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Speech detection and localization results and clinical outcomes for children receiving sequential bilateral cochlear implants before four years of age

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Abbreviations:
CI-1: cochlear implant that was received first
CI-2: cochlear implant that was received second
BiCI: bilateral cochlear implants
VRA: visual-reinforcement audiometry

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Abstract

The aim of this study was to describe the adaptation to bilateral cochlear implant use and the perceptual benefits demonstrated by 10 children who were successful users of a first implant when a second was received before four years of age. Although one subject rejected the second implant at switch-on, the nine subjects who accepted the device adapted easily to bilateral implant use and developed useful listening skills with the second implant. Tests of localization (left versus right) and speech detection in noise were administered in the unilateral and bilateral conditions, usually after six months experience. All subjects demonstrated some bilateral benefit on speech detection testing (mostly due to a headshadow effect), and the majority localized left versus right. Results suggested that outcomes may be negatively impacted by increased age at the time of second implant switch-on. The majority of the subjects adapted well to bilateral implant use within six months and demonstrated some perceptual benefit and, according to subjective parent reports, improved daily functioning; however, device rejection must be discussed pre-operatively as a possibility.

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Introduction

The benefits of listening with two ears compared to one ear in individuals with normal hearing are well described (Libby, 1980). In particular, listening with two ears improves speech perception in background noise, provides improved sound quality, and aids in the localization of sound sources. The literature also describes the benefits from listening with two ears for people with hearing impairment using two hearing aids, particularly for individuals with a more severe hearing loss and/or when operating in more demanding listening situations (Noble & Gatehouse, 2006; Noble, 2006). In addition, in the past decade, researchers have considered the two-ear advantages for cochlear implant users. When compared with performance using a single

implant, studies show improved performance for the combined use of an implant plus hearing aid in adults (Ching et al., 2004; Mok et al., 2006) and children (Ching et al., 2001; Dettman et al., 2004) and for the use of bilateral implants in adults (Gantz et al., 2002; van Hoesel et al., 2002; van Hoesel & Tyler, 2003). Given these generally positive results, attention has turned to assessing the additional benefit that children may receive from two cochlear implants rather than one.

Many international clinics now offer children bilateral implants. Children have received bilateral implants simultaneously – in one operation or in two operations close together – or sequentially – in two operations months or years apart. Despite the increase in this clinical practice, there are few peer-reviewed reports in the literature evaluating the benefits of bilateral implants for children. Kuhn-Inacker et al. (2004) presented open-set word recognition in noise scores for 18 children aged two to eight years who had six months to two years of bilateral experience. Performance was superior in the bilateral as compared with the unilateral condition for all individuals, with a significant group benefit of 18 percentage points. Peters et al. (2004) reported closed-set speech discrimination in noise results for six subjects aged 5 to 13 years with nine months of bilateral experience. Only group information was presented, and the performance in the bilateral condition was superior to the unilateral condition in all test settings. The authors reported no significant localization abilities in the unilateral or bilateral condition, though the number of subjects tested and the test protocol were unclear. Litovsky et al. (2006) presented localization acuity results, measured with minimum audible angle, for nine subjects aged 3 to 14 years who had 2 to 26 months bilateral experience. Performance was superior in the bilateral compared with the unilateral condition for eight individual subjects, though no statistics were reported. An analysis of variance considering the factors of device condition and device

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experience was reported for the group data. A significant difference in performance in the bilateral versus unilateral conditions was reported only for the five subjects with less than 13 months experience. For the remaining four subjects, performance in the unilateral condition was similar to that in the bilateral condition. Galvin et al. (2007a; 2007b) reported closed-set speech discrimination in noise and localization results, subjective data (for example, regarding children's attitude towards, and consistency of use of, the second implant), and parent questionnaire results for up to 10 children aged 4 to 14 years with 6 to 13 months of bilateral experience. Bilateral benefit varied greatly from no evident benefit and inconsistent use of the second implant to significant objective and subjective benefit and a strong user preference for bilateral use.

The results presented in these reports indicate that some children obtain significant benefit from bilateral implants. There is insufficient information however to predict the type and degree of benefit likely to be obtained by an individual child. In addition, there is a lack of information regarding children's consistency of bilateral implant use and functional benefit in daily life. In addition, these studies have made inconsistent recommendations regarding the need for intensive rehabilitation with a second implant, the upper age limit for benefit from a second implant, and other similar factors. As the majority of the subjects in these studies were school-aged children, one area of importance requiring further investigation is the benefit available to children using bilateral implants from a younger age.

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Clinical experience with unilateral implantation has clearly demonstrated that the younger a child is at implantation, the greater the benefit (Dowell et al., 2002; Svirsky et al., 2004). This is likely to be due to a combination of the plasticity of the younger child's neural system and a reduced period of auditory deprivation. For older children using sequential bilateral implants, the

development of listening skills with the second implant alone varies. The dominance of the first implant, reluctance to use the second implant alone, and a lack of confidence in the second implant can influence the progress made (Galvin et al., 2007a; Galvin et al., 2007b). Some children cannot overcome these difficulties and gain no additional benefit from a second implant. It is reasonable to expect that if a child is younger when receiving a second implant, and if the two implantations occur closer together in time, there will be less dominance for one device over the other and the development of listening skills will be more equal. The younger child is also in a better position to develop true binaural listening skills. Binaural listening involves detection of similarities and contrasts in information arriving at each ear, thereby contributing significantly to sound localization and to speech perception in noise via mechanisms such as binaural unmasking.

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Research so far, which has generally involved school-aged children receiving a second implant, has provided very limited evidence on the development of binaural listening skills.

Further research with children who have two implants is clearly needed, both to gain a detailed understanding of the type and degree of additional benefit available and to develop the knowledge base required for best-practice clinical management. From a clinical point of view, it is particularly important to understand the relationships between characteristics of the child, such as age and binaural listening experience, and the additional benefit gained from bilateral implants. Such information is vital in counselling families regarding options for their child, especially if there is a choice to be made between two implants or an implant plus a hearing aid.

The aim of the present study was to describe the process of adaptation to bilateral device use, and the perceptual benefits demonstrated, by young children receiving sequential bilateral cochlear implants. The study is part of a larger research project which aims to evaluate the speech

perception and localization benefits provided by bilateral implants and to relate the degree of benefit (or otherwise) gained by individuals to factors such as device experience, age, pre-operative hearing aid use, and time between the two implants. Outcomes from this project will allow evidence-based recommendations to be made to families regarding the potential benefits of bilateral implants in general and the influence of various user characteristics on the likely benefit for their child.

Method

Subjects

Recruitment and selection criteria: From August 2004, the research project was publicized to families, implant clinicians and early-intervention therapists of unilaterally implanted children aged less than four years who attended the Royal Victorian Eye and Ear Hospital/University of Melbourne Cochlear Implant Clinic (Implant Clinic).

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Selection criteria relating to the first implant (CI-1) included full-time use, no evidence or reports of compromised function, and the judgment of the child's implant clinician that development of audition, speech, and oral language was within the limits expected for that individual. For children ≤30 months the implant clinician judged development using the checklist "Auditory Development Criteria for Children <2.5yrs" (attached as Appendix A). This checklist is a formalization of the areas of development considered by very experienced clinicians in the Melbourne Implant Clinic when judging a child's progress. The cognitive ability inclusion criterion was cognitive assessment results in either the borderline normal range or the normal to accelerated range. As per the Implant Clinic's protocol for cognitive assessment, an assessment was only conducted if parents or professionals working with a child raised concerns regarding

cognitive ability. The assessment procedure is detailed in Appendix B. The audiological inclusion criterion was as per the Implant Clinic's protocol for a first implant, that is, predicted post-operative improvement in perceptual ability of the non-implanted ear alone, with predictions based primarily on unaided hearing thresholds. The medical criteria were imaging results suggesting that a full insertion of the array was likely and that there were no contraindications to surgery. The final criteria were that the family was considered by their implant clinician to be committed to the use of a second implant and likely to be able and willing to complete the research assessment battery. All children whose families wished them to be considered for a second implant fulfilled the selection criteria, with nine children receiving a second implant between January 2005 and October 2006. A tenth child (S3) had previously received a second implant in December 2003.

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Subject demographics: Hearing loss and hearing aid use details for the 10 subjects are presented in Table 1. Subject numbering is not consecutive as it includes older children participating in the same research project whose results are not discussed here. Unique subject numbering allows comparison of outcomes across the groups over time. All subjects had a bilateral profound loss that was assumed to be congenital; the loss was suspected or confirmed before 8 months of age for all except S13, who was diagnosed at 12 months of age. Only S10 and S16 consistently wore a contralateral hearing aid with their first implant.

Details of the age at implantation, the basis of ear choice, and the time between implants are presented in Table 2. All subjects were implanted with Nucleus CI24 implants bilaterally. Details of implant types, speech processors, and speech processing schemes used are provided in Table 3. For all subjects the primary communication method was auditory/oral.

Table 1: Hearing loss and hearing aid demographics for the 10 subjects who received a second implant.

Subj	Etiology	3FA[1] CI-1 ear	Consistent bilateral aid use pre CI-1	3FA CI-2 ear	Consistent contralateral aid use pre CI-2
S3	KIDD syndrome	NR[2]	no[3]	115[4](500Hz)[5]	no[3]
S10	unknown	NR[6]	yes	113	yes
S11	unknown	115[7]	no[8]	NR[9]	no[10]
S13	auditory neuropathy	105[6]	no[8]	107[6]	no[11]
S15	unknown	95[12](500Hz)	no[8]	110[4]	no[10]
S16	genetic	118[6]	yes	103[4]	yes
S17	unknown	115[6]	yes	107[4]	no[8]
S19	genetic	112[13]	Yes	117[13]	no[10]
S20	unknown	112[6]	no[8]	102[6]	no[8]
S22	Connexin 26	NR[7]	no[8]	113[7]	no[10]

[1] Average of unaided thresholds at 500Hz, 1kHz, and 2kHz. [2] Obtained via Auditory Brainstem Response (ABR) testing using click stimulus at 100dBHL. [3] Due to recurrent otitis media. [4] Obtained via play audiometry. [5] Response at 500Hz only. [6] Obtained via visual reinforcement audiometry (VRA). [7] Obtained via Steady State Evoked Response (SSEP) testing. [8] Aid(s) fitted but not worn because child removed. [9] Test procedure not specified. [10] Not fitted because child removed aid. [11] Parents refused aid fitting due to auditory neuropathy. [12] Obtained at 500Hz with freefield sound presentations using visual reinforcement audiometry (VRA); responses represent hearing of the better ear; no response at other frequencies. [13] Obtained via Behavioral Observation Audiometry (BOA).

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Table 2: Age at implantation, first implanted ear, basis of ear choice, and time between implants for the 10 subjects who received a second implant.

Subj	Age at CI-1 (yr;mo)	CI-1 ear /Advantage of ear chosen	Age at CI-2 (yr;mo)	Time between implants (yr;mo)
S3	1;3	L/none	3;11	2;8
S10	0;9	L/thicker skull	1;9	1;0
S11	1;0	R/R-handed	2;8	1;8
S13	1;2	R/R-handed	2;2	1;0
S15	0;7	R/clearer CT scan	3;9	3;2
S16	1;4	R/slightly poorer hearing	3;1	1;9
S17	1;11	L/slightly poorer hearing	3;1	1;2
S19	0;10	L/no infection	2;5	1;5
S20	1;7	L/no infection	2;1	0;6
S22	0;6	L/slightly poorer hearing	1;1	0;7
Mean(SD)	*1;1 (0;5)*		*2;7 (0;11)*	*1;6 (0;10)*

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Post-operative Clinical Management

The subjects received standard post-operative audiological and medical care from the Implant Clinic. Pre-operatively, the map for CI-1 was reviewed so that post-operative mapping focused on the second implant (CI-2). The "switch-on" of CI-2 (i.e., the session in which the processor for CI-2 was fitted and the implant stimulated for the first time) occurred 10 days to 2 weeks post-operatively. The mapping protocol called for the first post-switch-on mapping sessions at

Table 3: Cochlear implant types, speech processors and speech processing scheme for the 10 subjects who received a second implant.

	Implant type		Speech processor		
Subject	*CI-1*	*CI-2*	*CI-1*	*CI-2*	Processing scheme
S3	CI24RCS[1]	CI24RCA[2]	ESPrit3G[3]	Sprint[4]	ACE[5]
S10	CI24RCA	CI24RCA	ESPrit3G	ESPrit3G	ACE
S11	CI24RCS	CI24RCA	ESPrit3G	Sprint	CI-1:ACE CI-2:ACE+ADRO[6]
S13	CI24RCA	CI24RECA[7]	Sprint	Freedom (body-worn)	ACE+ADRO
S15	CI24RCS	CI24RECA	Sprint	Freedom (BTE)	CI-1:ACE CI-2:ACE+ADRO
S16	CI24RCA	CI24RECA	Sprint	Freedom (body-worn)	ACE+ADRO
S17	CI24RCA	CI24RECA	Sprint	Freedom (BTE)	CI-1:ACE CI-2:ACE+ADRO
S19	CI24RCA	CI24RECA	Sprint	Freedom (body-worn)	CI-1:ACE+ADRO CI-1:ACE
S20	CI24RECA	CI24RECA	Freedom(body-worn)	Freedom (body-worn)	ACE+ADRO
S22	CI24RECA	CI24RECA	Freedom (baby-worn)	Freedom (baby-worn)	ACE+ADRO

[1] CI24RCS: curved array implant with 22-electrodes plus 2 extra-cochlear electrodes. [2] CI24RCA: soft-tip curved array implant with 22-electrodes plus 2 extra-cochlear electrodes. [3] ESPrit3G: ear-level speech processor capable of higher-rate processing. [4] Sprint: body-worn speech processor capable of higher-rate processing. [5] ACE (Advanced Combination Encoder): filterbank strategy with variable high rate presentation. [6] ACE+ADRO: ACE combined with ADRO (Adaptive Dynamic Range Optimisation), an algorithm which works with the processing strategy to improve detection of soft sounds and speech, whilst maintaining a comfortable presentation level for loud sounds. [7] CI24RECA: soft-tip curved array Freedom Nucleus implant with 22-electrodes plus 2 extra-cochlear electrodes.

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week 1, then two sessions one to two weeks apart, followed by two sessions a month apart, and then four sessions two to three months apart. A standard unilateral approach to mapping was employed, and the processor was programmed with the same speech processing strategy as that used for CI-1. Only S10 required the application of a C-level modifier to decrease the loudness when listening in the bilateral condition. It was not feasible to attempt to "match" the implants or to trial alternative combinations of speech processing schemes because of the children's limited attention span and ability to provide accurate feedback on differences in sound, especially for a recent implant. The mapping protocol was followed for S11 for the first month, after which she returned home to Singapore. Mapping was provided in Singapore at 2 and 4 months post-operatively.

In the six months following switch-on of the second implant the majority of the subjects received no (S16, S19, S20, and S22) or a minimal amount (four hours for S3 and six hours for S10) of one-on-one habilitation in the CI-2 alone condition. The remaining subjects received weekly or twice-weekly habilitation focusing only on the use of CI-2 for a total of 27 hours for S11, 18 hours for S13, and 24 hours for S15.

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Bilateral Implant Assessment Battery

Parental reports of device use and daily performance were obtained. Perceptual tests of speech detection in noise and localization were administered. Given the extensive variation in performance across pediatric implant users in general, subjects were used as their own controls, with performance in the bilateral cochlear implant (BiCI) condition compared with that in the CI-1 alone condition and, in some instances, the CI-2alone condition.

Parental Reports

Parents recorded hours of device use and comments regarding performance with either or both of the devices in a diary. At two weeks after switch-on and, subsequently, at monthly points, the same parent was interviewed by phone (email for S11). This was an open ended interview in which any areas worthy of note by the parent were discussed. In addition, the parent was specifically asked to comment on the child's performance with either implant alone and both together, and the child's attitude towards use of either and both implants. This information provided an indication of the listening skills developed with the second implant, and the benefit gained from using two implants in complex, real life listening situations. Parents were also questioned regarding the habilitation received, and hours of use of CI-2 alone and both implants. These factors, along with the child's attitude, were considered to be potentially influential in the development of listening skills with CI-2 alone and the amount of additional benefit gained from bilateral implant use.

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Speech Detection in Noise

Testing established the signal-to-noise ratio at which the subject reliably detected the speech stimulus in background noise. Subjects were trained to respond to the test stimulus with a game-based motor response as per the standard hearing-threshold-testing method of play audiometry (Hodgson, 1985). Testing was conducted in a low-reverberation sound-proof booth. Three Tannoy Reveal loudspeakers were positioned at ear level at a distance of 115cm at 0^0 and at 90^0 to the right and left of the subject. The stimulus was /baba/ recorded by a male speaker with a total duration of 900 ms. The masker was continuous speech-shaped broadband noise presented at 65 dBSPL.

Detection signal-to-noise ratios (SNRs) were measured in two noise conditions (with speech always presented from 0^0 and noise from 90^0 to either the right or left) and in three device conditions (CI-1 alone, CI-2 alone, and BiCI). The order of noise and device conditions was varied across subjects and test sessions to account, as much as was possible, for order effects; complete balancing could not be achieved due to the limited and/or varied number of test sessions completed by individual subjects. The number of SNRs measured and the number of test sessions completed depended on the concentration span and availability of each subject. In a typical session, four to six SNRs were measured in each of the three device conditions for one of the noise conditions. When the device condition was changed, the subject was engaged in a minimum of five minutes of "conversational play" to allow adaptation to the new condition. Three to four sessions were usually required to complete the testing.

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The role of the tester was to present the stimuli and record the results, while an assistant tester maintained the subject's position (facing 0^0), concentration, and understanding of the task; judged whether a response had occurred; and provided social reinforcement for expected behaviour and appropriate responses. The subject and the assistant were seated at a low table, with the subject facing the front loudspeaker and the assistant contralateral to the loudspeaker presenting the noise. Supra-threshold stimuli were presented until the subject was conditioned to the stimulus. Conditioning was considered to be achieved when the subject consistently and clearly made the required motor response (e.g., inserting a peg into a peg board, throwing a block into a bucket) with a reasonable and consistent time delay between stimulus and response. Thresholds were then sought. Beginning subthreshold, the presentation level of the speech stimulus was increased in

2dB steps until a response was elicited; the SNR at which the presentation was made was recorded as the first detection SNR. The presentation level was then decreased by 4dB and the process was repeated. Stimulus and non-stimulus trials were presented randomly with probabilities of 0.67 and 0.33, respectively. A response occurring during a non-stimulus trial was recorded as a false alarm. The false alarm rate did not reach the criterion of 0.25 in any one noise/device condition in any session. Within any one noise/device condition in one test session, the first ascending threshold obtained and any outliers were discarded. A threshold was a potential outlier if it differed by 6 dB or more from any other threshold obtained in that condition in that session. If a potential outlier was recorded, a second threshold was measured. If this second threshold did not differ from any other threshold by $\geq$6 dB, it was accepted as a replacement for the original potential outlier. Conversely, if this second threshold also differed by $\geq$6 dB it was rejected and the original potential outlier accepted as a true threshold. Across all subjects, a single threshold was discarded as an outlier on three occasions, and two thresholds were discarded on one occasion.

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As noted, the standard procedure for testing hearing thresholds in this age group, play audiometry, was used, with the assistant tester not "blind" to the presentation of stimuli. Given that the presentations were made via loudspeaker, "blinding" would have required the assistant to wear earplugs and/or be subjected to a masking noise via headphones. Such auditory isolation of the assistant would have limited their ability to converse with the subject to maintain his or her concentration on, and understanding of, the task. In addition, it would not have allowed the assistant to provide immediate social reinforcement of a correct response, and may have resulted in the assistant sometimes

reinforcing an incorrect response, which would have compromised the subject's conditioning. A number of aspects of the experimental design compensate for the lack of "blinding" by increasing the reliability of the measurements: testing was conducted by experienced clinicians trained to avoid bias in judging responses; although potentially able to hear the stimulus, the assistant was unaware of the presentation level; the first measured detection SNR was discarded; control trials without stimuli were included; outliers were discarded; and the reported result was an average of repeated measurements.

Left versus Right Localization

Testing established if the subject could determine whether the auditory stimulus was presented from the loudspeaker at 90^0 to the left or right. Subjects were trained to respond to the stimulus using the standard hearing-threshold-testing methods of play audiometry (S3, S10, S11 and S15) or visual reinforcement audiometry (VRA) (S13, S16, S19, S20 and S22) (Hodgson,1985). Loudspeaker setup was as described for speech detection testing. The auditory stimulus was a series of four pink noise bursts, each of 170 msec duration with 10 msec rise and fall times, with an inter-burst duration of 50 msec. The presentation level was 62 dBA, with a jitter of 8 dB to limit the use of loudness cues. A 7-cm diameter, colored flashing light was positioned 30cm below ear level at 64.3^0 to the right (blue) and at 64.3^0 to the left (red) for use in the sound+light condition (described further below). Room lighting was dim to ensure that the flashing light was easily visible to the subject when facing 0^0.

Left versus right localization was assessed in two device conditions, CI-1 and BiCI, with the order of conditions balanced across sessions. There were two stimulus conditions: the

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sound-alone test condition, and the sound+light training condition. The sound+light stimulus (the auditory stimulus paired with a highly salient blue (right) or red (left) flashing light) was used to condition the subject. In the testing phase, blocks of sound-alone stimuli were alternated with blocks of sound+light stimuli (refer below). The number of presentations in each condition and the number of test sessions completed depended on the concentration and availability of each subject. In a typical session, 24 presentations were made (12 in each stimulus condition) prior to a change in the device condition. When the device condition was changed the subject was engaged in a minimum of five minutes of "conversational play" to allow adaptation to the new condition. Two test sessions were usually required to complete the testing.

Play audiometry was conducted as described above for speech detection testing, except that the subject sat on a chair facing the assistant tester seated at 0^0 (no table was used), and an identical item (e.g., pegboard, bucket) was positioned on either side of the subject to allow the required motor response to be made to the left or right side. For VRA, the subject sat on a parent's lap facing the assistant tester seated at 0^0. The roles of the tester and the assitant tester were the same as for play audiometry. The reinforcement was the illumination and movement of a toy in a box; one reinforcement toy was located in each of four smoked Plexiglas-fronted boxes positioned at 90^0 and at 64.3^0 to the subject's right and left. Sound+light presentations were made until the subject was conditioned to the stimulus, i.e. made the required motor response or head turn in the correct direction (note that only head turns such that the subject was facing the box containing the reinforcement toy were accepted as responses). The use of the salient sound+light stimulus, that the tester could be certain the subject was able to localise, was necessary to

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ensure conditioning occurred. In the subsequent testing phase, blocks of three sound+light presentations were alternated with blocks of three sound-alone presentations, beginning with the former. Pilot work with the test procedure indicated that providing the easier sound+light presentations was necessary for subject motivation, and to confirm during testing that the subject remained conditioned and willing to respond; this was particularly important in the CI-1 condition in which localisation of the sound-alone stimulus was difficult for all subjects. During testing, reinforcement was provided when the required head turn or motor response was made following a stimulus presentation, irrespective of the direction of that response. Pilot work indicated that consistent provision of reinforcement was necessary to motivate the subject to continue responding. In VRA testing, this necessitated presenting the reinforcer (an illuminated toy) on the side to which the subject (correctly or incorrectly) turned. The alternative procedure to deal with an incorrect response would have been to draw the subject's attention to the correct side to view the reinforcer there; however, this was not done because it may have had an undesirable training effect and it is often difficult to draw a young subject's attention in this way. Very occasionally, usually towards the end of the test session, the subject made no reponse to the stimulus and a second (or, more rarely, a third) presentation was required before the subject provided the head turn or motor response.

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As with the speech detection testing, the assistant tester was not 'blind' to the stimulus presentation. The disadvantages of such 'blinding' discussed above also apply here. Furthermore, for this test, it would be impossible to ensure complete 'blinding' to the supra-threshold auditory stimulus with the added visual stimulus, there was no possibility of false positives as the stimulus was suprathreshold, and the direction of the response

was easy to judge. The lack of 'blinding' was also compensated for by the use of experienced clinicians and the repeated presentations.

Results

Table 4 presents age and amount of experience with each implant at the time of assessment for individual subjects. Eight subjects were assessed at approximately six months post-switch-on of CI-2. At the time of assesment the subjects had a mean age of 2 years and 11months (SD=9mo), and a mean experience with CI-1 of 1 year and 11 months (SD=10mo). The ninth subject, S3, was assessed at 24 months post-switch-on of CI-2. The tenth subject, S17, refused to wear the second implant at the switch-on session and did not gain any experience or complete any assessments in the first 12 months after the operation (at the time of this writing, the subject was wearing both implants consistently but had not been assessed).

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Parental Reports: Device Use and Performance in Daily Life

Parental reports were collected for the nine subjects who wore CI-2. Table 5 summarizes each subject's experience using CI-2 alone**,** with both implants generally used in the remaining waking hours. The pattern of use varied. Three subjects (S10, S11 and S22) used CI-2 alone for a significant period daily (1/2 to 4 hours) for between 2 months and 4 months post-switch-on; all developed excellent CI-2 alone listening skills and the parents then encouraged full time bilateral use. Subject 13 also used the device for significant periods of time but only on alternate days and for the full six months. Four other subjects (S3, S15, S16 and S19) gained very little experience in the first three to four months, after

Table 4: Age and amount of experience with each implant at the time of assessment for the nine subjects who used the second implant.

Subject	Age (yr;mo)	Time since switch-on (yr;mo) *CI-1*	*CI-2*
S3	6;0	4;8	2;0
S10	2;4	1;7	0;7
S11	3;3	2;3	0;7
S13	2;9	1;6	0;6
S15	4;3	3;7	0;5
S16	3;7	2;3	0;6
S19	2;11	2;1	0;7
S20	2;8	1;0	0;6
S22	1;9	1;2	0;7

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which they were more confident with the device and tolerated wearing it alone for longer periods. Only S20 gained no experience using CI-2 alone.

Table 5: Reported amount of time using CI-2 alone daily in the first six months post-switch-on for the nine subjects who used the second implant (BiCis were generally used in the remaining hours awake).

Time post	Time per day CI-2 alone use (Days per week if <7)								
switch-on	*S3*	*S10*	*S11*	*S13*	*S15*	*S16*	*S19*	*S20*	*S22*
Mo 1	None	2-4hr[1]	2-3hr[1]	1hr/(3-4)	3-5min	1-5min	none	none	½hr
Mo 2	None	2-4hr	2-3hr	½-1hr(5)	3-5min	1-5min	none	none	1hr
Mo 3	5min	2hr	3-4hr	½-1hr(3)	3-5min	1-5min	none	none	none
Mo 4	5min	2hr	none	1hr(3-4)	35min	½hr	none	none	none
Mo 5	¾hr	none	none	1hr(3-4)	¾hr	¾hr	½hr(1-2)	none	none
Mo 6	¾hr(2)[2]	none	none	1hr(4-5)	½-1hr	½-2hr	½hr(3)	none	none

[1] No CI-2 alone use in first week post-switch-on. [2] In Mo 7, S3 used CI-2 alone for ½ hr on two days per week; between Mo 8 and 24 (when S3 was assessed) there was effectively no CI-2 alone use.

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Figure 1 summarises the points post-switch-on at which specific milestones were reported by parents as achieved in the monthly (and initial two-week) interviews. Eight of the nine subjects were using the two implants full time within one month, with seven doing so without the need for particular encouragement or reward from their parents. Six of the nine subjects were able to identify when one of the two implants stopped providing stimulation within three months; the longer time taken by the remaining subjects may have been due, in part, to age and behavioural issues.

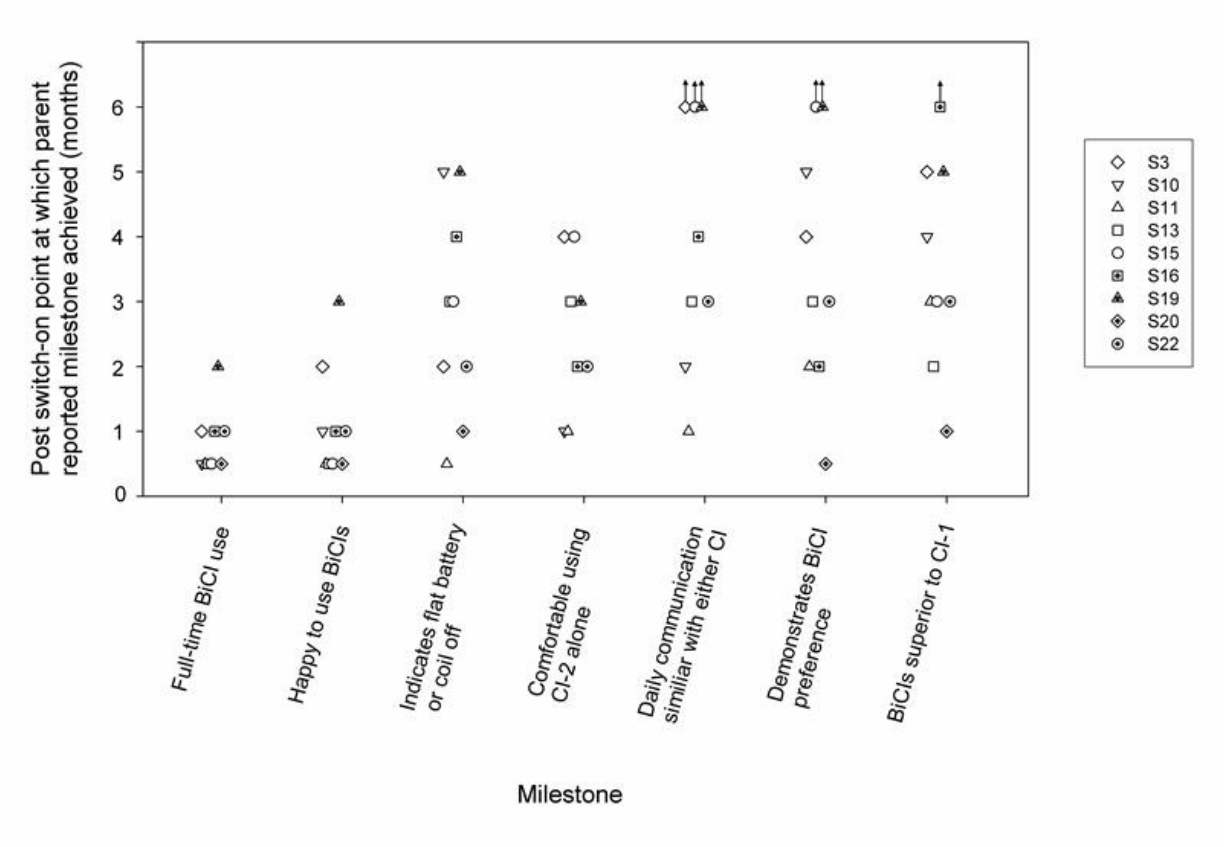


Figure 1: Post switch-on point (in months) at which parents reported specified milestones were achieved using CI-2 alone and BiCIs for the nine subjects who used the second implant (n=8 for milestones relating to unilateral use as S20 only used BiCIs). Arrows indicate the milestone was not achieved within six months.

One subject (S20) preferred bilateral implants at all times and refused to use either device alone, so that the parents were unable to report on milestones involving CI-2 alone. The remaining

eight subjects used CI-2 alone regularly at some point in the study. Of these eight, there was an even spread from one to four months before parents reported that the subjects were comfortable using CI-2 alone, with the two subjects who were the oldest at the time of the second implant taking four months. In a very similar pattern in terms of subject order, it took from one to four months for parents to report similar daily communication with either implant alone for five subjects; the milestone was not achieved by three subjects, including the oldest two subjects. For the four subjects achieving similar daily communication within 3 months, parents reported that performance with either device was equivalent in all situations**,** or in all except the most difficult listening situations, in which CI-1 was better. For the other subject achieving this milestone**,** the parent reported that daily communication was similar; however, CI-1 remained the superior implant.

The parents of seven of the nine subjects reported a demonstrated preference for BiCIs (with the other two subjects equally happy using one or two implants), and eight parents reported superior performance in daily life with BiCIs compared with CI-1 alone. The time taken to achieve these milestones was evenly spread from around two weeks to five months. Further details of the parents' observations of daily listening performance when using BiCIs compared with CI-1 alone, six months after the switch-on of CI-2, are provided in Table 6.

Post print

Table 6: Parental reports of areas of improvement in daily listening at six months post-switch-on when using BiCIs versus CI-1 alone for the nine subjects who used the second implant.

Subject	Area of reported improvement			
	Localisation	Communication in background noise	Sound awareness[1]	Other
S3	✓			copes better overall
S10	✓			
S11	✓	✓	✓	
S13	✓		✓	more confident
S15	✓	✓		less repetition required
S16	*parent reports insufficient opportunity to compare BiCI vs CI-1*			
S19			✓	more vocalisation
S20	✓	✓	✓	more vocalisations
S22	✓			less repetition required better listening overall

[1] Increased awareness of soft and/or distant sounds.

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Speech Detection

Speech detection testing was attempted with all nine subjects who wore CI-2; however, S19, S20, and S22 did not cooperate sufficiently to complete the testing. The mean detection signal-to-noise ratio for each of the six subjects in each of the three device conditions are presented in Figures 2 and 3 for the contralateral and ipsilateral noise conditions, respectively. Comparisons across conditions were made using two-tailed, paired t-tests, or, where the data failed the normality test, Wilcoxon Signed Rank tests. To consider the listening skill achieved with CI-2, performance in the CI-2 alone condition was compared with that in the CI-1 alone condition. As shown in Figure 2, in the easier listening condition with contralateral noise, performance was not significantly different with either device alone for S3, S13 ($n \geq 10$, $t \leq 1.77$, $p \geq 0.11$), S10, or S11 ($n \geq 9$, $W = 0.00$, $p = 1.0$). Performance in the CI-2 condition was significantly poorer for S15 ($n = 9$, $t = -8.32$, $p < 0.001$) and S16 ($n = 9$, $W = 45$, $p = 0.004$). As shown in Figure 3, in the more difficult listening condition with ipsilateral noise, performance in the CI-2 alone condition was significantly poorer for four subjects (S3, S11, S15, and S16: $n \geq 9$, $W \geq 21$, $p \leq 0.047$). Performance was not significantly different with either device alone for S13 only ($n = 10$, $t = 1.86$, $p = 0.096$), and S10 was not tested in the CI-2 condition due to time constraints of the family.

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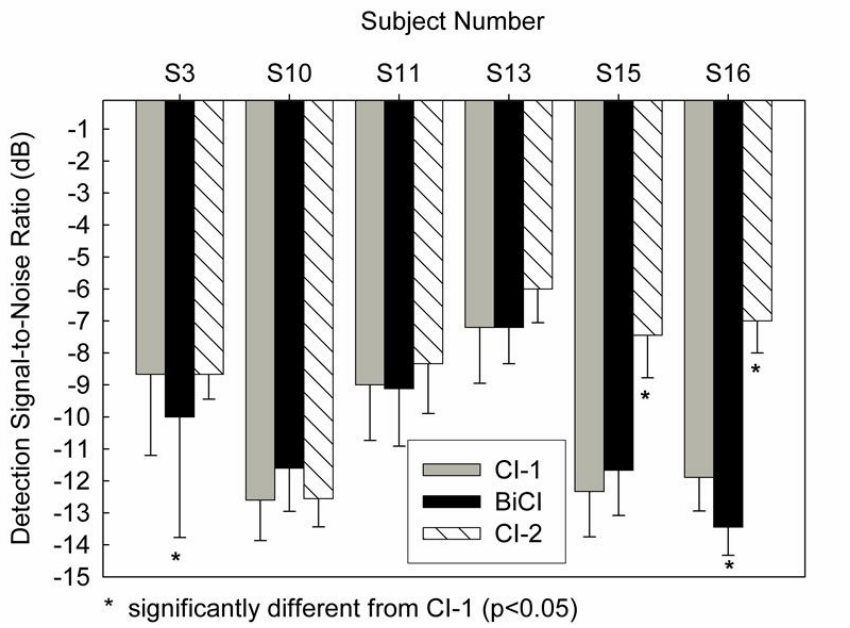


Figure 2: Detection signal-to-noise ratios with noise contralateral to the active implant (noise contralateral to CI-1 in the BiCI condition) for each of the six subjects tested in the CI-1, BiCI, and CI-2 conditions. Error bars represent +/- 1SD.

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To consider the advantage gained through the use of bilateral implants, performance in the BiCI condition was compared with that in the CI-1 alone condition. CI-1 was used as the comparative condition as performance with this device was either equal or superior to that with CI-2 for all subjects. In the BiCI condition, ipsilateral noise was presented on the same side as CI-1, and contralateral noise was presented on the opposite side to CI-1. As shown in Figure 3, ipsilateral noise performance in the BiCI condition was significantly superior for five subjects (S3, S13, S15: $n \geq 9$, $t > 3.28$, $p \leq 0.009$; S10, S11: $n \geq 11$, $W \geq 66$, $p < 0.001$), but not for S16 ($n=9$, $W=5$, $p=0.3$). As shown in Figure 2, contralateral noise performance in the BiCI condition was significantly superior only for S3 ($n=12$, $W=23$, $p=0.047$) and S16 ($n=9$, $W=21$, $p=0.031$); there was no significant difference for S10, S13, S15 ($n \geq 9$, $t \leq 1.86$, $p \geq 0.096$), or S11 ($n=17$, $W=6.0$, $p=0.85$).

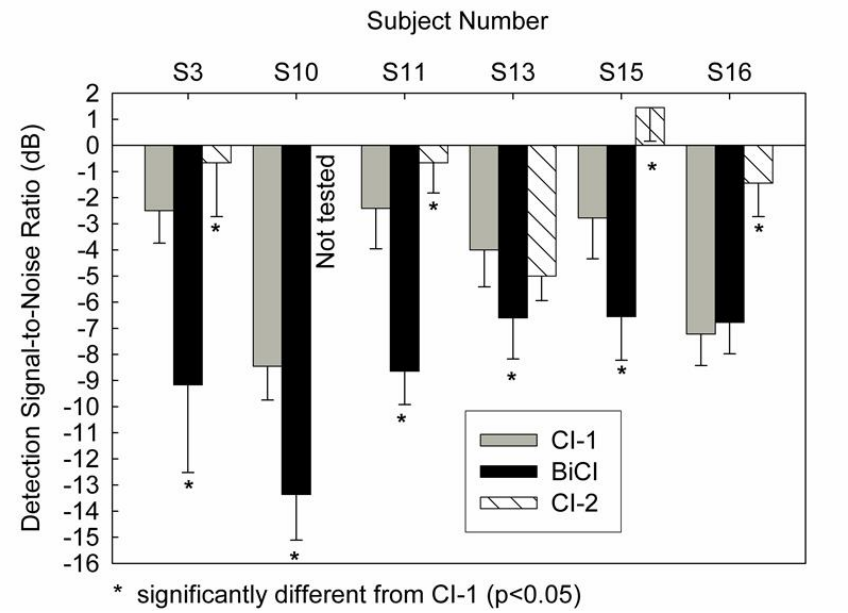


Figure 3: Detection signal-to-noise ratios with noise ipsilateral to the active implant (noise ipsilateral to CI-1 in the BiCI condition) for each of the subjects tested in the CI-1 (n=6), BiCI (n=6), and CI-2 (n=5) conditions. Error bars represent +/- 1SD.

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Left versus Right Localization

Left versus right localization testing in all conditions was attempted with all nine subjects who wore CI-2; however, due to a limited concentration span, S20 only completed testing in the BiCI condition with the sound-alone stimuli. In the sound+light stimulus condition, most subjects scored 100% in both the CI-1 and BiCI conditions, though S19 scored only 96% in the CI-1 condition. This result confirms that the subjects were capable of the task and were cooperating during testing. Figure 4 presents the percentage of correct turns made in response to the sound-alone stimulus for each subject in each of the CI-1 and BiCI device conditions. Binomial analysis indicated that performance in the CI-1 condition was not significantly different from chance for any subject (S3, S11, S13, S15, S19, S22: $n=24$, $k \leq 14$, $p \geq 0.12$; S10: $n=12$, $k=7$, $p=0.19$; S16: $n=21$, $k=9$, $p=0.14$). In contrast, performance in the BiCI condition was significantly above chance for seven of the nine subjects tested (S10, S15, S16, S19, S20, S22:

n=24, k≥17, p≤0.021; S19: n=12, k=11, p=0.003). Only for S3 and S11 was performance in the BiCI condition not significantly above chance (n=24, k≤14, p≥0.08).

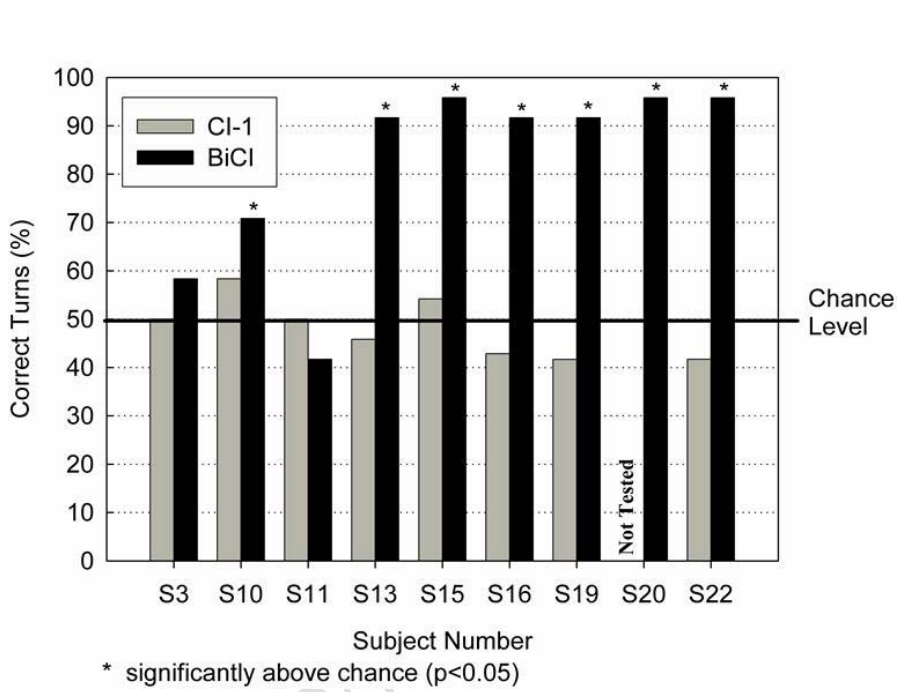


Figure 4: Percent correct turns in response to the auditory-alone stimuli for each of the nine subjects tested on the left vs. right localization task in the CI-1 and BiCI conditions.

Discussion

Ten subjects were sequentially, bilaterally implanted, with the second implant received before four years of age. One subject rejected the second implant at the switch-on session; therefore, the discussion of results here focuses only on the remaining nine subjects. The nine subjects encountered no significant difficulties in the post-operative period. All accepted using CI-2 alone and developed listening skills with the device relatively quickly. There may have been an effect of age on CI-2 alone use. Aged around 3 years 10 months at the time of their second implantation, S3 and S15 were the oldest subjects by at least 8 months. Both of these subjects

were initially resistant to using CI-2 alone, had less CI-2 alone experience, took longer to develop listening skills with CI-2, and continued to demonstrate superior daily listening performance with CI-1 compared with CI-2 at six months post switch-on. The same applied for S16 (aged 3 years 1 month at implant), though this subject did eventually (after four months) demonstrate similar daily listening skills with CI-1 and CI-2. The only other subject implanted over three years of age was S17, who initially rejected the device.

The unilateral speech detection results were generally consistent with the anecdotal reports at the six months point, that is, equivalent or similar performance with either implant for most subjects, with some evidence of the superiority of CI-1 in more difficult listening situations, and more consistent superiority of CI-1 for S15 and S16. It should be noted that, for S3, speech detection results were obtained at 24 months and the anecdotal reports at six months; therefore, the two cannot be compared directly.

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Although there were inter-subject differences, it is important to note that nine subjects developed useful CI-2 alone listening skills within six months, with five of the eight subjects who accepted unilateral device use consistently demonstrating skills with CI-2 similar to those developed with CI-1. The ability to listen with either ear allows conversation with a speaker on either side (e.g. in the car or at a dining table), allows better access to the headshadow effect, and provides a wider field of sound awareness that has benefits for environmental sound detection and social interaction. Parental reports also strongly emphasized the functional and psychological benefits of a "back-up ear", such as a child being able to hear when asked to replace a coil that had fallen off, not needing to have batteries and spare parts on hand at all times, still being able to communicate if a processor was being repaired, and feeling more comfortable with their child's current and future communication not entirely dependent upon one implant.

Establishing cooperative bilateral implant use was relatively quick and straightforward for most of the nine subjects, with only the oldest subject (S3) taking time to adapt. The time taken to achieve other milestones varied, perhaps due partly to personality and age differences. Nevertheless, after six months, seven parents reported that their child demonstrated a preference for bilateral use and eight reported at least some superiority of daily listening performance with BiCIs. The only parent not reporting evidence of bilateral superiority reported insufficient opportunity to compare bilateral and unilateral performance.

In terms of objectively measured bilateral benefit, on speech detection testing, five subjects demonstrated a significant benefit in the BiCI condition. It is likely that the major component of this benefit was the headshadow effect. For S16, who showed no benefit, the result suggests that CI-2 was so inferior to CI-1 that it did not contribute to the detection of the stimulus, despite being shadowed from the noise source. With contralateral noise, a small advantage was shown in the BiCI condition for S3 and S16 only. It is possible that binaural unmasking contributed to this result for S3, who had 24 months bilateral experience. For S16, the advantage is inconsistent with the other results and is unlikely to be due to binaural unmasking.

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During the left versus right localization testing, six subjects consistently localized the auditory stimuli with quick and confident responses when using BiCIs. With CI-1 alone, these subjects were more hesitant to respond, often turned from side to side, and performed at an essentially random level. BiCI performance was poorer for S10 than for the aforementioned six subjects; although it was still significantly above chance. This poorer performance may have been due to her young age and the use of play audiometry in testing; later experience indicated that VRA-style testing was more suitable for the localization task, even for those subjects easily capable of play audiometry. A further two subjects (S3 and S11) could not localize left versus right. Age

may have been a factor influencing localization ability for S3, as the oldest subject in the study. There is no obvious explanation for the poor localization ability of S11, given that this subject was a particularly keen and consistent user of CI-2, and demonstrated benefit in daily life.

As with a unilateral implant, an individual's performance with bilateral implants will be influenced by a combination of internal and external factors that are yet to be confirmed. One factor that does appear influential in the present results is age. The authors have previously applied a similar subjective and objective assessment protocol with children aged 4 to 15 years (Galvin et al., 2007a; Galvin et al., 2007b). In general, these older children took longer to adapt to bilateral device use, were resistant to using CI-2 alone, and did not demonstrate objective evidence of improved localization when using BiCIs (though a more difficult 8-loudpeaker test was used). Within the present subject group, there was a trend for the younger subjects to demonstrate easier adaptation to, and increased benefit from, BiCIs. Generally, more difficulty adapting to BiCIs, and some limitations on the benefit gained were demonstrated by all subjects aged over three years at the time of the second implant, including S17 who initially rejected the device. These results suggest that, to maximize the ease and speed of adaptation to bilateral use, as well as the benefit gained, the second implant should be received before three years and certainly before four years. However, it should also be noted that it is difficult to distinguish between the effects of age and time delay between implants, and that age is not the only important factor. Based on research with older children, it has been speculated that potential auditory capability (as indicated by performance with CI-1 alone), consistency of device use, and the attitude and motivation of the child may impact on the outcome with BiCIs (Galvin et al., 2007a).

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Although no results were collected for S17, the fact that this subject did not wear CI-2 until 14 months after the switch-on session is an important outcome, and highlights the need for pre-operative parent counseling regarding potential device rejection. When appropriate, counseling should also be provided to the child to prepare them for the experience of a second implant. The fitting and wearing of a second implant can be difficult, particularly for a child old enough to form expectations pre-operatively. In order to develop an accurate picture of outcomes from sequential bilateral implants, it is vital that researchers report the rates at which there is rejection or limited use of a second implant or, in this case, significantly delayed acceptance of the device.

Conclusions

The results of this study indicate that children who are successful users of a first implant and receive a second implant before the age of four years are likely to gain additional benefit, including a headshadow effect and the ability to determine if a sound was presented from the left or right side. Adaptation to bilateral implant use and the development of useful listening skills with the second implant alone can be expected within six months; however some dominance of the first implant may remain at this point, particularly in difficult listening situations. At least in the first six months, outcomes vary, particularly in the development of basic localization skills, and may be negatively impacted by increased age. Not all children will accept the use of a second implant and, as with a first implant, device rejection and other risks (such as surgical risks) must be discussed in detail with the family pre-operatively. To maximize a child's opportunity to adapt to bilateral implant use and to gain benefit, a second implant should be received before the age of three years.

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Further research is needed to more clearly identify which factors influence benefit from BiCIs and how they impact progress for an individual. Not only do families wish to know what benefit their child may ultimately gain, they also need to know what to expect and how best to manage their child's adaptation to BiCIs. To examine the effect of experience, the present subjects will be reassessed following 24 months of bilateral device use. Further subjects are being recruited into this ongoing project to investigate the influence of other factors.

Acknowledgements

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Appendix A

"Auditory Development Criteria for Children <2.5yrs"

☐ Wears device full-time with minimal interruption

Consistently demonstrates one of the following:

- ☐ Alerting response to environmental sounds
- ☐ Alerting response to a call
- ☐ Increase in vocalisation when device first goes on

Demonstrates detection by one of the following:

- ☐ Head turn in response to ar, ee, oo, m, sh or s
- ☐ Conditioned response to ar, ee, oo, m, sh or s

Demonstrates syllabic awareness by one of the following:

- ☐ Imitative canonical babble
- ☐ Syllabically appropriate word approximations
- ☐ Selection of the correct toy/object from a set through audition
- ☐ Recognition of a song consistently

Demonstrates the above skills by developing one of the following:

- ☐ Use of an expressive vocabulary of approximately 10 words developed since switch-on
- ☐ Follows a range of daily language instructions (without the use of gesture/sign). List these.

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Appendix B

Where a parent, Implant Clinician or any professional working with the child raised concerns regarding their cognitive capability, psychological evaluation was conducted by the educational psychologist who was a consultant to the Melbourne Cochlear Implant Clinic. Children were assessed using a standard psychological test suitable for their age and developmental level (e.g., Wechsler Preschool & Primary Scale of Intelligence (WPPSI-3)) . Each test used different descriptive terms requiring the formation of categories for general description of the results. The terms *normal, average, mid-average, high-average,* and *superior* were collapsed into the normal to accelerated category. The terms *mild delay, low-average,* and *borderline-normal* were collapsed into the borderline-normal category.

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