REVIEW
OTOLOGY
DOI: 10.5152/B-ENT.2023.21692

Consensus Statement on the Treatment with Implantable Bone Conducting Hearing Devices in Belgium

Annes Julia Claes[1], Rajae Bouzegta[2], Naïma Deggouj[3,4], Katleen De Voecht[5], Miek Devos[6], Ingeborg Dhooge[7,8], Pierre Dolhen[9], Paula Greenham[10], Sebastien Janssens de Varebeke[11,12], Bob Lerut[13], Maarten Rosseel[14], Vincent Van Rompaey[2,12], Nicolas Verhaert[15,16]

[1]Cochlear Benelux nv, Mechelen, Belgium
[2]Department of Otorhinolaryngology, Head and Neck Surgery, Antwerp University Hospital, Antwerp, Belgium
[3]Department of Otorhinolaryngology, Head and Neck Surgery, Cliniques universitaires Saint-Luc, Brussels, Belgium
[4]Audio-Phonological Center, Université Catholique de Louvain, Brussels, Belgium
[5]MUCLA, University Hospitals Leuven, Leuven, Belgium
[6]Amplifon, University Hospital Ghent, Ghent, Belgium
[7]Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Ghent, Ghent, Belgium
[8]Department of Otorhinolaryngology and Logopaedic-Audiologic Sciences, Ghent University Faculty of Medicine and Health Sciences, Ghent, Belgium
[9]Department of Otorhinolaryngology, Tivoli University Hospital, La Louvière, Belgium
[10]Greenham Research Consulting Ltd., Ashbury, UK
[11]Department of ENT Head and Neck Surgery, Jessa Hospital, Campus Virga Jesse, Hasselt, Belgium
[12]Department of Translational Neurosciences, University of Antwerp Faculty of Medicine and Health Sciences, Antwerp, Belgium
[13]Department of Otorhinolaryngology, Head and Neck Surgery, AZ Sint Jan Brugge-Oostende AV, Bruges, Belgium
[14]Department of Otorhinolaryngology, Ziekenhuis Oost Limburg, Genk, Belgium
[15]Department of Otorhinolaryngology, Head and Neck Surgery, University Hospitals Leuven, Leuven, Belgium
[16]Department of Neurosciences, KU Leuven, University of Leuven, ExpORL, Leuven, Belgium

Cite this article as: Claes AJ, Bouzegta R, Deggouj N, et al. Consensus statement on the treatment with implantable bone conducting hearing devices in belgium. *B-ENT*. 2023;19(2):127-133.

ABSTRACT

To provide guiding principles to deliver high-quality treatment with implantable bone conducting hearing devices and to guarantee the best possible outcomes for each patient in Belgium. A consensus meeting was convened on March 26, 2019, including surgeons and audiologists from different bone conducting hearing devices hospitals and fitting centers in Belgium, and an independent moderator. First, different care models for treatment with bone conducting hearing devices, currently applied in Belgium, were identified and discussed. It was agreed that bone conducting hearing devices surgery and fitting should be provided by clinicians with adequate training and experience and that bone conducting hearing devices care should be centralized as much as possible. Preferably sound processor fitting is carried out within the bone conducting hearing devices hospital or at a specialized fitting center outside the hospital. In any case, a close interdisciplinary collaboration between both the bone conducting hearing devices surgeon and the bone conducting hearing devices audiologist was considered critical to ensure good patient outcomes (e.g., to facilitate appropriate treatment in the event of complications). Second, general guidelines were debated and agreed upon to improve the quality of care for the different phases of the patient journey (referral, assessment, treatment, and follow-up). Providing a standard of care means that every person, regardless of the type or degree of hearing loss, the region in which they reside and the healthcare professional they see, has access to a standardized assessment and treatment process, resulting in the most efficient hearing solution for his or her indication. This consensus statement was a first step towards a more standardized approach for treatments with bone conducting hearing devices in Belgium.

Keywords: Audiologist, bone conducting hearing device, bone conduction, consensus, otologist, standard of care

Corresponding author: Annes Julia Claes, e-mail: aclaes@cochlear.com
Received: January 5, 2022 **Accepted:** October 3, 2022 **Publication Date:** April 27, 2023
Available online at www.b-ent.be

Introduction

Up to 24% of individuals fitted with conventional hearing aids (HAs) do not wear them.[1-3] The main reasons for non-use of HAs appear to be poor benefit and lack of comfort with the devices. Remarkably, it was also found that more than 1 out of 20 non-users experienced problems at the external ear (e.g., otitis externa and ear wax) or were fitted with HAs not suitable for the individual's *type* of hearing loss, impeding them from using the devices.[3] In these cases, a treatment with *bone conducting hearing devices* (BCHDs) instead of conventional HAs could be the preferred solution, possibly resulting in better sound quality and less skin issues and infections in the external ear. Untreated (or ineffectively treated) hearing loss does not only result in communicative disabilities, it is also associated with social isolation, decrease in quality of life, depression, cognitive decline, and dementia.[4-7] Providing timely and effective treatment for hearing loss may mitigate some of these consequences and is, therefore, of utmost importance.[8-10]

Bone conducting hearing devices capture sound waves and transform them into mechanical *vibrations*, which are transferred through the skull bone to the cochlea, bypassing the outer and middle ear. Many types of BCHD exist, differing greatly in terms of appearance and size, maximum power output, coupling of the bone conductor to the skull, etc. This article focuses on the use of *implantable* BCHDs, consisting of an externally worn sound processor connected to a bone-anchored implant either by an abutment (*percutaneous* coupling) or by a magnetic system (*transcutaneous* coupling). The sound processor can also be worn in a non-surgical manner, namely attached on a softband or another non-surgical wearing option (e.g., SoundArc). This is usually done during the trial period prior to implantation, or when implantation is not (yet) possible (e.g., in young children with thin skull bone).

BCHDs are indicated for individuals with *conductive ormixed hearing loss*, who cannot use conventional HAs (e.g., due to otitis externa or otitis media) or do not achieve sufficient benefit from them, and for individuals with *single sided deafness* (SSD). Common pathologies associated with conductive hearing loss are otitis media (with effusion), congenital malformations of the outer and/or middle ear (microtia or atresia), eardrum perforation, and otosclerosis. *SSD* can for instance be caused by a trauma, an acoustic neuroma, or a viral or bacterial infection. In Belgium, the internal parts (i.e., the implant and abutment/magnet) and external part (i.e., the sound processor) of a BCHD are reimbursed differently. If the patient meets certain criteria (e.g., air-bone gap $\geq$ 30 dB), the internal parts are completely reimbursed, whereas the sound processor is only partly reimbursed. The amount of reimbursement of the sound processor depends on the patient's age, the manner of coupling to the skull (bone-anchored or not), and whether it is a renewal of the sound processor or the first purchase.

According to data of the National Institute of Sickness and Disability Insurance (RIZIV/INAMI), 0.23% of reimbursed HAs in Belgium were BCHDs (period from March 2020 to March 2021). These numbers indicate that bone conduction care, unlike treatment with HAs, is *specialist* care. Moreover, Snik et al[11] concluded that the efficacy of implantable hearing solutions for patients with conductive and mixed hearing loss depends on the implant center providing the care, as demonstrated by the large variation in outcomes across centers. A standard of care for clinical purposes is therefore desired in order to ensure that the outcomes reached for each patient are as good as possible, irrespective of the implant and fitting center.

In recent years, various initiatives have been taken to establish a standard of care for the treatment with BCHDs. As an example, several consensus papers have been published by groups of clinicians, e.g. on bone-anchored hearing aid services in the United Kingdom of Great Britain and Northern Ireland (UK),[12] on the clinical application of the Baha system[13] and on quality standards for bone conduction implants.[14] Moreover, government organizations in several European countries have published quality guidelines for bone conduction treatment, such as the "Guideline for bone conduction devices" in the Netherlands[15] and the "Clinical commissioning policy on bone conducting hearing implants (BCHIs) for hearing loss (all ages)" by the National Health Service in the UK.[16] In the absence of government-driven guidelines in Belgium, there was a clear need to examine our current BCHD care models critically and to reflect on the implementation of existing, international consensus statements in Belgium.

Materials and Methods

In March 2019, a consensus meeting was convened in Diegem including 8 surgeons and 3 audiologists from academic and non-academic hospitals and fitting centers across Belgium specialized in BCHDs, and a moderator, co-author PG. The aim of the meeting was to discuss and agree on guiding principles to deliver high-quality bone conduction treatment in Belgium and to guarantee the best possible outcomes for each patient irrespective of the implant or fitting center.

The overall goal was twofold:

1. to identify the different care models for bone conduction treatment currently applied in Belgium and to make recommendations for improvement.
2. to reach a consensus on general guidelines to improve quality for the different phases of the patient journey, namely referral, medical and audiological assessment, treatment (consisting of surgery and activation of the sound processor), and medical and audiological follow-up.

This article is the result of discussions both during and after the consensus meeting.

Outcomes

Care Models for Bone Conduction Treatment

Current Care Models for Bone Conduction Treatment

The BCHD experts investigated the way in which bone conduction care is currently organized in Belgium. Whereas medical assessment, surgery, and medical follow-up are always performed in a hospital, the fitting of the sound processor and audiological follow-up may be provided in different types of settings, with varying relations to the BCHD hospital. Based on the setting where the sound processor is fitted and the relation to the hospital, 3 models have been distinguished:

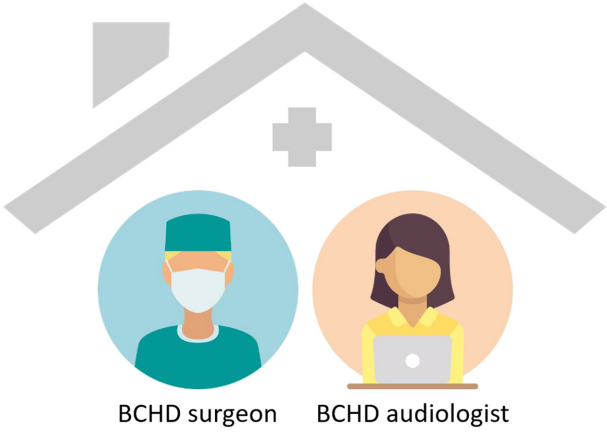

Figure 1. "BCHD in the hospital" model. (Icons are made by Roundicons and Freepik from www.flaticons.com.). BCHD, bone conducting hearing device.

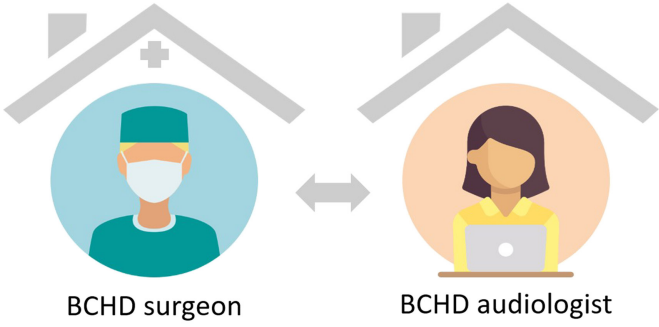

Figure 2. "Hospital plus specialist BCHD center" model. (Icons are made by Roundicons and Freepik from www.flaticons.com.). BCHD, bone conducting hearing device.

1. "BCHD in the hospital" model
   The ENT surgeon and the audiologist, both specialized in BCHDs, are based in the same hospital. Both the ENT services and the audiological services are provided in this BCHD hospital (Figure 1).
2. "Hospital plus specialist BCHD center" model
   Assessment, surgery, fitting, and follow-up are provided by a BCHD team consisting of a BCHD hospital and a specialist BCHD fitting center, which is located outside the clinic (Figure 2).
3. "Hospital plus multiple fitting centers" model
   Medical assessment, surgery, and medical follow-up are provided in a BCHD hospital and the initial audiological assessment, fitting and audiological follow-up is offered in one of multiple fitting centers located outside the clinic (Figure 3).

Definitions of terms are provided in Table 1.

Assessment of the 3 Care Models for Bone Conduction Treatment

The BCHD experts stated that, in accordance with Gavilan et al.[14] Snik et al.[13] and Hill et al.[12] the primary requirement for any BCHD service is to provide or have access to a *multidisciplinary* BCHD team consisting of an audiologist and an ENT surgeon, both specialized and experienced in BCHDs. It was argued that good collaboration between the audiologist and surgeon ensures efficient patient pathways and better patient outcomes in terms of hearing performance, complications, and satisfaction. The multidisciplinary team may be supplemented by a nurse, a psychologist, a speech therapist, or a social worker, depending on the needs of the patient. It was agreed that the members of a multidisciplinary BCHD team do not need to be present on the same site, although close and easy collaboration between BCHD audiology and ENT services is essential to obtain and maintain good patient outcomes throughout the different phases of the patient journey. Indeed, adequate and timely referral of BCHD candidates, optimal selection of the treatment, early identification of postoperative complications, etc. rely on close multidisciplinary collaboration.

The potential to provide an adequate level of service and quality of care to obtain and maintain good patient outcomes was evaluated for each of the 3 models. The "BCHD in the hospital" model was considered the most preferred model of care as this model guarantees the easiest flow of information and closest collaboration. If a specialized BCHD audiology service is not present in the hospital, the "hospital plus specialist BCHD center" model is perceived as a good alternative. Furthermore, it was reasoned that the "hospital plus multiple fitting centers" model is likely to offer the least certainty of good patient outcomes and is therefore discouraged. This is in line with the government guidance advice, stating that more centralization of care leads to a concentration of expertise and better outcomes.[17]

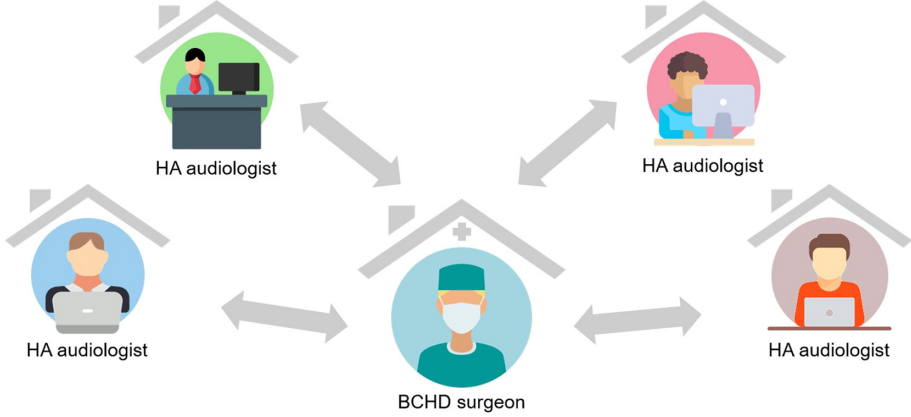

Figure 3. "Hospital plus multiple fitting centers" model. (Icons are made by Roundicons and Freepik from www.flaticons.com.). BCHD, bone conducting hearing device.

Table 1. Terms Used and Their Abbreviations

BCHD	Bone conducting hearing device, consisting of an external sound processor percutaneously or transcutaneously attached to an osseointegrated implant or worn as a non-surgical solution (e.g. sound processor on softband).
BCHD hospital	An institution which provides the medical assessment, surgery, and medical follow-up in relation to the BCHD. Some hospitals also have a specialist BCHD audiology service offering audiological assessment, BCHD fitting, and follow-up.
BCHD team	A multidisciplinary team consisting at least of an ENT surgeon and an audiologist, both specialized and experienced in BCHDs and collaborating closely to provide high-quality care to their patients. The audiological services can be provided within the BCHD hospital or outside the BCHD hospital by a closely collaborating BCHD audiologist.
Fitting center	A local fitting center or hearing aid shop that provides conventional hearing aids without specialist knowledge on and experience with BCHDs.

BCHD, bone conducting hearing device; ENT, ear, nose, throat

Recommendations

ENT surgeons and audiologists new to the field of BCHDs and aiming to provide BCHDs are encouraged to adopt the following recommendations:

ENT Surgeon The ENT surgeon's goal must be to offer ongoing, high-quality care to ensure good patient outcomes. Therefore, the ENT surgeon should have access to training as well as guidance from skilled colleagues in order to gain experience with candidate selection, surgery, postoperative treatment, etc. Furthermore, it is recommended to attend at least one specialized BCHD course every 3 years. In addition, the ENT surgeon should be able to perform a sufficient number of BCHD implantations per year to maintain medical and surgical competence, remain up to date with new techniques and products, and justify the purchase of operating equipment. Finally, close collaboration with an audiologist specialized in BCHDs is essential for sustained, high-quality patient care.

Audiologist By analogy with the ENT surgeon, the goal of the audiologist must be to offer ongoing, high-quality care to ensure good patient outcomes. Therefore, adequate knowledge and experience are needed, which can be acquired through formal and practical (product) training and guidance from competent BCHD audiologists. To maintain audiological competency and remain up to date with the latest fitting recommendations and technical solutions, the audiologist should provide fittings to an adequate number of BCHD recipients per year and is also advised to attend at least one specialized BCHD course every 3 years. Finally, close collaboration with an ENT surgeon specialized in BCHDs is crucial.

Bone Conducting Hearing Devices Team As well as providing appropriate patient selection, excellent surgical care, and fitting, BCHD teams must be competent to address reimbursement issues, audiological issues, wound healing problems, revision surgery, and preoperative and postoperative counseling. Multidisciplinary BCHD teams are expected to monitor the quality of their service provision by collecting routine data on patient outcomes, including data on hearing outcomes, patient satisfaction, surgical complications, and infection rates.

General Guidelines to Improve Quality of BC Care along the Patient Journey

Referral

In contrary to several other European countries such as the Netherlands and the UK, there are no government-driven standard referral criteria for BCHDs in Belgium. A patient can be referred to a specialist BCHD hospital via several pathways, including

- an ENT doctor who does not provide BCHD care,
- an audiologist in a HA fitting center,
- a general practitioner.

Patients with a conductive or mixed hearing loss in line with manufacturers' fitting ranges, who are unable to use conventional HAs for medical or anatomical reasons or do not achieve sufficient benefit from them, or patients with SSD are candidates for a BCHD. Whenever the indication for a BCHD is evident in a patient, a BCHD should be included in the treatment options discussed and a referral directly to the BCHD hospital for further assessment and a BCHD trial should be considered. The indication may become apparent at an early stage, in the case of conductive or mixed hearing loss with an air-bone gap of more than 30 dB or in the case of SSD. However, a BCHD may become a treatment option in a later stage as well, for instance when HAs do not or no longer provide the desired benefit. In all cases, it is essential to adequately inform the patient about all appropriate treatment options. This is in line with the deontological code for audiologists and hearing aid fitters, which states that "the audiologist or hearing aid fitter shall use all the resources within his/her area of expertise, including any referral to or cooperation with other healthcare providers. In doing so, he/she shall convey all necessary information, with the consent of the person seeking care, to enable the most efficient and effective provision of care."[18,19] The same principle applies to each doctor, based on the code of medical deontology.[20,21]

Children with specific needs, e.g. in case of congenital aural malformations or additional disabilities, should be referred and treated multidisciplinary and supra-regionally to ensure the provision of appropriate hearing and (if needed) reconstructive support. Congenital malformations are normally identified soon after birth, given the neonatal hearing screening in Belgium and the visibility of aural malformations (microtia/atresia). These patients are indeed referred to a BCHD hospital with expertise in pediatric BCHD care. However, children with unilateral hearing loss without congenial aural malformations are often lost to follow-up. For these cases, professional and parental awareness of BCHDs must be increased.

Medical and Audiological Assessment

Diagnostics The primary goal of the assessment is to ensure that a patient who opts for an implantation with a BCHD is an eligible candidate who has a high probability of experiencing benefits with the device. It must be ascertained that the patient's conductive hearing thresholds lie within the fitting range of the available BCHDs, that the patient is suitable for surgery, is aware of the expected benefits and potential risks, has the capacity to maintain and operate the device and is unlikely to become a non-user. All preoperative assessments should be completed by the specialist BCHD team prior to the decision to offer an implanted BCHD. The requirements of the medical and audiological assessment are explained by Gavilan et al[14] and do not need updating.

Audiograms should be repeated to ensure that air conduction and bone conduction thresholds are accurate for both individual ears. This is particularly important in cases of mixed hearing loss, where masking dilemmas may occur.

Trial with a Hearing Solution Once the medical and audiological assessment has been completed, a trial with the hearing solution(s) deemed appropriate for the patient should be undertaken. Candidates for BCHDs with contra-indications for conventional HAs should have the opportunity to trial a bone conduction solution on a softband or another non-surgical wearing option (e.g., SoundArc). If there are no medical contra-indications to fitting a conventional HA appropriate for their hearing loss, potential candidates should have a comparative preoperative trial with air conduction and bone conduction solutions.

Whether it is a trial with a HA or a BCHD, the hearing solution must be optimally fitted to the needs and expectations of the patient. In addition, the trial period must run for at least 2 weeks for each hearing solution being tested. It is recommended that a full BCHD trial is carried out by the specialist BCHD team, as they are trained and experienced, and have available to them the demo materials and fitting software required for a successful trial. In case of a comparative trial, the HA and the BCHD are compared in terms of subjective benefit and speech perception in quiet and noise. Comparing the ability to localize sound and to perceive speech with separated speech and noise sources is an additional recommendation in patients with SSD or asymmetric hearing loss, who are candidates for a BCHD and a (BI)CROS solution. A longer trial period may be needed in SSD, as well as in long-term or congenital hearing loss, as these patients may require more time to adjust to a hearing solution.

Additional Considerations It is recommended to give potential candidates the opportunity to meet with and talk to another BCHD user before deciding to move forward with implantation. Other surgical options or solutions such as active middle ear implants or cochlear implants (CI) and the associated risks, benefits, and costs of these different treatment options must be discussed with potential candidates.

If the candidate decides not to proceed with a BCHD, an alternative hearing solution should be provided by the BCHD team, if available within the BCHD hospital. Alternatively, the patient can be sent back to the referring ENT or audiologist for further follow-up and/or referral.

Treatment

Appropriate assessment is vital for the correct choice of treatment. Treatment consists of the implantation of the BCHD and (initial) fitting of the sound processor. Both are and remain the responsibility of the BCHD team. The fitting may be provided by a BCHD fitting center outside the BCHD hospital if a close collaboration with the hospital is in place. This way, access to medical support if required for wound healing issues, for example, is readily available.

Factors that should be considered when choosing a BCHD include those mentioned by Gavilan et al.[14] as well as the following:

- The fitting range of the device should be sufficient to compensate for the hearing loss of the patient both at the time of implantation and in the future, taking into account progressive hearing loss.
- Medical issues such as body mass index or previous radiotherapy.
- MRI compatibility and related artifact of the hearing solution.
- Lifestyle of the patient (e.g. helmets for work).
- Bilateral or unilateral treatment.
- Side of BCHD for patients with bilateral hearing loss but a unilateral implant.

The patients' needs and preferences should be considered, and the patients are to be given information on the different brands and types of hearing solutions which are suitable for their hearing loss. They should have the option of being referred to another BCHD hospital if the current hospital is not offering their BCHD of choice or other preferred solutions such as an active middle ear implant or CI.

BCHDs should comply with all regulatory and safety requirements as discussed by Gavilan et al.[14] Non-reimbursed treatments can also be discussed, provided that the funding situation is clearly explained to the patient.

Fitting of the sound processor should be carried out by an experienced BCHD audiologist and a validated prescription rule should be used. At each fitting appointment a health care professional, well-trained to recognize when to refer to an ENT doctor and who can identify potential issues with wound healing, cleaning, and implant stability must be present. This could be an audiologist, specialized nurse, or ENT surgeon.

Medical care should be readily and instantly available and audiologists should have same-day support from a BCHD-trained ENT surgeon or a specialized nurse, if required. Smaller BCHD hospitals are advised to cooperate with other clinics to achieve this.

Medical and Audiological Follow-Up

The BCHD experts supported the guidelines for postoperative assessment and follow-up as formulated by Gavilan et al[14] and further elaborated on them. A surgical follow-up consultation is recommended at 1 or 2 weeks, 3 months, and 6 months

post-surgery at which special attention must be paid to wound healing. Thereafter, a yearly follow-up is recommended, both for the medical and the audiological follow-up. However, the appointments should be based on patient need, with open access to additional appointments as required. Medical and audiological follow-up must be provided by the BCHD team, either completely in the BCHD hospital or in the BCHD hospital and a collaborating BCHD fitting center outside of the hospital, but not in local centers with little BCHD experience. This allows timely identification of problems which need rapid medical intervention or assessment. The follow-up can be patient-initiated. However, to reduce the risk of missing any non-users, a "call up system" is preferable, ensuring complete patient coverage. Such a system could also be designed to identify patients who previously had a negative BCHD trial but may benefit from new or upgraded hearing solutions.

The BCHD team is responsible for the management of damaged or malfunctioning sound processors. The BCHD team must be able to provide a qualitative approach in case of repairs. Sound processor replacements can either be stocked and managed by the BCHD team or, for some manufacturers, be outsourced to a repair service provided by the company. It should be aimed to ship sound processor replacements within the next working day if the patient is off the air and requests an urgent replacement of his/her damaged or malfunctioning sound processor.

If an issue with an internal part or a wound healing problem is suspected, the patient should be referred immediately to the BCHD hospital for medical assessment. All personnel handling the initial repair enquiry must have the training to recognize cases where further assessment is required. All materials should be readily available to quickly resolve abutment-fixture coupling issues.

Speech perception and subjective outcomes should be collected at least twice after the initial sound processor fitting to monitor progress over time. Standardized testing and data collection across different BCHD hospitals would allow multicentric analysis of the data. In this way, (potential) patients, funding bodies, and professionals could be better informed about the benefits of BCHDs. Moreover, the quality of care provided could be more effectively audited. A national system of outcomes registration would provide such standardized, long-term outcomes data. This has successfully been achieved in the UK under the guidance of the Ear Foundation: the national bone conducting hearing implant registry.[22]

Conclusion

The overall goal of this consensus statement on the treatment with implantable BCHDs was (1) to identify the different models of bone conduction care currently applied in Belgium and to make recommendations for improvement and (2) to reach a consensus on general guidelines to improve quality for the different phases of the patient journey.

There was a broad consensus among BCHD experts that the treatment with BCHDs should be primarily driven by specialist BCHD surgeons and audiologists. Centralized care concentrates experience and minimum standards must be met to ensure equivalent quality of care across the region. A multidisciplinary team is essential and BCHD hospitals should provide specialist audiological services either within the hospital or in close partnership with a fitting center experienced and trained in fitting BCHDs. The BCHD team should collaborate closely with general ENT doctors and audiologists, should invest in adequate education, and spread new insights and knowledge of BCHDs to the entire field.

The consensus meeting was a first step towards a more standardized approach for treatments with BCHDs in Belgium. Providing a standard of care means that every person, regardless of the type or degree of hearing loss, the region in which they reside, and the type of hospital or hearing professional they see, has access to a standardized assessment and treatment process, resulting in the most efficient hearing solution for his or her indication. The consensus meeting demonstrated that there are still efforts needed to define the best clinical protocol, as well as to streamline the referral process in Belgium, from the ENT surgeon and HA center to the BCHD hospital or fitting center.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.C., I.D., P.G., B.L., V.V.R., N.V.; Design – A.C., I.D., P.G., B.L., V.V.R., N.V.; Supervision – N.V.; Resources – A.C., R.B., N.D., K.D.V., M.D., I.D., P.D., P.G., S.J.d.V., B.L., M.R., V.V.R., N.V.; Materials – A.C., R.B., N.D., K.D.V., M.D., I.D., P.D., P.G., S.J.d.V., B.L., M.R., V.V.R., N.V.; Data Collection and/or Processing – A.C., R.B., N.D., K.D.V., M.D., I.D., P.D., P.G., S.J.d.V., B.L., M.R., V.V.R., N.V.; Analysis and/or Interpretation – A.C., R.B., N.D., K.D.V., M.D., I.D., P.D., P.G., S.J.d.V., B.L., M.R., V.V.R., N.V.; Literature Search – A.C., P.G.; Writing Manuscript – A.C.; Critical Review – A.C., R.B., N.D., K.D.V., M.D., I.D., P.D., P.G., S.J.d.V., B.L., M.R., V.V.R., N.V.

Declaration of Interests: Annes Julia Claes was an employee at Cochlear Benelux during all stages (drafting, reviewing, submission) of the manuscript. Rajae Bouzegta was employed at MED-EL Benelux at the time of submission. Miek Devos was employed by Cochlear Benelux at the time of submission. Paula Greenham is a research consultant and received a consulting fee from Cochlear Benelux for moderating the consensus meeting and drafting the consensus statement.

Funding: This study received no funding.

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