Are today's implantable hearing devices better than conventional devices for patients with conductive and mixed hearing loss?

ONLINE EXCLUSIVE

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In March 2014, we published a paper in ENT & Audiology News, with a similar title [1]. Below, an updated overview is presented of available devices (early 2021) for patients with conductive/mixed hearing loss. The focus is on effectiveness.

Patients with conductive/mixed hearing loss become candidates for amplification if reconstructive surgery is not an option or might lead to poor post-surgical hearing thresholds. Available amplification options are: behind-the-ear devices (BTE), conventional (non-surgical) bone-conduction devices (BCDs), (semi-) implantable BCDs and active middle ear implants. In the case of a malformed, atretic ear or chronically inflamed middle ear, BTEs cannot or should not be used (not discussed here), and BCDs are the next option.

Conventional, transcutaneous BCDs and recent 'updates'

Typically, conventional BCD comprises a sound processor (e.g., in a BTE housing) and actuator (bone vibrator). The actuator is pressed against the skin, behind the ear, by means of the steel spring headband. This traditional set-up has been updated during the last decades. Instead of the steel headband, a so-called softband has been introduced. More recently, BCDs with a magnetic coupling have been introduced (needing surgery; the Sophono device, (Medronic) and the Baha Attract (Cochlear) and a BCD with an adhesive coupling, the Adhear (Med-El).

A comparison is made between these devices, testing whether these new coupling options are as effective as the traditional coupling. Indeed, when comparing aided thresholds, minor differences were found. Furthermore, in patients with conductive hearing loss, the aided threshold (0.5-4kHz), averaged over studies, was 28dBHL (s.d. of 3 dBHL); so, in terms of aided thresholds, these transcutaneous BCDs seem to be equally effective. To choose a device, apart from effectiveness, other factors play a role like, costs, cosmetics and comfort. If implanted, stability of the implant and extra costs play a role. Regarding complications, skin problems might occur with all these transcutaneous devices; however, the percentage of serious problems is limited; below 5%.

BCDs with percutaneous coupling

Two more types of BCD are available that bypass the skin and subcutaneous layers, which attenuate the vibrations produced by BCDs. The first one is a BCD with a percutaneous coupling to the skull (referred to as the pBCD). This coupling is approximately 15dB more effective than the transcutaneous coupling, because of bypassing the skin and subcutaneous layers. Regarding aided thresholds, a systematically difference of 6-10dB was found (better thresholds with pBCD). Nowadays, as pBCDs, the Cochlear Baha and the Oticon Ponto are available.

Another approach to compare BCDs, instead of studying aided thresholds, is to compare maximum output levels (MPO) of different types of BCDs. The MPO, or the loudest sound that a BCD can produce, is a device-characteristic, objective measure that is easy to determine in vivo. Studying the MPO of BCDs led to similar conclusion regarding effectiveness as drawn from studying aided thresholds.

Problems with the skin around the percutaneous implant are not rare. Complications leading to revision surgery might happen; evidently, the longer the follow-up, the higher the chance. Therefore, on a group level, revisions were related to the total accumulated follow-up time. With the standard surgical approach, one revision had to be performed per 43 years of follow-up. Such a ratio, determined in adults, is considered as acceptable. Simplified surgical procedures have been introduced; revision ratios seemed to be somewhat worse. Note that complication rates are approximately three times higher in children.

Transcutaneous device with the actuator (vibrator) implanted, connected to the skull

In 2001, another concept was introduced that bypassed the skin and subcutaneous layer; the actuator of the BCD was totally implanted, under the skin, rigidly fixed to the skull. The actuator is connected to the sound processor by a transmission link. The first device on the market was the Bonebridge device (Med-El). When comparing the MPO of this device and, as a reference, the pBCD with standard sound processor, a difference of 4dB was found in favour of the pBCD; regarding audiological performance, rather similar outcomes have been reported. Recently, Cochlear released a similar device; the Osia.

Active middle ear implants

Another option, instead of a BCD, is to use an active middle ear implant with its actuator coupled to one of the cochlear windows; viz. the Vibrant Soundbridge (Med-El). The MPO is in the same range as that of

the most powerful pBCDs. Regarding the aided thresholds, in mixed hearing loss, no structural difference was seen between VSB users and pBCD users. Implantation of the VSB in an atretic ear might be challenging and the number of revisions in relation to follow-up is higher than with pBCD. However, a potential advantage of the VSB is that in contrast to BCD, cross-stimulation of the contralateral cochlea doesn't occur.

Conclusion

For optimal treatment, choosing the best device is a challenge. Given the effectiveness and the limitations of the different options, counselling is of utmost importance. Transcutaneous BCDs might be preferred as they are less vulnerable to skin reactions compared to pBCDs. However, the pBCD is by far the more powerful solution, leading to better hearing. Another advantage is that the processor of pBCDs can be updated to superpower versions. VSB is another option, however VSB implantation is more complicated and complications requiring revision surgery are (still) higher. On the other hand, as for pBCDs, longevity is not an issue. For hearing impaired children, sufficient powerful amplification options should be advocated. Good hearing is essential for children developing speech, language and scholastic skills. Before implantation (until age four-to-five years) a transcutaneous BCD with softband or adhesive coupling might be used. However, the mean aided threshold (28dBHL; see above) is significantly worse than the target of 15dBHL, as suggested by Northern and Downs in *Hearing in Children*, chapter 1 [2]. Replacement of the transcutaneous BCD with the more powerful pBCD, Bonebridge or VSB, should remain on the agenda and, meanwhile, speech and language development should be monitored. Loss of percutaneous implants occurs in ±15% of the children. However, implant loss with new implants with a wider diameter, seemed to be three times less than that of the older types.

The VSB has been applied in toddlers with aural atresia. However, during the last 10 years, little has been published on this issue; therefore, as of yet, evidence is lacking to advocate implantation at a very young age. Studying older children with aural atresia, using the VSB, showed that the mean aided thresholds were approximately 10dB worse than those obtained with pBCDs. This difference might decrease with growing surgical experience.

Reference

1. Snik A. Are today's implantable devices better than conventional solutions for patients with conductive or mixed hearing loss? *ENT & Audiology News* 2014;**23(1)**.
2. Northern JL, Downs MP. *Hearing in Children*. Lippincott Williams & Wilkins; 1991.

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