Journal of Speech and Hearing Research, Volume 35, 1126–1130, October 1992

Long-Term Measures of Electrode Impedance and Auditory Thresholds for the Ineraid Cochlear Implant

Michael F. Dorman
Arizona State University
Tempe

Luke M. Smith
Sinai Samaritan Medical Center
Milwaukee, WI

Korine Dankowski
Smith & Nephew Richards
Memphis, TN

Geary McCandless
James L. Parkin
University of Utah School of Medicine
Salt Lake City

Measures of electrode impedance and of detection thresholds for electrical stimuli were extracted from the records of patients implanted with the Ineraid cochlear prosthesis. An analysis of impedance measures, obtained at 1, 12, 24, and 36 months after surgery, demonstrated (a) a significant decrease in impedance over the first year for electrodes that carried current and (b) significant increases in impedance at 24 and 36 months for electrodes that did not carry current. An analysis of detection thresholds, obtained at the same times as the impedance measures, demonstrated that averaged thresholds for the current-carrying electrodes varied no more than 0.5 dB over the 3-year period. These results support the conclusion that stimulation with the Ineraid device does not produce deleterious changes in the electrodes or in the target neural tissue.

KEY WORDS: cochlear implant, threshold, impedance, long-term

A significant design feature of the Ineraid cochlear implant is a percutaneous pedestal with direct access to six intracochlear electrodes. The pedestal allows electrode impedance and auditory thresholds to be monitored over time. Changes in electrode impedance and/or thresholds can alert investigators to the possibility of changes in the integrity of the electrodes, to changes in the electrode/tissue interface, or to changes in bone, tissue, or neural elements in the region of the electrodes. In this report, we describe changes in electrode impedances and auditory thresholds for patients who have used the Ineraid implant for 3 years.

Animal studies with electrodes of several different designs have demonstrated the possibility of damage to the cochlea and related structures as a function of traumatic insertion of electrodes into the cochlea, foreign body reactions, and chronic electrical stimulation. Damage to the cochlea from insertion trauma has been shown to vary with the nature of the auditory prosthesis (Shepherd, Clark, Black, & Patrick, 1983; Sutton, Miller, & Pfingst, 1980). Damage to the cochlea from chronic stimulation has been shown to vary generally as a function of the charge density of the signal and the duration of stimulation (e.g., Duckert, 1983).

Neoossification and growth of fibrotic material near the electrode are two commonly reported conditions in animals that have received cochlear implants (e.g., Walsh & Leake-Jones, 1982). Degeneration of spiral ganglion cells following traumatic insertion of electrodes and following very high levels of stimulation has also been reported (Leake-Jones, Walsh, & Merzenich, 1981).

Eddington, Dobelle, Brackmann, Mladejousky, and Parkin (1978) and Parkin, Eddington, Orth, and Brackmann (1985) reported threshold and impedance measurements on the first patients fitted with the prototype of the Ineraid electrode system. Eddington et al. found that the auditory detection threshold for the first 2 patients decreased over the first 2 to 3 months following surgery and then remained stable over a period of 2 years. For 1 patient, impedance decreased initially and then

© 1992, American Speech-Language-Hearing Association 0022-4685/92/3505-1126$01.00/0

remained more or less constant over 2 years. For the other patient, impedance rose initially, then fell, and finally remained stable over a 2-year period. Parkin et al. reported that detection thresholds for 2 additional patients remained stable over a period of 5 to 7 years.

One of the patients studied by Eddington et al. (1978) has come to autopsy. Galey (1984) found osteoid extending 10 mm from the round window that encapsulated the two most basal electrodes. These two electrodes were not used for stimulation. The four more apical electrodes, which were used for stimulation, were free of osteoid.

In this report, we present impedance and threshold data obtained over a 3-year period for patients who received the commercial version of the Ineraid cochlear implant. Our aim was to assess whether significant changes occurred in electrode impedance or in threshold for electrodes that carried current and for electrodes that did not carry current.

Method

Subjects

The principal data for this report were drawn from the records of 19 patients. These records contained measures of threshold and impedance for all six intracochlear electrodes at 1, 12, 24, and 36 months after surgery. Additional data were drawn from a pool of 75 patients whose records contained some, but not all, of these measures. The most common omission in the data base for the larger group was data at 36 months after surgery.

Implant Design

The Ineraid prosthesis consists of (a) six monopolar electrodes implanted in the scala tympani with remote reference, (b) a percutaneous pedestal of pyrolytic carbon to which the electrode wires are attached, and (c) a portable speech-processing and electrode stimulation system (Eddington, 1980). The most apical electrode is located about 22 mm from the round window. The electrodes are spaced at 4-mm intervals. The four apical electrodes are activated in most patients. These four electrodes were activated for all of the patients in the main data analyses.

Test Stimulus

The test stimulus for the impedance measure was a continuous train of 500-μs biphasic, square-wave pulses (250 μs/phase) delivered at a rate of 200 pulses per sec and at a current intensity of 20 μA. Impedance was defined as the ratio of peak-to-peak voltage to peak-to-peak current. Patient isolation during testing was achieved by optical isolation devices on both the stimulus generation and monitoring sides of the test equipment. The patient and equipment grounds were separate. Stimulus generation and measurement was by means of custom-built hardware.

The test stimulus for the threshold measure was the stimulus described above. Stimulus amplitude and duration were under the control of the experimenter in the manner of conventional, manual audiometry.

Threshold Test

Thresholds for signal detection were determined for each electrode using a manual threshold-tracking technique that began with a clearly audible stimulus.

Results

Impedance Changes for Months 1–36

Electrode impedance as a function of months postsurgery and electrode number is shown in Figure 1. The impedance values were entered into a repeated measures analysis of variance with electrode number and months postsurgery as factors. The analysis revealed a significant main effect for electrode number [$F(5,108) = 12.28$, $p. < .001$], a significant main effect for months postsurgery [$F(3,324) = 9.04$, $p. < .001$] and a significant interaction of electrode number and months postsurgery [$F(15,324) = 5.92$, $p. < .001$).

Visual inspection of Figure 1 suggested that the impedance of electrodes 1–4 decreased over time. The impedance of electrodes 5 and 6 appeared to increase over time.

A repeated measures ANOVA with electrodes 1–4 and months postsurgery as factors revealed no main effect for electrode number [$F(3,72 = 0.35$, $p. > .05$] but a significant effect for months postsurgery [$F(3,216) = 29.45$, $p. < .001$]. Post tests using Fisher's LSD with alpha at .01 revealed that the impedance at 1 month (*mean* = 13.96 kOhm) differed significantly from impedances at all other times. The impedance values for 12 months (10.10 kOhm), 24 months (10.40 kOhm)), and 36 months (10.81 kOhm) did not differ.

A repeated measures ANOVA with electrodes 5 and 6 and months postsurgery as factors revealed no main effect for electrode number [$F(1,36) = 0.13$, $p. > .05$] but a significant effect for months postsurgery ($F(3,108) = 6.79$, $p. > .05$]. Posttests revealed that the impedance at 1 month (14.86 kOhm) and 12 months (16.66 kOhm) differed significantly from the impedance at 24 months (18.59 kOhm) and 36 months (17.95 kOhm). The impedance at 1 and 12 months did not differ significantly. The impedance at 24 and 36 months also did not differ.

Impedance Changes for Months 1–12

The data reported above indicated that the impedance of electrodes 1–4 decreased significantly over the period 1 month to 12 months. To assess when, during the first 12 months, the decrease occurred, the data base was inspected for patients who had impedance values recorded for 1, 2, 3, 6, 9 and 12 months postsurgery. Because the impedances of electrodes 1–4 did not differ in the analyses reported above, the data base was searched only for values for electrode 1. Forty-one patients were identified. Their data were entered into a repeated measures ANOVA with months postsurgery as the within-subjects factor. The effect of months postsur-

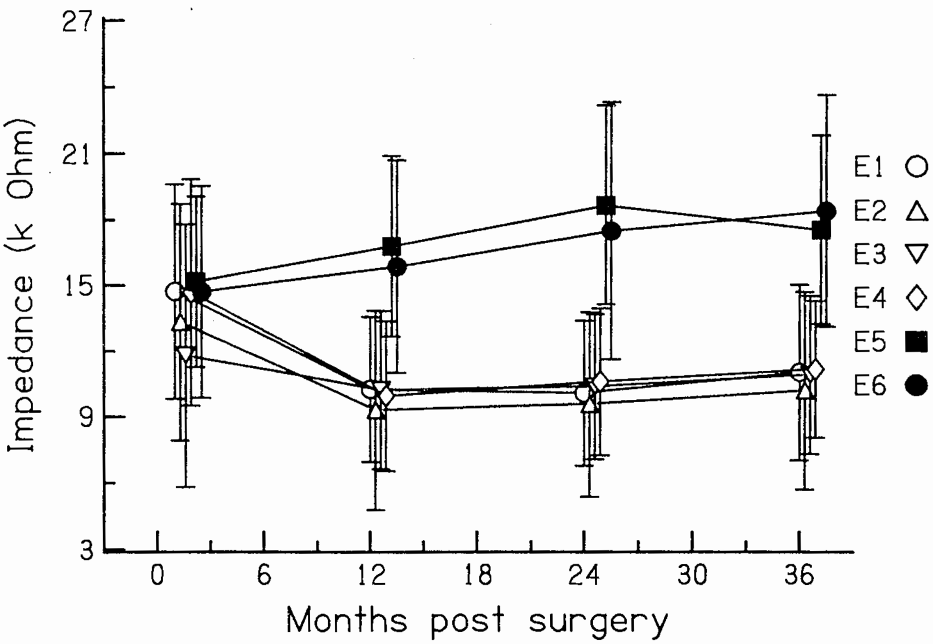

FIGURE 1. Mean impedance values for electrodes 1–6 as a function of months post fitting. Error bars indicate ± one standard deviation. At each test period, the symbols are offset for visual clarity.

gery was significant [$F(5,200) = 8.47$, $p. < .001$]. A posttest using Fisher's LSD with alpha set at .01 revealed that the impedance at 1 month (12.77 kOhm) differed significantly from the impedances at all other times. The impedances at 2 months (11.22 kOhm), 3 months (10.37 kOhm), 6 months (10.54 kOhm), 9 months (9.99 kOhm), and 12 months (10.00 kOhm) did not differ significantly.

Does Cochlear Place or the Presence of Current Determine Impedance Change?

The impedance of the current-carrying electrodes (1–4) decreased over time. The impedance of electrodes 5 and 6, which did not carry current, increased over time. Interpretation of this effect is confounded by the position of the electrodes in the cochlea. The electrodes that carried current were inserted deeper into the cochlea than the electrodes that did not carry current. Because Galey (1984) found osteoid extending 10 mm from the round window in his postmortem examination of an Ineraid patient, it is possible that cochlear place rather than the presence of current accounts for the difference in impedance.

In an attempt to separate these effects, we examined the records of 11 patients who had electrode 5 activated instead of electrode 4. These patients were matched for level of impedance at 1 month postsurgery with 11 patients who did not use electrode 5. Matching was accomplished by searching the data base for patients with a nonstimulated electrode 5 whose 1-month impedance score exactly matched the 1-month impedance score of a patient with stimulated electrode 5. We then examined impedance scores at 1 year for the two groups of patients. The mean score at 1 year for the group with electrode 5 activated was 11.63 kOhm while the mean score for the group that did not have electrode 5 activated was 18.60 kOhm. These scores differed significantly [$t(20) = 4.84$, $p. < .001$). Thus, it appears that an electrode that passes current will have a lower impedance at the end of 1 year than an electrode that does not pass current, regardless of its cochlear position.

Auditory Threshold

The mean thresholds for detection of the biphasic pulse train as a function of electrode number and months postsurgery are shown in Figure 2. The threshold data were entered into a repeated measures ANOVA with electrode number and months postsurgery as factors. The main effects for electrode number [$F(5,108) = 7.02$, $p. < .001$] and months postsurgery [$F(3,324) = 7.85$, $p. < .001$) were significant. The interaction was not significant [$F(15,324 = 0.42$, $p. > .05$]. A posttest using Fisher's LSD with alpha at .01 revealed that the thresholds of electrodes 1–4 differed from the threshold of electrode 6 but not from electrode 5 (when collapsed over months postsurgery). A posttest with months postsurgery collapsed over electrode number revealed a *U*-shaped relationship among threshold scores, that is, thresholds were relatively high at 1 month, fell gradually at 12 and 24 months, and then rose slightly.

The thresholds at 1 month were collected within less than 3 hours of the patients' first experience with electrical stimulation. It is reasonable to suspect that these thresholds were not representative of the patients' thresholds after some experience with stimulation. For that reason we cast the threshold data into another ANOVA with only the thresholds at 12, 24, and 36 months as repeated measures. In this

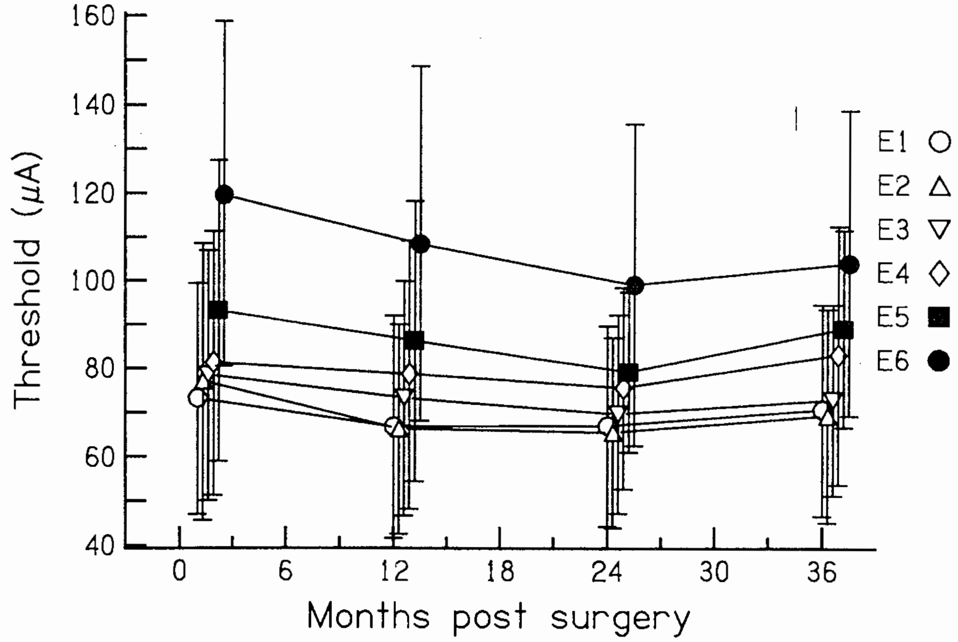

FIGURE 2. Mean threshold values for electrodes 1–6 as a function of months post fitting. Error bars indicate ± one standard deviation. At each test period, the symbols are offset for visual clarity.

analysis, the main effect of months postfitting remained significant [$F(2,216) = 6.45$, $p. < .01$].

To investigate further the changes in threshold, we cast the data for the current-carrying electrodes (1–4) into an ANOVA with scores at 12, 24, and 36 months as repeated measures. Once again the main effect for months postsurgery was significant [$F(2,144) = 4.15$, $p < .02$]. Because the main effect for electrode number was not significant, we collapsed the data over electrode number to determine the magnitude of the change in threshold. The mean score at 12 months postsurgery was 71.3 μA. At 24 months the mean score was 69.4 μA and at 36 months the mean score was 74 μA. The largest difference among means was equivalent to a change of 0.5 dB (re: 1 μA). Thus, the changes in threshold over time, while reliable, were very small.

Discussion

The aim of the research presented here was to assess changes in impedance and threshold over a 3-year period of implant use, and to infer from the results whether use of the Ineraid prosthesis produces deleterious changes in the peripheral auditory system. First, the impedance of current-carrying electrodes did not differ significantly for a 3-year period following the first postsurgical month. Furthermore, our results suggest the absence of deleterious changes, although thresholds increased slightly at 36 months after implantation. The threshold for signal detection remained within 0.5 dB over the period 1 to 3 years postsurgery.

The rapid decrease in impedance of electrodes 1–4 over the first 2 months following surgery may reflect changes at the electrode surface/fluid interface as a function of the initial passage of current. Loeb et al. (1983) have reported a rapid drop in electrode impedance after passing stimulation-level currents "for a few minutes" across electrodes in a saline bath. Loeb et al. (1983) reported a similar result for electrodes in 1 patient over a 3-day period. At present, the nature of the changes at the electrode surface/fluid interface and the mechanism that underlies the changes is unknown.

It is possible that the decrease in impedance is due to processes associated with postsurgical healing. However, the results from a patient who waited 12 weeks following surgery, instead of the usual 4–6 weeks, before receiving a signal processor argues against this hypothesis. This patient evidenced a reduction in electrode impedance over the first month of implant use similar to that of patients whose implant was activated 4–6 weeks following surgery. This outcome makes postsurgical healing an unlikely explanation for the impedance changes over time.

Our finding of stable detection thresholds over a 3-year period is consistent with previous reports of stable thresholds over many years for the initial patients in the Ineraid series (Parkin et al., 1985), and is consistent with reports of stable thresholds for the Vienna single-channel implant (e.g., Hochmair-Desoyer & Burian, 1985) and for the Nucleus multichannel implant (e.g., Waltzman, Cohen, & Shapiro, 1986). However, it is possible that these data underestimate changes in the target neural tissue. Pfingst, Glass, Spelman, and Sutton (1985) have reported for nonhuman primates that thresholds best reflect the range of spiral ganglion survival patterns when very low-frequency (under 100 Hz) sinusoids are used. Because stimuli lower than 100 Hz are rarely used in routine patient testing, it is possible that, over time, changes occur in the target neural tissue but these changes are undetected because of the insensitivity of the test stimulus.

References

Duckert, L. (1983). Morphological damage in the normal and neomycin-perfused guinea pig cochlea following chronic implantation and electrical stimulation: A light, transmission, and scanning electron microscope study. *Laryngoscope, 93,* 841–855.

Eddington, D. (1980). Speech discrimination in deaf subjects with cochlear implants. *Journal of the Acoustical Society of America, 68,* 885–891.

Eddington, D., Dobelle, W., Brackmann, D., Mladejousky, M., & Parkin, J. (1978). Auditory prosthesis research with multiple channel intracochlear stimulation in man. *Annals of Otology, Rhinology, Laryngology, 87* (suppl), 1–39.

Galey, F. R. (1984). Initial observations of a human temporal bone with a multichannel implant. *Acta Otolaryngologica, 411,* 38–44.

Hochmair-Desoyer, I., & Burian, K. (1985). Reimplantation of a molded scala typani electrode: Impact on psychophysical and speech discrimination abilities. *Annals of Otology, Rhinology, Laryngology, 94,* 65–70.

Leake-Jones, P., Walsh, S., & Merzenich, M. (1981). Cochlear pathology following intrachochlear electrical stimulation. *Annals of Otology, Rhinology and Laryngology, 90,* (suppl. 82), 6–8.

Loeb, G., Byers, C., Rebscher, S., Casey, D., Fong, M., Schindler, R., Gray, R., & Merzenich, M. (1983). Design and fabrication of an experimental cochlear prosthesis. *Medical & Biological Engineering & Computing, 21,* 241–254.

Parkin, J., Eddington, D., Orth, J., & Brackmann, D. (1985). Speech recognition with cochlear implants. *Otolaryngology Head Neck Surgery, 93,* 639–645.

Pfingst, B., Glass, I., Spelman, F., & Sutton, D. (1985). Psychophysical studies of cochlear implants in monkey: Clinical implications. In R. A. Schindler & M. M. Merzenich (Eds.), *Cochlear Implants,* Raven Press, pp. 305–321.

Shepherd, R., Clark, G., Black, R., & Patrick, J. (1983). The histopathological effects of chronic electrical stimulation of the cat cochlea. *Journal of Laryngology and Otology, 97,* 331–341.

Sutton, D., Miller, J., & Pfingst, B. (1980). Cochlear histopathology: a comparison of two implant designs for use in monkey scala tympani. *Annals of Otology, Rhinology and Laryngology, 89* (suppl. 66), 15–17.

Walsh, S., & Leake-Jones, P. (1982). Chronic electrical stimulation of auditory nerve in cat: Physiological and histological results. *Hearing Research, 7,* 281–304.

Waltzman, S., Cohen, N., & Shapiro, W. (1986). Long-term effects of cochlear implant usage. *Laryngoscope, 96,* 1083–1087.

Received May 9, 1991
Accepted December 9, 1991

Contact author: Michael F. Dorman, PhD, Department of Speech and Hearing Science, Arizona State University, Tempe, AZ 85287-0102.