IMPEDANCE AND ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL (ECAP) CHANGES OVERTIME IN PATIENTS WITH COCHLEAR IMPLANTS

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ABSTRACT:

Background: *Cochlear implantation referred to as the treatment of choice for hearing rehabilitation in patients with bilateral severe to profound sensorineural hearing loss that is no longer responsive to amplification by hearing aids. The integrity of this CI can be assessed intraoperatively and postoperatively through objective measures which include telemetric measurement of electrode impedance and electrically evoked compound action potential.*

Aim of the work: *To compare electrode impedance values and electrically evoked compound action potential (ECAP) thresholds intraoperatively and postoperatively to asses whether significant changes take place overtime or not.*

Patient and Methods *This study was carried on 25 subjects with age ranging from (3-60) yrs. 21 of the subjects were implanted unilaterally with a MED-EL devices and 4 implanted with cochlear devices. Impedance values and ECAP thresholds were monitored at the time of surgery then postoperatively at 1st day tunning, 1 month, 2 months and 6th months after 1st day tunning.*

Results: *Intraoperative impedance value was the lowest among all readings measured in all electrodes. The highest value was that measured at the 1st day tunning after surgery, after which impedance value continued to decrease significantly when compared to the 1st day tunning. ECAP thresholds showed the highest value intraoperatively after which the ECAP continued to decrease. However, the difference between readings was statistically nonsignificant.*

Conclusion: *During surgery, telemetry provides valuable information regarding integrity of electrodes, the electrical output of the implant and the response of the auditory system to electrical stimulation; however, it is not a valuable predictor of post-operative performance.*

Key words: *Cochlear Implant, telemetry, evoked compound action potential.*

INTRODUCTION:

Cochlear implantation provides the single most effective form of hearing rehabilitation in patients with bilateral severe to profound hearing loss that is no longer responsive to amplification **(1).** The integrity of this CI can be assessed intraoperatively and followed post-operatively through objective measures which are used as the first indicator of successful implant placement**(2).** Electrode impedance is used to check device integrity while ECAP used to check neural integrity**(3).**

Electrode impedance is the first objective assessment carried out during the

surgery and follow-up of cochlear implanted patients. This measure provides information on the integrity of electrodes and on the surrounding environment [(4)].

According to **Asal et al. (2018)[(5)],** the intraoperative impedance showed the lowest value among all readings measured in all electrodes. The highest value was that measured 1 month after surgery, after which impedance values continued to decrease significantly, but not to the intraoperative values. This increase in impedance is a result of fibrous tissue formation around the electrode within first few weeks of implantation[(6)].

Compound action potential is a synchronous response resulting from electrical stimulation of cochlear nerve fibres and it is the electrical version of the Wave 1 of the acoustically stimulated auditory potentials of the brainstem[(7)]. **Cosetti et al. (2010)** reported that neural response telemetry is routinely measured at the time of surgery. This gives us information regarding the electrical output of the implant, the response of the auditory system to electrical stimulation and preliminary device programming data.

Measurements of ECAP thresholds intraoperatively and postoperatively in the previous studies indicated that significant changes between the intraoperative and postoperative measures may or may not occur [(5)].

Lai et al. (2004) & Tanamati et al. (2009) reported no significant difference in ECAP thresholds in the first 12 months of the use of implants; they reported data obtained from a larger group of adult and pediatric CI users.

AIM OF THE WORK:

To compare electrode impedance values and electrically evoked compound action potential (ECAP) thresholds intraoperatively and postoperatively to asses whether significant changes take place overtime or not.

PATIENTS AND METHODS:

Study Population:

This study included 25 patients (18 adults and 7 children) who received cochlear implants at the Cochlear Implant Unit, Ain Shams University in the period between December 2020 and April 2022. Twenty-one patients (15 adults and 6 children) were implanted with the Med-El SONATA implant. Four patients (3 adults and 1 children) were implanted with the Cochlear Nucleus implant. The study was approved by the Medical Ethics Committees of Ain Shams University Hospitals and informed consent was taken from the patients or their caregivers.

Methods:

The 'activation' of the CI electrodes (1st day tunning) was performed 1 month after the surgery (to insure complete wound healing), which was the first activation time. The electrode impedance and auditory response telemetry (ART) telemetry recordings were collected using Maestro software 9.0.3 Build 10.270 for Med-EL cochlear implant and Cochlear custom sound pro (Custom Sound 6.2) for Cochlear cochlear implants.

In this study, electrode impedance and ECAP were measured intraoperatively and postoperatively at 1st day tunning, 1 month ,2 months and 6th months after 1st day tunning.

Impedance measurements:

Impedances were measured during and after surgery on all electrodes (12 electrodes in Med-EL cochlear implants and 22 electrodes in Cochlear cochlear implants) using the manufacturers default modes: For Med-EL devices, Impedance was tested at the end of the second phase of the biphasic

current pulse using only monopolar coupling mode. For Cochlear devices, Impedances were tested at the end of the first phase of the biphasic current pulse using the manufacturers 'default modes: common ground (CG) and all three monopolar modes (MP1, MP2, or MP1+2). The results were accepted when the electrode impedance was between 0.5 and 30 KΩ. Impedances less than 0.5 KΩ were flagged as short circuits and impedances greater than 30 KΩ were flagged as open circuits.

ECAP measurements:

Auditory nerve response telemetry (ART) in Med-EL devices was recorded from selected electrodes (E1, E4, E7, E10, E11, E12). The test stimulus used in the measurement was a biphasic current pulse, 30 μs/phase Minimum amplitude 200 cu and maximum amplitude 1000 cu, The stimulus current limit was estimated at each electrode, and 9 steps (100 current levels each) from 200 to 1000 were performed as stimulation applied on a given intracochlear electrodes.

Neural response telemetry (NRT) measurements in Cochlear devices were recorded from selected electrodes (E1, E2, E6, E11, E16 and E22). The test stimulus was set at the maximum current level (CL) of 256 current unit (CU). When a response was obtained (negative peak, N1), the CL was gradually decreased in steps of 5 CU until the threshold level (T-NRT) was found. Threshold was identified using the visual detection method as the lowest measurable amplitudes.

Ethical considerations:

Informed written consent was taken from the relatives of all patients involved in this study and the study protocol has been approved by the Ain-Shams Institute's Ethical Committee of Human Research.

RESULTS:

I- Demographic data:

Table (1): Age and gender distribution of the studied patients.

		Adult cases No=18	Pediatric cases N0=7
Age (years)	Mean± SD	30.94±10.58	4.86± 2.48
	Range	21 - 60	3 – 10
Gender	Female	10 (55.6%)	5 (71.4%)
	Male	8 (44.4%)	2 (28.6%)

Table (1) showed that the adult age at implantation ranged from 21-60 and children age at implantation ranged from 3-10 years.

Table (2): Distribution of patients as regards grade of education.

		Adult cases (21-60yrs)	Pediatric cases (0-18yrs)
		No. = 18	No. = 7
Grade of education	*Preschool		6 (85.7%)
	Primary education	1 (5.6%)	1 (14.3%)
	Secondary education	4 (22.2%)	
	University student	6 (33.3%)	
	Uneducated	7 (38.9%)	

Table (2) showed that most of the studied patients were educated so their reliability was good.

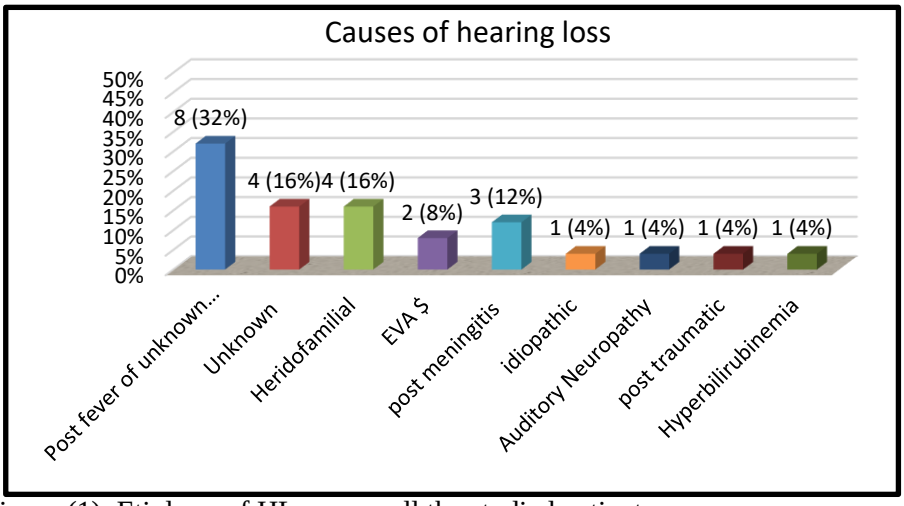

Figure (1): Etiology of HL among all the studied patients.

Table (3): Hearing data details among all the studied patients

		Pediatric cases No=7	**Adult cases No=18**	**Total cases**
Duration of HL (yrs)	Mean ± SD	4.21 ± 2.2	18.11 ± 9.11	14.22± 10.03
	Range	2.5 – 9	2 – 34	2 - 34
Onset of HL (yrs)	Mean ± SD	0.79 ± 0.37	12.78 ± 15.33	9.34± 14.07
	Range	0.17 – 1	1 – 58	0.17 - 58
Onset of HL	Prelingual	7 (100.0%)	8 (44.4%)	15 (60.0%)
	Postlingual	0 (0.0%)	10 (55.6%)	10 (40.0%)

Table (3) showed that the onset of hearing loss was prelingual in 15 (60%) of the patients and postlingual in 10 (40%) of the patients**.**

II. Impedance measurements:

Electrodes were divided into 3 groups according to frequency allocation into:

Med-EL cases	**Cochlear cases**
Apical (E1-E4)	Apical (E15-E22)
Middle (E5-E8)	Middle (E8-E14)
Basal (E9-E12)	Basal (E1-E7)

Table (4): Impedance values overtime in apical, middle and basal electrodes among Med-EL cases.

Impedance (kΩ)		MEDEL cases (n.=21)					P-value	Sig.
		Intra-operative	1st day tunning	1 month after	2 months after	6 months after		
Apical electrodes	Mean ± SD	5.37 ± 1.44	8.65 ± 2.30	7.88 ± 2.53	7.39 ± 2.13	6.99 ± 2.34	0.000	HS
	Range	3.4 – 9.09	4.15 – 13.63	2.79 – 13.01	2.98 – 11.14	3.41 – 12.43		
Middle electrodes	Mean ± SD	4.32 ± 0.98	6.80 ± 1.41	5.81 ± 1.55	5.44 ± 1.46	5.67 ± 3.02	0.002	HS
	Range	2.86 – 7.21	4.53 – 9.48	3.05 – 9.01	3.03 – 8.6	3.02 – 17.74		
Basal electrodes	Mean ± SD	4.52 ± 1.57	7.16 ± 1.42	6.44 ± 1.68	6.23 ± 1.72	6.76 ± 2.73	0.000	HS
	Range	2.34 – 8.97	4.72 – 10.02	2.91 – 9.63	3.05 – 10.13	2.88 – 12.88		

Table (4) showed that the intraoperative impedance was the lowest among all values. The highest value was that measured at the 1st day tunning after which it continued to decrease significantly.

-Statistical analysis was not done for Cochlear cases as their number was small (4 cases).

Table (5): Impedance values overtime in apical, middle and basal electrodes among Cochlear cases.

Impedance (kΩ)		Cochlear cases				
		Intra-operative	1st day tunning	1 month after	2 months after	6 months after
Basal electrodes	Mean ± SD	8.01 ± 2.80	14.26 ± 2.58	12.49 ± 3.00	11.66 ± 2.31	11.37 ± 2.35
	Range	6.06 – 12.16	11.57 – 17.79	9.28 – 15.96	8.74 – 14.38	8.15 – 13.75
Middle electrodes	Mean ± SD	10.00 ± 4.41	16.75 ± 0.65	11.08 ± 1.23	10.41 ± 0.79	11.45 ± 1.91
	Range	5.6 – 16.03	15.87 – 17.28	10.12 – 12.88	9.93 – 11.59	8.79 – 13.23
Apical electrodes	Mean ± SD	11.09 ± 5.07	16.79 ± 1.45	11.77 ± 1.39	10.70 ± 1.77	10.83 ± 1.41
	Range	6.71 – 17.97	15.4 – 18.23	10.12 – 13.12	9.11 – 12.89	9.13 – 12.53

-Statistical analysis was not done for Cochlear cases as their small number (4 cases).

ECAP measurement:

Table (6): Auditory nerve response telemetry (ART) thresholds overtime among Med-EL cases.

ECAP		MEDEL cases					P-value	Sig.
		Intra-operative	1st day tunning	1 month after	2 months after	6 months after		
E1	Mean ± SD	13.31 ± 4.66	8.93 ± 2.05	10.31 ± 2.36	10.32 ± 2.80	11.51 ± 2.61	0.054	NS
	Range	7.5 – 21.7	7.5 – 15.64	7.4 – 14.1	7.5 – 18.1	8.19 – 16.88		
E4	Mean ± SD	15.21 ± 4.33	9.41 ± 2.46	10.94 ± 3.57	10.60 ± 2.86	11.78 ± 3.46	0.008	HS
	Range	7.8 – 20.8	7.5 – 16.09	7.64 – 20.9	7.5 – 17.38	7.6 – 21.18		
E7	Mean ± SD	15.88 ± 6.51	9.72 ± 3.36	13.39 ± 3.99	13.03 ± 3.81	12.89 ± 3.39	0.065	NS
	Range	7.9 – 28.4	7.6 – 20.38	8.38 – 21.2	8.2 – 19.2	8 – 20.03		
E10	Mean ± SD	15.61 ± 5.57	10.44 ± 3.18	11.50 ± 3.39	11.72 ± 3.82	12.92 ± 3.50	0.052	NS
	Range	7.6 – 24.8	7.6 – 18	7.57 – 17.98	7.5 – 19.25	7.7 – 20.1		
E11	Mean ± SD	16.34 ± 4.87	10.77 ± 3.14	13.05 ± 3.81	13.51 ± 3.67	14.18 ± 3.70	0.210	NS
	Range	8.8 – 22.4	8 – 15.53	8.39 – 19.9	8.1 – 19	8.9 – 22.4		
E12	Mean ± SD	14.86 ± 3.65	12.69 ± 4.70	13.08 ± 4.61	13.54 ± 3.55	13.81 ± 4.10	0.078	NS
	Range	9.6 – 22	7.9 – 21.2	8 – 20.5	8.07 – 18.8	7.98 – 21.1		

Table (6) showed that the highest ECAP value was that measured intraoperatively after which ECAP value continued to decrease but this difference between readings was statistically nonsignificant**.**

Table (7): Neural Response Telemetry (NRT) values overtime among Cochlear cases.

NRT (CU)		Cochlear cases (n.=4)				
		Intra-operative	1st day tunning	1 month after	2 months after	6 months after
E1	Mean ± SD	200.00 ± 0.00	168.00 ± 0.00	172.00 ± 0.00	179.00 ± 0.00	176.00 ± 0.00
	Range	200 – 200	168 – 168	172 – 172	179 – 179	176 – 176
E2	Mean ± SD	219.67 ± 25.01	202.00 ± 32.05	203.33 ± 34.99	189.33 ± 11.72	192.33 ± 17.56
	Range	191 – 237	165 – 221	164 – 231	176 – 198	174 – 209
E6	Mean ± SD	203.50 ± 17.90	178.67 ± 28.36	189.33 ± 6.66	195.33 ± 8.96	186.67 ± 8.08
	Range	185 – 228	146 – 197	182 – 195	185 – 201	178 – 194
E11	Mean ± SD	197.00 ± 15.06	187.00 ± 17.26	186.75 ± 16.48	188.50 ± 14.73	187.00 ± 13.04
	Range	179 – 215	175 – 212	169 – 206	172 – 206	173 – 200
E16	Mean ± SD	172.50 ± 32.89	180.75 ± 13.55	175.50 ± 10.12	178.00 ± 9.06	180.25 ± 12.18
	Range	124 – 197	163 – 194	163 – 187	166 – 188	164 – 191
E22	Mean ± SD	168.75 ± 22.05	167.25 ± 24.12	163.50 ± 10.41	178.00 ± 21.59	177.25 ± 18.82
	Range	136 – 184	133 – 188	149 – 172	155 – 203	154 – 194

Statistical analysis was not done for Cochlear cases due to their small number (4 cases).

DISCUSSION:

The present study included 25 patients (18 adults and 7 children). Adult patients mean age at implantation was 30.94 years ± 10.58 SD. Children patients mean age at implantation 4.86 years ±2.48 SD (table 1). Most of the patients were educated, so their reliability was good (table 2). The most common cause of hearing loss was post febrile in (44%) of the patients (which includes post-fever of unknown etiology and post meningitic causes followed by the heridofamilial causes in (16 %) of patients (figure 1).

The mean duration of hearing loss prior to implantation was 18.11 years ± 9.11 SD in adults and 4.21 years ± 2.2 SD in children. The mean onset of hearing loss was 12.78 ± 15.33 SD in adults and 0.79 ± 0.37 SD in children. The onset of hearing loss was prelingually in 15 (60.0%) of patients and postlingually in 10 (40%) (table 3).

Impedance measurements: The current study showed that intraoperative impedance was the lowest among all readings measured in all electrodes. Morever, the highest value was measured at the 1st day tunning after surgery, after which impedance values continued to decrease significantly, when compared to the 1st day tunning measurement**.** This increase in impedance values at the 1st day tunning could be attributed to physiological changes and fibrous tissue growth which encapsulates the electrode array and new bone growth can occur, which directly affects the access resistance component of the overall impedance[(11)]**.** These findings were in agreement with the studies carried by **Van Wermeskerken et al. (2006), Manolache et al. (2012) & Asal et al. (2018)** who reported the same changes of increasing impedance postoperatively at the 1st day tunning compared to intraoperative values.

ECAP measurements: The current study revealed that the highest ECAP value was recorded intraoperatively after which the ECAP continued to decrease. However, the difference between readings was statistically nonsignificant (tables 6,7). This difference could be attributed to anatomical and physiological changes occured within the cochlea between surgery and postoperative time points[(13)]**.** Our results were in agreement with studies carried out by **Elshennawy et al. (2015) & Asal et al. (2018)** who reported nonsignificant changes in ECAP thresholds when comparing both intraoperative and postoperative measures. Also, studies carried out by **Lai et al. (2004) & Tanamati et al. (2009)** reported no significant differences in the ECAP Thresholds during the first 12 months using CIs, and this was in agreement with our results.

Conflict of interest:

No conflict of interest.

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معرفة التغيرات النى تحدث فى المقاومه والجهد المثار في المرضي مستخدمى القوقعه الالكترونية

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هدف البحث: مراقبه مقاومة القطب وعتبات الجهد المثاراثناء وبعد الجراحه لتحديد ما اذا كان هناك تغيير كبير في هذه القيم مع مرور الوقت ام لا.

المرضى والطرق:تمت هذه الدراسة علي ٢٥ مريض تتراوح اعمارهم مابين (٣-٦٠) سنه. جميع المرضي خضعو لعمليه زراعه قوقعه في اذن واحدة (تم زرع ٢١ مريضا بزرعه قوقعه ميديل و٤ مرضي بزرعه قوقعة كوكلير). تم قياس مقاومة القطب والجهد المثار اثناء الجراحة وبعد الجراحة (في ضبط اليوم الاول ثم شهر وشهرين و٦ اشهر بعد ضبط اليوم الاول).

النتائج: أظهرت النتائج ان قيمه مقاومه القطب اثناء الجراحه تكون اقل قيمه واعلي قيمه لها في ضبط اليوم الاول ثم تقل تدريجيا ولكن لا تصل الي قيمتها اثناء وقت الجراحه. اما اعلي قيمه للجهد المثار تكون اثناء الجراحه ثم تقل تدريجيا بعد تركيب جهاز القوقعه ولكن هذا الفرق بين القراءات غيرملحوظ .

النهاية: اثناء الجراحه تعطى اختبارات القياس عن بعد معلومات قيمه عن سلامه الاقطاب الكهرباءيه واستجابه الجهاز السمعى للمنبهات الكهرباءيه وبرغم ذلك لايمكن التنباء بالاداء السمعى بعد العمليه لمريض القوقعه باستخدام هذه القياسات.