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Effect of Cochlear Implant Electrode Design on Electrode Impedances and Stimulating Charge (Maximum Comfortable Level)

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Abstract

Introduction: design of cochlear implant electrode arrays plays an important role in the success of the cochlear implant procedure. The objectives of this study are to assess the evolution of electrode impedance and charge of maximum comfortable level and compare those parameters within and between recipients divided into two groups, the first group included 14 recipients (18 ears) who underwent cochlear implant surgery with FLEX24 electrode (MEDEL FLEX24 electrode array) that carry 12 electrode channels to distribute electric stimulation throw 19 intracochlear electrode contacts, whereas the second group included 12 recipients (18 ears) who underwent cochlear implant surgery with FORM24 electrode (MEDEL FORM24 electrode array) that carry 12 electrode channels to distribute electric stimulation throw 24 intracochlear electrode contacts. The Methods used in this retrospective study were applied to the two groups. The electrode impedance values and MCL (maximum comfortable level) were obtained at three-time points, at six months, 12 months, and 24 months after the cochlear implant surgery.

Results: The average electrode impedances were 5.82, 5.61, and 5.34 KΩ, respectively for the first group and 5.44, 5.35, and 5.21 KΩ, respectively for the second group. Thus, the electrode impedance and MCL differences were non statistically significant in both groups. However, the average impedance of the first five electrode channels was a little bit higher in the first group, this can refer to the different design in those five electrode channels compared to other electrode channels.

Conclusion: The average differences of electrode impedances and MCL were non-significant in both groups. However, the electrode design and the maneuvers done during CI surgery can affect the electrode impedance.

Keywords: Electrode Impedance Estimated Model, Wave-Shaped Wires, Minimal Invasive Cochlear Implantation Technique, Flex Electrode, Form Electrode, Single electrode contact, Double electrode contacts.

Abbreviations: CI: Cochlear implant; SSD: Single-Sided Deafness; RF: Radio Frequency; SC: Short-Circuits; CSF: Cerebrospinal Fluid; MCL: Maximum Comfortable Levels; MRI: Magnetic Resonance Imaging

Introduction

Cochlear implant (CI) overview

Cochlear implant surgery is considered the popular surgical treatment for severe to profound sensorineural hearing loss. Cochlear implants are usually recommended solution for pre-lingual under five years old children, for post-lingual adults and children, and it is approved also for Single-Sided Deafness (SSD) patients. The candidate patients who got a cochlear implant within 1 to 2 years of age obtains the best speech outcomes [1]. Conversely, prelingual deafened teenagers and adults are not good candidates for cochlear implantation, as they may use cochlear implant devices for sound detection only then finally, they become non-users. The long period of deafness could let the brain takes the region of auditory sensation at the level of the auditory cortex to be used by other somatosensory inputs [2]. For cochlear implant candidates, the cochlear nerve should exist [3]. The cochlear nerve works as a conductor to transmit the electrical stimulation that is produced as a response to processing and encoding of the incoming acoustic signal to the brainstem then to the auditory cortex. The cochlear implant system consists of two main parts, the internal part, and the external part. The internal part (the implant) consists of a Radio Frequency (RF) receiver coil that provides the implant with electric power emitted from the audio processor coil, the implant receiver coil also gets the encoded data transmitted from the audio processor to the implant, the implant magnet, the stimulator that contains the implant electronics which decoded the data sent from audio processor and convert it into electric stimulation that distributed over intra-cochlear electrode array, reference or ground electrode for mono-polar stimulation, telemetry system to record impedance and nerve response, and the electrode array that inserted into the cochlea through the round window or cochleostomy opening. Electrode array design plays an important role in cochlear implant treatment success factors. The external part (audio processor), the main audio processor components are the control unit which contains the microphones to pick up acoustic waves to be converted and encoded then transmitted to the implant through RF signal, audio processor coil, audio processor coil magnet to fix the audio processor coil over the implant coil through the magnetic attraction between implant magnet and audio processor magnet, coil cable to transmit the data and power from control unit to audio processor coil, and battery pack to provide the audio processor with the electric power. There are lots of accessories that can be used with an audio processor like fine tuner, water wear cover for swimming, different wearing options, mobile applications, and connectivity options.

Telemetry systems

The telemetry system is used to measure electrode impedances values [4], also used to measure auditory nerve responses that are fired as a result of electric stimulating. The electrical impedance of intra-cochlear electrode channels should be recorded as it reflects the implant's functionality and is used also to calculate the maximum current that the implant can deliver to each electrode channel (compliance level). During measuring electrode impedances, a voltage is applied to an electrode channel through fixed current flow (via current source), then the electrode channel impedance can be determined by applying Ohm's low as the ratio of the voltage between the stimulating and reference electrode contact divided by the stimulated current. Some implant systems calculate voltage as a function of time. The Impedance Field Telemetry system (IFT used in MEDEL implants) can provide information about implant functionality by measuring impedance values, the status of electrode channels, integrity of the implant, ground pass impedance, and the coupling efficiency between telemetry coil and implant coil. Impedance values can vary from a few kilo-ohms up to around 22 kilo-ohms. Status of electrode channels have many indicators, (i)OK means the electrode channel impedance is within normal range with no short-circuits founded with one or more electrode channels, (ii) HI or High Impedance, this means that the impedance measured is more than the maximum impedance limit which is around 22 kilo-ohms with the regular stimulating current. (iii) SC- or Short-Circuits, this indicates that there are short-circuits with one or more electrode channels, and (iv) HISC- or High Impedance and Short-Circuits, this indicates a problem with ground path impedance. The IFT can also measure the relation between electrode channels through IFT Voltage Matrix by measuring the voltage at the non-stimulated electrode channels.

FLEX24 Electrode Array

Regarding the FLEX24 electrode array from MEDEL (Figure 1), its length is a 24mm electrode array and is designed for hearing preservation surgeries to save internal cochlea structure. The patients that have residual hearing can use combined Electric Acoustic Stimulation (EAS) [5]. The electrode array will cover less than 1.5 turns of the cochlea and it is inserted slowly into the cochlea to avoid any trauma to the cochlea structure [6-8]. Flex electrode series (from MEDEL) have 19 electrode contacts, the first five channels have single electrode contact for each channel, while the last seven channels have double electrode contacts for each channel. The special design of the first five channels by reducing the number of contacts and number of electrode channel wires led to reducing the electrode insertion force plus slow insertion will ensure that the internal cochlea structure will be saved during electrode insertion. Flex electrode series (from MEDEL) have a marker as a guide for the surgeon to control the direction of electrode contacts to face the cochlea modulus

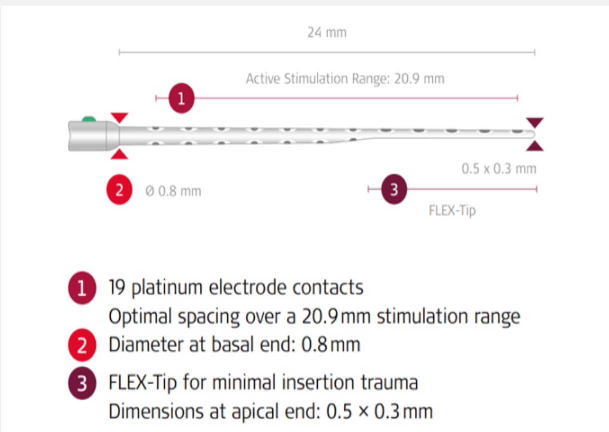

Figure 1: FLEX 24 electrode array. MI1250 synchrony 2.

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FORM24 Electrode Array

The FORM24 electrode array from MEDEL (Figure 2-5) is 24mm long designed for open (no obliteration or ossification) or mal-formed cochlea, especially incomplete partition Type II malformations. FORM24 has 24 electrode contacts, channels have double electrode contacts for each channel. A conical shape stopper at the end of the basal turn (insertion opening) is designed to control the leakage of Cerebrospinal Fluid (CSF) during surgery.

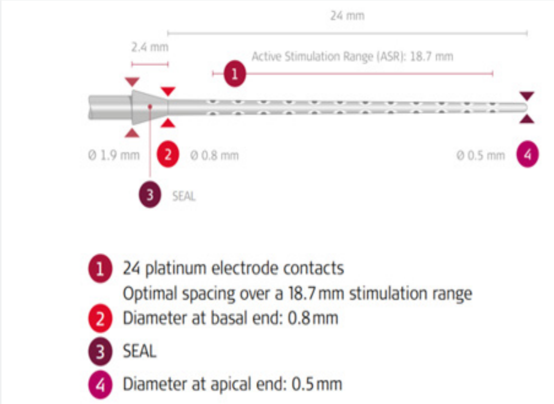

Figure 2: FORM 24 electrode array. MI1250 synchrony 2.

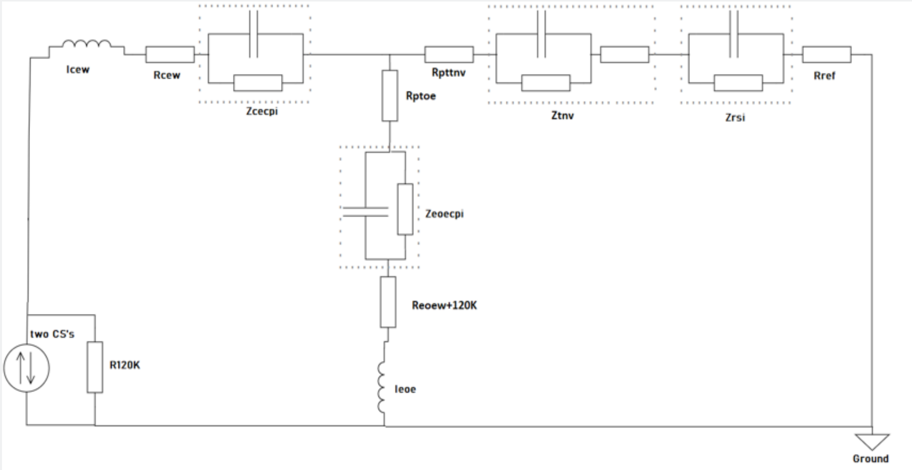

Figure 3: Estimated equivalate circuit model for one stimulating cochlear implant electrode channel (in monopolar stimulation) for single contact electrode channel.

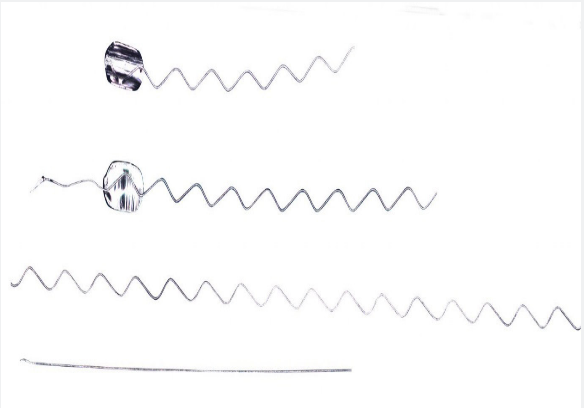

Figure 4a: Wave-shaped electrode wire. The components of an electrode array. From bottom to top: an electrode wire, an electrode wire after the wave shaping, an electrode contact in the middle of an electrode wire, and a contact on the very tip of an electrode wire.

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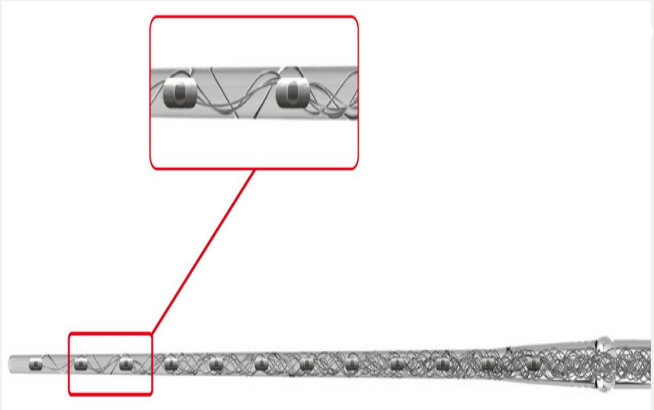

Figure 4b: Wave-shaped electrode wire.

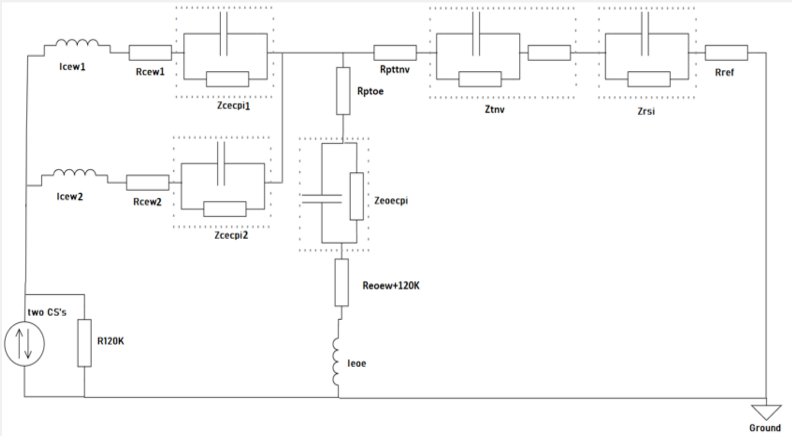

Figure 5: Estimated equivalate circuit model for one stimulating cochlear implant electrode channel (in monopolar stimulation) for double contacts electrode channel.

Modeling of stimulated electrode channel impedance

In general, electrode impedance is a combination of resistance, capacitance, and inductance (as a result of the wave-shaped electrode wires). The impedance value varies between patients as its value indicates the tissue-to-electrode contact interface impedance, the resistance of pre-lymph, and the surrounding environment inside the cochlea [9]. Furthermore, this impedance depends on the frequency of the alternating current (rate of stimulation) applied, which is considered a combination of inductive and charge storage (capacitance) properties. The electrode impedance values are near to becoming stable after 8 weeks from the cochlear implant surgery date [10]. The implant telemetry system uses current sources for stimulation as the current source will insure fixed current flow when the electrode impedance is within normal ranges. The current source provides the stimulating current to electrode contact through electrode channel wire. The current takes two main paths to the ground. The first path to ground is through intracochlear electrode channels. This path takes a small part (around 10%) of current to ground compared to the second path when the integrity and ground path impedance is within normal ranges. The second path is through tissues and nerve fibres, this path takes the bulk of stimulating current to the ground. The stimulating electrical current is delivered through two current sources (for MEDEL CI). One of those current sources delivers the positive phase of stimulating pulse and the other delivers the negative phase of the stimulating pulse. As the electrode wires are waved shaped and the stimulating current is an alternative current (positive and negative), then we can expect self-inductance and mutual-inductance effect [11, 12]. The inductance effect of stimulating electrode channel wire represented in the model as Icew (the inductance due to the electric current passing through the wave-shaped wire of stimulating electrode channel) and Ieoe (inductance due to other electrode channel wires that returns part of stimulating current to ground through it). The electrode channel wire resistance is represented in the model as Rcew (resistance of current stimulated electrode channel wire) and Reoew (the equivalent of other electrode channels wires resistance plus 120K resistors). The electrode channel contact–electrolyte (perilymph) equivalent impedance is represented in the model as Zcecpi (impedance due to stimulated electrode contact -perilymph interface) which is considered as paralleled resistor and capacitor or polarization

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impedance [13,14,4]. Zeoecpi (impedance due to other electrode channel contacts that return part of stimulating current to ground through it), Zrsi is the skin or tissues-reference electrode contact interface. The resistance of electrolyte (perilymph) to stimulating current going to ground through other electrode contacts is represented by Rptoe [13]. The resistance of electrolyte (perilymph) to stimulating current going to ground through tissues and nerve fibers is represented by Rpttnv. The impedance of tissues and nerve fibers is represented by Ztnv [15,16]. The reference electrode contact resistance is represented by Rref. For two wires and two contacts electrode channels, the below model could apply. The difference between the two models is the second wire and contact impedances in double contacts electrode channel.

Materials and Methods

In this retrospective study, a comprehensive review of medical records was performed to identify all patients who underwent CI surgery at a tertiary medical center between 2013 and 2015. The selected 26 patients were classified into two groups. The first group included 14 patients (18 ears) who underwent cochlear implant surgery with FLEX24 electrode (MEDEL FLEX24 electrode array), whereas the second group included 12 patients (18 ears) who underwent cochlear implant surgery with FORM24 electrode (MEDEL FORM24 electrode array). The electrode impedance and maximum comfortable level (MCL) were recorded at six, twelve months, and twenty-four months after the cochlear implant surgery. Both groups were matched for age at implantation, type of implant (MEDEL CONCERTO), and surgical procedure.

The inclusion criteria

The inclusion criteria are the following: normal inner ear anatomy; unilateral or bilateral implantation; implantation performed through the round-window insertion; same length of electrode array; normal intraoperative measurements; fully inserted electrode array confirmed by intra or post-op x-ray.

The exclusion criteria

The exclusion criteria are the following: a post-meningitis or head trauma; re-implantation; high impedance electrode channels even it happened after testing period; impedance increases more than 30% of its value at first time point; intra-op electrode impedances did not consider to avoid possible air bubbles on one electrode contact of the electrode channels that have double contacts.

Cochlear implant procedure

The minimally invasive cochlear implant procedures are done surgically by a specialized neuro-otologist. The procedure starts with a post-auricular incision is about 3 cm. The incision is double skin flaps. Then the posterior-superior flap was raised to create a pocket (Periosteum Pocket) that contain the implant (receiver-stimulator). Mastoidectomy and the posterior tympanotomy approach were used, followed by drilling a bed for implant stimulator and bony channel for electrode lead. Then, the electrode led was recessed in a bony channel drilled for that purpose. The distance between the lower edge of the implant (stimulator) to the nearest edge of mastoidectomy is about 10 to 15 mm. All electrode arrays were inserted through the round-window approach, and the window was sealed using fascia or using an electrode stopper (for form 24 electrode). The surgery was completed by the closure of skin layers with very close sutures. Mastoid radiography (X-ray) was performed to confirm the full insertion of the electrode array.

Audiological and fitting parameters

The fitting parameters are recorded at specific time points. Intra-operative measurements of electrode impedances and Auditory Nerve Response Telemetry (ART MEDEL's MAESTRO software) were performed. At each follow-up session, the impedances of the electrode channels were recorded. Then, Maximum Comfortable Levels (MCL) were measured and recorded. Electrode impedances and maximum comfortable levels were measured and recorded at six (6M), twelve (12M) months, and twenty-four (24M) months after CI surgery. The tested electrode array contained 12 electrode channels, starting from electrode channel number 1 as the most apical electrode channel and 12 as the most basal. In general, the electrode channels were divided into three combinations: the first five electrode channels (electrode channels E1 to E5), the next five electrode channels (electrode channels E6 to E10), and the last seven electrode channels (electrodes E6 and E12).

Statistical analysis

The mean and standard deviation were calculated first to describe the tested parameters of the subjects from both groups. Normality and the differences were tested using GraphPad Prism™ version 8.4.0 (GraphPad Software, La Jolla California, USA). Medical history records were reviewed to identify all patients who underwent CI surgery at a tertiary medical center between 2013 and 2015. The selected 26 patients were classified into two groups. The first group included 14 patients (18 ears) who underwent cochlear implant surgery with FLEX24 electrode (MEDEL FLEX24 electrode array), whereas the second group included 12 patients (18 ears) who underwent cochlear implant surgery with FORM24 electrode (MEDEL FORM24 electrode array).

Results

The first group included 14 subjects (10 unilateral and 4 bilateral; 18 ears) who underwent cochlear implant surgery with FLEX24 electrode (MEDEL FLEX24 electrode array). The second group included 12 subjects (6 unilateral and 6 bilateral; 18 ears) who underwent cochlear implant surgery with the FORM24 electrode (MEDEL FORM24 electrode array). The mean age of implantation of the first group was 3.51 years old (±2.35 years), while that of the second group was 3.15 years old (±2.39 years).

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Analysis of the impedances of the measured electrode channels (average for all electrode channels) in the first group showed an average value of 5.82 KΩ after 6M of surgery. The average value of electrode impedances decreased to 5.63 KΩ at 12M, and the recorded average value was 5.34 KΩ at the final time point (24M). Therefore, the average of electrode impedances value at 24M post-op was 8.3% lower than the values recorded at 6M (Figure 6) shows the average of electrode impedances (average for all electrode channels) in the first group at different time points. The average measured electrode impedances value in the second group was 5.44 KΩ at 6M of the surgery. The average value of electrode impedances decreased to 5.35 KΩ at 12M, and the recorded average electrode impedances value was 5.21 KΩ at the final time point (24M). Therefore, the average electrode impedances value at 24M post-op was 4.2% lower than the values recorded at 6M (Figure 6) shows the average of electrode impedances (average for all electrode channels) in the second group at different time points. The statistical analysis showed non-significant differences between the two groups (P=0.6031 at 6M, P=0.8930 at 12M, and P=0.9974 at 24M). The differences among all time points between the two groups are shown in (Table 1). Furthermore, a comparison of the first five electrode channels between the two groups showed non-significant changes at 6M,12M, and 24M (P=0.8848 at 6M, P=0.7842 at 12M, and P=0.8906 at 24M). The electrode impedances (average of the first five electrode channels) for the first group are a little bit higher at all time points. The differences among all time points between the two groups are shown in (Table 2) (Figure 7) shows the average of electrode impedances (average of the first five electrode channels) in the first group at different time points (Figure 7) shows the average of electrode impedances (average of the first five electrode channels) in the second group at different time points. Furthermore, a comparison of the next five electrode channels (E6:E10) between the two groups showed non-significant changes at 6M, 12M, and 24M (P=0.9634 at 6M, P=0.9995 at 12M, and P=0.8821 at 24M). The electrode impedances (average of the next five electrode channels E6:E10) for the two groups seem to be very closed at all time points. The differences among all time points between the two groups are shown in (Table 3) (Figure 8) shows the average of electrode impedances (average of the next five electrode channels E6:E10) in the first group at different time points. (Figure 8) shows the average of electrode impedances (average of the next five electrode channels E6:E10) in the second group at different time points. Furthermore, a comparison of the last seven electrode channels (E6:E12) between the two groups showed non-significant changes at 6M,12M, and 24M (P=0.9152 at 6M, P=0.9903 at 12M, and P=0.9858 at 24M). The electrode impedances (average of the last seven electrode channels E6:E12) for the two groups seem to be very closed at the second (12M) and last time points (24M), the differences among all time points between the two groups are shown in (Table 4) (Figure 9) shows the average of electrode impedances (average of the last seven electrode channels E6:E12) in the first group at different time points (Figure 9), shows the average of electrode impedances (average of the last seven electrode channels E6:E12) in the second group at different time points. We assessed the variations in MCL values in both groups (Figure 10). The MCL increased gradually in both groups over tested time points. However, this increment in MCL for both groups at each time point was non-significant. Then, we compared the MCL of both groups. The statistical analysis showed non-significant changes between the two groups (P=0.5521 at last time point (24M) when comparing the average MCL of the first five electrode channels in both groups) the average MCL charge in the first group seems to be a little bit lower (Figure 10) and P=0.9761 at last time point(24M) when comparing the average MCL of the last seven electrode channels in both groups (Figure 10).

Table 1: P values of the differences in electrode impedances (average of all electrode impedances) at different time points between the two groups.

Group	Flex 6M	Flex 12M	Flex 24M
Form 6M	0.6031		
Form 12M		0.893	
Form 24M			0.9974

*Indicates a significant difference.

Table 2: P values of the differences in electrode impedances (average of the first five electrode channels) at different time points between the two groups.

Group	Flex 6M	Flex 12M	Flex 24M
Form 6M	0.8808		
Form 12M		0.7842	
Form 24M			0.8906

*Indicates a significant difference.

Table 3: P values of the differences in electrode impedances (average of the next five electrode channels) at different time points between the two groups.

Group	Flex 6M	Flex 12M	Flex 24M
Form 6M	0.9934		
Form 12M		0.9995	
Form 24M			0.8821

*Indicates a significant difference.

Table 4: P values of the differences in electrode impedances (average of the last seven electrode channels) at different time points between the two groups.

Group	Flex 6M	Flex 12M	Flex 24M
Form 6M	0.9152		
Form 12M		0.9903	
Form 24M			0.9858

*Indicates a significant difference.

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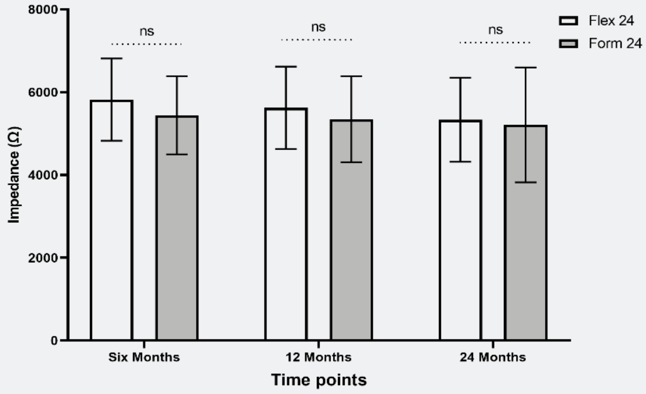

Figure 6: Variations in electrode impedance (average of all electrode channels) values after the CI surgery shows, (a-flex 24) the average electrode impedances (average of all electrode channels) at different time points of the first group subjects (implanted with MEDEL FLEX24 electrode), (b-form 24) the average electrode impedances (average of all electrode channels) at different time points of the second group subjects (implanted with MEDEL FORM24 electrode).

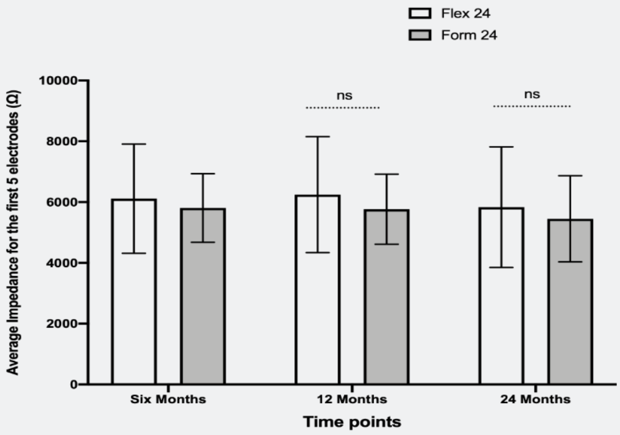

Figure 7: Variations in electrode impedance (average of the first five electrode channels E1:E5) values after the CI surgery shows, (a-flex 24) the average electrode impedances (average of the first five electrode channels E1:E5) at different time points of the first group subjects (implanted with MEDEL FLEX24 electrode), (b-form 24) the average electrode impedances (average of the first five electrode channels E1:E5) at different time points of the second group subjects (implanted with MEDEL FORM24 electrode).

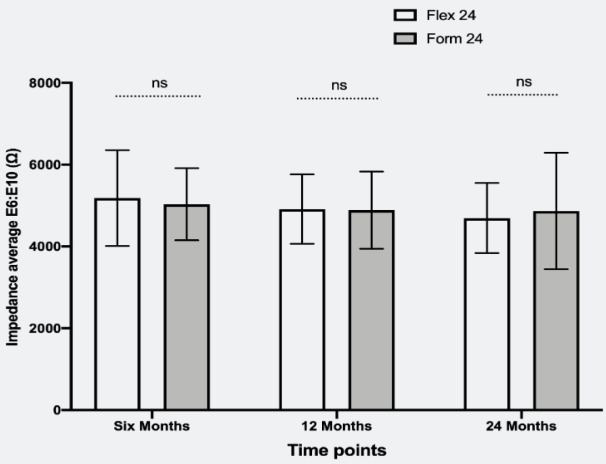

Figure 8: Variations in electrode impedance (average of the next five electrode channels E6:E10) values after the CI surgery shows, (a-flex 24) the average electrode impedances (average of the next five electrode channels E6:E10) at different time points of the first group subjects (implanted with MEDEL FLEX24 electrode), (b-form 24) the average electrode impedances (average of the next five electrode channels E6:E10) at different time points of the second group subjects (implanted with MEDEL FORM24 electrode).

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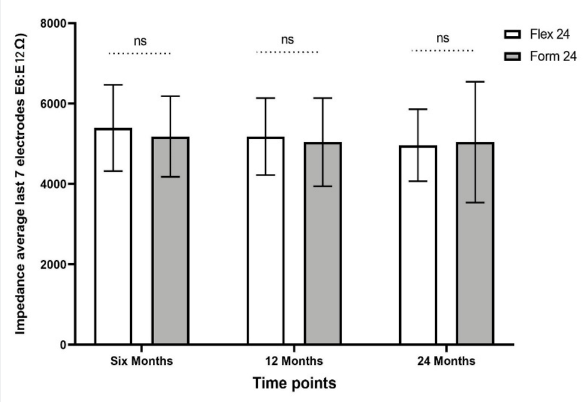

Figure 9: Variations in electrode impedance (average of the last seven electrode channels E6:E12) values after the CI surgery shows, (a-flex 24) the average electrode impedances (average of the last seven electrode channels E6:E12) at different time points of the first group subjects (implanted with MEDEL FLEX24 electrode), (b-form 24) the average electrode impedances (average of the last seven electrode channels E6:E12) at different time points of the second group subjects (implanted with MEDEL FORM24 electrode).

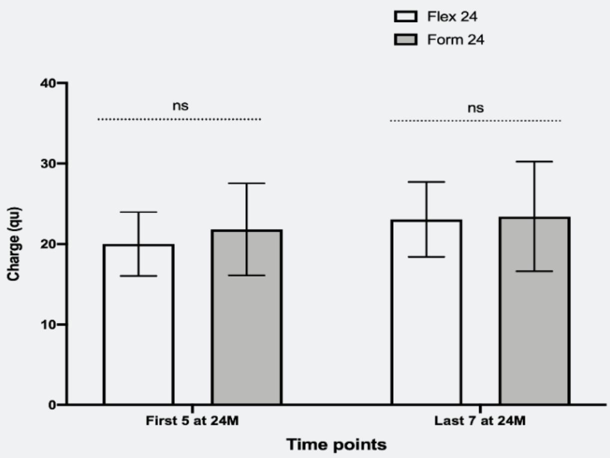

Figure 10: Variations in MCL charge values after the cochlear implant surgery shows, (a-First 5 at 24M) the average MCL charge when comparing the first five electrode channels in both groups) at 24M time point, ,(a-last 7 at 24M)the average MCL charge when comparing the last seven electrode channels in both groups) at 24M time point.

Discussion

The findings of the current study showed the decrease of averages in electrode impedances up to two years after CI surgery in both groups. Multiple factors influence the impedance values after cochlear implant surgery, including air bubbles around the electrode contacts (this happens temporally during and a few hours after the surgery, therefore we excluded the intra-op electrode impedances to avoid the effect of possible air bubbles on electrode impedances), electrode contact-perilymph interface, electrode contact surface area, and the tissue properties around the intra-cochlear electrode contacts [17,18]. This could be explained by the resistance characteristics of fluid (perilymph) and the possible foreign body inside the cochlea that may form tissues surrounding the electrode contacts. The effect of those factors becomes stable over time in most of the CI recipients [19, 4]. In some cases, the intra-cochlea fibrosis becomes more extensive, resulting in a reduction in the performance of cochlear implants leading to an increase of both electrode impedances and MCL [20]. The decrease in electrode impedances in this study could be attributed to the fact that the stimulated electrode contacts have a lower impedance when compared with the unstimulated electrode contacts [17]. Furthermore, the stimulating electrode contacts formed a layer around the electrode contacts leading to an increase in the equivalent surface area of the electrode contacts [21]. However, the changes in electrode impedances between both groups were non-significant. Both groups showed a gradual decrease of electrode impedances after the first time point at 12, and 24 months after CI surgery. The MCL shows non-significant changes after 24M of CI surgery in both groups. The electrode impedances in both groups were higher at the most apical electrode channels than the mid and the basal electrode channels in the cochlea during the study period. Furthermore, the surface area of the first five electrode channels (most apical) in the first group (implanted with MED-EL; Flex24

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electrode) is smaller by 0.01 mm2 than the last seven electrode channels, single electrode channel contact, and single connecting wire which may explain the little bit higher electrode impedances level in the first five electrode channels in the first group. The electrode impedance level is inversely related to the surface area of electrode contacts due to electrolytic reactions with electric stimulation [22, 4]. Moreover, the area of the cross-section of the cochlear duct decreases when moving from the basal segment towards the apical segment [23]. This could explain the higher electrode impedances values at the most apical electrode channels in both groups. Also, when comparing the average impedance for the first five electrode channels at all time points, we will find the average impedances for double contact electrode channels in the second group are lower than the average impedances for single contact electrode channels in the first group, even if it is not significant differences but it follows the fact of the equivalent impedance of parallel impedances will be lower than any of it (equivalent impedance of each branch of the parallel branches) [24]. This may verify the estimated model mentioned before (Figure 11) compares the average impedances of each electrode channel for both groups at 24 months. As introduced in the electrode impedance model estimated in the introduction, the possible effect of inductance and mutual inductance as a result of wave-shaped electrode wires and rate of stimulation (positive and negative stimulating phases) may explain why some cochlear implant users hear clicks or noises while performing Magnetic Resonance Imaging (MRI) scan [25].

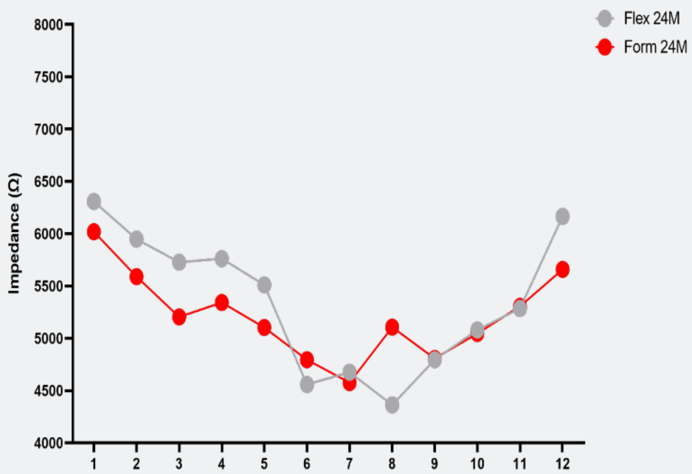

Figure 11: Comparing average impedances of each electrode channel at 24 months after cochlear implant surgery for both groups.

Conclusions

The current study showed a decrease in electrode impedances over time in the two groups. There are non-significant changes between the first 5 electrode channel impedances in both groups even it seems to be a little bit higher for the first group, this is back to the single wire that is connected to a single contact in this group. The rest of the electrode channels (E6 to E12) almost show closed averages at all time points. In addition, the MCL in the two groups has a non-significant difference even if the first five channels seem to be a little bit lower in the first group, while the rest of the electrodes (E6 to E12) almost shows the same averages at 24 months.

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