Averaged Electrode Voltages Used to Identify Nonfunctioning Electrodes in Cochlear Implants: Case Study

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Abstract

We present the case of an adult male whose internal cochlear implant unit failed. Several months elapsed following initial stimulation with the implant before the problem was identified and corrected. The sequence of the failure and its detection are detailed. Following reimplantation, the patient did not initially report improved sound quality. However, within a week of the initial stimulation of the second device, he reported being able to identify environmental sounds, and speech began to sound the way he remembered it before he lost his hearing. We suggest a method of detection that might improve the(110,710),(137,735)(110,735),(137,760)(110,760),(137,785)(110,785),(137,810)(110,810),(137,835)(110,835),(137,860)(110,860),(137,885)(110,885),(137,910)(110,910),(137,935)
case number 22

Key Words: Averaged electrode voltages (AEVs), cochlear implant integrity, electrophysiologic tests, failed device, mapping

According to Cochlear Corporation (1993b), the cumulative survival rate of the internal portion of the Nucleus 22 Channel Cochlear Implant, based on 4119 adult patients and 2459 pediatric patients worldwide, is 97.66 percent and 92.31 percent, respectively, after 5 years. Cochlear Corporation attributed the difference in survival rate of the device between adults and children to the higher prevalence of mechanical stress placed on the device by children. The report also indicated that there have been no device failures beyond 3 years of the surgery date. Device failures are extremely difficult to deal with for the individual and his or her family. Often centers do not routinely test the integrity of the internal device. Few centers are adequately equipped to evaluate such failures. In this paper, we report the history of a failed device and how we detected and remediated it.

A recommendation for improving detection of a defective device is also proposed.

CASE REPORT

A 60-year-old male developed a hereditary, progressive bilateral sensorineural hearing loss at about 18 years of age. By age 30, he had a severe-to-profound hearing loss.

In December 1992, the patient came to the Mayo Clinic for a cochlear implant evaluation and met the criteria for implantation. An oblique coronal high-resolution petrous bone CT without contrast material demonstrated deformity of the basal turns of both cochleae. Findings were consistent with cochlear otosclerosis. Surgery took place on March 11, 1993. The physician performed a cochleostomy 1 mm anterior and inferior to the round window niche. After drilling anteriorly as far as the basal turn extended, he entered the scala tympani. He then inserted the electrode array into the cochlea until it met resistance. Based on plain film X-rays in the operating room, we identified 15 electrodes (8 through 22) inside the cochlea.

On April 19, 1993, 6 weeks postsurgery, he returned to have the external portion of the device programmed. Since there was less than...
a full insertion of the active electrodes, the audiologist selected common ground (CG) as a diagnostic programming mode allowing independent examination of each electrode. When making the program, she did not use six electrodes that were inside the cochlea. Two of the six electrodes provided no stimulation and two required very high current levels relative to the other electrodes. The last two produced very unpleasant sound quality. This left nine electrodes available for programming the Mini Speech Processor (MSP). After evaluation of each electrode in CG, the audiologist selected bipolar plus one (BP+1) as the programming mode.

During electrode adjustment, the patient reported that the sounds did not have a tonal quality but were "raspy." He was able to balance the sounds for loudness but reported that there was little difference in pitch. Although the audiologist made 13 maps on the first day, the patient reported no improvement in sound quality. There was also no improvement in sound quality after reprogramming on the following day. The pure-tone average for 500 Hz and 1 and 2 kHz was 43 dB HL. A speech reception threshold (SRT) could not be obtained. The patient passed levels A and B of the screening test in the Cochlear Corporation's rehabilitation manual (see Table 1). Levels A and B test the suprasegmental cues of duration and amplitude for words and sentences.

He was unable to pass level C (vowel identification) or level D (open speech recognition) because he could not take advantage of second formant (F2).

On April 30, 1993, 10 days following initial stimulation, the patient returned for another adjustment. He reported that everything sounded the same. He had the sensitivity set at 1½ and said that his understanding of speech was worse. His dynamic range decreased from what it had been at the initial stimulation. After reprogramming, he reported that "everything sounded good except for a muffled sound on the end of each word."

On May 17, 1993, 4 weeks after initial stimulation, the patient again reported that all sounds were alike. There was no difference between speech and environmental sounds. It was no longer possible to program in BP+1, as he reached maximum stimulation levels before he obtained a sufficient loudness percept. He tried 20 new maps that day. The final map was in the BP+2 programming mode using 10 electrodes. He felt that the final map sounded clearer. The audiologist activated a new electrode since its sound quality had improved. With the sensitivity set at 3, the patient was able to understand a few simple statements without speechreading.

On May 24, 1993, 5 weeks post-stimulation, he returned to report that, as before, everything sounded "raspy" and too loud. The audiologist replaced all external equipment to rule out hardware problems. His dynamic range decreased again compared to what it had been 1 month post-stimulation. The audiologist programmed the final map in BP+2 and included only seven electrodes.

Thirteen weeks after the initial stimulation, the patient continued to report sound quality as "very bad." The number of usable electrodes had decreased to five. On September 24, 1993, the surgeon obtained comparison coronal CT and trispiral petrous tomograms to rule out the possibility of electrode extrusion from the cochlea or bone growth in the scala tympani. The CT and petrous tomograms demonstrated that the electrode array remained in good position and there had been no further changes of labyrinthitis ossificans and/or changes of otosclerosis.

After the surgeon confirmed proper device placement and no change in the cochlea, he asked Cochlear Corporation to do an integrity test on the internal unit. A representative from the company placed surface electrodes on the patient and using an isolation amplifier and an oscilloscope measured the electrical stimulation

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>First Implant</th>
<th>Second Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure-tone average</td>
<td>43 dB HL, 47 dB HL</td>
<td>45 dB HL</td>
<td></td>
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<tr>
<td>Speech reception threshold</td>
<td>No response</td>
<td>50 dB HL, 45 dB HL</td>
<td></td>
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<tr>
<td>Cochlear Corp. Screening</td>
<td>B (passed)</td>
<td>D (passed)</td>
<td></td>
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<tr>
<td>Iowa Vowel Recognition</td>
<td>36%</td>
<td>49%</td>
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<tr>
<td>Monosyllable, Troche, Spondee</td>
<td>Words</td>
<td>79%</td>
<td>88%</td>
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<tr>
<td>Stress</td>
<td>88%</td>
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<td>Words</td>
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<tr>
<td></td>
<td>Sentences</td>
<td>20%</td>
<td>60%</td>
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signal. He determined that the internal device was not functioning properly and recommended explantation and reimplantation of a new internal device.

**METHOD**

The cochlear implant team felt that it was important to assure the patient and his family that the second device was functioning normally. Of the several electrophysiological tests discussed by Shallop (1993), our implant team chose averaged electrode voltages (AEVs). See the Appendix for the AEV protocol.

In his normative data study, Shallop reported that AEV amplitude is greatest for the most basal electrodes. He reported that the mean response peak-to-peak amplitudes of the AEVs ranged from about 200 μV in the basal turn of the cochlea to less than 20 μV in the apical turn. The AEV recording reflects the averaged stimulus signal. Figure 1 illustrates the stimulus signal (A), a typical recording from a basal electrode (B), and an inverted recording that we sometimes see as the polarity of the implant electrode reverses due to the turn in the cochlea (C).

On January 19, 1994, the patient returned to surgery. Before explantation of the initial device, the audiologist measured the AEV of each electrode. None of the 20 electrodes measured in BP+1 produced a normal waveform.

![Averaged Electrode Voltages](image)

**Figure 1** Examples of cochlear implant signals. **A**, Electrical waveform generated by MSP. **B**, AEV signal from a basal electrode. **C**, AEV signal from an electrode that produces an inverted polarity.

![Figure 2](image)

**Figure 2** Actual AEV recordings from the defective device for all 20 electrodes. Low numbers represent basal electrodes and high numbers represent apical electrodes.

The surgeon then explanted the failed device and implanted the new internal unit. He obtained a full insertion of active electrodes and three stiffening rings. The audiologist recorded the AEVs of the new device with the flap down but before the surgeon closed the incision. Figure 3 illustrates the AEVs of the second internal device. The basal electrodes (bottom) in
Figure 3 illustrate a large biphasic waveform. There is an expected decrease in amplitude from base to apex. Electrodes 14 to 20 (top) illustrate a phase reversal. Note the broad symmetrical pulse width for most electrodes. Figure 4 illustrates the comparison of both devices along with Shallop's data. The first device falls below the normative range for electrodes 4 to 13, while the second unit is within or beyond the expected range for all electrodes. Based on this information, the implant team reassured the patient and his family that the new unit was functioning properly. Just before the patient left the hospital, the audiologist repeated a few AEV recordings. This allowed the patient to see the waveforms and hear sound with each stimulation. Since the patient was awake and had very low comfort levels with the first device, the audiologist set the stimulation level well below the 126 programming units used in the protocol to protect the patient from overstimulation. Therefore, results of these recordings are not included. He left feeling very reassured.

On March 3, 1994, the patient returned to the Cochlear Implant Rehabilitation Unit for the initial stimulation of his new cochlear implant. The audiologist selected BP+1 as the programming mode. The patient was reluctant to set the C-levels very high (increase the current amplitude) because his first implant was always uncomfortably loud due to a small but usable dynamic range.

The patient tried 15 maps the first day. He did not like the sound quality and reported that it was not any better than it had been with his first unit. However, with the sensitivity set on 3½ to 4, sound was not uncomfortable, and he could understand several statements without speechreading.

When he returned on March 9, 1993, he reported that environmental sounds were quite “normal” and he was able to identify them without difficulty. However, speech was still “raspy” and difficult to understand. During mapping, he reported that electrodes 18 and 16 sounded “raspy.” Both electrodes also had elevated T-levels. They were both turned off. All other electrodes had good tonal quality and each increased in pitch from base to apex. The dynamic range also increased compared to the first day. Speech was clearer without the “odd” and “garbled” sounds.

Three weeks after the initial stimulation of his second implant, he again returned for mapping and testing. As noted in Table 1, the patient did not complete many tests with his first implant because of his inability to separate speech from environmental sounds. He completed all tests using the second unit. Table 1 shows that he passed the highest levels in the Cochlear Corporation’s screening test and the Discrimination After Training Test that measures recognition of suprasegmentals of speech through discrimination of four spondaic words. All test scores except the Glendonald Auditory Screening Procedure scored for words correct demonstrated improvement.

**DISCUSSION**

Fortunately, the occurrence of an internal device failure is extremely rare. When it does occur, it is usually sometime after surgery.
It is often due to trauma. The manufacturer carefully tests each internal device to eliminate defects. Therefore, the possibility of receiving a damaged device is extremely low. However, damage to the electrode array during insertion is a possibility. When the audiologist identifies non-functioning electrodes at the time of surgery, he/she can eliminate them before initial stimulation begins. When a previously functioning device fails, the problem is usually identified quickly. An intermittent problem is more challenging. In both instances, it is helpful to have a baseline record of the electrode output for later comparison. If a patient, especially a child, does not respond to a sound percept, it may be difficult to determine the cause. First, the audiologist tests the external equipment. If all of the external equipment is functioning properly, several other explanations are possible. One is a lack of neural survival. Another is the patient's inability to recognize and respond to the stimulation. It could also be due to a malfunctioning internal device, as in this case.

When a young child does not initially respond to sound, it is critical to rule out any defects in the hardware before expending time and effort on habilitation or rehabilitation with a faulty device. External hardware problems are relatively simple to detect. Internal device failure is more difficult to determine. Equipment needs to be readily available at the implant center to rule out internal device problems and to check device integrity at any time that a change is suspected.

If the internal device is sufficiently defective to warrant removal at the time of surgery, the surgeon should explant it before the patient leaves the operating room (OR). This would eliminate the risk and expense of a second surgery as well as spare the patient the emotional disappointment of not hearing when the cochlear implant is activated. If a few electrodes do not stimulate during AEV testing at our center, perhaps due to damage, we eliminate them from the program before mapping the device of a young child. When programming a device for an adult, we check questionable electrodes and use them if possible.

We suggest taking AEV recordings in surgery after the device is in place and before closing the incision. An additional advantage of taking the recordings in surgery rather than later when the patient is awake is that one does not risk stimulating the individual beyond his or her comfort level. This measurement allows the surgeon to reassure the patient and family that the device is functioning properly. Interoperative AEV recordings provide a baseline for comparison at any time when the integrity of the internal device is in question. If AEV testing indicates the possibility of a defective internal unit, it is imperative to verify that all equipment is functioning properly. The audiologist must rule out radio frequency (RF) contamination and other test equipment problems. If the test equipment functions properly and normal AEV recordings are not obtained, the internal device would be considered defective and explanted at the time of surgery.

Currently, there is no commercial equipment designed specifically to perform AEV testing or to check the integrity of the test equipment. In addition, there are no standardized norms for determining what is normal performance. The audiologist must recognize electrical interference as it can distort the waveform, making it impossible to interpret the integrity.
of a given electrode. Waves smaller than about 10 μV are usually lost in RF artifact. However, if a robust pattern is present with the basal electrodes followed by good waveforms with diminishing amplitude, the audiologist can usually assume that the apical electrodes are functioning as well.

Cochlear Corporation suggests checking the RF signal by running the AEV test using a current level of one programming unit. The resulting wave represents only RF. The audiologist must identify the RF before he/she can accurately read AEV waveforms. If it is large, that is, greater than 10 μV, the test will probably be poor. The RF should not increase as the current increases. Therefore, the stimulus waveform should grow out of the RF as intensity increases.

It is important to understand that removing a device without the manufacturer's recommendation could void the warranty. "Warranty replacement of the internal device is made only after integrity testing is performed by Cochlear Corporation personnel and a recommendation is made to explant. Cochlear Corporation does not make recommendations regarding explantation and device replacement based on evoked potential tests or tests of averaged electrode voltages performed by the implant center personnel" (p. 157).

CONCLUSION

It is in the best interest of the patient to determine at the time of surgery that the internal device is fully functioning and to check its integrity at any time that it is in question. It is most time and cost effective for the implant team, the patient, and the manufacturer to have the implant team do the testing and make the necessary decisions based on the test results if they do the testing accurately. To help facilitate this process, we suggest that the manufacturer work with the implant centers to make the necessary equipment available to perform intraoperative testing. Perhaps the manufacturer could certify implant team personnel. Those individuals could then make decisions about explantation in conjunction with the manufacturer without risk of voiding the device warranty.

Acknowledgment. We gratefully acknowledge Jon Shallop, Ph.D. for providing us with a copy of his software for measuring averaged electrode voltages.

REFERENCES


APPENDIX

Averaged Electrode Voltage Protocol

Stimulus generating system: Dell System 200 computer (IBM compatible)
Dual Processor Interface Unit (DPI), Cochlear Corporation

Electrodes

Type
In OR: Tin surface electrodes produced at the Mayo Clinic, Rochester, MN
Postop: Disposable pregelled, foam-backed electrodes from Medicotest, Ølstykke, Denmark

Placement
Common: Fz
Positive: Anterior to the ipsilateral tragus
Negative: Contralateral mastoid

DPS Parameters

Pulse rate = 200 Hz
Pulse duration = 1000 msec
Interstimulus wait time = 1 msec
Mode = BP+1
Stimulation = current level
Pulse width = 200 μs
Stimulus level = 126 (or less if C level < 126)

Stimulus Averager

Nicolet Compact Auditory Electrodiagnostic System
Nicolet Biomedical Instruments Software
Compact Four EP
Version J.1
Revision 5/27/88
Averaged Electrode Voltages/Peterson et al

Developed by Jon Shallop, Ph.D., Denver Ear Institute, Denver, CO

Average Parameters

Number of sweeps = 200
Time window = 10 msec
Trigger = External
Low-frequency cutoff = 1 Hz
High-frequency cutoff = 10,000 Hz
Notch filter = off
Preamplifier sensitivity = 1000 µV

Electrodes were placed prior to draping the patient. The DPI was connected by cable FUZ033 (Cochlear Corporation) to the “trigger in” on the averager of the Compact Auditory System. The speech processor was connected to the Auxillary Outlet of the DPI by the MSP/DPI extension cable (Cochlear Corporation). A tri-cord cable connected the speech processor to the transmitter. While testing in the OR, the cable and transmitter were placed in a sterile bag and placed on the skin flap over the internal stimulator. The flap was temporarily immobilized with surgical staples.