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ORIGINAL ARTICLE

Comparison Between the Effect of Intra-Scalar Methylprednisolone and Sodium Hyaluronate in Impedance and Electrically Evoked Compound Action Potentials in Cochlear Implant Patients

Ali Eftekharian[1] · Mahdi Khajavi[1] · Soodabeh Moghadam[1] · Kourosh Eftekharian[1] · Leyla Azadeh Ranjbar[1] · Alireza Rezaei[1]

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Abstract To evaluate and compare the effect of intra-scalar methylprednisolone and sodium hyaluronate on cochlear implants' impedance and electrically evoked compound action potentials thresholds. In a prospective randomized clinical trial, 103 children with pre-lingual hearing loss candidates for cochlear implantation at a tertiary hospital were divided into three groups based on intervention. Intraoperatively, one group received intra-scalar methylprednisolone, the second sodium hyaluronate, and the third group was the control group. Impedance and electrically evoked compound action potentials (e-ECAP) thresholds on long-term follow-up were evaluated and compared in these three groups. Significant decrease in impedance and e-ECAP thresholds were observed in all groups in a 4-year follow-up. No statistically significant difference was observed among all mentioned groups. Impedance and e-ECAP thresholds decrease in the long term, and using topical intra-scalar Healon or methylprednisolone may not significantly affect these parameters.

Keywords Steroids · Methylprednisolone · Hyaluronic acid · Impedance · Evoked compound action potential · Cochlear implant

Introduction

Deafness occurs in 0.1–0.2% of newborns [1], and hearing loss affects up to 70% of the population over 75 years [2]. For the majority of causes of deafness, the auditory hair cells are lost or dysfunctional. The bipolar spiral ganglion neurons and their primary afferent dendrites remain intact and are available for direct electrical stimulation by the cochlear implant [3].

Cochlear implantation is now the best rehabilitation strategy for severe to profound sensorineural hearing loss. Cochlear implant devices convert sounds to electrical signals, and these signals are transmitted to spiral ganglions through electrodes inserted surgically in the scala tympani. Cochlear implants function by directly stimulating the residual auditory neuronal structures in the deafened ear, thereby bypassing the defective or missing mechanosensory cells, and the status of these remnant neural structures likely directly impacts cochlear implant outcomes [4].

The electrical impedance provides a measure for resistance against signal transduction in any tissue. It depends on factors like the type of material, the composition of surrounding tissues, or electrolytes. Increased impedance will result in increased voltage and energy expenditure, thus decreased battery durability [5].

Electrically evoked compound action potential (e-ECAP) is another hearing test, free of drawbacks of routine hearing tests, such as "dependence on audiologist's expertise." This test is readily applicable to prostheses made by all major manufacturers and can be used for objective regulation of the processor's system, assurance of implant and auditory nerve integrity during operation, and monitoring the recipient's progress [6].

There are several recommendations for decreasing the impedance. For example, special covers like iridium oxide decrease the resistance between electrode and tissue, or applying steroids in scala tympani with anti-inflammatory or anti-angiogenesis potentials decrease connective tissue

✉ Kourosh Eftekharian
kourosheftkharian@gmail.com

[1] Hearing Disorders Research Center, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

growth and fibroblast proliferation surrounding the electrode [5].

Insertion of cochlear implants may cause trauma to the basilar membrane, the spiral lamina, and the spiral ligament, resulting in overtime new bone formation at the cochleostomy and along the implant track [7]. Using lubricants to facilitate electrode insertion into the cochlea and prevent mechanical trauma to remnants of nerve fibers has been considered a means of reducing connective tissue growth and improving the outcome [8, 9]. Sodium hyaluronate (Healon®), one of these lubricants, is available as a viscoelastic agent.

This study was designed to evaluate and compare the potential effect of methylprednisolone and Healon on impedance and e-ECAP thresholds in cochlear implanted patients.

Materials and Methods

A randomized clinical trial was undertaken using children with pre-lingual bilateral severe to profound sensorineural hearing loss. The subjects were cochlear implant recipients from 2012 to 2015 at a tertiary academic center. Severe to profound sensorineural hearing loss was defined as a pure-tone average (averaged across 0.5, 1, 2, and 4 kHz) audiometric threshold higher than 70 dB HL.

Exclusion criteria included; post-lingual hearing loss, history of meningitis, any evidence of inner ear anomalies, retro cochlear disorders, or hearing loss with central causes.

The patients were randomly assigned to one of two groups. Randomization was done using a randomized block design in order to have an equal number of patients according to their gender in each group with the assistance of a biostatistician. The group to which patients were randomly assigned was unknown to the patients and the researchers at the time of enrollment. However, the surgeon could not be blinded during the surgery.

First, informed consent was obtained from the parents of the patients, and they were informed that we might introduce one of the two materials, methylprednisolone or Healon, into the cochlea of their child during the surgery.

After obtaining informed consent, surgeries were performed by a single surgeon at one center. Surgery was performed under general anesthesia, a postauricular incision was made, and cochlear access was achieved by the facial recess approach; then, using extended round window approach the scala tympani was opened.

The first group received topical corticosteroid (methylprednisolone), and the second group was administered Healon®. The methylprednisolone used was a 40 mg/ml solution manufactured by Pfizer pharmaceutical company. Healon® was a 1.0% sodium hyaluronate solution made by Johnson and Johnson company. The tip of a 23-gauge needle attached to a 2 ml syringe was inserted through the round window opening, and these two materials were slowly introduced to the scala tympani, pouring it to the edge of the round window without spillage of the material from it.

As intra-scalar use of both materials is off-label, a formal local institutional ethics committee approval was obtained, and written informed consent to participate in this study was provided by the parents of all patients enrolled. Moreover, they were informed that we might introduce one of the two materials, methylprednisolone or Healon, into the cochlea of their child during the surgery. Inserted electrodes were one of two types; Advanced Bionics HiRes90k1j (16 electrodes) or Cochlear CI24RE (22 electrodes). The insertion site was sealed by muscular tissue. The first fitting of the implants was done thirty days after the operation.

In order to add more data accuracy and comparability, a control group of patients who had not been included in the study was added to the study. This group was operated by the same surgeon and with the same approach, except that no material was introduced to the scala tympani.

Impedance and e-ECAP thresholds were measured intraoperatively, then 40 days and four years post-operation. It was measured in electrodes number 1,6,11, and 16 in Advanced Bionics devices and electrodes number 1, 6, 11, 16, and 22 in Cochlear devices. In Advanced Bionics devices, electrode number one is the most apical, but electrode number one on Cochlear devices is the most basal. The e-ECAP thresholds measurement in Advanced Bionics devices were done with biphasic current pulses, 32 µs in duration delivered at a rate of 30 pulses per second, and in Cochlear devices, 25 µs in duration delivered at 80 Hz by five chosen electrodes.

Impedance and e-ECAP thresholds changes between the first postoperative measurement (40th day's measurement) and the fourth year's measurement in each group were evaluated by paired *t*-test. This comparison was made to evaluate the effect of each material (Healon® and methylprednisolone) separately on impedance and e-ECAP threshold changes during four years of follow-up.

Next, impedance and e-ECAP thresholds changes between the first postoperative measurement and the 4th year's measurement were calculated for each group, and their difference was compared between the groups using independent samples t-test. This was done to compare the effect of each material on impedance and e-ECAP threshold changes during four years of follow-up. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, NY, USA), and *P*-value < 0.05 was considered statistically significant.

Results

One hundred and 5 patients were enrolled in the study. Two of the enrolled patients did not completely comply with the follow-up schedules; thus, their data were excluded from the results; and there were no further dropouts. The remaining patients, including 58 males (56.3%) and 45 females (43.7%), completed the study. The average age at implantation was 3.7 years ± 8 months. The age at which hearing aid use started was 1.5 years ± 1 month. Implants were done in the right ear in 61 cases (59.2%) and the left ear in 42 cases (40.8%).

Advanced Bionics devices were used in 39 patients (54.2%) and Cochlear prosthesis in 33 patients (45.8%). 37 (35.9%) patients were in the Healon group, 35 (33.9%) were in the methylprednisolone group, and 31 (30%) were in the control group. As there were no inner ear anomalies in our selected patients, full insertion of the electrodes was done in all patients, regardless of the type of their device.

Table 1 Shows impedance changes in Cochlear and Advanced Bionic prostheses after four years. Electrodes' impedance significantly decreased during this period.

Changes in e-ECAP thresholds in patients with both types of prostheses are shown in Table 2.

There was a significant decrease in e-ECAP thresholds in all groups within four years of follow-up.

Impedance changes between the first postoperative measurement (40th day's measurement) and the 4th year's measurement and its comparison between the two groups are shown in Table 3.

The impedance changes had not significantly changed between neither the study groups nor the study groups and the control group.

Table 4. shows e-ECAP threshold changes between the first postoperative measurement (40th day's measurement) and the fourth year's measurement and compares the groups. For this parameter, no statistically significant difference was found between either the study groups or the study groups and the control group.

Discussion

Change in impedance over time has been considered in several studies.

In a study on cochlear implanted guinea pigs, Charlet de Sauvage and colleagues [10] showed that the impedance increases over time. In another study on cochlear implanted guinea pigs, Wilk and colleagues [11] demonstrated a positive correlation between fibrous tissue growth and the impedance increase.

Paasche and colleagues [5] evaluated the effect of triamcinolone on intracochlear impedance in adult cochlear

Table 1 Comparison of the impedance (KΩ) for four years in each group

Device	En	Healon group			Corticosteroid group			Control group		
		At first measurement	After 4th year	*P*-value	At first measurement	After 4th year	*P*-value	At first measurement	After 4th year	*P*-value
AB	1	7.33 ± 2.02	6.05 ± 1.47	0.004	8.28 ± 2.88	6.42 ± 2.29	< 0.0001	8.92 ± 1.38	8.23 ± 2.20	0.003
	6	7.16 ± 2.79	6 ± 1.81	0.08	6.80 ± 2.15	5.80 ± 1.50	0.019	9.77 ± 1.54	8.23 ± 1.92	0.001
	11	6.83 ± 2.20	5.94 ± 1.76	0.04	6.85 ± 2.12	5.47 ± 1.66	0.001	10.92 ± 1.80	8.46 ± 1.56	0.468
	16	7.44 ± 2.77	5.72 ± 1.74	< 0.0001	7.52 ± 2.73	6.14 ± 2.10	0.01	10.08 ± 1.11	8.31 ± 2.25	0.339
Cochlear	1	9.94 ± 2.65	8 ± 2.53	< 0.0001	10.14 ± 1.46	8.57 ± 1.6	0.001	10.60 ± 2.77	8.60 ± 2.67	< 0.001
	6	9.36 ± 2.49	7.94 ± 1.98	< 0.0001	9.14 ± 2.41	8 ± 1.83	0.001	11.40 ± 3.20	8.93 ± 2.74	< 0.001
	11	9.52 ± 2.54	8 ± 2.05	< 0.0001	9.14 ± 2.53	8 ± 1.61	0.029	11.07 ± 2.52	8.80 ± 1.74	0.005
	16	10 ± 3.01	8.10 ± 1.79	0.001	8.85 ± 2.87	7.42 ± 2.10	0.006	11.40 ± 1.59	9.07 ± 2.22	0.001
	22	10.15 ± 2.91	7.94 ± 2.14	< 0.0001	8.64 ± 3.10	7.57 ± 2.65	< 0.0001	11.00 ± 1.813	9.07 ± 2.09	< 0.0001

En electrode number, *AB* advanced bionics device, *Cochlear* Cochlear® device, electrode number 1 in advanced bionics device is the most apical one, and the most apical one in Cochlear® device is the electrode number 22

Table 2 Comparison s of e-ECAP thresholds (current units) for four years in each group

Device	En	Healon group			Corticosteroid group			Control group		
		At first measurement	After 4th year	*P*-value	At first measurement	After 4th year	*P*-value	At first measurement	After 4th year	*P*-value
AB	1	121.58 ± 37.53	110.64 ± 33.05	0.001	128.05 ± 35.66	104.55 ± 41.01	0.03	157.38 ± 32.92	140.31 ± 31.60	0.012
	6	131.88 ± 39.5	114 ± 36.19	< 0.0001	144.21 ± 40.09	120.36 ± 36.84	< 0.0001	160.06 ± 41.59	141.94 ± 37.30	< 0.0001
	11	125.76 ± 29.90	120.68 ± 28.22	0.05	154.21 ± 29.33	136.52 ± 30.08	< 0.0001	147.27 ± 34.266	135.07 ± 27.40	< 0.0001
	16	156.82 ± 52.07	134.70 ± 41.38	< 0.0001	176.04 ± 58.86	155.28 ± 41.37	0.002	142.47 ± 34.68	137.13 ± 28.72	< 0.0001
Cochlear	1	178.94 ± 32.76	151.16 ± 29.07	< 0.0001	186.78 ± 36.95	176.78 ± 32.94	0.265	176.86 ± 28.32	159.71 ± 34.02	< 0.0001
	6	164.44 ± 31.93	136.16 ± 35.88	0.017	171.85 ± 35.09	156.71 ± 36.120	< 0.0001	186.14 ± 37.38	167.57 ± 34.31	< 0.0001
	11	163.50 ± 26.46	149.11 ± 23.48	0.005	169.76 ± 24	151 ± 23.1	< 0.0001	188.31 ± 30.78	159.31 ± 28.95	0.016
	16	166.38 ± 28.43	151.50 ± 25.98	< 0.0001	148 ± 46.7	147.64 ± 28.94	0.98	202.15 ± 27.97	176.62 ± 33.11	0.001
	22	167.77 ± 31.13	153.16 ± 33.34	0.003	163.14 ± 39.10	140.85 ± 35.37	0.006	214.33 ± 27.53	192.00 ± 26.69	0.004

En electrode number, first measurement; Measurement at forty days after the operation, *AB* advanced bionics device, *Cochlear* Cochlear® device, electrode number 1 in Advanced Bionics device is the most apical one, and the most apical one in Cochlear® device is the electrode number 22

implanted patients. They showed a significant effect of steroids on impedance reduction in a 2-week follow-up. De Ceulaer and colleagues [12], in a retrospective study with the aim of assessing the long-term effect of steroids on impedance reduction in 12 months, observed lower impedances in the steroid receiving group. Wilk and colleagues [11] assessed the impedance level following three months of implantation in guinea pigs. They concluded that dexamethasone eluting cochlear implants are a means to reduce tissue reaction and improve the functional benefits of the implant by attenuating electrode impedance.

The effect of different lubricants on cochlear implant electrode insertion forces was the topic of a study by Kontorinis and colleagues [8]. They inserted electrodes into an artificial model of human scala tympani filled with glycerin, sodium hyaluronate, and water or soap and measured the forces required for electrode insertion using a unique system. They concluded Healon to be a proper lubricant for this purpose. Huang and colleagues [13], in a study on Guinea pigs, showed that intra-scalar injection of Healon during cochlear implantation reduced the impedance of electrodes in the short term.

There are other articles with different findings. Ahmadi et al. [14], in a study measuring impedance over 120 days on Guinea pigs, found that either using dexamethasone with electrodes or not, the impedances for the electrodes started approximately at 6 kU and remained stable during the whole study period. Molisz and colleagues [15], in their long-term study on 20 patients using Nucleus 24RE implants, showed that in mid-portion and the apical electrodes, impedance values decreased between the first and the sixth postoperative months and stabilized in the latter course. The impedance of the most basal electrodes grew during the first postoperative months and stabilized later on.

We compared the effect of one type of corticosteroid and one lubricant substance (Healon). We demonstrated that in both groups (methylprednisolone and Healon), the impedance decreased over time, but this finding was also true for the control group No statistically significant difference was observed between all three groups regarding this parameter.

In addition to impedance measurement in other studies, we also used an e-ECAP threshold with which it is possible to monitor the performance of the cochlear implant device [16]. Molisz et al. [15], in their two-year interval study, showed that e-ECAP thresholds tend to decrease within the first three months after surgery but remain stable afterward. Telmesani and Said [17], in their study, stated that mean e-ECAP thresholds measured at 3-, 6-, and 12-months post-stimulation remained similar to initial stimulation levels. On the contrary, Brown et al. [18], in a long-term study on 134 Nucleus cochlear implant users, found a slight increase in mean e-ECAP thresholds between an early visit that occurred within 3–6 months following lookup and a late

Table 3 The comparison of impedance changes in 4th year

Device	En	Delta "I" in corticosteroid group	Delta "I" in Healon group	P-value	Delta "I" in control group	Control vs. corticosteroid group *P*-value	Control vs. Healon group *P*-value
AB	1	1.85 ± 1.68	1.27 ± 1.6	0.28	0.69 ± 1.49	0.05	0.29
	6	1 ± 1.78	1.16 ± 2.66	0.81	1.54 ± 1.13	0.31	0.59
	11	1.38 ± 1.59	0.88 ± 1.13	0.28	2.46 ± 2.11	0.11	0.01
	16	1.36 ± 1.62	1.72 ± 1.44	0.49	1.77 ± 2.20	0.55	0.94
Cochlear	1	1.57 ± 1.28	1.94 ± 1.31	0.41	2.00 ± 1.00	0.28	0.88
	6	1.14 ± 0.94	1.42 ± 1.12	0.45	2.47 ± 1.19	< 0.0001	0.01
	11	1.14 ± 1.74	1.52 ± 1.50	0.5	2.27 ± 1.83	0.08	0.21
	16	1.42 ± 1.65	1.89 ± 2.13	0.5	2.33 ± 1.45	0.09	0.47
	22	1.07 ± 0.82	2.21 ± 2.21	0.05	1.93 ± 1.16	0.02	0.63

En Electrode number, Delta "I"; Impedance change between first and last measurement, electrode number 1 in Advanced Bionics device is the most apical one, and the most apical one in Cochlear® device is the electrode number 22

Table 4 The comparison of e-ECAP changes in 4th year

Device	En	Delta "e" in corticosteroid group	Delta "e" in Healon group	P-value	Delta "e" in control group	CPontrol vs. corticosteroid group *P*-value	CPontrol vs. Healon group *P*-value
AB	1	23.5 ± 31.18	10.94 ± 11.55	0.126	17.06 ± 28.42	0.55	0.43
	6	22.84 ± 18.69	17.88 ± 13.72	0.375	18.12 ± 26.47	0.66	0.97
	11	17.68 ± 11.79	5.18 ± 10.14	0.23	12.20 ± 20.53	0.36	0.23
	16	19.76 ± 25.11	18.11 ± 15.53	0.81	5.33 ± 15.22	0.06	0.023
Cochlear	1	10 ± 32.12	27.77 ± 23.87	0.09	17.43 ± 12.59	0.36	0.11
	6	15.14 ± 20.64	28.27 ± 20.14	0.08	18.57 ± 16.97	0.60	0.13
	11	13.07 ± 30.95	14.38 ± 18.90	0.88	29.00 ± 24.98	0.11	0.07
	16	0.35 ± 51.18	15.94 ± 11.74	0.23	25.54 ± 19.08	0.06	0.10
	22	22.28 ± 25.56	16.58 ± 16.57	0.23	22.33 ± 18.65	0.99	0.35

En electrode number, Delta "e"; e-ECAP change between first and last measurement, electrode number 1 in Advanced Bionics device is the most apical one, and the most apical one in Cochlear® device is the electrode number 22

visit that occurred 4.8- 6 years later. In our study, there was a significant decrease in e-ECAP thresholds in all groups in the long term, and there was no significant difference between either the two study groups or the study ones and the control group.

According to Charlet de Sauvage and colleagues [10], impedance increases with time. However, Paasche and colleagues [5], De Ceulaer and colleagues [], and Wilk et al. [11] showed a decrease in impedance with the usage of corticosteroids over time. In the study conducted by Huang and colleagues [13], intra-scalar injection of Healon reduced the impedance of electrodes in the short term. Ahmadi et al. showed stable impedances during three months of study with or without using steroids. To our knowledge, our study has one of the most prolonged follow-up duration (4 years) in the literature for evaluating the effects of these materials in a sufficient number of cases.

We had a decrease in impedance and e-ECAP thresholds over time, either using corticosteroids, Healon, or not. In comparison, all the three groups had no statistically significant difference among each other.

We used two types of electrodes in our study. One was a perimodiolar type (Cochlear CI24RE), and the other was a lateral wall type (HiRes90k1j). The decrease of impedance and e-ECAP thresholds in the long term, whether using steroid, lubricant, or nothing in these two types of electrodes, means that even the electrode type has not influenced our findings.

Overall, in an overview of the literature and our long-term results, it seems we need more prospective, well-designed studies to find real changes in impedance and e-ECAP thresholds in the long-term and to see the influence of application of lubricants or steroids on these parameters.

Conclusion

Impedance and e-ECAP thresholds decrease in the long-term following cochlear implantation, and using topical intra-scalar Healon or methylprednisolone during electrode insertion may not significantly affect these parameters.

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Declarations

Conflict of interest The authors declare that they have no conflicts of interest. The authors have no relevant financial or non-financial interests to disclose.

Ethical Approval This study was approved by the Human Research Ethics committee of our institution (IR.SBMU.RETECH.REC.1400.860). The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Informed Consent All patients had given informed consent.

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