A Review of Research

Pediatric Evidence Summary for Cochlear Implants







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Together we reach further

We understand it takes a village to raise a child with hearing loss.

Cochlear fosters a partnership with you along a child's hearing journey, providing you with a wealth of resources to enrich their hearing progress and open up a world of possibilities.

Access to high quality data underpins evidence-based decision making, important in supporting and caring for pediatric cochlear implant (CI) recipients to achieve optimal outcomes.

This document outlines key insights from significant research studies around the benefits of cochlear implants for pediatric recipients.

THE IMPORTANCE OF EARLY ACCESS TO SOUND

Age at intervention has been shown to be highly correlated with longitudinal outcomes. Receiving a cochlear implant early in a child's life provides a greater chance of realizing personal best speech, social and language skills.¹⁸

Early access to sound can allow a child's speech and language development to be on par with normal-hearing peers, enabling a life of possibilities.^{1,2}

The Cochlear Nucleus system is intended for use in children 9 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.

Not all subjects in the research studies following would qualify for implantation in the United States and Canada.

Natalie S., - Nucleus recipient



EARLY IDENTIFICATION AND TREATMENT OF HEARING LOSS SUPPORT SPEECH AND LANGUAGE OUTCOMES

1. Dettman SJ, et al. (2016). Long-term communication outcomes for children receiving cochlear implants younger than 12 months: A multicenter study.

Prospective speech perception, production and language assessment data collected at school entry and then at late primary/early secondary school were pooled and analyzed.

Children from three Australian centers, implanted between 1990 and 2014, and before six years of age were included. They had bilateral, congenital severe profound sensorineural hearing loss (SNHL) and normal or borderline normal cognitive abilities (n = 403).

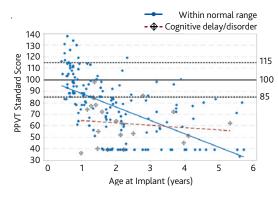
Children were divided based on implantation age: Group 1 implanted < 12 months (n = 151), Group 2 between 13 - 18 months (n = 61), Group 3 between 19 – 24 months (n = 66), Group 4 between 25 – 42 months (n = 82), Group 5 between 43 – 72 months (n = 43).

The study presents data showing the relationship between implantation and standard scores within the normal range for receptive and expressive language measures and for speech understanding and production assessments.

Regression analyses indicated significant relationships between implantation age and all speech and language results at beginning of school and at late primary/ early secondary school evaluations.

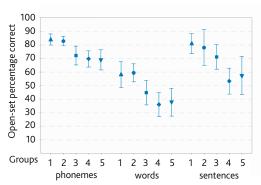
Mean open-set speech perception scores for Groups 1–3 were significantly higher than Groups 4 and 5. Cognition was significantly related to all outcomes (with the exception of phoneme scores) at both test intervals.

In terms of overall language standard scores, Group 1 had significantly better results than Groups 2 – 5. Group 1 also exhibited significantly better speech production abilities than Groups 2 – 4. (Children in Group 5 did not complete the speech production test.) Data analyses confirmed the hypothesis that a larger proportion of children implanted at < 12 months exhibited language abilities within the normal range by primary school entry. Cognitive abilities were a significant factor that affected speech perception, production and language outcomes.



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Graph showing PPVT standard scores for n = 207 at school entry; children with cognitive skill within the normal range (circles) and children with additional diagnosis of cognitive delay/impairment (diamonds).



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Implantation prior to 24 months of age can promote speech understanding and before 12 months can support speech intelligibility and language outcomes on par with normal-hearing peers.

Early implantation can increase the chances of attaining and maintaining age-appropriate spoken language abilities through to mid-elementary school years.

EARLY ACCESS TO SOUND SUPPORTS **DEVELOPMENT OF LONG-TERM SPEECH AND** LANGUAGE ABILITIES

2. Geers AE and Nicholas JG. (2013). Enduring advantages of earlier cochlear implantation for spoken language development.

Sixty children (30 boys and 30 girls) implanted at: 12 - 18 months (n = 22), 19 - 24 months (n = 16) and 25 - 38 months (n = 22) were tested at 4.5 and 10.5 years of age using a variety of standardized receptive and expressive language measures.

Between the two test intervals, participants scoring within the average range of children the same age with normal hearing on the complete test battery increased from 27% to 48%. At both test intervals, age at implantation was significantly correlated with outcomes for all tests.

Seventy-three percent of children implanted by 18 months of age scored within the average range over the full test battery. A clear predictor of language competencies at 10.5 years of age was children's language skills at preschool.

This emphasises the significance of young children meeting early language goals, before differences in language abilities between children with hearing loss and children with normal hearing become too large.

Findings highlight the importance of early implantation, in order to increase the likelihood of attaining and maintaining age-appropriate language abilities through elementary school.

Up to

of children who received cochlear implants younger than 12 months demonstrated **receptive** vocabulary knowledge within the normal range by school entry.

Dettman SJ, et al. 2016

From the group of children who received their first cochlear implant by the age of 18 months

scored within the **average** range for language skills assessed at 10.5 years.²

Geers AE, et al. 2013

Graph shows open-set (audition alone) word, phoneme, and sentence percentage accuracy for n=125 at school entry, Groups 1–5.

EARLY AGE AT FITTING OF HEARING AIDS OR COCHLEAR IMPLANTS PREDICTS BETTER SPEECH AND LANGUAGE DEVELOPMENT

3. Cupples L, et al. (2018). Spoken language and everyday functioning in 5-year-old children using hearing aids or cochlear implants.

Investigators reported on 339 children fitted with amplification (n = 228) or cochlear implants (n = 111) before three years of age, who were later tested at five years of age on receptive vocabulary, speech production, a standardized measure of receptive and expressive language, and non-verbal cognition.

Parents/caregivers answered three questionnaires: Parents' Evaluation of Aural/ Oral Functional Performance of Children (PEACH), Child Development Inventory (CDI) and a demographic questionnaire.

On average this cohort, which included children with additional disabilities (35%), performed worse (about 1 standard deviation below the mean or more) on receptive/expressive language, speech production and everyday functioning compared to normative results for normal-hearing children with typical development.

When data from children with additional disabilities were removed, the group mean scores were higher on all measures, especially for children using amplification, but still remained below group means for hearing children.

As a group, the strongest skill was receptive vocabulary (62% within the average range) compared to 57% and 52% for receptive and expressive language abilities, respectively.

In general, children's scores were positively correlated with each other; relative performance was similar across standardized tests as well as significantly related to parental indications of everyday functional abilities, making the PEACH a beneficial scale for monitoring performance.

For children using amplification, early fitting predicted better receptive and expressive language outcomes at five years.

Additional predictors of language and functional abilities were higher non-verbal IQ, lesser degree of hearing loss and higher maternal education.

For children with implants, earlier implantation and higher non-verbal IQ predicted better outcomes at five years of age; additional disabilities were associated with relatively poorer speech and language skills.

Using oral communication as part of early intervention was a predictor of receptive language abilities for children using hearing aids (HAs) or CIs.

EARLIER INTERVENTION LEADS TO GREATER POTENTIAL OUTCOMES^{*}

4. Ching TYC, et al. (2018). Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study: summary of 5-year findings and implications.

The most recent outcomes for 470 Australian children, who received hearing aids or cochlear implants before three years of age, are summarized for a longitudinal population-based study.

After diagnosis, Australian Hearing Services followed all children in a controlled manner throughout the study.

Children were initially evaluated at three years of age (Ching 2013); this paper reports on the findings from the cohort at five years of age.²⁰

Important results include: 1) early age at intervention, with a HA or CI, resulted in better outcomes in speech, language and functional performance across the full range of ages studied, the benefit increased with more hearing loss; 2) better non-verbal cognitive skills were linked to: higher receptive and expressive language, better speech perception and production and performance in daily life; 3) parental ratings of psychosocial abilities as measured on the PEACH (Parents' Evaluation of Aural/Oral Functional Performance of Children) were related to better language and functional skills; 4) examination of parental perceptions indicated they felt vital to the intervention process and answerable for their child's needs and outcomes; 5) better language outcomes were associated with: less severity of hearing loss, higher nonverbal cognitive skills, no additional disabilities, use of spoken language, and higher maternal education; 6) developmental outcomes for children with hearing loss are inter-related and strongly linked to early intervention and consistent use of amplification and/or cochlear implants.

"The LOCHI study has shown that early fitting of hearing devices is key to achieving better speech, language and functional performance outcomes by five years of age."

* The Cochlear Nucleus System is indicated for children ages: 9 months to 24 months with profound sensorineural hearing loss in both ears, limited benefit from appropriately fit binaural hearing aids with trial over 3 to 6 months, for children 25 months to 17 years indications are severe-to-profound sensorineural hearing loss in both ears, limited benefit from appropriately fit binaural hearing aids with trial over 3 to 6 months, MLNT scores of 30% or less in best-aided condition (children, 25 months to 4 years, 11 months) or LNT scores of 30% or less in best-aided condition(children, 5 years to 17 years, 11 months) and no medical contraindications.

Not all patients with hearing loss are candidates for cochlear implantation.



Longitudinal evidence demonstrates that early diagnosis followed by early intervention with hearing aids or cochlear implants leads to better functional performance, speech perception and psychosocial skills.

Benefits of improved speech and language outcomes are evident when early fitting of amplification or cochlear implantation is provided.

Children who need Cls must receive them early to achieve the best language and speech perception outcomes.4

Ching TYC, et al. 2018



TWO EARS ARE BETTER THAN ONE

Children spend most of their waking hours in complex noisy environments.¹¹ To improve speech understanding in noise, as well as localize where sounds are coming from, the brain needs input from both ears. Providing both ears with early input ensures the auditory pathways are supported to maximize a child's development.⁶

Teresa N., - Nucleus recipient



BILATERAL COCHLEAR IMPLANTATION BETTER ENABLES DEVELOPMENT OF AUDITORY AND LINGUISTIC SKILLS

5. Escorihuela García V, et al. (2016). Comparative study between unilateral and bilateral cochlear implantation in children of one and two years of age.

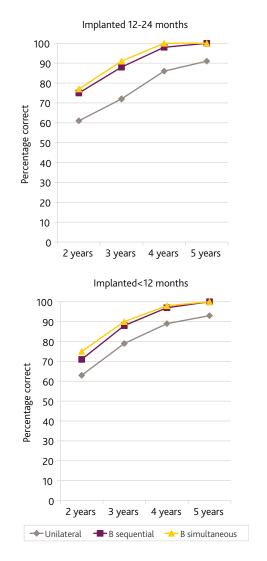
Eighty-eight children with bilateral, profound SNHL identified through a screening program between 1999 -2014, and implanted unilaterally (n = 56) or bilaterally (n = 32).

Twenty-seven children received implant/s before 12 months {unilateral = 13, sequential bilateral = 8, simultaneous bilateral = 6 and 61 between 12 – 24 months {unilateral = 43, sequential bilateral = 11, simultaneous bilateral = 7}.

Evaluations included: audiometric thresholds, simple closed-set tests, questionnaires, and open-set speech perception measures (two syllable words and sentences) at six months postoperatively and annually for five years.

Statistically significant differences between the two age groups for unilateral versus bilateral implants were not observed for audiometric thresholds. closed-set measures or questionnaire data over the five-year period.

However, children with bilateral implants, simultaneous and sequential, demonstrated 100% performance on the two open-set measures following two - three years of hearing experience compared to unilaterally implanted children who did not demonstrate similar results until five years of hearing experience.



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Graphs showing sentence test in children with sequential and simultaneous unilateral and bilateral implantation, before 12 months and between 12 and 24 months.



Bilaterally implanted children reach hearing performance goals earlier than unilaterally implanted children.

BILATERAL COCHLEAR IMPLANTATION SUPPORTS HIGHER ACADEMIC OUTCOMES COMPARED TO UNILATERAL IMPLANTATION

6. Sarant JZ, et al. (2015). Academic outcomes for school-aged children with severe-profound hearing loss and early unilateral and bilateral cochlear implants.

Forty-four children (23 boys and 21 girls) implanted unilaterally by three-and-ahalf years of age (n = 10) and bilaterally by six years of age (n = 34) participated. Seven of the ten unilateral children were implanted before two years of age and six of the ten were bimodal users (profound loss in their non-implanted ear).

Of the 34 bilaterally implanted children, 28 had their first implant before two years of age. Two children obtained simultaneous bilateral implants.

All children (with the exception of two) demonstrated cognitive abilities within the normal range and English was their primary language. When children were eight years of age (mean length of implant use = 6.9 and 7.3 years of age for the unilateral and bilateral groups respectively), children were evaluated using a norm-referenced test with age-based standard scores in: Oral Language, Mathematics, Written Language and Reading.

The study found that although the proportion of implanted children in average or above-average ranges was below that for normal-hearing children with typical development, many children with a cochlear implant attained educational results that were age appropriate.

Bilaterally implanted children showed significant improvements in oral and written language and mathematic ability compared to unilaterally implanted children.

The benefits of bilateral implantation were larger when the second implant occurred earlier. Additional significant factors that influenced overall results included the level of parents' involvement in their child's intervention and education, as well as time spent reading on a regular basis.



Children who receive bilateral implantation can achieve age-appropriate academic outcomes and bilateral input may provide significant benefits in oral language, written language, and mathematical ability.

Children with bilateral implants demonstrate

scores on select open set measures following 2 - 3 years of hearing experience which is significantly better than children with one implant.⁶

Escorihuela García V. et al. 2016

BINAURAL ACCESS SUPPORTS LOCALIZATION, SPEECH AND LANGUAGE OUTCOMES

7. Cullington HE, et al. (2017). United Kingdom national paediatric bilateral project: Demographics and results of localization and speech perception testing.

Longitudinal outcomes for 1,001 children implanted in the United Kingdom, were evaluated. The study aim was to collect outcome data on children receiving bilateral cochlear implants across 14 centers. N=465 children were implanted simultaneously (median age at implant of 2.1 years of age) while N=536 children received sequential bilateral implants (median inter-implant interval of 4.9 years of age). In children implanted sequentially, the interval between implants ranged from 0.1 to 14.5 years.

Children were assessed at four time points: prior to simultaneous bilateral cochlear implants or sequential implants, and at 1 year, 2 years, and 3 years following bilateral implantation. Performance measures included a range of age appropriate speech perception tests administered in guiet and noise, and an assessment of horizontal sound localization using a five speaker array.

For the localization task, the difference between the stimulus source and the response of the subject was scored as the location error in degrees.

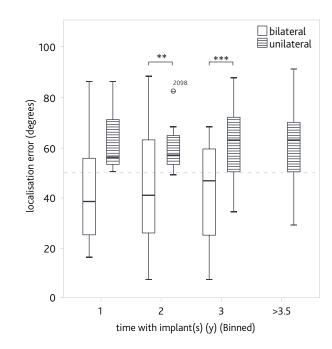
The mean absolute error was then calculated by

averaging the absolute value of the errors (ignoring direction) resulting in a continuous variable ranging from 0° to a maximum of around 120°.

Three years of data collection were completed. The results shows that, children with bilateral implants, simultaneous or sequential, localized better than those with one implant.

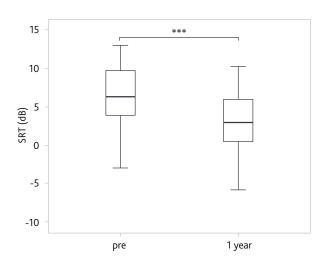
Speech understanding in noise was reported for a subset of children implanted sequentially. For this group, the addition of a second implant was shown to significantly improve speech recognition in noise at one year after the second implantation. Results suggest that the improvement shown was unrelated to an increase in age or length of use of the first implant.

The time interval between sequential implants had no effect on effect of localization ability, although a shorter inter-implant interval provided more improvement in speech recognition in noise.



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Boxplot showing localization error in bilaterally and unilaterally implanted children (Bilateral n = 44, 41, 25; unilateral n = 3, 8, 25, 193).



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Boxplot showing repeated measures (SRT, dB) with noise center (ATT and BKB combined) at the pre and 1-year interval (n = 49 sequentially implanted children). Difference was statistically significant, P = 0.000.

On average, children achieve an improvement in localization following simultaneous or sequential bilateral cochlear implantation. Children undergoing sequential bilateral implantation also demonstrated improved listening in background noise after two years of bilateral listening.

Children with bilateral implants, simultaneous or sequential, localize sound better

than those with one implant.³

Cullington HE, et al. 2017

EARLY BILATERAL IMPLANTATION PROMOTES AUDITORY DEVELOPMENT

8. Gordon KA, et al. (2013). Bilateral input protects the cortex from unilaterally-driven reorganization in children who are deaf.

Investigators recorded multichannel electroencephalography (EEG) in 34 children with implants (unilateral = 8, sequential bilateral = 16, simultaneous bilateral = 10) and seven peers with normal hearing.

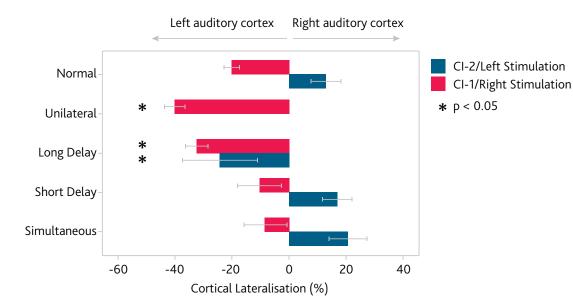
Children implanted sequentially had a short (<1.5 years) inter-implant delay (n = 7) or a long (>2 years) delay (n = 9). All children were implanted early (mean = 1.74 years of age).

At the evaluation, those implanted simultaneously had on average 3.3 years of bilateral hearing and those implanted sequentially had 3.6 years. Due to their previous unilateral hearing, this latter group had more general hearing experience than those implanted simultaneously.

EEG activity to acoustic stimulation showed abnormal cortical lateralization in children implanted unilaterally and in children with long inter-implant delay.

Children with long delays showed increased lateralization opposite to the ear stimulated, as well as reduced normal contralateral activity when the second ear, implanted later, was stimulated. This was associated with poorer speech understanding.

For children implanted simultaneously or with a short inter-implant delay, mean lateralization was not different from normal-hearing children.



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Graph showing percent cortical lateralization (mean +/-1 SE) is plotted for each participant group. Greater than normal contralateral lateralization to right/Cl-1 stimuli was found in long delay and unilateral cochlear implant users (P<0.05 and <0.0001, respectively) but not in short delay and simultaneous groups (P>0.05). The long delay group showed a decrease in contralateral lateralization/increase in ipsilateral lateralization relative to those with normal hearing in response to left/CI-2 stimulation. This did not occur in the short delay and simultaneous groups.

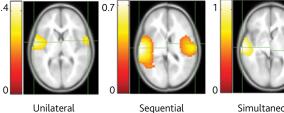
Results indicate that unilateral listening in early childhood restricts bilateral auditory pathway development by increasing cortical activity from the implanted ear in both hemispheres due to the loss of activity from the unstimulated (or long delay) ear.

This reorganization occurred after a short amount of unilateral listening and did not change with several years of bilateral hearing.

Children with long delays between implants had reduced normal contralateral activity in the cortex on the side of the stimulated ear, suggesting strengthened pathways from the stimulated side.

Children who were simultaneously implanted or experienced a short duration of unilateral hearing showed normal lateralization to the opposite hemisphere from the stimulated ear and contralateral dominance of auditory input in both hemispheres.

Overall results revealed that unilateral implantation disrupts bilateral auditory pathway development through increased activity from the only hearing ear in both cortices.



bilateral

Unilateral

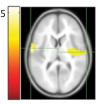
Simultaneous bilateral

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Axial tomographic beamformer images are shown for a child with normal hearing, two using bilateral cochlear implants (one implanted sequentially and the other simultaneously) and another using a unilateral cochlear implant.



Simultaneous bilateral or short delay (<1.5 years) sequential implantation promotes normal development of the bilateral auditory system, suggesting a sensitive period for binaural hearing.



[Cortical] reorganization can be avoided in children who are deaf when two cochlear implants are provided with minimal delay

(<1.5 years) with improvements in speech perception.

Gordon KA, et al. 2013



PROGRESS TRACKING AND MONITORING

Helping children and their families achieve their personalized goals is an important responsibility. At Cochlear, supporting you with industry-leading resources and ongoing care and support is our commitment.

As your partner in pediatric care, Cochlear offers you and the wider care team a range of interactive tools to help you track and measure a child's development and to support them in between visits with you.

With the most comprehensive suite of datalogs available²⁰, you can gain insights into their listening environment to help maximize hearing outcomes.

Justin P., - Nucleus recipient



CONSISTENT, DAILY LISTENING LEADS TO BETTER SPEECH UNDERSTANDING IN UNILATERAL AND BILATERALLY IMPLANTED CHILDREN

9. Easwar V, et al. (2018). Impact of consistency in daily device use on speech perception abilities in children with cochlear implants: datalogging evidence.

Datalogs from 65 children (ranging from 1.9 - 18 years of age) were analyzed retrospectively.

Average daily use was just under 12 hours; 85% (56/65) listened for > 8 hours per day.

Most children had good speech perception scores (mean = 65%); 82% (53/65) achieved > 50% correct.

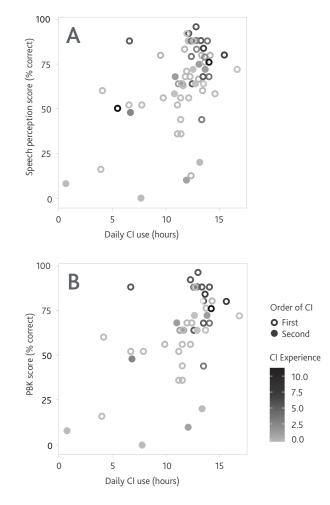
Better speech perception was correlated with more daily use and longer implant experience.

Simultaneous bilaterally implanted children showed marginally significant better right ear speech perception scores.

Sequentially implanted children demonstrated better speech perception with the earlier implanted ear.

Differences in speech scores between ears for a child with sequential bilateral implants can be explained by the time between implantation and the consistent use of both implants.

Differences in speech perception abilities between the ears declined with more listening experience and regular use; but only a few sequentially implanted children showed equal speech perception between ears.



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Graphs A and B illustrate percent correct scores across daily CI use and CI experience in all tests (n = 65) and in the PBK (n = 46), respectively. Speech perception tended to be better in children with longer daily CI use and CI experience (indicated in years). Speech perception ability of the CI received second tended to be lower than the CI received first; however, the scores among the second CI vary and some overlap with first CI performance.

ASSESSING AND UNDERSTANDING A YOUNG CHILD'S USE OF SOUND IN DAILY SETTINGS IS ESSENTIAL TO ONGOING **DECISION MAKING**

10. Davis A, et al. (2018). Shifting focus: Using functional listening skills to guide paediatric cochlear implant evaluation.

Retrospective data analysis of the Functional Listening Index[™] – Pediatric (FLI-P) from 543 children with hearing loss at a cochlear implant and early intervention center in Australia was performed.

The FLI-P provides parents and professionals with essential knowledge about an individual child's development of their real-world listening abilities, such as listening in noise and from a distance. It tracks auditory skill development from birth to six years of age and may be used to guide intervention and decisions. Such information is a necessary supplement to more traditional audiological and speech perception information available and may assist decision making during the cochlear implant candidacy process and ongoing intervention and educational programs. Analysis and validation of FLI-P results demonstrated post-implant outcomes earlier than shown via standardized speech and language measures. Moderate to strong linear relationships and statistically significant correlations were found for children's FLI-P scores at 3 years of age predicting language scores at 4 and 5 years of age.

Datalogs demonstrate the correlation of daily CI use and speech perception scores. Consistent use of bilateral CIs may reduce identified differences between ears in speech perception scores in children receiving sequential bilateral implants.



Assessing young children's functional listening abilities in the context of everyday communication provides a view to the level and growth of auditory skills of the child to parents and professionals. This information can support CI candidacy evaluation and ongoing diagnostic care.

Consistent and longer daily CI use demonstrates a

positive impact on children's listening abilities

and can bridge the difference in speech perception between ears.³

Easwar V. et al. 2018

"It's incredible, when you're working with a family and they see their child making progress or do that 'listening thing' that they never thought their child would do – it reinforces that they're on the right track."

Aleisha Davis General Manager, Clinical Programs The Shepherd Center

INSIGHT AND PATTERNS INTO THE DAILY USE OF SOUND PROCESSORS

11. Cristofari E, et al. (2017). A multicenter clinical evaluation of data logging in cochlear implant recipients using automated scene classification technologies.

Data recorded by the Nucleus[®] 6 Sound Processor was reviewed for 1,366 implant recipients using SCAN^{*}, to identify patterns for everyday use and across the age spectrum.

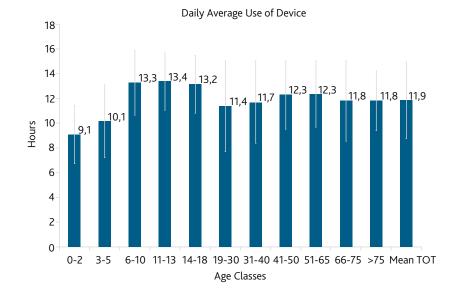
Datalogs were obtained across all age groups including: birth to two years of age (n = 121); three to five years of age (n = 206); six to 10 years of age (n = 229); 11 to 13 years of age (n = 100); 14 to 18 years of age (n = 137); 19 to 30 (n = 119); 31 to 40 (n = 72); 41 to 50 (n = 104); 51 to 65 (n = 128); 66 to 75 (n = 105); and >75 years of age (n = 45).

Daily implant listening was lowest for younger children, averaging nine to 10 hours for those in the first five years of life (n = 327); it was highest for those six - 18years of age (n = 466), with an average of 13.3 hours.

On average, children under five years of age listened to speech in quiet for 1.6 hours per day and speech in noise for 3.0 hours. Children six to 18 years of age listened to speech in quiet for a similar amount of time (1.4 – 1.8 hours), but listened to speech in noise more often (4.6 – 4.8 hours per day).

On average, all age groups spend most of the time in sound environments with speech between 50 and 69 dB SPL, which represent levels typical of conversational speech.

Datalogs are a valuable clinical asset to general troubleshooting, device fitting optimisation, and counselling of CI users, parents and carers of goals and expectations.



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Graph illustrates average daily use of the cochlear implant by age. Mean TOT, daily average use of the device regardless of age class.

Datalogs provide clinicians with insightful information about the patterns in device use by CI users of any age. Datalogs are useful when counseling parents and carers how to maximize their child's hearing performance based on their personal datalogs.

* SNR-NR. WNR and SCAN are approved for use with any recipient ages six years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings

ENCOURAGEMENT FOR CONSISTENT **BILATERAL IMPLANT USE FROM PARENTS/** CAREGIVERS IS IMPORTANT FOR LONG-TERM BILATERAL LISTENING

12. Galvin KL and Hughes KC. (2012). Adapting to bilateral cochlear implants: early post-operative device use by children receiving sequential or simultaneous implants at or before 3.5 years.

Children receiving bilateral implants may experience adaptation issues to the use of two devices. To support counselling and possible methods to minimize problems with adaptation, researchers report on the first 46 of 48 bilateral children (27 sequentially and 19 simultaneously) implanted under 3.5 years of age at the Melbourne Clinic, Melbourne, Australia. Children were grouped based on reported daily use of both implants at two months post activation and after 12 months of experience.

Thirty-seven children (95% simultaneous and 70% sequential of all children reviewed) used both implants full-time at two months and 35 children continued full-time use at 12 months. Two children with additional disabilities, who had been simultaneously implanted, discontinued use of both implants.

Of the remaining nine children, six used both implants for four hours or less daily and reached full-time use at 12 months. Furthermore, eight of the nine remaining children had received sequential implants.

Investigators found significant, weak to modest positive relationships between difficulty adjusting to bilateral hearing, the inter-implant time interval and age at bilateral implantation. Monitoring noted a tendency for the children to use only the preferred implant when tired, unwell, or upset. Furthermore, the younger children tended to remove the coil of the non-preferred implant many times per day, and older children required encouragement from caregivers if they were to put on the non-preferred implant, and ongoing encouragement if they were to keep it on.

To ensure the development of listening, speech and language skills are supported, device use and acceptance should be closely monitored. The observation that almost all children wore their implants full time after two months of listening experience is reassuring and emphasises the significance of early monitoring of implant use and encouraging consistent bilateral listening following activation.



Adaptation to the use of a second device can be supported with preoperative counselling of the potential influence of age at bilateral implantation and the time between implants. Intervening early when issues with device use first appear maximizes the chance that full-time use can be maintained or quickly re-established.

Insights into a child's daily device use

can support counselling and processor adjustments to maximize their daily experience and listening needs."

Cristofari E, et al. 2017

Full-time device use

maximizes the child's opportunity to develop their listening skills.

A primary area where the clinician can have an impact is in establishing and supporting full-time device use.¹²

Galvin KL and Hughes KC 2012

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SOCIAL COMMUNICATION

Cochlear is dedicated to making it easier for children with hearing loss to experience and engage with the world around them.

With Cochlear's latest implant and sound processor technology, children can confidently interact, learn and share what's most important with those close to them.¹⁵

(24)



PARENT-CHILD CONVERSATIONS INFLUENCE VERBAL SKILLS

13. Romeo RR, et al. (2018). Beyond the 30-Million-Word Gap: Children's Conversational Exposure Is Associated With Language-Related Brain Function.

Researchers used neuroimaging to study brain activation patterns of 36 children, four to six years of age, using functional magnetic imaging (fMRI) while they listened to children's stories.

Prior to imaging, children were assessed using standardized language and non-verbal cognitive measures to confirm they met study inclusion criteria; parents completed demographic and child development questionnaires.

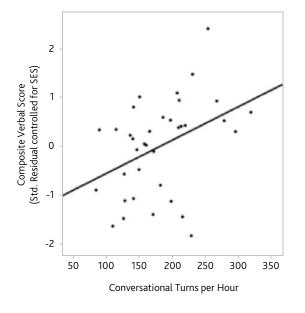
Using Language Environment Analysis Software (LENA), parents recorded two full consecutive days of audio content; this was analyzed for total number of adult words, child words and adult-child conversational turns.

These measures of daily language experience correlated with children's scores on standardized behavioral language assessments; conversational turns most strongly predicted the verbal composite score.

Neuroimaging results indicated no significant correlations with the number of adult words or child utterances.

Conversational turns correlated positively with Broca's area activation; more turns resulted in further activation during language processing, independent of socioeconomic status, cognitive ability, or numbers of adult words and child utterances. Children with more conversational turns showed more Broca's area activation during language processing, suggesting that conversational turns promote development of verbal skills by affecting activation of Broca's area.

This neural activation explained almost half of the relationship between conversational turns and verbal scores.



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Graph illustrates the relationship between children's language verbal score (controlled for parent education level and income) and the number of hourly conversational turns.

CONVERSATIONAL TURNS PREDICT LONG-TERM COGNITIVE, VERBAL AND LANGUAGE ABILITIES

14. Gilkerson J, et al. (2018). Language Experience in the Second Year of Life and Language Outcomes in Late Childhood.

Investigators used Language Environment Analysis Software (LENA) to automatically record day long, monthly audio of 146 children, two to 36 months old, for six months. The software estimated the number of adult words and adult – child turn-taking.

The children were followed up at nine to 13 years of age with standardized measures of cognitive function and receptive and expressive language abilities.

Conversational turn taking results for the 18 - 24 month age group support the predicted cognitive, comprehension and language outcomes at nine to 14 years of age; these associations held after adjusting for socioeconomic status.

No significant associations with language and developmental outcomes at school age were found for the younger (two to 17 months of age) and older (> 25 months) groups.

These findings underscore the importance of early intervention programs that emphasise actively participating in adult-child conversations rather than mere exposure to adult words.

A child's verbal skill development is positively influenced by the amount of adult-child conversational turns. Parents should be encouraged to have more interactive conversations with their child to improve their child's language skills and development.



A child's early language experiences (18 - 24 months of age), as measured by the number of adult – child conversational turns, can predict cognitive development, verbal understanding, and expressive and receptive language abilities 10 years later.

Estimates of turn-taking interactions

with children 18 to 24 months old **predicted IQ and language skills** 10 years later.¹⁴

Gilkerson J, et al. 2018

27

TECHNOLOGY TO MAKE HEARING EASIER—ESPECIALLY IN NOISE

Every day children are constantly moving through different environments¹¹—and their sound processor should adapt to all of them automatically.

Cochlear[™]Nucleus[®] Sound Processors provide children with the latest SmartSound[®] iQ^{*} processing technology, helping them hear their best by automatically adapting to different environments.

* SNR-NR, WNR and SCAN are approved for use with any recipient ages six years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings.

Raelyn H., - Nucleus recipient

29

AUTOMATIC SCENE CLASSIFICATION (SCAN') IMPROVES PERFORMANCE IN NOISE FOR CHILDREN

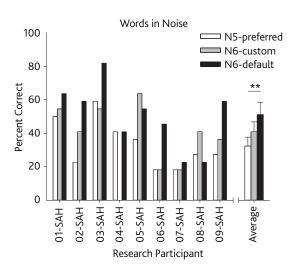
15. Plasmans A, et al. (2016). A multi-centre clinical evaluation of paediatric cochlear implant users upgrading to the Nucleus[®] 6 system.

Twenty-five children from four clinics upgraded from the Nucleus 5 to Nucleus 6 Sound Processor programmed with default settings (SCAN^{*} including noise reduction technologies).

Sixty percent (15/25) received at least one implant before five years of age and on average had six years of listening experience.

As expected, speech understanding in quiet was similar between the two processors.

Speech understanding in noise for monosyllabic words and sentences was significantly better with the SCAN* program on the Nucleus 6 Sound Processor compared to programs on the Nucleus 5 Sound Processor. Subjective preference questionnaires indicated that all children accepted the new processor.



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Graph shows percent correct scores on monosyllabic words in SWN noise for N5-default, N6-custom and N6-default programs. Group mean scores are shown on the right, with error bars showing SEM. For subject 04-SAH, no data was available for the N6- custom condition, so results for the other programs were removed from the group average and SEM calculation.

A BETTER SIGNAL-TO-NOISE RATIO (SNR) **IS REQUIRED FOR CHILDREN WITH** HEARING LOSS

16. Ching TYC, et al. (2018). Factors influencing speech perception in noise for 5-year-old children using hearing aids or cochlear implants.

At their five-year-old evaluation, 252 children in the LOCHI study completed speech in noise testing, 168 used hearing aids and 84 had cochlear implants. Signal-to-noise ratio (SNR) was determined based on the speech reception threshold (SRT) for 50% correct performance.

Children using implants needed on average 2 dB better SNR to attain similar performance compared to children using amplification. For children using amplification, non-verbal IQ and language skills were significant predictors of speech perception in noise.

Younger age at implantation and language scores predicted outcomes for those using implants. As a group, these children required a substantially better SNR than children of the same age without hearing loss.

On average, children in this study needed approximately 4.0 – 6.9 dB SNR for 50% speech understanding contrasted to approximately – 1.2 dB SNR for children without hearing loss. However, the children in this study and children with normal hearing demonstrate comparable levels of spatial release from masking (SRM), indicating similar ability to take advantage of binaural and spatial cues for understanding speech in noise.

Early intervention concentrating on language development is critical for children with implants and hearing aids to optimise functioning in realworld environments.

Automatic scene classification (SCAN') and noise reduction algorithms, on average, provide significant listening benefit to children.



Children using hearing aids or cochlear implants need a better signal-to-noise (SNR) ratio than their normal-hearing counterparts to attain the same level of speech understanding in noise.

* SNR-NR, WNR and SCAN are approved for use with any recipient ages six years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings.

* SNR-NR, WNR and SCAN are approved for use with any recipient ages six years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings

Not only is it crucial to provide cochlear implantation early, but their **language** development must also be the focus of educational intervention.¹⁸

Ching TYC, et al. 2018



Use of SCAN^{*} and background noise reduction is helpful for children as well as adults."

Plasmans et al., 2016



CHILDREN SPEND MOST OF THEIR TIME LISTENING TO SPEECH IN NOISE AND NEED THE RIGHT TECHNOLOGY TO OVERCOME THIS CHALLENGE

17. Easwar V, et al. (2016). Factors affecting daily cochlear implant use in children: datalogging evidence.

This study examined data logs from 146 children (226 ears) between 0.8 and 18.4 years of age (mean = 7.2 years of age).

There were five unilateral, 40 bimodal, and 101 bilateral implant recipients (simultaneous = 77). In general children were consistent users, even during the first year of implant listening.

On average, children used their implants almost 10 hours/day; 64% used their implants > 9 hours/day. Three children were limited users (< 2 hours/day).

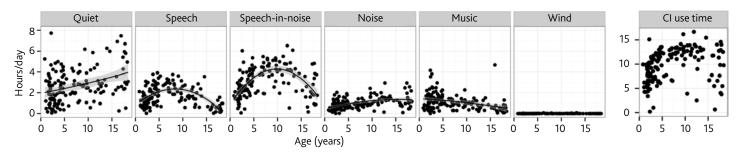
As would be expected, frequency of coil- off occurrences negatively affected amount of daily listening; the number of and time with the coil off decreased with age.

Coil retention is a real problem for parents/ caregivers and requires resolution to foster more listening experience for young recipients. Listening with the implant increased significantly with greater implant experience and amount of hearing experience before implantation.

The only significant predictors for the quantity of listening were the amount of time with coil off, length of implant experience, and amount of hearing time before implantation.

For bilaterally implanted children, typically the second implant was used as much as the first. Generally, most children listened to sounds ranging between 50 and 70 dBA.

All children listened to speech in noisy environments, in fact they listened to speech in noisy places more than in quiet, highlighting the importance of access to binaural hearing, improved signal processing and assistive technology to aid listening in noise.



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Graphs illustrate the time spent by the children wearing CIs in each environment type (classified by SCAN) as a function of age.

Children spend their time in a variety of listening environments and those with hearing loss require the additional support of advanced signal processing to enable improved speech perception in noise.

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www.Cochlear.com

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