

Active middle-ear implant fixation in an unusual place: clinical and audiological outcomes

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Abstract

Objective: The Vibrant Soundbridge is an active middle-ear implant for hearing rehabilitation that is usually placed in the long process of the incus or round window. This study reports on the unusual implant attachment to the short process of the incus in a patient with ear malformation, and describes their audiological and clinical outcomes.

Methods: Case report and literature review.

Results: Audiological evaluation with the Vibrant Soundbridge implant showed a pure tone average of 31 dB. The speech test, at 65 dB HL, revealed correct recognition of 92 per cent of disyllabic words. The Glasgow Hearing Aid Benefit Profile showed high levels of satisfaction, hearing aid use and benefit.

Conclusion: Fixation of the Vibrant Soundbridge implant on the short process of the incus is a feasible option, with good clinical and audiological outcomes. Coupling the floating mass transducer to the short process of the incus is a good surgical option, especially when the long process and the oval or round window are inaccessible.

Key words: Hearing Loss; Incus; Hearing Aids; Middle Ear Implant

Introduction

Congenital aural atresia results from a malformation of the first two branchial arches. There is a wide range of deformities in the pinna and tympanic bone, and in middle-ear development. Thus, congenital aural atresia is an important cause of conductive hearing loss, which can occur unilaterally or bilaterally, in isolation or as part of syndromic cases. Its incidence is estimated at 1:100 000 births.¹ Hearing rehabilitation methods in this group include surgical reconstruction, and the use of bone vibration arches, bone-anchored hearing aids (BAHAs) and, more recently, active middle-ear implants. The use of standard hearing aids is limited to patients with a pervious external auditory canal, which enables its fitting.

Active middle-ear implants are implantable hearing aid devices usually recommended in cases of moderate-to-severe hearing loss. These implants are among the newest hearing technology systems, and we still do not have complete data on all possibilities for clinical and surgical uses.

The Vibrant Soundbridge[®] is a semi-implantable hearing aid with an external audio processor and an internal implant that includes the floating mass transducer. The floating mass transducer is a vibrating device that delivers signals to the cochlea through the round or oval windows. The first report on Vibrant Soundbridge implantation was in 1996; it is classically fixed on the long process of the incus, perpendicular to the stapes footplate.² Recent publications have described placing the floating mass transducer directly in contact with the round window.^{3,4} The short process of the incus had been described theoretically as a possible structure

for implant fixation.⁵ However, to our knowledge, there are no clear clinical descriptions of placing the floating mass transducer here.

This study aimed to report on the unusual attachment of the floating mass transducer to the short process of the incus, and to describe the audiological and clinical outcomes. This alternative fixation was undertaken as the only viable option in a patient with external and middle-ear malformation.

Case report

This case report, which is based on a chart review, was approved by the institutional ethics committee.

The patient was a 17-year-old male with non-syndromic bilateral microtia and osseous atresia. He had previously undergone plastic surgery in the left ear, in 2011. Since 2012, he had used a bone vibration arch in the right side, with low acceptance for aesthetic reasons.

Conventional pre-anaesthetic and ENT evaluations were performed. A high-resolution temporal bone computed tomography scan revealed total atresia of tympanic bone, which was attached to a well-defined ossicular chain, with good mastoid pneumatization. The overall score on the Jahrsdoerfer grading scale for congenital aural atresia evaluation was 6 (out of a total possible score of 10).⁶

Pre-operative audiological evaluation consisted of pure tone audiometry (Figure 1) and bone vibration arch tests. Implantation of the Vibrant Soundbridge device (Med-EL, Innsbruck, Austria) took place in August 2014 and the device was activated one month later.

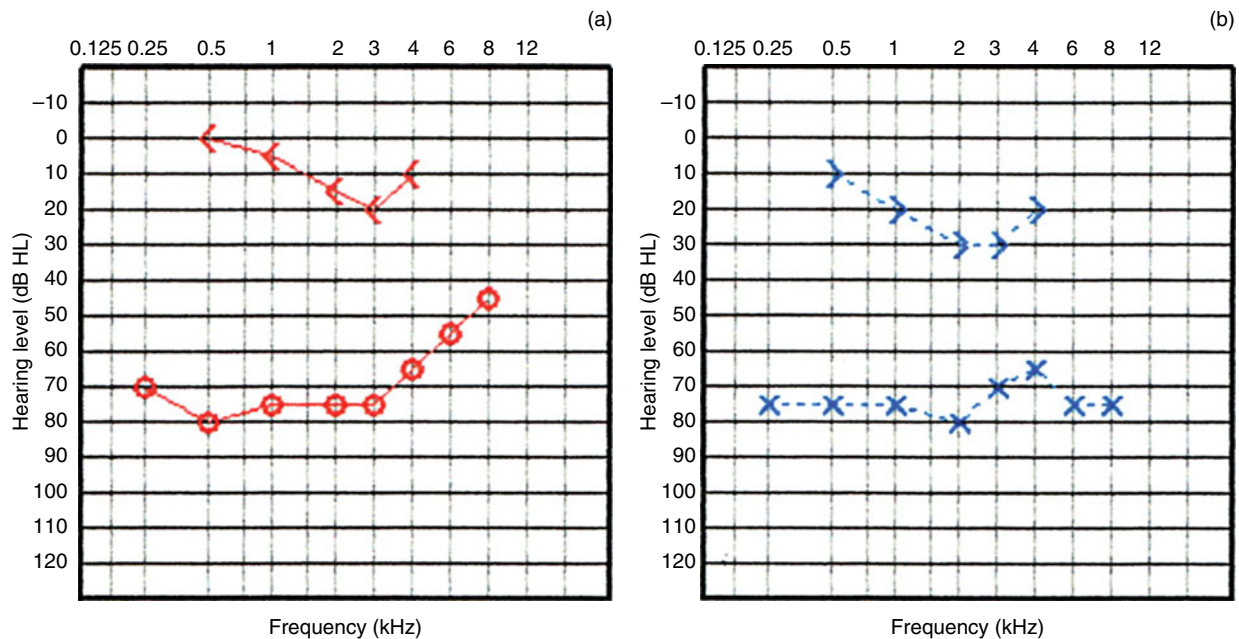


FIG. 1

Pre-operative pure tone audiometry for (a) right ear and (b) left ear. < = Bone conduction (unmasked) right ear; ○ = air conduction (unmasked) right ear; > = bone conduction (unmasked) left ear; × = air conduction (unmasked) left ear

The first steps of surgery were retroauricular incision followed by a cortical mastoidectomy, under general anaesthesia with facial nerve monitoring. The antrum was accessed and the area corresponding to the incudal fossa was identified, as was the incus. Adequate posterior tympanotomy was not possible because of the atretic tympanic bone overhang that occluded the middle-ear space, blocking the vision of the long process of the incus.

Having performed atticotomy, the body of the incus and head of the malleus became detached. Further drilling carried the risk of intense vibration to the ossicular chain.

Once the mobility of the ossicular chain was confirmed, and given that proceeding with drilling was not advised, the most feasible option was to fix the floating mass transducer to the short process of the incus. The titanium attachment clip was enlarged with ordinary forceps to make the device suitable for placement on the short process of the incus, and the device was then fixed (Figure 2).

There were no intra-operative or post-operative surgical complications. The bone conduction thresholds in the post-operative period were unchanged compared to pre-operative status, demonstrating the absence of inner-ear injury following the surgical procedure.

Audiological evaluation was performed 10 months after surgery, with free-field pure tone audiometry, in Vibrant Soundbridge aided and unaided conditions. At 0.25, 0.5 and 1 kHz, the functional gains were 45, 55 and 50 dB, respectively. At 2, 3 and 4 kHz, the functional gains were 50, 30 and 30 dB, respectively (Figure 3). The pure tone average (PTA) (0.5, 1, 2, 3 kHz warble tones) in free-field Vibrant Soundbridge aided conditions was 31 dB. Vibrant Soundbridge aided speech test results, at 65 dB HL, revealed correct recognition of 92 per cent of disyllabic words.

Evaluation of quality of life was performed using the Glasgow Hearing Aid Benefit Profile.⁷ The questionnaire results (on a scale of 0 to 100) showed high levels of satisfaction (score of 100), hearing aid use (score of 85) and benefit

(score of 85), with low levels of initial disability (score of 35), handicap (score of 32) and residual disability (score of 42).

Discussion

Conventional treatment of congenital aural atresia involves atresioplasty and ossicular chain reconstruction. Excellent results are rarely obtained, mainly because of surgical difficulties in severely malformed ears, frequently resulting in a significant residual air–bone gap and aesthetically poor results. In a long-term follow-up study, De la Cruz and Teufert published a hearing threshold of 30 dB or more in 50.8 per cent of early cases and in 39.1 per cent of revision cases.⁸ Non-surgical hearing rehabilitation methods have been limited to conventional bone conducting hearing aids, which also show evidence of low acceptance.

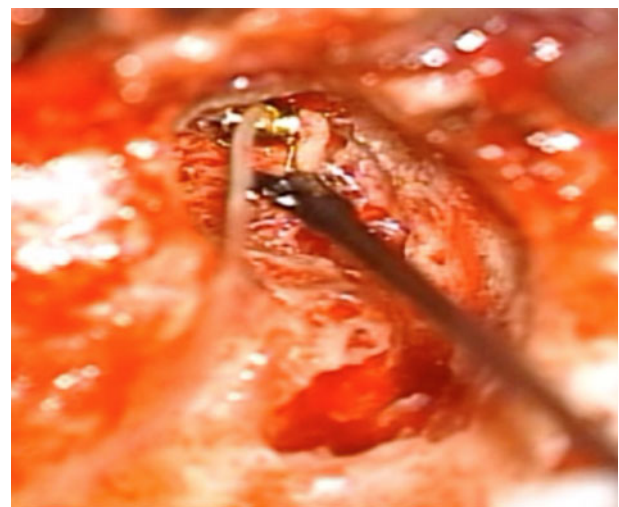


FIG. 2

Implant attachment to the short incus process.

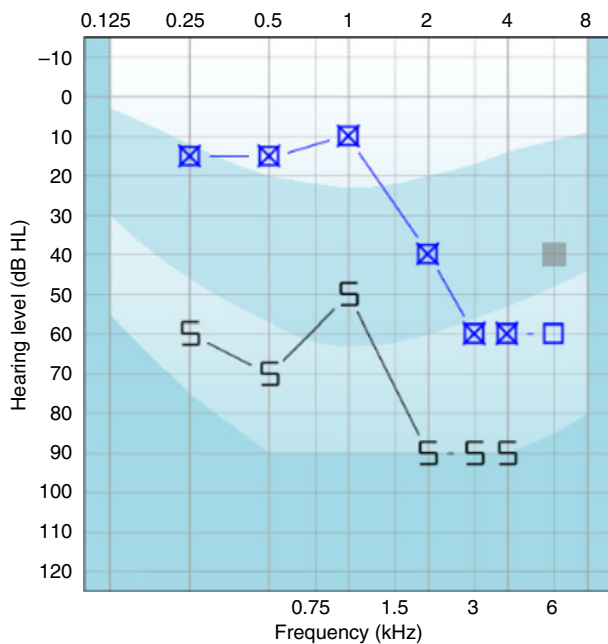


FIG. 3

Ten months' post-operative pure-tone audiometry in free-field conditions in Vibrant Soundbridge aided (X) and unaided conditions (S).

In recent years, BAHAs have become an alternative to conventional devices. Although an interesting option, these also have some limitations, mostly relating to skin and soft tissue problems around the abutment, and to aesthetics. A BAHA was offered to our patient but was declined, probably because of the aesthetics of the permanent percutaneous abutment. After the patient's rejection of the BAHA, we considered the option of active middle-ear implants.

Active middle-ear implants were originally prescribed for sensorineural hearing loss, but have since become an option for cases of mixed and conductive hearing loss.⁹ They have been successfully used in cases of aural atresia, with the floating mass transducer placed in the round window niche.^{10,11} A study by Clarós *et al.* evaluated Vibrant Soundbridge implantation in various medical situations, including in 13 patients with ear malformation in whom the implant was fixed in the oval window in contact with the stapes footplate.¹² The results showed that word recognition at 65 dB SPL improved, on average, from 13 per cent in the unaided condition to 97 per cent in the Vibrant Soundbridge aided condition. Another multicentre study, which involved 28 patients with congenital aural atresia who underwent Vibrant Soundbridge implantation with the device fixed on the long process of the incus, showed a speech threshold of 39 dB and speech recognition rate of 94 per cent.¹³ Our patient, in the Vibrant Soundbridge aided condition, correctly recognised 92 per cent of words at 65 dB SPL and the PTA was 31 dB. Despite the differences between our approach and the usual techniques, the results from our study show similar audiological outcomes to the aforementioned publications.

Coupling the floating mass transducer to the long process of the incus requires a posterior tympanotomy and, given the device's dimensions, a relatively wide opening of the facial recess to allow for its correct setting. This posterior tympanotomy carries some increased surgical risk, particularly to

the facial nerve. Although there are no reports of facial palsy in Vibrant Soundbridge implantation,⁵ avoiding posterior tympanotomy may be favourable in some anatomical situations.

In a cadaveric study, it was demonstrated that the floating mass transducer electromechanical velocity responses for fixation on the short process of the incus were similar to responses for fixation on the long process.⁵ In our patient, fixation on the short process led to good audiological and clinical outcomes.

- **The Vibrant Soundbridge is an active middle-ear implant for hearing rehabilitation usually placed on the long process of the incus or round window**
- **In some malformed ears, the long process of the incus and the oval or round windows are surgically inaccessible**
- **Fixation of the Vibrant Soundbridge on the short process of the incus is feasible, and has good clinical and audiological outcomes**

According to the Glasgow Hearing Aid Benefit Profile, the Vibrant Soundbridge device has a high level of benefit, satisfaction and daily use, and demonstrates a very high rate of aesthetic acceptance.

Conclusion

The short process of the incus is a feasible location for fixation of the Vibrant Soundbridge device, with very good clinical and audiological outcomes. Coupling the floating mass transducer to the short process of the incus is a viable surgical option, especially when the long process of the incus and the oval or round windows are surgically inaccessible and there is mobility of the ossicular chain.

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Dr J F Polanski takes responsibility for the integrity of the content of the paper

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