BRIEF COMMUNICATION

Initial Experience With the Sophono Alpha 1 Osseointegrated Implant

Vicente Escorihuela-Garcia, Ignacio Llópez-Carratalá, Ignacia Pitarch-Ribas, Emilia Latorre-Monteagudo, Jaime Marco-Algarra

Servicio de Otorrinolaringología, Hospital Clínico Universitario de Valencia, Universidad de Valencia, Valencia, Spain

Received 14 October 2013; accepted 12 January 2014

KEYWORDS
Bone anchored hearing aid; Microtia/atresia; Conductive hearing loss

Abstract In the last several years, bone anchored hearing aids have proven to be useful in treating conductive and mixed unilateral or bilateral hearing loss, as well as for sensorineural unilateral hearing loss. The Sophono Alpha 1 model has the advantage of not requiring an abutment, with it being coupled by magnetism instead. We report the cases of 3 infants with congenital malformations of external and middle ear. Audiometry showed conductive hearing loss. All 3 patients were implanted with Alpha 1 model (Sophono). Patients evolved satisfactorily. After 30 days we applied the processor and the control audiometry showed a marked improvement of hearing thresholds, although without a complete closure of the gap. With minimal care, the skin over the implant remained in excellent condition, with a very satisfactory cosmetic outcome.

© 2013 Elsevier España, S.L.U. and Sociedad Española de Otorrinolaringología y Patología Cérvico-Facial. All rights reserved.

PALABRAS CLAVE
Implante auditivo osteointegrado; Microtia-atresia; Hipoacusia de conducción

Experiencia inicial con el implante osteointegrado Alpha 1 de Sophono

Resumen En los últimos años los implantes osteointegrados han probado su utilidad en el tratamiento de la hipoacusia de transmisión mixta, unilaterales, o bilateral, y la neurosensorial unilateral. El implante Alpha 1 de Sophono ofrece una ventaja sustancial, la falta de acoplador externo y su unión al receptor por medio de magnetismo. Presentamos el caso de 3 niños que padecen malformaciones de oído externo y medio de origen congénito. Los estudios audiométricos revelan hipoacúsias de transmisión de carácter moderado. En los 3 pacientes se propuso la colocación del implante Alpha 1 de Sophono. Los pacientes evolucionaron de forma satisfactoria.

* Corresponding author.
E-mail address: zingaro85@hotmail.com (V. Escorihuela-Garcia).

2173-5735/© 2013 Elsevier España, S.L.U. and Sociedad Española de Otorrinolaringología y Patología Cérvico-Facial. All rights reserved.
Introduction

The usefulness of bone anchored hearing implants for the treatment of patients with pure or mixed, unilateral or bilateral conductive hearing loss has been more than demonstrated and has become a form of surgery which has seen the greatest advances in recent years. About 2600 people use bone anchored hearing implants in Spain. The typical patient who is suitable for this type of implant usually has conductive hearing loss and good cochlear reserve. This applies for patients with hearing loss as a sequel to chronic otitis media or radial mastoidectomy, microtia and atresia or acquired stenosis of the external auditory canal, ossicular chain malformations and all patients who are not able to receive functional surgical management. Furthermore, patients with unilateral neurosensory hearing loss who maintain contralateral hearing which goes from normal to a slight hearing loss, may also benefit from bone anchored implants as they stimulate the contralateral ear through bone conduction.

Conventional bone anchored implants require an external abutment which causes some problems with care. The processor has to be handled carefully when inserting or removing it from the abutment to avoid knocking the abutment which, as it is bone anchored, can cause considerable pain. Moreover, the skin tends to grow around the abutment and this can cause complications.

The Sophono Alpha 1 implant has a series of advantages: it involves a simple surgical technique; it offers the possibility of coupling the processor as soon as the skin of the surgical wound has completely healed, in a maximum of 3 or 4 weeks; the implant is completely hidden below the skin and there is no need to remove hair follicles; there is therefore less aesthetic alteration and the risk of the implant becoming damaged by handling is reduced; finally, its magnetic abutment allows the processor to be removed easily and skin care around the site of the implant is not so essential.

Material and Methods

We present the case of 3 children between 6 and 11 years of age with congenital malformations of the outer and middle ear. The first case is a child of 6 with micrognathia, cleft palate and anomalies of the outer ear and the ossicular chain determining major transmission hearing loss. In tonal audiometry of the patient, air-conduction thresholds of 60 dB were observed; the bone-conduction thresholds were within normal limits. The second case is a child of 8 of reduced stature and facial abnormalities with dysplastic ears, preauricular appendices and stenosis of the external ear canal. A varying degree of learning difficulty

Figure 1 Audiometry patients: (A) 6 year-old boy; (B) 8 year-old boy and (C) 11 year-old girl. Rhombuses, air-conduction with headphones ear which is the candidate for the implant. Squares, bone-conduction of this ear. Triangles, air-conduction of the implanted ear using free field with contralateral masking.
was also associated. Air-conduction thresholds around 65 dB and bone-conduction thresholds which did not exceed 25 dB were observed in this child. And finally, the third case is a girl of 11 with microtia with stenosis of the external auditory canal on only one side. In this case we used liminar tonal audiometry which showed normal hearing in the healthy ear compared to moderate conductive hearing loss in the contralateral ear, with air-conduction thresholds of 50 dB and a gap which oscillated around 35 dB (Fig. 1).

The 3 patients underwent computerised tomography which revealed obvious stenosis of the external ear canal caused by soft tissue, with partial or complete absence of the ossicular chain, and malformed remnants of same, and complete normality of the inner ear structures. Bone cortex thickness was confirmed in all of the cases in excess of 3 mm, essential to be able to make an adequate ream and sufficient to prepare the implant bed.

After audiometric and radiological study, placement of the Sophono Alpha 1 bone implant was proposed, due to the low morbidity associated with the surgery and the better aesthetic result provided by this implant, as well as the need for less postoperative care which would be difficult to ensure with patients of this age.  

![Figure 2](image-url) Main steps of surgery using Sophono Alpha 1 implant.

**Results**

The surgical procedures were performed without incident (Fig. 2). The 3 patients evolved satisfactorily and returned to their regular daily activities 4 or 5 days after the procedure. The processor was put in 30 days later. The free field audiomtries with contralateral masking a month and a half after surgery are shown in Fig. 1. In the case of the boy of 6, thresholds went from 60 dB to 30 dB the gap being obviously reduced, although no completely closed. The boy of 8 experienced a similar situation, going from thresholds of 65 dB to 40 dB. Closure of the gap was not complete either, although the improvement was undeniable. The parents also highlighted in both cases that their children showed, not only increased hearing ability, but also an improved ability to communicate which helped them towards greater self-sufficiency. Finally, the girl of 11 experienced restored air-conduction thresholds at intensities of 20 dB. The improvement in location and perception of the spatial distribution of sounds, and level of understanding was also evident for this girl.

The patients were reassessed 3 to 6 months after the initial surgery. No complications, faults or problems were
found with the working of the implant. The aesthetic result was excellent, the operation site and the processor could hardly be seen. The audiometric values remained similar to those of the first postsurgical audiometry. And, finally, the patients and their families were highly satisfied in all three cases.

**Discussion**

We have used traditional bone anchored devices in our hospital to date. These are characterised by the need for an external abutment to connect the processor to the implant. Several articles describe the complications involved with these types of bone anchored hearing aids. We can state that the main problem found has been the overgrowth of skin around the abutment, which hinders it properly connecting with the processor. A high percentage of patients require reoperation to remove the excess skin. The Sophono Alpha 1 model does not require this external abutment, achieving optimal connection between the processor and the implant using a magnetic system, thus reducing this type of complication, which can be difficult to manage in children. In the cases presented in this work, the skin over the implant remained in excellent condition, as did the scarring behind the ear, no strict monitoring or special care was required. The aesthetic result was, therefore, optimal. In terms of functional result—this was good—although we were not able to guarantee it would be like that expected of a conventional bone anchored system. Closure of the gap was not complete in the first 2 patients; this could be explained by the transcutaneous attenuation produced in the conduction of stimuli in these types of implant; this does not occur with traditional devices, as direct bone conduction is maintained. However there is clear improvement in the thresholds achieved by these 3 patients. In fact, various studies, such as that of Siegert, demonstrate that the average patient using a Sophono Alpha 1 device experienced an improvement of $38 \pm 8$ dB in hearing threshold; this data coincides with that found in our three patients, where the median gain varied between 25 dB and 30 dB. Other studies such as that of Hol, which compares percutaneous implants to transcutaneous implants, state that the Sophono implant offers attractive clinical benefits in hearing but that, in general, these do not reach the level achieved by conventional implants.

**Conflict of Interests**

The authors have no conflict of interest to declare.

**References**