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Planned simultaneous bilateral cochlear implant operations: How often do children receive only one implant?

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cochlear implants, simultaneous bilateral cochlear implants, sequential bilateral cochlear implants, pediatric, hearing impairment, pre-operative counseling

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Abstract

Objective:
The aim of this study was to determine the proportion of planned simultaneous cochlear implant operations that do not result in simultaneous cochlear implants on the day of surgery. The frequency with which this occurs has not been reported in the literature, and such information is important for parents' pre-operative decision making.

Methods:
A retrospective review was conducted of pediatric cochlear implant operations performed in the period January 2007 to July 2010 at the Melbourne Cochlear Implant Clinic. The number of planned simultaneous cochlear implant procedures and the results of these surgeries were catalogued. Reasons for not proceeding with simultaneous cochlear implants as planned were also identified.

Results:
In the time period examined, there were a total of 50 planned simultaneous cochlear implant operations. Of these planned simultaneous operations, 22% did not result in bilateral cochlear implants on the day of surgery, with all children involved receiving a first-side cochlear implant only. In the majority of cases, the reason for a first-side cochlear implant only was otitis media.

Conclusion:
In the time period examined, a considerable proportion of planned simultaneous cochlear implant operations did not result in simultaneous bilateral implantation on the day of surgery. It is important that the likelihood of this outcome is discussed with families during pre-operative counseling as it may influence their decision making.

Introduction

Pediatric bilateral cochlear implantation has become increasingly common in the past decade, with demonstrated benefits including improved spatial hearing and listening in noise [1-4]. Bilateral cochlear implantation can be performed as sequential or simultaneous procedures. In a sequential procedure the contralateral ear is implanted months or years after the first implant operation. In a simultaneous procedure two cochlear implants are inserted in a single operation. A multi-country survey of implant procedures conducted in 2007 showed that 65.6% (378 out of 576) of all pediatric bilateral cochlear operations were sequential procedures and 34.4% were simultaneous procedures [5]. For children under the age of 3 years, 58% of bilateral operations were simultaneous procedures. The lower proportion of simultaneous procedures in older children is a reflection of the fact that the majority of bilateral implant candidates in this age range will already have received a first implant.

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There are some advantages to receiving bilateral implants simultaneously rather than sequentially. Firstly, both implants will be received when the child is as young as possible, thus minimising the duration of deafness in both ears. Secondly, there will be no period of unilateral implant use, thus avoiding potential dominance within the auditory system of input via one ear. Electrophysiological studies suggest these advantages may promote the development of binaural processing [6]. There are also practical advantages for simultaneous implants as only one operation is required. The implant operation is emotional and stressful for the family and the child and it is preferable to only undertake this once. A single operation will also result in time and cost savings. Post-operatively, establishing full-time bilateral implant use has been shown to be easier and faster for simultaneously implanted children, and they are less likely to develop a preference for one implant over the other [7]. Given that age at implant and amount of listening experience are important factors in the outcomes achieved with a cochlear implant, early implantation of each ear at the same age and full-time use of both implants is likely to promote the development of equivalent listening skills with each implant alone.

To make an informed choice about proceeding with any cochlear implant procedure, families should be provided with as much information as possible [8]. Now that the multiple options of a unilateral cochlear implant, sequential bilateral cochlear implants, and simultaneous bilateral

cochlear implants are available at many clinics, the level of complexity in parental decision making has increased. The increased number of options adds to the amount of information clinicians need to provide during pre-operative counseling. A specific issue to discuss when families are considering simultaneous implantation is the possibility that both ears may not be implanted in a planned simultaneous procedure. There is limited information in the literature on which to base such a discussion. Ramsden et al. [9] examined 50 consecutive pediatric simultaneous procedures and reported that no operation resulted in a first-side cochlear implant only, however the author did emphasize that parents must understand this outcome is a possibility. There are no other reports in the literature which indicate the frequency with which a planned simultaneous procedure results in a first-side implant only, however, it is the clinical experience of the present authors that at least some planned simultaneous operations result in a first-side implant only. In order for evidence-based discussions to be conducted with parents pre-operatively, it is necessary for clinics to document the outcomes of planned simultaneous operations.

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The aim of this study was to examine planned pediatric simultaneous cochlear implant operations at the Cochlear Implant Clinic in Melbourne to determine the number of operations which proceeded as planned versus those which resulted in the implantation of a first-side cochlear implant only.

Method

A retrospective survey was conducted of cochlear implant operations on pediatric patients (less than 18 years of age at the time of surgery) at The Royal Victorian Eye and Ear Hospital/The University of Melbourne Cochlear Implant Clinic (the Melbourne Cochlear Implant Clinic). The Melbourne Cochlear Implant Clinic has been conducting pediatric bilateral cochlear implant operations since September 2003. Simultaneous cochlear implants have been an option for children meeting the audiological and medical criteria since January 2007. The audiological guideline for recommending simultaneous implantation is a 3-frequency (average of 500, 1k and 2kHz) pure tone average $\geq$ 95dB HL in both ears. It is important to note that simultaneous bilateral implants are not recommended for children with auditory neuropathy spectrum disorder

if the functional hearing level is difficult to assess, or there is significant cochlea or auditory nerve dysplasia. Nor are simultaneous implants recommended if there is dysplasia with a risk of CSF (cerebrospinal fluid) gusher. In these cases sequential bilateral cochlear implantation would be recommended. Also, as discussed below, a cautious approach is taking to simultaneous procedures in children with recurrent acute otitis media or serous otitis media. The audiological guidelines in place at the Melbourne Cochlear Implant Clinic for sequential implantation in the time period considered were more complex. The guidelines took into account hearing loss as well as factors such as hearing aid use and benefit, and first-side implant use.

The period included in the survey was January 2007 to July 2010 inclusive. Information regarding the number of implants provided (or planned for) in each operation was obtained from operation lists and patient files. Any explant or reimplant procedures were excluded.

Results

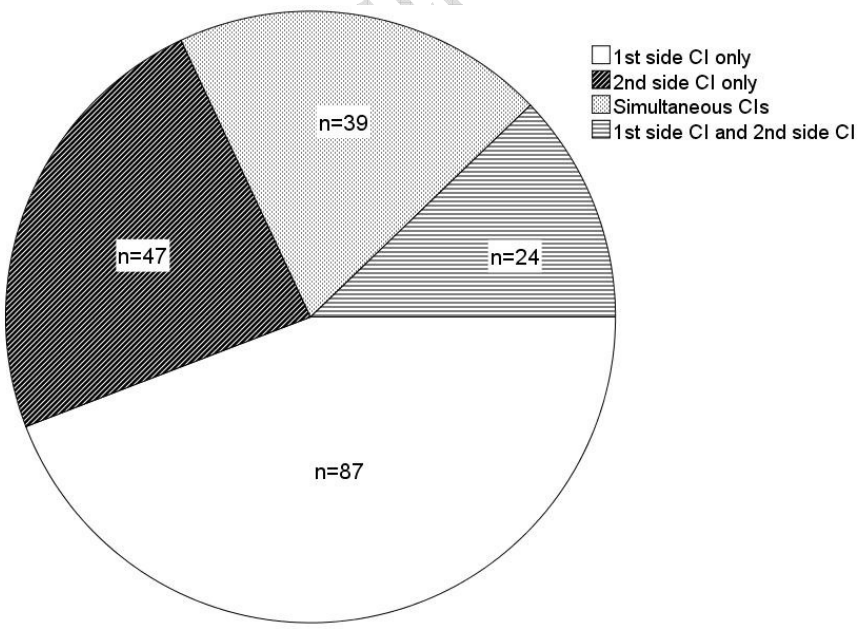


Figure 1: The proportion of patients who received (1) a first-side cochlear implant only, (2) a second-side cochlear implant (i.e., the first-side implant operation had occurred prior to the specified time period), (3) simultaneous bilateral cochlear implants, or (4) a first-side implant operation and a second-side implant operation (i.e., bilateral sequential cochlear implants obtained within the specified time period), between January 2007 and July 2010.

As shown in Figure 1, a total of 221 operations, involving 197 pediatric patients, were conducted from January 2007 to the end of July 2010. Eighty-seven (44.2%) patients received only a first-side cochlear implant. Although a proportion of these patients are likely go on to have a second-side cochlear implant in the future, the present report deals only with operations conducted up to the end of July 2010. As indicated by the shaded area of the figure, 110 (55.8%) of the patients received bilateral cochlear implants during the time period examined.

Examination of the patient files indicated that a simultaneous bilateral implant operation was planned for a total of 50 patients between January 2007 and July 2010. The outcomes for these 50 patients are presented in Figure 2. A majority of the patients, 39 out of 50 (78%), had a simultaneous cochlear implant operation as planned. The mean age for this group of 39 was 1.6 years (SD : 0.6). The remaining 11 patients (22%) received a first-side cochlear implant on the day of the planned simultaneous implant procedure. The mean age for this group of 11 was 1.5 years (SD : 0.6). In terms of the longer-term implant outcome for these 11 patients, 10 patients went on to have a second-side cochlear implant within the time period examined.

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For 9 of the 11 patients who did not receive simultaneous implants as planned, the decision to implant only one ear was made immediately prior to or during the implant operation. The most common reason for this decision was evidence of otitis media (n = 8). For the remaining 3 patients, the families were advised with short notice (1 to 3 days) that only a first-side cochlear implant operation would be attempted and not the simultaneous cochlear implant procedure that had been planned. For one of these patients the change in surgery plan was due to an injury to one ear three days prior to the planned operation, and for two patients simultaneous surgery did not proceed due to longer than expected operative time for the first side and limited available operating theatre time.

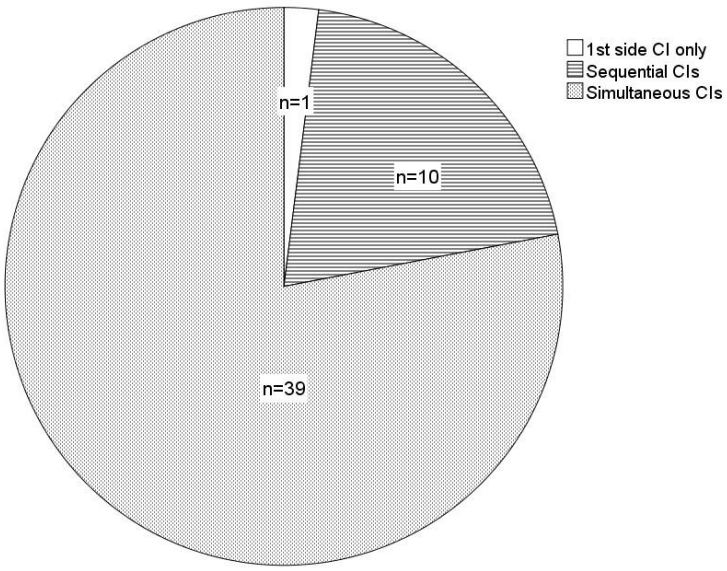


Figure 2: The proportion of pediatric patients for whom a simultaneous bilateral implant operation was planned who received, (1) a 1st side cochlear implant only, (2) sequential bilateral cochlear implants, or (3) simultaneous bilateral cochlear implants, between January 2007 and July 2010.

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Discussion

There has been a trend at the Melbourne Cochlear Implant Clinic for an increasing proportion of pediatric implant procedures to be bilateral operations. In the year 2006, bilateral implant operations made up only 17% (8 out of 47) of pediatric operations. From January 2007 to July 2010 (the time period examined in the present study) bilateral implant operations made up 49.8% (110 out of 221) of pediatric operations. Looking more specifically at the rates of simultaneous versus sequential pediatric implantation in this time period, 64.5% (71 out of 110) of the bilateral procedures were sequential and 35.5% were simultaneous. These proportions are consistent with those reported from a worldwide survey by Peters et.al. [5]. There is an increasing rate of bilateral implantation for children, and a high proportion of these children are receiving their two implants in a simultaneous procedure.. Pre-operative counseling should be evidence-based and these increasing numbers of simultaneous cochlear implant procedures emphasize the need for evidence relating specifically to simultaneous implantation.

For pre-operative discussions relating to simultaneous cochlear implants an area where evidence is lacking is the proportion of planned simultaneous bilateral cochlear implant operations which result in a first-side implant only. In the time period examined here, a simultaneous bilateral

cochlear implant operation was planned for 25.4% (50 out of 197) of the patients. In 11 of these 50 cases (22%) the initial cochlear implant operation resulted in a unilateral implant only on the day of surgery. This is a significant proportion and should be considered when counseling families pre-operatively.

Evidence of otitis media was the reason for a first-side implant only on the day of surgery rather than simultaneous bilateral cochlear implants for 8 of these 11 patients. This result is not unexpected taking into account the mean age at surgery of 1.6 years for the planned simultaneous bilateral cochlear implant group and a known high incidence of acute otitis media in children under the age of three years [10]. Otitis media, either in the acute suppurative or chronic serous form, can be a challenging management problem in pediatric cochlear implant candidates. Middle ear effusion complicates accurate assessment of hearing level and proceeding with cochlear implantation in the presence of middle ear infection is contraindicated. Whilst mastoiditis or cochlear implant infection is rare in the post-operative period in association with otitis media, it does occur and for this to be bilateral is potentially disastrous for the child. Our management is generally to insert middle ear ventilation tubes at least 6 weeks prior to cochlear implantation in children with persistent otitis media with effusion. All children are reviewed within the week prior to surgery to assess their middle ear status. We do not consider presence of dry, trouble-free, ventilation tubes a contraindication to bilateral simultaneous cochlear implantation, however if there has been recent otorrhoea or at operation there is mucosal edema and mucopurulent fluid, then we would consider unilateral but not bilateral implantation. Similarly for children without prior ventilation tube insertion, if there is evidence of otitis media with effusion at the time of operation, provided the effusion is mucoid and not purulent we would consider unilateral but not bilateral implantation. In our experience there is often an asymmetric degree of middle ear ventilation. In this situation we will implant the better ear and place a ventilation tube on the worse side with delayed second side implantation. This may be an overly cautious approach, however it does allow unilateral implantation and access to hearing without the delay of waiting for both ears to clear spontaneously. Interestingly, there is no comparable information in the literature regarding the proportion of planned first-side implant only operations which do not proceed due to evidence of otitis media.

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It is important to note that 10 out of the 11 patients who did not receive simultaneous cochlear implants as planned subsequently received a second-side cochlear implant within the time period examined. For this group of 10, the mean duration between the first-side and second-side cochlear implant was 5 months (SD: 3 months) with a maximum time between implants of 12 months. The eleventh patient had not received a second-side cochlear implant at the time of writing.

A first-side implant only on the day of a planned simultaneous bilateral implant surgery is clearly not going to be what a family was expecting. Families will have varying reactions to this outcome. Some families will feel a great degree of disappointment at their child not receiving simultaneous bilateral cochlear implants. Others may feel a degree of relief if the family found it difficult to make the choice between initially proceeding with one or two implants. Some families will want a second-side implant operation for their child as soon as possible after the first-side operation, while others may want more of a delay between first-side and second-side cochlear implant operations. It also cannot be discounted that families may no longer wish to proceed with bilateral implantation for their child. All families will require information and support in order to make an informed choice about any future implantation.

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In order to make an informed choice about future implantation families should be made aware of the most recent research evidence regarding outcomes of sequential bilateral implantation in children. Currently, studies have indicated that, with a younger age at implantation and a shorter inter-stage interval (time between first-side and second-side cochlear implants), electrophysiological recordings representing binaural processing are closer to the pattern for children with normal hearing [11-12]. Evidence from clinical studies is not as clear, though some studies have suggested poorer outcomes are more likely for older children with longer intervals and better outcomes are more likely for younger children with shorter intervals [4, 13-15]. As additional clinical and electrophysiological studies are conducted, updated information should be provided during counseling. Families will then need to balance this information with their own preferences for the timing of a second operation. However, timing will not necessarily be determined by a family's preference alone. The need for further medical management of middle ear issues may delay a second surgery. In addition, implant centre policies on the

prioritization of first-side and second-side cochlear implants surgeries for children will also have an impact on timing.

It is important to acknowledge that the results reported here were collected retrospectively from a specific clinic, beginning at the time simultaneous implants were first offered at that clinic. Data collected at the same clinic in a later time period, or from another clinic, may show different outcomes due to variation in pre-operative selection criteria, surgical techniques, and the management of middle ear issues. The continued collection of this type of data within individual clinics is necessary to ensure that parents can be supplied with up-to-date information relevant to the clinic they are attending.

In conclusion, of 50 planned simultaneous operations, approximately 20% resulted in a first-side cochlear implant only on the day of surgery. Given this is a substantial proportion, when simultaneous bilateral cochlear implants are planned families need to be informed during pre-operative counseling of this possible outcome and its implications. When a first-side implant only is the outcome, families will need further counseling in order to make an informed decision about any future implantation.

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