Clinical UM Guideline

Subject:	Bone-Anchored and Bone Conduction Hearing Aids		
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Description

This document addresses the use of implantable bone-anchored hearing aids, transcutaneously worn, non-surgical application of a bone-anchored hearing aid using a headband or Softband, partially-implantable magnetic bone conduction hearing aids, and an intraoral bone conduction hearing aid. These devices are proposed *as an alternative* to a conventional air conduction hearing aid in the treatment of moderate-to-severe hearing loss or to improve speech recognition in individuals with unilateral sensorineural hearing loss (also referred to as single-sided deafness).

Note: Please see the following documents related to implants and hearing aids for the treatment of hearing loss:
- CG-SURG-81 Cochlear Implants and Auditory Brainstem Implants
- SURG.00084 Implantable Middle Ear Hearing Aids

Note: Benefit language supersedes this document. Hearing aids are not a covered benefit under all member contracts/certificates. Please see the text in the footnote of this document regarding Federal and State mandates and contract language, as these requirements or documents may specifically address the topic of hearing aids.

Clinical Indications

Medically Necessary:

A fully- or partially-implantable bone conduction (bone-anchored) hearing aid is considered **medically necessary** for individuals who meet the criteria specified in either (A) **or** (B), below.
A fully- or partially-implantable bone conduction (bone-anchored) hearing aid is considered **medically necessary** as an alternative to an air conduction hearing aid for individuals 5 years of age or older who meet **both** audiologic and medical condition criteria as follows:

A. Audiologic criteria (must meet either a or b):
   1. Bilateral implant: Moderate to severe bilateral symmetric bone conductive or mixed (conductive and sensorineural) hearing loss. Symmetric bone conduction threshold is defined as less than:
      a. 10 decibels average difference between ears (measured at 0.5, 1, 2, and 4 kilohertz), or less than a 15 decibel difference at individual frequencies (BAHA® Divino®, Ponto™ Plus, Ponto Plus Power; Sophono® Alpha System); **or**

   b. 10 decibels average difference between ears (measured at 0.5, 1, 2, and 3 kilohertz) (4 kilohertz for OBC and Ponto Pro), or less than a 15 decibel difference at individual frequencies (BAHA Attract, BAHA Cordelle II; BAHA BP100; BAHA 4; BAHA 5 Power; BAHA Intenso™); **or**
2. Unilateral implant: Conductive or mixed (conductive and sensorineural) hearing loss with pure tone average bone conduction threshold (measured at 0.5, 1, 2, and 3 kilohertz) of less than or equal to 45 decibels (BAHA Attract, BAHA Divino, BAHA BP100, BAHA 4, OBC, Ponto Plus, Sophono Alpha System), 55 decibels (BAHA 5 Power, BAHA Intenso, Ponto Plus Power), or 65 decibels (BAHA Cordelle II); **and**

B. Medical condition criteria (must meet **at least one):**
1. Congenital or surgically induced ear malformations of the external or middle ear canal (for example, atresia); **or**
2. Severe chronic external otitis or otitis media; **or**
3. Tumors of the external ear canal or tympanic cavity; **or**
4. Dermatitis of the external ear canal, including reactions from ear molds used in air conduction hearing aids; **or**
5. Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid.

A fully- or partially-implantable bone conduction (bone-anchored) hearing aid is considered **medically necessary** to improve speech recognition in individuals 5 years of age and older with unilateral sensorineural hearing loss (that is, single sided deafness) and normal hearing in the other ear. Normal hearing in the non-affected ear is defined as pure tone average air conduction threshold less than or equal to 20 decibels at 0.5, 1, 2, and 3 kilohertz.

A transcutaneously worn, non-surgical application of a fully- or partially-implantable bone conduction (bone-anchored) hearing aid utilizing a headband or Softband is considered **medically necessary** as an alternative to a fully- or partially-implantable bone conduction (bone-anchored) hearing aid **or** air conduction hearing aid in individuals who meet the criteria specified in either (A) **or** (B), above, except for the age limitation of 5 years of age or older which does not apply for a transcutaneously worn bone conduction (bone-anchored) hearing aid.

Replacement parts or upgrades to existing bone conduction (bone-anchored) hearing aid components (for example, batteries, processor, headband or Softband) are considered **medically necessary** for individuals whose response to existing components is inadequate to the point of interfering with activities of daily living **or** when components are no longer functional.

Not Medically Necessary:

Replacement parts or upgrades to existing bone conduction (bone-anchored) hearing aid components (for example, batteries, processor, headband or Softband) are considered **not medically necessary** when the criteria specified in (A) **or** (B) **or** (C) above are not met **or** when requested for convenience **or** to upgrade to newer technology when the current components remain functional.

A fully- or partially-implantable bone-anchored hearing aid or a transcutaneously worn bone conduction (bone-anchored) hearing aid utilizing a headband or Softband is considered **not medically necessary** for all other indications when the above medically necessary criteria are not met, including, but not limited to, use in individuals with bilateral sensorineural hearing loss.

An intraoral bone conduction hearing aid is considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Fully- or partially-implantable or transcutaneously worn bone conduction (bone-anchored) hearing aids:

CPT

69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment of external speech processor cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment of external speech processor cochlear stimulator; with mastoidectomy

HCPCS

L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor; used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device, abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

ICD-10 Procedure

09HD04Z-09HD44Z	Insertion of bone conduction hearing device into right inner ear [by approach; includes codes 09HD04Z, 09HD34Z, 09HD44Z]
09HE04Z-09HE44Z	Insertion of bone conduction hearing device into left inner ear [by approach; includes codes 09HE04Z, 09HE34Z, 09HE44Z]
09HD0SZ-09HD4SZ	Insertion of hearing device into right inner ear [by approach; includes codes 09HD0SZ, 09HD3SZ, 09HD4SZ]
09HE0SZ-09HE4SZ	Insertion of hearing device into left inner ear [by approach; includes codes 09HE0SZ, 09HE3SZ, 09HE4SZ]
0NH50SZ-0NH54SZ	Insertion of hearing device into right temporal bone [by approach; includes codes 0NH50SZ, 0NH53SZ, 0NH54SZ]
0NH60SZ-0NH64SZ	Insertion of hearing device into left temporal bone [by approach; includes codes 0NH60SZ, 0NH63SZ, 0NH64SZ]

ICD-10 Diagnosis

H60.311-H60.329	Diffuse/hemorrhagic otitis externa
H60.391-H60.399	Other infective otitis externa
H60.40-H60.43	Cholesteatoma of external ear
H60.501-H60.599	Acute noninfective otitis externa
H60.60-H60.63	Unspecified chronic otitis externa
H60.8X1-H60.8X9	Other otitis externa
H60.90-H60.93	Unspecified otitis externa
H61.301-H61.399	Acquired stenosis of external ear canal
H65.20-H65.23	Chronic serous otitis media
H65.30-H65.33	Chronic mucoid otitis media
H65.411-H65.499	Other chronic nonsuppurative otitis media
H65.90-H65.93	Unspecified nonsuppurative otitis media
H66.10-H66.23	Chronic tubotympanic/atticoantral suppurative otitis media
H66.3X1-H66.3X9	Other chronic suppurative otitis media
H66.40-H66.43	Suppurative otitis media, unspecified
H66.90-H66.93	Otitis media, unspecified
H71.00-H71.93	Cholesteatoma of middle ear
H72.00-H72.93	Perforation of tympanic membrane
H74.01- H74.93	Other disorders of middle ear mastoid
H90.0-H90.8	Conductive and sensorineural hearing loss
H90.A11-H90.A32	Conductive and sensorineural hearing loss with restricted hearing on the contralateral side
H91.01-H91.09	Ototoxic hearing loss
H91.10-H91.13	Presbycusis
H91.20-H91.23	Sudden idiopathic hearing loss
H91.8X1-H91.8X9	Other specified hearing loss
H91.90-H91.93	Unspecified hearing loss

Q16.0-Q16.9	Congenital malformations of ear causing impairment of hearing

Intraoral bone conduction hearing aids:

HCPCS	
V5298	Hearing aid, not otherwise classified [when specified as an intraoral bone conduction hearing aid] Note: intraoral bone conduction hearing aids are considered not medically necessary.
ICD-10 Diagnosis	
	All diagnoses

Discussion/General Information

Hearing loss can be classified as conductive, sensorineural, or mixed hearing loss. Conductive hearing loss involves the external and middle ear and is due to mechanical or physical blockage of sound as a result of excessive cerumen, a punctured eardrum, birth/congenital defects such as congenital aural atresia, ear infections or heredity. In sensorineural or "nerve" hearing loss, the auditory cranial nerve or part of the bone of the inner ear is damaged due to birth-related condition, long-term viral or bacterial infections, trauma, exposure to loud noises, the use of certain drugs, fluid buildup in the middle ear, or a benign tumor in the inner ear (acoustic neuroma). Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss. Normal hearing range or no impairment of hearing occurs at 0 to 20 dB HL (decibel hearing level) threshold. Normal speech and conversation occurs at 40-60 dB within a frequency range of 500-3000 Hertz (Hz).

Conventional external hearing aids can be generally categorized as air conduction (AC) hearing aids or bone conduction hearing aids. AC hearing aids are designed for placement in several locations including fitted behind the ear or on the body (both require the use of an ear mold), in the outer ear, ear canal or almost entirely in the canal, or as a contralateral routing of offside signals (CROS) hearing aid where the microphone is located on the impaired hearing side and transmits a signal wirelessly over a radio frequency to the normal hearing ear via an ear mold. Use of ear molds may be problematic in individuals with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. In these individuals, bone conduction hearing aids may be an alternative. External bone conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear. The external aids must be closely applied to the temporal bone, with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of eyeglasses. These hearing aids may be associated with either pressure headaches or soreness.

The U.S. Food and Drug Administration (FDA) classifies bone-anchored hearing aids and bone conduction hearing aids as Class II devices: Hearing Aid, Bone Conduction with a Product Code of LXB and MAH. The FDA indicates that these hearing aids are substantially equivalent technology to AC hearing aids with digital sound processing. In December 2005, the Centers for Medicare and Medicaid Services (CMS) updated their benefit manual, clarifying coverage for specific hearing aid devices. CMS now considers bone-anchored hearing aids, referred to as osseointegrated implants, as prosthetic devices.

Implantable Bone-Anchored Hearing Aid Systems

The BAHA® System

The BAHA (Cochlear Americas, Centennial, CO and Cochlear Limited Bone Anchored Solutions AB, Molnlycke, Sweden) is a bone-anchored, bone conduction hearing aid system cleared for use in children ages 5 years and older and in adults for the following indications:

- Individuals who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Individuals with bilaterally symmetric conductive or mixed hearing loss (may be implanted bilaterally);
- Individuals with sensorineural deafness in one ear and normal hearing in the other (single sided deafness);
- Individuals who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS hearing aid.

The BAHA processor is coupled to a titanium fixture (screw) protruding through the skin located in the upper mastoid region on the temporal bone where it has fused with the bone in a process called "osseointegration." The BAHA system bypasses the middle ear altogether, sending sound around the area, naturally stimulating the cochlea through bone conduction. The difference between the standard bone conduction hearing aid and the bone-anchored hearing aid is direct stimulation of the bone instead of stimulation through the skin.

Numerous BAHA sound processors have received FDA 510(k) clearance for use with the BAHA auditory osseointegrated implant system (K021837; K011438; K984162):

- BAHA Cordelle II (K080363)
- BAHA Divino (K042017)
- BAHA Intenso (K081606) (digital signal processing)
- BAHA BP100 (K090720)
- BAHA 4 (K132278) (upgrades from the BP100)
- BAHA 5 Power Sound Processor (K142907; K161123) (upgrade from the BP100).

The BAHA Divino and BP100 are intended for use in individuals with a pure tone average (PTA) bone conduction threshold of 45 dB or better (FDA, 2004; FDA, 2009), the BAHA Intenso for individuals with PTA bone conduction threshold of 55 dB or better (FDA, 2008), while the Cordelle II is indicated for more severe hearing loss, with a PTA bone threshold of 65 dB or better (FDA, 2008). In May 2011, the FDA cleared a modified sound processor, the BAHA BP110 Power (K110996) a substantially equivalent upgrade to the predicate BAHA Intenso. The BAHA BP110 Power improvements in features and amplified sound processing are the same as those used in the BP100 sound processor, cleared for marketing for a less hearing-impaired population. The BAHA 4 and BAHA 5 Power Sound Processor have the same intended use as the predicate device (BAHA BP110).

Implantable or bone-anchored conduction hearing aids are clinically effective, and are recommended for individuals who are unable to use conventional AC hearing aids or have undergone ossicular replacement surgery because of chronic otitis media, congenital malformation of the middle/external ear or other acquired malfunctions of the middle or external ear canals which preclude wearing of a conventional AC hearing aid. Consideration should be given to the individual's psychological, physical, emotional and developmental capabilities for maintaining good hygiene, as the skin is adjacent to the implant abutment. For children and individuals with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation.

BAHA for Moderate to Severe Conductive or Mixed Hearing Loss

The peer-reviewed medical literature contains numerous prospective and retrospective clinical trials that evaluate the safety and efficacy of the BAHA for moderate to severe conductive or mixed hearing loss. Participants in these studies usually received unilateral hearing aids. The early studies of the BAHA (Granstrom, 1997 and 2001; Hakansson, 1990 and 1994) were reported by the BAHA implant programs at the Sahlgrenska Hospital at the University of Goteborg, Sweden (where the BAHA was originally developed); the Nijmegen University Hospital, The Netherlands (Snik, 1995 and 2001; Stenfelt, 2000; van der Pouw, 1998 and 1999); and the Birmingham Osseointegration Program (The Queen Elizabeth, Selly Oak, and Birmingham Children's Hospitals, Birmingham, UK) (Dutt, 2002a; Dutt 2002b; Dutt 2002c; Dutt 2002d; McDermott, 2002a; McDermott, 2002b; McLarnon, 2004). Results from each of the centers are reported in multiple articles with overlapping study populations. The authors suggest that the BAHA can provide significant improvements in functional gain, speech perception, and hearing ability in various listening situations. User satisfaction was also reported in self-assessed outcomes measurements including satisfaction with fit and comfort and with the quality and clarity of the sound. Follow-up in these studies varied widely, ranging from a few weeks or months to more than 20 years.

Most of the early studies from Canada and the United States describing the use of the BAHA were small, retrospective trials where investigators reported positive audiologic outcomes, few complications and high levels of user satisfaction in those who could not tolerate or were not suitable candidates for conventional AC hearing aids (Lustig, 2001; Niparko, 2003; Wazen, 1998). Additional case series and reviews have been published that report improved hearing outcomes and functioning in individuals with use of the BAHA. The evidence suggests that the majority of users prefer the BAHA over conventional hearing aids, reporting improved speech recognition scores and sound quality (Christensen, 2010; House, 2010; Ricci, 2011; de Wolf, 2011; Zeitler, 2012). The BAHA is also associated with improvements in language development in children 5 years of age and older. In a retrospective, treatment outcome study, Lloyd and colleagues (2007) reported that children (n=85 ears, mean age at primary implantation 8.7 years) had "significant additional benefits in terms of speech recognition, sound quality, ease of use, and overall quality of life," despite experiencing adverse outcomes (trauma and failure of osseointegration were the most common reasons for failure) when implanted with the BAHA.

Kiringoda and colleagues (2013) performed a meta-analysis of 20 studies evaluating complications related to 2310 BAHA implants in 2134 adults and children. The quality of available studies was considered "poor" due to retrospective designs, lack of uniformity in methodology, and wide variation in sample sizes and duration of

follow-up. Complications related to BAHA implants were mostly minor Holgers Grade 2 to 4 skin reactions occurring from 2.4% to 38.1% in all studies. Zero to 18% of implants failed osseointegration in adult and mixed population studies, while 0% to 14.3% failed osseointegration in pediatric population studies. Adult and mixed population studies reported revision surgery was required in 1.7% to 34.5% of cases, while pediatric population studies reported revision surgery was required in 0.0% to 44.4% of cases. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies. The authors concluded the relative lack of large prospective studies limited a more thorough characterization of the complications and limitations associated with osseointegrated hearing aids.

Bilateral BAHA for Conductive Hearing Loss

The implantation of bilateral BAHA has been evaluated in several small studies. Dutt and colleagues (2002b) reported user satisfaction and speech intelligibility in 15 individuals with unilateral BAHA subsequently fitted with a bilateral BAHA. The benefits of bilateral amplification were compared to unilateral amplification in 11 of these individuals who used their second BAHA for 12 months or longer. Following a subjective analysis in the form of comprehensive questionnaires, objective testing was undertaken to assess specific issues such as 'speech recognition in quiet,' 'speech recognition in noise' and a modified 'speech-in-simulated-party-noise' (Plomp) test. 'Speech in quiet' testing revealed a 100% score with both unilateral and bilateral BAHA. With 'speech in noise,' all 11 individuals were reported as scoring “marginally better” with bilateral aids compared to best unilateral responses. A prospective study of 12 individuals reported by Priwin and colleagues (2004) demonstrated a significant improvement in sound localization with bilateral BAHA fitting. Furthermore, the authors reported an improvement in speech reception threshold in both quiet and in noise, concluding that the outcomes with bilateral BAHA were better than with unilaterally fitted BAHA. Bosman and colleagues (2003) evaluated bilateral fittings of the BAHA in 25 individuals with at least 3 months experience with using two BAHAs. The authors reported a significant improvement in directional hearing and speech reception threshold for sentences in quiet ($p<0.01$) for the bilateral fittings compared to the unilateral fittings. Speech recognition in noise was also reported as significantly improved with a second BAHA.

Priwin and colleagues (2007) evaluated whether fitting of bilateral BAHA in children with conductive bilateral hearing loss provided additional hearing benefits. In this prospective case series, 22 children (15 controls) were studied with either conductive unaided or with unilateral hearing aid or conductive bilateral hearing loss (with unilateral or bilateral BAHA). Baseline audiometry, tone thresholds in a sound field, speech recognition in noise and sound localization were tested with and without unilateral and bilateral hearing aids. The authors reported an additional BAHA in the children with bilateral hearing loss resulted in a tendency to have improved hearing in terms of better sound localization and speech recognition in noise.

The BAHA has been reported as successfully used in children younger than 5 years of age in Europe and the United Kingdom. However, a 1999 update of the FDA notification lists age younger than 5 years as a contraindication to use of the BAHA. A number of reports describe experience with preschool children or children with developmental issues that might interfere with maintenance of the implant and skin integrity. A two-stage procedure is used in young children with the fixture placed into the bone at the first stage and, after 3 to 6 months to allow for

osseointegration, a second procedure to connect the abutment through the skin to the fixture. Davids and colleagues (2007) retrospectively compared auditory and speech-language development in 20 children 5 years of age and younger fitted with the BAHA to a control group of older children (n=20). Children with cortical bone thickness > 4 millimeters underwent a single-stage procedure. The interstage interval for children having two-stage procedures was significantly longer in the study group to allow implantation in younger children without increasing surgical or postoperative morbidity. Traumatic fractures occurred more frequently in older children (control group) compared to younger children (five vs. two fractures, respectively). Three younger children required skin site revision. McDermott and colleagues (2008) reported on the role of the BAHA in 15 children (ages 2 to 15 years) with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality of life outcomes. All of the children were using their BAHA after follow-up of 14 months. No fixtures were lost; skin problems were encountered in 3 children. All 15 children were reported as having improved social and physical functioning as a result of improved hearing.

The Health Technology Assessment Program (Colquitt, 2011) published a systematic review of 12 studies on the use of BAHAs for bilateral hearing impairment. No studies with control groups were identified for the review. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional bone conduction hearing aids or unaided hearing. Bilateral use of BAHAs improved hearing outcomes in some individuals over unilateral use, but the evidence was uncertain. Implant loss was noted to be between 6.1% and 19.4%. Improvements in hearing-specific quality of life with BAHAs were found by a hearing-specific instrument, but not general quality of life measures. Overall, adverse events data was limited and the quality of the studies was low. The authors concluded, however, that based on the available evidence, BAHAs appear to be a reasonable treatment option for individuals with bilateral conductive or mixed nearing loss.

Janssen and colleagues (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss. Studies were included if subjects of any age had permanent bilateral conductive hearing loss and bilateral implanted BAHAs. Outcome measures included any subjective or objective audiologic measures, quality of life indicators, or reports of adverse events. Eleven observational studies met the inclusion criteria. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Subjects ranged in age from 5 to 83 years of age. Heterogeneity of the methodologies between studies precluded meta-analysis; therefore, the authors performed a qualitative review. Three of the 11 studies were excluded from the qualitative review because some subjects were included in multiple publications. Adverse events were not an outcome measure of any of the included studies. In general, bilateral BAHA was observed to provide additional objective and subjective benefit compared to unilateral BAHA in measures of improvement in tone thresholds associated with bilateral BAHA (range, 2 dB to 15 dB), improvement in speech recognition patterns (range, 4 dB to 5.4 dB), and improvement in word recognition scores (range, 1% to 8%). These results, however, are based on a limited number of small observational studies consisting of heterogeneous study groups that varied in age, severity of hearing loss, etiology of hearing loss, and previous amplification experience.

Farnoosh and colleagues (2014) 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. A total of 68 children and adolescents were included, 49 who underwent external

auditory canal reconstruction (EACR) and 19 who received a unilateral or bilateral BAHA. Groups differed significantly in terms of age, presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 participants. At short-term (< 6 months postsurgery) follow-up, the BAHA group had larger hearing gains on AC than the EACR group (44.3 dB vs. 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). Quality of life scores and requirements for revision surgery did not differ significantly between the groups.

Amonoo-Kuefi and colleagues (2015) reported outcomes from a single-center, prospectively maintained New Zealand database of 24 children (26 ears/26 implants) younger than 5 years of age implanted with a BAHA via a two-stage surgical approach. Most children (52%) were implanted for isolated microtia or Goldenhaar syndrome (16%). A total of 20 children experienced post-implant Holgers Scale skin reactions: 13 children (54%, 14 implants) had grade 2 or grade 3 local reactions (that is, redness, moistness, and/or granulation tissue) and 7 children (29%, 8 implants) had grade 4 local reactions (extensive soft-tissue reactions), the latter group requiring removal of the abutment. Quality of life scores were reported by 18 caregivers using the Glasgow Children's Benefit Inventory (GCBI) (scoring range, -100 to 100), with a final mean score change of + 40 points. The average performance of the BAHA fell within the range of normal auditory perception in noisy and quiet environments.

Different surgical techniques for implanting BAHAs and specific BAHA designs have yielded improved safety outcomes across all age groups. Safety and adverse effects outcomes after BAHA placement are reported in observational cohort studies ranging in size from 47 to 974 participants (Calvo Bodnia, 2014; den Besten 2015; Larsson, 2015; Nelissen, 2014; Rebol, 2015). Across these studies, implant loss ranged from 4% to 18%.

BAHA for Unilateral Sensorineural Hearing Loss

The BAHA system was cleared by the FDA in 2002 for use in individuals with unilateral sensorineural hearing loss. The BAHA system is intended to improve speech recognition in these individuals with single sided deafness and normal hearing in the other ear. Baguley and colleagues (2006) reviewed the evidence for use of a BAHA in adults with acquired unilateral sensorineural hearing loss. None of the four controlled trials in this meta-analysis reported a significant improvement in auditory localization with the BAHA (Bosman, 2003; Hol, 2004; Niparko, 2003; Wazen, 2003). However, speech discrimination in noise and subjective measures improved with these aids; for these parameters, use of the BAHA resulted in greater improvement than that obtained with the CROS systems. Baguley and colleagues (2006) noted a number of limitations in these studies including bias in terms of participant selection (two studies), all four studies were underpowered, and double reporting of study participant outcomes.

Additional case series with sample sizes ranging from 9 to 145 participants have reported outcomes after BAHA implantation for unilateral sensorineural hearing loss (Lin, 2016; Morini, 2015, Pai, 2012). Overall, these studies report improvements in user-reported speech quality, speech perception in noise, and satisfaction with the device.

To date, the BAHA system has not received FDA 510(k) clearance for use in individuals with bilateral sensorineural hearing loss.

Transcutaneously Worn, Non-Surgical Application of an Implantable BAHA with Headband or Softband

The Softband (or headband) for BAHA received FDA 510(k) clearance in October 2000 as substantially equivalent to devices already on the market. The Softband is a transcutaneously worn, non-surgical (without osseointegration) application of the hearing aid part of a bone-anchored hearing aid, intended for use in individuals who meet criteria for moderate to severe mixed bone conductive hearing loss or single sided deafness. The BAHA with Softband has been suggested as a temporary solution for use in younger children until the strength and thickness of the bone of the skull behind the ear allows for surgical implantation of the titanium abutment. The Softband consists of an elastic band with a plastic disc-like snap connector sewn into the band. A BAHA sound process is attached to the plastic connector and adjusted to the size of the individual's head, secured with a Velcro® fastener (Velcro USA Inc., Manchester, NH). The sound processor is held against the skin behind the ear, or at another bony location of the skull, through pressure from the band. In this application there is no implantation surgery of an abutment into the skull. The Softband functions in the same manner as a conventional bone conduction hearing aid, with the amplified vibrational sounds transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The signal is weakened as it passes through the skin (attenuation). The manufacturer of the BAHA system cautions against use of the Softband during the titanium implant/fixture healing process. The sound processor must not be placed on top of the abutment/implant as it may jeopardize osseointegration. In addition, the Softband contains natural rubber latex that may cause an allergic reaction in some individuals.

In May 2010, the Otomag Bone Conduction Hearing System (Sophono, Inc., Boulder, CO; now owned by Medtronic, Minneapolis, MN) received FDA 510(k) clearance (K100193) as a bone conduction hearing aid. The FDA determined the system was substantially equivalent to predicate devices that use a headband or Softband such as the Oticon Medical Ponto Pro Bone Anchored Sound Processor (K090996) and the BAHA BP100 Sound Processor (K090720). The Otomag System includes the Otomag Alpha 1 (S) Sound Processor (K102199) which is attached magnetically to a headband or Softband and holds the sound processor against the head while vibrations are transduced through direct contact with the individual's skin and the bone below. The Otomag Alpha 1 (S) Sound Processor with headband or Softband is intended for use in individuals (with no age limitations) with conductive or mixed hearing losses, bilateral fitting, and single sided deafness. For bilateral conductive hearing losses, the BAHA with Softband has been suggested to provide an average of 40.5 dB functional gain across the speech spectrum.

A number of small retrospective case series, comparative studies, and review publications suggest that infants and children under 5 years of age with bilateral congenital aural atresia may benefit from an externally worn BAHA, prior to BAHA implantation (Dun, 2010; Priwin, 2007; Zarowski, 2011). Hol and colleagues (2005) evaluated the validity of a BAHA with Softband (fitted unilaterally and bilaterally) in 2 young children with severe bilateral conductive hearing loss due to congenital aural atresia. In a small multicenter comparative study, 12 children (including the 2 children in the Hol, 2005 article) with bilateral congenital aural atresia with a pure conductive hearing loss of around 60 dB hearing level were fitted with the BAHA with Softband (Verhagen, 2008). These children were retrospectively compared to a reference group of 8 children selected from a database of those who had a conventional bone conduction hearing aid for bilateral congenital aural atresia. The authors reported the mean aided hearing threshold of the children with the BAHA with Softband compared to the reference group was 27 dB

hearing level ± 6 dB hearing level to 25 dB hearing ± 6 dB hearing level, respectively. Further results compared psychological and language development in 5 of the 12 children available from the BAHA with Softband group.

Ramakrishnan and colleagues (2011) used the Glasgow Benefit Inventory (GBI) and Listening Situation Questionnaire to report quality of life findings in a retrospective cross-sectional survey administered to parents of 22 children (n=109 total participants), some with skull and congenital/chromosomal abnormalities from inherited syndromes that involve unilateral (hemifocal microsomia) or bilateral hearing impairment (Treacher-Collins Syndrome, n=4 of 22) due to microtia or aural atresia. The youngest child utilizing an externally worn BAHA with Softband was 6 months of age. Overall, parents reported short-term satisfaction in the mean GBI scores for the children after 3 months of implanted BAHA or externally worn BAHA with Softband use. Despite the heterogeneous etiology of children in the study population, the authors suggest that:

> The utility of BAHAs for children with syndromes and craniofacial anomalies is poorly recognized, resulting in delays in aid fitting and therefore in early hearing rehabilitation...In such cases, surgical reconstruction of the ear canal and middle-ear defects is not only technically challenging but also plagued by poor results (with a high rate of ear canal restenosis and limited functional hearing benefit). Hence, alternative treatment options such as Softband and BAHA may be of considerable benefit.

Christensen and colleagues (2010) conducted a retrospective 5-year case review of 10 children, 6 months to 16 years of age, with bilateral conductive hearing loss due to congenital aural atresia and/or microtia who were initially fit with traditional bone conduction hearing aids, progressed to the externally worn BAHA with Softband, and finally to a unilateral implanted BAHA. The amount of functional gain at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz delivered by the various devices was examined as well as the threshold measures with each device at each frequency. The participants showed a statistically significant improvement when using the externally worn BAHA with Softband over traditional bone conduction hearing aids.

Nicholson and colleagues (2011) retrospectively reviewed cases of 25 children, ages 6 months to 18 years with craniofacial disorders and bilateral conductive hearing loss, who were consistent full-time, externally worn, unilateral BAHA with Softband users as a prerequisite to surgical implantation. The primary study outcome used aided and unaided soundfield audiometric thresholds to measure functional gain. Audibility of the speech spectrum was verified by comparison with target aided thresholds. An analysis of the results revealed an improvement in soundfield thresholds using the BAHA with Softband for the four octave frequencies; percentages of thresholds meeting target levels were significant at all frequencies, exceeding the 80% criterion. The investigators concluded use of the BAHA with Softband provided audibility of the speech spectrum for infants and children with bilateral congenital conductive hearing loss.

In summary, while there are no published, randomized controlled trials comparing the efficacy of an externally worn BAHA with Softband to an implantable BAHA in measurements of directional hearing, sound localization, and speech recognition in noise, this device may be clinically appropriate for individuals under age 5 who are not

yet considered appropriate candidates for a surgically implanted device, in particular infants and children with bilateral congenital aural atresia who cannot be fitted for standard acoustic hearing aids placed in the ear canal.

Other Bone-Anchored Hearing Systems

In November 2008, the OBC Bone Anchored Hearing Aid System (Oticon Medical AB, currently located in Askim, Sweden; Oticon Medical, LLC, USA, Somerset, NJ) received FDA 510(k) clearance (K082108) as substantially equivalent to the BAHA Divino. The OBC system consists of an external sound processor unit and an implant with a surgically anchored skin penetrating abutment in the bone behind the ear. Vibrations generated by the sound processor are transmitted directly through the skull bone to the cochlea as bone conduction sound. The sound processor has a coupling so that it can be easily connected to and disconnected from the abutment by the user. The sound processor can alternatively be connected to headband accessories, to function as a conventional bone conductor. The OBC system is intended for use in individuals 5 years of age or older with conductive and mixed hearing losses, bilateral fitting and single sided deafness.

Subsequently, the FDA cleared the OBC Ponto Bone Anchored Hearing Implant System (K112053) in November 2011, intended for use with the Ponto, Ponto Pro, or Ponto Pro Power sound processors. In December 2013, the FDA cleared the Ponto Plus and Ponto Plus Power (K132775) sound processor systems for use in mixed hearing loss, bilateral fitting, and single sided deafness. The Ponto Pro, Ponto Plus, and Ponto Plus Power sound process can be used with either the Ponto Implant System or with specific compatible BAHA (Cochlear Americas) abutments/implant systems.

Bosman and colleagues (2013) compared the performance of the digital Ponto Pro Power sound processor (Oticon Medical AB, Askim, Sweden; Oticon Medical, LLC, USA, Somerset, NJ) with that of the analog BAHA Intenso sound processor. Both sound processors are intended for use with bone-anchored (bone conduction) hearing aid systems for individuals with conductive and mixed hearing loss and single sided deafness. In a nonrandomized study design, 18 subjects were initially tested with the Ponto Pro Power followed by the BAHA Intenso after a 4-week acclimatization period. Mean AC and bone conduction thresholds averaged across the frequencies of 500, 1000, 2000, and 4000 Hz were 73.9 and 34.2 dB hearing level, respectively. Performance of the two devices was evaluated objectively by measuring aided free-field thresholds, speech perception in quiet, and speech perception in noise. A subjective evaluation was carried out with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the SSQ questionnaire. Secondary outcomes data were collected by proprietary questionnaires concerning user experiences, user satisfaction, and device preference. Aided free-field thresholds and speech reception thresholds (SRTs) in quiet were not statistically significantly different for either sound processor ($p>0.05$). In contrast, SRTs in noise were 2.0 dB lower ($p<0.001$) for the Ponto Pro Power than for the BAHA Intenso sound processor. APHAB questionnaire scores on all subscales provided statistically significantly greater benefit ($p<0.05$) for the Ponto Pro Power than for BAHA Intenso sound processor. A total of 14 subjects reported a strong preference for the Ponto Pro Power over the BAHA Intenso sound processor. A limitation of this study design was the order of testing, as it may have affected test scores due to familiarization with test procedures and a tendency to prefer the last sound processor over the first sound processor.

In a single-blind, randomized, repeated measure trial, Oeding and Valente (2013) evaluated the performance of the Ponto Pro's adaptive multichannel directional microphone in 15 individuals with unilateral sensorineural hearing loss. The primary outcome was to determine if statistically significant differences existed in the mean Reception Threshold for Sentences (RTS in dB), utilizing the Hearing in Noise Test (HINT), in diffuse uncorrelated restaurant noise between unaided, an omnidirectional microphone (OM), split directional microphone (SDM), and full directional microphone (FDM) in the Ponto Pro. A secondary outcome was to assess subjective benefit using the APHAB questionnaire comparing the Ponto Pro to the participant's current BAHA system (BAHA systems: BP-100, n=5; Divino, n=6; Intenso, n=3; and Compact, n=1), and the Ponto Pro and participant's own BAHA system to unaided hearing. Participants' mean years of experience with the BAHA systems were 4.0 years. In addition, the study compared RTS data of the Ponto Pro to data from an identical study examining the BAHA Divino sound processor. Participants wore the Ponto Pro sound processor for 4 weeks. The primary outcome measure (evaluated by analysis of variance [ANOVA]) identified no statistically significant differences existed in mean RTS between unaided, the Ponto Pro's OM, SDM, or FDM ($p=0.10$). However, the Ponto Pro provided statistically significant benefit for the Background Noise (BN) ($p<0.01$) and Reverberation (RV) ($p<0.05$) subscales compared to the participant's own bone-anchored hearing system. The Ponto Pro (Ease of Communication [EC] [$p<0.01$], BN [$p<0.001$], and RV [$p<0.01$] subscales) and participant's own BAHA system (BN [$p<0.01$] and RV [$p<0.01$] subscales) overall provided statistically significant benefit compared to unaided hearing. Clinically significant benefit of 5% was present for the Ponto Pro compared to the participant's own BAHA system and 10% for the Ponto Pro and the participant's own BAHA system compared to unaided hearing. The Ponto Pro's OM ($p=0.05$), SDM ($p=0.05$), and FDM ($p<0.01$) were statistically significantly better than the Divino's OM. No significant differences existed between the Ponto Pro's OM, SDM, and FDM compared to the Divino's DM. In summary, participants preferred the Ponto Pro compared to the participant's own BAHA system and the Ponto Pro and participant's own BAHA system compared to unaided hearing. The RTS of the Ponto Pro's adaptive multichannel DM was similar to the Divino's fixed hypercardioid DM, but the Ponto Pro's OM was statistically significantly better than the Divino's OM.

Partially Implantable Magnetic Bone Conduction Hearing Aids

Partially implantable magnetic bone conduction hearing systems are available as an alternative to a bone-anchored hearing system that is connected percutaneously via an abutment. Two partially implantable magnetic bone conduction hearing aids that have received FDA 510(k) clearance are: the Otomag Bone Conduction/Magnetic Implant System (Otomag GmbH, manufacturers of the Sophono® Alpha System, acquired and integrated into Sophono, Inc., Boulder, CO [now owned by Medtronic, Minneapolis, MN]) (K102199), and the BAHA Attract System (Cochlear Americas, Centennial, CO) (K131240). Both systems shares similar indications for use in conductive or mixed hearing losses, bilateral fitting, and single sided deafness.

The Otomag Bone Conduction/Magnetic Implant System consists of two distinct configurations: the Alpha 1 (S) and Alpha 1 (M). In the Sophono Alpha 1 (M), the sound processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the person's skin and the bone below. To facilitate greater transmission of acoustics

between magnets, skin thickness may be reduced to 4 to 5 millimeters over the implant when it is surgically placed. The system is intended for use in individuals 5 years of age or older.

The BAHA Attract System consists of a percutaneously placed implant magnet and an external sound processor magnet forming a connection across healed skin. A BAHA sound processor is then attached to the sound processor magnet. Individuals should have sufficient bone quality and quantity to support successful implant placement. The system is intended for use in individuals 5 years of age or older.

The Bonebridge™ (MED-EL, Innsbruck, Austria) is another partially implantable bone-conduction implant system that is considered an active transcutaneous device. On March 7, 2019 the Bonebridge was granted 510(k) clearance by the FDA as substantially equivalent to other predicate devices for:

- Patients 12 years of age or older;
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5,1, 2, and 3 kHz) should be better than or equal to 45 dB H;
- Bilateral fitting of the BONEBRIDGE is intended for patients having a symmetrically conductive or mixed hearing loss;
- The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than15 dB at individual frequencies;
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or "SSD"). The PTA air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz);
- The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids (FDA, 2019).

Seigert (2011) reported on use of the Otomag Alpha System, a partially implantable bone conduction hearing aid that utilizes a twin magnet coupling for transcutaneous acoustic transmission. The hearing system was reported to have been implanted in more than 100 individuals followed for 5 years, but results were only reported on 12 individuals. Seigert reported sound attenuation was reduced by less than 10 dB with the Otomag Alpha System since the acoustics must pass through the skin rather than by direct bone stimulation through a percutaneous abutment on the BAHA-type implants. The preliminary results in 8 unilaterally and 4 bilaterally implanted individuals showed average hearing gains of 31.2 ± 8.1 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.

Siegert and Kanderske (2013) evaluated the clinical, surgical, and audiologic outcomes in 21 individuals with unilateral or bilateral congenital aural atresia who were implanted with the Sophono partially implantable bone conduction hearing aid magnets embedded into shallow bone beds in a one-step procedure. The skin above the

magnets was slightly thinned and the external device was fixed with counter magnets in a base plate. The follow-up period after implantation was 19.3 ± 12.2 months, with a range of 0.2 to 46.6 months. The average age of the individual at the time of implantation was 12.4 years (range: from 6.0 to 50.0 years). The average hearing gain was 31 ± 8 dB, and the suprathreshold word recognition tests increased by 57% ± 23%. The authors reported a very low risk for complications and a hearing gain similar to other bone conduction hearing aids.

Hol and colleagues (2013) performed a matched control group comparison of 12 children (age range: 5 to 12 years) with congenital unilateral conductive hearing loss from congenital aural atresia. Six children implanted with a percutaneous BAHA system (Divino, n=5; BP100, n=1) were compared to 6 children implanted with the Sophono Alpha 1 System. Sound field thresholds, speech recognition threshold and speech comprehension at 65 dB were somewhat better in children with the BAHA device than those with the Alpha 1 implant. Using a skull simulator, output was 10 dB to 15 dB lower with the Alpha 1 implant than the BAHA device. The authors summarized that these measurements suggest there is a potential for higher gain and output as validated by the audiologic benefit with the BAHA implant compared to the Alpha 1 implant. Limitations of this study include the small sample size and short follow-up period.

Centric and colleagues (2014) conducted a retrospective chart review of the first 5 children who underwent implantation with the Sophono Alpha 1 System. Pre- and postoperative audiometric data and clinical courses were evaluated. Outcome measures were reported indicating an average improvement in both pure tone average (PTA) of 32 dB hearing loss and in speech response threshold of 28 dB hearing loss. All participants responded in the normal to mild hearing loss range in the operated ear after device activation. Average improvement across individual frequencies was between 17 dB and 37 dB (standard deviation, 5.5-11 dB). Limitations of this study include the retrospective design, small number of participants, lack of speech response threshold data (n=1 child), and omission of data for another participant who had no preoperative responses in the operated ear, which limited audiometry testing. One participant required a postoperative course of oral antibiotics for a minor infection at the implantation site.

In follow-up to their initial experience, Baker and colleagues (2015) conducted a retrospective chart review of individuals implanted at their institution comparing the Sophono Alpha 1 System (n=10) to the BAHA Attract System (n=6). Preoperative and postoperative audiometric data, clinical course, and other outcomes data were reported. The average improvement in PTA for the Sophono Alpha 1 System and BAHA Attract System was 38 dB hearing level and 39 dB hearing level, respectively. Speech recognition threshold improvement for the Sophono Alpha 1 System and the BAHA Attract system was 39 dB hearing level and 56 dB hearing level, respectively. Considering all frequencies, the mean improvement for the Sophono Alpha 1 System and BAHA Attract System was 34 dB hearing level (range, 24-43 dB hearing level) and 39 dB hearing level (range, 32-45 dB hearing level), respectively. Using a chi-square test, the PTA and speech recognition data did not show a statistically significant difference between the systems (p-value, 0.68 and 0.56, respectively). The authors suggested that larger study populations are needed to assess long-term complication rates with use of partially implanted (magnetic), transcutaneous abutment systems.

Iseri and colleagues (2014) evaluated the BAHA Attract System in a multicenter clinical study conducted in Turkey of 12 individuals (mean age 27.6 years; range 5 to 65 years) with conductive hearing loss attributed to bilateral mastoidectomy due to chronic suppurative otitis media (n=11) or bilateral aural atresia (n=1). The mean air-bone gap was 41 dB. Bone smoothing around the implant was needed in 5 participants and the sound processor was placed in the fourth postoperative week for all participants. Only 9 individuals were available for post-implant audiological measurements. The free-field hearing thresholds (mean) at 0.5, 1, 2, and 4 kilohertz (kHz) frequencies was 45 dB with the BAHA Attract and 37 dB without the BAHA Attract. An average gain of 19 dB in the speech reception threshold was observed with the BAHA Attract compared with unaided speech. The investigators suggest that despite the apparent success of the BAHA Attract, potential limitations of the percutaneous system include daily hygienic care to prevent soft tissue complications around the implant and cosmetic concerns, especially in teenagers.

Iseri and colleagues (2015) conducted a retrospective, single-center study in Turkey comparing 21 individuals treated with a transcutaneous, fully implantable BAHA to 16 individuals treated with the BAHA Attract System. Most individuals had BAHA placement for chronic otitis media. Operating time was longer in individuals treated with the transcutaneous partially implantable devices (46 minutes vs. 26 minutes; $p<0.05$). Three individuals treated with percutaneous devices had Holger grade 2 skin reactions and 2 individuals had stopped using their devices for reasons unrelated to skin reactions. The 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. The mean hearing gain measured by speech reception threshold was statistically significant in the percutaneous group (24 dB vs. 36.7 dB; $p=0.02$).

Carr and colleagues (2015) reported outcomes for 10 adults implanted with the BAHA Attract System for conductive, mixed hearing loss or single sided deafness. The most common condition for use was hearing loss from chronic suppurative otitis media (n=3). The primary outcome did not demonstrate a significant improvement in word discrimination scores (that is, an increase at 30, 50, and 60 A-weighted decibels; $p=0.25$). The majority of subjects (n=8; 80%) complained of significant numbness in the area of the skin flap.

Briggs and colleagues (2015) prospectively evaluated the BAHA Attract System in 27 adults with conductive or mild mixed hearing loss or single-sided sensorineural deafness. Participants were followed for 9 months after implantation. Hearing performance was evaluated comparing unaided hearing with hearing with the sound processor on a Softband. Participant benefit, soft tissue status, device retention, and safety parameters were monitored continuously throughout the study. Statistically significant improvements in audibility and speech understanding in noise and quiet were recorded for the test device compared with preoperative unaided hearing. Speech recognition was similar or better than tests performed with the same sound processor on a Softband. Good soft tissue outcomes were reported, without major pressure-related complications. At 9 months, all participants continued to use and benefit from the device. A limitation of this study is the small sample size involving only adult participants; in addition, questions remain concerning the maximum audiometric fitting range for these systems. The findings of this study need to be validated by well-designed clinical trials with a greater number of participants.

Powell and colleagues (2015) reported outcomes from a retrospective observational study of individuals (2 adults, 10 children) treated by the study's primary author and others identified from an Australian national hearing database. A total of 12 individuals were implanted with the Sophono Alpha System (n=6) or the BAHA Attract System (n=6). In the BAHA Attract group, the mean AC thresholds across four frequencies (0.5, 1, 2, and 4 kHz) improved from 60.8 dB pre-implantation to 30.6 dB post-implantation. In the Sophono Alpha group, the mean four-frequency AC thresholds improved from 57.8 dB pre-implantation to 29.8 dB post-implantation; however, there was no statistically significant difference in aided thresholds or speech discrimination scores between the two groups.

Denoyelle and colleagues (2015) reported results of a prospective study of 15 children ages 5 to 18 years with unilateral or bilateral congenital aural atresia and complete absence of the external auditory canal with pure conductive deafness. A within-subject comparison of hearing results was obtained pre-and post-implantation for the Sophono Alpha 1 and the BAHA with Softband systems. The 6-month follow-up measurements were reported as a mean-aided AC PTA of 33.49 (mean gain, 35.53 dB), with a mean-aided sound reception threshold of 38.2 (mean gain, 33.47 dB). The study met its prespecified noninferiority outcome which was a difference in AC PTA between both systems (0.56 dB; CI upper limit, 4.42 dB). Adverse events with implantation of the Sophono Alpha 1 were reported as mild, including skin erythema (n=2), which improved by using a weaker magnet, and brief episodes of pain or tingling (n=3).

Gawecki and colleagues (2016) retrospectively evaluated the surgical, functional, and audiological results of a retrospective case series of 20 individuals implanted with the BAHA Attract System. Subjects were divided into two groups, those with either bilateral mixed conductive hearing loss or single sided deafness, and evaluated at 6 months follow-up. Postoperative hematoma occurred in 10% of subjects. Postoperative functional results included a GBI total score of 29.6 points and APHAB global score (mean gain) of 23.5%. Audiological results were reported as a mean gain of 32.9% for the bilateral mixed and conductive hearing loss group and 27.5% in the single sided deafness group.

In summary, the body of evidence in the peer-reviewed published medical literature evaluating outcomes associated with partially implantable magnetic bone conduction hearing aids for individuals with conductive or mixed hearing loss includes, but is not limited to, prospective studies evaluating different transcutaneous systems (Briggs, 2015; Denoyelle, 2015), nonrandomized comparative studies (Hol, 2013; Iseri, 2014; Iseri, 2015), a systematic review (Dimitriadis, 2016), and retrospective observational case series (Baker, 2015; Centric, 2014; Powell, 2015; Siegert, 2011; Siegert and Kanderske, 2013) involving small sample populations with short-term follow-up. Pertinent outcomes include evaluations of functional status, quality of life, and treatment-related morbidity. Most studies compare hearing thresholds with and without a partially implantable hearing system. These single-arm studies have shown improvements in hearing in the device-aided condition. For individuals unable to wear an external hearing aid, there may be few alternative treatments. The available evidence, along with the views of relevant medical specialists practicing in otolaryngology and neurotology, suggest that a partially implantable magnetic bone conduction hearing aid is associated with improvements in hearing similar to that of a fully-implantable bone conduction (bone-anchored) hearing aid. Results have demonstrated clinical effectiveness in producing meaningful improvements in select individuals with conductive or mixed (conductive and sensorineural) hearing loss.

Intraoral Bone Conduction Hearing Aid

In January 2011, the SoundBite™ Hearing System (Sonitus Medical, Inc., San Mateo, CA), a non-surgically implanted intraoral bone conduction hearing aid, received FDA 510(k) clearance (K100649) for use in individuals 18 years or older who have moderately severe, severe, or profound sensorineural hearing loss in one ear and normal hearing in the other ear (that is, single-sided deafness). The system consists of two main components: a behind-the-ear device which contains the receiver, a wireless transmitter and microphone; and a removable, custom-fit in-the-mouth oral retainer-like hearing device. Accessories include a system charger and programming software. According to the manufacturer, the behind-the-ear device uses a digital signal processor to process the sound and a wireless chip to transmit the signals to the hearing device worn in the mouth. The in-the-mouth hearing device in turn creates imperceptible vibrations using a piezoelectric actuator that are sent via the teeth through the skull bones, and ultimately to the cochlea. The individual must have at least two contiguous molar or premolar teeth with no untreated tooth decay, healthy attachment to those teeth with tooth pockets limited to no more than 5mm, no mobile teeth, and bone loss no greater than a 34% average on the mesial and distal sides of the tooth as measured on X-ray on the teeth on which the device will be worn.

The safety and effectiveness of the SoundBite Hearing System was evaluated in two small prospective studies of individuals 18 years of age or older with moderately severe, severe or profound sensorineural hearing loss in one ear (single sided deafness) and for individuals with conduction hearing loss where the PTA bone conduction hearing threshold was ≥ 25 dB hearing level.

The first study was a 1-month study of 28 subjects (Murray, 2011b); the second was a 6-month safety study of 22 subjects (Murray, 2011a). In the first multicenter, controlled, nonrandomized and unblinded study (Murray, 2011b), the primary efficacy endpoint was a 1.0 dB improvement in HINT score for the condition of speech front and noise to the better ear. The HINT scores improved an average of -2.5 dB after 30 days, compared with wearing no device. The APHAB scores improved for all participants for the Global and BN subscales and for all but 1 subject for the RV and EC subscales. No product-related adverse events or complications were reported. Limitations of the study include lack of randomization and the short-follow-up time.

The second safety and effectiveness study was a multicenter, controlled, nonrandomized and unblinded trial of 22 individuals wearing the SoundBite Hearing System over a 6-month period (Murray, 2011a). No related adverse events or changes in the medical or audiologic findings were reported from the onset of the trial compared to the end of the trial. At 3 or 6 months, there were no significant changes in the mean aided thresholds or the mean dental measures compared with pretrial measures. At 3 and 6 months, the mean APHAB scores showed improvement for the BN, RV, and EC subscales and the Global Scale. The vast majority of subjects (> 90%) reported satisfaction and improvement after wearing the SoundBite Hearing System in numerous areas of the single sided deafness questionnaire. Limitations of this study include the lack of randomization, small sample size, and short follow-up time.

Gurgel and Shelton (2013) evaluated the safety and efficacy of the SoundBite Hearing System in individuals over a 6-month period of use. A total of 34 participants with single sided deafness were enrolled in this multicenter, prospective, nonrandomized study measuring outcomes based on the APHAB questionnaire and self-reported assessment. The mean APHAB scores improved significantly for EC ($p<0.001$), BN ($p<0.001$), RV ($p<0.001$), and global benefit ($p<0.001$). Participants reported high rates of auditory benefit in a variety of listening situations and overall satisfaction with the SoundBite Hearing System. One adverse event with a superficial mouth sore was reported and resolved after appropriate dental care. Twelve participants (35%) reported acoustic feedback; however, the feedback was resolved in 6 of these participants after device adjustment.

In a subsequent prospective cohort study, Gurgel and colleagues (2015) assessed the safety and efficacy of the SoundBite after 12 months of use. At the end of 6 months and 12 months, individuals were asked to complete the APHAB questionnaire and SSD questionnaire in addition to audiometric testing. A total of 81 participants aged 18 years or older with single-sided deafness completed the study. Hearing thresholds remained the same throughout the study. The APHAB results showed a significant benefit in categories of ease of communication, reverberation, background noise, and global score. Among participants who completed the SSD questionnaire, 93.8% reported high satisfaction with the Soundbite and were likely to recommend the OBC; however, only 55.6% were satisfied with regard to the person's ability to eat with the hearing aid device. No serious adverse events were reported during the study. Limitations of this study include the lack of a control group, evaluation of outcomes obtained by questionnaire responses (which are subjective and subject to bias), and differences in the number of participants responding to the 6- and 12-month APHAB questionnaire (n=65 participants, n=80 participants, respectively). The latter had the potential to skew the results because of the different participation at the 2 time points. Finally, more than 90% of participants responded that they preferred the Soundbite compared with no device and would likely recommend the device; however, this percentage may be higher as 9 subjects withdrew from the study secondary to device-related problems and did not complete the evaluation.

In summary, the evidence in the peer-reviewed medical literature is limited in comparisons of the SoundBite Hearing System to other bone-anchored or bone conduction hearing aids currently available. Limitations in these studies include small sample sizes, short follow-up periods, and lack of appropriate control or comparator groups.

As of January 1, 2015, Sonitus Medical, Inc. informed consumers they had ceased operations and were no longer manufacturing the Soundbite Hearing System. To date, no new information is available concerning production of this oral hearing aid by another company.

Other Considerations

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2016) issued a position statement on bone conduction hearing devices which states:

> The American Academy of Otolaryngology-Head and Neck Surgery considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases

preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by-a qualified otolaryngologist-head and neck surgeon. Use of these devices, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and other similar regulatory agencies in countries other than the United States.

The AAO-HNS statement does not cite any new evidence from the peer-reviewed medical literature in support of this recommendation.

Definitions

Conductive hearing loss: Hearing loss that occurs when sound is conducted inefficiently through the outer ear canal to the eardrum and the small bones (ossicles) of the middle ear; involves a reduction in sound level or the ability to hear faint sounds.

Congenital aural atresia (CAA): A rare spectrum of congenital deformities present at birth that involve some degree of failure of the development of the external auditory canal; commonly accompanied by abnormalities of both the middle ear bones in various degrees, as well as the external ear, including microtia (small ear) or incomplete development of the auricle (the outer projecting portion of the ear).

Decibel (dB): A unit of measurement indicating the loudness of sound. The intensity relates to how loud or soft a sound is. Sound scales are based on either sound pressure level (dB SPL) or hearing level (dB HL).

Degree of hearing loss: According to the American Speech-Language-Hearing Association (ASHA, 2018) (Clark, 1981), refers to the severity of an individual's hearing loss range in decibels (dB):

Classification of Hearing Loss	**Hearing Threshold**
• Normal hearing	0 to 20 dB
• Mild	21 to 40 dB hearing loss
• Moderate	41 to 55 dB hearing loss
• Moderately-severe	56 to 70 dB hearing loss
• Severe	71 to 90 dB hearing loss
• Profound	91 dB or more hearing loss

Hearing in Noise Test (TEST): A commonly used speech recognition test consisting of 250 sentences (25 lists of 10 sentences per list) performed in the evaluation of an individual's ability to hear speech in quiet and in noise in the context of sentences.

Hearing loss: Any degree of impairment of the ability to apprehend sound.

Hertz (Hz): A unit of frequency equivalent to 1 cycle per second. Frequency of pitch is measured in Hz.

Mixed hearing loss: Hearing loss that is both conductive and sensorineural, occurring in one or both ears.

Otitis: Inflammation or infection of the ear.

Pure tone average (PTA): The average of hearing sensitivity (that is, the minimum volume that the person hears) calculated at multiple frequencies (perceived by pitch), typically within the range of 0.25 to 8 kHz (kilohertz).

Pure tone threshold audiometry: The measurement of an individual's hearing sensitivity for calibrated pure tones; includes manual air-conduction measurements at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (125 Hz under some circumstances) plus bone-conduction measurements at intervals from 250 Hz to 4000 Hz and at 3000 Hz as needed (ASHA, 2005).

Sensorineural hearing loss: A permanent hearing loss related to the sensory or neural structures responsible for hearing that involves a reduction in sound level or ability to hear faint sounds; affects speech understanding or the ability to hear clearly; the involved structures include, but are not limited to, the cochlea and the acoustic nerve.

Single sided deafness (SSD): Significant or total hearing loss in one ear; also known as unilateral sensorineural hearing loss. SSD may be a result of surgery to treat acoustic neuroma or other tumors of the eighth cranial nerve.

Speech reception threshold: The intensity at which speech is recognized as meaningful symbols; in speech audiometry, it is the dB level at which 50% of spondee words (a bisyllabic word with equivalent stress on each syllable) can be repeated correctly by the subject.

Temporal bone: A bone located on the side of the head that is part of the skull.

Transcutaneous: Refers to a device or medication applied directly to unbroken skin.

Tympanic membrane: The membrane in the ear that vibrates to sound; referred to as the eardrum.

References

Peer Reviewed Publications:

1. Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. Int J Pediatr Otorhinolaryngol. 2015; 79(4):474-480.
2. Baguley DM, Bird J, Humphriss RL, Prevost AT. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. Clin Otolaryngol. 2006; 31(1):6-14.
3. Bosman AJ, Hol MK, Snik AF, et al. Bone-anchored hearing aids in unilateral inner ear deafness. Acta Otolaryngol. 2003; 123(2):258-260.
4. Bosman AJ, Snik AF, Hol MK, Mylanus EA. Evaluation of a new powerful bone-anchored hearing system: a comparison study. J Am Acad Audiol. 2013; 24(6):505-513.

5. Bravo-Torres S, Der-Mussa C, Fuentes-Lopez E. Active transcutaneous bone conduction implant: audiological results in pediatric patients with bilateral microtia associated with external auditory canal atresia. Int J Audiol. 2018; 57(1):53-60.
6. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. Otol Neurotol. 2015; 36(5):834-841.
7. Calvo Bodnia N, Foghsgaard S, Nue Moller M, Caye-Thomasen P. Long-term results of 185 consecutive osseointegrated hearing device implantations: a comparison among children, adults, and elderly. Otol Neurotol. 2014; 35(10):e301-e306.
8. Carr SD, Moraleda J, Procter V, et al. Initial UK experience with a novel magnetic transcutaneous bone conduction device. Otol Neurotol. 2015; 36(8):1399-1402.
9. Centric A, Chennupati SK. Abutment-free bone-anchored hearing devices in children: initial results and experience. Int J Pediatr Otorhinolaryngol. 2014; 78(5):875-878.
10. Christensen L, Smith-Olinde L, Kimberlain J, et al. Comparison of traditional bone-conduction hearing AIDS with the Baha system. J Am Acad Audiol. 2010; 21(4):267-273.
11. Clark JG. Uses and abuses of hearing loss classification. ASHA. 1981; 23(7):493-500.
12. Colquitt JL, Jones J, Harris P, et al. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. Health Technol Assess. 2011; 15(26):1-200, iii-iv.
13. Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. Arch Otolaryngol Head Neck Surg. 2007; 133(1):51-55.
14. den Besten CA, Monksfield P, Bosman A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: six-month results from a multicenter study. Clin Otolaryngol. 2019; 44(2):144-157.
15. den Besten CA, Nelissen RC, Peer PG, et al. A retrospective cohort study on the influence of comorbidity on soft tissue reactions, revision surgery, and implant loss in bone-anchored hearing implants. Otol Neurotol. 2015; 36(5):812-818.
16. Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. Int J Pediatr Otorhinolaryngol. 2015; 79(3):382-387.
17. de Wolf MJ, Hendrix S, Cremers CW, Snik AF. Better performance with bone-anchored hearing aid than acoustic devices in patients with severe air-bone gap. Laryngoscope. 2011; 121(3):613-616.
18. Dimitriadis PA, Farr MR, Allam A, et al. Three year experience with the cochlear BAHA Attract implant: a systematic review of the literature. BMC Ear Nose Throat Disord. 2016; 16:12.
19. Dun CA, de Wolf MJ, Mylanus EA, et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. Otol Neurotol. 2010; 31(4):615-623.
20. Dutt SN, McDermott AL, Burrell SP, et al. Patient satisfaction with bilateral bone-anchored hearing aids: the Birmingham experience. J Laryngol Otol Suppl. 2002a; (28):37-46.
21. Dutt SN, McDermott AL, Burrell SP, et al. Speech intelligibility with bilateral bone-anchored hearing aids: the Birmingham experience. J Laryngol Otol Suppl. 2002b; (28):47-51.
22. Dutt SN, McDermott AL, Jelbert A, et al. Day to day use and service-related issues with the bone-anchored hearing aid: the Entific Medical Systems questionnaire. J Laryngol Otol Suppl. 2002c; (28):20-28.

23. Dutt SN, McDermott AL, Jelbert A, et al. The Glasgow benefit inventory in the evaluation of patient satisfaction with the bone-anchored hearing aid: quality of life issues. J Laryngol Otol Suppl. 2002d; (28):7-14.
24. Farnoosh S, Mitsinikos FT, Maceri D, et al. Bone-anchored hearing aid vs. reconstruction of the external auditory canal in children and adolescents with congenital aural atresia: a comparison study of outcomes. Front Pediatr. 2014; 2:5.
25. Gawecki W, Stieler OM, Balcerowiak A, et al. Surgical, functional and audiological evaluation of new Baha® Attract system implantations. Eur Arch Otorhinolaryngol. 2016; 273(10):3123-3130.
26. Granstrom G, Bergstrom K, Odersjo M, Tjellstrom A. Osseointegrated implants in children: experience from our first 100 patients. Otolaryngol Head Neck Surg. 2001; 125(1):85-92.
27. Granstrom G, Tjellstrom A. The bone-anchored hearing aid (BAHA) in children with auricular malformations. Ear Nose Throat J. 1997; 76(4):238-247.
28. Gurgel RK, Curtis SH, Shelton C. A novel intraoral bone conduction hearing prosthesis: one-year safety and efficacy study. Otol Neurotol. 2015; 36(1):106-110.
29. Gurgel RK, Shelton C. The SoundBite hearing system: patient-assessed safety and benefit study. Laryngoscope. 2013; 123(11):2807-2812.
30. Hakansson BE, Carlsson PU, Tjellstrom A, Liden G. The bone-anchored hearing aid: principal design and audiometric results. Ear Nose Throat J. 1994; 73(9):670-675.
31. Hakansson BE, Liden G, Tjellstrom A, et al. Ten years of experience with the Swedish bone-anchored hearing system. Ann Otol Rhinol Laryngol Suppl. 1990; 151:1-16.
32. Hol MK, Bosman AJ, Snik AF, et al. Bone-anchored hearing aid in unilateral inner ear deafness: a study of 20 patients. Audiol Neurootol. 2004; 9(5):274-281.
33. Hol MK, Cremers CW, Coppens-Schellekens W, Snik AF. The BAHA Softband. A new treatment for young children with bilateral congenital aural atresia. Int J Pediatr Otorhinolaryngol. 2005; 69(7):973-980.
34. Hol MK, Nelissen RC, Agterberg MJ, at al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol. 2013; 34(6):1071-1075.
35. House JW, Kutz JW Jr, Chung J, Fisher LM. Bone-anchored hearing aid subjective benefit for unilateral deafness. Laryngoscope. 2010; 120(3):601-617.
36. Iseri M, Orhan KS, Kara A, et al. A new transcutaneous bone anchored hearing device - the Baha® Attract System: the first experience in Turkey. Kulak Burun Bogaz Ihtis Derg. 2014; 24(2):59-64.
37. Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous bone-anchored hearing aids versus percutaneous ones: multicenter comparative clinical study. Otol Neurotol. 2015; 36(5):849-853.
38. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg. 2012; 147(3):412-422.
39. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. Otol Neurotol. 2013; 34(5):790-794.
40. Larsson A, Tjellstrom A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. Otol Neurotol. 2015; 36(2):336-340.
41. Lin L, Bowditch S, Anderson M, et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otol Neurotol. 2006; 27(2):172-182.

42. Lloyd S, Almeyda J, Sirimanna KS, et al. Updated surgical experience with bone-anchored hearing aids in children. J Laryngol Otol. 2007: 121(9):826-831.
43. Lustig LR, Arts HA, Brackmann DE, et al. Hearing rehabilitation using the BAHA bone-anchored hearing aid: results in 40 patients. Otol Neurotol. 2001; 22(3):328-334.
44. McDermott AL, Dutt SN, Reid AP, Proops DW. An intra-individual comparison of the previous conventional hearing aid with the bone-anchored hearing aid: the Nijmegen group questionnaire. J Laryngol Otol Suppl. 2002a; (28):15-19.
45. McDermott AL, Dutt SN, Tziambazis E, et al. Disability, handicap and benefit analysis with the bone-anchored hearing aid: the Glasgow hearing aid benefit and difference profiles. J Laryngol Otol Suppl. 2002b; (28):29-36.
46. McDermott AL, Williams J, Kuo MJ. The role of bone anchored hearing aids in children with Down syndrome. Int J Pediatr Otorhinolaryngol. 2008; 72(6):751-757.
47. McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. Laryngoscope. 2004; 114(5):942-944.
48. Murray M, Miller R, Hujoel P, et al. Long-term safety and benefit of a new intraoral device for single-sided deafness. Otol Neurotol. 2011a; 32(8):1262-1269.
49. Murray M, Popelka GR, Miller R. Efficacy and safety of an in-the-mouth bone conduction device for single-sided deafness. Otol Neurotol. 2011b; 32(3):437-443.
50. Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. Otol Neurotol. 2014; 35(8):1486-1491.
51. Nicholson N, Christensen L, Dornhoffer J, et al. Verification of speech spectrum audibility for pediatric baha softband users with craniofacial anomalies. Cleft Palate Craniofac J. 2011; 48(1):56-65.
52. Niparko JK, Cox KM, Lustig LR. Comparison of the bone anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. Otol Neurotol. 2003; 24(1):73-78.
53. Oeding K, Valente M. The effectiveness of the directional microphone in the Oticon Medical Ponto Pro in participants with unilateral sensorineural hearing loss. J Am Acad Audiol. 2013; 24(8):701-713.
54. Pai I, Kelleher C, Nunn T, et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. Acta Otolaryngol. 2012; 132(7):751-755.
55. Powell HR, Rolfe AM, Birman CS. A comparative study of audiologic outcomes for two transcutaneous bone-anchored hearing devices. Otol Neurotol. 2015; 36(9):1525-1531.
56. Priwin C, Jonsson R, Hultcrantz M, Granstrom G. BAHA in children and adolescents with unilateral or bilateral conductive hearing loss: a study of outcome. Int J Pediatr Otorhinolaryngol. 2007; 71(1):135-145.
57. Priwin C, Stenfelt S, Granstrom G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. Laryngoscope. 2004; 114(1):77-84.
58. Ramakrishnan Y, Marley S, Leese D, et al. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. J Laryngol Otol. 2011; 125(2):153-157.
59. Ratuszniak A1, Skarzynski PH2, Gos E3, Skarzynski H4. The Bonebridge implant in older children and adolescents with mixed or conductive hearing loss: audiological outcomes. Int J Pediatr Otorhinolaryngol. 2019; 118:97-102.
60. Rebol J. Soft tissue reactions in patients with bone anchored hearing aids. Ir J Med Sci. 2015; 184(2):487-491.

61. Ricci G, Volpe AD, Faralli M, et al. Bone-anchored hearing aids (Baha) in congenital aural atresia: personal experience. Int J Pediatr Otorhinolaryngol. 2011; 75(3):342-346.
62. Shohet JA, Kraus EM, Catalano PJ, Toh E. Totally implantable hearing system: five-year hearing results. Laryngoscope. 2018; 128(1):210-216.
63. Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. Adv Otorhinolaryngol. 2011; 71:41-46.
64. Siegert R, Kanderske J. A new semi-implantable transcutaneous bone conduction device: clinical, surgical, and audiologic outcomes in patients with congenital ear canal atresia. Otol Neurotol. 2013; 34(5):927-934.
65. Snik AF, Mylanus EA, Cremers CW. The bone-anchored hearing aid compared with conventional hearing aids. Audiologic results and the patients' opinions. Otolaryngol Clin North Am. 1995; 28(1):73-83.
66. Snik AF, Mylanus EA, Cremers CW. The bone-anchored hearing aid: a solution for previously unresolved otologic problems. Otolaryngol Clin North Am. 2001; 34(2):365-372.
67. Stenfelt S, Hakansson B, Jonsson R, Granstrom G. A bone-anchored hearing aid for patients with pure sensorineural hearing impairment: a pilot study. Scand Audiol. 2000; 29(3):175-185.
68. van der Pouw CT, Carlsson P, Cremers CW, Snik AF. A new more powerful bone-anchored hearing aid: first results. Scand Audiol. 1998; 27(3):179-182.
69. van der Pouw CT, Snik AF, Cremers CW. The BAHA HC 200/300 in comparison with conventional bone conduction hearing aids. Clin Otolaryngol Allied Sci. 1999; 24(3):171-176.
70. Verhagen CV, Hol MK, Coppens-Schellekens W, et al. The Baha Softband. A new treatment for young children with bilateral congenital aural atresia. Int J Pediatr Otorhinolaryngol. 2008; 72(10):1455-1459.
71. Wazen JJ, Caruso M, Tjellstrom A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. Am J Otol. 1998; 19(6):737-741.
72. Wazen JJ, Spitzer JB, Ghossaini SN, et al. Transcranial contralateral cochlear stimulation in unilateral deafness. Otolaryngol Head Neck Surg. 2003; 129(3):248-254.
73. Zarowski AJ, Verstraeten N, Somers T, et al. Headbands, testbands and softbands in preoperative testing and application of bone-anchored devices in adults and children. Adv Otorhinolaryngol. 2011; 71:124-131.
74. Zeitler DM, Snapp HA, Telischi FF, Angeli SI. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. Otolaryngol Head Neck Surg. 2012; 147(1):105-111.
75. Zernotti ME1, Chiaraviglio MM2, Mauricio SB2, et al. Audiological outcomes in patients with congenital aural atresia implanted with transcutaneous active bone conduction hearing implant. Int J Pediatr Otorhinolaryngol. 2019; 119:54-58.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Bone conduction hearing devices. September 17, 2016. Available at: http://www.entnet.org/content/position-statement-bone-conduction-hearing-devices. Accessed on April 15, 2020.
2. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products. Feb 25, 2009. Available at: https://www.fda.gov/media/75418/download. Accessed on April 15, 2020.

3. U.S. Food and Drug Administration (FDA). Premarket Approval Database. Rockville, MD: FDA. Bonebridge Active Implantable Bone Conduction Hearing System. NO: K183373. March 7, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183373.pdf. Accessed on April 15, 2020.

Websites for Additional Information

1. American Speech-Language-Hearing Association (ASHA). Available at: http://www.asha.org. Accessed on April 15, 2020.

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BAHA 4
BAHA 5 Power
BAHA Attract
BAHA BP100
BAHA BP110 Power
BAHA Cordelle II
BAHA Divino
BAHA Intenso
BAHA Bone-Anchored Hearing System
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OBC Ponto Bone Anchored Hearing Implant System
Otomag Bone Conduction Hearing System
Ponto Pro
Ponto Pro Power
Ponto Plus
Ponto Plus Power
Semi-implantable bone conduction hearing aids
SoundBite Hearing System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	05/14/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References, Websites, and Index sections.
Reviewed	06/06/2019	MPTAC) review. The Discussion, References and Index sections were updated.

New	07/26/2018	MPTAC review. Initial document development. Moved content of SURG.00020 Bone-Anchored and Bone Conduction Hearing Aids to a new clinical utilization management guideline document with the same title.