Measurement of Comfort Levels by Means of Electrical Stapedial Reflex in Children

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Background: Patient success and satisfaction with a cochlear implant largely depend on the adequacy of the speech-processing program. The program is generated by means of behaviorally determined threshold and comfort levels for each electrode. As the minimum age for implantation continues to decrease, behavioral methods of measuring comfort levels have become more problematic, and so the need for objective ways to program speech processors has become more important.

Objectives: To evaluate the use of electrically evoked stapedial reflexes (ESRs) to measure comfort levels for children and compare these results with behavioral measurements, and to report the results of a questionnaire assessing the acceptability and general performance of program before and after adjustment of comfort levels measured with ESRs.

Design and Setting: Before-after trial in the cochlear implant unit of a tertiary hospital.

Cochlear implants require programming on an individual basis to provide appropriate levels of electrical stimulation. This program, or “map,” is placed in the speech processor of the cochlear implant. Success of implantation largely depends on the adequacy of this map. The map is generated by means of an electrical dynamic range for each active electrode. This range is established by ascertaining a threshold (T) measurement, which serves as the lower limit, and a comfort (C) level, which is the upper limit of electrical stimulation. The T level is defined as the lowest stimulus level producing 100% detection. The C level is obtained by increasing the current from the T level until the patient indicates that the stimulus is loud but comfortable. These levels vary from electrode to electrode as well as among patients. They also vary over time and from one programming session to the next.

Traditionally, the C and T levels are set by means of behavioral methods. These methods are similar to those used in obtaining an audiogram and usually require the child to pair a stimulus with a response. Setting the level of minimal stimulation, the T level, is usually successfully achieved by standard pediatric audiology techniques. These include operant conditioning tasks, conditioned play audiometry, and visual reinforcement audiology. Children who have undergone cochlear implantation are usually familiar with such techniques. Although most young children can be conditioned to provide reliable T levels, obtaining C levels from children can be extremely difficult. Setting the T level requires the child to respond to the presence or absence of a sound. Although the same techniques are used in setting the C level, the child is now required to make a judgment about the sound beyond its simple presence or absence. Young children often lack the at-
PATIENTS AND METHODS

PATIENTS

The study included all children who were scheduled for programming in August and September 1999. Verbal consent was obtained from all parents. A total of 26 children were tested. The mean age was 4.9 years (range, 2–9 years), and the male-to-female ratio was 15:11. The mean length of implant use was 18.5 months (range, 2–36 months). Twenty children were using the Nucleus 24 cochlear implant with the Sprint processor (Cochlear Ltd, Sydney, Australia) and 6 were using the Nucleus 22 with the Spectra processor (Cochlear Ltd). All children were using the Spectral Peak speech processing strategy (Cochlear Ltd).

PROCEDURE

A middle ear analyzer (GSI 33, version 2.0, model 1733; Grayston Stadler, Milford, Ohio) was used to perform tympanometry and record the ESRs. All children underwent tympanometry before ESR testing. The Nucleus 22 speech processors were connected to the Nucleus diagnostic programming system, while the Nucleus 24 processors were connected to the clinical programming system. The recording system of the middle ear analyzer is very sensitive to movement. To minimize artifacts caused by movement, passive cooperation was obtained from the children. They were seated in front of a color television and provided with an age-appropriate video to watch, or they were allowed to read. Parents were encouraged to bring a selection of their child’s favorite cartoons or movies to the clinic.

After impedance checks and behavioral T-level measurements, each child had a short break and his or her processor was reactivated with their current map. Parents were encouraged during this interval to take the child for a short walk. We believe that this reduces the large contrast between listening at threshold levels and listening at suprathreshold measurements.

The recording of ESR was attempted in the ear contralateral to that implanted. An appropriate probe tip was inserted in the ear; occasionally, smearing the cuff with petroleum jelly provided a more stable and consistent seal. The probe case was retained on the strap and placed over the child’s or parent’s shoulder.

Once a normal tympanogram was obtained, the middle ear analyzer was set to the “special (reflex decay)” mode and the system was pressurized. Stimulation was derived via the appropriate interface by means of standard biphasic pulses and presented through the child’s own speech processor at the standard rate of 250 pulses per second. A change in acoustic admittance for the 226-Hz probe’s tone resulting from the stapedial reflex contraction was presented as a downward deflection of the prestimulus baseline.

Stimulation began at 20 programming units below the previously behaviorally measured C level. The number of presentations ranged from 1 to 3. For the Nucleus 24 users, this was controlled by the keyboard command for WinDPS (Windows Diagnostic Programming System) (version R16.02 [build 445], service release 2, Cochlear Ltd). For Nucleus 22 users, control was through the diagnostic programming system (version 6-10F; Cochlear Ltd). If a clear reflex was present, the stimulus level was decreased by 5 units. If no reflex was evident, stimulation was increased by 2 units until a reflex was present or there were behavioral signs of the signal producing loudness discomfort. The ESR threshold was taken as the lowest stimulus level that produced a deflection in baseline recording, synchronous with the stimulus presentation.

The C level was set at 2 programming units below the level at which the ESR threshold was identified. All available electrodes were tested.

STATISTICAL ANALYSIS

Statistical analysis used the paired means t test with the use of Minitab for Windows, version 12.22 (Minitab Inc, State College, Pa).

The recording of ESR was by means of electrical stimulation in cochlear implant recipients has been established since 1986.3 Shallop and Ash6 showed that ESR correlated with the most comfortable level rather than the uncomfortable level in an adult population, and Spivak et al7 showed ESR to be safely below the threshold for discomfort. Hodges et al8 demonstrated that maps generated by means of ESR to measure C levels resulted in speech-perception performance that matched that of behaviorally derived maps in an adult test group. Therefore, using ESR as an objective predictor of C levels is potentially a very useful tool in the pediatric population. Although measurement of ESR is clearly practical and efficient, there has been little research into the outcome of patients whose maps have been adjusted by means of ESR. Spivak et al9 looked at subjects’ performance on 2 measures of speech recognition and found that the maps based on ESR had acceptable sound quality and speech perception and compared favorably with maps based on behavioral C levels. However, to our knowledge, no researchers to date have looked at the outcome after altering the map in the pediatric population.

tension span, patience, and cognitive and language skills necessary to perform these tasks with good reliability and repeatability. Moreover, the concept of “most comfortable level” is often beyond young children’s capabilities, even among the hearing population.

Implant clinicians (ie, audiologists, medical physicists, and physicians) often rely on intuition and trial and error when deciding on a C level, and the lack of auditory experience in very young children, together with limited language abilities, makes the task of setting T and C levels a long-term, ongoing process. Overstimulation or understimulation of the device can occur easily and may lead to lack of appropriate progress. As the minimum age for implantation has continued to decrease, successfully achieving the C level is becoming more problematic. Clearly, the need for objective ways to program speech processors has become more important. A reliable, objective method would improve the accuracy and efficiency of mapping the speech processor.

The electrically evoked stapedial reflex (ESR) has been shown by researchers to correlate with C levels in the adult population.14 The ability to elicit the acoustic


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The aims of this study were to compare the results of behaviorally vs objectively recorded measurements of C levels with the use of ESR and to establish whether there were any changes in the child’s behavior or response to sound when a program with C levels set by ESR was used.

## RESULTS

The ESR technique could not be performed in 6 patients (23%). Middle ear effusion was present in the contralateral ear in 2 of these children. Three children reported loudness discomfort before reaching ESR threshold; all 3 of these had a history of previous middle ear disease. Sufficient cooperation was not obtained in 1 child on 2 separate occasions to allow the procedure to be performed. The 20 remaining children successfully completed ESR measurement. A total of 391 individual measurements were made. Nine electrodes were not tested because of nonauditory stimulation.

### BEHAVIORALLY VS OBJECTIVELY RECORDED MEASUREMENTS OF C LEVELS BY ESR

The T levels were remeasured by behavioral methods to ensure that they remained consistent with the T levels obtained in the previous programming session. There was no statistical difference between the T level measurements obtained during the 2 programming sessions (Figure 1).

The 2 methods of measuring the C level were compared and the average measurement for each electrode of the 20 children was calculated (Figure 2).

The C level obtained with ESRs was found to be consistently lower across all electrodes. Figure 3 shows the difference in C levels (behavioral−ESR); a positive value indicates that the behavioral C level was higher than ESR C level, whereas a negative value indicates that the ESR C level was higher. The minimum and maximum levels represent the range. The difference in C levels with the 2 measurements was found to be statistically significant across all electrodes. Of the 391 measurements made, 380 were positive values and only 11 were negative values.

## OUTCOME OF NEW PROGRAM WITH ESR C LEVEL

Parents were asked to complete a questionnaire relating to the new programming technique compared with that used on all the previous visits, ie, the behavioral method. Answers were completed in the form of a numerical analog scale ranging from 0 to 4, where 0 represented “never” and 4 represented “always.” Parents were required to rate the original program set based on behavioral methods and the new program set based on ESR. The questions consisted of 2 subgroups: the first group of questions (Figure 4) asked whether the child ever showed discomfort to a range of 8 different environmental sounds. The next 12 questions (Figure 5) pertained to the child’s willingness to wear the implant and are outlined in the Table. Across all the questions, the program based on ESR was rated better than behavioral programming, and the differences for 10 of the questions were statistically significant (Figures 4 and 5).
Testing of ESR is a clinically feasible procedure in patients with no middle ear effusion and was successfully used in creating the map for the speech processor. From the clinician’s perspective, it is an effective procedure that is easier to perform than behavioral tasks. It is both safe and reliable, and one can be confident that the sound is audible but not uncomfortable. From the patient’s perspective, the new program results in fewer situations that cause discomfort; therefore, patients are likely to wear the implant more. Since this study, measuring ESR has replaced behavioral techniques in programming the speech processor in our department and has become routine procedure. We believe that it is a superior technique and should replace traditional, subjective techniques when cochlear implants are programmed in the pediatric population.

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