Audiologic and Surgical Outcomes of a Novel, Nonpercutaneous, Bone Conducting Hearing Implant

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Objective: To assess the selection criteria, surgical technique, audiologic, and quality of life outcomes for a novel, nonpercutaneous bone conductor hearing aid.

Study Design: Retrospective case review.

Setting: Secondary otology practice.

Patients: Eighteen patients (16 adults and 2 children).

Intervention: Implantation of unilateral (n = 16) or bilateral (n = 2) devices.

Main Outcome Measures: Mean preoperative and postoperative air conduction and bone conduction free-field testing, BKB-SIN aided and unaided at 0-degree 70 dB SPL, Speech, Spatial, and Qualities of Hearing Scale (SSQ), aided and unaided measures of localization and discrimination in single-sided deafness (SSD), surgical complications.

Results: Implants have been fixed under general or local anesthesia without perioperative complications. Two patients noted minor skin irritation only. Audiologic gain was greatest for those with bilateral conductive loss (21.9 ± 10.4 dB HL). For those with bilateral and unilateral mixed loss, gain was 6.2 ± 5.3 dB HL and 5.5 ± 6.5 dB HL, respectively. A greater improvement was seen with BKB-SIN at 70 dB SPL at 0 with all groups except for SSD, gaining statistically significant benefit. Localization and discrimination studies in patients with SSD or unilateral conductive loss failed to detect benefit from aiding. SSQ scores show an improvement in all domains for each patient group.

Conclusion: The surgical procedure requires no specialized equipment and can be performed as a day case. This device complements treatment for patients requiring bone conduction aids and presents as an alternative to conventional percutaneous bone-anchored implants. Key Words: Bone anchored hearing device—Hearing implant—Nonpercutaneous implant.

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position to conventional BAHDs. The implantable twin magnets are composed of samarium cobalt hermetically sealed within a titanium case. The implant is fixed into the bone with titanium screws through the 5 side arms of the magnet (Fig. 1). The external twin magnets are embedded into an acrylic baseplate, which is firmly connected with the vibrator (Fig. 2). The geometric pattern is similar to that of the internal component; the 4 high-strength magnets provide rotational stability and prevent magnetic disturbance of the vibrator. The vibrator is controlled by a digital 4-channel processor with 16 frequency bands, adaptive noise reduction, and 5 adjustable notch filters (2).

Per manufacturer’s instructions, the Sophono Alpha 1(M) is suitable for patients with conductive or mixed loss and children older than 5 years. Bone conduction should be 45 dB or lower or preferably 40 dB or lower for better results (Fig. 3). It is also suitable for SSD patients with BC of 20 dB or lower.

Surgical Technique

The twin magnets can be implanted under day-case local or general anesthesia procedure. After skin preparation and infiltration, the position of the magnets is marked (templates are available). To assist in placement, marking with methylene blue through the skin can be used. A curved incision approximately 7 cm superior and posterior to the external ear canal is made through the skin and extended down to the bone (Fig. 4). An area of bone approximately 30 × 15 mm is exposed so that the magnets can be positioned approximately 6 cm away from the external ear canal but not directly under the incision (Fig. 5). Shallow bone beds are drilled out with a depth of at least 2.6 mm for the magnets (Fig. 6). The implant is then fixed into the bone beds with 1.5 mm mini-screws (Fig. 7). Finally, the skin may need to be thinned. This is not necessary in children, but in adults, a skin thickness of 4 to 6 mm is optimal to reduce the attenuation of vibration. The incision is closed with a subcuticular absorbable suture and a pressure dressing is applied for 1 day. The device can be used once the incision has healed and any tenderness settled (usually at approximately 4 weeks postoperative).

MATERIALS AND METHODS

We recruited 18 patients (16 adults and 2 children) with conductive and mixed hearing loss, in whom the Sophono Alpha
1(M) was implanted between December 2010 and June 2012. Two of the patients received bilateral implants; therefore, 20 devices were implanted in total. In all cases, surgery was performed in a single session. The causes for which the patients received a Sophono Alpha 1(M) implant were bilateral mixed loss (7 patients) bilateral conductive hearing loss (CHL) (4 patients), SSD (3 patients), unilateral mixed loss (2 patients), and unilateral CHL (2 patients). The following parameters were assessed for each patient:

- Mean preoperative and postoperative air conduction (AC) free-field testing at the frequencies of 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz;
- Mean preoperative and postoperative bone conduction (BC) at the frequencies of 500, 1,000, 2,000, and 4,000 Hz;
- BKB-SIN (Bamford-Kowal-Bench Speech-in-Noise test), aided and unaided at 0 degrees, 70 dB SPL;
- Quality of life gain, calculated using the Speech, Spatial, and Qualities of Hearing” (SSQ) questionnaire (SSQ-B version 5.6);
- Aided and unaided measures of discrimination and localization ability in patients with SSD and unilateral CHL;

RESULTS

Audiologic Data

As shown in Figure 8, for those with bilateral mixed loss, mean preoperative AC thresholds were $58.1 \pm 9.4$ dB HL, BC thresholds were $25.9 \pm 22.9$ dB HL with an average air-bone gap of $31.7 \pm 26.3$ dB HL. Aided with the Sophono Alpha 1(M), the average gain for this group across all frequencies was $6.2 \pm 5.3$ dB HL.

For bilateral CHL, mean preoperative AC thresholds were $52 \pm 6.4$ dB HL, BC thresholds were $6 \pm 0$ dB HL with an average air-bone gap of $46 \pm 6.4$ dB HL. Aided with the Sophono Alpha 1(M), the average gain for this group across all frequencies was $21.9 \pm 10.4$ dB HL.

For unilateral mixed loss, mean preoperative AC thresholds were $32.3 \pm 24.6$ dB HL, BC thresholds were $32.1 \pm 15.4$ dB, with an average air-bone gap of $23.6 \pm 14.1$ dB.
Aided with the Sophono Alpha 1(M), the average gain for this group across all frequencies was $5.5 \pm 6.5$ dB HL.

For those with unilateral CHL, mean preoperative AC thresholds were $46.3 \pm 4.3$ dB HL, BC thresholds were $8.1 \pm 0.6$ dB, with an average air-bone gap of $38.5 \pm 4.8$ dB. In the aided results for these and the SSD patients, functional gain cannot be calculated as free-field testing is not valid for this group. Therefore discrimination, localization studies, and quality-of-life measurements were used (see below).

**Bamford-Kowal-Bench Speech-in-Noise Test**

Average improvement in BKB-SIN at 70 dB SPL at 0 degree is summarized in Figure 9. The greatest improvement is seen in those with bilateral CHL. The level of significance is taken as $2.2$ dB (95% confidence interval).

**Quality-of-Life Outcomes**

Results for the improvement in quality of life using the SSQ-B score (10 points in 3 categories; speech, spatial, and qualities) are summarized in Figure 10. Again, the greatest overall improvement is seen in those with bilateral CHL.

**Localization Testing**

For BKB-SIN testing signal 0 degree and noise 0, 90, and 270 degrees, no significance difference was seen aided versus unaided in the SSD patients. A similar result was seen with the sound localization studies at 15- and 30-degree intervals. For the unilateral CHL group, there was no detectable difference between unaided and aided values as all had normal localization preimplantation.

**Complications**

In the 20 operations that were performed, transient, minor skin complications only were reported in 2 cases (10%). In 1 patient, skin erythema settled with topical treatment, and in the other, irritation settled after magnet strength reduced. There were no major complications.

**DISCUSSION**

Looking at our audiologic results, good outcomes were seen for those patients with unilateral mixed hearing loss and reasonable outcomes for those with bilateral CHL. For those with the bilateral mixed loss, however, the results were a little disappointing. These were a heterogeneous group of patients with variable bone conduction; 1 patient in fact had bone conduction of 48 dB and so was strictly just out of criteria for implantation. Perhaps this accounts for the slightly poorer audiologic performance of this group. An improvement was seen when we take into the account the SSQ-B score; however, this was not statistically significant in any of the parameters. Those with bilateral CHL saw the greatest improvement on BKB-SIN scores, and those with SSD and unilateral mixed loss, perhaps predictably seeing little improvement as aiding is to primarily help with localization of sound and the ability to hear on the side with hearing loss.

To date, the only other available series on outcomes of the Sophono Alpha 1(M) was that by Siegert (2) who have published preliminary clinical and audiologic results of 12 patients (8 unilateral and 4 bilateral) of more than 100 patients implanted with the Sophono Alpha 1(M). They reported an average hearing gain in free-field pure tone audiogram to be $31.2 \pm 8.1$ dB HL and supra-threshold speech perception at 65 dB in free-field increased from 12.9 without the hearing device to 72.1% with the hearing device. The authors did not specify the nature of the hearing loss in these patients.

In comparison to our series, the audiologic results from the long established BAHA device are better. Lustig et al. (3) reported an average improvement of $32 \pm 19$ dB HL with the use of the BAHA in their series of 40 patients. Similarly, Ricci et al. (4) reported a mean postoperative free-field threshold of $26.2 \pm 13.9$ dB HL versus a mean preoperative threshold of $58.3 \pm 23.6$ dB HL, and air-bone gap closure in 40 (85.1%) of 47 patients. In a series of 20 pediatric patients, Seeman et al. (5) achieved a mean postoperative free-field threshold of $16$ dB HL (range, 10–28 dB), with a mean preoperative threshold of $49$ dB HL in the better ear. The reason why the results for the “abutment” system are better is perhaps attributed in part to the attenuation in signal through the transcutaneous route. This is estimated to be 10 to 15 dB HL (1).

Our results for aided sound discrimination and localization in those patients with SSD showed no objective
gain with the Sophono Alpha 1(M). The results for the BAHA have also been disappointing. Although a few studies have demonstrated an improvement in sound discrimination testing using BKB-SIN in different listening conditions (6,7), several studies on the use of BAHA for SSD using BKB-SIN testing have also failed to detect any significant improvement (8–11). Similarly, localization ability with BAHA in those patients with SSD was not significantly from the aided condition (6,9), although Hol et al. did record a self-reported perceived benefit in localization (6).

The advantages of the Sophono Alpha 1(M) are, however, apparent when we look at the complication rates associated with the BAHA device. The most common complication seen with abutment-based BAHDs is peri-abutment soft tissue reaction. Holger’s skin reaction classification ranges from skin irritation and erythema to an overt infection causing implant extrusion (12). Reported complication rates from the BAHA have ranged from 8% to 59%, and reported revision rates were from 5% to 24% (3,13–26). In the largest series (602 implants) to date, the overall complication rate was 23.9%, and rate of revision surgery was 12.1% (27). The main complication was soft tissue overgrowth (8% patients), abutment site infection (5.1%), abutment and fixture dislodgement (4.3%), and trauma (1%). The longest follow-up of BAHA patients, 14 years (average of 9 yr) by Wallberg et al. (28) reported substantial rates of implant because of loss of osseointegration (12.9% patients), direct trauma (6%), and removal (12.1%). We anticipate that skin reactions (apart from local irritation over the magnet site), infections, and overgrowth and loss of osseointegration will not occur with the Sophono Alpha 1(M) device.

CONCLUSION

The Sophono Alpha 1(M) represents an alternative choice in the rapidly expanding array of alternative devices for patients in whom a BAHD is indicated. The audiologic and quality-of-life outcomes are less favorable than the long-established BAHA to some extent; however, in the carefully selected patients (i.e., in those with “good” bone conduction) the audiologic results are comparable, and the cosmetic and wound care benefits are undeniable. A soft band trial device, the Sophon Alpha 1(S), is available, and we would strongly advise that any potential patients have adequate trials with this before implantation.

REFERENCES


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