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Sophono Systems in 5 Pediatric Cases in Philadelphia

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

Published Int J Pediatr Otorhinolaryngol. 2014 May

Summary of a Clinical Study
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Objective

- Assessing the Sophono Alpha 1, a new transcutaneous abutment-free system, as compared with other percutaneous bone conduction systems, which have a complication rate of more than 20% that arise mainly from the skin-penetrating abutment.

Patients and Study Design

- 5 patients – all underwent Sophono implantation
- The patients were between 5 years to 12 years, median 10 years
- 1 patient moderate bilateral conductive hearing loss, 1 patient unilateral sensorineural hearing loss, 2 patients had moderate conductive hearing loss, 1 patient severe conductive hearing loss
- Average length of follow up: 145 days
- Conduction of 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 the institution and reporting on the patients' pre- and post-operative audiometric data and clinical courses.

Evaluations

1 week after implantation	Wound check
6 weeks after implantation	Individual frequency data using conventional audiometry, pure-tone averages (PTAs), speech recognition thresholds (SRT), and masking of the unaided ear.

Other Parameters

Average length of time from implantation to activation	**145 days (SD 57)**
Sophono Processor Type	**Alpha 1**

Timeline

- At the time of submission the average length of follow-up was 145 days (SD 57)

Clinical Results

	Pre-Op (unaided)	Post-Op (aided)	Change (improvement)
Pure-Tone Average	57 dB	25 dB	32 dB
SRT	56 dB	28 dB	28 dB

- Pressure points over the implant for one patient were resolved after compliance to the proper post-activation instructions as provided by Sophono, by adjusting the appropriate strength of the magnet and short spans of time of use until full accommodation.
- 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

- The surgical procedure is relatively simple, and morbidity is low while recovery is fast. Audiometric results have been consistent with published data on other bone-anchored hearing devices.

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