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Infants versus older children fitted with cochlear implants: Performance over 10 years

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ABSTRACT

Objectives: To investigate the efficacy of cochlear implants (CIs) in infants versus children operated at later age in term of spoken language skills and cognitive performances.
Method: The present prospective cohort study focuses on 19 children fitted with CIs between 2 and 11 months ($X = 6.4$ months; SD = 2.8 months). The results were compared with two groups of children implanted at 12–23 and 24–35 months. Auditory abilities were evaluated up to 10 years of CI use with: Category of Auditory Performance (CAP); Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS); Peabody Picture Vocabulary Test (PPVT-R); Test of Reception of Grammar (TROG) and Speech Intelligibility Rating (SIR). Cognitive evaluation was performed using selected subclasses from the Griffiths Mental Development Scale (GMDS, 0–8 years of age) and Leiter International Performance Scale-Revised (LIPS-R, 8–13 years of age).
Results: The infant group showed significantly better results at the CAP than the older children from 12 months to 36 months after surgery ($p < .05$). Infants PPVT-R outcomes did not differ significantly from normal hearing children, whereas the older age groups never reached the values of normal hearing peers even after 10 years of CI use. TROG outcomes showed that infants developed significantly better grammar skills at 5 and 10 years of follow up ($p < .001$). Scores for the more complex subtests of the GMDS and LIPS-R were significantly higher in youngest age group ($p < .05$).
Conclusion: This study demonstrates improved auditory, speech language and cognitive performances in children implanted below 12 months of age compared to children implanted later.
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1. Introduction

Cochlear implants (CIs) in young children have shown dramatic results in restoring nearly normal levels of auditory function [1–4]. In early development deaf children fall behind normally hearing children of the same age on auditory skills and language development, but show a normal rate of development once implanted. The potential negative consequences of later implantation are becoming clear [2,4–9]. Theoretically, earlier sensory experience should provide benefit in sensory development as well as in cross-modal and cognitive development. Sensory input must be provided early to take advantage of the developmental period of neural plasticity [10,11]. Sininger et al. [12], showed that the age at fitting of amplification in children between 1 and 72 months has the largest influence on speech perception, speech production, and language outcomes. The present paper addresses issues of auditory, language and cognitive development as a function of age at implantation: specifically if implantation below 12 months of age is indeed beneficial. Sensory perception and environment exploration contribute to the development of cognition in children. Infants demonstrate an extraordinary ability in processing and integrating sensory experiences to form cross-modal associations between various forms of sensory stimuli [13]. Since auditory experience begins before full term birth [14–17], auditory deprivation has already begun in congenitally deaf infants even before birth. Early CI intervention produces significant improvements in both audition and cognition [18–21], but it remains to be clarified whether additional improvements result from implantation below one year of age.

The present study expands previous investigations [22,23] in term of number of children below 12 months (19 infants), range of language skills measured, cognitive development and duration of the follow-up (10 years of CI use). The population of infants in the present study has the lowest mean age (6.4 months) with the longest follow-up described to date.

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2. Methods

From 1998 to 2008, 243 children were implanted by the present surgeon (VC) in Verona and elsewhere. The present study compares outcome measures from the 73 children who met the following inclusion criteria: (1) implanted under 3 years old, (2) congenital deafness, (3) no prior hearing experience (including hearing aid use), (4) etiology not Meningitis, (5) no other nonauditory disabilities, (6) normal inner ears and cochleovestibular nerves, (7) nucleus implant, and (8) no device failures. These children had follow up times of three months to 10 years.

Pre-implantation audiological assessments were performed in all children and included neonatal auditory screening using otoacoustic emissions, which led to a suspicion of profound hearing loss. Subsequently, auditory brainstem recording (ABR), round window electrocochleography, electrically evoked round window ABR and behavioral (visual reinforcement) or conditioned play audiometry confirmed bilateral deafness [24]. All children received pre-operative radiological investigations. Computed tomography scans and magnetic resonance imaging showed normal inner ears and cochleovestibular nerves in all subjects. Pediatric, neuropsychiatric, and genetic evaluations were also performed. Children with additional nonauditory disabilities diagnosed by the pediatrician and/or the neuropsychiatrist or deafened from meningitis were excluded.

CI was suggested to all children as soon as a proper diagnosis was achieved. Children came to our Department at different ages and were submitted with parental consent to CI as soon as protocols for surgery had been completed.

For the purpose of comparison all children included had the same implant device (Nucleus CI 24M) and were congenitally deaf with no prior hearing experience (including no experience with prior use of hearing aids).

All children were operated on using a posterior tympanotomy approach by the same surgeon (VC). The mean duration of surgery was approximately 45 min. As described before [23], impedance measurements of electrodes, neural response telemetry (NRT), and electrically evoked ABR (EABR) recordings were performed intraoperatively in all patients to test the stimulating activity of each electrode. All CIs were activated after a period of around 30 days post-surgery. The threshold level and maximum comfortable level of each electrode were first assessed, based on intraoperative NRT and EABR measures, to select the optimal electrode configuration.

Children were subdivided in 3 groups according to age at implantation: the first group comprised 19 infants aged 2 to 11 months (mean 6.4 months; SD = 2.8 months), the second group included 21 children aged 12–23 months (mean 19.3; SD = 3.8) and the third group incorporated 33 children aged 24–35 months (mean 30.1; SD = 5.9). The numbers of children in each group at each follow-up test interval are presented in Table 1.

The causes of deafness were genetic in 27, infective from cytomegalovirus in 12, from perinatal anoxia in 6, and unknown in 28 patients. Informed consent was obtained from the parents before surgery.

All children's families used spoken Italian as their primary communication method, and all the participants attended an identical post-implantation rehabilitation program, with individualized intensive auditory training, conversation and speech stimulation.

Table 1
Numbers of children in each group at each follow-up test interval.

	1 year	3 years	5 years	10 years
2–11 months	19	16	13	10
12–23 months	21	19	18	16
24–35 months	33	26	23	21

Postoperatively, all children were evaluated at the latest follow-up, from three months to 10 years from activation, with the following tests: Category of Auditory Performance (CAP) [25] and the Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) [26,27] to examine auditory abilities; Peabody Picture Vocabulary Test (Revised 3rd Edition) (PPVT-R) [28] to test receptive language level; the Test of Reception of Grammar (TROG) [29] to examine understanding of grammatical contrast in Italian; Speech Intelligibility Rating (SIR) [30] to measure the speech intelligibility of the implanted children.

The Griffiths Mental Developmental Scale (GMDS) is a test instrument administered to measure motor maturity and development, ability to cope with routine situations, auditory and speech functions, hand and finger motor mobility and eye and hand coordination, body consciousness, physical activity, and memory. In order to provide measures of non verbal-cognitive function in children from 0 to 8 years three separate subscales of the GMDS were administered: locomotor, eye and hand coordination and performance. The GMDS revisions of 1987 [31] and 1996 [32] were chosen to longitudinally evaluate these children with the same version of the GMDS since the study began in 1998.

The Leiter International Performance Scale-Revised (LIPS-R) [33] test battery has been used to evaluate the non-verbal cognitive effects of CIs on children from 8 years of age. Since children are not expected to complete all 20 subtests, in this study, the analysis of the LIPS-R was based on the following subscales: figure ground and form completion for visual/spatial attention, sequential order and repeated patterns for fluid reasoning. The two scales (GMDS and LIPS-R), adopted in this study, were chosen because the administration of their subtests can be achieved through non-verbal instructions in a very accessible and enjoyable way. All children attempted the same subtests.

Statistical analysis was performed using the Wilkoxon Mann–Whitney test, Pearson's Chi square test and Kruskal–Wallis test, as appropriate.

Ethics approval was obtained from the University of Verona Ethics Committees.

3. Results

No statistically differences between groups emerged in terms of sex distribution ($p > .05$). The rate of minor peri-operative complications was extremely low since we could only identify one case of wound seroma in the 12–23 month group and a case of wound infection in the 24–35 month group that were both treated conservatively. No anesthesiological or major surgical complications such as flap breakdown were observed.

No significant differences emerged among the three groups in terms of CAP median scores within the first six-months of follow-up (Fig. 1). According to the Kruskal–Wallis test, the infant group

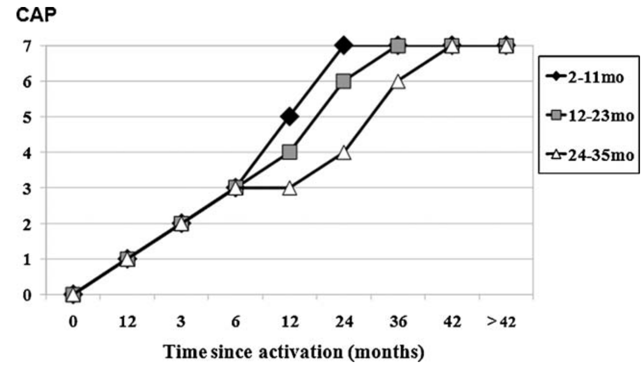

Fig. 1. Median CAP score over time in the three groups of children.

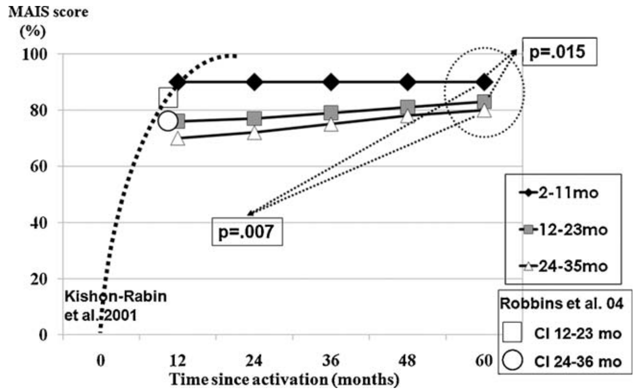

Fig. 2. Average IT-MAIS score over time: comparison of results of the IT-MAIS at 1, 2, 3, and 5 years post-activation for the three groups. The dashed line presents the normative data from the MAIS on normal hearing children from Kishon-Rabin et al. [27]. The unfilled square and circle present results at one year follow up from Robbins et al. [2].

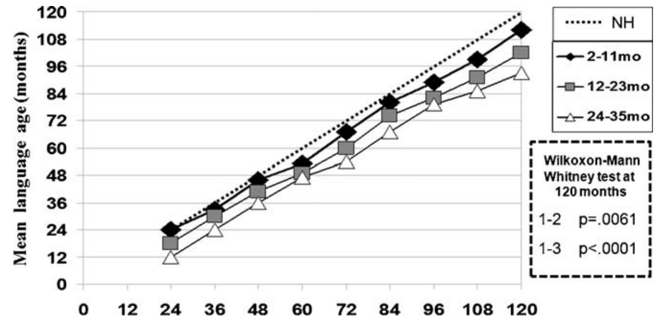

Fig. 4. Receptive language growth (PPVT-R) score over time (months) in the three groups of children. The dashed line represents normal language development.

showed significantly better results than the older children at the 12 month and 36 month post-op test times ($p < .05$). All groups of children achieved a median CAP score of 7 by 42 months after CI.

The IT-MAIS is a structured parental report on the auditory listening behavior of their children. Normative data on the IT-MAIS from normal-hearing infants has been published [27] and it has been used to evaluate auditory progress in infants with CIs [2]. Fig. 2 presents the comparison of the IT-MAIS results at 1, 2, 3, 4 and 5 years post-activation for the three groups. The dashed line presents the normative data from the MAIS on normal hearing children from Kishon-Rabin et al. [27]. The difference in IT-MAIS scores between the 2–11 month group and both other age groups was statistically significant at each time interval (12–23 month group: $p = .007$ at one year, $p = .008$ at 3 years and $p = .015$ at 5 years; 24–35 month group: $p = .0004$ at one year, $p = .0007$ at 3 years and $p = .007$ at 5 years). The difference between the older two implant groups was marginally significant or not significant at all three time intervals ($p = .049$ at one year, $p = .058$ at 3 years and $p = .819$ at 5 years). The empty square and circle present the one year follow up results from Robbins et al. [2]. Note that the absolute value of the scores observed in the present study for the 12–23 month and 24–35 month groups are similar to those observed by Robbins et al. [2].

The SIR test measures normal-hearing listener's ability to recognize the speech of the child. Fig. 3 shows the results of the SIR test as a function of time since activation for the three implant groups. Five years after initial activation, all the children of the 2–11 month group (100%), 67% of the children of the 12–23 month group and 61% of the children of the 24–35 month group developed speech intelligible to the average listener (Category 5 of the SIR scale). The Chi Square Test showed significant differences between the 2–11 and the 12–23 month groups and between the 2–11 and the 24–35 month group of children, with $p = .020$ and $p = .009$, respectively. At 10 years of follow-up the percentage of children that reached category 5 in the 12–23 and 24–35 month group, was 69 and 67%, respectively. At 10 years of follow-up, the differences between the 2–11 and the 12–23 month group and between the 2–11 and the 24–35 month group of children were statistically significant, with $p = .049$ and $p = .038$, respectively.

On vocabulary development (PPVT-R) the 2–11 months group exhibited progress in receptive language very close to normal hearing children whose development is represented in Fig. 4 by the dashed line. Children in the 2–11 month group scored significantly better than those in the other age groups ($p = .0061$ and $p < .0001$, respectively) according to the Wilkoxon–Mann Whitney test, at the 10 year follow-up.

Grammar development scores on the TROG demonstrated that at five years from activation no child of the 12–23 and 24–35 month group was above the 75th percentile, whereas 77% of children of the 2–11 month group were above the 75th percentile of their normal-hearing peers (Fig. 5). The difference between the 2–11 month group and the others was highly significant ($p < .0001$). At the 10 year follow-up the percentages increased to 100% for the children of the 2–11 month group who were above the 75th percentile, to 38% of the children of the 12–23 month group and to 19% of the children of the 24–35 month group, respectively. The difference between the 2–11 month and the 12–23 month group ($p = .0001$) and between the 2–11 and the 24–35 month group ($p < .0001$) were statistically significant.

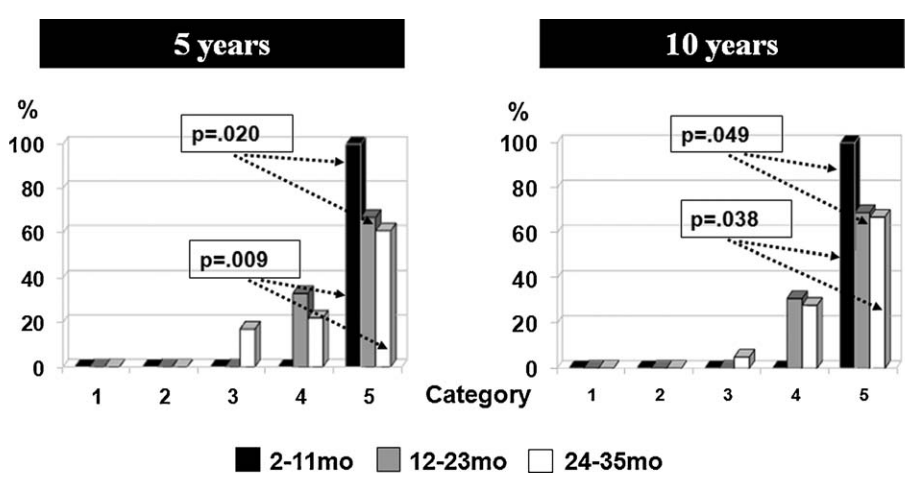

Fig. 3. Results of the SIR test (mean speech intelligibility rate) as a function of time since activation (5 and 10 years) for the three implant groups.

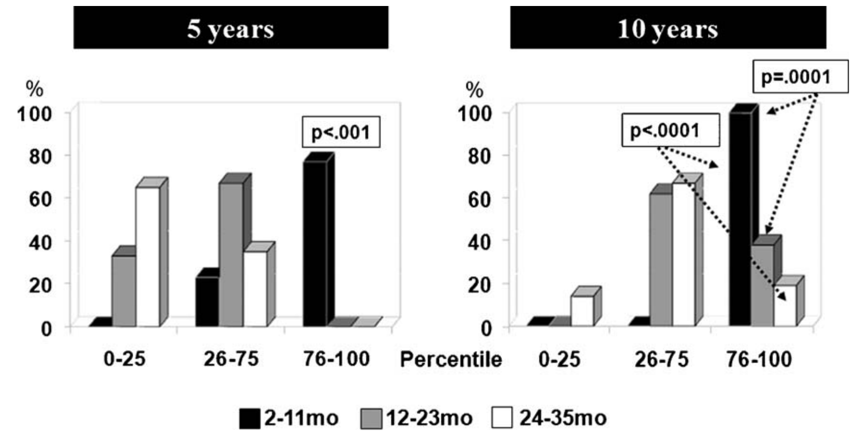

Fig. 5. Average grammar development scores on the TROG over time as a function of time since activation (5 and 10 years) for the three implant groups.

The baseline results of all subscales of the GMDS showed no statistical differences between age groups. Scores of two of the three subtests (eye and hand coordination, performance) of the GMDS increased significantly at the 5 year point compared to baseline in all age groups ($p < .05$). When comparing the performance mean scores of the infants (101 ± 12) with the 12–23 (91 ± 13) and 24–35 month group (88 ± 8) children, the differences were statistically significant with $p = .0446$ and $p = .0065$ respectively (Fig. 6). No statistically significant differences were observed for the other two subtests at 5 years among different age groups.

Statistically significant improvements in non-verbal cognitive function with the LIPS-R were found at the 10 year follow-up between the 2–11 and 24–35 month group at the form completion ($p = .0472$), sequential order ($p = .0325$) and repeated pattern ($p = .0160$) subscales (Fig. 7). When comparing the youngest group with the 12–23 months children, statistically significant difference were found for the sequential order ($p = .0469$) and repeated pattern ($p = .0440$) subscales. No significant differences emerged between the two older groups of children for all subtests.

4. Discussion

Does early cochlear implantation restore sufficient auditory experience to overcome the negative effects of early deprivation on auditory, language and cognitive performance? Does implantation at ages under 12 months provide additional benefits compared to

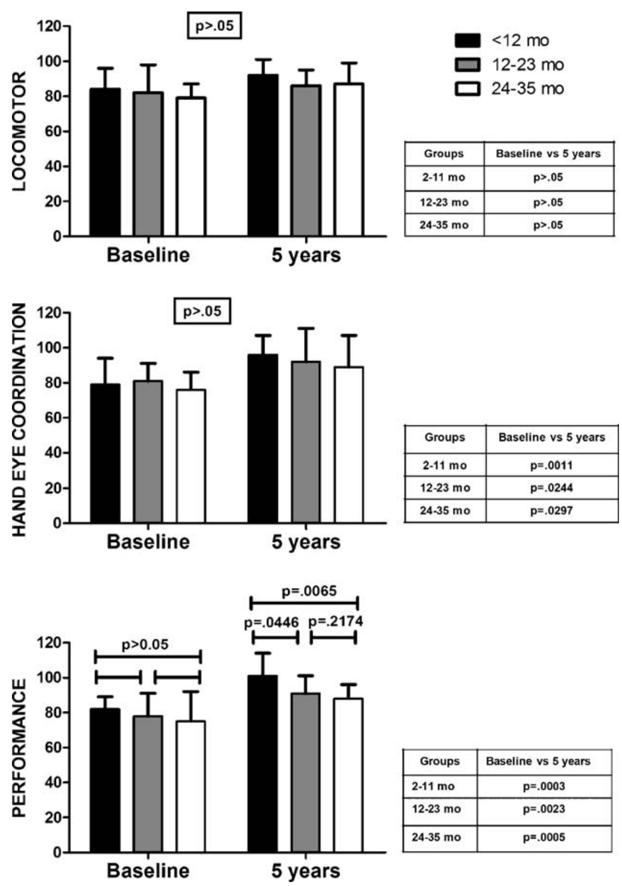

Fig. 6. Average results of the three subscales (locomotor, hand-eye coordination, performance) of the GMDS over time for the three implant groups.

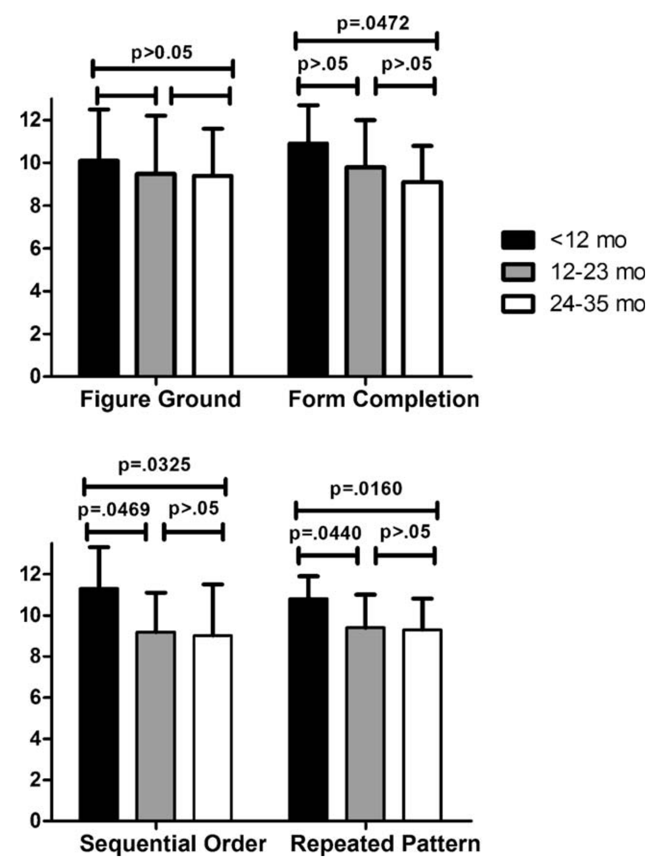

Fig. 7. Average results of the four subscales (figure ground, form completion, sequential order, repeated pattern) of the LIPS-R over time for the three implant groups.

implantation at older ages? To date published research on early implantation presents a conflicting message. Holt and Svirsky [34] conclude that there is no additional benefit in performance based on a small number of children implanted under 12 months of age. However, Colletti et al. [22] showed a clear advantage in CAP scores and babbling measures in 10 infants implanted before 12 months. Dettman et al. [4] also showed clear advantages in early implantation based on results from 19 children implanted under 12 months of age. Colletti [23] demonstrated that very early cochlear implantation (below 12 months of age) provides normalization of audio-phonologic development with no complications. A recent meta-analysis concluded that evidence of improved performance on auditory perception/speech production outcomes is limited for children implanted below 12 months [35].

When children are implanted later, the delays in the development of auditory performance could represent significant challenges for the development of working memory and general cognitive development [8,36,37]. Indeed, auditory development begins even before full term birth, as it is known that hearing begins early in intrauterine life. The newborn and even the fetus not only can hear relatively well, but also they are capable of distinguishing their mother's heartbeat and voice from others [14,38] and respond to changes in musical notes [16]. Other sensorimotor and cognitive development also rely on auditory development and can be seriously delayed the longer implantation is delayed. Indeed, some developmental trajectories have a biological window that closes if the necessary elements are not available within the "critical period" of development.

The infant population of the present study is the youngest described in the literature with a mean age: 6.4 months (range: 2–11 months; SD = 2.8 months) and with the longest follow-up (10 years). Waltzman et al. [39] and Valencia et al. [40] presented data from children implanted at a mean age of 9.6 months (range: 7–11) and 9.2 months (range: 6.7–11.7) months, respectively. Holt and Svirsky [34] evaluated six children with a mean age of 10.2 months (range: 6–12) followed for up to 5 years. More recently Roland et al. [41] reported data on 50 infants with a mean age of 9.1 months (range: 5–11) followed for up to 7 years. On all auditory and speech tests the youngest group showed superior performance to results from children implanted later. The children implanted below 12 months of age developed auditory capabilities faster (CAP), produced more intelligible speech earlier (SIR), developed language at normal rates and levels (PPVT) and developed grammar skills earlier than children implanted after 12 months of age. This superior performance persisted out to 10 years of follow-up. These data show clear evidence that earlier implantation results in faster development and these children continue to out-perform children implanted later.

Furthermore, the additional sensory input provided by the CIs clearly supports non-auditory cognitive development. The infant group showed significantly increased results on the GMDS performance subtest scores compared to the older children. This finding might be ascribed to the higher demand in term of sensory input integration to complete the performance subscale task. Early additional auditory verbal and non-verbal stimuli provided by the CIs may offer the infant the chance of developing a more complex and effective learning strategy in a very "critical period" of their development. The activation of the auditory channel enriches the children's sensory stimulation [21] and brings the level of attention to a more sustained level on a wider range of stimuli. On the other hand, the locomotor subscales showed no significant differences as a function of CI fitting age. This subtest evaluates a "lower order" cognitive function compared to the performance subscale. It confirms the role of early auditory stimulation in building complex cognitive function. In view of the results of the GMDS subscales at 5 years post-implantation, children were tested again at 10 years with the LIPS-R to compare the long term cognitive outcomes. Data from several subtests of the LIPS-R showed that the infants were able to achieve higher scores on non-verbal cognitive tests. The sequential order and repeated patterns items on fluid reasoning showed the highest improvement in implanted infants compared to older children. Both tests require the "higher" ability to understand the relationship between stimuli and generate rules governing them. Despite the small number of subjects tested, the outcomes of the GMDS and LIPS-R underline the positive effect of early implantation in complex non-verbal cognitive functions. Similar results were recently described in children fitted with the auditory brainstem implant [37]. These findings support the hypothesis that early auditory stimulation might play a fundamental role in the development of higher cognitive functions where multisensory integration is essential. Thus, delays in the onset of hearing can delay aspects of cognitive development.

In conclusion, the present results clearly show better auditory reception, speech production and language development in children implanted younger than 12 months of age than in children implanted later. While all implanted children made excellent progress on all tasks, those implanted under 12 months of age made the gains faster and achieved higher levels of asymptotic performance.

It is important to note that a highly specialized pediatric team of experts is critical for obtaining the best outcomes in infants with CIs. In addition to experienced pediatric surgeons and anesthesiologists, the team should include an experienced pediatric audiologist and pediatric neuroradiologist to achieve the proper diagnoses, treatment and rehabilitation. The risks of cochlear implantation under 12 months of age are minimal in the hands of experienced pediatric surgeons and anesthesiologists [22,39,42]. Restoration of hearing in infants by cochlear implantation shows beneficial effects auditory, language and cognitive development and should be undertaken as soon as a diagnosis of profound deafness can be confirmed.

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Ethical approval

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Contributors

All authors declare that they made substantial contributions to the intellectual content of the paper and they finally approved it for submission.

All Authors declare that there is no one else who fulfils the criteria but has not been included as an author.

Conflict of interest statement

All authors declare that they have no conflicts of interest.

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