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Experience of bone-anchored hearing aid implantation in children younger than 5 years of age

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ABSTRACT

Objective: To assess the practicality and benefit of Bone-anchored hearing aid (BAHA®) implantation in children younger than 5 years of age. FDA approval for use of BAHA® only exists for children 5 years of age and older. Their use in Australia is also rare, however their use for younger children is approved by the European Union. We wish to share our experience of implantation in an antipodean setting in this age group.

Methods: Institutional board approval was obtained for this study. All children undergoing BAHA® implantation under 5 years old were included from our prospective database. We examined the variety of surgical techniques, (including skin grafting, limited soft tissue reduction and no soft tissue reduction), BAHA® implants and abutments used, and use of the new series 400 hydroxyapatite coatings. Demographic data obtained included age at surgery, follow up duration, gender, ethnicity and indication for surgery. Anonymous benefit questionnaires (Glasgow children's benefit inventory (GCBI) and parents' evaluation of aural performance of children (PEACH)) were completed online as well as a questionnaire on device use. Complications recorded included soft tissue reactions, implant loss/removal, abutment replacement/removal. We also assessed whether patient weight, ethnicity or socioeconomic status were risk factors for these complications.

Results: 24 Children (26 ears/26 implants) under five years were identified from the database and included in the study. There was a 14:10 male to female ratio. Patient caregivers reported subjective benefit and improved quality of life (QOL) despite setbacks and complications related to BAHA® usage. 10/24 (42%) of children required treatment for significant peri-implant skin reactions whilst 25% required replacement of their abutments and/or implants. An increased risk of major complication was associated with socioeconomic deprived backgrounds and in patients of New Zealand Maori and Pacific Island ethnicity but not in patients with increased weight centiles.

Conclusions: The BAHA® implant and hearing aid system is of value to children under age 5 years. Parents tolerate the skin reactions and complications because of the perceived benefit in hearing and quality of life. Careful counselling of parents of potential young BAHA® implant candidates is necessary in light of this.

Introduction

Bone anchored hearing aids (Baha®) were developed by Tjellstrom and Carlsson and first utilized in adults in 1977 in Gothenburg, Sweden. Use in children occurred nearly two decades later in 1983. The BAHA® is indicated for use in treating conductive hearing loss (e.g. in children with aural atresia, chronic otitis media, ossicular abnormalities) and mild to moderate sensorineural hearing loss as well as single sided sensorineural deafness. The Food and Drug Administration (FDA) approved its use in adults in 1996 and in children over 5 years old in 1999 [1]. Approval for its use in single sided deafness was granted in 2002. There is no current approval for use in children under 5 years of age.

Numerous studies have outlined beneficial outcomes encompassing improved quality of life, improved hearing outcomes as well as compliance with device usage [2–4]. Some advantages of the BAHA® over conventional headband worn bone conducted (BC) hearing aids include improved aesthetics, reduced pressure headaches, skin ulcers and improved user compliance [4].

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Complications occurring at the interface between the soft tissue and the titanium implant are well described in the literature [5,6]. Immunochemical studies have demonstrated increased inflammatory cells surrounding the implant following insertion of the BAHA® device even when the soft tissues remain clinically non-inflamed and non-infected [7–9]. A number of surgical techniques for managing the skin and soft tissues with BAHA® implant insertion have been described to reduce inflammatory responses including split skin grafting, limited soft tissue reduction and no soft tissue reduction [10].

Method

All children undergoing BAHA® implant surgery in the tertiary Otolaryngology unit at the Starship Children's Hospital in the North Island of New Zealand were operated on by the two senior authors (CB, MN). Operative details were prospectively recorded on a password-protected database. We reviewed the clinical records and identified all children under the age of five fitted with a BAHA® from 2002 to 2013. Institutional approval was sought and obtained for the purpose of the study.

Demographic data obtained included age at surgery, patient weight, gender, ethnicity, indication for surgery and follow up duration. Deprivation index (socioeconomic status) and patient weight were also recorded. Complications recorded included soft tissue reactions, implant loss or removal, abutment removal or replacement and failure of osseo-integration.

The New Zealand Deprivation Index 2006 (NZDep2006) is an updated version of an index of socioeconomic deprivation derived from the patient's address and census variables (educational qualifications, home ownership and income in the immediate locale). This is an ordinal scale ranging from 1 to 10, with 1 representing areas of least deprivation and 10, areas with most deprivation [11].

Weight percentile based on age was derived based on US centre for disease control and prevention growth charts 2000. This data was obtained from recorded weight measurement against age at Stage I BAHA® surgery. For the purpose of this study this was converted to standard deviation score (SDS) for statistical analysis. SDS is based on US centre for disease control and prevention 2000 sex-specific weight for age reference population data [12].

Improvement of quality of life (QOL) was evaluated using the validated Glasgow Children's Benefit Inventory (GCBI). This is comprised of 24 questions with five possible responses (with score ranging from −2 to +2). The total overall score is divided by 24 (number of questions) and then multiplied by 50, yielding a final score ranging from −100 to +100.

The Parents' Evaluation of Aural/Oral Performance of Children (PEACH) is a questionnaire designed to evaluate children's hearing and communication when using their hearing implant. It is comprised of 11 questions with five possible responses (scoring ranging from −2 to +2). The total score is divided by 48 and multiplied by 100 to give a percentage score. Children with 70% and above scores tend to be performing as expected with lower scores requiring review of the hearing devices.

Parents were surveyed using an online anonymous self-reporting questionnaire developed for this study. We obtained information regarding whether or not devices were still being utilized and whether any devices had undergone repairs in the study period.

Surgical description

Insertion of the BAHA® was performed in two stages in the majority of patients. For the two-stage technique, skin and subcutaneous tissues were elevated during the first stage leaving periosteum intact. A burr hole was drilled utilizing a high-speed drill with copious irrigation. A 3 mm or 4 mm implant (flange fixture) was inserted depending on skull bone thickness. In many patients a sleeper fixture was inserted at the time of the first stage procedure.

A 3–6 month period to enable osseo-integration was allowed prior to second stage implantation surgery. Patients had osseo-integration assessed and verified clinically at the time of 2nd stage surgery.

Initially, we used a skin graft technique using the BAHA® dermatome with soft tissue reduction. A 5.5 mm titanium abutment was secured and the skin graft sutured down to the periosteum. If revision surgery was required an 8.5 mm titanium abutment was used. Latterly we utilized a single skin incision with limited soft tissue reduction, and most recently no soft tissue reduction.

Since 2013, hydroxyapatite (BAHA® 400 series) coated abutments (according to skin thickness) have been utilized with primary insertions and also following revision surgery.

Follow up was arranged 3–6 monthly once the BAHA® site had fully healed and all families were counselled about abutment and peri-abutment cleaning and maintenance. Follow up data recorded included minor and major wound complications. Major complications were defined as requiring revision surgery. Minor complications were defined as local wound infections not requiring revision surgery. Clinical information was used to assign a highest Holgers grade for wound complications. Audiological assessment included functional benefit whilst using the BAHA® as well as audiometric hearing assessments.

Statistical analysis

Continuous data (e.g. age, follow up time) was reported as means or medians as appropriate. Categorical variables (e.g. gender) were reported as frequencies with percentages. Comparisons were made between patients that had major complications versus those that did not. Differences in weight were compared using the Wilcoxon's rank sum test. Differences in the frequency of upper or lower socioeconomic status as well as ethnicity were compared using the Fisher's exact test.

Results

A total of 24 children (26 ears/26 implants) younger than 5 years were identified from the database and included in the study. There were 14 males and 10 females. One patient (a bilateral implantee) emigrated and was lost to follow up and therefore not included in the analysis. The mean duration of follow up was 2.8 years (range 6 months to 10.2 years).

Fig. 1 depicts the age distribution of children at the first and second stages of surgery. The mean age at 1st stage was 40 months with a range 24–59 months. The mean time interval between first and second stage surgery was 6 months (Fig. 2). 1 patient had their BAHA® implanted as a single stage procedure. Two patients had bilateral implants inserted. These were done simultaneously.

There were 11 patients of New Zealand Maori ethnicity, 10 European, 2 South East Asian and 1 Pacific Islander (Fig. 3). The surgical indications for BAHA® insertions are shown in Table 1 with concomitant syndromes shown in Table 2 and Fig. 4.

20 patients (22 implants) had a 3 mm implant with 4 patients (4 implants) fitted with a 4 mm implant. The patient undergoing a single stage procedure had a 4 mm implant. Patients with bilateral implants had 3 mm implants inserted. In our series, no sleeper implant was used in the single stage BAHA® insertion.

12 patients (12 implants) received the generation 2 BAHA® implant, 7 patients (8 implants) had a generation 3 (BIA 300 series)