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Surgical Considerations for an Osseointegrated Steady State Implant (OSIA2®) in Children

Short title: Surgical Consideration for OSIA2 in Children

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Introduction

Bone conduction devices provide access to sound in children who are otherwise unable to wear or gain benefit from conventional hearing aids. They are used to treat conductive and sensorineural hearing losses resulting from a variety of etiologies, such as aural atresia or single sided deafness. The application of such devices has been limited in part by soft tissue complications, particularly those associated with skin penetrating abutments. The Osseointegrated Steady State Implant 2 (OSIA2®) System was developed to provide hearing through bone conduction while avoiding complications previously reported in children using percutaneous devices.(1) We aim to describe the candidacy and surgical technique developed for implantation of this device in a pediatric cohort.

Methods and Materials

The study protocol was approved by the Research Ethics Board at the Hospital for Sick Children (REB# 1000073263) (REB#1000058120). All devices were purchased by our institution. The first 5 devices were inserted following case-by-case approval through Health Canada's special access program. The remaining 38 devices were implanted after the OSIA2 was approved for clinical use. The described use of the OSIA2 in children under 12 is considered off label from the perspective of the US FDA.

Participant recruitment

Children who were 18 years of age or younger and who lacked sufficient benefit from percutaneous osseointegrated or non-surgical bone conduction devices were eligible for participation in this study.

Surgical procedure

Device Placement and Pre-operative Marking

Placement of the device was carefully determined using a modified silastic model (Figure 1,2). The silastic model was modified with a 2mm biopsy punch through the neck of the model to allow for correct positioning of the external component (Figure 2). Considerations for implant placement include positioning the actuator no more than 2 cm posterior to the external auditory canal (EAC) and in line with a line drawn through the outer canthus of the eye to superior attachment of the pinna, which roughly denotes the vertical position of the cochlea. In patients who lack an EAC, device location is estimated based on surface landmarks, such as topography and curvature of the temporal bone as well as location of the mastoid tip, which is underdeveloped in aural atresia.

The thickness of the skin overlying the coil the receiver stimulator was measured using a 27gauge needle. Surgical instructions from the manufacturer suggest reducing skin flap thickness if initially greater than 9 mm for optimal coupling of the internal and external devices. Further details on skin flap reduction techniques are described below.

Methylene blue was used to identify the location for the implant, as well as the neck of the receiver-stimulator, through the holes in the template (Figure 1B). An incision was drawn allowing for at least 1 cm of soft tissue clearance from the perimeter of the actuator (Figure 1A). This incision was posteriorly based in the scalp for those with microtia and aural atresia (Figure 1C) and anteriorly based in the postauricular region for children with a typical pinna (Figure 1D).

Implant Placement

The implant was then placed using a conical guide drill, followed by a widening drill. In all cases, a 4mm implant was placed. The dura was often encountered in this young cohort, but there were no dural injuries. Of note, a 3mm implant is available and could have been placed as an alternative. A bone bed indicator was attached to the implant and rotated to ensure that the bone surrounding the implant was level enough for placement of the OSIA2. Bone polishing using a 3mm diamond burr was performed if bony clearance was not achieved. A subperiosteal pocket was created for the receiver stimulator in similar fashion to a cochlear implant. The direction of placement of the device, which ultimately dictates the site of the external component, was guided by the preoperative placement of a methylene blue mark on the neck of the silastic model (Figure 1A, B). The actuator was seated and fixed to the implant. The wound was then irrigated and closed in layers. Post-operative skull radiographs were performed only on the initial 5 patients in this series.

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Additional Surgical Considerations

Management of the thick skin flap.

The need for surgical flap thinning should be rarely required in the pediatric population. Children under 7 years of age rarely have a skin flap thickness of more than 3 to 4mm in this portion of the scalp(2). In older children, skin thickness increases with age and with body mass index (BMI)(2). Six of the 43 patients had skin flap thickness nearing or greater than 9mm. In these patients the coil of the receiver was placed lateral to the temporalis muscle and fascia. In addition to this manoeuvre, one patient (BMI of 35) underwent concurrent soft tissue reduction. For this patient, the incision was designed to facilitate flap thinning by bringing it to within 1cm of the neck of the device. In addition, the coil of the receiver stimulator was placed in the plane overlying the temporalis fascia. Experience with a prior cohort receiving the first generation OSIA device outlines the utility of a separate incision above the coil of the receiver stimulator to better access the area of the flap to be thinned.

Management of prior implants and devices.

Children in our cohort had previously received percutaneous abutments ipsilateral to the planned side of OSIA2 placement. When the goal was to transition from a percutaneous abutment to an OSIA2, the abutment was first removed, and the soft tissues were left to heal over a period of 6-12 weeks prior to OSIA2 placement. In some children, the retained implants approximated the OSIA2 receiver stimulator, and were removed to avoid contact with it. These implants were so osseointegrated that they needed to be drilled out by an otologic drill. With appropriate planning, removal of the prior implant(s) when necessary, can be done at the time of the abutment removal or at the time of the OSIA2 placement. In children with prior percutaneous devices or transcutaneous devices (i.e. Baha® Attract), the incision for OSIA2 was carefully planned to avoid having compromised skin sitting over the actuator while also allowing access for removal of prior implants when required.

Results

Participants

A total of 42 children received 43 OSIA2 devices; mean age was 10.9 years (SD=4.1 years; range 4.9 to 18 years). Demographic details and characteristic of hearing loss are provided in Table 1.

The type and etiology of the hearing impairments being rehabilitated with the OSIA2 were heterogeneous but representative of the pediatric population that may seek surgical bone conduction hearing habilitation. The hearing characteristics of the participants are provided in Table 2.

Most participants who elected to pursue an OSIA2 device had experience with other hearing technology and an outline of prior device use is provided in Table 3.

Twelve of the 42 children had secondary diagnoses including 4 children with Trisomy 21, 2 with chromosome 18Q deletion, as well as one child each with Goldenhar, Treacher Collins, Branchio-Oto-Renal, Waardenburg 2E Syndrome, Trisomy 8 and 22 and multiple congenital anomalies. Many of these children had associated developmental delay of variable degree and presentation.

<u>Surgical results</u>

Mean surgical time was 69 min (SD=16 min; 39 to 158.0 mins). Soft tissue reduction was required in 1 child who was obese (BMI=35, weight > 100 kg). There were no subsequent post-operative issues with magnet fitting in this patient. One patient required bone polishing to achieve clearance for placement of the actuator.

Surgical complication occurred in two children who experienced irritation at the magnet and incision site due to frequent usage. The soft tissue irritation and mild skin breakdown resolved upon the addition of a magnet soft pad to the external processor.

Discussion

This paper outlines successful surgical implantation of the OSIA2 System in 42 children over a wide range of ages whose characteristics of hearing loss are representative of the clinical pediatric populations for whom such devices are indicated.

A suggested benefit of OSIA2 is the reduced risk of soft tissue complication when compared to prior percutaneous technology. Only 2 of the 42 children experienced inflammation at the site of the magnet. This occurred at the magnet site many months following surgery and was resolved by application reduction of magnet strength with or without the application of a magnet soft pad as well as removal of the external processors for daily periods (commonly during nighttime sleep). Similar findings have been shown in cochlear implant users who can experience breakdown of skin between the magnets(3). This preliminary study suggests that complications of the OSIA2 are low in contrast to percutaneous bone conduction devices, in which soft tissue complications can be seen in approximately 50% of pediatric users even with typical durations of daily use(1, 3, 4).

Summary and conclusion

Surgical application of the OSIA2 device in a representative group of young children was feasible and demonstrated low rates of complication. Miniaturization of bone conduction technologies, along with increasing experience in their surgical application, may help to reduce the developmental consequences of hearing loss by allowing early intervention (5) and provision of bilateral hearing with fewer complications.

References

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Figure Legends

Figure 1. **A**. Initial drawings outlining surgical approach to OSIA2. Direction of placement for processor (1). Site of implant placement (2). >1cm clearance between perimeter of the actuator and incision placement. Note the curvilinear nature of the incision given the rectangular nature of the actuator. **B.** Placement of the device posterior to the predicted location of the pinna and external auditory canal. **C.** Posterior scalp incision in the setting of aural atresia and microtia. **D.** Postauricular scalp incision in the setting of an intact pinna. Soft Tissue Preparation

Following preparation of the skin, the marked skin incision was opened, angling the scalpel at 45 degrees in the hair-bearing skin to preserve hair follicles. A curvilinear periosteal incision was then made with care taken not to reduce the distance between the incision and the perimeter of the actuator. The periosteum was elevated, and the site marked previously with methylene blue for the implant was identified.

Table 1. Participant details. * received sequential bilateral devices.

Participant	Age (years)	Sex	Etiology of Hearing Loss	Configuration and Type of Hearing Loss	Secondary Diagnosis
1	9.5	M	bilateral aural atresia	bilateral conductive	
2*	13.1/14.6	M	bilateral aural atresia	bilateral conductive	
3	11.1	M	bilateral aural atresia	bilateral conductive	Goldenhar syndrome
4	14	F	bilateral aural atresia	bilateral conductive	
5	6.1	F	bilateral aural atresia	bilateral conductive	chromosome 18 Q deletion
6	13.3	F	cochlear nerve aplasia	SSD	
7	7.2	F	bilateral canal stenosis +/- OME	bilateral conductive	chromosome 18 Q deletion
8	16	F	cochlear nerve aplasia	SSD	
9	12.0	M	unilateral EVA	Mixed loss	
10	6.1	M	Right cochlear nerve aplasia, left aural atresia	SSD right/ conductive left	
11	18	F	bilateral aural atresia	bilateral conductive	
12	17.9	F	bilateral medial canal fibrosis	bilateral conductive	
13	6.8	F	unilateral atresia	unilateral conductive	
14	8.4	F	unilateral atresia	unilateral conductive	
15	14.8	M	bilateral aural atresia	bilateral conductive	obesity
16	7.4	F	bilateral canal stenosis +/- OME	bilateral conductive	trisomy 21
17	5.5	M	bilateral canal stenosis +/- OME	bilateral conductive	trisomy 21
18	5.9	F	bilateral canal stenosis +/- OME	bilateral conductive	dev delay, BOR
19	15	F	bilateral aural atresia	bilateral conductive	Treacher Collins
20	6.6	M	unilateral atresia	unilateral conductive	
21	8.4	M	unilateral atresia	unilateral conductive	
22	15.4	F	unilateral atresia	unilateral conductive	
23	9.5	F	cochlear nerve aplasia	SSD	

24	11	M	bilateral canal stenosis +/- OME	bilateral conductive	
25	4.9	F	unilateral atresia	unilateral conductive	
26	5.6	M	unilateral atresia	unilateral conductive	
27	6.7	M	unilateral atresia	unilateral conductive	
28	11	F	unilateral atresia	unilateral conductive	
29	8.3	M	unilateral atresia	unilateral conductive	
30	8.4	F	unilateral EVA	SSD	
31	5.3	M	unilateral atresia	unilateral conductive	
32	15.7	M	unilateral atresia	unilateral conductive	
33	8.7	F	bilateral canal stenosis +/- OME	bilateral conductive	
34	11.4	F	bilateral canal stenosis +/- OME	bilateral conductive	trisomy 21
35	7.1	F	unknown etiology	SSD	
36	14.8	M	unilateral atresia	unilateral conductive	
37	16.4	M	cochlear nerve aplasia	SSD	Waardenburg 2E
38	17	M	unilateral atresia	unilateral conductive	
39	13.2	M	bilateral microtia	bilateral conductive	
40	11	M	bilateral microtia	bilateral conductive	
41	15.8	M	bilateral canal stenosis +/- OME	bilateral conductive	Trisomy 21
42	17	F	bilateral atresia	bilateral conductive	Trisomy 22 and 8

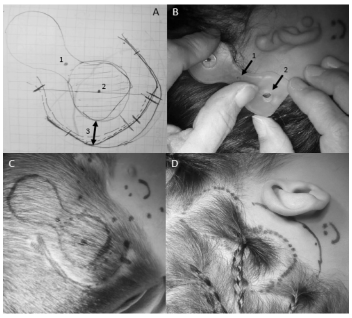
Table 2. Type of hearing loss and underlying etiology for the participant group. * One child had single sided deafness due to cochlear nerve aplasia on one side and conductive hearing loss due to atresia on the contralateral side. ** One child with enlarged vestibular aqueduct had a mixed loss.

Type of HL	Etiology of HL	Number of patients
Conductive Loss	**Bilateral conductive hearing loss**	**20**
	Bilateral EAC atresia/stenosis	19
	Bilateral acquired canal stenosis	1

	Unilateral conductive hearing loss	**14**
	Unilateral aural atresia	14
Sensorineural/Mixed	**Single sided deafness**	**8**
	Cochlear nerve aplasia*	5
	Enlarged vestibular aqueduct**	2
	Unknown	1

Table 3. Characteristics of prior rehabilitative device use.

Mode of hearing aid	Type of device	Number of patients
Bone conduction aid	Headband retained	25
	Percutaneous (BAHA connect)	11 (3 ipsi, 8 contra)
	Passive transcutaneous (BAHA Attract)	1 (ipsi)
	Active transcutaneous (OSIA1 and 2)	3 (contra)
Conventional hearing aid(s)		4
No rehabilitation		1



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