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A functional and anatomical comparison between two passive transcutaneous bone conduction implants in children

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ABSTRACT

Objective: To compare anatomical and functional outcomes of two passive transcutaneous bone conduction implant systems: Sophono™ and BAHA Attract™.

Materials and methods: Twenty patients, affected by bilateral conductive hearing loss, underwent unilateral transcutaneous bone conduction implant surgery. Ten children received a Sophono™ implant (6 males, 4 females, mean age 11 years, mean unaided Pure Tone Average (PTA) 0.25-4kHz = 69.70dB HL) and 10 a BAHA Attract™ system (7 males, 3 females, mean age 19 years, mean unaided PTA0.25-4kHz = 66.40dB HL). The following outcomes were considered: incidence of local complications, hearing aid benefit, hearing aid gain and changes in quality of life (QOL), as measured by the Glasgow Children's Benefit Inventory (GCBI).

Results: One patient in the Sophono group experienced magnet-related skin decubitus, while two patients (one per group) had skin hyperemia in the area overlying the magnet. The mean BAHA-aided threshold was 23.70dB, whereas the mean Sophono-aided threshold was 31.60dB. The mean gain was significantly different for lower frequencies, the BAHA having better functional outcomes. All patients reported an improvement in their QOL.

Conclusion: Given the lower thickness of the internal magnet, the Sophono™ system might be more suitable for younger children, whereas BAHA offered better functional results. Both systems can be considered valid and safe options for the functional rehabilitation of conductive hearing loss in children, provided that precautions are observed, such as a gradual use of the device and use of the least powerful magnets in the first months after the activation.

1. Introduction

Bone conduction implants successfully rehabilitate good quality hearing for people suffering from conductive hearing loss that cannot be either corrected by otomicrosurgery or are not suitable for aiding with conventional air-conduction hearing aids. They provide a direct activation of the cochlea through vibration of the skull. Initially, bone conduction hearing aids are put on a vibrating transducer on a headband, glasses or an elastic arch. After a satisfactory trial period, a titanium screw is implanted on the skull as part of a semi-implantable bone-conduction hearing device, based on the osseointegration concept of Branemark and Harders [1,2]. These first percutaneous bone-anchored hearing solutions provided an uninterrupted coupling of the external and the implanted component, thus allowing an optimal hearing gain for both adult and pediatric subjects [3,4]. However, the high rate of soft tissue complications (local infection or skin overgrowth), the poor cosmetic outcomes, loss or failure of the implant, together with the need for a complete osseointegration of the fixture before loading, have been a strong drive for the development of transcutaneous bone conduction devices. Transcutaneous systems send vibrations to the skull via a "passive" implant which is driven by an external mechanical transducer, however, unlike percutaneous solutions, they are abutment-free, thus stimulating bone vibration through an intact skin due to the magnetic coupling between the external and implantable components. In turn, this allows a better cosmetic result and elimination of the risk of local infection and extrusion, while maintaining good functional gain [5–7]. In 2013, Siegert reported the first series of 20 patients with the Sophono, a transcutaneous bone conduction implant, which uses dual magnets implanted snugly onto the bone with five screws [8]. Shortly after, the BAHA Attract was released, which transmits sound through the same single osseointegrated titanium screw used in their percutaneous device. Both these devices provide a transcutaneous bone-anchored solution, and they are suitable for bilateral conductive hearing loss, bilateral mixed hearing loss with bone-conduction Pure Tone Average (PTA) $_{0.5–4\ kHz} \leq 45$ dB-HL (up to 55 dB-HL if appropriate sound processor is used) and single-sided sensorineural deafness. Such implants have been approved by the US Food and Drug Administration for use in children aged 5 years and older. To

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date, there is a lack of reports comparing the anatomical and functional outcomes of the Sophono and BAHA Attract passive transcutaneous bone conduction implants in a sizable pediatric cohort. Powell et al. [9] published their results in a study that compared outcomes between 6 patients with BAHA Attract and 6 that were implanted with the Sophono Alpha 1. They concluded that both systems improved audiological outcomes and there was no statistically significant difference in aided thresholds or speech discrimination scores between the two devices.

The aim of the present study is to compare the audiological, clinical, and Quality of Life (QOL) outcomes of the two types of passive transcutaneous bone conduction implants in pediatric patients: the Sophono Alpha (Sophono Inc., Boulder, CO, U.S.A.) and the Cochlear BAHA Attract (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden).

2. Materials and methods

Our methods were reviewed and approved by the Institutional Review Board and are in accordance with the ethical standards laid down in the Declaration of Helsinki. Parents of all patients gave their informed consent for study inclusion. Audiological criteria for enrollment were the same as the ones applied for traditional BAHA candidacy, which is pure bilateral conductive hearing loss, as reported in previous papers [10–12]. No patients with single-sided sensorineural deafness were included. The age limit was set at ≥5 years, and the only anatomic criterion was skull thickness ≥3 mm as assessed by a preoperative high-resolution computed tomography (CT) scan of the head, which in our institution is part of the routine preoperative work-up of all candidates of bone-conduction implant. Once the above-mentioned criteria were fulfilled, the senior otosurgeon of the institution gave patients and their parents the choice of treatment modality with BAHA or Sophono, after a counseling session in which models of both devices were shown and the advantages and drawbacks of each were explained.

The internal (implantable) component of the BAHA attract system is made of a 3- or 4-mm titanium fixture of the Bi300™ series and of a circular magnet (Bim400™) 27 mm in diameter and 2.4 mm in thickness, which is coupled to the fixture. The internal component of the Sophono is made of two Samarium-Cobalt 2.6 mm height twin magnets encased in titanium; five little arms protrude from the magnets and can be fixated to the bone by means of 5 mini-screws.

Twenty patients were implanted; 10 with the Sophono and 10 with the BAHA Attract system. Before being implanted, 18 out of 20 patients had been using an external steelband bone-conduction hearing aid. One patient experienced an extrusion of the fixture of his previous BAHA Connect implant. The only one patient of our cohort suffering from bilateral conductive deafness due to chronic otitis media who had been using no hearing aid, gave consent for implantation after experiencing the bone conduction by the classic Rod Test.

All patients received their external BAHA 5™ or Alpha-2 processor one month after surgery. On the day of processor loading, each patient was invited to try magnets of increasing strength in the clinic, until the one was found allowing good hearing and processor stability on the scalp at the same time.

The following outcome measures were considered:

- Intraoperative and postoperative complications: the latter were assessed at postoperative visits, which were scheduled at 1 and 2 weeks after surgery, at processor coupling time, and after 1 and 2 months of processor use;
- Air-conduction and bone-conduction $PTA_{0.25–4\ kHz}$, according to the guidelines issued by the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology–Head and Neck Surgery [13];
- Free-field $PTA_{0.25–4\ kHz}$, measured in the unaided and aided conditions with the conventional bone-conduction hearing aid and with Sophono and BAHA Attract. Free-field audiometry with either processor was obtained after 6 months of processor use;
- Hearing gain, as measured by aided free-field $PTA_{0.25–4\ kHz}$ minus unaided free-field $PTA_{0.25–4\ kHz}$;
- QOL after 6 months of device fitting was assessed through the Glasgow Children's Benefit Inventory (GCBI), a validated 24-item health-related questionnaire that allows one to retrospectively assess the effect of a specific intervention in children. The questionnaire has a total score ranging from −100 to +100: positive scores indicate a benefit from the intervention, whereas scores below zero indicate a negative effect of the intervention on the patient's QOL. More specifically, according to the validation study conducted on children undergoing tonsillectomy and ventilation tube placement [14], increasingly positive scores relate to higher levels of parental satisfaction with the intervention.

Statistical analysis was conducted using the Medcalc Software (Marienkerke, Belgium) version 12. Due to the non-normal distribution of data, outcome variables were compared across groups using the non-parametric two-tailed Mann-Whitney test for independent samples () and the Kruskal-Wallis test when comparison was across more than two groups; correlations were calculated by means of Spearman's rank correlation coefficient ρ; alpha error was set at 0.05.

3. Results

3.1. Patient characteristics

Twenty patients were included in the study (13 males and 7 females; median age 10.57 ± 3.43 years; age range, 5.45–16.56 years), whose demographic and clinical characteristics are detailed in Table 1.

Sixteen subjects had a pure bilateral, conductive hearing loss due to bilateral aural atresia. Those patients suffering from chronic otitis media (patients 3, 8, 9, 15), whose parents refused conventional reconstructive surgery, had a conductive hearing loss, with a bilateral bone-conduction $PTA_{0.25–4\ kHz}$ better than 35 dB HL in the worst ear. In each patient, the bone conduction implant was the only planned surgical procedure.

Ten patients out of 20 underwent Sophono surgery (6 males, 4 females, mean age 11.49 years), while the other 10 opted for the BAHA Attract (7 males, 3 females, mean age 9.65 years). The reasons why these subjects (and their parents) opted for Sophono were: aesthetic preference (patients 10, 12, 15, 18–20); poor tolerance of the external bone conduction hearing aid due to retroauricular skin marks and pain from prolonged pressure (patient 14); a poor thickness of the temporal bone due to young age (patient 17) and complex craniofacial malformation (patients 11–13 and 16). The BAHA Attract was chosen for aesthetic reasons (patients 1, 3, 4, 6, 7, 9 and 10); patients 2 and 5 had already been using the BAHA on a softband, whereas patient 8 had an unsuccessful BAHA Connect surgery several years before and suffered from recurring skin overgrowth around the abutment.

3.2. Observed peri-operative complications

The surgical procedure was uneventful for all included patients. Fig. 1 depicts the placement of the magnet for each device. Intraoperatively, no major complications were observed; in patient 16 the dura was exposed during drilling of the bone bed for the implant. In this case, the surgeon preferred to drill a second bone bed in an area of sufficient skull thickness and covered the exposed dura with bone paté. In patient 13, due to thin skull bone, drilling of two different bone beds was necessary before a suitable place for fixture insertion could be found. In the post-operative period, only minor complications occurred: patient 11 experienced skin hyperemia with no ulceration, which was seen 3 months after external processor coupling. This complication occurred painlessly in the skin area of magnet contact and without implant exposure. The clinicians noticed that the subject had been