant loss ranged between 6.1% and 19.4%. The authors noted that hearing-specific quality of life (QOL) improved, but overall QOL did not differ.

Observational Studies

Since publication of the systematic reviews, a number of observational studies have evaluated specific aspects of BAHA implantation or reported outcomes in specific populations. Several have suggested that newer generation BAHAs with fully digital signal processors improve hearing to a greater degree than older generation devices.3,4

In 2014, Farnoosh et al retrospectively compared BAHA placement with reconstruction of the external auditory canal for children and adolescents with congenital aural atresia or stenosis who were treated at a single institution from 1988 to 2011.5 Sixty-eight patients were included; 49 underwent external auditory canal reconstruction (EACR) and 19 received a BAHA. Groups differed significantly in terms of age, presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 patients. At short-term (<6 months postsurgery) follow-up, the BAHA group (44.3 dB) had larger hearing gains on AC than the EACR group (20.0 dB; p<0.001); similarly, the BAHA group had larger hearing gains at long-term (>1 year postsurgery) follow-up (44.5 dB vs 15.3 dB; p<0.001). QOL scores and requirements for revision surgery did not differ significantly between the groups.

In 2011, Ramakrishnan et al retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults in a single center.6 The patient population was unique in that many had craniofacial or genetic syndromes and hearing loss (22/109). Criteria for selection of the implanted device or the Softband were not described, though authors noted an uneven distribution by age, sex, and syndromic comorbidity. Primary measures were the Glasgow Benefit Inventory or Listening Situation Questionnaire (parent version) administered at least 3 months after hearing aid intervention.

Mean overall Glasgow Benefit Inventory scores were +29 (range, 11-72). Mean Listening Situation Questionnaire score was 17, which was less than a referral cutoff of 22. Based on mean scores, authors concluded that this population benefitted from bone-anchored and Softband-held conductive hearing aids. Conclusions were affected by the heterogeneous patient population, lack of preintervention measures, and lack of a controlled comparator group. Other series describing outcomes for pediatric patients treated with bone-anchored devices have reported a benefit in hearing scores, including den Besten et al (2015) in 79 children ages 17 and under.7

Older case series have reported patient-reported benefits and satisfaction after BAHA placement.8,9

Some have suggested that the BAHA improved hearing better than early bone-conducting devices and AC hearing aids10,11 and produced acceptable hearing outcomes in individuals unable to tolerate an AC hearing aid.12,13

Efficacy of Bilateral BAHA Devices in Conductive or Mixed Hearing Loss

A number of studies have demonstrated a consistent improvement in speech recognition in noise and in sound localization using bilateral devices for people with conductive (CHL) or mixed hearing loss.

Janssen et al (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL.14 The literature search included studies in all languages published between 1977 and July 2011. Studies were selected if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. Outcomes of interest were any subjective or objective audiologic measures, QOL indicators, or reports of adverse events. Eleven studies met inclusion criteria; all were observational. The studies included a total of 168 patients, 155 of whom had BAHAs and 146 of whom had bilateral devices. In most studies, comparisons between unilateral and bilateral BAHA were intrasubject. Heterogeneity of the methodologies between studies precluded metaanalysis, therefore a qualitative review was performed. Results from 3 (of 11) studies were excluded from synthesis because their patients had been included in multiple publications. Adverse events were not an outcome measure of any of the studies. In general, bilateral BAHA provided additional objective and subjective benefit compared with unilateral BAHA. For example, the improvement in tone thresholds associated with bilateral BAHA ranged from 2 to 15 dB, the improvement in speech recognition patterns ranged from 4 to 5.4 dB, and the improvement in the Word Recognition Score ranged from 1% to 8%. These results were based on a limited number of small observational studies consisting of heterogeneous patient groups that varied in age, severity of hearing loss, etiology of hearing loss, and previous amplification experience.

Examples of individual studies include the following. In 2001, Bosman et al reported on 25 patients who were using bilateral devices.15 They found that both speech recognition in noise and directional hearing improved with the second device. Priwin et al (2004) reported similar findings in 12 patients with bilateral devices.16 A 2005 consensus statement concluded that bilateral devices resulted in binaural hearing with improved directional hearing and improved speech-in-noise scores in those with bilateral CHL and symmetric bone-conduction thresholds.17 A number of other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin.15,16 Positive outcomes continue to be reported: Dun et al (2010)18 identified improvements in the Glasgow Benefit Inventory in 23 children, while Ho et al (2009)19 reported the same benefit in 93 adults.

Efficacy of BAHA Devices for Unilateral Sensorineural Hearing Loss

In 2015, Peters et al reported results from a systematic review of studies comparing BAHA devices with contralateral routing of signal (CROS) systems to hearing aids with CROS for single-sided deafness (SSD).20 Six studies met eligibility criteria, including 1 RCT and 3 prospective and 2 retrospective case series, 5 of which were considered to have moderate-to-high directness of evidence and low-to-moderate risk of bias. The 5 studies with low or moderate risk of bias included a total of 91 patients; they were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was no consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization and QOL outcomes for both hearing conditions.

Baguley et al (2006) reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss.21 None of the 4 controlled trials reviewed showed a significant improvement in auditory localization with the bone-anchored device. However, speech discrimination in noise and subjective measures improved with these devices: the BAHAs resulted in greater improvement than that obtained with the conventional AC CROS systems.

Since publication of the Peters systematic review, 1 prospective, interventional study compared patient satisfaction with transcutaneous BAHA devices to CROS hearing aids for SSD. Leterme et al assessed 24 adults with SSD, 18 of whom were evaluated with trials of both hearing aids with CROS and bone conduction Assisted hearing using the Baha Softband.22 Most (72%) patients, after completing trials of both devices, preferred the BAHA device to hearing aid with CROS. Glasgow Benefit Inventory and Abbreviated Profile of Hearing Aid Benefit (APHAB) scores did not differ significantly between devices. Sixteen of the 18 subjects elected to undergo implantation of a percutaneous BAHA device. In general, hearing improvement with the Baha Softband trial correlated with hearing improvements following device implantation.

Several centers have reported on findings from observational studies that evaluated the benefits of BAHA for patients with unilateral SSD. Most of these studies were retrospective. Studies representative of this group are described next.

Zeitler et al (2012) reported on a retrospective case series of 180 patients with SSD and residual hearing in the implanted ear who underwent unilateral or bilateral BAHA placement at a U.S. university medical center.23 Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHA varied across patients based on results from the Glasgow Hearing Aid Benefit Profile, but patients with residual hearing in the affected ear tended toward improved satisfaction with their device postoperatively.

Additional series from various countries, with sample sizes ranging from 9 to 145 patients, have reported on outcomes after implantation of BAHA device for SSD. In general, these studies have indicated improvements in patient-reported speech quality, speech perception in noise, and patient satisfaction.24-31

Efficacy of BAHA Devices in Children Younger Than Age 5 Years

The BAHA device has been investigated in children younger than 5 years in Europe. A number of reports have described experience with preschool children or children with developmental issues that might interfere with device maintenance and skin integrity. A 2-stage procedure may be used in young children. In the first stage, the fixture is placed into the bone and allowed to fully osseointegrate. After 3 to 6 months, a second procedure is performed to connect the abutment through the skin to the fixture.

The largest series in children under 5 years we identified, described by Amonoo-Kuofi et al (2015), included 24 children identified from a single center’s prospectively maintained database.32 Most patients underwent a 2-stage surgical approach. Most (52%) patients received the implant for isolated microtia or Goldenhar syndrome (16%). Following implantation, 13 (54%) patients had grade 2 or 3 local reactions assessed on the Holgers Scale (redness, moistness, and/or granulation tissue) and 7 (29%) had grade 4 local reactions on this scale (extensive soft-tissue reaction requiring removal of the abutment). QOL scores (Glasgow Children's Benefit Inventory; scoring range, -100 to 100) were obtained in 18 subjects/parents, with a finale mean score change of +40 points. Audiologic testing indicated that the average performance of the device fell within the range of normal auditory perception in noisy and quiet environments. Marsella et al (2012) reported on their center's experience in Italy with pediatric BAHA from the inception of their program in 1995 to December 2009.33 Forty-seven children (21 girls, 26 boys) were implanted; 7 of them were younger than 5 years. Functional gain was significantly better with BAHA than with conventional bone-conduction hearing aids, and there was no significant

difference in terms of functional outcome between the 7 younger patients and the rest of the cohort. Based on these findings, study authors suggested that implantation of children at an age younger than 5 years can be conducted safely and effectively in such settings. Report conclusions were limited by the small number of very young children in the study and the limited statistical power to detect a difference between younger and older children.

Davids et al (2007) at the University of Toronto provided BAHA devices to children younger than 5 years of age for auditory and speech-language development, and retrospectively compared surgical outcomes for a study group of 20 children younger than 5 years and a control group of 20 older children.34 Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group versus 4 in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at the time of writing. McDermott et al (2008) reported on the role of BAHAs in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and QOL outcomes for 15 children ages 2 to 15 years.35 All used their BAHA devices at a 14-month follow-up. No fixtures were lost; skin problems were encountered in 3 patients. All 15 patients had improved social and physical functioning, attributed to improved hearing.

Safety and Adverse Events Related to BAHA Devices

In addition to the efficacy literature on the BAHA devices, studies have assessed complications with these devices.

In 2013, Kiringoda et al reported on a meta-analysis of complications related to BAHA implants. Selected were 20 studies that evaluated complication in 2134 adult and pediatric patients who received a total of 2310 BAHA implants.36 The quality of available studies was considered poor and lacking in uniformity.

Complications related to BAHA implants were mostly minor skin reactions: The incidence of Holgers

Scale grade 2 to 4 skin reactions was 2.4% to 38.1% in all studies (grade 2 = red and moist tissue; grade 3 = granulation tissue; grade 4 = infection leading to removal of the abutment). The incidence of failed osseointegration was 0% to 18% in adult and mixed population studies and 0% to 14.3% in pediatric population studies. The incidence of revision surgery was 1.7% to 34.5% in adult and mixed population studies and 0.0% to 44.4% in pediatric population studies. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and in 0.0% to 25% in pediatric studies.

In 2012, Dun et al assessed soft tissue reactions and implant stability of 1132 percutaneous titanium implants for bone-conduction devices in a retrospective survey of 970 patients undergoing implants between September 1988 and December 2007 at a university medical center in the Netherlands.37 Study investigators also examined device usage and comparisons between different patient age groups (children, adults, elderly patients) over a 5-year follow-up period. Implant loss was 8%. In close to 96% of cases, there were no adverse soft tissue reactions. Significantly more soft tissue reactions and implant failures were observed in children than in adults and elderly patients ($p<0.05$). Implant survival rates were lower in patients with than without mental retardation ($p=0.001$).

In 2010, Hobson et al reviewed complications of 602 patients at a tertiary referral center over 24 years and compared their observed rates to those published in 16 previous studies.38 The overall observed complication rate of 23.9% (144/602) was similar to other published studies (weighted mean

complication rate, 24.9%). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of surgical revision of 12.1% (73/602) was also similar to previously published rates (weighted mean, 12.7%). Top reasons for revision surgery were identical to observed complications. In 2011, Wallberg et al reported on the status of 150 implants placed between 1977 and 1986 at a mean follow-up of 9 years.39 Implants were lost in 41 (27%) patients. Reasons for implant loss were: removal in 16 patients, osseointegration failure in 17 patients, and direct trauma in 8 patients. In the 132 patients with implant survival, BAHAs were still being used by 119 (90%) patients at the 9-year follow-up. For children, implant complications were even more frequent, as reported by Kraai et al (2011) in a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009.40 In this retrospective report, soft tissue reactions occurred in 24 (89%) patients; implant removal or surgical revision was required in 10 (37%) patients; 24 (89%) patients experienced soft tissue overgrowth and infection; and 7 (26%) patients experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 (11%) patients.

In 2014, Allis et al conducted a prospective observational cohort study with a retrospective historical control to evaluate complication rates of skin overgrowth, infection, and the need for revision surgery associated with a BAHA implant with a longer (8.5-mm) abutment.41 Twenty-one subjects were treated with the 8.5-mm abutment implant from 2011 to 2012 and were compared to 23 subjects treated with a 5.5-mm abutment implant from 2010 to 2011. Groups were generally similar at baseline, except that patients with the 8.5-mm abutment implant were older (62 years vs 48 years, p=0.012). Patients in the longer abutment group were less likely to experience infection (10% vs 43%; p=0.02), skin overgrowth (5% vs 41%; p=0.007), and need for revision (10% vs 45%; p=0.012), respectively.

Other observational cohort studies, ranging in size from 47 to 974 subjects, have reported safety and adverse effects outcomes after BAHA placement.42-45 Across these studies, implant loss ranged from 4% to 18%.

Different surgical techniques for implanting BAHA devices and specific BAHA designs have yielded better safety outcomes. In a systematic review of 30 articles on the association between surgical technique and skin complications following BAHA implantation, the dermatome technique (vs a skin graft or linear technique) was linked to more frequent skin complications.46 Fontaine et al (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011.47 Complications requiring surgical revision occurred in 20% of cases who had a skin flap implantation method (n=20) and in 38% of cases who had a full-thickness skin graft implantation method (n=21; p=0.31). Hultcrantz and Lanis (2014) reported shorter surgical times and fewer cases of numbness and peri-implant infections in 12 patients treated with a non-skin-thinning technique, compared with 24 patients treated with a flap or a dermatome implantation technique.48 In a comparison of 2 types of BAHA devices, one with a 4.5-mm diameter implant with a rounded 6-mm abutment (n=25) and one with a 3.75mm diameter implant with a conically shaped 5.5-mm abutment (n=52), Nelissen et al (2014) reported that implant survival was high for both groups over a 3-year follow-up, although the conically shaped abutment had greater stability.49 Singam et al (2014) reported results of a BAHA implantation technique without soft tissue reduction in conjunction with a longer device abutment in 30 patients.50 Twenty-five patients had no postoperative complications. Five subjects developed postoperative skin reactions, of whom 3 required soft tissue reduction.

Partially Implantable Magnetic BAHA Devices

A smaller body of literature addresses outcomes associated with transcutaneous, partially implantable bone-anchored devices that magnetically couple the sound processor with the implant. Similar to the literature available for percutaneous bone-anchored devices, most studies use a within-subjects comparison of hearing thresholds with and without the device. The indications for partially implantable systems are the same as those for transcutaneous bone-anchored devices.

Prospective Trials

Two prospective trials evaluating different transcutaneous systems were identified. Both trials were small (27 and 15 individuals, respectively), but both demonstrated improvements in hearing outcomes.

Briggs et al (2015) reported on a prospective interventional evaluation of the percutaneous, partially implantable Baha Attract System among 27 adults with a CHL or mild mixed hearing loss in the ear to be implanted.51 The choice of sound processor was based on patient preference and hearing tests with various sound processors in conjunction with Baha Softband prior to device implantation. All 27 patients enrolled received an implant. Sound processor fitting occurred 4 weeks postimplantation in all but 1 patient. At 9-month follow-up, pure-tone audiometry (means of 500, 1000, 2000, and 4000 Hz) was significantly improved with the implant and sound processor compared with unaided hearing (18.4-dB hearing loss, SD=6.9 dB; p<0.001). Patients generally showed improvements in speech recognition in noise, although comparing results across test sites was difficult due to different languages and methodologies used for testing speech recognition at each site. Compared with the preoperative unaided state, scores on the APHAB overall score (p=0.038) and reverberation (p=0.016) and background noise (p=0.035) subscales.

Denoyelle et al (2015) reported on a prospective trial of the Sophono device in children ages 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure CHL.52 The study included a within-subject comparison of hearing results with the Sophono devices to those obtained with the Baha Softband preoperatively. All 15 patients enrolled were implanted (median age, 97 months). At 6-month follow-up, mean aided AC pure-tone audiometry was 33.49 (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 (mean gain, 33.47 dB). The difference in AC PTA between the Baha Softband and the Sophono device was 0.6 dB (confidence interval upper limit, 4.42 dB), which met the study's prespecified noninferiority margin. Adverse effects were generally mild, including skin erythema in 2 patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in 3 patients.

Nonrandomized Comparative Studies

A limited amount of data is available comparing transcutaneous to percutaneous bone-anchored conduction devices. In 2013, Hol et al compared percutaneous BAHA implants to partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients (age range, 5-12 years), who had congenital unilateral CHL.53 Sound-field thresholds, speech recognition threshold, and speech comprehension at 65 dB were somewhat better in patients with the BAHA implant (n=6) than in those with the partially implantable hearing device (n=6). Using a skull simulator, output was 10 to 15 dB lower with the partially implantable device than with the BAHA device.

Iseri et al (2015) described a retrospective, single-center study from Turkey comparing 21 patients treated with a transcutaneous, fully implantable BAHA to 16 patients treated with a percutaneous

device (the Baha Attract).54 Groups were generally similar at baseline, with most individuals undergoing BAHA placement for chronic otitis media. Operating time was longer in patients treated with the transcutaneous partially implantable devices (46 minutes vs 26 minutes, p<0.05). Three patients treated with percutaneous devices had Holgers Scale grade 2 skin reactions and 2 had stopped using their devices for reasons unrelated to skin reactions. Mean thresholds for frequencies 0.5 to 4.0 kHz were 64.4 dB without the BAHA and 31.6 dB with the BAHA in the percutaneous device group, and 58.3 dB without the BAHA and 27.2 dB with the BAHA in the transcutaneous device group. Frequency-specific threshold hearing gains did not differ significantly between groups. Mean hearing gain measured by speech reception threshold was statistically significantly smaller in the percutaneous group (24 dB vs 36.7 dB, p=0.02).

Observational Studies

A moderately sized body of observational studies¾most at a single center and with fewer than 10 patients¾has reported outcomes for transcutaneous, partially implantable hearing systems. These studies are briefly described here to provide an overview of the functional gain and complications seen with the transcutaneously coupled devices.

In an early (2011) study, Seigert reported on the use of a transcutaneous, partially implantable boneconduction hearing system (Otomag).55 Among 12 patients who received the system, there were average hearing gains of 31.2 dB in free-field pure-tone audiogram. The free-field suprathreshold speech perception at 65 dB increased from 12.9% preimplantation to 72.1% postimplantation.

Powell et al (2015) reported outcomes from a retrospective study that included 6 patients treated with the Otomag Sophono device and 6 treated with the BAHA Attract device.56 Ten subjects were identified as the primary author's patients and the remaining were identified through an Australian national hearing database. In the BAHA Attract group, mean AC thresholds across 4 frequencies (0.5, 1, 2, and 4 kHz) improved from 60.8 dB in the unaided state to 30.6 dB in the aided state. In the Sophono group, the mean 4-frequency AC thresholds improved from 57.8 dB in the unaided state to 29.8 dB in the aided state. Speech discrimination in noise scores did not differ significantly between devices.

O'Niel et al (2014) reported outcomes for 10 pediatric patients with CHL treated with the Otomag Sophono device at a single center.57 Fourteen ears were implanted with no surgical complications. The skin complication rate was 35.7%, including skin breakdown (n=2) and pain and erythema (n=5); negative outcomes resulted in 5 (36%) of 14 ears having sufficient difficulties to discontinue device use for a period. Mean aided PTA was a 20.2-dB hearing level, with a mean functional gain of a 39.9-dB hearing level. Patients without skin complications consistently used their devices (average daily use, 8-10 hours).

Centric et al (2014) also reported outcomes for 5 pediatric patients treated with the Otomag Sophono device at a single center.58 Etiologies of hearing loss were heterogeneous and included bilateral moderate or severe CHL and unilateral sensorineural hearing loss. Average improvement in PTA was a 32-dB hearing level, and the average improvement in speech response threshold was a 28-dB hearing level. All patients were responding in the normal-to-mild hearing loss range in the implanted ear after device activation. In a follow-up study from the same institution, Baker et al reported pooled outcomes for the first 11 patients treated with the Otomag Sophono and the first 6 patients treated with the Baha Attract.59 Pre- and postimplant audiometric data were available for 11 ears in the Sophono group and 5 in the Baha Attract group. Average improvement over all frequencies ranged from a 24- to 43-dB hearing level in the Sophono group and from a 32- to 45-dB hearing level in the Baha Attract group. Average improvement in PTA was a 38-dB hearing level in the Sophono group and a 41-dB hearing level in the Baha Attract group.

Other single-center observational series have described clinical experience with transcutaneous partially implantable BAHA devices. Marsella et al (2014) reported outcomes for 6 pediatric patients treated with the Otomag Sophono device for CHL or mixed hearing loss.60 Median improvement in PTA was 33-dB hearing loss and median free-field PTA (0.5-3 kHz) with the device was 32.5-dB hearing loss. Carr et (2015) reported outcomes for 10 patients treated with the Baha Attract device, most commonly for chronic suppurative otitis media (n=3) and SSD (n=3).61 Patients did not show significant improvement in word discrimination score. Magliulo et al (2015) reported outcomes for 10 patients treated with the Otomag Sophono device after subtotal petrosectomy for recurrent chronic middle ear disease, a procedure associated with a CHL of 50 to 60 dB.62 Postsurgery with the Sophono device, there was an average acoustic improvement in AC of 29.7 dB, which was significantly better than the improvement seen with traditional AC hearing aids (18.2 dB).

In addition to studies of partially implantable bone-conduction devices currently approved by the Food and Drug Administration, a number of case series identified evaluated the Bonebridge implant, which is not currently cleared for marketing in the United States. Case series with at least 5 patients are summarized in Table 1.

Table 1: Case Series Evaluating the Bonebridge Implant

Table 1: Case Series Evaluating the Bonebridge Implant

Study Outcomes	N	Patient Population	Main Hearing Results	Safety
Rahne et al (2015)[63]	11	• SSD (n=6; 1 sensorineural, 3 mixed, 2 conductive) • Bilateral CHL (n=2) • Bilateral mixed hearing loss or mixed/sensorineural (n=3)	• Aided sound-field threshold improvement: 33.4 dB • WRS improved from mean of 10% unaided to 87.5% aided	1 case of chronic fibrosing mastoiditis requiring mastoidectomy and antrotomy; no other complications
Laske et al (2015)[64]	9	? Adults with SSD and normal contralateral hearing	? Speech discrimination signal-to-noise improvement for aided vs unaided condition, sound presented to aided ear: 1.7 dB	Not reported
Study	**N**	**Patient Population**	**Main Hearing Results**	**Safety Outcomes**
			? Positive improvements on quality-oflife questions	
Riss et al (2014)[65]	24	• Combined hearing loss (n=9) • EAC atresia (n=12) • SSD (n=3)	• Average functional gain: 28.8 dB • Monosyllabic word scores at 65-dB sound pressure increased from 4.653.7 percentage points	Not reported
Manrique (p=0.01) et al discrimination (2014)[66] (p=0.016)	5	? Mixed hearing loss (n=4) No perioperative ? SSD (n=1) complications reported	? PTA improvement: 35.62 dB ? Disyllabic word improvement: 20%	
Ihler et al (2014)[67]	6	• Mixed hearing loss (n=4) • CHL (n=2)	• PTA functional gain (average, 0.5-4.0 kHz): 34.5 dB • Speech discrimination at 65 dB improvement: o In quiet: 63.3 percentage points o In noise: 37.5 percentage points	Prolonged wound healing in 1 case
Desmet et reported	44	? All unilaterally deaf adults	? Statistically significant improvement	Not

al (2014)[68]			on APHAB and SHHIA	
Iseri et al (2014)[69]	12	• CHL (n=9) • “Primarily conductive hearing loss” (n=3)	? Speech reception threshold increase: 19 dB	Postoperative hematoma requiring aspiration in 1 case

APHAB: Abbreviated Profile of Hearing Aid Benefit; CHL: conductive hearing loss; EAC: external auditory canal; PTA: pure-tone average; SHHIA: Short Hearing Handicap Inventory for Adults; SSD: single-sided deafness; WRS: word recognition score.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01264510	The Evaluation of the Effectiveness of Bone-anchored Hearing Aids (Baha) in Patients With Conductive or Mixed Hearing Loss, or Unilateral Deafness	150	Aug 2015 (ongoing)
NCT02022085[a]	Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear Baha Attract System)	52	Mar 2017
NCT01858246	A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid With Bonebridge	60	Dec 2017
Unpublished			
NCT01715948	Comparison of BAHA and CROS Hearing Aid in Single-Sided Deafness	9	Oct 2013 (completed)
NCT01822119[a]	Clinical Performance of a Transcutaneous Bone Conduction Hearing Solution (Baha® Attract System). A Multicentre, Open, Prospective Clinical Investigation. 3 Months Investigation With a 6 Months Follow-up	27	Feb 2014 (completed)
NCT02092610[a]	Long Term Stability, Survival and Tolerability of a (Novel) Baha® Implant System	77	Mar 2015 (completed)

NCT: national clinical trial. a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing device with a percutaneous abutment or a partially implantable bone-anchored hearing device with transcutaneous coupling to the sound processor, the evidence includes observational studies that report pre-post differences in hearing parameters after treatment with bone-anchored hearing aids (BAHAs). Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially implantable bone-anchored devices have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct comparisons other than within-individual comparisons with external hearing aids were identified, but, for individuals unable to

wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable bone-anchored hearing device with contralateral routing of signal, the evidence includes 1 randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 145 patients, generally have reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone-anchored devices to hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
The American Academy of Otolaryngology: Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery considers bone conduction hearing devices (BCHD) as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select patients with single-sided deafness. BCHD include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States.

CODES

69710	69711	69714	69716	69719	69726
69727	69728	69729	69730	L8690	L8691
L8692	L8693				

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