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ORIGINAL ARTICLE

The Use of ESRT in Fitting Children with Cochlear Implants

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Objective; Fitting of the cochlear implant speech processor on young children is often a challenge for the clinician. One way to obtain a reliable programme is to use an objective fitting method such as eSRT. This paper aims to demonstrate validity and reliability of using eSRT as a fitting tool, and to show outcomes through a series of small studies.

Materials & Methods; A number of groups of children participated in a series of small eSRT studies assessing correlation to behavioural programmes, test-retest reliability, incidence, stability and measurement in the awake and sleep state. Sound field measurements and speech perception tests were conducted.

Results; There is a significant correlation to behavioural programmes, good test-retest reliability, high incidence, higher eSRTs measured under sedation and stable programmes over time. Sound field scores range from 37 to 33dB across the audiogram, mean closed-set monosyllable scores were 81% and GASP scores were 7.6/10.

Conclusion; A series of small studies demonstrate the viability of using eSRT to programme a cochlear implant in small children.

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The advent of newborn hearing screening and early intervention programmes has meant that younger children are presenting as candidates to cochlear implant centres. A number of issues arise when considering very young children for implantation. These may include surgical issues, confidence in audiological diagnosis and appropriate fitting of the device.

One means of ensuring appropriate device fitting is to use objective measures. It is extremely important to have an appropriate speech processor programme. Consistent use of the speech processor and thus access to speech sounds is dependent on the appropriateness of speech processor programme. The programme is generated by establishing the maximum comfort level (MCL) and threshold level on each active electrode. Unfortunately, young children with little or no previous auditory experience or language are unable to give adequate feedback to the clinician during the fitting process. The clinician has to make decisions based on observation of the child's reactions to various stimuli. Subjective fitting procedures can be very tedious and may be stressful and uncomfortable for the child and his family. Fitting the child in such a way could thus result in an inappropriately programmed speech processor. A delay in generating an appropriate programme may contribute to slower speech and language development because innacurate measurement of MCL impacts directly on a child's acoustic perception. This, in turn, can have an impact on speech perception and may result in a delay in speech and langugae development. It is therefore vital that objective ways to programme speech processors are found and tested.[1] One means of objective measurement is the stapedius reflex.

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The literature shows that stapedius reflexes can be elicited electrically. A contraction of the stapedius muscle can be elicited by an adequately intense electrical stimulus. Contraction of this muscle leads to stiffening of the ossicular chain and reduced compliance of middle ear system. This change in compliance can be measured easily with immittance testing equipment. The electrically elicited stapedius reflex has a threshold and demonstrates amplitude growth till saturation. These responses can be recorded ipsi or contralaterally.[2]

A high correlation between electrically elicited stapedius reflex thresholds (eSRTs) and comfort levels set through subjective judgements has been reported in the literature. As early as 1988, it was found eSRT levels corresponded closely to preferred listening levels in seven experienced Nucleus cochlear implant users.[3] Recent research supports a high correlation between eSRT and behavioural MCL (r=0.9).[4-8]

Many clinics, from first fit onwards, attempt to generate programmes from eSRTs[9]. These eSRTs may be measured on all or some of the electrodes. It may be useful to measure on all active electrodes, in case the required charge varies from one electrode to another, however, other centres (e.g. International Centre of Hearing and Speech, Warsaw, Poland) measure six alternate electrodes and then interpolate.

An issue with measuring eSRTs in young children is that they are required to remain still during the eSRT measurements. eSRT measurements can be measured during natural sleep. In rare cases where a child is totally uncooperative and when no auropalpebral reflex is obtainable and if the middle ear is normal, then eSRTs may be attempted using non-prescription sleep medication. Sedation may be required under medical supervision in rare cases where a child does not sleep. Reflexes measured under sedation maybe found at supra-threshold levels, depending on the anaesthetic agent used. It was suggested that an increase in reflex thresholds may be due to anaesthetic agents[10]. Programmes made under sedation should be applied with caution, with lowered volumes. The authors have found that a starter volume of 65% is not too loud for the user. Even if eSRTs are found at supra-threshold levels, the clinician can benefit from seeing the profile of required charge across the whole electrode array.

One main cause for concern among some clinicians about using eSRT generated programmes is that the generated programme may be above the child's comfortable loudness level, or that the child may be overstimulated. eSRT is reported to occur below behaviourally perceived levels of uncomfortable loudness[3]. Similar results were reported by others using the the Vienna device[11-13]. Meanwhile, other researchers reported that CI users prefer programmes where eSRT levels are used as MCLs at least as much or better than programmes where MCLs have been set behaviourally[4,5]. Clinicians using eSRT routinely, report that eSRTs are found before the user feels any discomfort.

The aim of this paper is to demonstrate the viability of using eSRT as a reliable, effective and objective measure for programming a cochlear implant speech processor through a series of small studies managed by the first author and conducted on a number of different children over a number of years. The contributions of experienced clinicians in the field of clinically relevant research is considered valuable, particularly considering the wide range of experience using eSRT as a routine technique on a large number of children.

Method used to record eSRTs

Reflexes were recorded using the same procedure for each study. Reflex measures were recorded using a standard immittance meter. eSRTs were measured either in an awake state or during natural sleep. If testing occurred during the awake state, children were passively entertained to ensure they remained still during testing. After an otoscopic examination, tympanometry was performed on both ears to determine middle ear pressure. Reflex measures were only attempted when the middle ear pressure was within normal limits (-150 to + 50daPa). The tympanometer probe was placed in the ear with the closest to normal middle ear pressure either contralaterally to the implanted ear or in the implanted ear. Reflexes were elicited through the MED-EL fitting software using a tone-burst of 500ms with a gap between bursts of 1000ms[14]. Initially the pulse duration on each electrode was set to the default, then current levels were increased until a reflex was recorded or until saturation was reached indicated by a white bar across each channel in the fitting software. Charge was further increased by widening the pulse duration until a reflex was recorded. At all times, the child was closely observed for any signs of discomfort. The search for a reflex was abandoned if the child showed any signs of discomfort. The criteria for determining the presence of a reflex was a definite, repeatable deflection of at least 0.5ml. If no reflex is obtained before reaching uncomfortable loudness level on three, different non-adjacent electrodes (not including the most basal electrodes, as these may be extra-cochlear), testing was terminated. Reflexes were measured on all active electrodes (starting at the most apical electrode), as charge may vary from one electrode to another. After finding eSRTs on each active electrode, this level was used to stimulate across electrodes to balance MCLs by ensuring reflexes were of a similar size.

An objective programme was generated by setting MCL levels at eSRT levels without any adaptation and by setting threshold levels at 10% of MCL level. Electrodes where an eSRT is not elicitable are deactivated. The clinician may choose to deactivate electrode/s where the eSRT is only elicitable at a much higher charge level as compared with adjacent electrodes. Electrodes requiring high charge ie. wide pulse durations to elicit a stapedius reflex may be deactivated to keep up the rate of processing. The average measurement time is 10 minutes.

Part One-Methods ande Results: Validity of eSRT as a fitting method

1) Correlation between eSRT and behaviourally determined MCL programmes

Method: eSRT recordings were compared to behaviourally determined MCL levels in 40 paediatric implant users, who had a minimum of six months device experience using behavioural programmes. The average age of subjects was 7 years 3 months (range: 3 years 4 months to 16 years 3 months). Fifteen of the older children were able to give reliable feedback about loudness. MCLs were set at the level chosen by the child. Various techniques were used, e.g. pointing to various size objects, indictaing the various levels of loudness by rasing their hand to a certain height. An attempt was made to balance loudness between the electodes. For the 25 children not able to co-operate at this level, MCLs were set by observing auropalpebral reflexes (MCL were set at 2-4 steps below this level) or adverse reactions to loud sounds. Threshold was set at four steps below the last sound heard using play audiometry techniques. .The correlation between eSRT and behaviourally determined MCL programmes was evaluated by using Spearman's rank correlation. A correlation coefficient of greater than 0.7 indicates a high to very high correlation between the two variables[15].

Results: Averaging data for all electrodes (n=420) a correlation of 0.82 was found between eSRT and behavioural MCL. Figure 1 shows individual correlations for each electrode. All correlations were statistically significant ($p<0.001$).

2) Test-retest reliability of eSRT

Method: Twenty of the group of forty children mentioned in study 1 were available for re-recording of eSRT levels either on the same day or within one week of the initial eSRT recording. The same eSRT recording procedure mentioned above was used. All of these children were tested in an awake state. This second recording was conducted by another audiologist using a different immittance audiometer. This tester was blinded to the child's programme, as well as to the outcomes of the previous reflex testing. The second tester agreed with the initial tester on active electrode selection in all cases. eSRTs were re-recorded. Test-retest reliability of eSRT was estimated

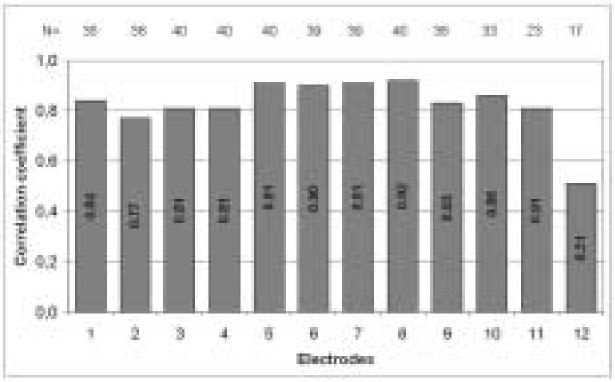

Figure 1. Correlations between eSRT determined programmes and behaviourally determined fitting programmes for each electrode are shown. A correlation coefficient of greater than 0.7 indicates a high to very high correlation between the two variables (Altman, 1991).[15]

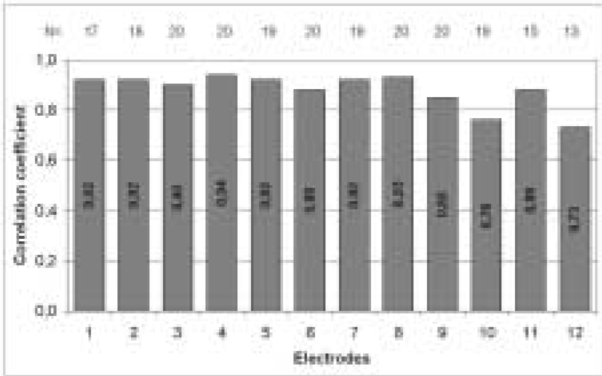

Figure 2. Test-retest reliability of eSRT: correlation between initial eSRT recordings and re-recordings of eSRT to demonstrate repeatability of the measure for each electrode. A score of greater than 0.75 is graded as excellent reliability (Fleiss, 1986).[16]

by calculating the intraclass correlation coefficient. A score of greater than 0.75 is graded as excellent reliability[16].

Results: An average correlation of 0.88 for 220 electrodes was found between initial eSRTs and re-recorded values. Figure 2 shows individual correlations for each electrode. All correlations were statistically significant (p>0.001). The correlation result for electrode 12 is slightly lower as there are fewer numbers in the sample - probably because the 12th electrode often lies within the cochleostomy or extra-cochlear, and is often not activated.

3) Incidence of eSRTs

Method: The incidence study was conducted in four Turkish clinics. Fitting data for 254 children of varying ages and with varying lengths of device use was analysed in May 2005. All of the children had used their device for at least 3 months and had had at least 3 fitting sessions Children consistently using programmes generated from eSRT measures were identified from this sample group. This demographic data was analysed using descriptive statistics.

Results: Fitting data showed that 211 of 254 children had consistently measureable reflexes. This results in an incidence of 83%. This incidence is calculated from children fitted over time, and not from once-off fitting sessions. This means that in some instances children normally fit using eSRT technique may at one point have had a middle ear problem preventing eSRT testing which was later resolved. 43 of 254 children did not have measurable eSRT's at all. This comprises 17 % of the children whose fitting data was analysed. Ten children with no recordable eSRTs had chronic middle ear problems. The remaining children had normal tympanograms on at least 1 ear. Out of these children, 7 had had meningitis, 7 had cochlear malformation, 3 had facial nerve stimulation and one child could not tolerate louder sounds. For 15 of the children with no recordable eSRT's, there is no obvious cause.

One of the children with meningitis, one with a cochlear malformation, all the children with facial nerve stimulation and the child with intolerance to loud sounds had sound field implant thresholds with at least 1 frequency worse than 50 dBHL. The other children with non recordable eSRT's had sound field implant thresholds within the range of 25 -50 dBHL.

4) Measuring eSRT in the awake state compared to under sedation

In cases where a child has normal middle ear functioning but will not participate in reflex testing, and the child cannot participate in traditional behavioural measurement (i.e. no demonstration of eye-blink or obvious signs of discomfort), it may be advisable to measure eSRTs under medically supervised sedation.

Method: Three children (aged 1.7, 1.7 and 1.8 years) were assessed under sedation and then were remeasured within a week in the awake state. Differences in eSRT measurements between the two conditions (sedation and awake state) were analysed by using nonparametric Wilcoxon-signed rank tests.

Results: Results of 3 children assessed under sedation and then in the awake state are shown in Figure 3. There are significant differences in eSRT measurements between the conditions (sedation and awake state) in subject 1 and 2. On average, both have higher values under sedation than in the awake state (Subject 1: p=0.007; Subject 2: p=0.002). Subject 3 has slightly higher values in the awake state than under sedation. This difference is not statistically significant. Thus the clinician needs to show caution when generating a programme from eSRTs measured under sedation in terms of setting the volume.

5) Stability of eSRT over time

Method: eSRT thresholds were compared for five children (average age 4.5 years, range 4-5 years) over three fitting intervals to investigate change in MCL level within the initial fitting period of six months (Figure 4) The fitting intervals were first fitting, two to three months later and five to six months later. eSRT thresholds for ten children with one year's device experience were comapred to their eSRT thresholds at an interval of nine to fifteen months later (Figure 5). Stability of eSRT over time was assessed with the non-parametric Friedman-Test for each electrode. To compare average changes before and after the nine to fifteen month interval for each electrode, nonparametric Wilcoxon-signed rank tests were used.

Results: Results showing a steady increase in MCL in the initial period are shown in Figure 4. This increase is statistically significant for electrodes 1, 2, 3, 4, 5, 6, 8, 9, 11 and 12 (p<0.05).

Results showing stability of MCL over time are shown in Figure 5. There are no significant differences in average charges between these two fitting intervals for each electrode.

Part Two: Methods and Results: Performance of children using eSRT generated programmes

1) Sound field measurements

Method: Sound field measurements in 53 children (average age: 6 years 4 months, range: 4-12 years) from five clinics in Turkey, whose programmes were generated using eSRT and had six months device experience were measured. Measurements were made in sound proof rooms using play audiometry and warble tones. The following frequencies were assessed: 250 Hz, 500 Hz, 1.000 Hz, 2.000 Hz, 4.000 Hz and 6.000 Hz.

Results: The average sound field thresholds in dBHL were 37 dB at 250 Hz, 37 dB at 500 Hz, 33 dB at 1.000 Hz, 34 dB at 2.000 Hz, 35 dB at 4.000 Hz and 33 dB at 6.000 Hz. Individual implant sound field thresholds are shown in Figure 6. There is little variation between children's audiograms, showing that all children had threshold levels allowing them access to all speech sounds.

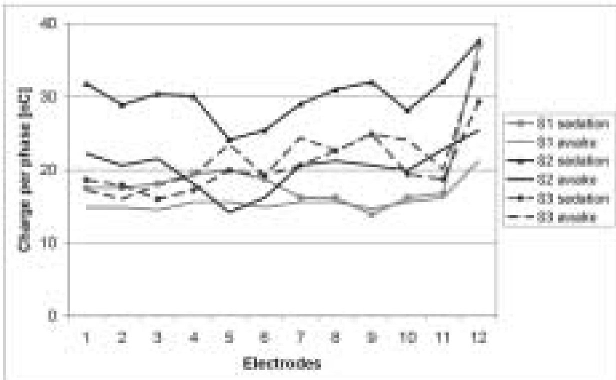

Figure 3. eSRT measurements in the awake state are compared to under sedation. Three children were assessed for each electrode.

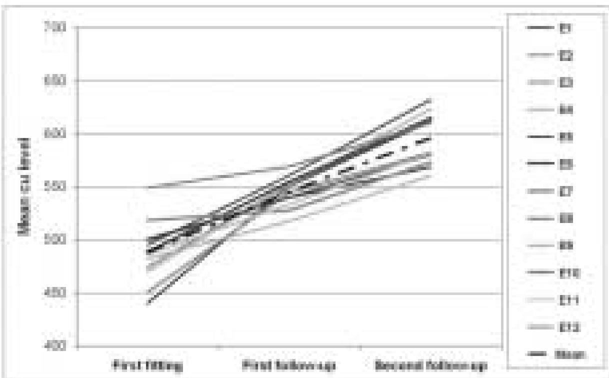

Figure 4. Change in eSRT levels over time from first fitting up to six months after first fitting. Data of 5 subjects are shown for each electrode.

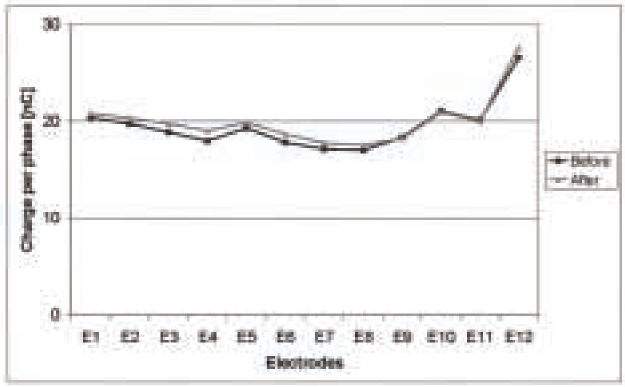

Figure 5. Stability of eSRT over time: Average charges before and after the nine to fifteen months interval are compared. Data of 10 subjects are included in this analysis.

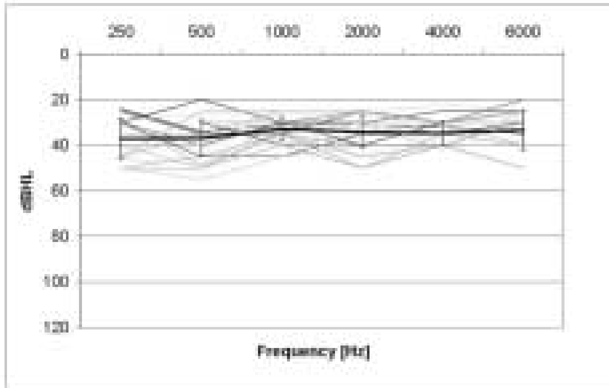

Figure 6. Mean and individual implant sound field thresholds of 53 children are shown. The thin lines show individual results. The fat black line connects mean sound field thresholds at different frequencies and the error bars represent the corresponding standard deviations.

2) Performance in children using speech perception tests

Method: Thirty-nine pre-lingually hearing-impaired children using a MED-EL cochlear implant were assessed on speech perception measures to determine benefit with eSRT generated fitting programmes. All of these children have only ever used eSRT generated programmes. Not all children participated in each speech perception measure due to age and availability for testing. The children had a minimum of 1 year device experience at time of testing. The children were assessed on a closed-set monosyllabic word test, a minimal sound difference test and the GASP sentences[17]. The monosyllables were presented in three sets of ten very similarly sounding words. Each word was presented twice. Thirty-nine children participated in this test with an average age of 7.4 years (range: 3 to 13 years). The minimal sound difference test is comprised of 20 sets of three words that differ by one phoneme (following the principle of a minimal pairs test). From each set, a child was required to recognise a word five times, for a total of 100 words for the entire test. Twenty-six children were able to participate in this test. Their average age was 7.7 years (range: 3-12 years). The GASP test comprises ten open-set questions. The child was required to answer each question fully or repeat each sentence word for word. Twenty-three children were able to perform this test, with an average age of 8.2 (range: 6-12 years) participated in the test.

Results: The average closed-set monosyllable score was 81%. Results of children who had device experience for 1, 2, 3, 4 and 5 years are shown in Figure 7. Of interest was the similarity in scores between each of these groups of children. The average scores for the minimal sound differences test was 83%. Results for children with 2, 3, 4 and 5 years of cochlear implant experience are shown in Figure 8. Again, results are similar for each experience group and between children. Twenty three children achieved an average of 7.6 (out of a possible score of 10) on the GASP sentence test. Figure 9 shows a wide variation in individual performance on the GASP test regardless of length of device use.

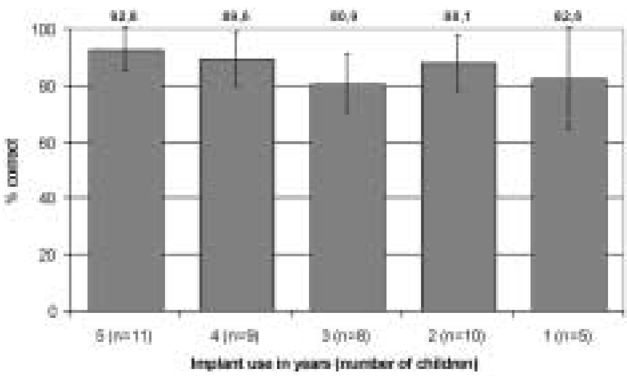

Figure 7. Performance of children using speech perception tests. Mean closed-set monosyllable scores of children with device experience of one, two, three, four and five years are shown. The error bars represent standard deviations.

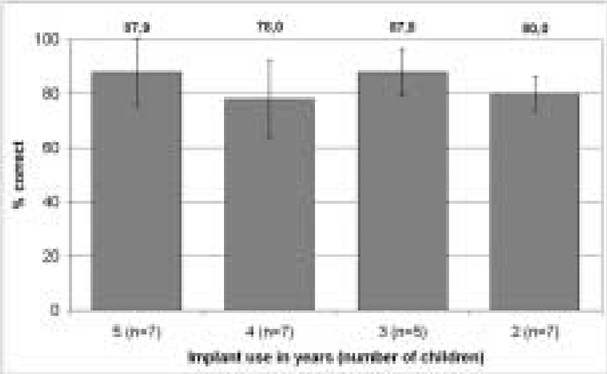

Figure 8. Performance of children using speech perception tests. Mean Minimal Sound Differences Test scores of children who had device experience for two, three, four and five years are shown. The error bars represent standard deviations.

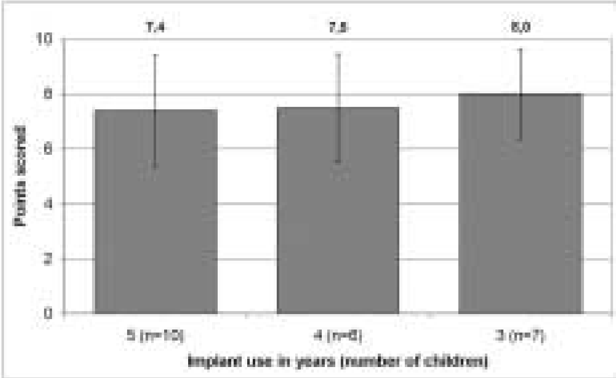

Figure 9. Performance of children using speech perception tests. Mean GASP Sentence Test scores of children who had device experience for three, four and five years are shown. The error bars represent standard deviations.

Discussion

Results from a series of small studies demonstrate that eSRT is a reliable, effective and objective measure for programming cochlear implant speech processors, particularly in small children who cannot provide reliable behavioural responses.

Validity of eSRT as a fitting method

Results demonstrate high correlation between eSRT and behaviourally measured speech processor programmes. eSRT recordings are attempted on all electrodes, but may not be obtainable on all electrode contacts and are therefore de-actived in the programme, hence the discrepancy in number of subjects per electrode in Figure 1. Results for electrode 12 are also more variable. This electrode contact is on the basal end and often lies within the cochleostomy or extra-cochlear. It is known to be variable for behaviourally measured MCLs as well. This is the reason why MCLs on apical electrodes (e.g. electrodes 11 and 12) should not be interpolated from eSRT recordings on other electrodes. Results shown are of all active electrodes. These correlations matched those reported on by others[18], where a correlation of 0.789 was reported in a series of experienced paediatric cochlear implant users. The average correlation value between MCL and eSRTs is only slightly below the reported value for adult study groups in the literature[5,8]. This may be due to the fact that twenty-five of the children showed limited co-operation at behavioural MCL setting. This highlights the importance of having an objective method to fit children who are unable to provide adequate feedback regarding their programme levels, particularly in the case of fitting young children. One issue in fittings is the importance of test-retest reliability, to ensure accuracy of the generated programme over time. In the current study, the average correlation for re-recorded eSRTs of 0.88 reveals a high reliability of the measurement across time, equipment and personnel.

One concern with using eSRTs as a means to generate a programme is that not all children may present with an eSRT. There may be criticism that, due to this fact, eSRTs may not be suitable as a standard fitting method. This study reports an eSRT incidence of 83% - that is the large majority of children can be fit using eSRTs, contrary to concerns that eSRTs cannot be recorded in many children. This is far greater than the number of children who cannot be fitted using traditional behavioural methods. For example, the 25 of 40 children in the current correlation study, who could not perform acceptable behavioural measures. Incidence results correspond to those reported for 24 paediatric Nucleus users[7]. The data from the current study lends weight to the incidence reporting, as it was conducted on a large sample of children. Seventeen percent of this sample needed to be fit using traditional behavioural methods. One main reason for not finding reflexes was non-resolvable middle ear problems; in a few instances the reason for not eliciting a reflex was inability to generate sufficient charge in the presence of ossification and non-auditory stimulation. This is confirmed by the child having poorer than normal implant sound field thresholds. For many children there is no obvious reason for not being able to record a reflex. One reason maybe that the reflex is difficult to separate from artifacts. Spontaneous movement of the tympanic membrane in children with flaccid membranes can make it difficult to isolate the reflex from background noise.

There may be instances when it is not possible to obtain an eSRT in a child without sedation. In such cases, inducing sleep using non-prescriptive sleep medication or calming agents should be tried. However, it may be necessary to measure eSRTs, in rare cases, under medically supervised sedation. Anaesthetics that do not cause muscle relaxation should be used. Increases in reflex thresholds may be seen and are reported to be due to anaesthetic agents[10]. In one case, reflexes measured under sedation were found to be at supra-threshold levels. Clinical experience has shown this to be true for a number of other cases. Programmes generated from such data should be applied with caution by lowering the starter volume e.g.65% volume. However; it is still useful to do eSRT under sedation, as the profile of required charge across the whole array can be seen.

Finally, longer-term stability of eSRT demonstrates the accuracy of the measurement tool, and clinically this means fewer fitting sessions required. The reported data and general clinical experience show that there is a trend for eSRT levels to increase in the initial period and then stabilise, highlighting the need for regular fitting sessions during the first few months of device use. Subsequent to this, fitting intervals can be extended, unless telemetry findings change significantly.

Performance of children using eSRT generated programmes

The foundation on which all spoken speech and language can develop is based on hearing. In the case of children with cochlear implants, this means an accurate speech processor programme must be provided as soon as possible. One means of assessing the accuracy of the speech processor programme is to evaluate auditory perception outcomes of children. Whilst all speech perception tests are partly dependent on linguistic and cognitive maturation, they are an accepted measure of auditory function.

Sound field measures show that implant thresholds generated by eSRT programmes are within the speech range. This indicates that children have access to all speech sounds. The relatively small standard deviation (of less than 10 dB for most frequencies, with a range of 10 to 20 dB across frequencies) between individual audiograms suggest that eSRT generated programmes provide a reliable, fairly consistent and acceptable audiogram for most children. Exceptions may include children implanted at a later age with minimal pre-implant auditory experience. Even though these children have obtainable eSRTs, their soundfield thresholds may be lower than expected, or lower than those for younger implanted children because of their inability to pay attention to sound and listen well.

This appropriate audiogram is also reflected in outcomes on speech perception tests. Mean closed-set monosyllable scores were 81%, and a mean score of 83% was recorded on the Minimal Differences Test. Mean GASP scores were 76%. These results are consistent, and often above scores seen in children assessed using the MED-EL EARS test battery. One study reported closed-set monosyllable scores of 100% at 12 months and GASP scores of 100% by 3 years after receipt of a cochlear implant[19]. Another reported 80% monosyllable scores at 12 months[20]. While a further study reported GASP scores of 10% at 1-year, 70% at 2-years and 90% at 3-years after first fitting[21]. These cohorts of children would have been fitted using a variety of different techniques - which may impact on the differences in outcomes. Interestingly, in the current study, results were similar across experience groups and for all children - irrespective of length of CI use for the first two tests. This is because these tests are not so dependant on linguistic and cognitive maturation, but they do require acute hearing. However, this was not the case for the GASP test, which is a more language-based test.

Conclusion

Through a series of small studies, it can be demonstrated that eSRTs can be measured quickly and reliably. eSRTs correlate highly with behaviourally measured MCLs and thus can be used to generate appropriate speech processor programmes for a high percentage of children. In some children (17%), an eSRT could not be measured at all; mostly due to aetiological factors, 35% of this goup had no apaprent reason for no eSRT recording. The eSRT occurs below perceived levels of uncomfortable loudness, reassuring the clinician that the eSRT generated programme will not over-stimulate the child. Finally, children using eSRT generated programmes have sound field thresholds well within the speech range, facilitating the development of spoken language

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Odyomed Rehabilitation Centre, Bursa
MEDers Hearing and Speech Centre, Ankara

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