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MINIMAL OUTCOME MEASUREMENTS IN PAEDIATRIC COCHLEAR IMPLANT USERS: A CONSENSUS PAPER

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Abstract

Introduction. The benefits of cochlear implantation in children with severe hearing impairments are widely known, however there is no consensus regarding which minimal outcome measurements (MOM) should be used to determine outcomes in this paediatric cochlear implant (CI) population. Therefore, the authors of this study aim to identify a MOM test battery for paediatric CI recipients that can facilitate international multi-center research and collaboration.

Methods. A paediatric MOM test battery was developed and agreed-upon by members of the HEARRING group across 30 expert clinics in the field of hearing implantation. This group consisted of surgeons, audiologists, speech and language therapists, and other skilled professionals. The MOM test battery was chosen based on a literature search that focused on outcome measurements applied in clinical trials involving children with a hearing implant. Members of the HEARRING group were then asked to evaluate each of the paediatric MOM tests used. To reach a final consensus, the suggestions and comments were discussed during the HEARRING meeting in Perth, Australia, in November 2017.

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Results. The final paediatric MOM test battery was defined for the following chronological age categories: six weeks - five months; six months- two years; two years - six years; and older than six years. The suggested test intervals were prior to implantation; three, six, and twelve months after CI activation; and yearly thereafter, which is in line with current clinical practice. The paediatric MOM test battery includes objective hearing measurements, aided and unaided audiometry, speech perception tests in quiet and in noise, subjective hearing assessments, assessment of language development, and mental and motor development.

Conclusion. This study presents a consensus on a MOM test battery for paediatric CI recipients that was agreed-upon by members of the HEARRING group. This test battery should allow for international multi-center research to be able to extend and share evidence that will guide future clinical practice and research efforts in paediatric CI populations.

Keywords: Sensorineural Hearing Loss, Paediatric Cochlear Implant Recipients, Cochlear Implantation, Minimal Outcomes Measurements, Testing Framework, Standardization.

Cover letter

Minimal outcome measurements in paediatric cochlear implant users: a consensus paper

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To whom it may concern,

We are submitting the manuscript, article type Research Article, entitled **"Minimal outcome measurements in paediatric cochlear implant users: a consensus paper"** to International Journal of Pediatric Otorhinolaryngology. This is an original work that has not been published or submitted elsewhere and that is approved for submission by all authors.

Thanks to extensive research, cochlear implantation is now recognized as a safe and effective gold standard treatment for both adults and children with a severe hearing impairment. As a result of new-born hearing screening, the attitude towards cochlear implantation in children has improved in recent years. Consequently, the number of longitudinal multi-center studies has also increased with the aim of guiding future clinical practice and research efforts. Nonetheless, there is still a growing need for a widely used set of international quality standards on minimal outcome measurements (MOM) to determine outcomes in CI recipients. Predefined MOM would allow us to monitor the auditory progress of CI recipients over time. Moreover, the use of a predefined MOM test battery would allow for more international multi-center research studies and collaborations.

It is against this background that we are pleased to present a consensus about a MOM test battery that should be used for paediatric CI recipients worldwide.

We hope that our work is acceptable for publication in International Journal of Pediatric Otorhinolaryngology.

On behalf of all authors, we would like to thank you very much for the effort of reading this paper.

Prof. dr. Griet Mertens

MINIMAL OUTCOME MEASUREMENTS IN PAEDIATRIC COCHLEAR IMPLANT USERS: A CONSENSUS PAPER

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- **Keywords.** Sensorineural Hearing Loss, Paediatric Cochlear Implant Recipients, Cochlear Implantation, Minimal Outcomes Measurements, Testing Framework, Standardization.

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Therefore, the authors of this study aim to identify a MOM test battery for paediatric CI recipients that can facilitate international multi-center research and collaboration.

Methods. A paediatric MOM test battery was developed and agreed-upon by members of the HEARRING group across 30 expert clinics in the field of hearing implantation. This group consisted of surgeons, audiologists, speech and language therapists, and other skilled professionals. The MOM test battery was chosen based on a literature search that focused on outcome measurements applied in clinical trials involving children with a hearing implant. Members of the HEARRING group were then asked to evaluate each of the paediatric MOM tests used. To reach a final consensus, the suggestions and comments were discussed during the HEARRING meeting in Perth, Australia, in November 2017.

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Conclusion. This study presents a consensus on a MOM test battery for paediatric CI recipients that was agreed-upon by members of the HEARRING group. This test battery should allow for international multi-center research to be able to extend and share evidence that will guide future clinical practice and research efforts in paediatric CI populations.

Keywords. Sensorineural Hearing Loss, Paediatric Cochlear Implant Recipients, Cochlear Implantation, Minimal Outcomes Measurements, Testing Framework, Standardization.

Introduction

More than 50 years ago, cochlear implants (CI) were introduced as a treatment option for individuals with severe to profound hearing loss who did not benefit (or only had a minimal benefit) from using hearing aids. Thanks to extensive research, cochlear implantation is now recognized as a safe and effective gold standard treatment for both adults and children with a severe sensorineural hearing impairment. Progressive longitudinal research continues to examine the outcomes of CI recipients with the aim of guiding future clinical practice and research efforts.

Nonetheless, there is still a growing need for a widely used set of international quality standards on minimal outcome measurements (MOM) to determine outcomes in CI recipients [1]. Predefined MOM would allow us to monitor the auditory progress of CI recipients over time and to be able to relate on important issues as the most ideal age for implantation and the cut-off audiological thresholds for CI indication. Moreover, the use of a predefined MOM test battery would allow for more international multi-center research studies and collaborations.

Variations in MOM exist between different clinics and are mainly attributable to legal, reimbursement or language differences between countries. However, many aspects of CI management can be standardized worldwide, thus improving international collaborations. Kleine Punte et al. were the first group to report a MOM test battery that mainly focused on adult CI recipients [2]. The authors suggested that a MOM test battery should address a number of criteria: (a) the outcome measurements should answer the scientific criteria of simplicity, reliability, validity, and sensitivity; (b) the measurements should address dimensions that are important to clinicians and the CI recipient (symptoms, disability, and user perspective); (c) the measurements should be sensitive to meaningful changes in hearing abilities, such that they reflect the outcome of treatment or intervention; and (d) the measurements should address one of the World Health Organization (WHO) outcome domains of impairment, activities, participation, or quality of life.

As a result of new-born hearing screening, the landscape of cochlear implantation in children has shifted dramatically [3]. Consequently, the number of longitudinal multi-center studies has also increased. Since hearing abilities and the age of paediatric CI recipients are crucial for choosing a MOM test battery, there exists a clinical need to develop a homogeneous MOM test battery for this population. Therefore, the HEARRING group set out to develop and agree upon a MOM test battery that could be used for paediatric CI recipients worldwide.

Methods

HEARRING group

The paediatric MOM was developed, discussed, and eventually agreed-upon by members of the HEARRING group. The HEARRING group consists of members from across 30 expert clinics that aim to identify evidenced-based standards that can provide each potential implant recipient, regardless of age or where in the world he/she is treated, with the best possible hearing implant solution for the individual hearing loss. The multidisciplinary network includes surgeons, audiologists, speech and language therapists, and other skilled professionals, who collaborate as part of the HEARRING group.

Data Collection

A PubMed US National Library of Medicine (http://www.ncbi.nlm.nih.gov/pubmed/) database search was performed to collect a list of MOM that were reported in the literature. The search focused on MOM that were applied in clinical trials that included children with hearing implants. Experts in the field of hearing implants were also asked to provide information on additional MOM that are currently used. To reach a final list of MOM, the data collected were discussed during the HEARRING meeting in Perth, Australia in November 2017.

Results

Paediatric MOM test battery

The final pediatric MOM test battery, as chosen by the HEARRING group, is shown in **table 1**. The final MOM test battery was divided into four chronological age categories; (i) six weeks – six months; (ii) six months – two years; (iii) two years – six years; and (iv) older than six years. The test intervals included assessments prior to implantation; three, six and twelve months after CI activation; and yearly thereafter. The calibration of the validated test instruments should be checked routinely by appropriate experts to ensure that the equipment will produce results which meet or exceed defined criteria with a specified degree of confidence. For all measurements, the used material and test condition (i.e. best aided condition, CIright ear only, etc.) should be registered.

Although many more valuable outcome measures were considered for inclusion, the chosen set was kept as minimal as possible to guarantee to fit in most clinical settings. Suggestions of useful additional measurements are listed in a later section (**section 8**). Interested centers should add additional outcomes to meet their specific requirements.

Case example

To provide a realistic overview of the paediatric MOM test battery, a fictitious case example will be described. This case involved a bilaterally severely hearing impaired girl who received a CI in her right ear at the age of eight months old and in her left ear at the age of 16 months old. Her results on the MOM test battery were registered at each suggested time interval and are shown in **table 2**.

1. Background information

The HEARRING group agreed that background information should be made available about the variables known to affect post-implantation performances [4]. The child's gender and date of birth; implant information; if applicable, the presence of multiple disabilities or medical issues; mode of communication; linguistic environment (monolingual vs. bilingual); rehabilitation and school information; aetiology of hearing loss; onset of hearing loss in each ear; and the type of hearing device used are indispensable for monitoring the child's progress and allow for direct comparisons within multi-center research studies. Moreover, as shown in the case example in **table 2**, the inclusion of test dates is required to provide accurate information about the chronological age and the hearing age of 84 the child at each of the different test intervals.

2. Objective hearing assessment

Tympanometry

As part of the objective assessment, tympanometry (including measures of middle ear pressure, ear canal volume, and tympanic membrane mobility) should be performed prior to implantation in children across all age categories in order to identify any middle ear pathologies (e.g. otitis media).

Depending on the anatomy of the ear and the age of the child, a higher frequency probe tone should be used. A compliance peak within the normative values of the used equipment suggests a normal tympanic membrane mobility and middle ear pressure. Typically, the middle ear pressure is considered "normal" in the range of -155 to +30 daPa in children seven months of age and -165 to 45
daPa in in children 24 months of age [5]. A peak outside of these limits or the absence of a compliance peak may suggest one of several pathologies. In the case example, bilateral type A tympanograms measured prior to implantation indicated that there is no middle ear effusion or no Eustachian tube malfunction in both ears (**table 3**).

Transient Evoked Otoacoustic Emissions (TEOAEs)

Low-intensity sounds emitted by functioning outer hair cells of the cochlea are known as otoacoustic emissions (OAEs). These emissions are caused by the energy produced by the outer hair cells in response to a brief single click stimulus that covers a broad frequency range (such as transient evoked otoacoustic emissions, TEOAEs). A probe is inserted into the ear canal containing speakers that produce sounds and a microphone to measure the resulting TEOAEs. OAE testing requires no behavioral or interactive feedback by the individual being tested. The HEARRING group decided that TEOAEs should be administered prior to implantation in all age categories to characterize sensitivity and functional hearing and to differentiate between the sensory and neural components of hearing loss. For the case example presented in this study, the bilateral absence of TEOAEs in the presence of A type tympanogram prior to cochlear implantation is suggestive of cochlear (outer hair cell) dysfunction (**table 3**). Further investigation is required to support and confirm this finding.

Auditory Brainstem Response (ABR) Audiometry

Extensive literature searches support a strong correlation between estimated auditory brainstem (ABR) thresholds and behavioral pure-tone audiometry thresholds. As a result, ABR evaluation is widely accepted for the identification and diagnosis of hearing loss in the paediatric population [6]. Therefore, ABR is essential as a preoperative objective tool to quantify the degree of hearing loss in all age categories as shown in **table 3** [7]. Prior to implantation, no reproducible ABR responses could be found at hearing levels up to and including 90 dB nHL in the case example presented.

Evoked compound action potentials (eCAP) of the auditory nerve

It is recommended that the evoked compound action potentials of the auditory nerve (eCAP) are measured intraoperatively across all age categories (**table 3**). These measurements are frequently used to verify nerve function by stimulating one electrode contact in the cochlea and recording the resulting changes in voltage over time on another electrode contact. It is important to monitor the responses close to the round window and cochleostomy. eCAP elicited on electrodes close to the round window or cochleostomy is indicative of full insertion. The recorded eCAP measurements typically consist of a negative peak (N1) and a positive peak (P2). Although a review by Miller et al. reported that while the absolute values of the eCAP thresholds cannot be directly used for the prediction of the fitting parameters [8], the eCAP threshold profile can be used as a basis for creating fitting maps. eCAP thresholds can represent a level at which the stimulus should be audible but probably not uncomfortable. However, in addition to the eCAP profile, further fine-tuning adjustments during fitting are indispensable [9].

Electrical Impedance and Field Telemetry (IFT)

The conductivity for stimuli transmission between the surface of the electrode contact and the surrounding environment can be determined by electrical impedance measurements. Therefore, impedance telemetry of individual intracochlear electrodes can serve as an informative evaluation tool, which can provide information about efficient electrical stimulation, presence of air bubbles, extracochlear electrode positions, open or short circuits between electrodes. Since these measurements yield important information for eCAP, eABR measurements and audio processor programming, they should be administered to all age categories and at all test intervals. A normal IFT process was observed in the presented case example, i.e. a progressive increment of IFT values during the first week after implantation, followed by a decrease and stabilization of the IFT values (**table 3**). Since no abnormal values were observed, all channels remained activated during fitting.

3. Audiometry

Although (e)ABR is a more reliable method for defining hearing thresholds in new-borns and in infants up to six months of age, behavioral observation audiometry (BOA) must be added to investigate the minimal response levels in very young infants. Observing subtle unconditioned changes in behavior in response to free field sound stimuli can also be useful for parental education, particularly in terms of demonstrating the subtlety of infant hearing responses. With older children, between approximately six months to 2.5 years of age, visual reinforcement audiometry (VRA) can also be used to test their hearing thresholds. Conditioned responses to sound are recorded by reinforcing the natural tendency to turn towards a sound with a reward of an illuminated puppet or movie. From two to 2.5 years of age onwards, play audiometry can be used, whereby the child is asked to perform a simple task when they hear the sound. This may include putting a ball in a bucket or completing a puzzle. As with BOA and VRA, the volume and pitch of the sound are varied during play audiometry to determine the quietest sounds the child is able to hear. Depending on the child, ear specific information can be obtained during VRA and play audiometry.

Unaided audiometry

Due to the introduction of hearing and structure preservation into the field of cochlear implantation, the inclusion criteria for CI candidacy were expanded, resulting in greater numbers of adults and children receiving a CI. Today, individuals with some low-frequency hearing are also considered as suitable CI candidates. Therefore, it is important to evaluate, if the age and the cooperation of the child allows, the unaided residual hearing of individuals with partial deafness over time in order to offer the maximum benefits of electric acoustic stimulation [10]. The limitations of the standard supra- aural headphones to measure unaided residual hearing are well described in the literature and include: little exclusion of environmental background noise, the existence of cross-hearing with high- intensity stimuli presentation, the possibility of an ear canal collapse, and introduction of vibrotactile responses [11]. The risk of vibrotactile responses is significantly higher in CI candidates due to the high intensity levels that are required in the low frequencies. Therefore, the HEARRING group recommends
the use of insert earphones to test unaided hearing thresholds in all age categories in order to provide a solution to a number of these limitations.

Aided audiometry

Aided hearing thresholds should be measured through free field audiometry using warble tones. The loudspeaker should be placed at a distance of one meter, at head level, in front of the child. If the child wears a hearing system in both ears, then the free field thresholds should be measured with each hearing system separately, if possible, as shown in the example (**table 4**).

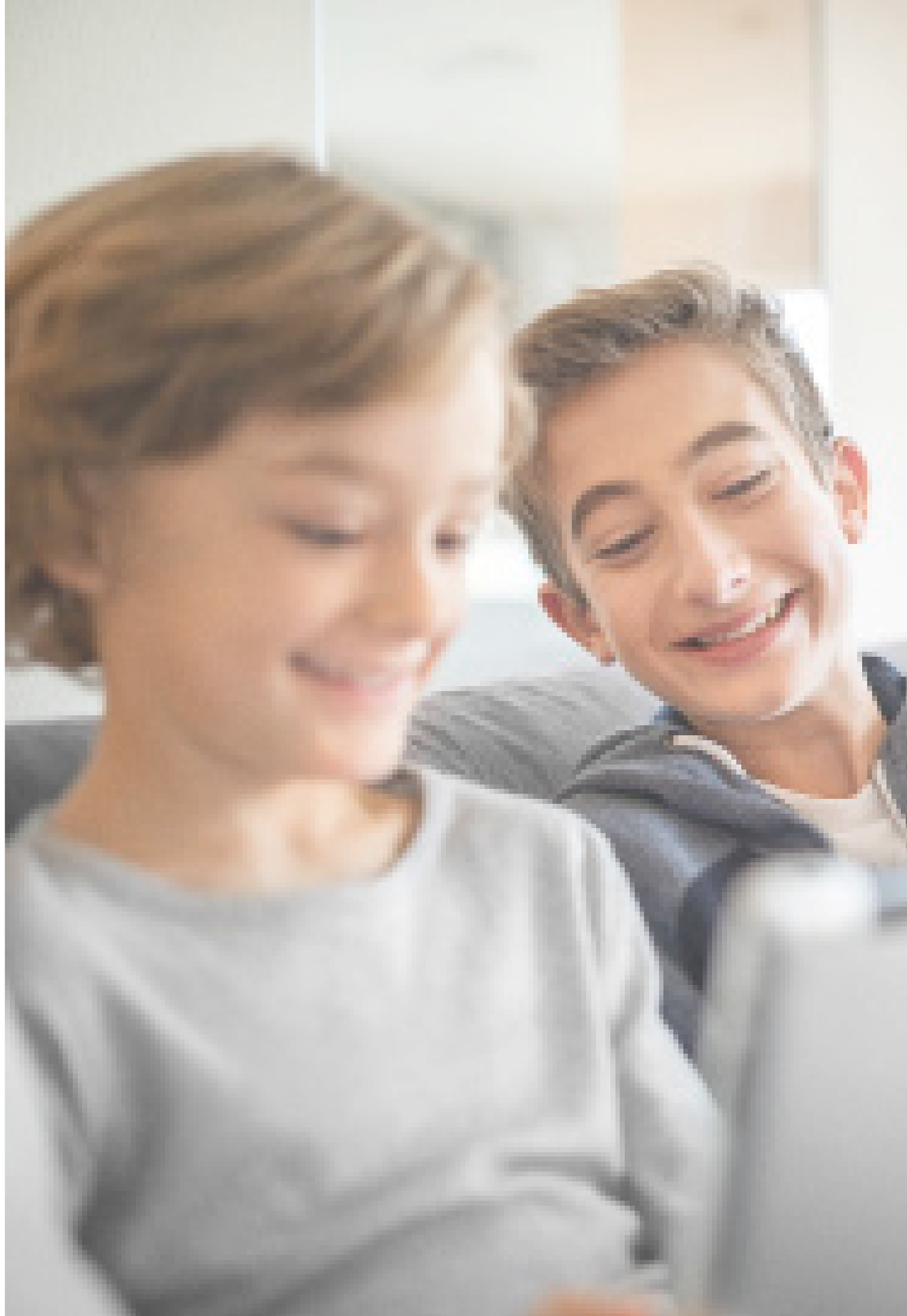
4. Speech perception

Speech audiometry is an indispensable component of the MOM test battery in children since it provides information about the understanding of speech at supra-threshold intensities **(table 4**). Moreover, it is can be used to measure the speech, language, reading, and cognitive abilities of children. The retrieved outcomes can be used to monitor the child's progress and can support the planning and implementation of auditory rehabilitation [12]. Consequently, speech perception skills must be assessed at all defined follow-up intervals using valid and reliable clinical assessment methods suitable for the paediatric CI population. The importance of speech perception testing was also discussed by Uhler et al. In 2017. They concluded that the adoption to a standardized protocol could facilitate continuity of care by constructing a Pediatric Minimum Speech Test Battery (PMSTB) [13].

In the case of bilateral hearing systems, one should start with the best aided condition, which provides the most realistic representation of the daily listening condition. Additionally, if possible, ear specific speech perception skills should also be assessed. Kosky and Boothroyd suggested that appropriate behavioral tests of speech perception performance in children should meet the following criteria: the cognitive, motoric, and attentional demands of the test should be age-appropriate; the task must be interesting and motivating; performance should be independent of vocabulary knowledge and higher- level language abilities; tests should not require phonological knowledge or speech production skills; and tests should ultimately assess a person's ability to communicate in everyday situations [14]. Moreover, age specific normative data should be available for the free field condition for the speech test that is used. Where possible, standardized recorded stimuli rather than live voice should be used. Live voice introduces significant variability and for paediatric patients may overinflate scores on speech tests [13].

Speech perception in quiet

Using age-appropriate closed-set tests, the speech perception of children between the age of two and six years should be determined at a fixed level of 65 dB SPL. Children aged six years and older should be tested with open sets at the same fixed level of 65 dB SPL, which is in accordance with the test level advised in the adult MOM test battery [2].



Speech perception in noise

Starting from the age of five years, speech perception in noise testing should be considered. Preference should be given to sentences in noise with the use of an adaptive procedure [2].

5. Subjective hearing assessment

LittlEARS

In the age categories ranging from six weeks to two years, auditory development and early speech production development of children with a hearing impairment should be assessed with the parent LittlEARS questionnaire [15]. The questionnaire contains 35 “yes/no” questions and documents the receptive, semantic, and expressive behaviors that normally constitute an infant or toddler’s reactions to auditory stimuli in the natural environment. In this way, the LittlEARS questionnaire should be used pre-operatively and at the post-operative test intervals to document general progress and the age appropriateness of the auditory behaviors exhibited (**table 5**).

Categories of Auditory Perception (CAP) Scale

The HEARRING group agreed that the categories of auditory perception scale (CAP) should be used to measure the speech perception performance of implanted children in all age categories during all test intervals **(table 5**). The CAP measures supraliminal performance, which reflects everyday auditory performance in a more realistic way. The CAP comprises a hierarchical scale of eight performance categories arranged in order of increasing difficulty, ranging from 0 “displays no awareness of environmental sounds” to 7 “can use the telephone with a familiar talker” [16].

Speech Intelligibility Ratings (SIR)

In addition to the CAP, the speech intelligibility rating (SIR) test should be administered at all intervals in all age categories to measure the speech intelligibility of the implanted child (**table 5**). By listening to a short passage of everyday speech, speech intelligibility can be quantified using a scale between 0 and 10. The SIR consists of five performance categories ranging from “pre-recognizable words in spoken language” to “connect speech is intelligible to all listeners” [17].

6. Language development

In 1991, language development was introduced as an outcome measurement for assessing CI intervention. In the following years, language development was also used for prelingually deafened CI recipients [18]. Since communication acquisition is a complex process that includes pragmatics, semantics, syntax, morphology and phonology, not all areas can be evaluated within a clinical set of MOM. Therefore, the HEARRING group agreed that expressive and receptive language should at least be covered in the paediatric MOM test battery and that these areas should be evaluated prior to implantation and yearly thereafter using age-appropriate assessment tools (**table 6**).

MacArthur-Bates Communicative Development Inventories (CDI)

The MacArthur-Bates Communicative Development Inventories (CDIs) can be used to assess language and communication skills between the age of six months and two years. These inventories consist of standardized parent-completed forms and a set of normative data and guidelines [19].

Reynell Developmental Language Scales (RDLS)

The Reynell Developmental Language Scales (RDLS) can be used to administer the comprehension and the production of language in children between the age of two and six years [20].

Clinical Evaluation of Language Fundamentals (CELF)

The Clinical Evaluation of Language Fundamentals (CELF) can be administered to evaluate the language abilities of school-age children (aged six years and older) over time. The CELF was designed to determine the severity of a language disorder, to identify relative strengths and weaknesses, to make recommendations regarding accommodations and interventions, and to measure the efficacy of intervention.

7. Mental and motor development

Although language development in paediatric CI recipients is the central feature of the empirical picture, mental and motor development should also be considered. There is considerable evidence that the paediatric population with a hearing impairment is vulnerable to mental and motor developmental delays. From birth onwards, auditory stimulation directs visual orientation behavior. The infant's earliest responses to auditory stimuli include the visual-motor behavior of moving the eyes or head to localize sound. Consequently, it has been suggested that the lack of early auditory input could contribute to motor delays in children who are deaf or hard of hearing [21]. The HEARRING group agreed that mental and motor development should be covered in the paediatric MOM test battery and that these should be evaluated prior to implantation and yearly thereafter using age-appropriate assessment tools.

Bayley Scales of Infant and Toddler Development

The Bayley scales are individually administered scales designed to measure the developmental functioning of infants and toddlers. Therefore, the HEARRING group recommends the use of the Bayley scales to identify possible developmental delays in the paediatric CI population between six and 24 months of age.

Snijders-Oomen nonverbal intelligence (SON) test

The Snijders-Oomen nonverbal intelligence (SON) test was developed to investigate the nonverbal intelligence of children with a hearing impairment [22]. General intelligence tests were not considered due to their reliance on verbal skills. The SON test, on the other hand, covers a wide area of intelligence with nonverbal subtests related to abstract and concrete reasoning, without being dependent on the use of verbal language. Mental age norms are available for children aged two years and older.

8. Other additional measurements

Since the consensus includes only a minimal set of outcome measures, one could argue that other outcome measures not included are as least as important to meet local specific requirements. It is self-evident that interested centers should add additional outcomes to meet their specific requirements. Auditory steady-state responses (ASSR) for example are often added to allow frequency-specific stimulation at intensities up to 120 dB HL (instead of 95 dB HL in case of ABR testing). By adding ASSR to the clinical test battery, the clinician is able to distinguish between severe and profound hearing loss and to investigate residual hearing, which contributes to appropriate selection and fitting of hearing aids before implantation [23]. Moreover, if the clinical setting allows/ requires, vestibular assessment can also be considered as an essential part of the pediatric CI test battery. Sensorineural hearing loss is associated with a vestibular dysfunction in a third of the CI candidates. Additionally, cochlear implantation might have a potential impact on motor development by a (transient) vestibular deficit. It is against this background that pre- and postoperative vestibular investigation should be considered whenever possible [24]. Another outcome measure of interest is the Quality of Life of hearing impaired children. The HEAR-QL for example, can serve as an excellent complement to the described MOM test battery to assess the hearing-impaired child's overall well- being [25].

Discussion

This paper describes a consensus on MOM test battery that can be used to evaluate the progress and outcomes of paediatric CI recipients. Application of a uniform test battery on MOM will also allow for international multi-center research studies to share evidence which will guide future clinical practice and research efforts in paediatric CI populations. This test battery should be used as part of the daily clinical practice since it only contains the minimal indispensable outcome measurements, which cover objective and subjective hearing assessments, (speech) audiometry, language, motor and mental development. Additional testing upon individual demand is outside the scope of aim of this paper.

This MOM test battery is based on measurements that were previously applied in clinical trials that involved children with hearing implants. The test battery was developed, discussed, and eventually agreed-upon by all members of the HEARRING group. Additionally, the criteria for assessing the quality of outcome evaluation tools in rehabilitation that were previously reported in the literature were also taken into account [26, 27]. The final paediatric MOM test battery was critically evaluated using the criteria described by Bagatto et al [26]. All of the tests included in the test battery cover the relevant domains that were intended to be measured (i.e. hearing thresholds, speech understanding, receptive and expressive language, etc.).

The HEARRING group recommends that the calibration of the used materials should be routinely checked by appropriate experts and that age appropriate normative data should be available for each of the tests used. Moreover, the tests should be able to capture the true breadth and detail of the differences that exist within the heterogeneous paediatric population with a hearing impairment. Measurement tools with existing floor and ceiling effects were avoided insofar as possible, with ceiling effects only reported with the SIR.

The MOM test battery did not show any evidence of bias when used with children with a hearing impairment. Additionally, the results obtained were not affected by differences in culture or social circumstances. The criterion ‘respondent burden’ was also met in the final MOM test battery with minimal patient or parental distress or burden associated with participation in the test battery. Since the test battery only contains the minimal indispensable measurements that are acceptable to both the respondent and the administrator -in terms of duration and content, it can therefore be implemented into clinical practice. Another advantage with the MOM test battery is that some of the tests can be delivered electronically or on paper and in different languages, such as the LittlEARS questionnaire.

We know from previous evidence that the included outcome measures are reliable. They have been shown to provide consistent results across time and testers, indicating good clinical value. Outcome measurements that were used in previous studies investigating two subgroups of the population (e.g. children with normal hearing vs. children with a hearing impairment) were chosen to be part of the MOM test battery. As such, the criterion for ‘Discriminant validity’ was also met.

In conclusion, the information presented within this study establishes a basic set of MOM that can be used for monitoring and standardizing clinical practice. Additionally, the MOM test battery can be used as a guideline for data collection and the establishment of a registry.

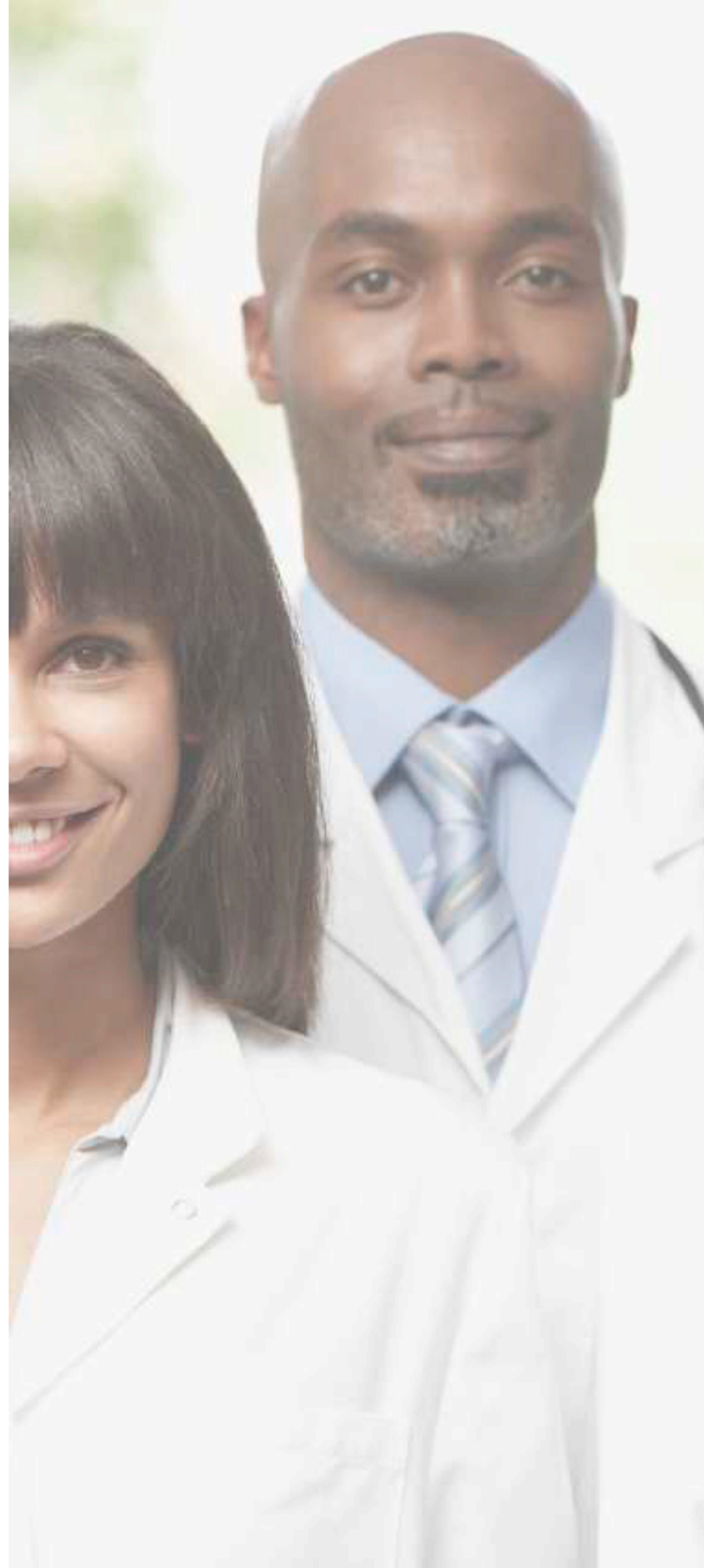


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Table 1 Overview Minimal Outcome Measurements (MOM) in paediatric cochlear implant users.

[a]Otoacoustic Emissions; [b]Auditory Brainstem Response Audiometry; [c]Electrically evoked Compound Action Potential; [d]Pure Tone Average; eCategories of Auditory Perception Scale; [f]Speech Intelligibility Ratings; [g]MacArthur-Bates Communicative Development Inventories; [h]Reynell Developmental Language Scales; [i]Clinical Evaluation of Language Fundamentals; [j]Snijders-Oomen nonverbal intelligence tests.

<table>
<tr><td>PAEDIATRIC MOM CI</td><td></td><td>6 weeks - 6 months</td><td>6 months - 2 years</td><td>2 years - 6 years</td><td>> 6 years</td></tr>
<tr><td rowspan="6">Objective measures</td><td colspan="5">Pre-operatively</td></tr>
<tr><td colspan="5">OAE[a] + Tympanometry + ABR[b]</td></tr>
<tr><td colspan="5">Per-operatively</td></tr>
<tr><td colspan="5">eCAP[c] + Electrical Impedance Telemetry</td></tr>
<tr><td colspan="5">Activation, 3M, 6M, yearly</td></tr>
<tr><td colspan="5">Electrical Impedance Telemetry</td></tr>
<tr><td rowspan="4">PTA[d]</td><td rowspan="2">Unaided</td><td colspan="5">Pre-operatively, 3M, 6M, yearly</td></tr>
<tr><td colspan="2">Inserts / free field 125 - 8000 Hz</td><td colspan="3">Inserts 125 - 8000 Hz</td></tr>
<tr><td rowspan="2">Aided</td><td colspan="5">Pre-operatively, 3M, 6M, yearly</td></tr>
<tr><td colspan="5">Warble tones
Right ear $_{aided}$ only
Left ear $_{aided}$ only
125 - 8000 Hz</td></tr>
<tr><td colspan="2">Speech in quiet</td><td colspan="2"></td><td colspan="3">Pre-operatively, 3M, 6M, yearly</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td colspan="2">Closed set
Best aided*
Right ear $_{aided}$ only
Left ear $_{aided}$ only
65 dB SPL</td><td>Open set
Best aided*
Right ear $_{aided}$ only
Left ear $_{aided}$ only
65 dB SPL</td></tr>
<tr><td colspan="2">Speech in noise</td><td colspan="2"></td><td colspan="3">Pre-operatively, 3M, 6M, yearly</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td></td><td>5-6YR
Open set
Best aided*
Right ear $_{aided}$ only
Left ear $_{aided}$ only</td><td>Sentences
Adaptive procedure
Noise fixed at 65 dB
Best aided*
Right ear $_{aided}$ only
Left ear $_{aided}$ only</td></tr>
<tr><td colspan="2">Subjective assessment</td><td colspan="5">Pre-operatively, 3M, 6M, yearly</td></tr>
<tr><td colspan="2"></td><td colspan="2">LittleEARS
CAP[e]
SIR[f]</td><td colspan="3">CAP[e]
SIR[f]</td></tr>
<tr><td colspan="2">Language development</td><td></td><td>12M, yearly</td><td colspan="3">Pre-operatively, 12M, yearly</td></tr>
<tr><td colspan="2"></td><td></td><td>CDI[g]</td><td colspan="2">Language test
Expressive + receptive
(RDLS)[h]</td><td>Language test
Expressive + receptive (CELF)[i]</td></tr>
<tr><td colspan="2">Mental & motor development</td><td></td><td colspan="4">Pre-operatively, 12M, yearly</td></tr>
<tr><td colspan="2"></td><td></td><td>Bayley</td><td colspan="2">SON[j]</td><td></td></tr>
</table>

* In case of bilateral hearing systems, one should start with the best aided condition. Additionally, if the state of the child allows, ear specific speech perception skills should be assessed.

Table 2

Table 2. Minimal background information for the interpretation of the Minimal Outcome Measurements for the case example. HL: Hearing loss; C.A.: Chronological age in the YY;MM,DD format.

MINIMAL BACKGROUND INFORMATION				
Gender	Female	Intervals	Right Ear	Left Ear
Date of birth	05/06/2011	Pre-operatively	29/02/2012 C.A. 00;08,24	02/10/2012 C.A. 01;03,27
Aetiology HL	Bilateral: Cytomegalovirus	Implant	Synchrony pin FLEX[28]	Synchrony pin FLEX[28]
Onset HL	Bilateral: Congenital			
Rehab. onset	16/04/2012 C.A. 00;10,11	Implantation	01/03/2012 C.A. 00;08,26	03/10/2012 C.A. 01;03,28
Rehab. end	27/06/2014 C.A. 03;00,22	Activation	15/03/2012 C.A. 00;09,10	20/10/2012 C.A. 01;04,15
Rehab type	Aural rehabilitation	3M post-activation	14/06/2012 C.A. 01;00,09	20/01/2013 C.A. 01;07,15
Education onset	01/09/2014 C.A. 03; 02,26	6M post-activation	02/10/2012 C.A. 01;03,27	12/04/2013 C.A. 01;10,07
Education type	Mainstraem school	1YR post-activation	12/04/2013 C.A. 01;10,07	12/10/2013 C.A. 02;04,07
Communication	Oral	2YR post-activation	15/04/2014 C.A. 02;10,10	30/10/2014 C.A. 03;04,25
Linguistic environment	Monolingual	3YR post-activation	02/04/2015 C.A. 03;09,27	14/10/2015 C.A. 04;04,09
Multiple disabilities	None	4YR post-activation	07/04/2016 C.A. 04;10,02	02/10/2016 C.A. 05;03,27
Medical issues	None	5YR post-activation	10/04/2017 C.A. 05;10,05	29/09/2017 C.A. 06;03,24

Table 3.

Table 3. Results of the objective hearing assessments of the Minimal Outcome Measurements at each suggested interval for the case example. OAE: Oto-acoustic emmisions; M: number of months post- activation; YR: number of years post-activation; ABR: Auditory brainstem response; eCAP: evoked compound action potentials of the auditory nerve; THL: Threshold level; qu: Current unit; IFT: Impedance and field telemetry.

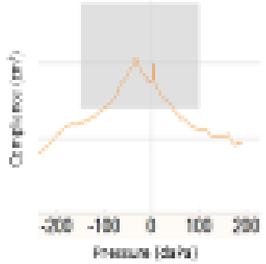
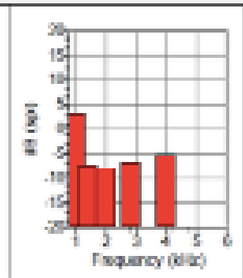
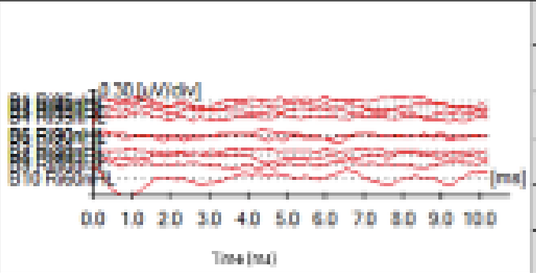
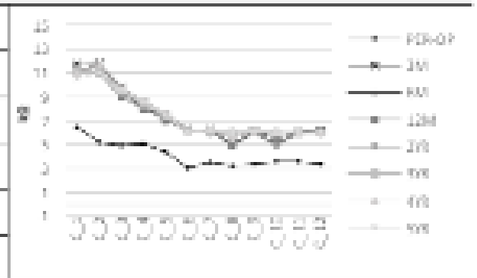
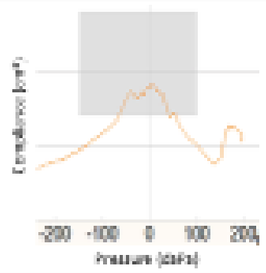
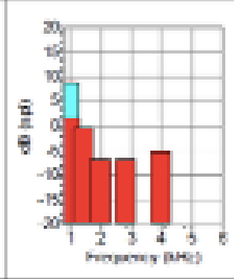
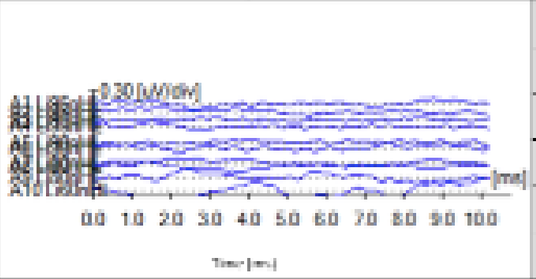
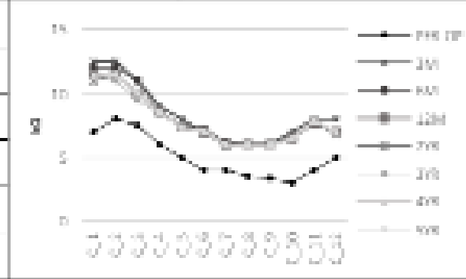
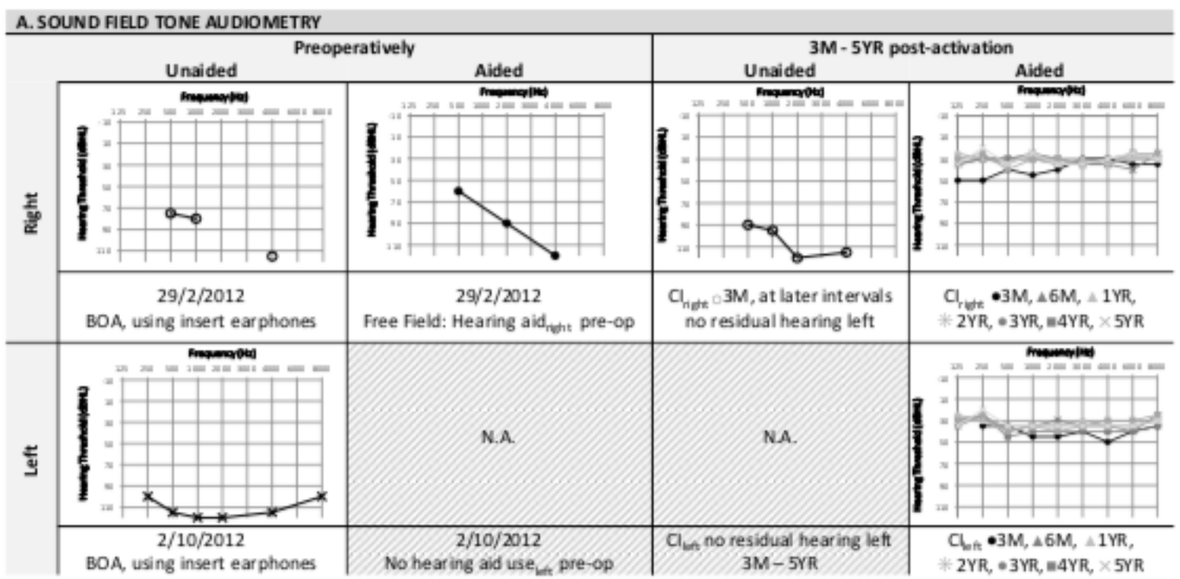
OBJECTIVE HEARING ASSESSMENT								
Pre-operatively				Per-operatively				Per-operatively, 3M - 5YR
Tympanometry	OAE	ABR		eCAP THL				IFT
				e1	17.37 qu	e7	15.14 qu	
				e2	15.03 qu	e8	18.17 qu	
				e3	14.29 qu	e9	22.71 qu	
				e4	12.51 qu	e10	18.98 qu	
				e5	12.24 qu	e11	14.63 qu	
				e6	12.31 qu	e12	17.31 qu	
29/02/2012 Type A curve	29/02/2012 Absent OAEs	29/02/2012 No ABR resp. ≤ 90 dBnHL		01/03/2012 eCAP threshold profile				Reference perop IFT profile Stable IFT profile 3M – 5YR
				e1	22.49 qu	e7	19.37 qu	
				e2	17.50 qu	e8	14.60 qu	
				e3	14.46 qu	e9	15.63 qu	
				e4	12.86 qu	e10	12.78 qu	
				e5	20.94 qu	e11	09.04 qu	
				e6	10.61 qu	e12	11.61 qu	
02/10/2012 Type A curve	02/10/2012 Absent OAEs	02/10/2012 No ABR resp. ≤ 90 dBnHL		03/10/2012 eCAP threshold profile				Reference perop IFT profile Stable IFT profile 3M – 5YR

Table 4. Audiometric results of the Minimal Outcome Measurements at each suggested interval for the real case example. A. Aided and unaided sound field tone audiometry. B. Speech perception in quiet. C. Speech perception in noise. BOA: behavioral observation audiometry; CI: Cochlear Implant).



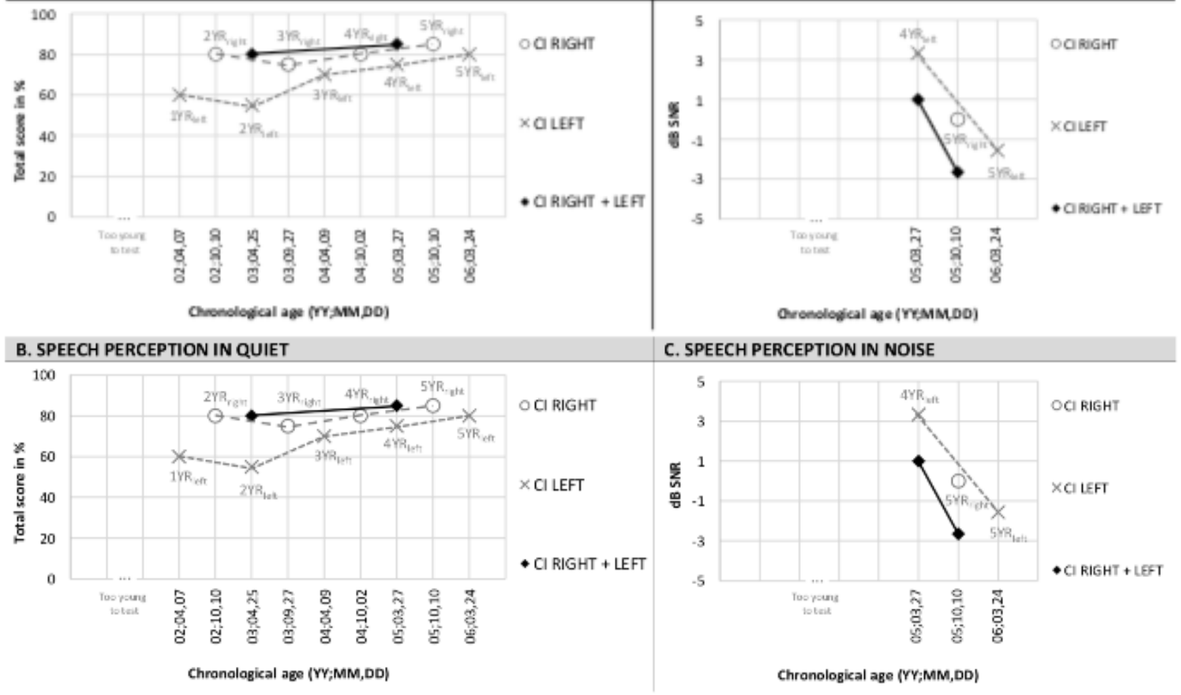


Table 5

Table 5. Results of the subjective hearing assessments of the MOM test battery at each suggested interval for the case example. M: months post-activation; YR: years post-activation; CI: Cochlear Implant; CAP: Categories of Auditory Perception scale; SIR: Speech Intelligibility Ratings.

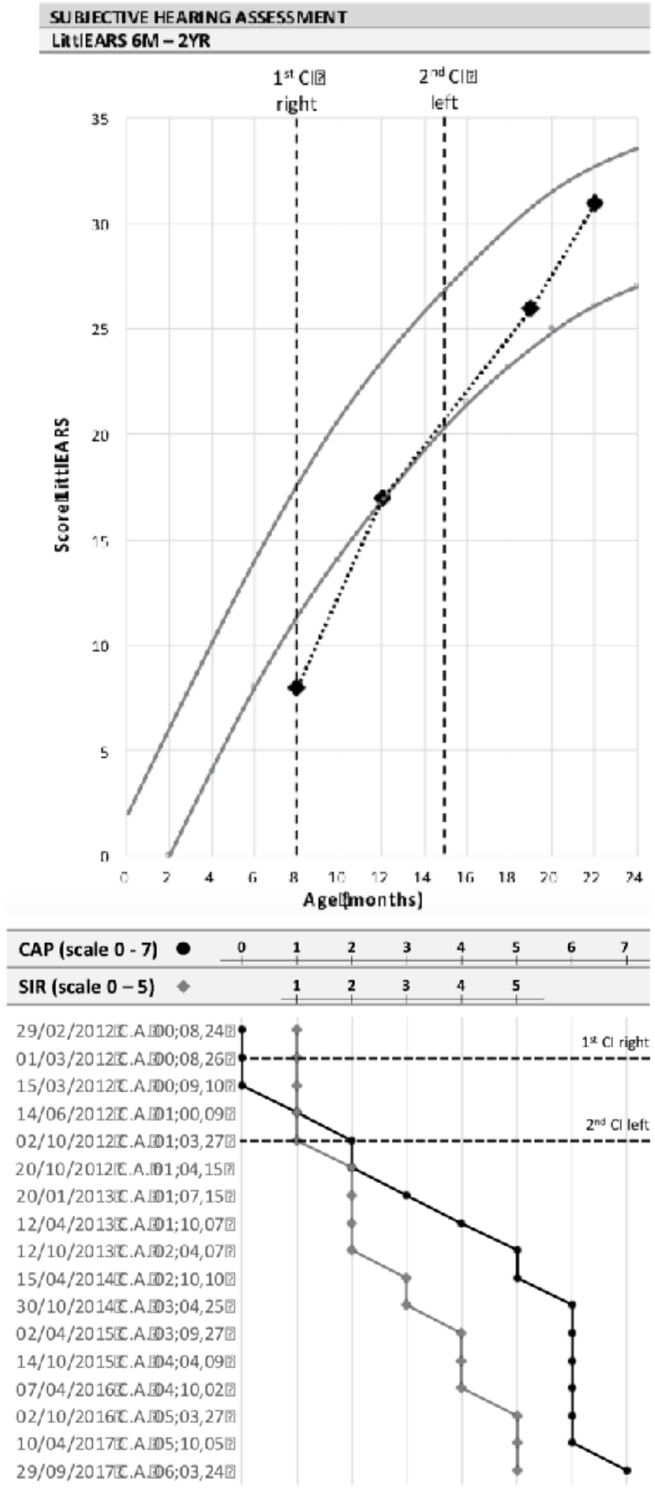


Table 6

Table 6. Results of the assessment of the language development of the case example as a part of the Minimal Outcome Measurements at yearly follow-up intervals. CDI: MacArthur-Bates Communicative Development Inventories (age 6M – 2YR); RDLS: Reynell Developmental Language Scales (age 2YR – 6YR).