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Case report

Abutment-free bone-anchored hearing devices in children: Initial results and experience

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ABSTRACT

Objectives: Bone-anchored implantable hearing devices are widely accepted as a surgical option for certain types of hearing loss in both adults and children. Most commercially available devices involve a percutaneous abutment to which a sound processor attaches. The rate of complications with such bone conduction systems is greater than 20%. Most complications arise from the abutment. Recently, the Sophono (Boulder, CO) Alpha 1, an abutment-free system, has been introduced.
Study design and methods: We conducted a retrospective chart review of the first five patients who underwent implantation with the Sophono abutment-free bone conduction hearing system with the Alpha 1 processor at our institution and report here on these patients' pre- and postoperative audiometric data and clinical courses.
Results: Average improvement in pure-tone average was 32 dB hearing loss and average improvement in speech response threshold was 28 dB hearing loss. All patients were responding in the normal to mild hearing loss range in the operated ear after device activation. Average improvement across individual frequencies was between 17 and 37 dB (SD 5.5–11 dB).
Conclusion: Our audiometric results to date are promising and have been consistent with published data on other bone-anchored hearing devices.

1. Introduction

Bone-anchored implantable hearing augmentation (BAHA) devices are widely accepted as a surgical option for certain types of hearing loss in both adults and children [1]. The U.S. Food and Drug Administration (FDA) approved the BAHA system for patients who have conductive or mixed hearing loss and can still benefit from sound amplification; patients with bilaterally symmetric conductive or mixed hearing loss (may be implanted bilaterally); patients with sensorineural deafness in one ear and normal hearing in the other; and patients who are candidates for an air-conduction hearing aid using contralateral routing of signals but who cannot or will not wear one. The BAHA device is approved for use in children older than 5 years. BAHA use in children has been well described and is typically undertaken for children with microtia or chronic suppurative otitis media precluding the use of conventional hearing aids [2,3].

Complication rates with BAHAs are between 23% and 33%, mainly relating to minor skin infections around the abutment [4–6]. In one series of 63 patients who received implants, 33% experienced skin infection, 17% experienced skin thickening around the abutment, and 2% experienced device failure related to the abutment [4]. Over a 20-year study period including 602 BAHA implants, one group reported an overall complication rate of 23.9% and a revision surgery rate of 12.1% [6].

Complication rates with the BAHA system are much higher in children than in adults generally, particularly in lower socioeconomic status populations [7]. Our practice is located at a tertiary-care children's hospital in urban Philadelphia, and a large proportion of our population falls under the poverty line. This prompted us to look for alternative methods for managing hearing loss in our patients.

The Sophono (Boulder, CO) Alpha 1 processor with an abutment-free bone conduction hearing system was introduced in 2006 and received approval for use in Europe via CE (Conformité Européenne) mark in and in the United States via FDA approval in 2010. Indications are the same as for the BAHA. The Sophono is also FDA approved for magnetic resonance imaging with field strength up to 3 Tesla [8]. We present our experience with the first five children who received the implant at our institution, their pre- and postoperative audiometric data, and clinical courses.

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2. Materials and methods

We report here on the first five patients who underwent implantation with the Sophono abutment-free bone conduction hearing system with the Alpha 1 processor at our institution. All five patients received implants in 2012.

We considered patient selection carefully and members of the implant team followed patients' pre- and postoperative courses closely. All patients had undergone medical evaluation by a pediatric otolaryngologist and audiologist, including appropriate imaging and screening tests. A trial of a BAHA Softband was offered to each patient prior to the Sophono implantation to determine his or her likely response to BAHA. Our surgical procedure followed the basic outlines described by Mulla et al. (see Fig. 1a–c) [1]. We made one small modification after our experience with our first patient, extending the flap incision 0.5 cm past the borders of the template provided into a "half circle" rather than a "bow" (Fig. 1a). This allowed improved retraction of the flap while adding minimal morbidity to the procedure. The rest of procedure remained as previously described.

Patients were seen in clinic for a wound check 1 week after implantation, and processors were initially placed at a 6-week

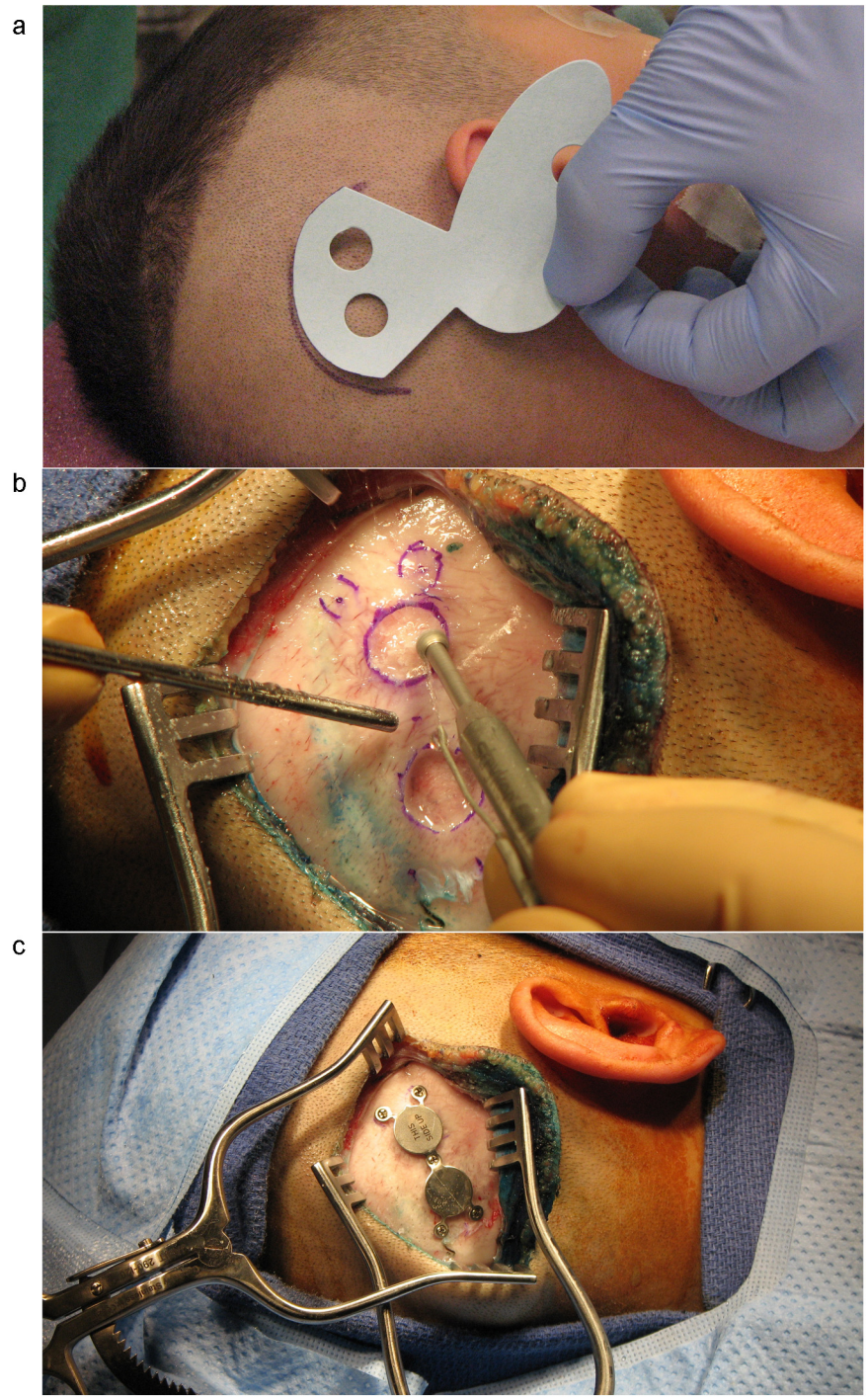

Fig. 1. Surgical procedure for implantation of the Sophono abutment-free bone conduction hearing system with the Alpha 1 processor. (a) Planned incision extending 0.5 cm past template on each end to allow for additional exposure. (b) Wells for implant being drilled. (c) Implant secured with titanium screws.