International Journal of Pediatric Otorhinolaryngology 74 (2010) 119–126

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Review article

Cochlear implantation under the first year of age—The outcomes. A critical systematic review and meta-analysis

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ARTICLE INFO

Article history:
Received 12 August 2009
Received in revised form 5 October 2009
Accepted 8 October 2009
Available online 5 November 2009

Keywords:
Cochlear implants
Infants
Under 1
Deaf
Hearing impairment
Children
Outcome
Speech
Development
Auditory
Perception
Results
Early
Implantation

ABSTRACT

Objective: To review the current knowledge on cochlear implantation in infancy, regarding auditory perception/speech production outcomes.
Study-design: Meta-analysis. EBM level: II.
Methods: Literature-review from Medline and database sources. Related books were also included.
Results: The number of cohort-studies comparing implanted infants with under 2-year-old children was five; three represented type-III and two type-II evidence. No study was supported by type I evidence. Overall, 125 implanted infants were identified. Precise follow-up period was reported in 82. Median follow-up duration ranged between 6 and 12 months; only 17 children had follow-up duration equal or longer than 2 years. Reliable outcome measures were reported for 42 infants; 15 had been assessed with open/closed-set testing, 14 with developmental rating scales, and 13 with prelexical speech discrimination tools.

Ten implanted infants assessed with open/closed-set measures had been compared with under 2-year-old implanted children; 4 had shown better performance, despite the accelerated rate of improvement after the first postoperative year.
Conclusion: Neuroplasticity/neurolinguistic issues have led cochlear implant centers to implant deaf children in infancy; however, widespread policies regarding the aforementioned issue are still not justified. Evidence of these children's outperformance regarding auditory perception/speech production outcomes is limited. Wide-range comparisons between infant implantees and under 2-year-old implanted children are lacking. Longer-term follow-up outcomes should be also made available. There is a need to develop and validate robust measures of monitoring implanted infants. Potential factors of suboptimal outcomes (e.g. misdiagnosis, additional disorders, device tuning, parental expectations) should also be weighted, when considering cochlear implantation in infancy.

Contents

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0165-5876/$ – see front matter
doi:10.1016/j.ijporl.2009.10.004

1. Introduction

The wide application of neonatal hearing screening in many countries has facilitated earlier identification, referral, and diagnosis of children with hearing loss [1]. This has led, in turn, to earlier clinical intervention and a steadily decreasing age of cochlear implantation for profoundly deaf children [2].

Encouraged by the promising results of pediatric implantation under the age of 2 years in terms of early development of auditory processing [3], the improved technology [2], and the enhanced awareness regarding the safety of cochlear implants in young children [4], children under the age of 12 months are now being implanted in some centers, in an attempt to shorten even more the time-lag of auditory access to spoken language.

Although it is widely accepted that age at implantation is a significant factor for the development of speech perception and intelligibility in pediatric implantees [5–8], the question remains whether there is an additional benefit from implantation in the first year of life, taking into account the risk of misdiagnosis in an age that behavioural audiometry and measures of progress may not be very reliable.

The aim of the present paper was to review the current knowledge on pediatric cochlear implantation before the first year of life with regard to the outcomes in auditory perception and speech production. Age-appropriate outcome measures for evaluating cochlear implantation in infancy will also be explored.

2. Materials and methods

An extensive search of the literature was performed in Medline and other available database sources for the period 1982–2008, having as primary end-points the assessment of auditory perception and speech production outcomes following cochlear implantation in infancy.

Using an initial framework of results, the retrieved studies were critically appraised, according to levels of evidence I through V regarding the primary research questions (Table 1) [9]. In addition, two secondary categories of outcomes were also analysed:

(a) the functional impact of cochlear implantation in the developing human nervous system, taking into account the time-point at which this intervention is attempted, and
(b) the existence of appropriate clinical tools in order to document the progress of implanted infants.

Table 1
Levels of evidence regarding the primary research question in studies that investigate the results of a treatment.

Category of evidence	Study design
Level I	• High quality randomized trial with statistically significant difference, or no statistically significant difference but narrow confidence intervals • Systematic review of Level I randomized control trials (and study results were homogenous)
Level II	• Lesser quality randomized control trial (e.g. <80% follow-up, no blinding, or improper randomization) • Prospective comparative study • Systematic review of Level II studies or Level 1 studies with inconsistent results
Level III	• Case–control study • Retrospective comparative study • Systematic review of Level III studies
Level IV	• Case series
Level V	• Expert opinion

During the search, the keywords “cochlear implants”, “age”, “infants”„ “under 1”, “neural”, “expressive”, “receptive”, and “development” were utilized. The keywords “cochlear implants”, “infants”, and “under 1” were considered primary and were either combined to each of the other keywords individually, or used in groups of three. Information from electronic links and related books was also included in the analysis of data. In addition, reference lists from the retrieved articles were manually searched.

3. Results

Fifty-one publications met the defined criteria and were included in the study selection. They included two meta-analyses, nine prospective controlled studies, five retrospective controlled studies, six prospective cohort studies, ten retrospective cohort studies, five animal studies, three guidelines, two review articles and nine books. Nine cohort studies among them had addressed the primary end-points of the present meta-analysis.

Overall, 125 children receiving cochlear implants before the first year of age were identified. Precisely determined follow-up period was reported in 82 of them. The median duration of follow-up ranged between 6 and 12 months (Fig. 1). However, reliable outcome measures were only reported for 42 infant implantees. Fifteen children among them had been assessed with open- and/or closed-set testing, 14 had been evaluated using developmental rating scales, whilst the assessment of the remaining 13 implantees was based on prelexical speech discrimination tools. A follow-up period of at least 2 years could only be identified in 17 of the aforementioned implanted infants.

With regard to the type of evidence supporting cochlear implantation in infancy, out of the total of nine cohort studies that had reported auditory perception or speech production outcomes in implanted infants, five studies represented type III evidence, and four type II evidence. No study was supported by type I evidence (Tables 2 and 3).

In addition, only five of the aforementioned studies had actually compared children receiving implants before the first year of life with children implanted between the first and second year of life. Among these studies, three could be classified as evidence-based level III, whilst the remaining two were level II studies. No study was supported by type I evidence.

4. Discussion

4.1. Neural reorganization as a function of cochlear implantation

It is widely accepted that if listening is not developed during the critical language learning years, the acquisition of spoken language is severely compromised [10]. However, the extent and potential reversibility of the related changes in the neural architecture are topics of ongoing investigation [11].

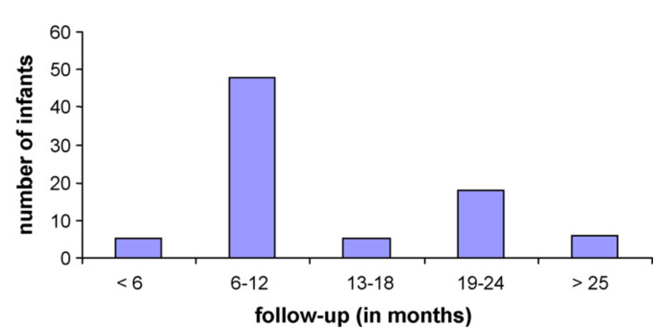

Fig. 1. Duration of follow-up for infant implantees.

Table 2
Studies comparing implantation outcomes between less than 1-year-old pediatric implantees and children implanted between 1 and 2 years of age.

Authors	Study type	Evidence level	No. of children (age < 1 year)	Outcome measure	Reported advantages	Problems	Remarks
Holt and Svirsky [48]	Controlled retrospective cohort	III	6	Mr. Potato Head task/ RDLS/MCDI	Development of receptive language skills is better in under 1 compared with under 2 implantees; regarding the other language aspects, no significant difference was evident	The small sample size made demonstration of performance differences difficult	Both the risks and benefits of implantation under the age of 1 year seem relatively low
Dettman et al. [1]	Controlled retrospective cohort	III	19	RI-TLS	(a) The average rate of growth for language comprehension in implanted infants under 1 year was better than their older-implanted peers (b) The average rate of growth for language expression was better than their older-implanted peers (c) Implanted under 1 year demonstrated language comprehension and expressive development comparable to their NH peers	1 child was readmitted due to mastoiditis 6 days after discharge	Children with cognitive delays were removed from the analysis
Miyamoto et al. [25]	Controlled sequential cohort	II	8	VH/PLP/maternal speech	(a) Implanted under 1 year showed more consistent learning of the associations between speech sounds and objects (b) Maternal speech styles towards earlier implanted infants were more closely matched to the respective styles towards NH babies	n.r.	Learning associations between speech sounds and objects is an essential requirement to learning words
Lesinski-Schiedat et al. [30]	Controlled retrospective cohort	III	27	MAIS/MUSS/ FDA/TAPS/GASP	(a) Implanted under 1 year almost showed ceiling effect at 1.5 years post-op regarding response to noise (b) Open-set testing showed greater improvement after 2 years of rehabilitation in under 1 compared with between 1 and 2 pediatric implantees	n.r.	Implanted between 1 and 2 years seem to have lost the age-related developmental advantage, compared to the younger implanted children
Schauwers et al. [2]	Prospective controlled	II	5	Babbling onset/ babbling spurt/ CAP/A§E	(a) Auditory performance of children implanted under 1 year follows the normal line (b) Only implantation under 1 year is able to keep the babbling onset of infants within the normal age range	n.r.	Mainstream school integration at the age of 2.5–3 years is feasible for early implanted children

RDLS: Reynell developmental language scales, MCDI: McArthur communicative development inventories, RI-TLS: Rossetti infant-toddler language scales, VH: visual habituation, PLP: preferential looking paradigm, MAIS: meaningful auditory integration scale, MUSS: meaningful use of speech scale, FDA:, TAPS: test of auditory perception of speech for children, GASP: Glendonald auditory screening procedure, CAP: categories of auditory performance, and A§E: auditory speech sound evaluation.

Table 3
Implantation outcomes in children under the age of 1 year (non-comparative studies).

Authors	Study type	Evidence level	No. of children (age $<$ 1 year)	Outcome measure	Reported advantages	Reported problems	Remarks
Valencia et al. [50]	Retrospective chart review	III	15	IT-MAIS	(a) Cochlear implantation can be safely performed in children under 1 year (b) Auditory perception in implanted children is evolving appropriately after surgery	(a) CSF leak occurred in a recipient with anatomic malformations and less than full insertion was achieved (b) 2 device failures required reimplantation (c) 1 case of persistent infection required device removal and reimplantation	Less than optimal outcomes can be achieved in children with additional disabilities even after very early implantation
Tait et al. [40]	Prospective controlled	II	10	Tait video-analysis	(a) Mean vocal autonomy of children implanted under 1 year is not different from their NH peers (b) NLVT in children implanted under 1 year and NH children is not different	n.r.	NH children use meaningful vocal communication more frequently than children implanted under 1 year
Colletti et al. [4]	Retrospective controlled	III	10	CAP/babbling onset/babbling spurt	(a) CAP showed excellent results in children implanted under 1 year (b) There was no statistically significant difference between children implanted under 1 year and NH children, regarding bubbling onset, or bubbling spurt	Surgical risk is an issue of concern and should be weighed on an individual basis	(a) The outcomes should be considered preliminary, because only 3 children were followed for up to 2 years (b) CAP score improvement was an encouraging prognostic indicator of perceptive and communicative skills in very early implanted children
Waltzman and Roland [21]	Prospective	II	18	IT-MAIS/GASP/CP/LNT/MLNT	(a) All children are developing speech and language skills with a natural-sounding voice (b) Implantation can be performed safely in under 1 year children (c) Implantation in under 1 year children leads to functional benefit over and above conventional amplification	1 case of flap breakdown and persistent infection necessitated device removal and reimplantation	Potential additional disabilities may require delay in implantation in order to provide parents with more informed prognosis

NH: normal hearing, IT-MAIS: infant-toddler meaningful auditory integration scale, CAP: categories of auditory performance, GASP: Glendonald auditory screening procedure, CP: common phrases, LNT: lexical neighborhood test, and MLNT: multisyllable lexical neighborhood test.

Early deafness in animals results in a number of vocal output consequences which affect the segmental and suprasegmental properties of voicing (i.e. intensity, fundamental frequency, harmonic structure, syntactical organization) [12,13]. In addition, cochlear removal in young mice, gerbils, and chicks, results in severe transneuronal degeneration, whereas adult animals exhibit little or no such changes [14]. However, Ryugo et al. reported that successful restoration of the abnormal synaptic structures in the auditory nerve endings of deaf cats to a normal state is feasible after continuous stimulation of their auditory nerves with a six-channel cochlear implant for 3 months [15]. Nevertheless, electrical stimulation of the inner ear is more effective in younger animals compared to older ones in eliciting gene expression that is associated with the development of a functional network in the auditory pathways [16–18].

The above experiments support the notion that critical periods exist for the preservation or restoration of the auditory system in profoundly deaf children [19]. These periods may extend between the 6th month of fetal life and the first post-natal year with regard to phonology [20] and beyond that in the other spoken language elements. It is also interesting to note that the speech perception capacities which are exhibited by infants during the first 6 months of life appear to be language-universal rather than language-specific. However, from this time-point onwards, phonemic discrimination seems to play a crucial role in spoken language development. As a result, it appears reasonable from a neuro-linguistic perspective to attempt pediatric cochlear implantation, not only early enough to pursue normal (or near-normal) spoken language progress, but also before significant delays are present.

However, the critical periods for language development have not yet been adequately explored, in order for specific time periods to be readily identified. In addition, such periods may vary among children, and even the whole concept of critical periods should not be taken as entirely inflexible, as neuroplasticity in humans never ends, although it decreases substantially with age.

4.2. Age at implantation as a critical parameter of cochlear implantation

The trend to decrease the age of pediatric cochlear implantation aims to limit the gap between chronological and language age. Indeed, preliminary studies have reported that early implanted children develop language skills more rapidly than their non-implanted peers and at a rate comparable to that of hearing children with similar initial language skills [21,22]. Therefore, it is not surprising that age at implantation is a strong predictor of speech and language outcomes following cochlear implantation [5,8,23–25]. Indeed, age at implantation has been found to influence the auditory performance in profoundly deaf children significantly [26] and thus the development of their speech perception and intelligibility [5–8]. However, it should be highlighted that there is still a wide variation in individual outcomes [8], and exact contributing factors for this phenomenon have yet to be determined [27].

Having compared children implanted between the first and second years of age with older implanted children, Tait et al. reported that vocal and auditory preverbal skills develop much more rapidly in the younger pediatric implantees, and that younger implantees are significantly more likely to adopt an auditory/oral mode of communication by 1 year post-implantation [5]. The beneficial effects of early cochlear implantation seem even more apparent in children with some residual hearing, which undergo cochlear implantation after having received even a limited benefit from early amplification [11].

These outcomes indicate that there may be an added benefit for spoken language acquisition when a child is receiving an implant in infancy, and this may in turn lead to an earlier and more successful transition to the mainstream educational system. However, the evidence which support the trend of cochlear implantation in infancy is limited and not well explored, thus necessitating systematic reviews, such as the present one.

4.3. Early outcome measures for evaluating implantation in infancy

It is of critical importance for clinicians to evaluate the progress of early implanted children and make comparisons with their normal-hearing or later-implanted peers. However, the evaluation of speech perception and speech production in very young deaf children represents a formidable challenge [28]. Moreover, the prelexical speech development in implanted children has hardly been investigated [2,29]. The task becomes more difficult taking into account that younger children usually perform worse on auditory tests and scales at the first intervals after implantation and may outperform their older implanted counterparts at later intervals, e.g. 2 years post-implantation [8,30].

The gold standard for assessing the outcomes of early implantation would be the use of validated instruments, such as the Bamford–Kowal–Bench or other equivalent speech discrimination tools, as well as language developmental scales, such as the Reynell scales [31,32]. However, these measures can only be applicable in long-term follow-up intervals after infant implantation. Indeed, the results of the present review highlight the fact that the use of such measures remains considerably limited in this group of pediatric implantees. To date, only 15 children have been assessed with any form of open and/or closed set tests so far, thus making any relevant conclusions invalid, due to the small population size.

The short-term functional outcome may be assessed with regard to two different, though highly related domains, which emerge in infancy; the auditory skills and the prelinguistic vocalizations. However, the outcome measures in these fields are usually considered as "soft" measures—in the vast majority they are subjective, indirect (sometimes assessing parental views), not adequately validated, with questionable reliability and validity, easily reaching a plateau.

Categories of auditory performance (CAP), a global measure of auditory receptive abilities, listening profile (LiP), a summary of listening skills development that covers a wide range of auditory abilities, and infant-toddler meaningful auditory integration scale (IT-MAIS), a criterion-based measure for parental assessment of the child's auditory responses, have been widely used in assessing the progress of auditory performance in very young children [33–36]. Subsequently speech pattern perception can be initially assessed by using behavioural testing, such as the visual habituation (VH) procedure [22]. The early speech perception (ESP) test, which evaluates the speech perception skills in children with limited vocabulary and language skills [37], can also be employed relatively early, thus estimating the rate of acquisition of a skill that is attained from an early developmental stage.

Speech discrimination is the next milestone of auditory skills that should be evaluated in young implantees. Phoneme discrimination tools, such as the auditory speech sound evaluation (A§E) score, can provide information about the discriminatory skills of the implanted children, independently of lexical items [38]. Finally, the ability of future word acquisition in implanted infants can be predicted by using the preferential looking paradigm (PLP) [24], a behavioural model that determines the consistency of children at this age in learning associations between speech sounds and objects.

The evaluation of preverbal skills is also of critical importance to document the link between the auditory and prelinguistic domains of infant development, as they are considered natural precursors of language development in all children, whether normally hearing or deaf [39]. Observational methods, such as the Tait video-analysis, which examines the development of communicative behaviours of implanted infants in their home environment, have proven relatively reliable in monitoring preverbal behaviours in infancy [40]. Another instrument is the production infant scale evaluation (PRISE), a questionnaire-based parental report that evaluates the evolvement of prelinguistic skills in infants [41].

Initially the onset of babbling, which is the presence of multiple articulatory movements in one breath unit combined with continuous or interrupted phonation [42], may serve as a critical time point in prelinguistic development, indicating that speech production is triggered by the cochlear implant. The next hierarchical prelexical step is the time of babbling spurt (the time-point were the frequency of babbled utterances shows a significant increase). The rate of progress after the onset of infant vocalizations may also be monitored with the use of parental-based reports, such as the meaningful use of speech scale (MUSS) questionnaire. These are helpful in assessing the voice control, oral competence and preferred communication strategies of infants after implantation [43].

The emerging need of early outcome measures has led the Nottingham team to propose the Nottingham early assessment package (NEAP), which combines a number of assessment scales and tests which can be applicable in very young children [44]. However, such packages with numerous outcome measures and scales only highlight the complexity of the effort to evaluate early outcome measures in infant implantees, and the lack of actual gold standards.

Hence, it seems that there is lack of objective, reliable and validated tools for early cochlear implantation, with regard to assessing the progress of very young children. There is an emerging need to develop such instruments at the earliest possible time.

4.4. Auditory perception and speech production outcomes of implantation in infancy

Although several cochlear implant centers worldwide have followed the trend to implant children under the first year of age, the present systematic review has found very limited data to support this policy. Some papers have, indeed, reported encouraging results in very young implantees. However, the follow-up intervals are usually very short, assessments are often performed with "soft" outcome measures or scales, and statistical comparisons with older implanted peers, or normal-hearing children are often lacking.

Waltzman and Roland reported an alerting-to-sound score of 77% after cochlear implantation in children younger than 12 months, indicative of an emerging auditory competence [21]. Moreover, the auditory performance of such pediatric implantees seems to reach the level of hearing children earlier compared with their older-implanted counterparts, and an equivalent CAP score can be reached as early as 3 months after implantation [2]. In addition, while both groups of implanted children show very good responses to noise in terms of sound detection at 3 months postoperatively, the younger implanted infants nearly reached a ceiling effect after 18 months of stimulation, whereas the older implanted ones did not seem to gain such an advantage [30].

Data based on behavioural testing have also suggested that young deaf infants show more consistent preference for speech inputs, than their later-implanted counterparts. They also seem able to discriminate continuous versus discontinuous sounds very soon after cochlear implantation [24]. Thus, even though the ability to perceive different speech patterns is a skill which older pediatric implantees already possess, younger-implanted children reach high scores of acquisition soon after implantation [45]. In another study, almost every phoneme pair tested could be discriminated by the infant implantees, as early as 6 months postoperatively [2]. In addition, the infants who were implanted before the age of 12 months were found capable of learning associations between speech sounds and objects, a skill that is central in order to learn words. By contrast, similarly consistent learning of the associations was not observed in children who received implants after the first year of life [24].

With regard to the preverbal behaviours of children implanted prior to the first year of life, it seems that the early provision of a cochlear implant may establish a more effective parent–child interaction, which may serve as the basis for future language development [46]. To understand the latter, the triangular scheme of communication which leads to vocal development must be considered. The child's and caregiver's lines of visual regard form two sides of the triangle, and the language input from the caregiver, which is received by the child through audition, forms the third side. A communication link is formed as the caregiver communicates with the child while the child is looking at something, making their interaction meaningful. When a baby is profoundly deaf the third side of the triangle is practically absent. By providing a cochlear implant very early during the critical period of prelexical development, the third line of the triangle is, at least partially restored, and children are expected to follow the normal procedure of receiving communication through audition [3]. This perspective is not only a theoretical possibility of infant implantees, as it seems that very early implantation is able to keep the infants within the normal age range for babbling onset. A positive influence to the age of babbling spurt has also been reported [2,4].

Parental assessments regarding the rate of vocal progress of implanted infants is another way of evaluating infant implantees. The vast majority of children receiving implants under 1 year of age showed a satisfying voice control at 12 months postoperatively. They also performed at least as good as their older-implanted and more mature peers, in terms of oral competence, 2 years following surgery. This finding shows a dynamic trend towards the use of spoken language as the preferred communication strategy [30]. In addition, the mean vocal autonomy in implanted children 1 year after surgery was found very close to the respective one of hearing children of the same age, and although implanted children were not as vocal as their hearing peers from an expressive point of view, their communication purposes were expressed vocally in nearly 60% of instances [3].

Dettman et al. used an infant language scale partially based on parental views, and reported that children who had received a cochlear implant earlier than the age of 12 months had language comprehension and expressive development comparable to that of their hearing peers [1,47]. The rate of growth was significantly better than the rate of comprehension and expressive growth which was observed in children who were implanted between the first and second year of life. This was present even after removing from the analysis children with cognitive delays, in which slower progress in the area of speech perception is usually expected [1]. Holt and Svirsky on the other hand, though acknowledging that there are significant differences in the developmental trajectories of children implanted earlier rather than later in early childhood years, found evidence of significantly improved skills only with regard to receptive language development, when they examined children implanted before the 12th month of age and children operated on between the ages of 1 and 2 years. Statistically significant differences in expressive language or word recognition between these two categories of pediatric implantees were not observed [48].

With regard to open- and/or closed-set testing outcomes following cochlear implantation in infancy, a meta-analysis of the published interventional studies has identified specific performance differences in only a small number of children. In detail, 15 children out of a cohort of 125 implanted infants have been assessed with open- and/or closed-set measures, with a median follow-up duration of 2 years. Among them, 10 implanted infants have been compared with children receiving their implant between the first and second year of life. Only 4 had shown statistically better performance regarding this comparison, despite the accelerated rate of improvement that implanted infants demonstrate after the first postoperative year.

Hence, the evidence of these children's outperformance with regard to auditory perception and speech production outcomes is still limited. Wide-range comparisons between infant pediatric implantees and children implanted between the first and second year of age are still lacking. The number of the related studies in the literature is only five, among which two can be classified as evidence-based level II, the remaining representing level III studies. No study is supported by type I evidence.

Moreover, the majority of the 125 infant implantees previously mentioned, appear to have actually been followed-up for a period not exceeding 1 year's time (Fig. 1), whilst it is well known that the outcomes of cochlear implantation may need many years to become evident [49]. Finally, very few children have been assessed with reliable long-term open-set outcome measures.

Hence, any widespread policy to implant all deaf children under the age of 1 year does not seem to be justified from the results of the present review. In addition, related factors of suboptimal outcomes (e.g. misdiagnosis, hidden additional disorders, suboptimal device tuning, unrealistic parental expectations, etc.) [50,51] should also be taken into account, when considering cochlear implantation in infancy.

5. Conclusion

The present paper has shown that neuroplasticity and neurolinguistic issues have led cochlear implant centers to the decision of implanting children younger than 12 months of age. However, robust and reliable outcome measures of monitoring implanted infants are still lacking, and the need for developing and validating such measures has now become urgent. Finally, despite the accelerated rate of improvement that implanted infants demonstrate, evidence that supports infant implantation, with regard to speech perception and production outcomes, is still limited and of lower quality. Long-term, high quality studies comparing implanted infants with children implanted between first and second year of life are needed, in order to support widespread implantation policies in this early age stage.

Acknowledgement

The authors would like to thank Dr. Jessica Bewick for her assistance in preparing the revised form of this manuscript.

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