Long-Term Impedance Trend in Cochlear Implant Users with Genetically Determined Congenital Profound Hearing Loss

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Abstract

Background Impedance is a basic parameter registered at any cochlear implant (CI) fitting section. It is useful in monitoring electrode functioning and the status of the surrounding anatomical structures.

Purpose The main aim of this study is to evaluate the 5-year impedance-value trend in patients affected by congenital genetically determined profound hearing loss implanted with Cochlear Nucleus devices.

Research Design Observational, retrospective, monocentric study.

Study Sample Twenty-seven consecutive patients (9 females: 12.0 ± 7.6 years old; range: 4.2–40.4) with genetic diagnosis of GJB2 mutation causing congenital profound hearing loss who underwent cochlear implantation from 2010 to 2020 with good auditory benefit.

Intervention Impedance values of the CIs were obtained from the CIs' programming software that registers those parameters for each follow-up section of each patient.

Data Collection and Analysis Impedance values were measured over time (activation, 6, 12, 24, and 60 months after cochlear implantation), for each of the 22 electrodes, in common ground, monopolar 1, monopolar 2, and monopolar $1+2$ stimulation modes.

Results A significant variation was found between CI activation and 6-month follow-up. This difference was found for each of the 22 electrodes. Electrodes 1 to 4 showed higher impedance values compared with all other electrodes in each time interval. Repeated-measures analysis of variance ruled out significant variations in impedance values from 6-month to 5-year follow-up.

Conclusions Impedance values were extremely stable after activation, at least for the first 5 years. In these cases, even minimal impedance variations should be carefully evaluated for their possible implications on hearing performance.

Keywords
- ► impedance
- ► cochlear implants
- ► telemetry
- ► hearing loss

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Cochlear implantation is now a widely available technology used to rehabilitate significant hearing loss in patients presenting poor benefit with hearing aids, particularly in

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regard to speech intelligibility.[1] The most frequent cause of genetic hearing loss is mutations at the Connexin GJB2 gene,[2] responsible for the codification of a gap-junction protein that is essential for the physiological function of supporting cells in the cochlea.[3] This microscopic structural damage is frequently related to normal macroscopic anatomy of the inner ear, without signs of progressive ossification or fibrosis, such as in meningitis or otosclerosis, making these patients the ideal candidates for early surgical intervention. Patients affected by congenital profound hearing loss undergo (unilateral or bilateral) cochlear implantation around the first year of life with minimal surgical risk, good auditory outcome, and good development of communicative skills.[1] These patients are expected to be cochlear implant (CI) users for decades and, while optimal fitting is frequently obtained within the first year after surgery, they should undergo regular testing to check the status of the device.

CI status can be checked by using different types of objective measures; among them, impedance telemetry has a crucial role.[4] Impedance is defined as the measure of opposition to electrical current flow through an electrode lead and across an electrode contact.[4] It is given by the vector sum of resistance and reactance components; although the factors that might influence impedance values are still not completely understood, the role of the physical properties of the electrode lead and contact and of the medium surrounding them seem to be extremely important.[4–8] Consequently, it can give information about the function of the electrode contacts, and it is a crucial parameter for the implant fitting, as it is used to calculate the compliance. In addition, impedance of electrode contacts correlates strongly with the current levels used for CI fitting.[9] The test lasts a few seconds, and it is harmless. Some patients might perceive an extremely slight auditory stimulus during the impedance telemetry.

Abnormal impedance levels are classified as open circuit (OC) for extremely high values and short circuit (SC) for extremely low values.[10] A particular case is the partial SC that is a specific pattern of high–low sequence of impedance values that needs specific attention and strict follow-up of the patient.[11,12] These abnormalities should raise clinicians' attention because they may be a sign of CI dysfunction. Also, in-range variations might be of interest as they might be precocious signs of electrode dysfunction or inflammatory processes within the cochlea, progressive fibrosis/ossification, or fluctuations of the array's position.[4,5,13] Early identification of these anomalies is crucial to minimize the impact on the hearing performance.[10] In some cases, the identification of major problems affecting the CI functioning might also lead to explant of the device. For all these reasons, it is recommended to evaluate impedance telemetry during cochlear implantation and in each programming session.[4]

Very few studies are available in medical literature describing the trend of impedance values over time for the Cochlear Nucleus devices.[5,13–17] All studies had the limitation to be conducted in heterogeneous populations in terms of hearing loss cause, including etiologies characterized by progressive ossification processes such as meningitis or otosclerosis. Consequently, it is still unknown if impedance trend may or may not be influenced by the cause of the hearing loss. In addition, in most studies the impedance-value trend was investigated in a short period of time.[14–16] To date, only two studies[13,18] considered a 2-year post cochlear implantation follow-up period, and only one[13] considered a 3-year period.

The present retrospective monocentric study has been conducted on a cohort of patients affected by genetically determined congenital hearing loss who underwent cochlear implantation with Cochlear Nucleus devices. The primary endpoint of the study was to describe the trend of CI impedance values in the present cohort at the 2-year follow-up. The secondary endpoint was to evaluate the trend in a 5-year span considering a subgroup of the cohort. The assessment of these trends should be considered a valuable tool that could be further used for the systematic comparison with impedance trends of other implanted patients affected by different disorders.

Materials and Methods

Type of Study

This is an observational retrospective monocentric study. Data were analyzed in accordance with Italian privacy and data laws (D. Lgs 196/03).

Sample of the Study

The cohort of the study is composed of 27 consecutive patients who underwent CI from 2010 to 2020 at the Azienda Ospedale - Università Padova (University of Padova, Italy). All patients underwent cochlear implantation with Cochlear Nucleus (Cochlear Ltd, Macquarie, NSW, Australia) devices. The type of implant was CI532 in 6 patients, CI512 in 10, and CI24RE(CA) in 12. For all patients, the chosen array was perimodiolar half-banded, with 22 electrodes. The mean age of the patients was 12.0 ± 7.6 years; range, 4.2–40.4 (18 males and 9 females); and median age 10.6 years.

All patients had genetic testing consistent with Connexin 26 (GJB2) mutation causing congenital profound hearing loss. The cochlear implantation was performed with the same surgical procedure (mastoidectomy with posterior tympanotomy and round window insertion) performed by the same surgeon, with full insertion of the array. All patients were considered full-time users (more than 10 hours/day checked by means of data logging) with optimal performance (pure-tone audiometry under 30 dB HL at tested frequencies of 250–500–1,000–2,000–4,000–6,000 Hz).

Impedance Values Measurements

Impedance measurement data at 5 years after implantation were available for 16 patients (mean age 13.4 ± 8.3 years, range 7.8–40.4, median age 11.5 years).

Impedance values were measured over time (at activation, 6, 12, 24, and 60 months after cochlear implantation), for each of the 22 electrodes.

In Cochlear Nucleus devices, impedance is tested at the end of the first phase of the single biphasic pulse. During the

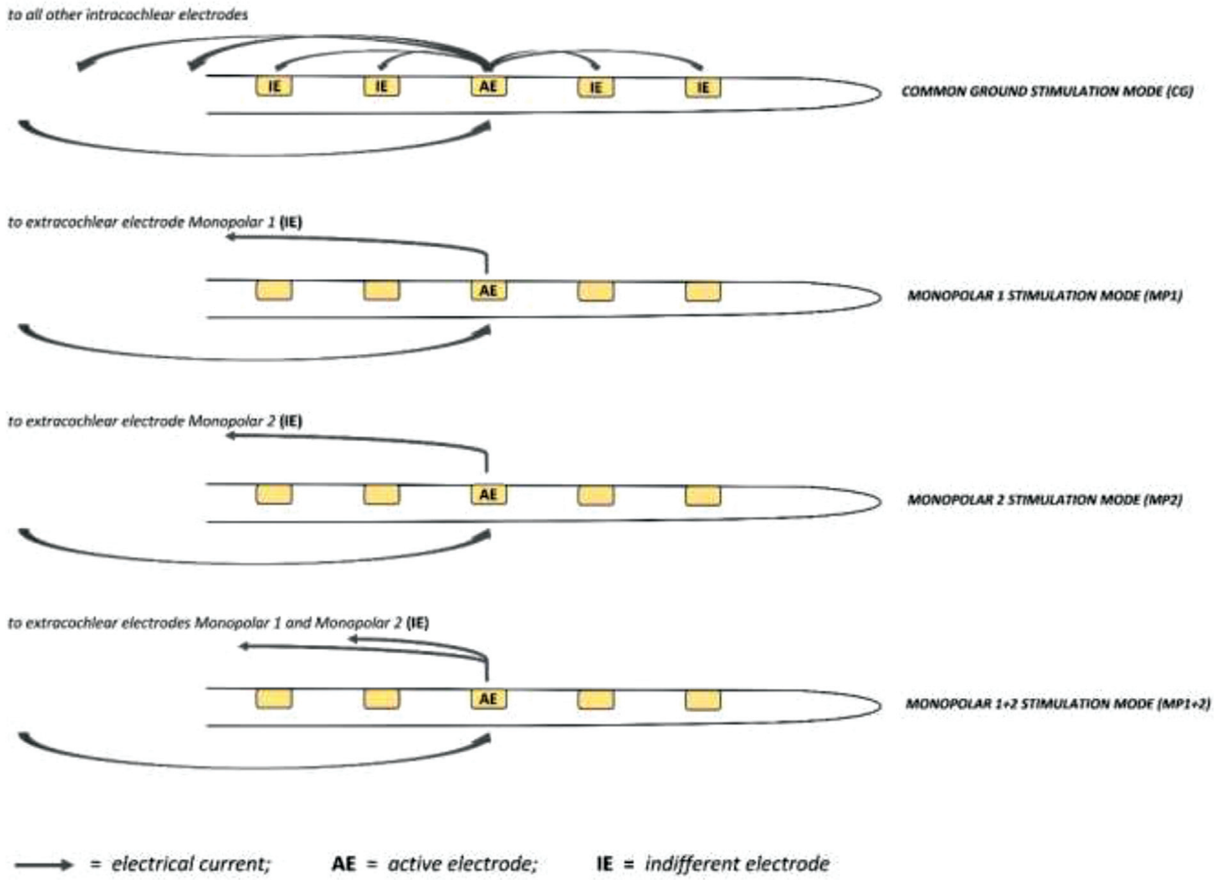

Fig. 1 Schematic representation of the coupling modes used to measure impedance levels for each electrode in Cochlear Nucleus devices.

measurement, the software stimulates each electrode at 80 Current Levels in postoperative and intraoperative testing, using a pulse width of 25 µs.[19] In Custom Sound/Custom Sound EP clinical software, impedance telemetry is measured in four coupling modes or configurations: common ground (CG), monopolar 1 (MP1), monopolar 2 (MP2), and monopolar 1 + 2 (MP1 + 2). In CG stimulation, current flows between the active electrode and all the other electrodes on the array, which are connected together electronically to form a single indifferent or reference electrode. In monopolar (MP) mode, the active electrode is inside the cochlea, and the indifferent electrode is outside the cochlea. There are three MP configurations. In MP1 mode, current flows between the active intracochlear electrode and the extracochlear electrode MP1 (located at the tip of a separate lead and placed in the temporal muscle). In MP2 mode, current flows between the active intracochlear electrode and the extracochlear electrode MP2 (located on the internal receiver/stimulator case). In MP1 + 2 mode, current flows between the active intracochlear electrode and the extracochlear electrodes (MP1 and MP2) shorted together. In general, the pattern of impedance values for each electrode is expected to be similar for all the four testing configurations.[4–20] See ►**Fig. 1** for a schematic explanation of the different coupling modes. Valid impedance values range from 0.565 to 30 kΩ for half-banded arrays, and from 0.565 to 20 kΩ for full-banded arrays.[5]

Statistical Analysis

Repeated-measures analysis of variance (ANOVA) was applied to the data, and the main effects (time and electrodes) and interaction effects were evaluated using the Greenhouse–Geisser method.

It was decided to consider a more robust statistical method to correct for violating the assumption of sphericity with repeated-measures ANOVA.

Significance level was set at $p < 0.05$.

All analyses were performed using the Statistical Package for Social Sciences, version 12.0.

Results

Mean impedance values and standard deviations measured in CG are shown in ►**Table 1**.

Statistical analysis for repeated measures showed a significant time-linked variation (F [1.786] = 5.747, $p = 0.01$) regarding the analysis on CG data available up to 24-month follow-up. This difference, as can be seen in ►**Fig. 2**, is due to activation-time data. As a matter of fact, the same analysis, considering only 6, 12, and 24 months of follow-up controls, showed no significant effect of time factor (F [1.658] = 1.383, $p = 0.3$) while statistically significant variation was found between CI activation and 6-month follow-up (F [1.000] = 8.012, $p = 0.009$).

Table 1 Electrode impedance values in kΩ, measured in common ground modality for each interval time

	Activation ($n = 27$)	6 months ($n = 27$)	12 months ($n = 27$)	24 months ($n = 27$)	5 years ($n = 16$)
Electrode	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
1	11.13 ± 4.75	10.21 ± 2.68	10.40 ± 2.79	10.07 ± 2.98	11.23 ± 3.69
2	10.67 ± 4.10	9.57 ± 2.39	9.43 ± 2.43	9.49 ± 2.44	10.19 ± 3.53
3	10.17 ± 3.19	9.44 ± 2.23	9.54 ± 2.45	9.22 ± 2.73	10.06 ± 3.72
4	9.92 ± 3.3	9.11 ± 2.43	9.05 ± 2.30	8.92 ± 2.65	9.33 ± 3.87
5	9.32 ± 3.65	8.24 ± 2.10	8.28 ± 2.06	7.75 ± 2.68	8.92 ± 3.54
6	9.48 ± 3.23	8.05 ± 2.45	7.97 ± 2.34	8.01 ± 2.72	9.00 ± 3.87
7	9.50 ± 3.41	7.78 ± 2.28	7.72 ± 2.27	7.67 ± 2.61	8.80 ± 3.62
8	9.26 ± 3.23	7.69 ± 2.19	7.91 ± 2.33	7.45 ± 2.79	9.04 ± 3.80
9	8.85 ± 3.66	7.23 ± 2.56	7.71 ± 2.36	7.18 ± 2.75	8.10 ± 3.98
10	8.82 ± 3.84	7.71 ± 2.22	7.80 ± 2.45	7.50 ± 2.71	8.14 ± 2.86
11	9.08 ± 3.54	7.77 ± 2.09	7.99 ± 2.54	7.52 ± 2.74	8.74 ± 3.61
12	9.05 ± 3.48	7.74 ± 2.32	7.74 ± 2.29	7.67 ± 2.78	8.09 ± 3.08
13	9.40 ± 3.89	7.99 ± 2.39	8.01 ± 2.17	7.63 ± 2.54	8.34 ± 2.89
14	9.38 ± 3.72	7.84 ± 2.39	8.22 ± 2.55	8.08 ± 3.00	8.72 ± 3.38
15	9.39 ± 4.19	8.03 ± 2.40	7.93 ± 1.86	7.70 ± 2.55	8.51 ± 3.39
16	9.16 ± 3.78	7.59 ± 1.81	7.82 ± 1.91	7.54 ± 2.55	8.11 ± 3.28
17	9.07 ± 3.72	7.77 ± 1.97	7.70 ± 1.96	7.51 ± 2.30	7.82 ± 3.08
18	9.36 ± 3.67	8.03 ± 1.79	8.15 ± 2.29	7.72 ± 2.29	7.84 ± 2.82
19	9.56 ± 3.84	7.94 ± 1.27	7.66 ± 1.49	7.59 ± 1.86	7.97 ± 2.88
20	9.06 ± 4.33	7.14 ± 1.36	7.09 ± 1.55	6.97 ± 1..66	7.51 ± 3.33
21	9.45 ± 4.22	7.41 ± 1.66	7.24 ± 1.77	7.04 ± 1.99	7.17 ± 2.95
22	10.18 ± 3.96	8.09 ± 2.32	8.26 ± 2.06	7.72 ± 2.22	7.87 ± 3.64

Abbreviation: SD, standard deviation.

A significant main effect of electrodes was also detected from ANOVA analysis (F [5.758] = 7.881, $p = 0.001$).

Additionally, a post-hoc analysis with the Tukey method was performed. A comparison between the average of the mean impedance values from electrode number 5 to electrode number 22 and the mean impedance values of electrodes 1, 2, 3, and 4, for each follow-up, were performed. No significant difference was found with regard to the activation follow-up (F [4] = 0.9, $p = 0.5$), while significant differences were observed for the other follow-ups (6 months: (F [4] = 4.151, $p = 0.003$); 12 months: (F [4] = 4.162, $p = 0.003$); 24 months: (F [4] = 2.898, $p = 0.025$).

Multiple comparisons, except for the activation follow-up, also show significant differences (p-value ranging from 0.001 to 0.013) between the mean impedance values from number 5 to number 22 and the other four (1, 2, 3, and 4), while no difference was observed between the latter four electrodes (all p-value greater than 0.05 for each comparison).

Electrodes 1, 2, 3, and 4 (which are located in the basal cochlear region, next to the round window) were found to have higher impedance values compared with all other electrodes, in each time interval (see ►**Fig. 3**).

In ►**Fig. 3**, it can also be observed that all 22 electrodes followed the same trend over time. Instead, no significant interaction effect was found between electrode and time interval (F [8.960] = 0.988, $p = 0.45$). Comparable results were obtained from the analysis assessed up to 5 years of follow-up (►**Figs. 4** and **5**). Finally, very similar results have been also found in MP1, MP2, and MP1 + 2 test modalities.

A comparison between all four test modalities has also been performed, and the CG mean impedance values across all electrodes were lower than the other modalities in all analyzed follow-ups, while impedance levels were found to be higher in MP1 modality. The paired sample t-test, in particular, showed statistically significant differences between CG and the other modalities (all p-values less than 0.005). To note, the difference is never greater than 2 kΩ.

The other plots related to all repeated-measures ANOVA are available in **Supplementary Material**.

Discussion

The present study analyzed the impedance values over time in a sample of CI users. The results highlighted the long-term stability of these values in a 5-year span, including follow-up recordings at activation, 6-month, and 1-, 2-, and 5-year post-CI switch on. These data were observed retrospectively in a

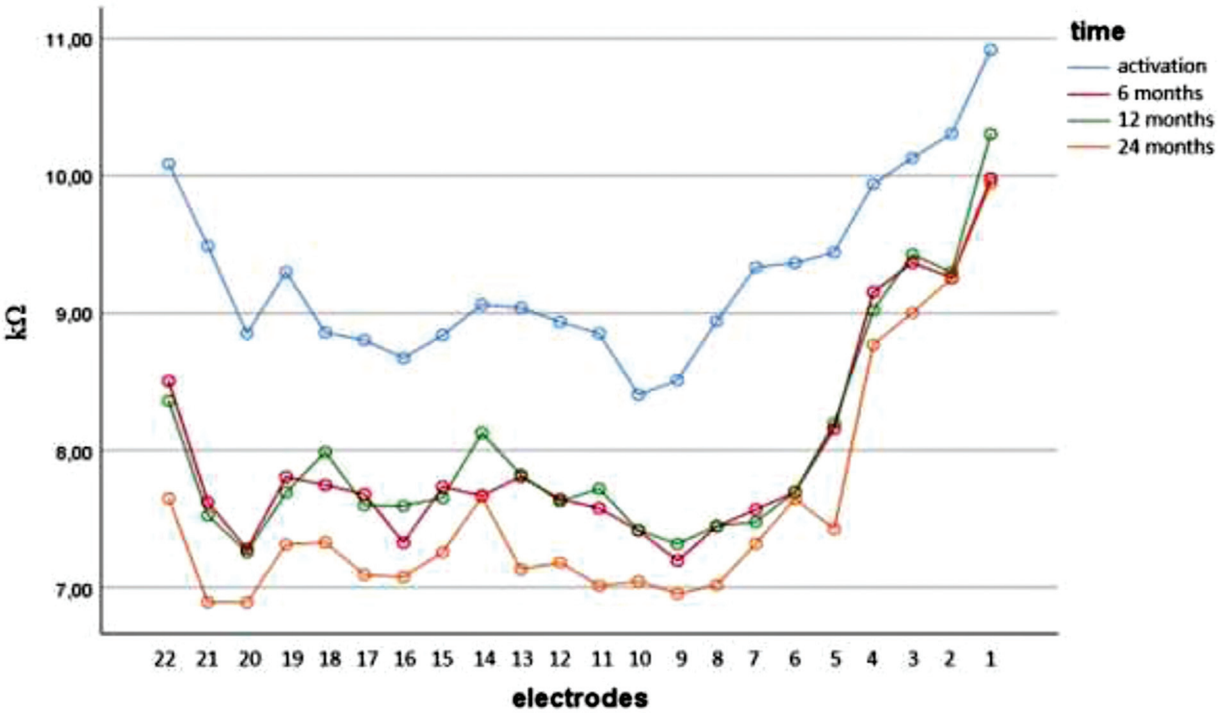

Fig. 2 Impedance-estimated marginal means differentiated according to time intervals (activation, 6, 12, and 24 months) and related to all 22 electrodes—common ground values.

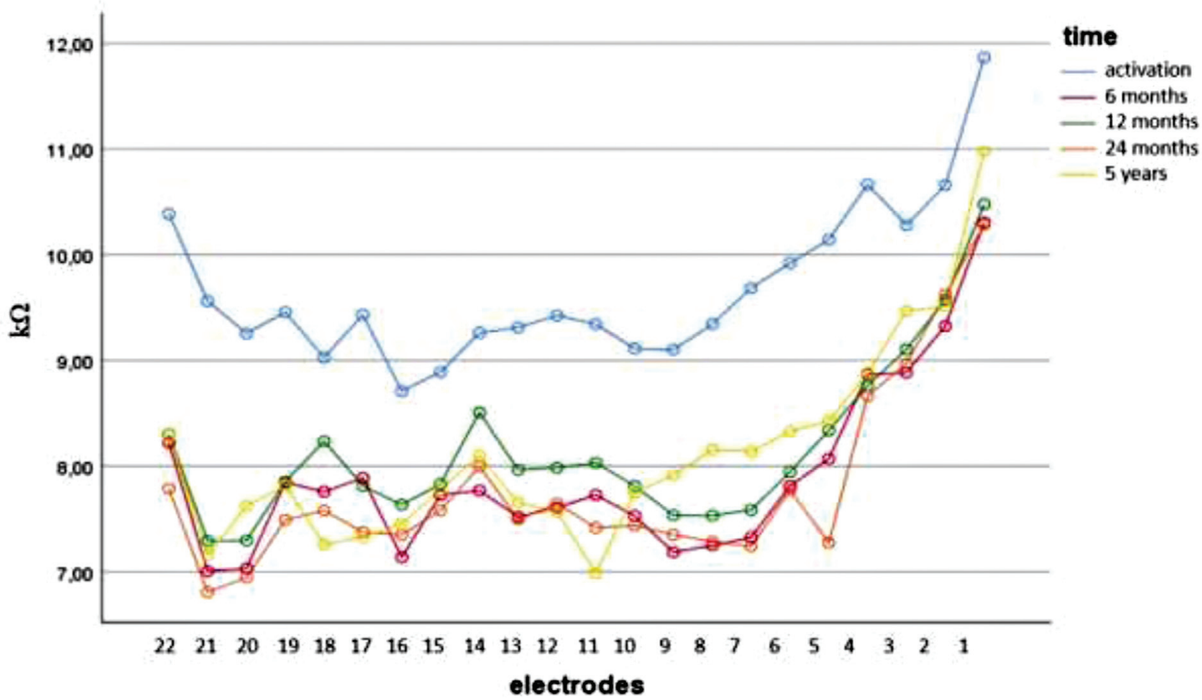

Fig. 3 Impedance-estimated marginal means differentiated according to time intervals (activation, 6, 12, and 24 months and 5 years) and related to all 22 electrodes—common ground values.

cohort of patients all affected by congenital profound hearing loss with genetically diagnosed GJB2 mutation. All patients were operated by the same surgeon with the same surgical technique. All patients were implanted with Cochlear devices, all with a perimodiolar Contour Advance electrode.

Impedance telemetry is considered an unskippable test that should always be performed in CI users' follow-up controls at the beginning of every programming session.[4] Being a harmless and extremely rapid test, which requires no patient collaboration, it is useful both in the intrasurgical testing

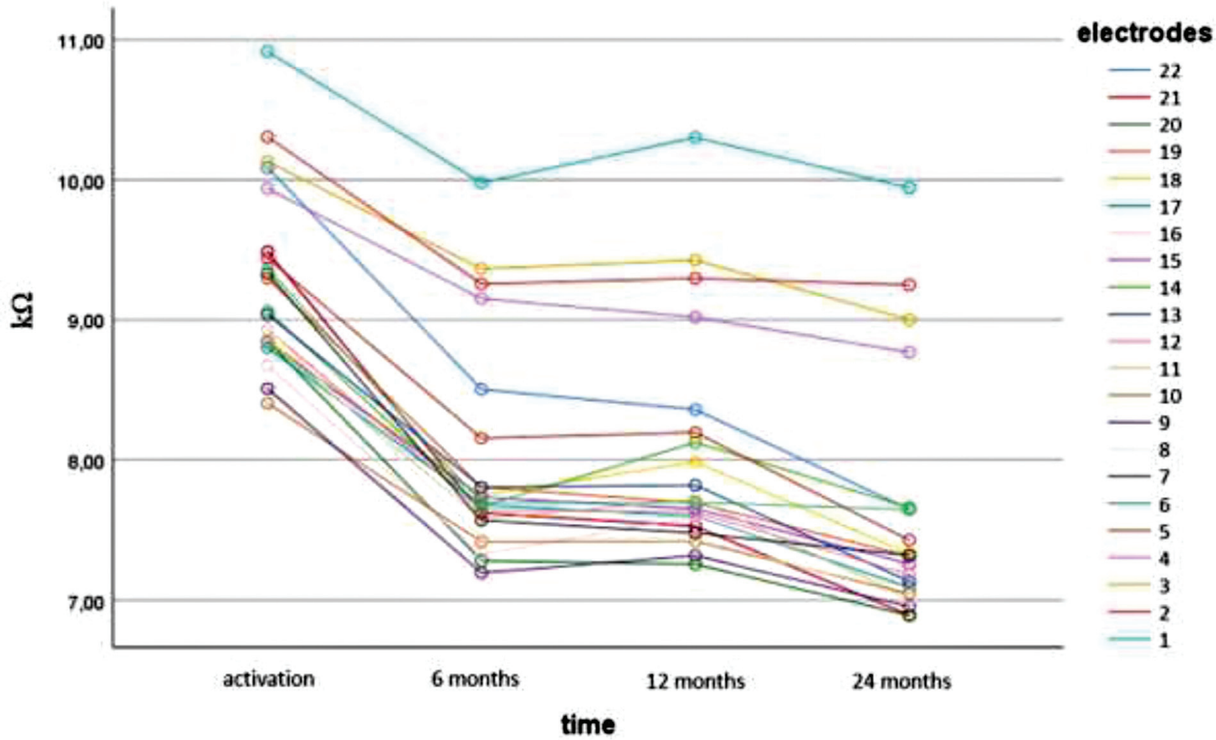

Fig. 4 Impedance-estimated marginal means differentiated according to electrodes and related to time intervals (activation, 6, 12, and 24 months)—common ground values.

and in postsurgical fitting. Normal range of impedance values has been established by each CI brand. In patients who can be considered good users with good auditory outcome, out-of-range values are clearly reported by the fitting software, and they are a sign of electrode dysfunction or loss of its integrity.[10]

Nonetheless, the analysis of in-range unexpected variations should be considered essential since those variations could also be an early sign of electrode dysfunction or possible changes in the environment surrounding the CI array.[5] Even in these cases, variations of impedance may be a predictor of inflammatory processes within the cochlea, of progressive fibrosis/ossification, or of fluctuations of the position of the electrode.[12,21] In these situations, not only speech perception is at risk,[19,22] but also sometimes patient health.

What can be understood from available literature is that impedance values of the whole array were low when measured in intrasurgical setting.[23] In some cases, air bubbles could be adherent to the surface of the electrode determining short-lasting, high-impedance spikes that underwent spontaneous reduction until the bubbles were reabsorbed.[24] This can be prevented by a slow insertion dynamic.

According to some authors, impedance values increased in the first hours after surgery,[22,25] reaching the highest values at the activation (when it was performed some weeks after surgery), probably because of the deposition of a layer of fibrous tissue around the electrode. Inflammatory processes, exudation of proteins, or deposition of macrophages/fibroblasts on the surface of the array were supposed to be the cause.[11,14,18,23,26,27] The constant electric stimulation (determined by the use of the CI) induced the decrease in impedance values in the following weeks.[14,18,24,26] Those values were reported to be stable in the first year.[14,15] Activation within hours from surgery seems to not have a significant effect on impedance values after 1 month post-surgery.[28] In addition, it is known that basal electrodes almost in all cases present in-range but higher impedance values than those in the middle and apical electrodes of the array.[10,29] This is supposed to be the consequence of the histologically documented chronic inflammatory/fibrotic reaction involving inflammatory cells, fibrosis, and neo-ossification affecting the part of the cochlea next to the site of the array surgical insertion.[30,31]

The present study confirmed these findings showing higher impedance values in the four most basal electrodes. To note, all patients of our cohort had all electrodes active and impedance telemetry was measured for each of them. As all surgeries were performed by the same surgeon, it is possible that this may be due to the surgical technique. Another explanation can be the use of low current levels frequently applied to basal electrodes (responsible for representing high-frequency sounds, frequently less tolerated by patients). Only one study,[32] conducted on patients with a different CI brand, showed increased impedance values in the apical part of the array, which could be due either to the different characteristics of that array or to the trauma of the surgical insertion.

Early activation may have an impact on the inflammatory processes involving the array's surface, thus determining different patterns of impedance-value trend.[24] Soft surgery technique seems to have a positive influence in reducing postsurgical impedance levels; according to some authors,[13] this can be related to the reduced production of fibrotic tissue due to the atraumatic insertion of the array within the

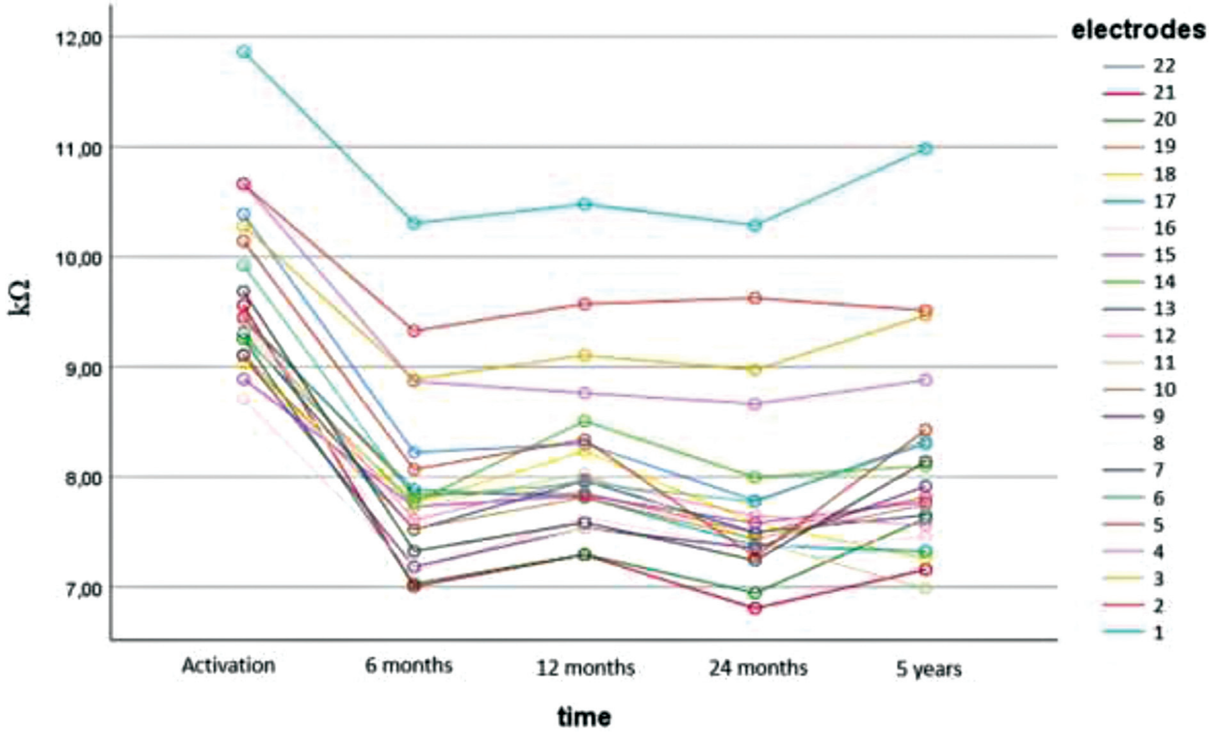

Fig. 5 Impedance-estimated marginal means differentiated according to electrodes and related to time intervals (activation, 6, 12, and 24 months and 5 years)—common ground values.

cochlea. Also, the choice of the electrode may have an influence on impedance levels. It is likely that different electrode arrays cause varied micro-damage of the intracochlear structures and different distances of the array from the modiolus, which may impact impedance levels.[33] For example, perimodiolar and lateral wall electrodes may vary in distance from the modiolus.[17] In addition, the use of a dexamethasone-eluting Cochlear Contour Advance electrode has been shown to determine different impedance values than standard electrodes.[34,35] These data suggest that intracochlear inflammation is present, and it can be modulated and it may influence impedance levels.

As previously highlighted,[24] the present study confirms that, among all the modalities used to measure impedance, CG provides the lowest values. This should be considered the standard result during the fitting of the CI when impedance values in all the four modalities are measured to check the integrity of the system.

In literature, long-term data are still missing, even if their importance can be considered as crucial. The considered population was composed of congenitally deaf patients. These patients currently undergo cochlear implantation around the first year of life and they are expected to live for several decades with their devices. In addition, the optimization of the CI fitting is frequently reached within the first year after implantation and subsequent follow-ups are spread over time, with minimal need for further variations in terms of current levels required for each electrode. Moreover, minor changes of hearing performance are frequently difficult to be detected by patients and impedance variations may be an early sign of pathologic processes that can go unnoticed until clinical symptoms arise. Consequently, follow-ups should be performed even in long-term CI recipients. In cases without symptoms and with self-perceived positive outcome, in the future, impedance telemetry may be performed remotely via telehealth.[36] According to the new long-term data from the present study, even in-range but small variations should draw clinician attention. In these cases, telemetric data need to be considered in the context of the patient's medical history, otoscopic evaluation, and hearing tests results; in addition, close follow-up controls should be considered. In the case of further variations, even imaging (by means of computed tomography) and/or surgical inspection should be considered.

The novelties provided by the present study are the relatively large number of patients, the homogeneity of the cohort in terms of etiology of the hearing loss, and the long time-span considered in comparison with the existing studies in literature. On the contrary, the limitations are the heterogeneity in terms of type of implants (even if all patients had a perimodiolar electrode) and the limited number of patients with a 5-year follow-up.

In conclusion, our findings show that impedance values are extremely stable at least in the first 5 years after implantation in CI recipients with genetically determined congenital profound hearing loss. These data seem to confirm that minimal modifications occur in the fluid and tissue around the electrode in absence of specific external stimuli known to have an impact on impedance telemetry (medications, autoimmune disorders, etc.).

In absence of these factors, even minimal differences in terms of impedance telemetry should be considered with caution. A strict follow-up might be advisable to prevent a late diagnosis of electrode dysfunction or disorder affecting the cochlea.

Future studies are necessary to investigate the association between different hearing-loss etiologies and trends of impedance values in CI users.

Note

Informed consent by participants and Institutional Review Board approval were not required since the study is retrospective and data are acquired for clinical management of the patients. For retrospective studies, informed consent and Institutional Review Board approval are not required in Italy.

Availability of Data and Material

Full data can be requested to the corresponding author of the study.

Geolocation Information

https://goo.gl/maps/i1YMWvAapHh7RKZ87

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Conflict of Interest

None declared.

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