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Clinical outcomes following Cochlear™ BIA300 bone anchored hearing aid implantation in children☆

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ABSTRACT

Objective: Bone anchored hearing implants (BAHI) have been in use for over 30 years, and are commonly implanted in children for a range of indications. The Cochlear™ BIA300 system was launched in 2010 and used at The Birmingham Children's Hospital from 2011. Here we report the long-term outcomes of children implanted with the Cochlear™ BIA300 BAHI system in our centre.

Methods: A retrospective case note analysis was performed to identify outcomes in all children who underwent BIA300 implantation between 2011 and 2013.

Results: 52 children with a total of 78 implants were included. Mean age at implantation was 8.7 years. Mean follow-up was 43.5 months. Overall, 60 (77%) implants developed soft tissue complications requiring treatment. Forty-eight (62%) required topical treatment; 27 (35%) required systemic treatment; and 27 (35%) required surgical soft tissue revision under general anaesthesia.

Conclusions: The Cochlear™ BIA300 system appears to be associated with higher than expected rates of soft tissue reaction in children, with late as well as early soft tissue complications requiring both medical and surgical treatment.

1. Introduction

Bone anchored hearing implants (BAHI) have been in clinical use for more than 30 years, and the indications for implantation, as well as the technology and surgical techniques have evolved significantly in recent years. The Cochlear™ BIA300 implant was released in 2010 following clinical trial data showing this wider implant system was associated with increased implant stability and reduced soft tissue reaction compared with older implant systems [1]. The participants in the original study were all adults, and currently more information is available from the paediatric population.

In our tertiary paediatric centre we noticed an increased rate of late soft tissue complications with the BIA300 implant system, and published a comparison with another centre in 2015 [2]. This article describes a 5-year longitudinal review of the early UK cohort of children implanted with the Cochlear™ BIA300 implant system at our centre. This implant system was only used at our institution between December 2011 and December 2013.

1.1. Objectives

To review the clinical outcomes of the Cochlear™ BAI300 implant system in children over a 5-year period.

2. Methods

This was a retrospective 5-year longitudinal case records review of a cohort of 52 children who were implanted with the Cochlear™ BAI300 implant system at BCH.

2.1. Patients

All children on the paediatric BAHI programme at The Birmingham Children's Hospital who were implanted with the Cochlear™ BIA300 implant system between December 2011 and December 2013 were included in the review. No child was excluded from the review. The demographics were recorded including age (defined as age at first stage surgery in cases of sequential implantation), gender, significant co-

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morbidities and Body Mass Index (BMI). The underlying aetiology for BAHI surgery was also noted.

2.2. Surgical technique

The various surgical techniques were reviewed for both the single stage and the two stage BAHI procedures. Implant and abutment length, as well as osseointegration periods, were documented.

2.3. Post operative care

Post-operative dressings were standard for all children. The abutment was routinely wrapped in antibiotic ointment-soaked ribbon gauze, a healing cap was applied and a head bandage left on for 24 h. The first follow-up review was at one week when the healing cap and ribbon gauze were removed, and a steroid-antibiotic cream was prescribed along with advice on cleaning the abutment and local skin. The timing of sound processor fitting was also recorded.

Post-operative complications were evaluated paying particular attention to fixture losses, peri-abutment reactions - especially those requiring additional visits to the General Practitioner or hospital - and any further surgery needed at the BAHI site. The usual post-operative regime at our centre is a review appointment with the BAHI nurse at 1–2 weeks, 3 months, 6 months, 9 months, 12 months then yearly thereafter. Any additional visits recorded were considered a complication due the impact of time away from the child's education and other duties or work for the carer.

Peri-abutment skin treatments were divided into local treatment, systemic treatment and/or surgical treatment in the form of skin reduction or abutment change. Local treatment in the first two weeks following surgical stage 2 abutment placement was excluded due to the policy of routinely prescribing steroid-antibiotic cream at the first follow up visit. Finally length of follow up, defined as the period between surgical abutment placement and last clinic appointment was calculated and continued BAHI usage was noted.

2.4. Statistical analysis

Data was recorded using Microsoft Excel (Redmond, WA, USA) and analysed using Graphpad Software (La Jolla, CA, USA). Categorical data is reported as frequencies, and continuous data is reported with means, standard deviations and ranges. Where appropriate, the Fisher's exact test was used to compare categorical data from subgroups. A p-value of 0.05 was used to define statistical significance.

3. Results

3.1. Patient characteristics

A total of 52 children were implanted with a Cochlear™ BAI300 implant system. 26 children had bilateral implants and 26 had unilateral implants giving a total of 78 implant systems to evaluate. Mean age at surgery was 8.7 years (SD 4.01, range 3y 11 m to 16y 2 m), and the gender distribution showed a slight male predominance, with 30 out of 52 patients (58%) being male.

Congenital conductive hearing loss was the most common underlying aetiology for BAHI in this cohort of children (22 of 52 patients) and congenital sensorineural loss was identified in 7 patients. The remaining children underwent BAHI surgery for acquired disease as seen in Table 1.

Significant cardiopulmonary comorbidity was identified in 19 of 52 children (37%). Four patients suffered with a recognised skin disease: three with eczema, and one with harlequin icthyosis. Learning disability requiring special educational needs was documented for 46 of 52 children (88%). Of the 78 implants in total, 46 (59%) were in children with a learning disability. Table 2 summarises these co-morbidities.

Table 1
Basic demographics and indications for BAHI.

	Number of patients	(%)
Total	52	100
Male	30	58
Female	22	42
Type of hearing loss		
Congenital	29	56
Acquired	23	44
Aetiology of hearing loss		
Chronic otitis media	23	44
Congenital microtia/atresia	20	38
Unilateral profound hearing loss	7	13
Congenital middle ear malformations	2	4

Table 2
Syndromes and co-morbidities.

	Number of patients	(%)
Total	52	100
Syndrome		
Total	29	56
Down	7	13
Goldenhar/hemifacial microsomia	5	10
CHARGE	5	10
DeGrouchy	1	2
Comorbidities		
Skin disease	4	8
Diabetes mellitus	0	
Obesity	8	15
Cardiopulmonary disease	19	37
Learning disability	46	88

The mean BMI was 19.14 kg/m^2 (SD 6.03, range 14.7–46.3). This represents a healthy weight for the mean age of our cohort (8 years 8 months). The mean length of follow up was 43.5 months (SD 14.09, range 5–66 months).

3.2. The surgery

A total of 78 implant systems were placed. Fourteen implants (18%) were performed as single stage and 64 (82%)implants were placed as sequential procedures. For sequential procedures, the most common surgical technique was a U shaped incision for the first implant placement surgery followed by a skin punch technique without skin reduction (56%) for abutment placement surgery. Other techniques included a linear incision followed by a repeat linear incision (32%), and a U-shaped incision followed by a dermatome technique (12%), which was combined with skin reduction.

Soft tissue reduction was performed in 71% of second stage procedures, and 58% of all procedures overall. The mean osseointegration time following sequential procedures was 16 weeks. Surgical techniques are summarised in Table 3.

Of the 14 single stage procedures, a dermatome technique was used in 8 (57%) with skin reduction, linear incision in 3 (21%) and U-shaped incision on 3 (21%). The mean osseointegration time following single stage procedures was 103 days.

Three surgeons carried out all operations, and there were no statistically significant differences in soft tissue complication rates between surgeons or incision techniques. The only significant difference noted was that following soft tissue reduction at the time of initial