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Innovation in abutment-free bone-anchored hearing devices in children: Updated results and experience

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ABSTRACT

Introduction: Bone-anchored hearing devices are an accepted treatment option for hearing restoration in various types of hearing loss. Traditional devices have a percutaneous abutment for attachment of the sound processor that contributes to a high complication rate. Previously, our institution reported on the Sophono (Boulder, CO, USA) abutment-free system that produced similar audiologic results to devices with abutments. Recently, Cochlear Americas (Centennial, CO, USA) released an abutment-free bone-anchored hearing device, the BAHA Attract. In contrast to the Sophono implant, the BAHA Attract utilizes an osseointegrated implant.
Objectives: This study aims to demonstrate patient benefit abutment-free devices, compare the results of the two abutment-free devices, and examine complication rates.
Methods: A retrospective chart review was conducted for the first eleven Sophono implanted patients and for the first six patients implanted with the BAHA Attract at our institution. Subsequently, we analyzed patient demographics, audiometric data, clinical course and outcomes.
Results: Average improvement for the BAHA Attract in pure-tone average (PTA) and speech reception threshold (SRT) was 41 dB hearing level (dBHL) and 56 dBHL, respectively. Considering all frequencies, the BAHA Attract mean improvement was 39 dBHL (range 32–45 dBHL). The Sophono average improvement in PTA and SRT was 38 dBHL and 39 dBHL, respectively. The mean improvement with Sophono for all frequencies was 34 dBHL (range 24–43 dBHL).
Conclusion: Significant improvements in both pure-tone averages and speech reception threshold for both devices were achieved. In direct comparison of the two separate devices using the chi-square test, the PTA and SRT data between the two devices do not show a statistically significant difference (p-value 0.68 and 0.56, respectively). The complication rate for these abutment-free devices is lower than that of those featuring the transcutaneous abutment, although more studies are needed to further assess this potential advantage.

1. Introduction

Over the past three decades, bone-anchored hearing aids have become increasingly popular for the restoration of various types of hearing loss in the adult and pediatric populations. Though the idea of bone-conduction for sound amplification has been known and studied since the Renaissance, the concept of an aid fully implanted within bone was not developed until the 1970s [1]. According to the U.S. Food and Drug Administration (FDA), the current indications for use of such devices, included in Table 1, are unilateral and bilaterally symmetric conductive or mixed hearing loss, unilateral sensorineural hearing loss with normal hearing in the contralateral ear, and for any patient that meets indications for air conduction contralateral routing of signal (AC CROS) but cannot, or will not, wear the device. The FDA approved age includes those patients who are five years of age and older [2].

The published data demonstrates a complication rate between 20% and 30% for the abutment based BAHA implants. In a small pediatric retrospective review of 31 abutment based BAHA devices, the vast majority of patients had minor skin reactions around the abutment (89%) [3]. The major complication rate reported was as high as 37% with the commonest reactions being soft tissue overgrowth and infection, failure of osseointegration, and recurrent need for antibiotic [3]. In this study, 10/31 patients required

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Table 1
United States Food and Drug Administration (USFDA) indications for Bone-conduction hearing devices.

Unilateral conductive or mixed hearing loss
Bilaterally symmetric conductive or mixed hearing loss
Unilateral sensorineural hearing loss with a normal hearing contralateral ear
Patients that meet indication for air conduction contralateral routing of signal (AC CROS) but cannot or will not wear the device

* Indication for those aged 5 years and older.

either revision surgery or explantation as a result of local complications. This rate of complication is inflated from other studies and potentially is related to a two-stage procedure. The first being placement of the implant without soft tissue reduction, followed by excision of tissue around the implant and placement of a pedicled flap using a dermatome [3]. In a study by Wilkinson et al., a single vertical incision was used with soft tissue reduction and yielded a complication rate of 16.9% in 71 patients [4]. Chronic pain associated with implantation has been reported in the literature and in select cases has required removal on an elective basis. One study of 602 implants found that 2% of patient required removal as a result of chronic associated pain [5].

Our institution, located in an urban setting with a low socioeconomic demographic, has been using abutment-free bone-conduction devices for the past three years and initially used and reported on the Sophono (Boulder, CO) Alpha 1 processor. In our initial experience with the first five implanted patients for this device, our average improvement in PTA for this device was 32 dBHL and 28 dBHL for the SRT (both ranges 15–50 dBHL). We found a lower rate of complication, particularly major complications, than the abutment based conductive hearing systems [6].

The Sophono was made available following FDA approval in 2010 while, more recently, the BAHA Attract from Cochlear Americas (Centennial, CO, USA) was granted approval at the end of 2013. Both are compatible with MRI; however, the Sophono was approved to withstand field strength of 3 T, while the BAHA Attract was approved for 1.5 T [7,8]. Here, we present the experience with our first 6 BAHA Attract implant patients, their clinical course with both preoperative and postoperative audiometric data and compare the results to our updated list of Sophono recipients to include those implanted subsequent to the publication of our previous study.

2. Materials and methods

An IRB approved retrospective case series was undertaken at our institution to report on the first 6 BAHA Attract patients that underwent implantation at our institution. All BAHA Attract patients received their implants in 2014 and 2015. Additionally, we updated our experience with the Sophono Alpha-1 abutment-free conduction system with our latest 11 implants on 10 patients. These implants were placed in 2012 and 2013. Selection of patient subjects and surgical steps are described below.

Each patient was carefully selected to meet the indications set forth by the USFDA, and attempts were made to identify patients with appropriate social support to care for and utilize the devices implanted. All patients had an evaluation by a pediatric otolaryngologist and audiologist. Preoperative audiogram was conducted with inset or supra-aural headphones unless soundfield was appropriate. The evaluation included a soft band BAHA trial to assist in identifying those who would perceive the greatest benefit from implantation. The patients with suspected underlying disease or congenital aberrations underwent further medical and/or genetic screening. The surgical procedure for the Sophono device entailed a 5 cm bow shaped incision 7.5 cm posterosuperior to the external auditory canal and two injections of methylene blue through the periosteum. Around these two marked areas, wells for the implant were created with a diamond drill burr, the implant secured with titanium screws, and the incision closed. Our procedure followed these basic steps described by Mulla et al. with the exception of 0.5 cm extension of the flap past the template borders to improve exposure [9].

The BAHA Attract was implanted per the surgical guidelines set forth by the Cochlear Americas®. Briefly, the steps include incision, dissection to the periosteum and creation of small window through periosteum for the implantable titanium screw. The guide drill is then used to create the hole for the implant followed by the widening drill to make sure the hole is properly sized. The screw is then placed into the bone and bone bed indicator is used to make sure there is no bone that contact the magnet once attached. Once bone clearance is obtained, the magnet is screwed onto the implanted screw and the wound closed in layers [10]. Fig. 1 depicts some of the more important steps utilizing intra-operative photographs.

Postoperative appointments were made at one week to evaluate the wound and monitor for complications. The patients were seen by the audiology team roughly 4–6 weeks after surgery for placement, adjustment of processors, and determination of the proper magnet strength for each individual patient. In order to test the bone-anchored hearing aid, the patients had audiometric testing in a soundfield given the inability to use inset or supra-aural headphones for proper testing of the device. Both pure-tone average and speech reception threshold were consistently included in the battery and these measures were repeated during follow-up visits to ensure validity.

After approval was granted through the Drexel University College of Medicine Institutional Review Board, the data was collected retrospectively through a chart review of the practice and hospital electronic medical records (EMR) that utilizes NextGen™ Healthcare Information Systems, LLC software. Patient demographic, surgical, preoperative/postoperative audiometric data were collected from the practice database and analyzed. Statistical data was compiled and analyzed using Microsoft Office Excel database (Microsoft Corp., Redmond, WA, USA).

3. Results

In Tables 2 and 3, we include the demographic information for both the Sophono and BAHA Attract patients. A total of 17 ears implanted at our institution comprise this evaluation. Of these patients, one Sophono was never activated and another BAHA Attract patient is still pending his activation and thus the audiometric data is not available for those two implants. The preoperative and postoperative frequency data were determined using conventional audiometry with pure-tone averages, speech reception threshold and collected for analysis on the remaining 15 ears in 14 patients. The range of data from follow-up for the Sophono group is 445 days (range 121–763) and 224 (range 37–378) for the Attract group. This range does not indicate the time of activation, but the length of follow-up records available for review. The discrepancy in ranges is based on the later approval of the Attract device and thus shorter time for follow-up. The average age at implantation was 10.7 for both groups with a standard deviation of 3.3 and 4.5 years for the Sophono and Attract groups, respectively. The Sophono group was comprised of 80% (8/10) male patients and 20% (2/10) female patients, as opposed to the Attract group that included 67% (4/6) male and 33% (2/6) female patients.

The initial evaluation of hearing was performed with inset or supra-aural headphones as clinically appropriate and in soundfield postoperatively. Masking was utilized on the non-test ear (NTE) to reduce the chance of crossover given the limited interaural