Practice guidelines for bone-anchored hearing aids in children

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Summary After more than 20 years of clinical experience in children, bone-anchored hearing aids, essentially BAHA®, have become the standard treatment for conductive or mixed hearing loss. Based on a general review of the literature and the authors’ own experience, this article reviews the use of bone-anchored hearing aids in children. The main indications for bone-anchored hearing aids are a minimum age of 5 years at the time of implantation and/or cortical bone thickness ≥ 3 mm. Fixture loss is observed in 40% of children under the age of 5 years versus 8% for children aged 5 to 10 years and 1% for children over the age of 10 years, i.e. identical to the rate observed in adults. Skin complications are similar to those observed in adults and must be prevented by parental education and regular follow-up. Surgery is generally performed in two stages or as a one-stage procedure for fixtures ≥ 4 mm. The functional success rate, correlated with medium- and long-term use of BAHA® is about 96%. BAHA® may be indicated in children with profound unilateral hearing loss following a trial period wearing a BAHA® headband for several weeks with the child’s active participation. Sequential bilateral implantation requires complementary investigations and appears to provide improved perception in noise. This type of hearing aid provides an improvement of the quality of life of children with bilateral conductive and/or mixed hearing loss which should be further improved as a result of recent technical developments.

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Introduction

The first bone-anchored hearing aid (BAHA®) was implanted in an adult in Sweden in 1977 [1]. This rehabilitation technique for conductive and mixed hearing loss then became commercially available in 1987 [2] and was used for the first time in France by Manach in the same year [3]. Since then, this technique has gradually become a valuable alternative to other bone conduction (BC) hearing aids because of a better gain in the high frequency range with less distortion, improved comfort and the possibility of bilateral implantation. This technique consists of a simple, reversible surgical procedure, not exposing the patient to any risk of additional hearing loss. In adults, BAHA® surgery is performed as a one-stage procedure under local anaesthesia with few complications [4]. However, in children, this surgery is usually performed as a two-stage procedure under general anaesthesia on thinner cranial cortical bone and in medically more complex patients. Due to the increased risk of skin complications, fixture loss and for
cosmetic reasons, healthcare professionals as well as children and their parents often consider BAHA® to be a less attractive alternative than in adults.

Based on a general review of the literature and our own experience, we have reviewed the place of bone-anchored hearing aids in children.

**Principles of functioning of BAHA®**

The BAHA® is an implantable system comprising three parts. An osteointegrated titanium fixture (screw) surgically implanted in the cortex of the temporoparietal bone behind and above the external ear generates a frequency-dependent elastic deformity of the bone cortex. A cone-shaped, percutaneous titanium abutment attached to the implant transmits vibrations to the implant. An external sound processor transforms sound into vibrations of variable intensity transmitted from the percutaneous abutment to the osteointegrated implant (Fig. 1).

**Indications**

BAHA® is indicated in cases of conductive and/or mixed hearing loss in which middle ear surgery cannot be performed and in which conventional air or bone conducting hearing aids are ineffective or impossible. Severe unilateral sensorineural hearing loss also constitutes an indication for BAHA® to restore binaural hearing, depending on the patient’s needs [5]. Audiometric criteria for BAHA® implantation are defined by BC thresholds (measured at 0.5, 1, 2 and 3 kHz), which are also used to select the type of hearing aid. A BAHA® Divino or BAHA® BP100 can be used for BC thresholds ≤ 45 dB HL, a BAHA® Intenso can be proposed for BC thresholds ≤ 55 dB HL, and a BAHA® Cordelle II is indicated for BC thresholds ≤ 65 dB HL with speech discrimination by BC ≥ 60%. Bilateral BAHA® is indicated when the right BC is equal to the left BC with a mean maximum difference < 10 dB. BAHA® is indicated for unilateral cophosis when BC thresholds of the healthy ear are ≤ 20 dB.

Indications related to the minimum age of implantation vary from one country to another with an age greater than or equal to 5 years in the USA [6] and Canada [7], while, in France, age is taken into account indirectly by measuring cortical thickness (≥ 3 mm).

**Complications**

The main short-term, medium-term and long-term postoperative complications consist of fixture loss and skin complications.

The Birmingham team [8] reported a retrospective review of their experience between 1992 and 2007, based on 182 children (mean age: 7 years, range: 2–16 years), including 35 children under the age of 5 years in whom 2-stage surgery was performed (96% cases). The fixture loss rate in the overall population of implanted children was 14% (32 fixtures lost over a period of 15 years). However, in the group of children under the age of 5 years, the fixture loss rate was 71% and even 100% when a 3 mm screw was used. In their review, published in 2009, McDermott and Sheehan reported a mean fixture loss rate of about 40% for children under the age of 5 years, 8% for children between the ages of 5 and 10 years and 1% for children over the age of 10 years [9]. In our experience of 11 BAHA® fitted in nine children with a mean age of 12.5 years (± 3.5), all operated by a one-stage procedure and with a mean healing time of 3 months, the fixture loss rate was zero with 4 mm screws and 50% for 3 mm screws (2 out of 4 cases).

Adverse skin reactions have been evaluated since 2001 according to the Holgers classification (Table 1). Studies have shown that these complications constitute the main problem after BAHA® implantation [4] with a higher mean incidence in children than in adults [8,10–12]. These complications are due to rubbing of the skin graft against the abutment. Poor hygiene and insufficient resection of hair follicles during surgery also predispose to skin irritation. Adolescents are also at increased risk of skin complications due to the presence of acne. Parents are also often responsible for regular, daily skin care around the abutment, which may be difficult to ensure in children with behavioural disorders and/or mental retardation. These potential skin complications must be prevented as far as possible by parental education and regular follow-up by the surgeon.

**Table 1** Holgers classification.

<table>
<thead>
<tr>
<th>Grade 0</th>
<th>Reaction-free skin around the abutment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Redness with slight swelling around the abutment</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Redness, moistness and moderate swelling</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Redness, moistness, and moderate swelling with tissue granulation around the abutment</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Overt signs of infection resulting in removal of the implant</td>
</tr>
</tbody>
</table>

Other intraoperative complications are sometimes observed, such as bleeding, or exposure of the dura mater or sigmoid sinus. Bleeding is generally controlled by placement
of the fixture. Exposure of the dura mater and/or sigmoid sinus, observed in almost 70% of paediatric cases, is not considered to be associated with any particular risks [8]. The use of neuronavigation systems should help to limit these complications.

**Surgical aspects**

Two-stage surgery consists of implantation of the screw in the mastoid bone followed, after waiting for 4 to 6 months to obtain osteointegration, insertion of the percutaneous abutment onto the screw. Another interval of several weeks must be observed before connecting the sound processor to the abutment. One-stage surgery, performed in adults since 1995, consists of placing the screw and the percutaneous abutment during the same operation, thereby avoiding the need for a second operation. In 1996, we proposed this one-stage technique routinely in adults and children [13] without observing any increase of the complication rate. Tietze and Papsin proposed this one-stage surgery for children over the age of 9 years, when a fixture of at least 4 mm is implanted [2]. Kohan et al. proposed one-stage implantation of two fixtures, including a dormant safety fixture, in children after evaluation of cortical bone thickness by preoperative CT [11]. According to this author, 3 mm and 4 mm fixtures were implanted with good osteointegration. In our experience, one-stage surgery can be performed in children, but should not be recommended for fixtures smaller than 4 mm in view of the risks of extrusion [8, 14].

The detailed one-stage surgical procedure is similar to that performed in adults (Fig. 2). The specific features of two-stage surgery consist of creation of a flap with reduction of the subcutaneous tissue during the second operation at least 3 months later. In patients with complete aural atresia requiring subsequent autologous reconstruction, the implantation site must be placed more posteriorly (generally 60 to 65 mm) and more superiority to take into account the shape of the skin flap (Fig. 3). In order to decrease the surgical time and skin flap complications, some teams perform a vertical retroauricular incision [15, 16]. These various techniques can be performed in children, although no particular technique has been shown to be superior to the others.

**Functional results**

The functional success rate is correlated with medium-term and long-term use of the BAHA®. This success rate is about 96%. The audiometric improvement varies according to the initial level of the BC curve, but mean hearing aid thresholds of about 17.5 dB are classically obtained in patients with conductive hearing loss due to severe aplasia [11]. Questionnaire-based evaluations of patients have also reported good results in terms of sound quality, ease of use and quality of life [17, 18]. Conditions ensuring these good results include multidisciplinary management in paediatric structures, especially for children with associated craniofacial malformation syndromes.

**Special indications**

**Unilateral hearing loss and BAHA®**

The consequences of unilateral hearing loss in children are currently correlated with a higher risk of delayed language acquisition and school difficulties, which have led some authors to propose hearing aids in these children [19].

In children with congenital unilateral conductive hearing loss with good sound localization capacities, Kunst et al. showed that BAHA® did not significantly improve hearing
in noise [20,21]. Similarly, Priwin et al., in 2007 showed that BAHA® did not provide any improvement in sound localization in this type of hearing loss [22,23]. The study by Christensen et al., published in 2010, used a questionnaire to evaluate the benefit of BAHA® in children with a mean age of 12.6 years (range: 6 to 19 years) presenting profound unilateral hearing loss, but neither the origin nor the date of onset of this hearing loss were specified. In a series of 23 implanted children, quality of life and perception in noise were improved with a complication rate of 17% [24]. On the basis of this study, this type of indication could be considered in children following a trial of BAHA® headband for several weeks with the child’s active participation (Fig. 4).

Bilateral BAHA®

The main advantage of bilateral cochlear stimulation is improvement of sound localization capacities and speech understanding in noise. The results of bilateral BAHA® in adults have demonstrated improvement of binaural capacities [25]. Development of binaural capacities appears to occur essentially during the first 4 years of life, justifying early bilateral implantation in children with hearing loss [26]. This age-related development validates the proposal of bilateral BAHA® headband during the first years of life. Few studies on bilateral BAHA® in children over the age of 5 years have been published. The questionnaire-based study by Dun, published in 2010 and based on 27 bilaterally implanted children between 1996 and 2008 showed improvement of sound quality in 70% of cases and a global benefit was obtained by permanent bilateral BAHA® in 90% of cases. One or both hearing aids had to be temporarily turned off because of excessive noise in seven children. Our experience of two children treated by sequential implanta-

tion of bilateral BAHA® indicates that both children used the two implants permanently and daily and reported an additional sense of security in the event of unilateral implant failure.

Children with associated mental retardation

Rehabilitation of conductive hearing loss has been successfully performed in children with trisomy 21 or learning difficulties [27,28]. This requires careful preoperative assessment of the child’s capacity to accept future daily skin care around the abutment, the risks of trauma and, in institutionalized children, the possibility of delegation of care to staff. A conclusive trial of BAHA® headband must also be systematically performed to validate this indication.

Medicoeconomic aspects

Following the CEPP (Pricing committee) opinion dated 24 June 2008, the external part (sound processor), and the implantable part (abutment and implant) have been registered on the list of products and services reimbursed by French national health insurance, as defined in Article L.165-1 of the French Social Security Code by decree dated 23 October 2009 (Official Journal dated 30 October 2009). Consumable items and repairs are reimbursed in the form of an annual fixed sum (LPPR 2331043). Prescription modalities in children are rigorously defined in the Official Journal article. In practice, the screw and the abutment are fully reimbursed by French national health insurance, while the fixed sum reimbursement of the external hearing aid is 900 Euros. The processor can be replaced after expiry of the guarantee when processor-related deterioration of performances (auditory or nonauditory) is observed.

Future prospects

Alternatives to BAHA®

Since 2007, middle ear implants (MEI) have been used for functional rehabilitation of conductive and mixed hearing loss in children. A French team was the first to implant a totally implantable Otologics Carina MEI in a 14-year-old boy with bilateral aural atresia in the context of Franceschetti syndrome [29]. More recently, in June 2009, the indications for another MEI, the vibrating Med-El, were extended to include conductive and mixed hearing loss in children. Pediatric cases of functional rehabilitation by MEI for unilateral or bilateral aural atresia, with conductive or mixed hearing loss have been reported in the literature [30,31].

A new “closed skin” bone-anchored hearing aid called Alpha 1 (M) is currently under evaluation. It is indicated for conductive or mixed hearing loss with BC thresholds greater than 45 dB, and for unilateral sensorineural hearing loss when the normal ear presents a BC threshold greater than that of the affected ear. The implanted part is a magnet contained in a tightly sealed titanium case and soldered to a fixation plate attached to the bone by four screws. No results are yet available in the scientific literature.
Innovations for BAHA®

Since 2010, Oticon® has marketed a bone-anchored hearing aid called Ponto. The Ponto-Pro sound processor can be programmed with automatic multiband adaptive directionality, trimodal noise management, wind noise reduction and volume control. No data are currently available on the results of this system in children.

Cochlear® is developing a new implant, which should significantly decrease healing time. This new implant has a larger diameter and a moderately roughened surface, which should ensure better primary stability and more rapid and stronger osteointegration, respectively. The sound processor fitting time could therefore be individually predicted by sound frequency analysis, which provides an indirect measure of implant stability, in the same way as for dental implants. The frequency of adverse skin reactions around the abutment should also be decreased due to a watertight connection between the abutment and the fixture.

Conclusion

Rehabilitation of conductive and mixed hearing loss in children by bone-anchored hearing aids is a robust technique that has been developed for many years with a long-term functional success rate of more than 96%. However, children are exposed to a higher risk of fixture loss and skin complications than adults. Technical improvements ensuring greater solidity and more rapid osteointegration are currently under evaluation. The combination of these various factors should therefore encourage ENT surgeons to familiarize themselves with this technique so that they can propose it to children and their families. Alternatives to bone-anchored hearing aids are also under evaluation.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References


