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Clinical experience with sophono alpha 2 mpo™ in conductive, mixed and sensorineural hearing losses patients

Abstract

Aim: Transcutaneous bone conduction devices such Sophono™, help to overcome the problems with the skin of percutaneous bone conduction hearing aid devices such as BAHA connect™ (Revisional surgery, infection/granulation, implant covered by skin). To assess the outcomes and clinical safety of the Sophono Alpha 2MPO™ in a series of patients with conductive, mixed and neurosensorial hearing losses, we conducted this study.

Method: Cross-sectional cohort study. Patients with unilateral or bilateral conductive, mixed or neurosensorial hearing losses were included in this study. Repeated-measures within-subjects for assess pure tone thresholds (four frequencies) and speech discrimination score (Disyllabic test), in unaided (or preoperative) and aided situations were recorded and compared. T-tests for paired samples were used for statistical analysis. The follow-up looking for major and/or minor complications were done to establish security or adverse effects and their frequencies are reported. All patients underwent surgeries in two tertiary referral centers, using the same technical surgery (recommended by the manufacturer) and using uniform selection criteria. At the time of the last measurement, all patients were using the Sophono Alpha 2MPO™ processor.

Results: 72 patients underwent implantation with Sophono™, at the cut-off time of review the files for this study. Of all of them, complete information of 65 patients was obtained and their results are reported. 34 patients were male (52.3%) and the right side was more frequently implanted (44 cases, 67.7%). The age of implantation was between 5ys -73ys (mean=28.5ys; SD=20.8ys).

The mean follow-up of the group was 21.2±15.3 months (minimum=1m; maximum=65.8ms). The mean pure tone average (four frequencies) and the speech discrimination score (65dB SPL-free field) in aided condition were significantly better that in unaided condition ($p<0.05$), both for conductive hearing losses, as well as mixed and sensorineural hearing losses. The mean gain was over 25dB in all three groups of patients.

As major complication only one patient (1.5%) had necrosis of the flap and required surgical revision, with success outcome and implant survival. As an aspect to be taken into account, adherence to the use of the device was lower in patients with sensorineural hearing loss (single sided deafness) respect to conductive or mixed losses patients ($p<0.05$).

Conclusion: in our experience with Sophono™ implant device, the outcomes and clinical safety are satisfactory and supports it's the reliable use, for patients with conductive, mixed and sensorineural hearing losses. A special attention would be taken with patients with sensorineural hearing losses respect to their adherence to device and counseling should be emphasized in this regard in the preoperative period.

Keywords: conductive hearing loss, mixed hearing loss, sensorineural hearing loss, deafness, bone conducted sound

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Conflicts of interest

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