Routine Use of the Crystal Device Integrity Testing System in Pediatric Patients

Daniel L. Monin*
Ken Kazahaya†‡
Kevin H. Franck†§

Abstract
Crystal Device Integrity Testing System (CITS), the first commercially available testing system of its type, allows rapid assessment of cochlear implant function by measuring averaged electrode voltages—the scalp-recorded fields generated by electrode currents. We describe our experience performing routine integrity tests on 44 pediatric cochlear implant patients using the CITS. We present our findings focusing on the monopolar and common ground scans to provide a framework from which CITS scans can be evaluated in the future. We also describe selected cases in which abnormal results using the CITS influenced clinical treatment, demonstrating the utility of performing routine integrity tests.

Key Words: Cochlear implant, device failure, electrode voltage

Abbreviations: AEV = averaged electrode voltages; CG = common ground; CITS = Crystal Device Integrity Testing System; CL = Current Level; MP = monopolar

Sumario
El Sistema de Evaluación de la Integridad del Dispositivo de Cristal (CITS), el primer sistema de evaluación comercialmente disponible de este tipo, permite una rápida evaluación de la función del implante coclear, midiendo los voltajes promediados de los electrodos – los campos de registro en el cráneo generados por las corrientes de los electrodos. Describimos nuestra experiencia utilizando el CITS. Describimos nuestra experiencia realizando pruebas rutinarias de integridad en 44 pacientes pediátricos con implantes cocleares usando el CITS. Presentamos nuestros hallazgos concentrándonos en las revisiones mono-polares y de campo común, para aportar un marco desde el cuál los estudios con el CITS puedan ser evaluados en el futuro. También describimos casos selectos en los que resultados anormales utilizando el CITS influyeron en el tratamiento clínico, demostrando la utilidad de realizar pruebas rutinarias de integridad.

Palabras Clave: Implante coclear, falla de dispositivo, voltaje de electrodo

Abreviaturas: AEV = voltajes promediados de electrodo; CG = tierra común; CITS = Sistema de Evaluación de la Integridad del Dispositivo de Cristal; CL = nivel de corriente; MP = mono-polar

*University of Pennsylvania School of Medicine, Philadelphia, PA; †Department of Otorhinolaryngology—Head and Neck Surgery, University of Pennsylvania School of Medicine, Philadelphia, PA; ‡Division of Pediatric Otolaryngology, Children’s Hospital of Philadelphia, Philadelphia, PA; §Center for Childhood Communication, Children’s Hospital of Philadelphia, Philadelphia, PA

Kevin H. Franck, Ph.D., Center for Childhood Communication, Children’s Hospital of Philadelphia, 34th Street and Civic Center Blvd., Philadelphia, PA 19104; Phone: 215-590-0531; Fax: 215-590-5641; E-mail: franck@email.chop.edu
Traditionally, a cochlear implant failure is detected and investigated only after the patient reports impaired performance of the implant. However, in young children who are often unable or unwilling to communicate, device failures may be difficult to recognize, and it is desirable to have a method that can demonstrate that the internal device is functioning properly independent of any responses from the patient. With young children there is added pressure to make a timely diagnosis of an implant malfunction to capitalize on the limited period when language development occurs. In these patients, any delay in diagnosis of an implant failure has the potential to result in lifelong consequences for the patient.

For many years, it has been known that certain device failures can readily be detected by measuring surface potentials, the stray voltages from the flow of current in the electrode array, which can be recorded from the scalp (Mahoney and Proctor, 1994; Mens and van den Broek, 1994a; Cullington and Clarke, 1997; Garnham et al, 2001; Hughes et al, 2004). Although these potentials are often large enough to be seen on an oscilloscope, signal averaging is employed; hence, the potentials are known as averaged electrode voltages (AEVs). In past years, AEV recording has been a bit cumbersome. An averager, such as is used for auditory brainstem response measurement, was needed in addition to the computer that controls the implant’s signal processor. The various test signals were selected manually, one at a time.

There is now a commercial device, the Crystal Device Integrity Test System (CITS) supplied by Cochlear Limited, that greatly simplifies the process. The CITS was developed for use with the Nucleus 22 and 24 models, but it can be used with devices from other manufacturers. CITS allows noninvasive integrity tests to be performed on the implant by measuring surface potentials emanating from functioning intracochlear electrodes. At the present time, the CITS is the only commercially available system that can be used to perform integrity tests of this type.

Over the last two years, using the CITS system, we have routinely performed integrity tests on pediatric patients, both to detect unsuspected problems and to provide a baseline in case of suspected device failure in the future. This series has allowed us to define norms and on occasion to identify anomalies. Although normal range measurements of averaged electrode voltages have received some attention in the past (Mahoney and Proctor, 1994; Cullington and Clarke, 1997; Garnham et al, 2001), normative data collected with the CITS has not been described. This normative data should shed light on the CITS system and can be used to assist in the future interpretation of CITS tests performed on patients with Nucleus cochlear implants. We will also discuss a few patients in which the results of the CITS were found to be abnormal.

**MATERIALS AND METHODS**

The CITS scans were performed between the dates of October 28, 2002, and June 24, 2004, on 44 pediatric patients who had received Nucleus cochlear implants. Of these patients, 15 had Nucleus 22 implants and 29 had Nucleus 24 implants. Testing was performed in an outpatient setting using the CITS following the procedure described by Cochlear Limited (2001). In accordance with the protocol, the recording electrodes were placed on both earlobes of the patient, and a ground electrode was held by the patient or taped to the patient’s skin. This technique differs from some previous techniques for measuring AEVs that used recording electrodes placed over the mastoids (Hughes et al, 2004). However, a previous study showed little change in AEV amplitudes comparing the traditional mastoid placement of the recording electrodes to either earlobe or tragal placement (Cullington and Clarke, 1997). Because the AEVs are orders of magnitude larger than such electrophysiological signals as the auditory brainstem response, no sedation is needed. Patients with known cochlear abnormalities were not included in the sample used to determine the norms for the tests performed. AEV scans were performed anywhere from four months to 11 years following implantation.

The CITS system can be used to evaluate the cochlear implant using a variety of electrode configurations. AEV testing using the pseudomonopolar and bipolar+1 modes has been described in detail in the past.
(Mahoney and Proctor, 1994; Cullington and Clarke, 1997; Hughes et al., 2004) and will only be given brief attention in this paper. In our study, the stimulation levels were controlled by the operator and ranged from 50 Current Level (CL) to 150 CL in the common ground (CG) and monopolar (MP) modes.

The MP configuration checks the function of each intracochlear electrode individually and is only available for use with the Nucleus 24 model because the Nucleus 24 model has two extracochlear grounding electrodes, while the Nucleus 22 model has none. The grounding electrodes are labeled MP1, a ball electrode placed beneath the temporalis muscle, and MP2, an electrode located on the casing of the implant’s internal receiver/stimulator. The monopolar 1 test uses the MP1 electrode as the reference electrode, and the monopolar 2 test uses the MP2 electrode as the reference electrode. The MP modes have replaced the pseudomonopolar mode that was utilized on the Nucleus 22 models. In the pseudomonopolar mode, electrode number 1, the most basal electrode, is used as the reference electrode when testing the remaining 21 electrodes. This configuration is used to approximate the MP mode; however, it produces a more limited set of data, and therefore is not utilized in the Nucleus 24 models. In CG mode, one electrode is stimulated with the remaining 21 electrodes functioning as reference electrodes. In either mode, the stimulation pattern results in one biphasic waveform for each electrode tested.

The data recorded by the CITS procedure is presented in a graphical format and saved as a JPEG file. Results from multiple tests are organized in a hypertext markup language (HTML) format. The waveforms generated for all 22 electrodes are displayed on the same image, allowing for easy comparison of the response at each electrode. In the image displayed for each scan, “1” refers to the most basal electrode, and “22” refers to the most apical electrode of the implant (Figure 1). Although this graphical presentation is ideal for a quick assessment of implant function and would be sufficient for routine clinical use, numerical values for the amplitudes of the waveforms are not provided. In order to analyze this data for the purposes of this paper, we enlarged the graphs and printed them so the waveforms could be measured and amplitudes could then be calculated. We used these measurements to evaluate the decrease in amplitude from the most apical to the most basal electrodes in the MP scans and also to aid in the determination of the location of the null point in the CG mode scan. The inset in Figure 1 shows a graphical representation of these waveform measurements.

**Figure 1.** Display generated by CITS program in the MP2 (monopolar referenced to case electrode) mode. In this test, 100 CL biphasic pulses have been delivered to each of the 22 electrodes in turn. Inset: Graph of waveform amplitudes. Black bars represent initial phase of pulse. Phase reversal is easily seen with this representation. These are the same data as in Figure 4.
RESULTS

Data Collection

The time needed to perform each scan after the ear electrodes were attached ranged from 1.8 to 13.6 min (mean = 5.1 min, SD = 2.7 min, median = 4.2 min). In patients who were found to have abnormalities during the scanning process, it is possible to repeat portions of the exam to check to see if these findings persist. This rechecking of patients’ scans increased the overall time of the exam.

Monopolar Scans

The monopolar tests (MP1, MP2) typically produce a biphasic waveform with the leading phase being positive at all electrodes. There is a minimal decrease in waveform amplitude moving from apical to basal. A typical MP1 scan is demonstrated in Figure 2. Note that there is no change in polarity moving across electrodes and there is only slight change in amplitude moving from electrode to electrode. The MP2 scans are similar to the MP1 scans except that the amplitude of each waveform significantly decreases compared to the MP1 scan, and that the decrease in amplitude moving from apical to basal is more pronounced. This was a consistent finding across all patients. Figure 3 demonstrates an MP2 scan taken from the same patient as the MP1 scan in Figure 2. A subgroup of MP2 scans showed a slightly different pattern. In these scans, following the decrease in amplitude moving from apical to basal, an inversion occurred followed by an increase in amplitude in the most basal electrodes, typically involving electrodes 1 through 3. This pattern was noted in eight of the MP2 scans performed. Since this pattern was seen in otherwise normal patients, we believe that this is a normal variant. Figure 4 shows a scan that exhibited a null point and phase change.

Although a range of stimulation levels were used performing the CITS scans, a substantial proportion of the scans were performed using a stimulation level of 100 CL. Figure 5 shows the peak-to-peak amplitudes of 14 normal MP scans obtained at a stimulation of 100 CL in patients with properly functioning implants. Two scans
also performed at the same stimulation level were excluded from these calculations due to abnormalities. In one case there were much higher amplitudes than normally observed, and in the other case there was no change in amplitude moving from electrode to electrode due to device failure (case 2). These cases are described in more detail. Four of the MP2 scans recorded at a stimulation level of 100 CL had an inversion in the basal electrodes. For these scans in which an inversion was present, a negative value was assigned to the affected amplitude. Table 1 presents details of the data collected from electrodes 1 and 22 in the MP modes at stimulation of 100 CL.

In the MP1 mode, for scans with measurable amplitudes at both electrodes 1 and 22, the amplitude at electrode 1 averaged 77.6% of the amplitude at electrode 22 (range = 21.9% to 94.9%, SD = 17.3%). In the MP2 mode, the amplitude at electrode 1 averaged -7.7% of the amplitude of electrode 22 (range = -207.6% to 70.4%, SD = 95.3%).

### Common Ground Scans

The common ground mode scan typically produces a negative-leading waveform in the basal electrodes, which decreases in amplitude as the stimulation site moves toward the more apical electrodes. The waveform amplitude decreases to the level of the baseline noise. As the scan proceeds to the more apical electrodes, the waveform reappears as a positive-leading waveform, which increases in amplitude but typically does not reach the amplitude recorded with stimulation of the most basal electrodes. The electrode where the generated signal disappears or undergoes this phase reversal is referred to as the “null point.” As in the MP scans, the changes from electrode to electrode follow a smooth progression.

Figure 6 is an example of a normal CG scan recorded from a patient with a properly functioning implant that exemplifies this pattern, its null point being electrode 8. Note that at electrode 7, a negative-leading waveform is clearly visible and at electrode 9 a positive-leading waveform is visible.

In some cases the null point is more difficult to determine than in the provided example. In these cases, we identified the last clearly visible negative-leading waveform and the first clearly visible positive-leading waveform moving in the apical direction. The value for the null point was assigned as the mean of these two identifiable waveforms. Because this technique of averaging was
used, some of the null points fall between electrodes. For example, if the last negative-leading waveform identified was at the position of electrode 6 and the first positive-leading waveform was at electrode 9, the null point would be assigned as the average of these two positions, in this case, 7.5.

Of the 39 CG scans we studied where full insertion was achieved during implant placement, the location of the null point ranged from electrode positions 4.5 to 11.5 (mean = 7.8, SD = 1.3) with a normal distribution. Thirty-six (92%) of the scans had null points ranging from 6 to 10.

**Selected Cases with Abnormal Scans**

In this section, we discuss a few patients in which abnormal scans were obtained. The majority of scans had no abnormalities. Only 3 (14%) of 22 scans had abnormalities in the MP modes. Two of these patients had abnormally large amplitudes across all electrodes in both MP modes, and one patient had no drop in amplitude moving from apical to basal in both MP modes. In the CG mode, abnormalities were noted in 6 (14%) of the 44 scans performed. The same patient who exhibited no drop in amplitude in the MP modes also had an atypical waveform with no change in amplitude moving across electrodes in the CG mode. Four patients had abnormalities limited to specific electrodes, including phase flips and abnormal voltages. Voltages were defined as abnormal if they differed by greater than 20% from the mean amplitudes of the two neighboring electrodes as described by Mens et al (1994a). The other patient had an abnormal CG scan due to a known partial insertion. A sampling of these cases is provided below to demonstrate the types of abnormalities that can be detected using the CITS.

**Case 1**

In this CG scan (Figure 7), the basal electrodes show a steady decrease in amplitude followed by an unexpected increase in amplitude at electrode 9. The remaining electrodes vary in morphology and amplitude; asymmetry is also evident. This scan lacks the smooth decrease in amplitude to a null point followed by a gradual increase in amplitude that normally occurs in the CG scan. Both MP scans were normal. Clinically, this patient had all electrodes active in the program and did not complain of any unusual perceptions upon programming. Electrode 9, the most aberrant waveform in the scan, was eliminated from the program. The patient’s overall performance did not improve, nor did he notice a perceptible difference in sound quality.

**Case 2**

This patient had a normal CG scan with abnormal MP scans. The MP1 scan showed unusually high voltages for a stimulation...
level of 100 CL (Figure 8A) while the MP2 scan showed unusually low voltages for the same stimulation level (Figure 8B). One of the tests available in CITS is an amplitude modulation scan—a sequence of pulses of varying current, delivered to a single electrode. In Figure 9B, the AEVs from a normal patient have been replotted, showing a nearly linear input-output function. This patient’s implant showed an inability to modify its response to different levels of stimulation as seen in the abnormal amplitude modulation function (Figure 9A). In this case, the patient (age 1.5) was able to detect sounds. WIN-DPS reported MP2 errors but normal MP1 function. The device was determined to have failed, and the patient was explanted and then reimplanted with a new device. Manufacturer testing confirmed a failure in the old device electronics. The new device has normal scans.

Case 3

This patient’s CG scan (Figure 10) reveals obvious phase reversals at multiple electrodes with additional electrodes showing decreased amplitudes compared to the surrounding electrodes. The manufacturer determined that the device was functioning properly. Nevertheless, electrodes 20 and 22 were eliminated from the program because they exhibited clear phase reversals. No formal speech perception testing was performed.

Case 4

This scan is from a patient with a known partial insertion. In this case, only four electrodes were reported to be inserted at the time of implantation. This CG scan (Figure 11) shows how a partial insertion can affect the overall morphology of the scan. Amplitude increases then decreases for the extracochlear electrodes (1–18), possibly reflecting their positions in the middle ear or the presence and absence of direct contact with the mucosa. The responses of the intracochlear electrodes are remarkably asymmetrical.

DISCUSSION

The norms that we have presented can be used as a framework to evaluate future CITS scans. There are a few typical features of monopolar scans. Positive-leading waveforms are present at the most apical electrodes. In most cases, the amplitudes of these waveforms smoothly decrease from apical to basal electrode position and are positive-leading at all electrodes. However, in the MP2 mode, it is common for the amplitudes to decrease to a null point in the basal region followed by an inversion of the waveform at the most basal electrodes. This pattern was found in 8 of the 22 MP2 scans we performed. MP2 scans have lower amplitudes and a steeper decrease in amplitude compared to the MP1 scans. In
both scans, no waveform should differ by greater than 20% from the mean of the two neighboring waveforms. Because amplitudes are more uniform in MP1 scans, this may be the preferred mode for detecting anomalies in individual electrodes.

The MP1 and MP2 scans are not available for the N22 implants because they lack extracochlear ground electrodes. Normal CG scans have negative-leading waveforms at the most basal electrodes with a smooth decrease in amplitude to a null point (typically at electrodes 7–10). This should be followed by a smooth increase in positive-leading waveforms in the remaining apical electrodes. As in the MP scans, no waveform should differ by greater than 20% from the mean of the two neighboring waveforms.

Consistent with the findings of previous studies of MP tests, values of the apical electrodes were generally larger than those of the more basal electrodes. This pattern of an increase in amplitude with increased distance between the stimulated electrode and the reference electrode corroborates a previous description of pseudomonopolar
stimulation (Mens et al, 1993), where the reference electrode is within the cochlea (electrode 1). Not only when considering distance within a stimulation mode, differences across stimulation modes result in consistent effects on waveform amplitude. A reliable finding is that MP1 scans yield larger amplitudes than MP2 scans. The MP1 electrode, located beneath the temporalis muscle, is farther from the electrode array than the MP2 electrode, located on the casing of the internal receiver/stimulator. In a similar fashion, pseudomonopolar scans, utilizing a receiving electrode even closer to the electrodes being stimulated, produce even smaller amplitudes.

The finding that a greater change in amplitude occurs between electrodes in MP2 compared to MP1 scans may also be explained by considering the placements of the receiving electrodes. Since the MP2 electrode is relatively closer to the electrode array, moving from electrode to electrode would produce a proportionally greater change in the distance to the reference electrode than would occur when using the more distant MP1 electrode as the reference electrode. This greater proportional change could account for the greater change in amplitude observed in the MP2 scan.

The significance of the null point present in the CG mode scans continues to be a subject of debate. Previous studies have found the null point to occur at electrodes 4–10 with full insertion (Garnham et al, 2001). This range is consistent with the findings of our study as only 2 of the 39 CG scans we studied, excluding the patient with a known partial insertion, had null points that fell outside of this range with 92% occurring at electrodes 6 to 10.

To better understand the phenomenon of the null point and the pattern of waveforms generated, it is helpful to review some of the background research that has been performed examining the relative conductivities of the tissues surrounding the cochlea. The conductivity of scala tympani fluid has been demonstrated to be about ten times higher than that of the bone surrounding the cochlea (Frijns et al, 1995). With this great difference in conductivity, the scala tympani could be modeled as an insulated fluid filled cylinder, with an open end at the region of the round window where the implant has been inserted (Mens et al, 1995; Mens et al, 1999). In the CG mode with no extracochlear electrode, most current would be confined to the cochlea. Of the current that does escape, the great majority will pass through the open end before traveling to the surface electrodes instead of directly passing through the bone surrounding the implant. An exception to this is the case in which patients with otosclerosis have been shown to have cochleas that are much more permeable compared to the cochlea of normal patients. In patients with otosclerosis, it is believed that a much larger proportion of current flows directly through the cochlear bone to reach the recording electrodes, therefore causing abnormalities such as phase reversals in the waveforms generated during AEV testing (Mens et al, 1994b; Mens et al, 1995; Mens et al, 1999).

In the CG mode, current flows from the active electrode to all of the remaining electrodes, which are set as reference electrodes. When a basal electrode is stimulated, the bulk of the current flows in the apical direction, and conversely, when an apical electrode is stimulated, the bulk of the current flows in the basal direction. The difference in direction of current flow may explain the phase change from negative leading to positive leading that is observed when moving from basal to apical stimulation. It has been postulated that the null point occurs at the location where an approximately equal amount of current flows from the active electrode to the reference electrodes on either side (Garnham et al, 2001). This in effect would lead to a cancellation of the signal recorded by the surface electrodes. Alternatively, some authors suggest that the location of the null point is instead related to the positioning of the implant or more specifically to the smallest radius of curvature that the implant makes within the cochlea (Peterson et al, 1995). However, this assumption has been challenged by others who argue that since the electrode array is fully inside the insulated tube of the cochlea, its orientation is unimportant in explaining the surface potentials recorded (Cullington and Clark, 1997). To further investigate the phenomenon of the null point, we measured the insertion depth by examining x-rays of a subgroup of patients with common ground scans performed to determine if these two variables were associated. On review of our data, no relationship between these two
variables was readily apparent, so no quantitative measurements were made. A lack of relationship between the insertion depth and the location of the null point would lend support to the view that the shielding effect of the cochlea renders the exact positioning of the implant unimportant in contributing to the null point as long as a full insertion is achieved.

AEVs have been shown to be useful in the identification of a wide range of device malfunctions. Previous authors have noted that the amplitude during stimulation of a particular electrode rarely differs by greater than 20% from the mean amplitudes of the two neighboring electrodes. A deviation from this pattern can be used as a possible indicator for electrode malfunction (Mens and van den Broek, 1994a). The application of this 20% normal range has been shown to be effective in identifying electrode malfunctions with the CG mode being more reliable compared to the MP modes (Hughes et al, 2004). Interestingly, in our study, while there were four CG scans that violated the 20% rule at one or more electrodes, no MP scans violated the 20% rule. Instead, the three scans with MP abnormalities seemed to indicate global implant dysfunction instead of malfunctions at specific electrodes.

When evaluating an abnormal result, it is also important to be aware of certain cases in which a normal result would not be expected. Previous studies of AEVs have shown the presence of phase reversals in patients suffering from otosclerosis (Mens et al, 1995), osteogenesis imperfecta (Mens and Mulder, 2002), and an enlarged vestibular aqueduct (Mens and Mulder, 2002). Abnormalities have also been noted in a patient whose electrode array rested in a trough of drilled out bone (Shallop et al, 1995). These cases illustrate the importance of considering the patient’s history when evaluating abnormal AEVs.

A variety of electrophysiological testing systems have been developed to aid in the detection of cochlear implant internal device failures. These systems include impedance telemetry, electric field testing, averaged electrode voltage (AEV) testing, and electrically evoked compound action potential testing. All of these tests can be performed quickly and easily in an awake patient when manufacturer-supported testing systems are available. Results of each of these tests should be considered together when assessing device function.

For cochlear implants that lack a back-telemetry function, such as the Nucleus 22 model, AEVs remain useful to assess proper implant function. Some have suggested that the future of AEVs will be of reduced importance as cochlear implants are increasingly manufactured with back-telemetry capabilities. However, Mens and Mulder (2002) gave three reasons that AEVs could be a useful adjunct to back telemetry: (1) they provide a device-independent means to test the integrity and stability of the implanted electronics and the electrode contacts even if the telemetry circuits are malfunctioning; (2) they can be useful when intermittent failures are suspected; and (3) they are potentially useful in identifying electrodes that disrupt normal tonotopy or cause side effects, especially in cases in which electrode insertion was difficult, in malformed cochleas, and in highly permeable cochleas (e.g., cases of otosclerosis). Case 2 indicates the importance of routine integrity testing. For this case, the data were measured at the child’s first annual evaluation when he was approximately two years old. Both parent and teacher reported excellent use of the device. Indeed, the child was making spoken language milestones, and the child’s audiogram indicated that all speech frequencies were detectible. Standard clinical impedance measures revealed an anomaly on the MP2 electrode but normal MP1 function. A reasonable clinical action would be to simply disconnect MP2 from the ground path. Routine integrity testing revealed that the stimulation was not varying in amplitude. The patient’s performance with the malfunctioning device is consistent with relatively good speech perception results in an experiment where amplitude modulation cues were removed (Franck et al, 2003). We also recently encountered a case in a patient with a Clarion 1.2 cochlear implant in which the diagnosis of an implant failure was delayed until AEV testing was performed (Franck and Shah, 2004).

The ease of use of the CITS system provides a great opportunity to expand the use of AEV testing to assess the functioning of cochlear implants, and we hope that the data that we are presenting will provide a framework for the evaluation of AEV tests performed in the future.
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REFERENCES


