The impact of electrode type on intraoperative and postoperative telemetry measures in cochlear implant using different surgical technique

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Background
Cochlear implantation (CI) is largely considered successful based on the device's ability to reliably send electrical signals to the auditory nerve fibers. Telemetry (electrode impedance) is a bidirectional communication system. The telemetry system allows us to test the basic functions of a CI and to detect the electrical problems in each electrode.
Aim
The aims of this study were to monitor electrode telemetry at the intraoperative and initial-activation postoperative periods and to correlate the telemetry measures with the type of inserted electrode and surgical technique.
Patients and methods
A retrospective analysis of impedance data from 69 CI surgeries occurring at the Hearing and Speech Institute was conducted. Intraoperative and postoperative impedance values were available in 69 pediatric and adult patients during the first fitting 3 weeks to 1 month postoperatively. The data obtained in this study were divided into four groups depending on the type of implanted electrode and device used. In this research, four types of electrodes (Mid Scala, 1J, Flex 28, and Standard) and two surgical techniques (cochleostomy and round window) were used.
Results
Findings showed that there is a statistically significant difference between intraoperative and postoperative mean average of telemetry measure for 1J and Flex 28 electrodes that increased postoperatively. There was no statistically significant difference between intraoperative and postoperative mean±SD of each of the two electrodes (Mid Scala, 1J, Flex 28, and Standard). Comparison between intraoperative and postoperative average of the four electrodes shows statistically significant difference in intraoperative average. The study also showed that there is no statistical difference between telemetry results when either cochleostomy or round-window approaches were used.

Conclusion
Findings of this research showed increase in postoperative impedance with all types of electrodes, which can be referred to the absence of electrical stimulation prior to initial activation of the device. There is statistically significant difference in intra-operative telemetry average between four types of used electrode.

Keywords:
cochlear implant, electrodes, telemetry

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Introduction

Technological development in cochlear implant (CI) is mainly concerned with gathering objective information that is used to assess the technical condition of the implant over time; it can be an important reference point to guide clinicians in controlling the implant, especially when dealing with children.

CI is largely considered successful based on the device's ability to reliably send electrical signals to the auditory nerve fibers. Device and individual electrode function is often assessed at intraoperative and postoperative intervals as part of clinical management of the patient. A common objective measure used to assess device and electrode function is impedance (a measure of the resistance to current flow).Impedance measures are affected by the electrode–tissue interface, resistivity in the fluid/tissue medium, and resistivity of the electrode contact and lead wires [1].

The exterior communicates with the inside, allowing the system to carry out operational control, detecting failures occurring at the electrodes before, during, and after implantation. The telemetry system allows us to test the basic functions of a CI and to detect the electrical problems in each electrode [short circuit (SC) between electrodes, and open circuits (OC) because of the cable being cut off] [2]. Currently, all CI devices include a telemetry system for checking the operation of the impedance of each electrode in the system and the electrical interaction between them [3].

The electrode impedance is a method of measuring resistance encountered by electricity passing through wires, electrodes, and biological tissue [4]; it is calculated as the ratio of the effective voltage applied to a particular circuit and the actual amount of electrical power intensity absorbed by the circuit. The unit of impedance is the Ω. The electrode impedance does not confirm the electrode placement, nor does it replace the radiographies after the implant [5].

Impedance measures are affected by the electrode–tissue interface, resistivity in the fluid/tissue medium, and resistivity of the electrode contact and lead wires [1]. It is not uncommon to encounter impedance abnormalities such as SC or OC at the intraoperative or postoperative time periods. These abnormalities can negatively affect patient performance with the device and should be identified as soon as possible for proper clinical management. Commercial CI software makes it relatively easy to identify OC and SC. The definitions of OC and SC differ slightly across manufacturers; however, an SC is characterized by low impedance (~1 kΩ or less) and an OC has very high impedance (usually >20–30 kΩ). The prevalence of SC or OC among CI recipients is not well documented [6].Thus, it is not clear as to what percentage of intraoperative abnormal electrode impedances resolve by the time of the initial activation.

Since the introduction of CIs, and the first US Food and Drug Administration approval for clinical use in 1984, efforts continue to try to improve their benefits. Intracochlear lesions and new tissue formation (new bone and fibrous tissue) induced by electrode insertion should be minimized by surgical technique and electrode design.

The first published evaluation of CI electrode insertion trauma was in 1985 [7]. This has led to growing interest in performing ‘soft’ surgery to maintain residual hearing [8].

CI electrode placement into the scala tympani was first described using the round-window (RW) technique [9]. Since then, different approaches have been proposed to improve visualization, ease of electrode insertion, and, more recently, for emphasis on preservation of residual hearing. When performing CI, the surgeon has the options to insert the electrode into the scala tympani through the RW, with or without drilling its edges, or through a cochleostomy adjacent to the RW, based on anatomy and/or surgeon preference.

When RW anatomy is favorable, insertion directly through the RW is assumed to be the least traumatic approach. When the anatomy is less favorable and the patient has no residual hearing, the RW and the area of the hook can be enlarged, allowing good visualization of the scala tympani. Finally, when anatomy requires and residual hearing is present or by surgeon preference, a cochleostomy may be the method of choice, as it involves less drilling and may also be advantageous with particular electrode designs.

Some authors have used the term ‘cochleostomy’ to also designate a RW enlargement, referring to this annular bone removal as a ‘RW margin’ cochleostomy [10]. Others group such a technique with RW insertion rather than cochleostomy [11].

Intracochlear trauma due to a CI includes two kinds of lesions: immediate or initial lesions, which are represented by the trauma caused by the path of the electrode on the intracochlear structures, and delayed lesions, defined as new fibrous tissue or bone formed secondary to this initial trauma [12]. Previous studies have shown great variations in the amount of fibrosis and new bone formation [12–14], but none have focused on the proximal cochlear lesions as a function of the surgical method of insertion.

Aim

The aim of the study were:

(1) Monitoring of electrode telemetry intraoperatively and at initial activation postoperatively.
(2) Correlate the telemetry measures with the type of inserted electrode and surgical technique.

Materials and methods

A retrospective analysis of impedance data from 69 CI surgeries occurring from 2014 to 2015 at the Hearing and Speech institute was conducted. Intraoperative and postoperative impedance values were available in 69 pediatric and adult patients.

The data obtained from 69 patients in this study were divided into the following four groups depending on the type of implanted electrode and device used.

Group 1: This group included 19 (27%) patients implanted with Hifocus 1J electrode (Advanced Bionics, Sylmar, California, USA); approaches included a cochleostomy.

Group 2: This group included 20 (29%) patients implanted with Hifocus Mid Scala electrode (Advanced Bionics); RW approach was used.

Group 3: This group included 11 (16%) patients implanted with Sonata TI100+ titanium implant footprint with Standard electrode (SA; Med-El, Innsbruck, Austria); approaches included a cochleostomy.

Group 4: This group included 19 (28%) patients implanted with Sonata TI100+ titanium implant footprint with Flex 28 electrode (SA; Med-El); RW approach was used.

The mean age of patients was 6 years 7 months (range: 2 years 1 month to 42 years). There were 31 (44.93%) male and 38 (55.07%) female patients; among them, there were seven (10.14%) adults and 62 (89.85%) children.

Patients

Institutional Review Board approval was obtained, and we only enrolled children whose parents consented to participate in the study. This was a prospective nonrandomized study.

Eligibility criteria included the presence of severe to profound sensorineural hearing loss bilaterally, and residual hearing thresholds measured by auditory brainstem response or pure-tone audiometry according to patient age in the clinic. Approval for CI by the multidisciplinary team at the Hearing and Speech Institute Imbaba, Giza, Egypt according to established clinical criteria was obtained.

CI devices from two companies (Advanced Bionics and Med-El) approved by the US Food and Drug Administration were eligible to be included in this study.

The choice of device selection was made solely by the parents, and this decision was made before offering them inclusion into this study.

Intraoperative protocol

Cochlear implant surgeries were performed by four surgeons

After induction by general inhalation anesthesia, preoperative routine antibiotic prophylaxis, currently ceftriaxone, was administered intravenously, with one dose at induction and four further doses given according to our standard protocol for CI. Hospital stay has been reduced to 24 h from days after surgery, which reflects the rapid recovery of these children.

The pinna was reflected anteriorly, and the postauricular area was prepped and draped in a sterile manner.

The surgery for CI was then begun. We first drilled a mastoidectomy with a facial recess approach to the RW. Care was taken not to remove the incudal buttress or contact the incus with the drill. We then drilled the well to countersink the implant body. The wound was thoroughly irrigated, and we changed our gloves and gowns to maximize sterility. The implant was then opened and the body was secured in place within the well.

Next, the opening into the cochlea was made, and a variety of surgical techniques were used; approaches included a cochleostomy positioned inferior and anterior to the RW in 31 (44.93%) cases and RW approach in 38 (55.07%) cases. We drilled a cochleostomy using a Skeeter Microdrill (Xomed-Treace, Jacksonville, Florida, USA) anterior–inferior to the RW [15]. A 1-mm diamond drill bit was used, and care was taken to expose the cochlear endosteum, but not open it, as previously described [16]. For the Med-El device, we did not make a cochleostomy. Instead, we accessed the scala tympani directly through the RW. To completely visualize the circumference of the RW membrane, we used the 1-mm microdrill to remove the superior lip of the RW niche.

We then applied hyaluronic acid (Healon, 10 mg/ml; Advanced Medical Optics, Santa Ana, California, USA) over the planned opening to the cochlea. For the cochleostomy approach, the endosteum was gently splayed opened with a fine straight pick. For the RW approach, the membrane was separated from the otic capsule bone at the anterior–inferior margin first, and then gently pulled superiorly. In either case, careful suctioning technique with a 22-G suction was performed to prevent aspiration of any cochlear perilymph.

Finally, the electrode array was advanced into the scala tympani as gently as possible. A small piece of temporalis fascia was harvested and placed around the electrode at the site of entry into the cochlea. Care was taken so that it did not enter the cochlea, nor contact the stapes or tympanic membrane.

Postoperative radiograph was obtained to confirm the position of the electrode array.

Intraoperative impedances were measured on selected electrodes during closure of the incision and before electrically evoked compound action potential measurements. Postoperative impedance was measured during first fitting 3 weeks to 1 month postoperatively at the beginning of initial activation.

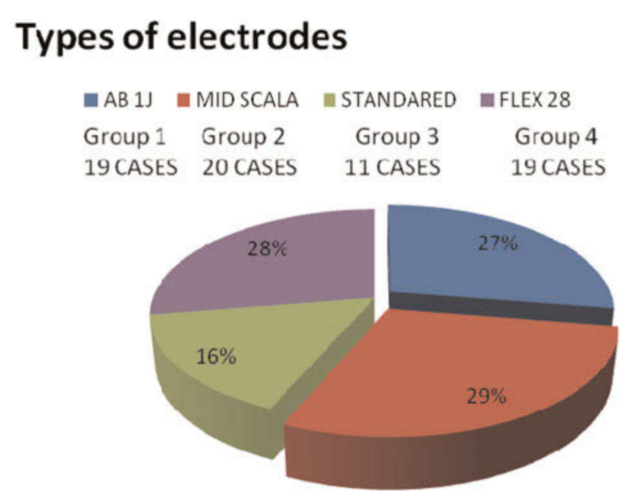
In the event that multiple impedance measures were collected for a single patient at the intraoperative or postoperative intervals, the first measurement for each interval was used for analysis to maintain consistency across recipients and top control for effects of repeated electrode stimulation, which results in lower impedances.

Results

In this research, four types of electrodes (Mid Scala, 1J, Flex 28, and Standard) and two surgical techniques (cochleostomy and RW) were used. Their distribution is shown in Figs 1 and 2, respectively. Figures 3–6 show mean of each active electrode impedance measured in patients intraoperatively and 1 month postoperatively using a different electrode.

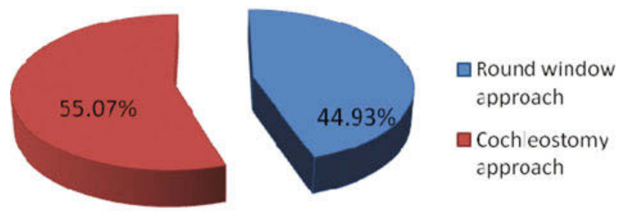
Table 1 shows comparison between intraoperative and postoperative mean average of telemetry measure for all electrodes. Paired sample *t*-test shows statistically significant difference for Hifocus 1J and Flex 28-electrode telemetry that increased postoperatively. This is also shown in Fig. 7, which presents the

Figure 1



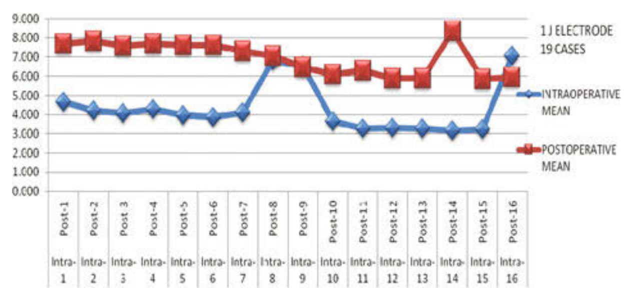
Distribution of the number of patients by category of electrode.

Figure 2



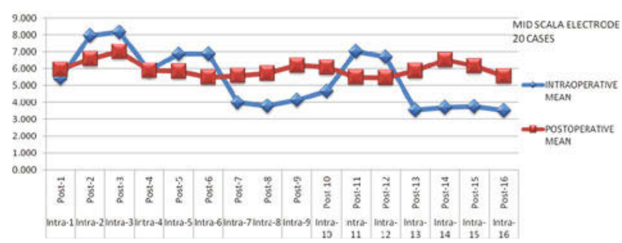
Distribution of the number of patients by category of type of surgical approach.

Figure 3



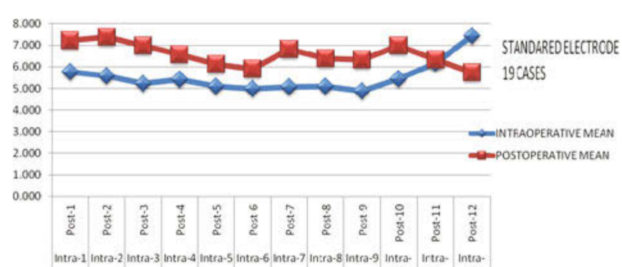
Mean of each active electrode impedance measured in patients intra-operatively and1 month postoperatively using 1J electrode.

Figure 4



Mean of each active electrode impedance measured in patients intraoperatively and 1 month postoperatively using Mid Scala electrode.

Figure 5



Mean of each active electrode impedance measured in patients intraoperatively and1 month postoperatively using standard electrode.

mean of active electrode impedance for intraoperative and postoperative results regarding different types of electrodes used in this study.

Comparison between intraoperative and postoperative mean±SD of each two electrodes (Mid Scala, 1J, Flex 28, and Standard), which is presented in Table 2, shows no statistically significant difference. The results also showed that there is no statistical difference between telemetry results when either cochleostomy or RW approaches were used.

Table 3 shows comparison between intraoperative and postoperative telemetry average of the four electrodes by Kruskal–Wallis test and P less than 0.05, which is statistically significant in intraoperative average.

Discussion

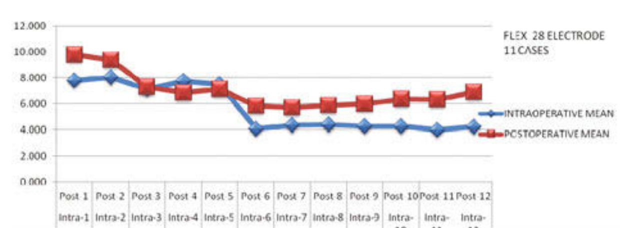
Previous researches of Lin *et al.* [17] and Neault *et al.* [18] have indicated that the incidence of devices having at least one OC or SC postoperatively ranges from ~9 to 19.7%. This matched with our findings in which we have one case with standard Med-El electrode, and one case with Hifocus 1J Advanced Bionics electrode has OC.

In this research, the results showed an increase in postoperative impedance with all types of electrodes. Mid Scala Advanced Bionics electrode shows an increase mainly in mid and high frequencies. Statistically significant difference was found for 1J-electrode and Flex 28-electrode telemetry that increased postoperatively. Findings showed statistically significant difference in intraoperative telemetry average between the four electrodes.

Manolache *et al.* [19] found that there is an increase of impedance on all electrodes in all models of CI because of the absence of the electrical stimulation, during the time between surgery and the device activation, and this is in agreement with our research findings. This can be explained by local postoperative tissue repair phenomena. They also noticed that the trend of increased postoperative impedance is maintained, but even though from 1 to 3 months there are generally decreasing values on most electrodes they remain significantly higher than intraoperative measurements.

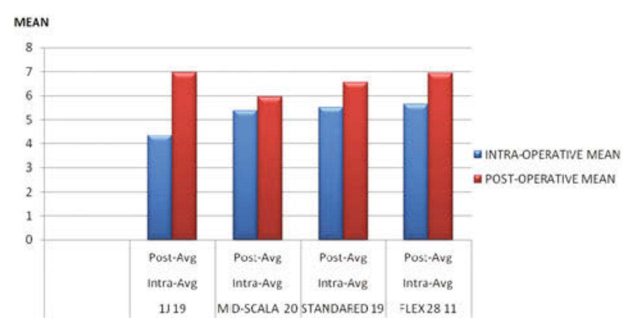
Other literature regarding the incidence of abnormal impedances identified at the time of surgery appears more limited. Schulman [2] identified 8.8% (14/160) of patients having abnormally high intraoperative impedances that all resolved by the initial activation. It was assumed that the abnormalities were caused by air bubbles, which resolved during the time between surgery and activation identified 10% of cochlear devices with abnormal impedance values at the time of surgery; however it was unclear from their report how many of those resolved postoperatively [20]. Finally, Carlson *et al.* [21] noted that 57.9% of postoperative abnormalities were also present

Figure 6



Mean of each active electrode impedance measured in patients intraoperatively and1 month postoperatively using Flex 28 electrode.

Figure 7



Mean of active electrode impedance for intraoperative and postoperative results regarding different types of electrodes used in this study.

Table 1 Comparison between intraoperative and postoperative mean average of telemetry measure for all electrodes

Electrodes	Intraoperative average	Postoperative average	P-value
1J	4.34	6.95	0.001*
Mid Scala	5.37	5.95	0.434
Standard	5.50	6.55	0.756
Flex 28	5.64	6.94	0.002*

Paired sample t-test shows significant difference between intraoperative and postoperative mean average of telemetry measure for 1J and Flex 28 electrodes. *$P<0.05$ is statistically significant.

Table 2 Comparison between intraoperative and postoperative mean±SD of each two electrodes (Mid Scala, 1J, Flex 28, and Standard)

	Mean±SD			Mean±SD	
	Intraoperative	Postoperative		Intraoperative	Postoperative
Mid Scala (round window)	5.373±5.243	5.595±1.800	Flex 28 (round window)	5.645±2.791	6.948±1.209
1J (cochleostomy)	4.346±3.608	6.951±2.141	Standard (cochleostomy)	5.507±2.292	6.557±1.214
Mann–Whitney *U*-test (*P*-value)	0.888	0.062		0.763	0.505

Table 3 Comparison between intraoperative and postoperative telemetry average of the four electrodes by Kruskal–Wallis test

	Intraoperative average	Postoperative average
χ^2	8.247	6.143
P-value	0.041*	0.105

$P<0.05$ is statistically significant in intraoperative average.

intraoperatively, but did not delineate the incidence of SC or OC at specific time intervals. Both of the latter studies reported that some abnormalities resolved from the time of surgery to initial activation, whereas others remained [21].

In our study, no statistical difference was found between telemetry results when either cochleostomy or RW approaches were used. This does not match with the work of Clark *et al.* [22], Kawano *et al.* [23], and Shiroma *et al.* [24], who found that the impact of new bone and fibrosis in the implanted cochlea can include an electrode–tissue impedance, leading to increased electrical stimulus threshold. However, the influence of the approach to the scala tympani on vestibular function still remains unclear [11]. However, this may be because of their long-term study, which studied cases with CI with a mean duration of 8 years and 8 months.

Conclusion

Findings of this research showed an increase in postoperative impedance with all types of electrodes, which can be referred to the absence of the electrical stimulation before initial activation of the device.

There is statistically significant difference in intraoperative telemetry average between the four types of electrodes used.

Recommendation

Monitoring of telemetry measures is valuable in detecting failures occurring at the electrodes intraoperatively and postoperatively that may affect performance of the patient. Overcoming these problems early will achieve good prognosis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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