

Averaged Electrode Voltage Testing to Diagnose an Unusual Cochlear Implant Internal Device Failure

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Abstract

This paper describes an unusual Clarion 1.2 cochlear implant failure in order to demonstrate the need for the clinical availability of electrode voltage testing. The case report describes a patient with a Clarion 1.2 cochlear implant who exhibited poor auditory progress in spite of grossly normal impedances and electric field testing, and an appropriate educational and psychosocial environment. For a subset of electrodes, however, electrode voltage testing was abnormal. At explanation it was found that the epoxy that protects the connection between the electrode leads of the array and the output contacts on the internal controller had fractured. This failure was not associated with reported head trauma. This case report demonstrates the utility of and clinical need for electrode voltage testing as a helpful tool to diagnose internal device failure.

Key Words: Cochlear implant, device failure, electrode voltage

Sumario

Este trabajo describe una falla inusual de funcionamiento de un implante coclear Clarion 1.2, con el propósito de demostrar la necesidad de disponer de una prueba de voltaje de electrodos. El reporte de caso describe un paciente con un implante coclear Clarion 1.2, quien mostró un pobre progreso auditivo a pesar de mostrar impedancias y pruebas eléctricas de campo consideradas como normales, y de desenvolverse en un ambiente educativo y psico-social adecuado. Sin embargo, para un sub-grupo de electrodos, la prueba de voltaje de electrodos resultó anormal. Se encontró como explicación que el epóxido que protege las conexiones entre las terminales del electrodo y los contactos de salida del controlador interno, se había fracturado. Esta falla no se asoció con ningún trauma craneal reportado. Este reporte de caso demuestra la utilidad y la necesidad clínica de una prueba de voltaje de electrodos, como una herramienta útil para diagnosticar fallas internas del dispositivo.

Palabras Clave: Implante coclear, fallas del dispositivo, voltaje del electrodo

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It has become easier to diagnose internal device failure as cochlear implants become more sophisticated and more clinical tools become available. These tools include standard radiographic studies (computed tomography scans, plain film skull radiography), as well as measurement of electrode impedances, electric fields, electrode voltages, and electrically evoked compound action potentials. Table 1 summarizes the manufacturer-supported, clinically available tests for each of the multichannel implant systems. None of the electrical or electrophysiological tests require sedation.

With cochlear implants, electrical impedance measurements are made between each electrode within the cochlea and an electrode outside the cochlea. These measurements are made by the implanted device itself. It is the electrical resistance and capacitance of the fluids, tissues, and bone between the intra- and extracochlear electrodes that is measured. Impedance values in the order of 5 to 20 kOhms are typical, but this number varies depending on the stimulation signal and characteristics of the electrode being tested. Unusually low readings may imply that electrode wires have short-circuited. Unusually high readings may imply that electrode wires have broken.

Electric field measurements read the voltage at each of the electrodes of an array when current is applied to one of them. Typically, the largest voltage is measured on the stimulating electrode contact, and the voltage drops off precipitously as the distance from this electrode increases in both the apical and basal direction.

Electrical potentials from the implant electrodes can be directly measured from electrodes on the skin. These electrode voltage measurements can identify a variety of device

failures, as well as problems with positioning of the electrode array. This testing can be done without the use of manufacturer-specific tools, whereby standard clinical programming systems create cochlear implant stimulation waveforms that can be measured with evoked potential measurement systems. A number of previous reports describe the procedure in detail (Mens et al, 1993, 1994; Mens et al, 1995; Peterson et al, 1995; Shallop et al, 1995; Mens and Mulder, 2002). However, arbitrary stimulus presentation abilities are not possible on any clinical programming system; therefore, the tests are not as complete as they might be. Cochlear Limited has developed the Crystal Device Integrity Test System for Nucleus 22 and 24 models for clinical measurement of electrode voltages, but similar systems are not available to clinicians from other manufacturers.

In electrically evoked compound action potential testing, the implant stimulates the primary afferent auditory neurons from one intracochlear electrode and records their responses on another. Successful recording of a neural response indicates proper function of the device and electrode array (Brown et al, 1998; Franck and Norton, 2001).

A hard cochlear implant failure describes when cochlear implant dysfunction can be verified with these tools. Implant failure may be suspected when clinical tools do not report device problems but do not perform as the clinician would expect. This is termed a "soft failure." Soft failures are difficult to detect when the patient has little auditory experience or lacks communication skills.

We discuss one experience with device failure in order to explore diagnostic challenges in detecting device failures, specifically the important role of surface-potential recordings.

Table 1. Manufacturer Supported Clinically Available Implant Diagnostic Tools

	Impedance	Electric Field	Average Electrode Voltage	Electrically Evoked Compound Action Potential
Nucleus 22			Yes	
Nucleus 24	Yes		Yes	Yes
Clarion 1.2	Yes			
Clarion II/HiRes90K	Yes			Yes
Med-El Combi 40+	Yes	Yes		

CASE REPORT

The patient in this report was implanted with a Clarion 1.2 cochlear implant with HiFocus electrode and the Electrode Positioner at age 26 months after a diagnosis of severe to profound bilateral sensorineural hearing loss. The child had bilaterally enlarged vestibular aqueducts. The device was seated in a bony well through the temporoparietal skull to the dura, with a triangular wedge cut into bone anteriorly to accommodate the fantail. A channel was drilled from the tip of the triangle to the mastoid bowl to carry the cable. Bone wax was placed around the edges of the trough for hemostasis, and over the electrode channel. The receiver-stimulator was held flush against the dura by two nylon sutures, passed through holes drilled through bone superior and inferior to the well. Fascia, muscle, and skin were then reapproximated over the device.

At activation, the patient's internal device reported normal function and normal electrode impedance. However, one month after activation, her maximum stimulation levels were out of voltage compliance—the implant lacked sufficient voltage to deliver the required current—in a processing strategy that uses bipolar electrode configuration, and her sound detection thresholds were higher than optimal. Therefore, she was switched to a monopolar processing strategy on odd-numbered electrodes, because the monopolar electrode configuration results in greater loudness percepts given the same charge output. Her audiometric thresholds were then typical for implanted children, and remained so throughout the first year of use. Charge was increased by manipulation of stimulation amplitude and pulse width during the first year of device use due to the patient's behavioral responses to implant stimulation during tuning appointments. Approximately six months after activation, electrode 10 (an electrode not used in her program) reported an open circuit. Months later, electrode 3 reported increased reading, and stimulation was moved to the even electrode of the channel pair (in this device there are eight stimulus channels, each with a pair of electrodes; in monopolar stimulation, the current can be delivered to the even or odd electrode of the pair). By her first anniversary of device activation, the impedance of

electrode 3 remained stable and high, while that of electrode 10 began to decrease but still was high.

After one year of device use, the patient communicated verbally using single-word utterances with two-word utterances emerging. The patient demonstrated some articulation errors including initial and final consonant deletion. The patient's overall language age-equivalent score on the *Preschool Language Scale-3* (Zimmerman et al, 2002) was 2 years, 1 month.

Throughout her second year of device use, audiometric thresholds remained within typical limits. Pulse widths continued to increase to 225 μ sec. The resulting stimulation rate was 271 Hz. This stimulation rate is relatively slow for a processing strategy that relies on temporal rather than spectral representation. The patient's internal device continued to report no problems. The impedance of electrode 3 remained high and stable, while that of electrode 10 continued to decrease to within normal limits. Just before the second anniversary of device use, parents noted concerns with consonant perception, despite normal detection levels of high-frequency speech stimuli. At the second annual evaluation, the patient presented as an oral communicator, never using signs or gestures to communicate answers, wants, or needs. Receptively, the patient was unable to show understanding of pronouns, expanded sentences, inferences, or qualitative words. Expressively, the patient was unable to use a number of grammatical structures that required her to add word endings. The patient's overall language age-equivalent score on the *Preschool Language Scale-4* was 2 years, 7 months. Given the excellent parental, therapeutic, and educational support, oral language progress was expected to increase at a normal rate, though delayed with respect to her chronological age. In the second year of implant use, the patient only showed one-half year's progress, despite audible access to all speech sounds.

Shortly after two years' device use a variety of programming manipulations were made to try to improve performance, particularly in the area of high-frequency consonant sound detection. Included in these manipulations was a paired pulsatile stimulation programming strategy, used to attempt to increase loudness perception and stimulation frequency by concurrent

Table 2. Electrode Impedance Values after Two Years Device Use

Location ^a	Electrode															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Top		7.5		8.2		8		12		46		31		38		53
Bottom	38		999		43		21		751		999		999		999	

^a See Figure 3 for location of even- and odd-numbered electrodes.

stimulation of two electrodes at a time. The patient rejected this coding strategy. Pulse widths of the basal-most electrodes were increased to 300 μ sec, reducing the overall stimulation rate to 250 Hz.

At a programming visit 2½ years after activation, electrodes 9, 11, 13, and 15 reported open circuits. Even-numbered electrodes reported impedance within the normal range, though electrodes 10, 12, 14, and 16 reported impedances approximately five times the magnitude of 2, 4, 6, and 8. See Table 2. Programming channels were

switched to even-numbered electrodes. At this point, further investigation of the device was warranted, and Advanced Bionics Corporation sent a clinical engineer out to perform electric field testing.

The electric field testing showed significant current spread and open circuits on electrodes 3, 9, 11, 13, and 15. Signal amplitudes were relatively large for electrodes 10, 12, 14, and 16. Because the device was reporting normal impedance readings on the even-numbered electrodes, the manufacturer recommended use of the even electrodes until further information could be collected. The child was scheduled for device-replacement surgery, nevertheless.

At the cochlear implant program's request, Advanced Bionics returned for electrode voltage testing. The electrode voltage system developed at Advanced Bionics enables one to stimulate with the implant, acquire directly the far field surface potential, and analyze the data on the same computer. The test uses three Nicolet disposable electrodes attached to the patient's forehead (+), ipsilateral mastoid (-), and contralateral mastoid (ground), providing input into a National Instruments data acquisition card. The custom software reads the data, applies filtering and gain, and displays the output for interpretation. Results of this test from stimulation of odd electrodes showed no current output for electrodes 3, 9, 11, 13, and 15. Testing of the even electrodes revealed output failures for electrodes 10 and 12 and phase output reversal for electrodes 14 and 16. Averaged electrode voltage testing revealed failures on electrodes 10, 12, 14, and 16 that were not detected by impedance or electric field testing (see figure 1).

The patient's device was stable and secure by physical examination. There were no reported incidents of head trauma. This examination was unchanged at the follow-up at month 20. At the time that further loss of electrode output was detected by average

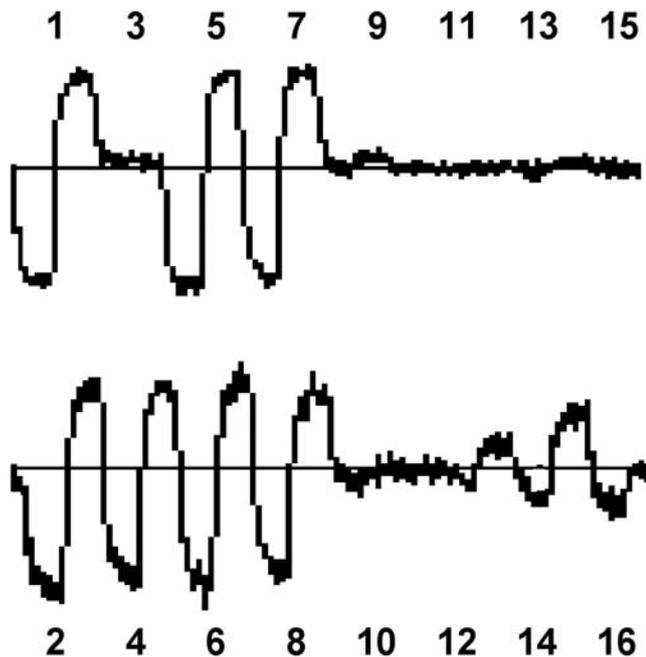


Figure 1. Averaged electrode voltage measurements. The top and bottom panels show the response measured on the skin to stimulation of the odd and even electrodes, respectively. Electrode numbers are labeled above or below the stimulus waveform. Normal responses on electrodes 1, 2, 4, 5, 6, 7, and 8 show biphasic waveforms of 75 μ sec per phase duration. Absent responses on electrodes 3, 9, 11, 13, and 15 are consistent with abnormal electrode impedance values. Absent or abnormal responses on electrodes 10, 12, 14, and 16 are not consistent with impedance values.

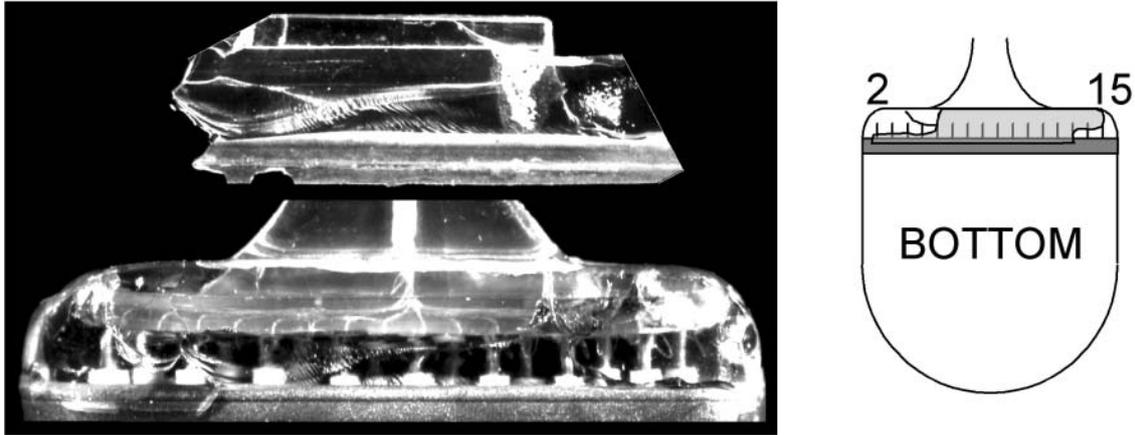


Figure 2. On the left is a picture of the anterior medial aspect of the Clarion implant. One epoxy chip is shown directly above where it chipped off the device below. On the right is an illustration of the extent of epoxy failure. The region with the epoxy is the top of the device covering the pins. The grayed-out portion of the epoxy indicates the location and size of the fractured piece.

electrode voltage testing, plain film radiography indicated that electrodes were within the cochlea, and no obvious defect was seen of the case.

Surgery to remove the old device and replace it was performed at 4 years, 10 months of age. At surgery, the anterior aspect of the clear epoxy casing was found to be fragmented, primarily on the undersurface of the device (Figure 2). Several epoxy fragments, ranging in length from 1 mm to 6 mm, were embedded in fascia from which

they were removed. The child received a new cochlear implant system. It was then sent to Advanced Bionics for failure analysis. An adverse event report was sent to the United States Food and Drug Administration.

CASE INTERPRETATION

The largest area of defective epoxy was on the medial aspect (the bottom, or underside as it sits on the patient) of the device, closest to where the posts from the internal device connect to the leads of electrodes 3, 9, 11, 13, and 15. See Figures 2 and 3. These electrodes showed open circuits on impedance and electric field imaging readings. Presumably, the epoxy failure had broken the leads. Directly above these broken leads are those of channels that had elevated impedance levels, equivocal electric field imaging results, and unusual electrode voltage results, but allowed perception of signal passed through them. Presumably, these leads were damaged, allowing current to flow not through the typical path from the electrode to the grounding band but, rather, through a spurious current path available from the damaged post to the grounding band.

In our patient, a specific traumatic episode could not be linked to device failure, both because there is a lack of reported trauma and because even if there had been

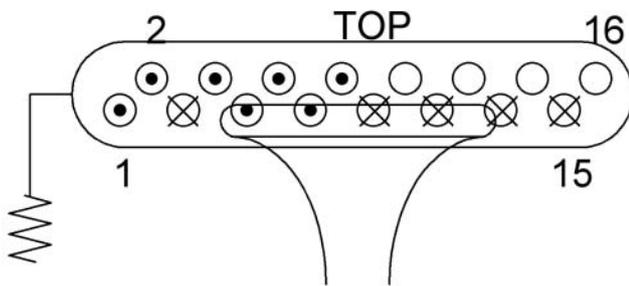


Figure 3. Illustration of location of electrodes in failure mode. Electrodes are depicted by circles. Black circles within circles indicate electrodes found to be normal by all tests. X-ed out circles indicate failure consistent across tests. White circles indicate normal electric field imaging and impedance measurement but absent electrode voltage readings.

a single traumatic event unknown to the parents, our patient's device failure seemed to be progressive rather than immediate. It is not implausible that normal childhood activity would result in frequent, low-impact trauma to this device that was slightly elevated relative to the skull. Trauma against the anterior ledge of the bony well is possible, given that it was the epoxy on the underside of the device that was cracked, and that the device was not enveloped in fascia but rather placed such that to-and-fro motion against a sharp bony edge could shear or crack the epoxy. If the epoxy were under stress, a crack could slowly propagate.

This device experienced a hard failure that all manufacturer-supported clinical tools could not detect. Averaged electrode voltage testing confirmed that the stimulation pulses being put out from the device were not typical. Were such a tool available, the failure may have been detected earlier. At our clinic, we routinely perform electrode voltage testing on supported platforms and repeat the testing when any sign of electrode malfunction warrants it. Our routine use of electrode voltage testing has led to clinically relevant interventions that have improved patient outcomes.

CONCLUSIONS

A full range of testing options is mandatory when caring for children with cochlear implants. Averaged electrode voltage testing is indicated in the presence of any suspected electrode or internal device malfunction. Manufacturer-designed electrode voltage testing systems (such as the Crystal Device Integrity Test System) allow for quick and flexible data collection.

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