



AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY



September 2, 2014

Marilyn Tavenner, RN
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Attention: CMS-1614-P, P.O. Box 8010
Baltimore, MD 21244-8010

Re: Scope of Hearing Aid Coverage Exclusion in the Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule

Dear Administrator Tavenner:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), American Otological Society (AOS), American Neurotology Society (ANS), we respectfully submit the following comments on the “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” published in the *Federal Register* as a proposed notice on July 11, 2014. The proposal to revise the hearing aid exclusion to encompass osseointegrated implants and all other bone conducting auditory prosthetics will have a significant detrimental impact on many *patients*. After reviewing the proposed rule, it seems that there may be a misunderstanding of the physiology of the ear, so we would like to provide a brief overview of the parts of the ear and sound energy pathways involved in hearing. Further, we provide comments on the amplifying effect of the middle ear and why we ***strongly disagree*** with the proposed rule in the cases of maximal conductive hearing loss, mixed hearing loss, and in unilateral deafness. Finally, we would like to offer a suggestion for CMS to consider as the agency works to finalize the rule so that Medicare beneficiaries who do not benefit from hearing aids and require bone conducting auditory prostheses receive access to care.

I. Impact of Hearing Loss on Patient Safety and Quality of Life

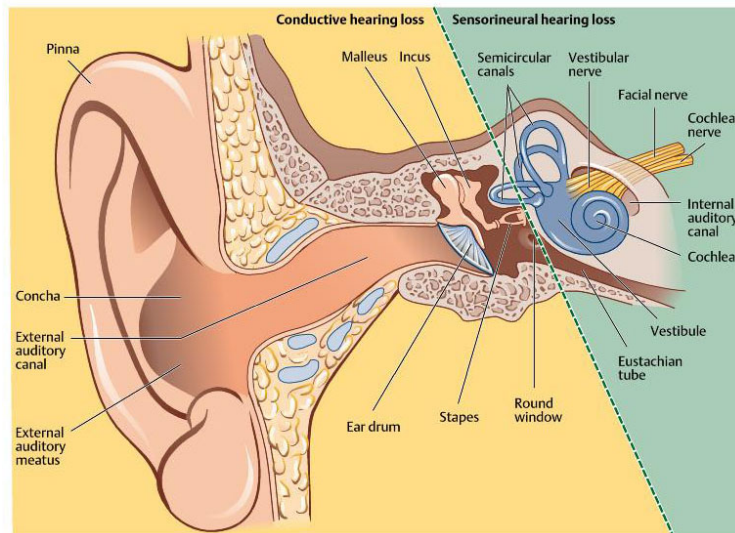
Hearing loss in both ears reduces an individual’s sound awareness and ability to communicate. Unilateral hearing loss impairs an individual’s ability to localize sound and hear in the presence of competing background noise and is both a communication and personal safety issue. In both cases, untreated hearing loss alters a person’s ability to function in day to day listening situations and thus, can negatively impact on employment opportunities, health and safety, and quality of life. Recently, the detrimental effects of

hearing loss in the elderly have been recognized in the areas of physical activity, frailty, health care expenditures, social isolation, depression, cognition, dementia, and even earlier mortality (1-11). Hearing loss is not just an inconvenience, but a significant health condition when untreated.

While hearing loss commonly occurs in the elderly population as a result of aging (i.e. presbycusis or “common, usual or regular hearing loss”), it can also occur as a consequence of medical conditions that effect the ear such as infections, tumors, trauma, developmental, ototoxic (such as side effects from medications), and other disorders. A conductive hearing loss results from dysfunction or absence of the external auditory canal, tympanic membrane (TM or eardrum), and ossicular chain (middle ear bones: malleus, incus, stapes) (yellow area in figure below). Sensorineural hearing loss (often called “nerve deafness”) occurs when cochlear and neural dysfunction exists (Green area in figure below).

II. Anatomy and Physiology Considerations for Prosthetic Hearing Devices

As CMS considers how to define the scope of the hearing aid exclusion, it is important to understand the anatomy and physiology of the ear. The ear is an organ with three parts - the outer ear, the middle ear and the inner ear - two of which are internal to the body (See the figure below).



The outer ear collects acoustic energy (sound waves) from the air, the middle ear focuses and amplifies this acoustic energy and transforms it into mechanical energy (yellow area above). The inner ear receives the amplified mechanical energy at the oval window where it is transformed into hydraulic energy that moves the cochlear fluids. This in turn, activates the hearing receptors (i.e. hair cells) as it moves over them to generate nerve impulses to the brain (green area above). If any part of the system stops functioning, hearing is lost and in order to restore hearing, the non-functioning portion of the ear must be replaced. For example, if one or more of the bones of the middle ear (the ossicles) are

unable to receive and transmit mechanical energy, hearing will be lost because the cochlea requires the highly amplified mechanical energy it receives from the middle ear and responds poorly without it. Depending on what portion of the ear is not working, there may be a number of ways to restore hearing. In some cases, use of a prosthetic device is the most appropriate, and may be the only treatment option. There are several FDA approved prostheses that otolaryngologists use to replace the function of the deaf ear. Some of these devices require surgery while others do not. ***The following more detailed review of the anatomy and physiology of the ear is essential to establishing the understanding for why some patients need bone conducting auditory prosthetics as these devices do not provide the same effect as a hearing aid, that a hearing aid would not allow patients who need bone conducting auditory prostheses to be able to hear because these patients are missing a part of the ear, and why CMS should continue to provide coverage for these prostheses.***

The outer ear (pinna and external auditory canal or EAC) and the middle ear (TM, ossicular chain, Eustachian tube (ET) and aerated middle ear space) are essential in the physiology of hearing. Each element provides not only a collecting mechanism, but a measurable and highly significant amplification and transfer function for hearing. Without the amplification and energy transfer capabilities of the outer and middle ear, the cochlea along with the auditory nerve cannot perform the functions that enable hearing. Therefore, any device that replaces any portion of the outer or middle ear improves the “perception” of sound.

More specifically, the middle ear and its structures are not just passive transmitters of sound, but are essential amplifiers, modulators and transformers of acoustical energy as they transmit sound across the air-fluid interface and in to the fluid-filled cochlea. Normally, when airborne vibrations of sound impinge on a fluid surface, more than 99.9% of the sound energy is reflected back from the surface. A properly functioning hearing system overcomes the problem of the air-fluid interface through the functions of the middle and outer ears. Anatomically, the consistency, shape and size of the TM focuses acoustic energy into the middle ear ossicles. The acoustic energy is transformed into mechanical energy at that point and the mechanical energy travels through the ossicles and impinges on the oval window through stapes vibrations, which is the door to the inner ear. The surface area of the oval window is 28 times smaller than the TM. The combination of focusing acoustic energy 28 fold along with the 1.32:1 amplifier effect of the ossicles provides a mechanical advantage that creates a ~30 dB increase in the effectiveness of hearing. Thus, when the TM and middle ear ossicles are absent (with a patent ear canal), there is a loss of approximately 35 dB of the sound transmitted. In other words, if sound entering the ear canal travelled directly to the inner ear via the round window, it would leave a significant hearing loss owing to the lack of the conducting and amplifying mechanism. If one adds to that any additional barriers such as scar tissue from ear infections, atresia (severely narrowed or totally closed ear canal), inflammation, or debris (cerumen, skin), the deficit is even greater. In the worst of instances, if the TM were to be intact without hearing bones (i.e. ossicles), sound energy travelling down the ear canal would be reflected at the TM without delivery to the cochlear partition, thereby imparting a 60 dB hearing loss. The dB scale rating is a logarithmic scale, thus a 60 dB

loss would indicate a relative loss of power 1,000,000 times less than normal hearing at 0 dB. In summary, the combination of an intact, mobile, normally configured TM together with the transformer lever action of the ossicular chain are critical functions of the organ we call the middle ear that enable us to hear. We also note that the Eustachian tube ventilates the middle ear space and must function normally to avoid any pressure differential between the middle ear and inner ear hearing mechanisms and the surrounding environment of sound.

III. Therapeutic Considerations as it Relates to Ear Diseases

In some instances, disease renders the conductive mechanism non-functional and irreparable using medical/surgical restorative approaches (e.g. canalplasty, atresioplasty, tympanoplasty, or ossiculoplasty), thus the individual has permanent hearing loss. In these instances, the external auditory canal may be absent, closed, or severely deformed. Moreover, the TM and ossicular chain may also be unavailable for use or absent. In each case, conventional air conduction hearing aids will be unable to provide sufficient delivery of sound energy to the inner ear for the reasons previously discussed.

Similarly, the sensorineural mechanism (cochlea, auditory nerve and brain) can be damaged from diseases (congenital, traumatic, inflammatory or neoplastic), resulting in significant hearing loss on one side. In such cases, a conventional air conduction hearing aid is unable to provide sufficient sound energy input to the brain for interpretation.

In the former condition (i.e. conductive hearing loss), an option exists to deliver sound energy through the bone of the skull (i.e. bone conduction), bypassing the damaged or deficient ear canal, TM or ossicular chain, to activate the cochlea and restore hearing for these patients. This procedure reestablishes the amplifying and transfer functions that a normal middle ear performs. For the unilateral sensorineural hearing-impaired patients, sound can also be passed through the bone of the skull, to activate the functioning cochlea on the opposite side of the head. In this instance, patients can have better hearing in noise on the deaf ear side. The preferred treatment option for both conductive and unilateral sensorineural hearing loss will vary depending on the patient's anatomy and underlying condition and is best deciphered by the treating physician together with the patient. Importantly, in some patients (e.g., patients with irreparable middle ear damage), the only treatment option will be use of a bone conducting auditory prosthetic.

IV. CMS Proposed Policy Change

“The hearing aid exclusion” statute excludes the coverage for hearing aids. CMS has the latitude to interpret this statute through policy as below:

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or B for any expenses incurred for items or services “where such expenses are

for...hearing aids or examinations therefore...” This policy is further reiterated at the 42 CFR 411.15(d) below and included in the proposed rule:

§ 411.15 Particular services excluded from coverage.

(d) Hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids

- (1) ***Proposed Rule Scope.*** The scope of the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, and implanted).
- (2) ***Devices not subject to the hearing aid exclusion.*** Cochlear Implants and auditory brainstem implants that replace the function of the cochlear structure or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays. These devices produce the perception of sound and do not meet the definition of hearing aid.

Since 2006, the Medicare Benefit Policy Manual definition of hearing aids has been the following:

“Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.”

CMS policy states: “Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.”

V. Suggested Alternative to Proposed Rule

In response to the proposed rule, we propose that a hearing aid is an amplifying device that compensates for impaired hearing. Hearing aids include air conduction devices that provide amplified acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include non-osseointegrated bone conduction devices that provide amplified mechanical energy to the cochlea via ***indiscriminate*** stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

An osseointegrated implant is clearly a prosthesis, as defined by CMS which is supportable and reasonable. It replaces the missing or non-functional organ or component

of part of the hearing system in the body. It replaces the conductive mechanism of the external auditory canal, TM, and/or ossicular chain in cases where these structures are not available or are non-functional. ***These devices are used only when use of a hearing aid is either not possible or has been ineffective in providing adequate auditory information.*** Examples of when a hearing aid is not possible include but are not limited to: absent or deformed external ear, pinna, or ear canal; absent or perforated TM; open mastoid cavity; chronic infection; or large or inflamed meatus (opening of the ear canal to the outside world that cannot be fit). Conditions in which a hearing aid is ineffective in providing adequate auditory information could include but are not limited to instances such as a lack of satisfactory gain, intolerable or persistent feedback, non-function of one cochlea, ear canal occlusion, related infection, chronic otorrhea (drainage from the ear, usually infected), edema, chronic dermatitis of the ear canal and/or ear canal opening, and chronic pain related to device retaining bands.

Osseointegrated implantable devices are able to mitigate many or all of these factors that make air conduction or bone conduction hearing aids that are applied indiscriminately to the skin surface unusable. The osseointegrated implant is physically and functionally distinguishable from a bone-conduction hearing aid in that they: (1) are **never** retained by a headband, and (2) supply **focused** stimulation to the temporal bone structures through an implant that is physically integrated (osseointegrated) into the bone of the skull. The purpose of the osseointegrated implant is to replace the function of an absent or diseased body part (i.e., a prosthesis). In many instances, these are the only options for hearing restoration for some patients.

The medical literature strongly supports the viability of osseointegrated implants as safe, effective, and cost-effective, for patients (12-109). Osseointegrated implants improve hearing for patients with bilateral conductive hearing loss, mixed hearing losses, and single sided deafness. A recent clinical trial also clearly shows that osseointegration of an implant provides improved patient hearing performance over conventional bone-conduction hearing aid that use only a headband (Reference Note 1).

In addition, from an economic and patient outcomes/safety/satisfaction perspective, for patients that have failed previous surgical attempts at hearing reconstruction using conventional techniques, it potentially makes better sense for Medicare to provide osseointegrated implants for these patients indicated only after careful and thorough evaluation by an otolaryngologist-head & neck surgeon in lieu of repeated, costly traditional surgical attempts without an osseointegrated implant. In other words, the lack of coverage may have the unintended consequence of incentivizing revision surgical encounters. In fact, recent literature looking at the cost of care for such patients suggests an opportunity for cost savings, improved performance and quality of life using a paradigm based on implantable devices. (110).

On behalf of our patients, we therefore respectfully request that CMS adhere to carefully crafted and defensible definitions it has followed since 2006 (with minor modification as above), providing needed help to those patients who require these implants and **do not** benefit from hearing aids.

VI. Conclusion

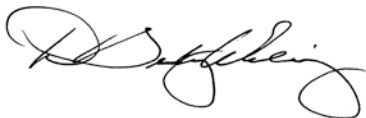
We thank you for the opportunity to provide our comments and concerns with respect to the proposed change to the scope of the hearing aid coverage exclusion and our suggested alternative to the proposal. The AAO-HNS, AOS, and ANS physician leaders and staff have met with leadership at CMS and we strongly urge HHS to ensure the proposed rule includes the necessary changes prior to final rule publication so that Medicare patients with appropriate medical indications receive needed treatment. We would welcome the opportunity to meet with you directly to answer any questions you may have regarding our comments. If you require further information, please contact Jenna Kappel, MPH, MA, Director of Health Policy at jkappel@entnet.org or 703-535-3724.

Thank you for your attention to this matter.

Sincerely,



David R. Nielsen, MD, FACS
Executive Vice President and CEO
American Academy of Otolaryngology – Head and Neck Surgery



D. Brad Welling, MD, PhD
President
American Otological Society



Anil K. Lalwani, MD
President
American Neurotology Society

Cc: Craig Buchman, MD, AAO-HNS Chair, Implantable Hearing Devices Committee

Douglas D. Backous, MD, AAO-HNS Chair, Hearing Committee

References

1. Gispén FE, Chen DS, Genther DJ, Lin FR. Association Between Hearing Impairment and Lower Levels of Physical Activity in Older Adults. *J Am Geriatr Soc*. 2014 Jul 15. doi: 10.1111/jgs.12938. [Epub ahead of print] PubMed PMID: 25041032.
2. Genther DJ, Betz J, Pratt S, et al; for the Health ABC Study. Association of Hearing Impairment and Mortality in Older Adults. *J Gerontol A Biol Sci Med Sci*. 2014 Jul 14. pii: glu094. [Epub ahead of print] PubMed PMID:25024235.
3. Albers MW, Gilmore GC, Kaye J, et al At the interface of sensory and motor dysfunctions and Alzheimer's disease. *Alzheimers Dement*. 2014 Jul 8. pii: S1552-5260(14)00642-6. doi:10.1016/j.jalz.2014.04.514. [Epub ahead of print] Review. PubMed PMID: 25022540.
4. Foley DM, Frick KD, Lin FR. Association between hearing loss and healthcare expenditures in older adults. *J Am Geriatr Soc*. 2014 Jun;62(6):1188-9. doi: 10.1111/jgs.12864. PubMed PMID: 24925555; PubMed Central PMCID: PMC4058650.
5. Kamil RJ, Li L, Lin FR. Association between hearing impairment and frailty in older adults. *J Am Geriatr Soc*. 2014 Jun;62(6):1186-8. Doi 10.1111/jgs.12860. PubMed PMID: 24925554.
6. Lin FR, Albert M. Hearing loss and dementia - who is listening? *Aging Ment Health*. 2014;18(6):671-3. doi: 10.1080/13607863.2014.915924. PubMed PMID: 24875093; PubMed Central PMCID: PMC4075051.
7. Chen DS, Genther DJ, Betz J, Lin FR. Association between hearing impairment and self-reported difficulty in physical functioning. *J Am Geriatr Soc*. 2014 May;62(5):850-6. doi: 10.1111/jgs.12800. Epub 2014 Apr 29. PubMed PMID: 24779559; PubMed Central PMCID: PMC4084895.
8. Contrera KJ, Choi JS, Blake CR, Betz JF, Niparko JK, Lin FR. Rates of long-term cochlear implant use in children. *Otol Neurotol*. 2014 Mar;35(3):426-30. doi: 10.1097/MAO.0000000000000243. PubMed PMID: 24518403; PubMed Central PMCID:PMC3927162.
9. Mick P, Kawachi I, Lin FR. The association between hearing loss and social isolation in older adults. *Otolaryngol Head Neck Surg*. 2014 Mar;150(3):378-84. doi: 10.1177/0194599813518021. Epub 2014 Jan 2. PubMed PMID: 24384545.
10. Mener DJ, Betz J, Genther DJ, Chen D, Lin FR. Hearing loss and depression in older adults. *J Am Geriatr Soc*. 2013 Sep;61(9):1627-9. doi: 10.1111/jgs.12429. PubMed PMID: 24028365; PubMed Central PMCID: PMC3773611.
11. Genther DJ, Frick KD, Chen D, Betz J, Lin FR. Association of hearing loss with hospitalization and burden of disease in older adults. *JAMA*. 2013 Jun 12;309(22):2322-4. doi: 10.1001/jama.2013.5912. PubMed PMID 23757078; PubMed Central PMCID: PMC3875309.
12. Boleas-Aguirre MS, Bulnes Plano MD, de Erenchun Lasa IR, Ibáñez Beroiz B. Audiological and subjective benefit results in bone-anchored hearing device users. *Otol Neurotol*. 2012 Jun;33(4):494-503.
13. Lekue A, Lassaletta L, Sánchez-Camón I, Pérez-Mora R, Gavilán J. Quality of life in patients implanted with the BAHA device depending on the aetiology. *Acta Otorrinolaringol Esp*. 2012 Aug 9.

14. Flynn MC, Hillbratt M. Improving the Accuracy of Baha® Fittings through Measures of Direct Bone Conduction. *Clinical and Experimental Otorhinolaryngology* Vol. 5, Suppl 1: S43-S47.
15. Okonkwo OC, Beech TJ, Jindal M. Re: The importance of an extended preoperative trial of BAHA in unilateral sensorineural hearing loss: a prospective cohort. *Clin Otolaryngol*. 2012 Feb;37(1):78-9; author reply 79-80. doi: 10.1111/j.1749-4486.2012.02432.x
16. Snapp H, Angeli S, Telischi FF, Fabry D. Postoperative validation of bone-anchored implants in the single-sided deafness population. *Otol Neurotol*. 2012 Apr;33(3):291-6.
17. Heywood RL, Patel PM, Jonathan DA. Comparison of hearing thresholds obtained with Baha preoperative assessment tools and those obtained with the osseointegrated implant. *Ear Nose Throat J*. 2011 May;90(5):E21-7.
18. Rahne T, Böhme L, Götze G. Influence of implantable hearing AIDS and neuroprosthesis on music perception. *ScientificWorldJournal*. 2012;2012:404590. Epub 2012 May 3.
19. Szyfter W, Borucki L, Dobosz P, Domka W, Drela M, Gawęcki W, Gibasiewicz R, Grajewski G, Horbacz-Jary G, Iciek WM, Jankowski A, Jurkiewicz D, Kibiłda B, Kida M, Komar D, Kuśmierczyk J, Maron K, Matuszczyk T, Mierzwa T, Mierzwiński J, Olszewska E, Przytuła-Kandzia K, Pyd M, Stankiewicz C, Stieler M, Slaska-Kaspera A, Wróbel M, Zadroźniak M. Epidemiological and demographic analysis of indications for Baha(®) surgery in Poland - multicenter study. *Otolaryngol Pol*. 2012 Jul;66(4):285-290. Epub 2012 May 11.
20. Agterberg MJ, Snik AF, Hol MK, Van Wanrooij MM, Van Opstal AJ. Contribution of monaural and binaural cues to sound localization in listeners with acquired unilateral conductive hearing loss – improved directional hearing with a bone conduction device. *Hear Res*. 2012 Apr;286(1-2):9-18.
21. Pfiffner F, Caversaccio MD, Kompis M. Audiological results with Baha in conductive and mixed hearing loss. *Adv Otorhinolaryngol*. 2011;71:73-83. Epub 2011 Mar 8.
22. van Wieringen A, De Voecht K, Bosman AJ, Wouters J. Functional benefit of the bone-anchored hearing aid with different auditory profiles: objective and subjective measures. 2011 Apr;36(2):114-20. doi: 10.1111/j.1749-4486.2011.02302.x.
23. Saroul N, Gilain L, Montalban A, Giraudet F, Avan P, Mom T. Patient satisfaction and functional results with the bone-anchored hearing aid (BAHA). *Eur Ann Otorhinolaryngol Head Neck Dis*. 2011 Jun;128(3):107-13. Epub 2011 May 20.
24. Pfiffner F, Kompis M, Stieger C. Bone-Anchored Hearing Aids: Correlation Between Pure-Tone Thresholds and Outcome in Three User Groups. *Otol Neurotol*. 2009 Sep 2. [Epub ahead of print]
25. Mylanus EA, Snik AF, Cremers CW. Patients' opinions of bone-anchored vs conventional hearing aids *Archives of Otolaryngology Head Neck Surgery*, 1995 Apr;121(4):421-5
26. Liepert DR, Di Toppa JC. The Nobelpharma auditory system bone-anchored hearing aid: the Edmonton experience *The Journal of Otolaryngology*, 1994 Dec;23(6):411-8
27. Hedegaard J, Salomon G, Bonding P. The bone-anchored hearing aid - measurements of the clinical function. *Journal of Audiological Medicine*, 2, 175-187, 1993.
28. Abramson M, Fay TH, Kelly JP, Wazen JJ, Liden G, Tjellström A. Clinical results with a percutaneous bone-anchored hearing aid. *Laryngoscope*. 1989 Jul;99(7 Pt 1):707-10.
29. Hultcrantz M(1), Lanis A. A Five-Year Follow-up on the Osseointegration of Bone-Anchored Hearing Device Implantation without Tissue Reduction *Otol Neurotol*. 2014 Apr 24. [Epub

ahead of print

General Articles

30. Flynn MC Challenges and recent developments in sound processing for Baha®. Flynn MC. *Adv Otorhinolaryngol.* 2011;71:112-23. Epub 2011 Mar 8.
31. Dun CA, Faber HT, de Wolf MJ, Cremers CW, Hol MK An overview of different systems: the bone-anchored hearing aid. Dun CA, Faber HT, de Wolf MJ, Cremers CW, Hol MK. *Adv Otorhinolaryngol.* 2011;71:22-31. Epub 2011 Mar 8.
32. Bovo R, Prosser S, Ortore RP, Martini A. Speech recognition with BAHA simulator in subjects with acquired unilateral sensorineural hearing loss.. *Acta Otolaryngol.* 2011 Jun;131(6):633-9. Epub 2011 Jan 31.
33. Ghossani SN, Spitzer JB, Borik J. Use of the bone-anchored hearing cochlear stimulator (Baha) and satisfaction among long-term users. *Seminars in hearing* 2010 31(1):3-14.
34. Hodgetts WE, Hagler P, Hakansson BE, Soli SD. Technology-Limited and Patient-Derived Versus Audibility-Derived Fittings in Bone-Anchored Hearing Aid Users: A Validation Study. *Ear Hear.* 2010 Sep 8.
35. de Wolf MJ, Shival ML, Hol MK, Mylanus EA, Cremers CW, Snik AF. Benefit and quality of life in older bone-anchored hearing aid users. *Otol Neurotol.* 2010 Jul;31(5):766-72.
36. Dumper J, Hodgetts B, Liu R, Brandner N Indications for bone-anchored hearing AIDS: a functional outcomes study *J Otolaryngol Head Neck Surg.* 2009 Feb;38(1):96-105
37. Monroy B, Juan F, Jaramillo S, Rafael P, Dunia P, Josoe A, Josoe , Lora F, Josoe G First Two Years of Experience With BAHA: Results in 12 Patients. *Acta Otorrinolaringol Esp.*
38. Soanchez-Camoon I, Lassaletta L, Castro A, Gaviloan J Quality of life of patients with Baha *Acta Otorrinolaringol Esp* 2007 Aug-Sep, Vol 58, no 7, pp. 316-320.
39. Forton GEJ, Van De Heyning PH. Bone anchored hearing aids (BAHA) *B-ENT* 2007, 3, Suppl 6, 45-50.
40. Goodyear PW, Raine CH, Firth AL, Tucker AG, Hawkins K. The Bradford bone-anchored hearing aid programme: impact of the multidisciplinary team. *J Laryngol Otol.* 2006 Jul;120(7):543-52.
41. Johnson CE, Danhauer JL, Reith AC, Latiolais LN A systematic review of the nonacoustic benefits of bone-anchored hearing AIDS *Ear Hear.* 2006 Dec;27(6):703-13.
42. Burkey JM, Berenholz LP, Lippy WH, Lippy Latent demand for the bone-anchored hearing aid the Lippy Group experience. *Otol Neurotol,* August 1, 2006; 27(5): 648-52.
43. Thill MP, Lurquin P, Lambert O, Vincent Y. Baha: an efficient aid for treatment of tinnitus patients with a dead ear. *J Laryngol Otol* 2008 Dec 122 (12) 1368-70.
44. Zelachowska M, Pietruszka D Application and usage of the bone anchored hearing aid. *Otolaryngol Pol,* Vol 58 No. 3, 2004.
45. Kadhim A, Colreavy MP, O'Donovan C, Blayney A Bone anchored hearing aids: Reality, failure and current status *Ir Med J.* 2004 Nov-Dec;97(10):312-4.
46. Hol MK, Spath M, Krabbe P, van der Pouw CT, Snik AF, Cremers CW, Mylanus EA The Bone-Anchored Hearing Aid: Quality-of-Life Assessment *Archives of Otolaryngology Head & Neck Surgery,* April 2004;130:394-399.
47. Habal M, Frans N, Zelski R, Scheuerle J Percutaneous bone anchored hearing aid *J Craniofac Surg.* 2003 Sep;14(5):637-42.
48. Hill P, Norman G, Davison T, Andrew R, Shanks M, Johnson I, Burrell S, Reid A, Archbold S. Adult bone anchored hearing aid services in the United Kingdom: Building a consensus for

- development. *Cochlear Implants Int.* 2012 Nov;13(4):228-36.
49. Finley EJ. Bone anchored hearing devices. *NASN Sch Nurse.* 2011 Nov;26(6):338-9.
 50. Tjellström A. Bone anchored hearing aids from a test project to an established clinical routine. *ENT & Audiology news Vol 19 No 1 2010.*
 51. Spitzer J, Ghossaini S, Wazen JJ. Evolving Applications in the Use of Bone-Anchored Hearing Aids *American Journal of Audiology,* 2002;11(2):96-103.
 52. Burrell SP, Cooper HR, Mcdermott AL, Donaldson I, Dutt SN, Irving RM, Jelbert A, Pahor AL, Proops DW, Reid AP, Tziambazis A It works - the patients say so: the evidence base for aural rehabilitation with bone-anchored hearing aids *Journal of Laryngology & Otology ,* 2002;116(6) Supplement 28.
 53. Tjellström A, Håkansson B, Granström G Bone-anchored hearing aids: current status in adults and children *Otolaryngol Clin North Am.* 2001 Apr;34(2):337-64.
 54. Portmann D, Dutkiewicz J, Boudard P. The use of osseointegration of hearing aids. *Otolaryngol Pol,* Vol 49 No. 6, 1995.
 55. Rydzewski B, Pruszewicz A, Szmeja Z, Chmielecka K The application and usage of the bone-anchored hearing aids (BAHA) *Otolaryngol Pol,* Vol 48 No. 6, 1994.

Bilateral Fitting

56. 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 Jun 19. [Epub ahead of print].
57. Colquitt JL, Loveman E, Baguley DM, Mitchell TE, Sheehan PZ, Harris P, Proops DW, Jones J, Clegg AJ, Welch K. Bone-anchored hearing aids for people with bilateral hearing impairment: a systematic review. *Clin Otolaryngol.* 2011 Aug 4. doi: 10.1111/j.1749-4486.2011.02376.x.
58. Colquitt JL, Jones J, Harris P, Loveman E, Bird A, Clegg AJ, Baguley DM, Proops DW, Mitchell TE, Sheehan PZ, Welch K. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. *Health Technol Assess.* 2011 Jul;15(26):1-200, iii-iv.
59. Ho EC, Monksfield P, Egan E, Reid A, Proops D Bilateral Bone-Anchored Hearing Aid: Impact on Quality of Life Measured With the Glasgow Benefit Inventory. *Otol Neurotol.* 2009 Aug 19. [Epub ahead of print]
60. Priwin C, Stenfelt S, Granström G, Tjellström A, Håkansson B Bilateral Bone-Anchored Hearing Aids (BAHAs): An Audiometric Evaluation *The Laryngoscope* 2004; 114(1):77-84.
61. Dutt SN, McDermott AL, Burrell SP, Cooper HR, Reid AP, Proops DW Speech intelligibility with bilateral bone-anchored hearing aids: the Birmingham experience. *J Laryngol Otol Suppl,* June 1, 2002; : 47-51.
62. Burrell SP, Cooper HR, Reid AP, Proops DW Patient satisfaction with Bilateral bone-anchored hearing aids: the Birmingham experience. *J Laryngol Otol Suppl,* June 1, 2002; 37-46.
63. van der Pouw CT, Snik AF, Cremers CW Audiometric results of bilateral bone-anchored hearing aid application in patients with bilateral congenital aural atresia *The Laryngoscope,* 1998;108(4 Pt 1):548-53.

Mixed Conductive Hearing Loss

64. Orús Dotú C, Santa Cruz Ruíz S, De Juan Beltrán J, Batuecas Caletrio A, Venegas Pizarro

- Mdel P, Muñoz Herrera A. Treatment of severe to profound mixed hearing loss with the BAHHA Cordelle II. *Acta Otorrinolaringol Esp.* 2011 May-Jun;62(3):205-12. Epub 2011 Feb 5.
65. Agterberg MJ, Snik AF, Hol MK, van Esch TE, Cremers CW, Van Wanrooij MM, Van Opstal AJ. Improved Horizontal Directional Hearing in Bone Conduction Device Users with Acquired Unilateral Conductive Hearing Loss. *J Assoc Res Otolaryngol.* 2010 Sep 14. [Epub ahead of print]
 66. Verhaegen VJ, Mulder JJ, Mylanus EA, Cremers CW, Snik AF. Profound mixed hearing loss: bone-anchored hearing aid system or cochlear implant? *Ann Otol Rhinol Laryngol.* 2009 Oct;118(10):693-7.
 67. Flynn MC, Sadeghi A, Halvarsson G Baha solutions for patients with severe mixed hearing loss *Cochlear Implants Int.* 2009 Feb 4. [Epub ahead of print]
 68. Pffiffner F, Caversaccio MD, Kompis M. Audiological results with Baha in conductive and mixed hearing loss. *Adv Otorhinolaryngol.* 2011;71:73-83. Epub 2011 Mar 8.
 69. Watson GJ, Silva S, Lawless T, Harling JL, Sheehan PZ Bone anchored hearing aids: a preliminary assessment of the impact on outpatients and cost when rehabilitating hearing in chronic suppurative otitis media *Clin. Otolaryngol.* 2008, 33, 338–342.
 70. Kunst SJ, Hol MK, Mylanus EA, Leijendeckers JM, Snik AF, Cremers CW Subjective benefit after BAHHA system application in patients with congenital unilateral conductive hearing impairment. *Otol Neurotol,* April 1, 2008; 29(3): 353-58.
 71. Kunst SJ, Leijendeckers JM, Mylanus EA, Hol MK, Snik AF, Cremers CW Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results *Otol Neurotol Vol 29, 1,* 2008 Jan, 2-7
 72. Hol MK, Snik AF, Mylanus EA, Cremers CW Does the Bone anchored hearing aid have a complementary effect on audiological and subjective outcomes in patients with unilateral conductive hearing loss? *Audiol Neurootol* 2005 May-Jun; 10(3):159-68.
 73. Snik AF, Bosman AJ, Mylanus EA, Cremers CW. Candidacy for the Bone-Anchored Hearing Aid. *Audiology & Neuro Otology,* 2004 Jul-Aug;9(4):190-6.

Single-Sided-Deafness

74. Kuppler K, Lewis M, Evans AK. A review of unilateral hearing loss and academic performance: is it time to reassess traditional dogmata? *Int J Pediatr Otorhinolaryngol.* 2013 May;77(5):617-22.
75. Nicolas S, Mohamed A, Yoann P, Laurent G, Thierry M. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. *Otol Neurotol.* 2013 Jan;34(1):111-4. doi: 10.1097/MAO.0b013e31827a2020.
76. Wesarg T, Aschendorff A, Laszig R, Beck R, Schild C, Hassepass F, Kroeger S, Hocke T, Arndt S. Comparison of speech discrimination in noise and directional hearing with 2 different sound processors of a bone-anchored hearing system in adults with unilateral severe or profound sensorineural hearing loss. *Otol Neurotol.* 2013 Aug;34(6):1064-70.
77. Faber HT, de Wolf MJ, Cremers CW, Snik AF, Hol MK. Benefit of Baha in the elderly with single-sided deafness. *Eur Arch Otorhinolaryngol.* 2013 Mar;270(4):1285-91. doi: 10.1007/s00405-012-2151-z. Epub 2012 Aug 19.
78. Doshi J, Banga R, Child A, Lawrence R, Reid A, Proops D, McDermott AL. Quality-of-life outcomes after bone-anchored hearing device surgery in children with single-sided sensorineural deafness. *Otol Neurotol.* 2013 Jan;34(1):100-3. doi:

10.1097/MAO.0b013e318277a3dd.

79. Faber HT, Kievit H, de Wolf MJ, Cremers CW, Snik AF, Hol MK. Analysis of factors predicting the success of the bone conduction device headband trial in patients with single-sided deafness. *Arch Otolaryngol Head Neck Surg*. 2012 Dec 1;138(12):1129-35. doi: 10.1001/jamaoto.2013.754.
80. 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 Jul;147(1):105-11. Epub 2012 Feb 24.
81. Pai I, Kelleher C, Nunn T, Pathak N, Jindal M, O'Connor AF, Jiang D. Outcome of bone-anchored hearing aids for single-sided deafness: A prospective study. *Acta Otolaryngol*. 2012 Apr 12. [Epub ahead of print].
82. Saliba I, Nader ME, Fata FE, Leroux T. Bone anchored hearing aid in single sided deafness: Outcome in right-handed patients. *Auris Nasus Larynx*. 2011 Feb 11. [Epub ahead of print].
83. Saroul N, Akkari M, Pavier Y, Gilain L, Mom T. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. *Otol Neurotol*. 2013 Jan;34(1): 111-4. Doi: 10.1097/MAO.0b013e31827a2020.
84. Wazen JJ, Spitzer J, Ghossaini S, Fayad J, Niparko JK, Cox K, Brackmann D, Soli S. Transcranial contralateral cochlear stimulation in unilateral deafness. *Otolaryngology Head & Neck Surgery*, 2003; 129(3):248-54.
85. Wazen JJ, Van Ess MJ, Alameda J, Ortega C, Modisett M, Pinsky K. The Baha system in patients with single-sided deafness and contralateral hearing loss. *Otolaryngol Head Neck Surg*. 2010 Apr;142(4):554-9.

86. Pediatric Use of Osseointegrated Devices

87. Marsella P, Scorpecci A, D'Eredità R, Della Volpe A, Malerba P. Stability of osseointegrated bone conduction systems in children: a pilot study. *Otol Neurotol*. 2012 Jul;33(5):797-803.
88. Doshi J, Sheehan P, McDermott AL. Bone anchored hearing aids in children-an update. *Int J Pediatr Otorhinolaryngol*. 2012 Mar 3 Epub.
89. Saliba I, Froehlich P, Bouhabel S. One-stage vs. two-stage BAHA implantation in a pediatric population. *Int J Pediatr Otorhinolaryngol*. 2012 Dec;76(12):1814-8. doi: 10.1016/j.ijporl.2012.09.007. Epub 2012 Sep 23.
90. Marsella P, Scorpecci A, Pacifico C, Presuttari F, Bottero S. Pediatric BAHA in Italy: the "Bambino Gesù" Children's Hospital's experience. Marsella P, Scorpecci A, Pacifico C, Presuttari F, Bottero S. *Eur Arch Otorhinolaryngol*. 2011 Jul 8.
91. Roman S, Nicollas R, Triglia JM. Practice guidelines for bone-anchored hearing aids in children. *Eur Ann Otorhinolaryngol Head Neck Dis*. 2011 Nov;128(5):253-8. Epub 2011 Sep 28.
92. McDermott AL, Sheehan P. Paediatric Baha. *Adv Otorhinolaryngol*. 2011;71:56-62. Epub 2011 Mar 8.
93. de Wolf MJ, Hol MK, Mylanus EA, Snik AF, Cremers CW. Benefit and quality of life after bone anchored hearing aid fitting in children with unilateral or bilateral hearing impairment. *ARCH OTOLARYNGOL HEAD NECK SURG/VOL 137 (NO. 2), FEB 2011*.
94. Nicholson N, Christensen L, Dornhoffer J, Martin P, Smith-Olinde L. Verification of Speech Spectrum Audibility for Pediatric Baha Softband Users with Craniofacial Anomalies. *Cleft Palate Craniofac J*. 2010 Feb 22. [Epub ahead of print].

Device Performance

95. Flynn MC, Hedin A, Halvarsson G, Good T, Sadeghi A. Hearing Performance Benefits of a Programmable Power Baha® Sound Processor with a Directional Microphone for Patients with a Mixed Hearing Loss. *Clinical and Experimental Otorhinolaryngology* Vol. 5, Suppl 1: S76-S81.
96. Oeding K, Valente M, Kerckhoff J Effectiveness of the directional microphone in the Baha® Divino™. Oeding K, Valente M, Kerckhoff J. *J Am Acad Audiol.* 2010 Sep;21(8):546-57.
97. Christensen L, Smith-Olinde L, Kimberlain J, Richter GT, Dornhoffer JL. Comparison of traditional bone-conduction hearing aids with the Baha system. *J Am Acad Audiol.* 2010 Apr;21(4):267-73.
98. Lustig LR, Arts HA, Brackmann D, Francis HF, Molony T, Megerian CA, Moore GF, Moore KM, Morrow T, Potsic W, Rubenstein JT, Srireddy S, Syms CA, Takahashi G, Vernick D, Wackym PA, Niparko JK. Hearing rehabilitation using the BAHA bone-anchored hearing aid: results in 40 patients. *Otol Neurotol* May 1, 2001; 22(3): 328-34.
99. Lin LM, Bowditch S, Anderson MJ, May B, Cox K, Niparko JK 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 Feb;27(2):172-82.
100. Snik AF, Mylanus EA, Proops DW, Wolfaardt J, Hodgetts WA, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellström A Consensus statements on the BAHA system: Where do we stand at present? *Annals of Otology, Rhinology & Laryngology* Dec 2005; 114, 12 p2.
101. Kompis M, Kurz A, Pfiffner F, Senn P, Arnold A, Caversaccio M. Is complex signal processing for bone conduction hearing aids useful? *Cochlear Implants Int.* 2014 May;15 Suppl 1:S47-50.
102. Niparko JK, Cox K, 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

Cost Effectiveness

103. Badran K, Bunstone D, Arya AK, Suryanarayanan R, Mackinnon N. Patient satisfaction with the bone-anchored hearing aid: a 14-year experience. *Otol Neurotol.* 2006;27:659–66. [[PubMed](#)]
104. Dutt SN, McDermott AL et al. The Glasgow benefit inventory in the evaluation of patient satisfaction with the bone-anchored hearing aid: quality of life issues. [The Journal of Laryngology & Otology](#) / Volume 116 / Supplement S28 / June 2002, 7-14
105. Colquitt JL, Jones J, Harris P, Loveman E, Bird A, Clegg AJ, Baguley DM, Proops DW, Mitchell TE, Sheehan PZ, Welch K. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. *Health Technol Assess* 2011 Jul;15(26):1-200, iii-iv. doi: 10.3310/hta15260. Review.
106. Health Quality Ontario. Bone anchored hearing aid: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2002;2(3):1-47. Epub 2002 Sep 1. PMID: 23074440.
107. McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of

benefit by patient subgroups.

108. [Laryngoscope](#). 2004 May;114(5):942-4.
109. Watson GJ, Silva S, Lawless T, Harling JL, Sheehan PZ. Bone anchored hearing aids: a preliminary assessment of the impact on outpatients and cost when rehabilitating hearing in chronic suppurative otitis media. *Clin Otolaryngol*. 2008;33:338–42. [[PubMed](#)]
110. Roche JP, Adunka OF, Pillsbury HC 3rd, Buchman CA. Cost of cholesteatoma care at a tertiary medical center. *Otol Neurotol*. 2013 Sep;34(7):1311-5.

Reference Note

1. Luntz M, Cowan R, Van Hasselt A, Goycoolea M. Clinical performance of a transcutaneous bone conduction hearing solution (Cochlear™ Baha® Attract System). A multicenter, open, prospective clinical investigation. FINAL results after 9-months of follow-up. Presented at the 13th International Conference on Cochlear Implants and Other Implantable Auditory Technologies, Munich, Germany, June 18-21, 2014.