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What is This?
Sophono in Pediatric Patients: The Experience of an Italian Tertiary Care Center

Pasquale Marsella, MD¹, Alessandro Scorpecci, MD¹, Maria Vittoria Vallarino, SLP¹, Simona Di Fiore, AuD¹, and Concettina Pacifico, MD¹

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Abstract

Objective. Since 2011, a transcutaneous bone-anchored auditory implant (Sophono) has been available for patients affected by bilateral, conductive hearing loss that cannot be corrected by surgery. To date, very few cases of device application in the pediatric population have been described. The aim of the present study is to report on complications, functional outcome, and health-related quality of life of the first pediatric cases in Italy.

Study Design. Case series with planned data collection.

Setting. Tertiary care pediatric center.

Subjects and Methods. Of 25 candidates with bilateral, conductive hearing loss screened between January 2012 and July 2013, 6 were included in the study (3 male and 3 female; median age, 9 years; age range, 5-17 years). Data concerning surgery, complications, functional outcome, and health-related quality of life were gathered prospectively.

Results. No major intraoperative complications occurred. Postoperative complications included 1 patient developing a skin ulceration below the external magnet and 1 patient reporting pain from using the device for more than 4 hours a day consecutively. Median free-field pure tone average (0.5-3 kHz) with the device was 32.5 dB HL, and median functional gain was 33 dB HL. Median Glasgow Children's Benefit Inventory score was 142.

Conclusion. Sophono implants can be a valuable alternative to percutaneous implants in patients with bilateral, conductive hearing loss. To ensure the success of the treatment, several precautions should be taken, including a careful preoperative assessment of skull bone thickness and a close postoperative follow-up of the skin under the external processor, especially over the first months.

Keywords

bone conduction implant, Sophono, transcutaneous, children

Introduction

Bilateral conductive hearing loss that cannot be corrected by otomicrosurgery can benefit from semi-implantable bone-conduction devices. Classically, percutaneous devices have been successfully used to treat this condition, both in adult and in pediatric subjects.1-3 Percutaneous devices have the advantage of direct transmission of vibrations through the bone, thus allowing an optimal hearing gain; however, their drawbacks include the need for osseointegration, risk of local infection, and poor aesthetic outcome.

Since 2011, a semi-implantable bone conduction transcutaneous hearing aid (Sophono; Sophono Inc, Boulder, Colorado, USA) has been commercially available since its precursor (Otomag) was successfully experimented with as an alternative to Baha in past clinical research.4 Its audiologic indications include bilateral, conductive hearing loss; bilateral, mixed hearing loss (with bone-conduction pure tone average [PTA] 0.5-3 kHz ≤ 45 dB HL); and single-sided sensorineural deafness.

The transcutaneous implant has also been approved for pediatric age, with the US Food and Drug Administration having cleared Sophono for use in children ages 5 years and older, whereas so far no age limit has been set in Europe.

The device consists of an internal and an external component. The internal (implantable) component is made of 2 Samarium-Cobalt twin magnets encased in titanium; 5 little arms protrude from the magnets and can be fixated to the bone by means of 5 mini-screws. The external component includes 2 twin magnets embedded in an acrylic baseplate and a digital processor (Alpha-1 or the new-generation Alpha-2).

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The results of Sophono application reported in published case series have been encouraging. A recent article on children\(^5\) describes a complication rate that is comparable to the one observed with traditional Baha and has quite a satisfactory functional outcome, although the percutaneous implant’s output is 10 to 15 dB HL higher than reported with the transcutaneous device. In the largest case series on Sophono available in the literature,\(^6\) which includes both adult and child subjects, neither surgery-related nor postoperative complications are described. Concerns for the application in children include poor skull thickness, which may not allow drilling of the minimum required 2.5-mm deep bone bed, and local lesions due to prolonged magnet pressure on thin skin.

Bambino Gesù Pediatric Hospital is an Italian tertiary care center for pediatric disease with extensive experience with bone-conduction implants, being the first Italian hospital in which a Baha was implanted in a child, back in 1995. Since January 2012, the Audiology and Otology Unit of the institution has decided to propose Sophono as an alternative to Baha for all patients who could be audiologically suitable candidates.

The aim of the present study is to describe the center’s experience with the device in pediatric patients, focusing on complications, functional outcome, and modifications of patients’ health-related quality of life.

**Methods**

Our methods were reviewed and approved by the Institutional Ethic Committee (Prot. N. 248 LB, 2012) and are in accordance with the ethical standards laid down in the Declaration of Helsinki. Parents of all patients gave their informed consent to include their child in the study.

Audiologic criteria for enrollment were the same as the ones applied for traditional Baha candidacy, that is, bilateral, conductive hearing loss that cannot be corrected by surgery. Patients with a mixed hearing loss were also considered suitable for the study, as long as their bone-conduction PTA (0.5-3 kHz) did not exceed 45 dB HL. No patients with single-sided sensorineural deafness were included, so that the sample might be as homogeneous as possible. 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 patients who will receive a 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 surgical technique was the same as described by Siegert\(^7\) and Siegert and Kanderske\(^8\) and includes a curved incision behind and above the auricle, bone surface exposure, drilling out of 2 shallow bone beds, implant placement, and fixation with 5 mini-screws. Skin thinning was performed on a case-by-case basis and not routinely. The following outcome measures were considered:

- Intraoperative and postoperative complications: the latter were assessed at postoperative visits, which were scheduled 1 and 2 weeks after surgery, at processor switch-on, and after 1 and 2 months of processor use.
- Air-conduction and bone-conduction PTA averaged for frequencies 0.5, 1, 2, and 3 kHz, according to the guidelines issued by the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology–Head and Neck Surgery.\(^7\)
- Free-field PTA averaged for frequencies 0.5, 1, 2, and 3 kHz and measured in the unaired and aided conditions with the conventional bone-conduction hearing aid (BCHA) and with Sophono. Free-field audiometry with the Alpha processor was obtained at switch-on and after 1 and 2 months of processor use.
- Hearing gain, meant as aided free-field PTA (0.5-3 kHz) minus unaired free-field PTA (0.5-3 kHz).
- Speech perception was tested by means of an Italian adaptation of the closed-set identification task “Northwestern University Children’s Perception of Speech Instrument,”\(^18\) translated as “Test di Identificazione di Parole Infantili” (TIP).\(^9\) The TIP assesses overall phoneme perception skills by using 25 sheets depicting disyllabic words. Each sheet depicts 4 words: 1 target word; 1 phonetically similar word, ie, differing from the target word by either a vowel or a consonant; and 2 phonetically different words whose purpose is to check the child’s attention level while administering the test. The final score is calculated as the percentage of correctly identified words, multiplied by 2.
- Quality of life after 4 months of device best fitting was assessed by means of 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.\(^10\) 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 quality of life. More specifically, according to the validation study\(^10\) conducted on children undergoing tonsillectomy and ventilation tube placement, increasingly positive scores relate to higher levels of parental satisfaction with the intervention.

**Results**

Of 25 audiologically suitable candidates screened until January 2012, 19 were excluded because of patient or
parental refusal of surgery (n = 10), insufficient skull thickness (n = 6), and personal preference for Baha (n = 3). Six patients were included in the study (3 male and 3 female; median age, 9 years; age range, 5-17 years), whose demographic and clinical characteristics are detailed in Table 1.

The reasons that these subjects (and their parents) opted for Sophono were aesthetic preference (patients 2, 3, and 4); poor tolerance of the external BCHA due to retroauricular skin marks and pain from prolonged pressure (patient 1); and unsuccessful Baha surgery several years before in patient 5, who had not been using his Entific Baha because of recurring skin overgrowth around the abutment. Five subjects (patients 1, 2, 3, 5, and 6) had a pure bilateral, conductive hearing loss. Patient 4 had a mixed hearing loss, mainly conductive, with a bilateral, bone-conduction PTA (0.5-3 kHz) = 22 dB HL in the right ear and 27 dB HL in the left ear.

In 4 subjects (patients 1, 2, 4, and 6), the Sophono implant was the only planned surgical procedure. In patients 3 and 5, orthodontic treatment and bilateral episthesis placement, respectively, were performed under the same general anesthesia as Sophono surgery.

Intraoperatively, no major complications were observed, whereas minor complications occurred only in patient 3, in whom 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 (Figure 1). The external processor was switched on after a median of 58 days postoperatively (range, 30-61 days). Patients 1, 2, and 6 received an Alpha-1 processor and patients 3, 4, and 5 an Alpha-2 processor because by the time they were implanted, the latter had become available on the market.

Postoperatively, 1 patient (patient 4) experienced initial ulceration of the skin under the magnet, which was seen 3 months after external processor switch-on. This complication occurred without the patient feeling pain in the skin area of magnet contact and without implant exposure. The patient was found to be using a No. 4 magnet and admitted using the device all day long, sometimes even at night. Moreover, the clinicians noticed that the subject had been applying the magnets incorrectly, so that only 1 magnet matched with its subcutaneous counterpart and all the attractive pressure had been concentrated in 1 spot. Application of the Alpha-1 processor was immediately suspended, and the lesion was treated with local medications (application of gentamycin pomade for 1 week). The patient was then instructed to suspend processor use until complete healing of the wound, which occurred about 45 days later. Afterward, she was told to resume device use for a maximum of 3 to 4 hours a day with a No. 2 magnet, which she did without any other complications.

Patient 5 complained about pain and mild hyperemia in the skin area under the magnet shortly after processor switch-on. He was using a No. 4 magnet and was instructed to switch down to a No. 3 and eventually to a No. 2 magnet, thereby obtaining only attenuation and no resolution of the symptoms. Thus, since 1 month after switch-on, he has become a nonuser of the device and has resumed using the same steelband bone-conduction hearing aid as he had been wearing before Sophono implantation. No postoperative complications were observed in the other patients.

Individual functional results and quality-of-life outcomes are detailed in Table 2. Median unaided free-field PTA (0.5-3 kHz) was 63 dB HL (range, 60-73 dB HL), median

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age at Surgery, y</th>
<th>Side</th>
<th>Etiology</th>
<th>Previous BCHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>5</td>
<td>L</td>
<td>nonsyndromic bilateral aural atresia</td>
<td>steelband</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>9</td>
<td>R</td>
<td>bilateral CWD TPL (bilateral CCOM)</td>
<td>steelband</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>8</td>
<td>R</td>
<td>Goldenhar syndrome</td>
<td>steelband</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>16</td>
<td>L</td>
<td>Stilling-Turk-Duane syndrome</td>
<td>steelband</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>17</td>
<td>R</td>
<td>Treacher-Collins syndrome</td>
<td>steelband/Baha</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>9</td>
<td>R</td>
<td>nonsyndromic bilateral aural atresia</td>
<td>steelband</td>
</tr>
</tbody>
</table>

Abbreviations: BCHA, external, bone-conduction hearing aid; CCOM, bilateral, chronic cholesteatomatous otitis media; CWD TPL, canal wall down tympanoplasty; F, female; L, left; M, male; R, right.

Figure 1. Intraoperative photograph showing the 2 attempts at bone bed drilling in patient 3.
PTA (0.5-3 kHz) with the external BCHA was 38 dB HL (range, 35-45 dB HL), and median PTA (0.5-3 kHz) with Sophono was 32.5 dB HL (range, 27-39 dB HL). Median gain with Sophono was therefore 33 dB HL (range, 29-26 dB HL). The median speech perception score as assessed by the TIPI was 89% (range, 80%-96%) with the external bone-conduction hearing aid and 93% (range, 80%-100%) after 2 months of Sophono use.

Glasgow Children’s Benefit Inventory score was positive in all patients but patient 5, who has gradually become a nonuser of the device because of the above-mentioned skin pain experienced during application of the magnet. Median GCBI score was +42 (range, 0 to +62.5).

### Discussion

Overall, the case series presented in this report suggests that Sophono surgery is safe and that the device can be a beneficial alternative to traditional percutaneous bone implants. Nonetheless, some of our patients experienced complications that deserve special attention, in that they are potential causes of unsuccessful treatment, especially in pediatric age.

Intraoperatively, the only complication was a minor one, consisting of a low thickness of the calvarial bone in 1 patient, and it did not represent an impediment to placing the device. Since in children, the preoperative CT scan may not always be reliable in assessing skull bone thickness, the authors feel that pediatric patients and their parents should be counseled concerning the possibility that implant of Sophono may not be feasible, and a decision to implant a percutaneous device with a 2-stage procedure might be taken intraoperatively.

The skin ulceration observed in patient 4 was likely due to incorrect and prolonged device use in the first months after switch-on. This suggests that the patients and their parents should be carefully instructed on the most appropriate way to apply the processor to the skin. Specifically, based on our experience, we recommend processor use for no longer than 3 to 4 hours a day and with the least powerful magnet in the first 3 months after switch-on. Several attempts to find the most suitable magnet should be performed, together with a close monitoring of the underlying skin, promptly suspending processor use in case of skin hyperemia.

The impossibility to find a balance between tolerability of the magnet and benefit from the device was the main reason that patient 5 gradually abandoned his Sophono. In addition, this patient had an unaided free-field PTA (0.5-3 kHz) of 68 dB HL and one of the worst hearing gains with the device, which may have contributed to his dissatisfaction.

If compared to the results reported by Siegert and Kanderske, our data show a Sophono-aided PTA (0.5-3 kHz) about 5 dB HL worse (33 vs 28 dB HL, respectively), probably due to a greater mean unaided PTA (65 dB HL), in our series.

As for quality of life, our overall outcome seems to be as good as the one observed in children with bilateral, conductive hearing loss receiving a Baha. Except for 1, all the subjects of the present series obtained a positive score in the range of +34 to +62.5, which relates to the highest degree of satisfaction with a surgical operation in the validation study. So far, published studies have reported no cases of patients who are not using the external processor after implantation.  It is notable that the 1 subject in our series who is not using his Sophono (patient 5) was also the only Baha recipient in our institution (among more than 50) who was not using his percutaneous implant in the past due to chronic skin problems, which were mostly caused by poor personal care of the skin around the abutment and failing to show up for routine follow-up visits. Due to low numbers in the present series, a direct comparison of the rate of Baha and Sophono users would be inappropriate. However, our data suggest that, besides anatomic and audiologic issues, clinicians should also consider psychological and motivational aspects while assessing patient candidacy for Sophono.

In conclusion, Sophono appears to be a valuable alternative to classic percutaneous bone-conduction implants for pediatric patients with a bilateral, conductive hearing loss.

Nonetheless, the local complications we observed suggest that the manufacturer’s instructions should be issued on how the external processor should be applied and that a close clinical follow-up is mandatory in the first months after switch-on.
The heterogeneous outcomes observed among our patients clarify that not all subjects with a bilateral, conductive hearing loss are equally good candidates for a Sophono implant. However, even if patients with severe hearing loss may not obtain a greater hearing gain than with an external BCHA, they can be very satisfied from a cosmetic point of view.

**Author Contributions**

Pasquale Marsella, substantially contributed to conception and design, to data acquisition, and to data analysis and interpretation, drafted the article and revised it critically for important intellectual content, and approved of the final version to be published; Alessandro Scorpecci, substantially contributed to conception and design, to data acquisition, and to data analysis and interpretation, drafted the article and revised it critically for important intellectual content, and approved of the final version to be published; Maria Vittoria Vallarino, substantially contributed to conception and design, to data acquisition, and to data analysis and interpretation, drafted the article and revised it critically for important intellectual content, and approved of the final version to be published; Simona Di Fiore, substantially contributed to conception and design, to data acquisition, and to data analysis and interpretation, drafted the article and revised it critically for important intellectual content, and approved of the final version to be published; Concettina Pacifico, substantially contributed to conception and design, to data acquisition, and to data analysis and interpretation, drafted the article and revised it critically for important intellectual content, and approved of the final version to be published.

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