Clinical guidance on bilateral fitting of bone conduction solutions in children and adults

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The benefits of binaural hearing are well known, and in air conduction hearing amplification patients with bilateral hearing loss have been fitted with bilateral hearing amplification as the standard of care for decades.[1] However, the benefits of fitting bilateral conductive or mixed hearing loss with bilateral bone conduction solutions have been debated. The guidance statements and clinical recommendations presented in this paper provide a viewpoint from experts on when bilateral fitting should be performed and considerations for a successful outcome.

Background

Signal transmission by way of bone conduction results in stimulation of both the ipsilateral and contralateral cochlea. This cross-stimulation, or "cross-hearing", may serve to disrupt the interaural timing and level cues required for binaural processing of auditory signals, and thereby the binaural processing benefit may be negated by the natural effect of bone conduction. Additional questions have been raised regarding phase cancellation of signals under bilateral bone conduction stimulation, and whether this would also lead to reduced benefit.[2] Increasing evidence suggests that while cross-hearing does occur with bilateral bone conduction, patients demonstrate significant benefit with bilateral fitting in terms of both speech perception[3-5] and localization performance.[3, 6-11] Indeed, there are 30 clinical publications available as of 2017 where the outcomes from bilateral bone conduction fitting have been investigated both in terms of audiological outcome, subjective improvements and technical measurements.[1-30] Although the binaural processing benefit from bilateral bone conduction is tempered by cross-stimulation, the combined evidence demonstrates improved outcomes in patients with bilateral conductive and mixed hearing loss.

However, according to fitting statistics and a recent market investigation funded by Cochlear Bone Anchored Solutions this growing body of evidence on the benefit of bilateral fitting has not yet fully been translated into clinical practice. In order to provide guidance on bilateral fitting of bone conduction hearing solutions, a panel of independent clinical and scientific experts from Europe and the Americas was established. The aim of this panel was to create a clinical guidance statement on the principles and evidence base to support the application of bone conduction devices in the management of bilateral conductive and mixed hearing loss.

Introduction

In May 2018, a panel of leading experts in the field of bone conduction together with Cochlear Bone Anchored Solutions, convened a consensus on the benefits of bilateral fitting of bone conduction devices in conductive and mixed hearing loss. The following statement is based on the results from two independent consensus meetings held in Denver, Colorado, USA, and Amsterdam, The Netherlands, to discuss their joint experience from bilateral fitting of implantable bone conduction solutions. This consensus statement is intended to serve as a clinical guide in the application of bone conduction devices for the management of bilateral conductive hearing loss. The experts convened to address 1) audiological benefits of bilateral bone conduction fitting, 2) candidacy for bilateral bone conduction, and 3) surgical and audiological considerations in management of bilateral conductive or mixed hearing loss. The guidance statements and clinical recommendations presented in this paper provide important direction on when bilateral fitting should be performed and considerations for a successful outcome.

1. Consensus statements

Statements on audiological benefits from bilateral bone conduction fitting.

Improved hearing sensitivity

"In patients with a bilateral conductive or mixed hearing loss, bilateral fitting of a bone conduction solution enables audibility from both sides of the head, and a summation effect can also be expected.[3-5] This enables improved spatial awareness and hearing sensitivity, facilitating better speech recognition in quiet."

There was a consensus based on the experience of the participants that bilateral fitting will lead to improvements in hearing performance both in terms of improving the dynamic range and improving hearing in quiet due to the summation effect. Additionally, this statement is supported by several peer reviewed publications showing improved speech reception thresholds in quiet of up to 5.4 dB.[3-5]

Binaural processing

"A bilateral bone conduction fitting will provide patients with increased access to binaural cues which will improve spatial awareness and hearing in noise in most listening situations."

Bilateral amplification should be the goal of any hearing intervention for patients with a bilateral hearing loss, as this potentially will provide the auditory system with binaural cues. The experience from the group is that binaural processing can be expected in bilaterally fitted patients with symmetrical*

Participants from the US consensus meeting, from left to right: Catherine Moyer, Anne Ferrugiaro, Seilesh Babu, Benjamin McGrew, Jack Wazen, Colleen Ittner, Melody Mathews, Judy Wong, Lisa Christensen, Nathan Page. Participants at the European consensus meeting not in picture.

bone conduction thresholds. Even though the cross-hearing in bone conduction might limit the binaural processing compared to normal hearing, it has been demonstrated to improve SNR up to 4.6 dB in hearing in noise when the speech and noise sources are spatially separated.[3, 4, 6, 11, 12, 15, 19] Indeed, the most important objective benefit of bilateral fitting versus unilateral is the cancellation of the head shadow effect and an increase of the dynamic range. However, there are also situations where a bilateral fitting may perform worse as noise that was previously directed to the non-aided side is amplified.[4]

* Symmetrical thresholds are defined as up to 10 dB difference on average between the bone conduction thresholds of the two ears measured at 500, 1000, 2000 and 4000 Hz, or up to 15 dB difference at individual frequencies.

Localization

"Evidence indicates that patients with bilateral bone conduction solutions experience improvements in their ability to localize sound compared to those with a unilateral solution."

"This will be beneficial in everyday life situations such as locating the speaker in a group discussion or locating sounds in traffic."

Patient reported outcomes and objective evidence indicate that bilateral fittings can be expected to lead to improvements in the patients' ability to localize sounds. Results from clinical studies support this experience demonstrating improvements in patients' ability to localize.[3, 6-11] The improvement is not necessarily based on processing of binaural cues.

Subjective outcomes

"For a patient with symmetrical bilateral mixed or conductive hearing loss, a bilateral bone conduction solution can provide the best outcome, and patient satisfaction can be expected to improve with the bilateral fitting."

There are also clinical studies demonstrating higher levels of patient satisfaction from bilateral fittings compared to unilateral both in adults and children.[14, 15]

2. Clinical guidance statements on candidacy for bilateral bone conduction

Pediatric candidacy

"In children with a bilateral hearing loss indicated for a bone conduction solution, a bilateral fitting should be strongly recommended at an early age. This potentially allows them to use all auditory cues to develop binaural hearing." [8, 15, 23, 28]

"Hearing with two ears will be beneficial to their speech and language development and for their performance in school." [26]

The Joint Committee on Infant Hearing (JCIH) recommends intervention by 6 months of age.[32] General consensus of the group is that pediatric patients should be provided a non-invasive unilateral bone conduction solution from 3 months of age where the point of stimulation can be adjusted based on what is practical. This should be converted to a bilateral fitting as soon as they have sufficient head control to successfully manage it, usually around 6-12 months of age. From 4-5 years of age transition to an implanted system should start to be considered and as the percutaneous application provides better amplification this should be advocated. The hearing care professional should make sure to counsel parents on the importance of providing their child with bilateral input during the critical period[33] to enhance speech and language development, and maximize the opportunity for incidental learning.[34] It is also recognized that lack of binaural stimulation may lead to auditory processing deficits[35] and cortical reorganisation.[36]

Adult candidacy

"For adults with symmetric bilateral conductive or mixed hearing loss indicated for a bone conduction solution, bilateral fitting should be recommended."

Adults with a bilateral hearing loss indicated for an implantable bone conduction solution demonstrate benefit in the bilateral condition over the unilateral condition.[14,18,19] Group data across a large body of evidence demonstrates improved speech perception,

improved hearing in noise and more accurate sound localization in bilateral over unilateral fittings.[1-5, 7,9-13, 15-21, 23, 26, 28-30]

Even though some patients may express an aversion to bilateral fitting of devices, a trial with a second device is recommended in all patients to allow them to ascertain the degree of benefit obtained from a bilateral fitting. Counselling for management of bilateral hearing loss should include consideration of bilateral fitting.

3. Clinical considerations

Audiological considerations:

1. Bone conduction thresholds – Bone conduction thresholds are an important indicator when considering the potential benefit of a bilateral fitting. In the experience of the participating clinicians, the better and more symmetrical the bone conduction thresholds the greater the expected binaural benefit. In patients with hearing asymmetry of more than 10 dB by bone conduction, binaural processing benefits are expected to be limited.[2, 7, 13, 21] The primary benefit in such cases is expected to be audibility, although individual benefits from a bilateral bone conduction fitting have large variances.[2]
2. Audiological evaluation – Thorough pre-operative candidacy evaluations should include tests of audibility and speech perception in noise. All assessments should be conducted in the unilateral and bilateral fitting condition to assess bilateral benefits. The test environment should provide the candidate with a good understanding of the benefit of the bilateral fitting and assist them in making an informed decision. Additionally, the fitting range of the sound processors should be considered to ensure that they have sufficient output to compensate for the sensorineural part of the hearing loss, especially in non-surgical or magnet based systems.
3. Subjective benefit – Conducting a listening test with demonstration devices fitted using a soft or hard headband is an important part of the evaluation and counselling process.[37] This test will allow the candidate to hear and experience the difference between a unilateral and a bilateral fitting. These listening tests should be conducted where possible under real life situations or simulated real-world listening environments.
4. Additional factors – In addition to hearing benefit, factors such as the listening environment, vocation/school, dexterity, device management and lifestyle should be considered as part of the device selection and counselling process.
5. System selection – In order to achieve optimal bilateral stimulation and improved binaural hearing benefits, hearing devices should be similar in mode (i.e. abutment versus magnet based), gain/output (i.e. standard versus power processors), device characteristics (frequency response) and fitting strategies (i.e. prescriptive methods). Careful consideration of these factors is important to obtain symmetry in hearing.

Surgical considerations:

1. Symmetry – Symmetrical placement of the implants is an important aesthetic factor for bilateral patients. For new candidates there are some ways of achieving this, either two pens can be used during surgery, one is placed onto the first implanted abutment, the second pen can then be used to mark the symmetrical implant position on the skin of the second side. Using a linear incision straight to the periosteum of the bone, the position of the second implant can then be correctly identified through the incised periosteum. Alternatively the sound processor indicator can be used prior to surgery to both mark where to place the implants and give the patient an understanding of how they will look when implanted. At surgery these markings should be transferred to the bone. This will reduce the risk of misalignment, as markings on the skin tend to move once the incision is made.

2. Implant placement – Surgeons should make sure not to place the implants too far back on the head, as that can be inconvenient for the patient when using headrests or when lying down. However, in cases of microtia, implants should be placed in a supero-posterior position to avoid compromising the area of future auricle reconstruction. The new auricle should be drawn on the skin and based upon this the implant position is defined. Commonly this will result in a position about 7 cm from the ear canal instead of the usual 5.5 cm. In case of transcutaneous devices the incision should be placed supero-posteriorly of the implant position to preserve the temporal fascia.
3. When to progress from a non-surgical to an implanted system – From the age of 4-5 years, the question of transitioning to an implanted solution needs to be addressed. In the experience of the group, this decision can be driven by the parents or children due to the increased ease of use and output of an implanted system. In other cases, physicians and audiologists play a more prominent role as the experts whom the parents and child rely on for information about alternatives, direction and treatment. In all cases, it is recommended to balance clinical recommendations founded on evidence based medicine and patient preferences in this discussion, reaching the conclusion in a patient centered and shared decision making process.

NOTE: In the USA and Canada implantation is contra-indicated below 5 years.

Conclusion

Sixteen international experts with experience in bone conduction hearing and device application participated in this working group. The conclusions are as follows:

- Hearing outcomes: Bilateral fitting facilitates improved localization ability, improved hearing in quiet and in noise, both in children and adults.
- Informed decision making: The benefits of bilateral bone conduction should be demonstrated to candidates during counselling. Potential benefit of bilateral bone conduction fitting should be evaluated in a listening test with bilateral input through a non-surgical bone conduction solution.
- Pediatric candidates: Parents should be provided age appropriate counselling on speech and language development, benefits and limitations of unilateral versus bilateral bone conduction fittings, and expected hearing outcomes. It is the opinion of the authors that early intervention should include bilateral fitting where possible to facilitate speech and language development and to maximize opportunities for incidental learning.

Bilateral management of bilateral conductive and mixed hearing loss is likely to provide increased benefit and improved hearing outcomes over unilateral management. Clinicians should take care to ensure that the treatment approach accounts for the full spectrum of hearing loss, taking into consideration the deficits of unilateral hearing and expected benefits of bilateral hearing.

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Disclosure: Participating hearing care professionals received compensation from Cochlear for their travel costs.

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BUN712 ISS1 DEC18

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