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Research Article

Multi-Year Longitudinal Study of Electrode Impedance Stability

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Abstract

Objective: Impedance is an important measure of electrode integrity and guides cochlear implant stimulation parameters. The goal of the current study was to investigate the long-term stability of electrode impedance measurement over a prolonged period of time. The efficacy of cochlear implants over the long-term may be subject to unsuspected electrical deterioration or minor diminished function that may affect programming or performance.

Study Design: Retrospective case review.

Setting: Cochlear implant center in a tertiary care university hospital.

Patients: Thirty-seven adult cochlear implant recipients implanted from 1998 to 2008 with a minimum of 5 years (Range 5 to 14 Years) of device usage. The average age at implantation was 50.6 years (Range: 21.8-82.9).

Main Outcome Measures: Electrode impedance measurement at an early versus late time period for basal, middle and apical loci. Means and standard deviations were calculated. Differences were assessed using t-tests.

Results: Electrode impedances were relatively stable over years in the basal and middle regions. Significant variations were noted in electrode impedance in basal electrodes of the Cochlear device and the Advanced Bionics device.

Conclusions: In this, the longest study of electrode impedance measurement over time, impedances were found to be stable in the basal and middle regions of the array, but noted to decrease over time in the apical aspect. Future studies in larger cohorts are needed to determine if these changes have functional consequences.

Keywords: Cochlear Implant; Impedance Stability

Introduction

The electrode impedance measure is fundamental for revealing information about electrode integrity, current flow, the power consumption of implants, and to give guidance for setting of clinical stimulus levels [1]. An open electrode indicates infinite resistance to current flowing through wires to an electrode; a zero value implies a shorted electrode. Initial impedance increases post operatively but prior to initial stimulation is attributable to new bone growth and fibrous tissue growth around the electrodes. Electrical stimulation prompts a hydride layer to form around the electrode. This additional and uneven increase in the electrode's surface area prompts a corresponding decrease in impedance [2]. The importance of following impedance values is to track significant variations in resistance, as abnormal levels may indicate incipient deterioration of a cochlear implants performance.

Previous longitudinal studies investigated electrode impedances of a Nucleus 24 Cochlear device over a two year period, [3] revealing an initial rise in impedance before stimulation, a decrease in impedance values after stimulation, and stable values in adults thereafter up to a 24 month period. Another longitudinal study examined the electrode impedance in children using a Med-El array over a 3-year period, [4] measuring at intervals of one month, 3 months, 9 months, 1 year, 2 years, and 3 years. An increase in impedance was noted during the first three months for all electrodes, with the mean value decreasing and stabilizing for the apical and middle electrodes after three months; the mean of the impedance values for the basal electrodes remained high at the 1 and 3 year mark.

Several case studies note a manifestation of problems concurrent with rising impedances. In one case, the rate or pulse width of the signal had to be modified to reduce a patient's otalgia, vertigo, and spontaneous nystagmus, in addition to medical treatment of cortisone and antibiotics [5]. The authors further noted several instances of inflammatory events that corresponded to increased impedances, including upper respiratory infections and labyrinthitis. Adjustments to pulse width were made to prevent the cochlear implant from becoming out of compliance with its stated and optimal electrical specifications. However, not all impedance increases were triggered by colds and infections; the increased stimulation rates of newer processors may also contribute to the problem. As impedance increases, the voltage cannot always adequately follow the transitions of the pulsatile stimulation, leading to distortions of the signal and inefficient power consumption. This faster rate further increases impedances by attracting cells to grow on the electrodes' surface asymmetrically. Increasing the pulse width tended to reduce impedance levels, although not for all electrodes.

One study described a series of patients with suspected or confirmed damage to the electrode's insulation and provided a list of possible causes for alterations in impedances: fibrous tissue encapsulation, nonuse of the device, ossification, electrode migration, medication changes, or other medical issues [6]. The concerns were prompted by impedance changes and/or deteriorations in performance. The patients in this group had impedance patterns that were described as a "Slight decrease", "Decrease", "Slight increase", "No change" or "Zigzag" relative to prior findings. In these cases, unaffected electrodes showed a median impedance decrease of 10%; abnormal electrodes had a median decrease of 28%. The researchers stated that insulation damage should be suspected if a change of 25% in impedance were seen over previously stable data.

A retrospective study of the long-term stability of electrical measurements in adult cochlear implant recipients was conducted at Columbia University Medical Center (CUMC), with data derived from paper and electronic records. The aim of this study is to determine 1) whether electrode impedance changes over time and 2) whether electrode impedance changes over time are similar in the apical, middle, and basal areas of the array.

Methods

Participants

Subjects, aged over 18 years and implanted over a 10-year period, were selected for this study from the database of adult cochlear implant patients at CUMC. The included participants were required to have a minimum of 5 years of external device usage. From the initial sample, several individuals were excluded on the basis of insufficient records of electrode impedance. The final sample consisted of 23 subjects (14 Males and 9 Females), two of whom had bilateral cochlear implants; thus, the sample included 25 ears. Data from users of Cochlear and Advanced Bionics (AB) were segregated by manufacturer.

Procedure

A retrospective review of paper and electronic medical records was conducted to extract each subject's "First" measurement and most recent impedance measurement. The first measurement was defined as the closest measurement to the day of stimulation excluding measurements which were made during the first 15 days following stimulation, as this acclimatization period normally may include impedance fluctuations [7]. The stimulation impedance measurement and data within the first month were excluded due to probable initial fluctuations in impedances during an acclimation period.

Data Analysis

Data from each device manufacturer (Cochlear versus AB) were treated in separate analyses. In order to reduce the number of points to be analyzed, data were clustered into "Basal", "Middle" and "Apical" groups, taking the average across electrodes in each group. For the Cochlear data, electrodes 2-4 were defined as basal; electrodes 11-13were defined as middle, while electrodes 19-21were defined as apical. For the AB data, electrodes 13-15 were defined as basal; electrodes 7-9 were defined as middle, and 2-4 were defined as apical. Stable measurements were defined as those which remained within the acceptable range mitigated by the device manufacturer guidelines. If one of the impedance values in a group was not stable (out of Range), we took the average of the other two values. If two of the impedance values in a group were out of range, we took the third value to represent that electrode. Paired t-tests were employed to evaluate the change in impedance from the earliest to the latest measurement.

Results

Characteristics

Characteristics of the study participants are shown in (Table 1). Age at implantation ranged from 24.6 to 82.9 years. Mean age at implantation was similar in Cochlear and AB device users (51.5

vs. 49.8, p=0.806). The sample included 14 male participants and 9 female participants. Eleven participants had a device implanted in their left ear, 10 subjects had a device implanted in their right ear, and 2 subjects had devices implanted in both ears. Etiology was varied, and included autoimmune (n=1), congenital (n=2), Cogan's syndrome (n=1), Meniere's (n=2), brain tumor (n=1), Cogan's syndrome (n=1), head trauma (n=1), hereditary (n=4), ototoxic medication (n=1), Pendred syndrome, possible progressive (n=1), presbycusis (n=1), sudden sensorineural hearing loss (n=1), and unknown (n=6).

	All	**Cochlear**	**Advanced Bionics**
	(n=23)	**(n=13)**	**(n=10)**
Age at implantation in years, Mean (SD)	50.8 (15.6)	51.5 (17.7)	49.8 (13.2)
Age at implantation in years, Range	24.6, 82.9	24.6, 82.9	29.7, 67.9
Sex, N (%)			
Male	14 (60.9)	6 (46.2)	8 (80.0)
Female	9 (39.1)	7 (53.9)	2 (20.0)
Ear			
Left	11 (47.8)	6 (46.2)	5 (50.0)
Right	10 (43.5)	6 (46.2)	4 (40.0)
Both	2 (8.7)	1 (7.7)	1 (10.0)
*Characteristics from the first implantation are used for the bilateral patients.			

Table 1: Characteristics of participants, by device type (Cochlear and Advanced Bionics) (N=23).

Electrode Impedance Changes Over Time

The mean (SD) time between stimulation and the first impedance measurement was 127 (89) days with a range from 18 days to 329 days. The last measurement took place a mean (SD) of 5.8 (1.0) years (minimum 4.6 years, maximum 8.0 years) after stimulation.

The first and last impedance measurements were compared in order to determine stability, by location (apical, middle, and basal) (Figure 1). There was a significant change in impedance at the apical location from a mean (SD) of 7.41 (4.7) to 5.47 (3.7), with an average decrease of -1.94 (95% confidence interval: -3.21, -0.66); p=0.004. Impedance at the middle location did not significantly change between the first and last measurement. The mean (SD) impedance was 7.45 (3.5) at the first measurement and 6.68 (5.3) at the last measurement; average change was -0.66 (95%confidence interval: -2.18, 0.85); p=0.37. Finally, impedance at the basal location also did not significantly change between the first and last measurement. The mean (SD) impedance was 8.95 (4.1) at the first measurement and 8.99 (5.1) at the last measurement; average change was 0.04 (95% confidence interval: -1.95, 2.02); p=0.97.

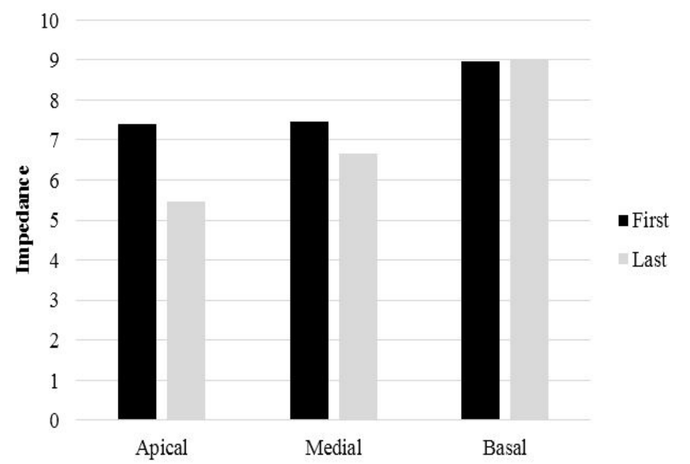

Figure 1: Mean impedance for the first and last measurement at the apical, middle, and basal locations.

		All		Cochlear		Advanced Bionics	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Apical	**First**	7.41	4.65	5.66	1.88	9.63	6.13
	Last	5.47	3.71	4.44	1.61	6.78	5.13
	Change	-1.94*	3.08	-1.22	1.48	-2.85	4.28
Middle	**First**	7.45	3.46	6.07	2.18	9.20	4.06
	Last	6.68	5.28	5.84	3.20	7.60	6.94
	Change	-0.66	3.50	0.20	2.01	-1.61	4.54
Basal	**First**	8.95	4.11	8.03	2.96	10.12	5.14
	Last	8.99	5.14	8.06	3.02	10.17	6.98
	Change	0.04	4.80	0.03	3.63	0.05	6.19

Table 2: Mean (SD) impedance for the first and last measurement (and change) at the apical, middle, and basal locations, stratified by device type.

Discussion

In this study, we investigated the change in electrode impedance in cochlear implant recipients over an extended time interval (Minimum of 5 Years). In general, there was relative stability of impedances over several years. However, significant variations in impedances were noted in apical regions of the electrode depending on the device. Significant reductions in impedances were confined to the apical end in the aggregated sample. The present results contrast with those of [3,4] who reported stabilization of impedances after 3 months of use; a major difference is that the current subjects were followed for much longer (Minimum of 5 Years, as Much as 14 Years) than in other studies (Maximum of 3 Years).

Changes in electrode impedances may be due to a variety of causes and include fibrous tissue encapsulation, nonuse of the device, ossification, electrode migration, medication changes, or other medical issues [6]. Analyzing impedance values is essential to track a cochlear implant's ability to perform effectively. Varying impedances may indicate an evolving situation, related to either physiology or hardware that requires attention. Conditions that should be considered are: potential device failure, insulation damage to the internal device, an underlying autoimmune condition, worsening signal quality, and inefficient power consumption. The clinician, upon noting significant impedance increases or fluctuations should query and/or formally evaluate the CI recipient as to alterations in speech perception, sound quality or health status.

Significant changes in electrode impedance may be a harbinger of damage to the internal device [6]. Reported on a series of patients with suspected or confirmed damage to the electrode's insulation in which the concerns were prompted by impedance changes and/or deteriorations in performance. The patients in this group had impedance patterns that were described as a "Slight decrease", "Decrease", "Slight increase", "No change" or "Zigzag" relative to prior findings. In her cases, unaffected electrodes showed a median impedance decrease of 10%; abnormal electrodes had a median decrease of 28%. [6]. Stated that insulation damage should be suspected if a change of 25% in impedance were seen over previously stable data. In the current report, the changes in electrode impedance fell below this threshold.

Similarly, several other case studies have also noted problems concurrent with rising impedances. In one case, the rate or pulse width of the signal had to be modified to reduce a patient's otalgia, vertigo, and spontaneous nystagmus, in addition to medical treatment of cortisone and antibiotics [5]. The authors further noted several instances of inflammatory events that corresponded to increased impedances, including upper respiratory infections and labyrinthitis. Adjustments to pulse width were made to prevent the cochlear implant from becoming out of compliance with its stated and optimal electrical specifications. However, not all impedance increases were triggered by colds and infections; the increased stimulation rates of newer processors may also contribute to the problem. As impedance increases, the voltage cannot always adequately follow the transitions of the pulsatile stimulation, leading to distortions of the signal and inefficient power consumption. This faster rate further increases impedances by attracting cells to grow on the electrodes' surface asymmetrically. Increasing the pulse width tended to reduce impedance levels, although not for all electrodes.

The current study, while the first to provide significantly longer term stability data regarding electrode impedance measurement than in previous studies is limited by the small cohort size. Studies with large cohorts are needed to replicate the findings as well as to investigate the functional consequences of identified variation in electrode impedance.

Conclusion

It is well established in the literature that best practice for the care of cochlear implant recipients includes continual monitoring of impedance values as changes can indicate a problem with the internal device, nonuse, hormonal changes, etc. Furthermore, changes in impedance values have been documented to affect compliance levels and patient reported sound quality. However, to date, there is limited data about the "Normal" long-term pattern of the change in impedance values past a period of 3 years. Previous studies suggest the typical pattern of change in impedance values to be that after a period of initial fluctuation, impedance values stabilize and remain stable for years. However, when examining data for specific portions of the electrode array over a longer time period, the typical pattern of change in impedance values seems to include continued decrease impedance at the basal portion while other portions of the array remain stable.

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