**EXAMINATION AND COMPARISON OF THE PHYSIOLOGICAL RESULTS
FROM COCHLEAR IMPLANT ELECTRODES THAT ARE DESIGNED TO
ADJUST TO THE PROPERTIES OF THE HUMAN COCHLEA**

PhD Thesis

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ABBREVIATIONS

[ref.]	self-citation from our published manuscript
3D	three dimensional
ANOVA:	analysis of variance
ASSR	auditory steady-state response
BERA	brainstem evoked response audiometry
CA	Contour Advance™ electrode array
CI	cochlear implant
C-level	electrically evoked comfort level
CS	cochleostomy
CT	computed tomography
cu	"current unit" - represent the current amplitude of programming stimulus at the specified pulse width.
dBHL	decibels Hearing Level
DPOAE	distortion product otoacoustic emissions
ERW	extended round window
ESRT	electrically evoked stapedial reflex threshold
HP	hearing preservation
MRI	magnetic resonance imaging
NRT	neural response telemetry
RW	round window
SM	Slim Modiolar™ electrode array
SSD	single-sided deafness
T-level	electrically evoked hearing threshold
T-NRT	neural response telemetry threshold

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I. INTRODUCTION

466 million people worldwide have a varying severity of hearing loss, of which 34 million are children. Hearing loss may have a genetic background, but it can come from complications at birth, possible infectious diseases, chronic ear infection; a side effect of medicines (i.e. ototoxicity), noise and aging. Up to 60% of the causes of hearing loss in childhood can be prevented and treated. Early diagnosis is essential. Treatment of people with hearing loss is much more cost effective than providing long-term financial support for those who are unable to run an independent lifestyle. Most treatment options offer better quality of life for people with hearing loss. People with hearing loss benefit from early identification, use of hearing aids, assistive devices such as cochlear implants captioning and sign language; and other forms of educational and social support [1].

I.1. Cochlear implant

In recent years, almost all severe types of hearing loss have been rehabilitated with an implantable hearing enhancement system [2-7]. Cochlear implants (CI) have been providing functional rehabilitation for decades in children and adults with severe functional hearing loss due to cochlear damage of various backgrounds [8]. The CI is a surgically, partially implanted, hearing aid. It stimulates the remaining working peripheral cells of the auditory nerve through a series of electrodes, directly in the lumen of the cochlea, acting as a hair cell prosthesis. [9,10]

The operation principle of cochlear implants are as follows: the external speech processor converts the sounds of the environment into electrical signals, which are transmitted by the transmitter coil to the internal implant unit, which is located under the intact scalp. The electrical impulses then pass through a series of electrodes connected to the internal electronics, directly to the spiral ganglion cells and then through the central auditory pathway to the auditory cortex (Figure 1/A-E).

Figure 1. Schematic structure and operation of the cochlear implant. The external speech processor (A) converts the sounds of the environment into electrical signals, which are transmitted by the transmitter coil (B) to the internal implant unit (C) under the intact skin. Electrical impulses then reach the auditory cortex directly through the electrode array (D) that is connected to the internal electronics, directly to the spiral ganglion cells (E) and then along the central auditory nerve.

There are currently different trends in cochlear implant electrode design [11]. The manufacturers provide a variety of implant configurations including different receiver-stimulators, electrode arrays (e.g. straight or pre-curved, full-length or short) and sound processors to choose from. This can facilitate decision making on an individual basis. Further important aspects of implant design such as: proximity to the modiolus [13],[14], electrical current requirements [15][13], energy consumption, trauma to the cochlea [15], combined electro-acoustic stimulation [16][17], preservation of cochlear structures with low-trauma surgical technique [13],[18]-[20] and hearing preservation [21]-[24] have become the focus of many discussions and studies. For example, recent evidence suggests that speech discrimination is not improved by deep insertion, but it is significantly improved by perimodiolar position of the electrode [25].

Studies in implanted recipient groups with multiple implant types are difficult to compare the influence of the implant electrode characteristics on outcomes in the presence of additional variables for example: implant electronics, sound processors and speech coding paradigms. Hence, to reduce the number of variables, comparison of the influence of the electrode designs on outcomes could be interpreted more effectively if a consistent receiver-stimulator design and a common sound processor are used. Recent publications [26-30] have shown imaging and electrophysiological results with CI532, but no comparative studies have yet been published.

Our center's postoperative radiological comparative study demonstrated that the Slim Modiolar electrode array took a closer position to the modiolus than the Contour Advance electrode array [(ref III, [31])].

I.2. Postoperative hearing preservation

Since the CI's launch, they have undergone significant technical advancement, necessitating the adaptation of surgical techniques from time to time. From the outset, efforts have been made to preserve the patient's residual hearing after surgery [32]. This concept was particularly prominent in all cases where the patient's low frequency hearing could be rehabilitated including cases with conventional hearing aids. However speech comprehension was accompanied by acoustic amplification, due to the simultaneous presence of severe mid- and high-tone loss representation, was almost impossible. This has led to the emergence of implant systems based on the principle of electro-acoustic stimulation (EAS), which use conventional acoustic amplification as well as implanted electrical stimulation [33]. The former provides amplification in the low frequency range, whilst the latter provides adequate stimulation in the higher frequency range to optimize the patient's speech intelligibility.

Residual hearing sensitivity may deteriorate due to perioperative traumas or complications with delayed onset. The applied surgical approach (round window (RW), extended round window (ERW), and cochleostomy (CS)) and the implanted electrode profile mainly lead to immediate or short-term damage, while delayed

alteration in cochlear function usually derives from the fibrous or bony remodelling of the endocochlear compartments.

Surgically important properties are: the physical attributes of the electrode configuration (perimodiolar vs. straight; rounded vs. smoothened tip; short vs. regular; with or without stylet, etc.), the type of cochlear fenestration (RW, ERW, CS), the method of electrode insertion (standard vs. soft surgery with advance-off-stylet), the use of lubricants or drugs in the cochlea (e.g. hyaluronic acid, intrascalar corticosteroids) and the intrascalar position of the electrode array (perimodiolar, mid-scala, or lateral wall) [34,35],(ref.I.[36]).

However, the possible disproportion between the physical dimensions of the electrode profile and the endocochlear compartments (e.g. diameter, shape, length of scala tympani) also play a significant role in preserving inner ear structures and functions.

Minimizing the damage in the inner ear enhances the possibility for hearing preservation, thus leads to better hearing performance. Systemic and/or intratympanic administration of steroids may contribute to hearing preservation. The beneficial effects of glucocorticoids are thought to be mediated through several different pathways: the anti-inflammatory effects; the down-regulation of production of inducible nitric-oxide synthase; and direct inhibition of the MAP/JNK cell death signal cascade [35]-[38],ref.I.]

I.3. Cochlear™ Nucleus® CI500 Profile™ Series

Competing companies (Advanced Bionics, Cochlear, Med-El and Oticon, etc.) provide different types of receiver-stimulators, implant electrodes and speech processors. There are several pros and cons when opting for an electrode profile (straight or perimodiolar), cochlear coverage (total or partial), receiver-stimulator (physical attributes) and speech processor (electric or electroacoustic stimulation), to meet the individual needs. One of the primary aims of cochlear implant system engineering is to promote atraumatic electrode insertion, to maintain optimal postoperative hearing sensitivity, by protecting and preserving the delicate inner ear structures.

A critical aspect of the design is the dimensions of devices. Decreasing the size (thickness of implant body, diameter of electrode array) facilitates minimally invasive surgical techniques, as thin implants can be implanted without a bony well [34,35]. Most implantable hearing device manufacturers have aimed to decrease the thickness of their cochlear implants, the most ambitious change can be observed across the Cochlear™ Nucleus® Profile implant series. Before 2017, the latest Profile devices from Cochlear Ltd. (Sydney, Australia) had an ~ 50 % decrease in thickness compared to older Nucleus® Freedom devices.

The Nucleus Profile cochlear implant series have a thin implant body profile that is beneficial especially for young patients. The Nucleus Profile family is available with precurved electrode arrays (Contour Advance CI512, Slim Modiolar CI532) and a straight electrode array (Slim Straight CI522) [41].

The maximum thickness of the Nucleus Profile is 3.9 mm which makes it the thinnest cochlear implant body. There is no pedestal or pin for fixation. The added protection; reinforced silicone rubber surrounding the implant and titanium casing, the implant body is resistant to larger forces. The new design is symmetric, so it can be used either for the right or left ear. The reference and the stimulator electrode arrays leave the implant body side by side. Smooth external surface minimizes biofilm formation and reduce risk of infection [41].

I.3.1. Cochlear™ Nucleus® Profile™ Contour Advance® (CI512)

CI532 device has a precurved perimodiolar electrode array. It has a diameter at the basal end of 0.8 mm and at the apical end of 0.5 mm (Figure 2.). Firstly, the electrode array is stabilized in a straight position with a metallic wire, and later, during the insertion the wire is held stable and the electrode array is more forward so that electrode array takes the perimodiolar position and the wire is removed (this is the so called advance off-stylet technique) [41]. (Figure 3.)

Figure 2. Cochlear Nucleus Profile Implant with Contour Advance Electrode CI512 [41]

Figure 3. Cochlear Nucleus Contour Advance Electrode (CI512) for perimodiolar electrode insertion[41]

I.3.2. Cochlear™ Nucleus® Profile™ with Slim Straight Electrode (CI522)

The CI522 system is equipped with a fully straight electrode array. The soft tip of the electrode array measures 0.3 mm in diameter at the apical end to minimize insertion trauma. The diameter at its basal end measures 0.6 mm (Figure 4.). Two white markers indicate the insertion depth range at 20 mm and 25 mm. The stiffener enables a smooth, single motion insertion to minimize insertion trauma. Handling and optimized lead angle for electrode orientation and ease of surgery due to the new design [41].

Figure 4. Cochlear Nucleus Profile Implant with Slim Straight Electrode CI522 [41]

I.3.3. Cochlear™ Nucleus® Profile™ with Slim Modiolar Electrode (CI532)

This new electrode array design has been built on 30 years of experience and has been developed in collaboration with CI surgeons. [41]

Figure 5. Comparison of perimodiolar electrode arrays. The figure shows the dimensions of the Nucleus CI532 thin perimodiolar electrode profile and the CI512 Contour Advance electrode profile. [36]

The CI532 is one of the thinnest electrode arrays and it is a full length perimodiolar electrode platform with 60% less volume than the CI512 (Figure 5.). This perimodiolar design makes the developed electrode array soft, flexible and

atraumatic. The distance from electrode tip to the most proximal electrode contact is 14.4 mm with a dimension at the basal end of 0.475×0.5 mm and at the apical end of 0.35×0.4 mm [41] (Figure 6.)

Figure 6. Cochlear Nucleus Profile with Slim Modiolar Electrode (CI532) [41]

I.3.4. Cochlear™ Nucleus® Profile™ Plus

Designed for 1.5 Tesla and high-resolution 3.0 Tesla MRI scans without the need to remove the magnet. The magnet can be removed if this is required to significantly reduce artifacts around the magnet (i.e MRI of the skull). The dimensions of new Profile Plus series are identical with their predecessors, only the magnet technology changed. [41]

II. OBJECTIVES

1. To compare the influence of various electrode designs upon selected electrophysiological outcomes for cochlear implant recipients using the same model of receiver- stimulator, Cochlear™ Nucleus® Profile Series and sound processor in a retrospective study.
2. Postoperative preservation of residual hearing and the maximization of hearing performance depends on minimizing the trauma during implantation of the electrode array. To achieve this, minimal invasive methods and thinner, low-trauma electrode arrays were required. Our aim is to monitor the possibility of postoperative acoustic hearing preservation and demonstrate it in one special case.
3. To analyze statistical data of the registered long-term hearing preservation in a non-randomized, prospective clinical cohort with specialized slim, perimodiolar cochlear implant systems based on methods and results of above special case.

III. MATERIALS AND METHODS

III.1. Electrophysiological measurements with Profile implant devices

The attributes of CI500 Profile family provide an opportunity to examine the practical value of such changes and allows us to assess the first experiences with the device from the user and the clinician perspective.

III.1.1. Inclusion and allocation of subjects

A total of 139 consecutive subjects who were implanted between 13 June 2014 and 4 May 2017 with a Profile CI532 (referred to as CI532), a Profile CI512 (referred to as CI512), and a Profile CI522 (referred to as CI522) device manufactured by Cochlear Ltd., Australia and gave their informed consent were enrolled into this retrospective study from two tertiary referral implant centers (referred to as Department of Otorhinolaryngology, Albert Szent-Györgyi Clinical Center, University of Szeged, Hungary (Clinic 1) and Department of Otorhinolaryngology, Karl Landsteiner University Hospital of St. Pölten, Austria (Clinic 2)). Time periods of the study recruitment were from 13 June 2014 to 14 December 2015 for CI512, from 13 November 2015 to 4 May 2017 for CI532, and 11 March 2015 to 29 November 2016 for CI522. All subjects were examined with high resolution computed tomography (CT) and/or magnetic resonance imaging (MRI) before surgery. Exclusion criteria were cochlear malformations, cochlear otosclerosis, obliterative postmeningitis changes and electrode tip fold-over. To the authors knowledge there were no neural disorders in either group. Postoperative radiography was performed in each subject to confirm that the active electrode array occupied an intracochlear position with no complications or abnormal electrode position.

The subjects were allocated into groups based on the electrode type implanted (Table 1). Those who received a CI532 formed group 532, those who received a CI512 formed group 512, and those who received a CI522 formed group 522. Subjects were consecutively treated as part of routine clinical practice that was comparable at each respective implant site. A total of 159 ears in 139 subjects were

implanted with devices, including the same implant receiver stimulator electronics. CI532 had an array with 22 electrode endpoints which was perimodiolar and with a relatively smaller diameter (named Slim Modiolar), CI512 had a 22 electrode array which was perimodiolar with a relatively larger diameter (named Contour Advance), and CI522 had a 22 electrode array which was straight, also with a relatively small diameter (named Slim Straight).

Table 1. Subject demographics for each subject group. Note: For continuous variables, the mean and + 1 standard deviation are shown in brackets

Subject group	532	512	522
Device	CI532	CI512	CI522
Electrode type	Slim modiolar	Contour Advance	Slim straight
Number of patients	46	45	48
Number of ears	54	54	51
Age (year $\pm$ SD)	25.17 $\pm$ 26.29	20.80 $\pm$ 25.87	55.36 $\pm$ 28.59
Sex (male female no./ears)	25/29	23/31	33/18
Duration of deafness (year $\pm$ SD)	2.94 $\pm$ 7.46	3.06 $\pm$ 9.34	3.13 $\pm$ 12.99
Cause of deafness			
Congenital	29%	28%	17%
Progressive	22%	26%	23%
Unknown	16%	28%	35%
Others	33%	17%	25%

A total of 54 ears were implanted with CI532 (all in Clinic 1), 54 ears with CI512 (51 in Clinic 1 and 3 in Clinic 2), and 51 ears with CI522 (47 in Clinic 2 and 4 in Clinic 1). Patients who were implanted with CI532 formed the test group. Two control groups were formed from patients who were implanted with 512 and 522. The underlying causes of hearing loss were congenital, progressive, unknown and others (e.g. cholesteatoma, infection, Meniere's disease, meningitis, ototoxic drugs, sudden hearing loss, trauma) in 29, 22, 16, and 33% for group 532, 28, 26, 28, and 17% for group 512, and 17, 23, 35, and 25% for group 522, respectively.

III.1.2. Implantation technique

The electrode arrays were inserted into the cochlea according to the manufacturer's instructions provided in the physician's surgical guide. The method of electrode insertion was identical in both implant clinics [31]. Full insertion was achieved via the extended round window approach with CI532 and CI512 and via the round window approach with CI522 in all ears. The AOS (advance off-stylet) technique was used for CI512 and the freehand technique was used for CI522. Electrode choice was dependent on the type of implant availability for each center (regulated by the health authorities). The age of the patients did not influence implant choice. Discussion of hearing preservation was not an objective of this study.

III.1.3. Electrophysiological testing

The three different types of electrode arrays were compared with regards to outcomes from intraoperative and 3-months postoperative electrophysiological testing performed as per routine clinical protocol (Table 2). Intraoperative electrophysiological tests were carried out as part of the regular fittings with Nucleus Custom Sound 4.4 software: impedance was measured for each electrode, the electrical stapedial reflex threshold (ESRT) with 25 μ s pulse width for every second electrode contact (No. 2, 4, 6 etc.) and neural response telemetry threshold (T-NRT) for 6 (No. 2, 6, 10, 14, 18 and 22) electrode contacts. ESRT values were compared in groups 532 and 512. T-NRT values in group 532 were compared with those in both control groups. A common sound processor (Nucleus CP910) was used. The centers followed their normal routine protocol, thus the electrophysiological measurement protocol of the two centers was not identical, i.e. intraoperative ESRT testing, postoperative T-NRT measurements were not included in the routine protocol by Clinic 2, and CI522 was not analyzed with regards to these parameters. Furthermore, postoperative NRT cases were not measured for subjects in each group, where the current required to elicit a threshold response exceeded their discomfort or pain level. In every case first fitting was performed 4 weeks post-surgery. In order to determine the electric threshold (T-levels), and comfort threshold (C-levels), the subjective fitting method was used in adults and the semi-

objective NRT based fitting (based on the intraoperative T-NRT results) was applied in children [36,37]. Default MAP parameters (25 μ s pulse width, 900 Hz stimulation rate and 8 maxima) were used. Postoperative NRT was measured 2 months after the first fitting, i.e. 3-months follow up. C-levels at first fitting and 3-months follow-up fitting and T-NRT at 3-months follow-up were compared. Outcomes for precurved slim perimodiolar electrode design, used at one implant clinic were compared to outcomes for two control groups of recipients implanted with precurved perimodiolar and straight electrodes in both implant clinics. Electrode designs were compared on the basis of outcomes for intraoperative objective electrophysiological measurements and postoperative threshold levels and comfort levels to characterize electrode position within the cochlea.

Table 2. Summary of the intraoperative and postoperative evaluation protocols and available data sets for each type of electrode. The routine protocol in Clinic 2 did not include measurement of intraoperative ESRT, and postoperative T-NRT.

	Group 532 Nucleus CI532 (n/54 implants)	Group 512 Nucleus CI512 (n/54 implants)	Group 522 Nucleus CI522 (n/51 implants)
intraoperative ESRT	44	47	0
intraoperative T-NRT	50	47	43
postoperative C-level (1 month)	54	54	51
postoperative C-level (3 month)	54	54	51
postoperative T-NRT (3 month)	32	36	0

III.1.4. Statistical analysis

Statistical analysis with the Student's t-test ($P < 0.05$) and one-way repeated measures ANOVA test were performed with 95% confidence interval ($p < 0.05$). Before the calculation, tests for normality of data distribution were performed. Bonferroni correction was used as needed to consider multiple variables (e.g. comparison of all three implant groups). The comparison was made on each electrode and all of the electrodes (Grand average). The tests were performed with Microsoft Excel 2016 and SPSS for Windows.

III.2. Possibility of postoperative preservation of residual hearing by CI532 with one case

Several studies have shown the positive properties, location and dimensions of CI532 Slim Perimodiolar electrode, which provide the possibility of preserving residual hearing after implantation. There are some surgical techniques of approaching the scala tympani (i.e., RW, ERW, CS) with varying risks of harming the fine structures of the cochlea with prompt or delayed onset [49]. Such late complications, for example the appearance of endocochlear connective tissue or new bone formation, may lead to a gradual partial or complete loss of residual acoustic hearing [68]. This is most likely to be seen when the RW is extendedly exposed, where endothelial lesions trigger new tissue proliferation. The tendency to harm the endocochlear structures is decreased when minimally invasive, soft surgery is applied [49]. Physical attributes of the electrode profile may also interfere with postoperative cochlear function. Theoretically, the endocochlear hydrodynamics may also be altered, as the vibration of the basilar membrane is restricted due to the presence of an electrode array. At this point, as the travelling waves to the apical region are modified, the basilar membrane would react to sounds differently, which leads to an endocochlear “conductive” hearing loss [70],[71].

III.2.1.Nucleus CI532 Slim Modiolar electrode profile

Electrode profiles can be classified into the following categories perimodiolar, 'mid-scala' or 'lateral-wall'. Those are based on their distance from modiolus (Figure 7.) [27].

Figure 7. Grouping electrode profiles based on their distance from modiolus. Electrode profiles can be classified as (A) perimodiolar, (B) mid-scala, (C) lateral-wall.

The studied cochlear implant system has a slim, full-length (98 mm total length) perimodiolar electrode (Figure 8.).

Figure 8. (A) Atraumatic electrode insertion in optimal position with the reloadable sheath. (B) Slim, perimodiolar electrode configuration with total insertion of the electrode array

The electrode array is easy and smooth to insert through RW or CS with the guiding sheath that is the main handle assist tool and it is reloadable. The thin electrode array allows unobstructed access to the scala tympani that has a tip diameter of 0.35×0.4 mm and 0.45×0.5 mm at the base. At the last edge of the electrode array there are 3 white marker rings for controlling the insertion depth that are followed by 22 half banded platinum electrode contacts. These properties make this implant configuration easier to use with shorter incision and surgery time. The insertion assistant sheath platform and the physical attributes of the electrode array facilitate to approach the modiolus and thus prevent the electrode from dislocation into the scalae media or vestibuli. [29],[44]

Figure 9. Cochlear® Nucleus CI532 with Slim Modiolar electrode profile in the endocochlear location. The most common surgical gates for opening the inner ear. (A) The schematic diagram depicts the structure of the labyrinth, which clearly shows the electrode array (orange) introduced through the fenestra rotunda (black arrow). As an alternative surgical penetration, the location of the cochleostoma hole is indicated by a black star in the figure. The enlarged section on the right shows the microscopic sketch of the cochlea, showing the fluid spaces essential for successful implantation (ST - scala tympani; SV - scala vestibuli; DC - ductus cochlearis).

(B) In relative cross-section view could be seen CI532 electrode array (orange solid, solid cross-section) takes up to 60% less volume in scala tympani than the CI512 (orange, dashed outline) electrode array

Due to the electrodes' special, flexible three-dimensional (3D) conformation it can be located under the lamina spiralis ossea, ensuring that the stimulation points are near the spiral ganglion cells (Figure 9./B). Its atraumatic design ensures the preservation of endo-cochlear structures [45]. It has a unique insertion mechanism that allows the surgeon to choose the most appropriate approach depending on cochlear anatomy. For safety, the electrode has a reusable supporting tool (sheath), which significantly increases the chance of electrode location in optimal position [27].

III.2.2.Minimally invasive surgical technique

Preserving the residual hearing requires minimally invasive techniques of (1) cochlear fenestration, (2) management of endocochlear fluid compartments and (3) atraumatic electrode insertion, known as soft surgery. Thinner and atraumatic electrode arrays are also designed to accomplish these aims, as postoperative hearing

performance can be maximized by minimizing the insertion trauma [32],(ref.I., [36]), [44],[46],[47].

Several important factors contribute to intracochlear damage during implantation: (1) direct physical trauma, (2) pressure wave propagation in the perilymphatic fluid, (3) vibration and/or heat trauma from drilling, (4) loss of perilymph, (5) changes in homeostasis/hydrodynamics of the endocochlear fluid compartments, (6) delayed fibrotic changes and new bone formation within the cochlear lumen [(ref.I., [36]),[48]-[52].

The physical attributes (length and diameter) of the electrode array may each limit the postoperatively achieved residual hearing [53].

Comprehensive analysis of imaging diagnostics of the middle and inner ear provide indispensable information for planning the proper surgical access route and electrode [53],[54].

III.2.3.Soft surgery

The term soft surgery was introduced by Lehnhardt in 1993 and it provided basis for numerous publications [32],[55]

Our routinely applied minimally invasive surgical technique involved electrode insertion via the Round Window (RW). In order to reduce bleeding and to prevent blood from accessing the cochlea, we filled the tympanic cavity with adrenaline solution after having completed the posterior tympanotomy. To prevent bone fragments entering the cochlea, the tympanic and mastoid cavity were flushed with abundant amount of saline. To remove the bony overhang of the round window, we used a 1 mm diamond burr at low speed (max. 350 rpm) in order to avoid noise and heat injury. Surgeon opened the RW membrane with a microscopic needle or hook. After opening the inner ear, suction was applied with care in order to avoid the reduction of the amount of perilymph. Furthermore, the scala tympani was left open for the shortest possible period, to prevent bone fragments, blood or other substances entering the inner ear, which may lead to primary and/or secondary injuries and eventually loss of residual hearing. As a preventive measure, after having opened

the RW, we placed a piece of gel-foam soaked in corticosteroid solution into the RW niche.

The slim modiolar electrode of the CI532 implant was soaked into methylprednisolone solution (40 mg powder dissolved in 10 ml saline) and it was retracted into the insertion sheath. The insertion sheath together with the electrode array was inserted into the scala tympani with the lowest possible force. Any minute resistance felt by the surgeon would have indicated physical contact of the electrode array to the basilar membrane or the lateral wall of the scala tympani or stria vascularis resulting in possible injury of these structures. After the electrode had been inserted in full length, indicated by the 1st marker ring, the RW was immediately sealed with an autologous tissue (e.g. fascia or muscle) in order to prevent loss of perilymph [32].

III.2.4. Patient data

Our female patient was born in 1987. Due to her congenital loss of hearing, she has been wearing conventional air-conductive hearing aids on both ears since childhood. 6 months prior to cochlear implantation, she had pronounced progression in her hearing loss on both sides, therefore she did not have sufficient speech comprehension ability even when wearing her hearing aids. The implantation was evaluated by detailed audiological and radiological tests.

Subsequently, the implantation was performed when the patient turned 30, under general anesthesia. Since the patient had residual hearing on both ears prior to surgery, we decided to use a thin perimodiolar electrode profile (CI532 Slim Modiolar implant). The operation was performed on the patient's right ear using the minimally invasive surgical technique described above via the RW.

III.3. Long-term postoperative hearing preservation with CI532

In our previous series of case, we performed audiological measurements on a larger group of successes that could demonstrate the atraumatic effect of CI532.

Table 3. *Population of study patients.*

No.	Gender	Age (year)	Implanted ear	Hearing Loss w/wo genetic origin	Total Hearing Loss (THL) after implantation
1	Male	55	Left	No	No
2	Male	59	Left	Yes	Yes
3	Male	16	Right	No	No
4	Male	24	Right	No	No
5	Male	15	Left	No	Yes
6	Male	72	Right	No	No
7	Female	70	Right	No	No
8	Female	71	Left	No	No
9	Female	10	Right	Yes	Yes
10	Male	11	Right	No	No
11	Female	43	Left	Yes	Yes
12	Female	28	Right	No	No
13	Female	28	Left	No	No
14	Female	11	Right	No	No
15	Female	70	Right	No	No
16	Female	24	Right	No	No
17	Male	62	Right	No	No
18	Female	77	Right	No	No
19	Female	42	Right	No	No
20	Female	48	Right	No	Yes
21	Female	71	Left	No	No
22	Female	53	Right	No	Yes
23	Female	59	Right	No	No
24	Male	13	Right	No	No
25	Female	27	Right	No	No
26	Female	35	Left	No	Yes
27	Female	59	Left	No	No
28	Female	30	Right	No	No
29	Male	53	Right	No	No
30	Male	69	Right	No	Yes
Average	Male=10 Female=20	(Mean $\pm$ SD) 43.32 $\pm$ 24	Right=21 Left=9	Genetic disorder=3 No evidence=27	THL=8

III.3.1. Study cohort

Out of the total number of cochlear implantees with slim perimodiolar implant system (n=94) our study population was recruited on the basis of the following criteria: (1) patient with good compliance; (2) measurable preoperative hearing threshold; (3) slim perimodiolar electrode array implant system; (4) minimum one-year follow-up period.

30 consecutive subjects were enrolled into this prospective, non-randomized clinical study. 20 females and 10 males with mean age at implantation of 43.32 years, ranged between 10 years to 77 years. All subjects were implanted at the University of Szeged from 2015 - 2017. The postoperative follow-up duration lasted 1.72 years on average (ranging between 1.1 and 2.55 years). All subjects met the official indication criteria of cochlear implantation. Anatomical or structural malformation was not revealed by the preoperative radiological examinations. For detailed patient data, please see Table 3.

III.3.2. Radiological validation

Radiography (skull AP axial/Towne view) was performed on the first postoperative day to confirm the proper intracochlear electrode position (Figure 10).

Figure 10. Skull AP axial on the first postoperative day confirms the proper in situ electrode position. The depicted subject (not included in the present study due to completely missing preoperative hearing) was chosen to interpret the differences between sequentially implanted systems (A: right ear: CI512 Contour Advanced; B: left ear: CI532 Slim Perimodiolar). A decreased electrode array curvature is seen with the slim perimodiolar system (B).

III.3.3. Pure-tone audiometry

Pure-tone air-conduction thresholds were used to register residual hearing using the ascending method, with 5 dBHL intensity steps. The audiometer (GSI 61 Clinical Audiometer; Grason-Stadler, MN USA) was calibrated according to the standards of the International Organization for Standardization (ISO 389-1:2017). THD-50P (Telephonics Corporation/Griffon Company, NY USA) headphone was used for air conduction hearing measurements.

IV. RESULTS

All subjects received Nucleus Profile implants. The only difference was the type of electrode. The patient groups were similar in subject numbers, etiology, duration of deafness, and indications.

IV.1. Electrophysiology testing

The electrophysiology testing: Intraoperative and postoperative measurements

IV.1.1. Intraoperative measurements

Firstly, intraoperative electrical stapedial reflex threshold (ESRT, Figure 11) and Neural Response Telemetry (T-NRT, Figure 12), results were compared across implant groups. The stapedial reflex was tested in all subjects in group 532 and 512 and could be elicited in 44 out of 54 cases in group 532 and in 47 out of 54 cases in the control group (group 512). Figure 11 shows that the mean ESRTs were lower in group 532 than in group 512. This difference was significant (t probe: $p = 0.007$) for electrode contact 2. Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between groups 532 and 512 ($p < 0.05$).

Figure 11. The mean intraoperative ESRT values in patient groups with different types of CIs: group 532 ($n = 44$) and group 512 ($n = 47$). The “+” means a significant difference between groups (a) and (b). Error bars stand for the standard deviation (SD). „A” stands for Nucleus CI532 and „B” for Nucleus CI512 implants. Grand $T_{532-512}$ means statistical comparison between groups 532 and 512. cu -“current unit” represent the current amplitude of programming stimulus at the specified pulse width.

Figure 12. Intraoperative T-NRT values in all groups: Groups 532 ($n = 50$), 512 ($n = 47$) and 522 ($n = 43$). The “+” stands for significant difference between groups 532 and 512. The “*” represents a significant difference between groups 532 and 522. The error bars represent the standard deviation (SD). The mean NRTs proved to be lower in each electrode in group 532 when compared with both control groups. The difference was significant in 5 measured electrodes when compared with 522 and 3 measured electrodes when compared with 532 (t-probe: $p < 0.05$). Grand $T_{532-512}$ means statistical comparison between groups 532 and 512. Grand $T_{532-522}$ means statistical comparison between groups 532 and 522.

Intraoperative NRT measurements were performed in all three groups. The neural response threshold was tested in all subjects and could be elicited in 50 out of 54 (group 532), 47 out of 54 (group 512), and 43 out of 51 (group 522) cases. Repeated ANOVA analysis revealed significant difference ($p < 0.05$) between the three groups. On examining the significance in pairs, we found that the mean T-NRTs (Figure 12) proved to be lower in each electrode in group 532 when compared with each control group. The difference was significant in 5 measured electrode contacts when compared with CI522 and 3 measured electrode contacts when compared with CI512 (t-probe: $p < 0.05$). Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$ and Grand $T_{532-522}$) showed significantly lower T-NRT values in group 532 compared with the two control groups ($p < 0.05$).

IV.1.2. Postoperative C-levels

The subjects were scheduled for the first fitting 4 weeks after surgery. C-levels during the first fitting were compared in patient groups with different implants

(Figure 13). No significant difference in mean C-levels was seen on any electrodes between groups 532 and 512, but grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between the two groups ($p < 0.05$). C-levels were considerably higher on every electrode in group 522 compared to groups 532 and 512, and the difference was significant for apical electrodes 2 to 12 ($p < 0.05$, Figure 13.A). Grand average (all electrodes) statistic calculation (Grand $T_{532-522}$) showed significant differences between the groups ($p < 0.05$). However, no significant difference was present on any electrodes in C-levels 2 months after the first fitting, only the grand average statistical analysis (Grand $T_{532-522}$) showed significant differences between groups 532 and 522 (Figure 13.B).

Figure 13. The mean postoperative C-levels in patient groups with different types of CI: Group 532 ($n = 54$, $n = 54$), group 512 ($n = 54$, $n = 54$) and group 522 ($n = 51$, $n = 51$) at first fitting (A) and 2-month follow-up fitting (B). The “*” stands for a significant difference between groups 532 and 522. Error bars represent the standard deviation (SD). Grand $T_{532-512}$ means statistical comparison between groups 532 and 512. Grand $T_{532-522}$ means statistical comparison between groups 532 and 522

IV.1.3. Postoperative T-NRT

In groups 532 and 512, T-NRT measurements were attempted in all subjects at the two-month follow up fitting and the measurements were successfully carried out in 32 subjects in group 532 and 36 subjects in group 512. The intraoperative

electrophysiological measurements could be performed in all subjects under general anesthesia, whereas the postoperative measurements were performed in vigil subjects. In the latter case, some of the subjects complained about unpleasant sound volume before a neural response could be measured, for this reason the electrophysiological testing could not be performed.

Figure 14. The mean postoperative T-NRT values in subject groups with CI532 ($n = 32$) and CI512 ($n = 36$). The „+” represents a significant difference between groups 532 and 512. Error bars represent the standard deviation (SD). Grand $T_{532-512}$ means statistical comparison between groups 532 and 512

Figure 14 shows the postoperative mean T-NRT values. The mean T-NRT results in the basal section were lower in group 532 than in group 512. The difference was significant ($p < 0.05$) on two electrodes (No 14 and No 16). Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between the groups ($p < 0.05$).

IV.2. Hearing Preservation after Cochlear Implantation in one subject

Preoperative and postoperative hearing diagnostics consisted of complete subjective and objective tests.

IV.2.1. Preoperative hearing tests

The pure-tone threshold audiometry performed at speech frequencies (0.25 to 1.0 kHz) showed a hearing threshold of 83,33 dBHL (Figure 15/A), while speech understanding hearing test was not possible to perform due to the poor

Figure 15. Pre-and postoperative Pure-tone Threshold audiometry results. The implantation was done on right ear (red curves); the opposite side hearing is indicated by a blue curve. Preoperative Pure-tone Threshold Audiometry at speech frequencies (0.25 to 1.0 kHz) demonstrated an average hearing threshold of 83.33 dBHL (A). During the 4th Postoperative Week, we registered hearing threshold decreasing in terms of speech frequency range at 0.25 to 1.0 kHz 5-10 dBHL and 20 - 25 dBHL at 2.0 to 4.0 kHz (B). In 6th week Hearing threshold 1 kHz showed progression again (C), but the postoperative 12th month was an improvement, we measured similar hearing thresholds than in the 4th week (D). In the 6th month hearing threshold test demonstrated close to a social hearing threshold with an average hearing threshold of 35 to 40 dBHL with a cochlear implant on the right ear. In postoperative 12th month free field audiometry test showed better hearing threshold with CI as an average of 25 - 30 dBHL.

Nominations: – X – = left air conductive Hearing threshold; – O – = opposite side air conductive hearing threshold; – Δ – = with CI hearing threshold in free field

The objective tests were performed with normal middle ear ventilation (normal, type A tympanogram, on both sides). By measuring distortion product

otoacoustic emissions (DPOAE), no external hair cell activity was registered on either side, which confirms the origin of sensorineural hearing loss in the inner ear. With a brainstem electric response audiometry test (BERA), we have registered with high intensity measuring low amplitude and reproducible responses with normal latency, which is also in favour of problems in the organ of Corti. In the brain stem section, no signs of neural involvement were seen (so-called retrocochlear lesion). At the Auditory Steady-State Response test (ASSRs), objective hearing threshold was estimated to severe degrees on both sides (Figure 16).

Figure 16. Preoperative objective hearing thresholds on the right and left. The hearing threshold on the right (A) is 80 - 90 dB corHL, while on the left (B) is 90 to 100 dB corHL. The residual hearing at 500 Hz on the left is relatively spared. (corHL: sound intensity correction factor, reflecting the age of the patient and the conditions of recording)

According to our results, the patient had a certain degree of residual hearing, but this would not have been sufficiently rehabilitated with conventional air-conductive hearing aids. The objective tests did not raise concern of a cochlear nerve damage (retrocochlear lesion), and such a contraindication of cochlear implant was also excluded by the preoperative MRI scan. An internal ear malformation was not detectable.

The patient met the audiological and radiological criteria of cochlear implantation, therefore surgery was recommended.

IV.2.2. Postoperative hearing tests

The first control measurement, as pure-tone hearing threshold test, was in the 4th postoperative week (Figure 15/B). A 5-10 dBHL threshold decrease was registered in the range of speech frequencies, at 0.25-1.0 kHz. At 2.0 to 4.0 kHz, we experienced 20-25 dBHL loss.

Further hearing tests were performed in the 6th and 12th month after implantation. The registered hearing threshold in the 6th month showed progression above 1 kHz (Figure 15/C), but in the postoperative 12th month (Figure 15/D), after improvement, hearing thresholds were the same as in the 4th month. The postoperative tests were done with pure tone audiometry, whilst the speech processor of the cochlear implant was turned off.

IV.2.3. Electrophysiology

The Nucleus CI532 is equipped with a perimodiolar electrode array that has 22 channels. The impedance measurements that were made parallel with the postoperative pure tone audiometries show a number of fluctuations on some electrodes. Firstly, the 10th —22nd electrode range became relative stable in the sixth month, while the electrodes 1-9 became stable in the twelfth month (Figure 17), which may indicate the proper integration of the electrode array, inner ear homeostasis.

Figure 17. Postoperative electrode impedance changes. On the top axis of the chart, the average of frequency range of different electrodes is indicated

Nominations: -●- = postoperative 4th week; -▲- = postoperative 6th month; -■- = postoperative 12th Month

IV.3. Results of Hearing Preservation cohort

Pre- and postoperative pure tone hearing threshold measurements were completed for all of the 30 recruited subjects. Figure 18 frequency-dependently illustrates the number of patients pre- and postoperatively, where hearing sensitivity was measurable. It is well demonstrated that hearing is the most stable within the 250 to 1000 Hz range, and the least is beyond 4 kHz. This statement is true either pre- or postoperatively.

Figure 18. Number of implantees with measurable hearing threshold at different frequencies. Preoperative (striped pattern columns); postoperative (checked pattern columns). On the top horizontal axis, the frequency-specific success rate of hearing preservation is presented in percentages.

The average preoperative thresholds of the hearing within the lower frequency range were 61.75 dBHL at 125 Hz (no response from 10 patients); 78.52 dBHL at 250 Hz (no response from 3 patients). At the middle frequency range, mean values were 88.67 dBHL at 500 Hz (response from all patients); 97.07 dBHL at 1 kHz (no response from 1 patient) and 100.50 dBHL at 2 kHz (no response from 10 patients). At the higher frequencies, the average values were 91.36 dBHL at 4 kHz (no response from 19 patients) and 84.00 dBHL at 8 kHz (no response from 25 patients).

The difference in height between the striped and checked pattern columns represents the percentage of successful hearing preservation at specific frequencies.

Figure 19. Preoperative (striped pattern columns) and postoperative (dotted pattern columns) hearing thresholds in dBHL at the measured frequencies (* $p < 0.05$).

One year postoperatively the average values of the hearing thresholds at the lower frequency range were: 93.89 dBHL at 125 Hz (no response from 17 patients); 87.86 dBHL at 250 Hz (no response from 10 patients). At the middle frequencies mean values were 102.86 dBHL at 500 Hz (no response from 10 patients); 111.61 dBHL at 1 kHz (no response from 14 patients) and 113.75 dBHL at 2 kHz (no response from 21 patients). At the higher frequencies, average values were 115.18 dBHL at 4 kHz (no response from 24 patients) and 99.29 dBHL at 8 kHz (no response from 29 patients). Figure 19 illustrates the preoperative (striped pattern columns) and the postoperative (dotted pattern columns) hearing thresholds in dBHL at the measured frequencies. A decrease was detected at each examined frequencies but the grade of it varied. The highest decrease was measured at 500 Hz with an average decrease of 14.19 dBHL and at 1000 Hz with an average decrease of 13.77 dBHL. At the lower frequency range, hearing remained substantially stable. At 125 Hz only 3.06 dBHL, while at 250 Hz only 7.19 dBHL loss was detected. At the high frequencies, from 2 to 8 kHz preoperative hearing sensitivity had been already proved to be rather poor, thus further loss had just little consequences.

Figure 20. Loss of acoustic sensitivity interpreted in dBHL ranges, while exhibiting the number of implantees frequency-specifically (with different patterns of columns).

Figure 20 frequency-specifically demonstrates the degree of loss of acoustic sensitivity grouped into dBHL ranges, whilst exhibiting the number of implantees. It is clearly shown that only minute threshold decay with less than 5 dBHL loss is the most frequently found, while prominent postoperative loss of hearing appears less often.

IV.3.1. Subjects with complete loss of hearing following surgery

9 implantees (9/30=30%) showed up with total loss of residual hearing at every measured frequency following the surgery. Their preoperative hearing sensitivity is presented in Figure 21. It is clearly seen that within this subgroup of this cohort the measured average hearing threshold have been already poorer prior to surgery compared to those with preserved hearing. Genetic screening of the 30 recruited subjects revealed mutations in three cases in the background of hearing loss. All of these subjects suffered complete hearing loss postoperatively (3/3=100%), therefore genetic alteration may serve as a predictor when opting for an electro-acoustic/hybrid device, should be taken into consideration when indicating these systems [25].

Figure 21. Preoperative threshold of HP (striped pattern columns, n=number of patients) and THL (squared pattern columns, m=number of patients) patients. (continuous line measurable threshold level).

V. DISCUSSION

V.1. Electrophysiological measurements with different types of perimodiolar electrode array

A wide range of cochlear implants with different electrodes are available for rehabilitation of hearing-impaired patients with severe to profound sensorineural hearing loss. Hearing rehabilitation outcomes may be influenced by optimizing device and electrode choice for the individual. Several comparative studies have been conducted including electrophysiological (ESRT, NRT) test methods to evaluate the influence of straight and perimodiolar electrode designs and their in-situ characteristics on clinical outcomes [11-13],[55-57]. Our study is unique in that it measured the influence of various electrode designs combined with a common receiver-stimulator alongside electrophysiological assessments for a relatively large routinely treated multicenter study cohort. As such, it is the first study to report on the influence of electrode design while using consistent implant receiver-stimulator electronics. The cooperation of Department of Otorhinolaryngology, University of Szeged, Hungary and Department of Otorhinolaryngology, Karl Landsteiner University Hospital of St. Pölten, Austria the was established in 2017 with the aim to compare the perimodiolar and the straight electrode arrays. The study clinics followed a standard protocol enabled by the manufacturer's software, thus a conclusion from their individual results can be made. The results of *Hey et al.* from their multicenter study on CI532 are in good correlation with our results which proves that our methodology and results are reliable [30].

The Contour Electrode was the first perimodiolar electrode from Cochlear. As reported by researchers, some intracochlear trauma has been associated with its insertion, with a more reliable and less traumatic insertion achieved when deployed using the recommended advance off-stylet technique [13]. This is largely due to an inherent reduction in intracochlear outer wall force generation when using this technique for this electrode [13].

The Slim Modiolar Electrode is designed for insertion with minimal cochlear trauma. It has the advantage of taking 60% less volume in the scala tympani

compared to the Contour Advance Electrode and is therefore placed in a position close to the modiolus. Perimodiolar proximity is an important clinical consideration as *Holden et al.* [20] concluded, observing that total insertion depth was not associated with better speech discrimination outcomes, however, the distance from the electrodes to the modiolus did indicate a significant influence. The Slim Modiolar electrode array takes a closer position to the modiolus than the Contour Advance electrode array as confirmed by a comparative radiological evaluation [31].

In this retrospective study the data from recipients with the three main types of electrode arrays used in each of the two author implant centers were included. Although the electrode of CI522 was known to take the lateral wall position within the cochlea, the authors' decided to enroll those subjects who were implanted with CI522 to gain a more detailed overview. Although results of two different implant centers were combined for evaluation, upon review, the authors considered the routine clinical practices employed and device parameters used at each site as sufficiently comparable.

Results from the objective intraoperative measurements indicated that the electrode contacts of the CI532 array were located closer to the modiolus than those of CI512. A previous study found that withdrawal of the stylet in the Contour Advance Electrode resulted in better NRT and ESRT responses, than with the stylet in place. They concluded that this is most probably due to a more favorable position of the electrode array towards the modiolus within the scala tympani once the stylet is removed [51]. In our study, although the mean ESRT was only slightly lower with CI532, the difference was statistically significant at the basal most electrodes tested. However, the mean T-NRT for CI532 was significantly lower than for CI512, especially in the apical-middle section, which is considered to be indicative of closer positioning towards the modiolus. An expected rate of scalar dislocations could be 26% with precurved electrode (i.e. CI512) and 3% with straight electrode (i.e. CI522) with round window insertion technique [58] and this dislocation should have a significant impact on the NRT threshold in the apical part of the electrode. In order to minimize scalar dislocation, the ERW insertion technique was used. Although the regular institutional protocols did not include postoperative computed tomography,

the results from T-NRT and ESRT, both being constantly higher for CI512 when compared with CI532 and T-NRT being constantly lower for CI512 when compared with CI522 are not indicative of significant dislocations between scalae tympani and vestibuli. The sizeable reduction in both T-NRT and ESRT observed in our study are considered sufficiently large to potentially influence differences in clinical outcomes as observed for subjective comfort level [56],[59].

The surface area of an electrode is inversely proportional with the resistance and therefore current is proportional with the surface area. If the electrode with a smaller surface is capable of eliciting the same response it means that it is closer to the stimulated structure. The lower objective electrophysiological thresholds of CI532 suggest that the electrodes are capable of eliciting reflex responses with lower stimulation intensity, resulting from closer proximity to the modiolus.

V.2.Hearing Preservation

Preservation of acoustic hearing associated with cochlear implantation improves the postoperatively achievable periodicity and spectral resolution, which improves the patient's speech comprehension and the localization of the tone in particularly difficult conditions [60]-[65]

The effects of cochlear implantation on residual hearing have been discussed in several studies in which a number of surgical and technical factors have been identified [66]. There are some surgical techniques of approaching the scala tympani (i.e. RW, ERW, CS) with varying risks of harming the fine structures of the cochlea with prompt or delayed onset [48]. Late complications, such as the appearance of endocochlear connective tissue or new bone formation, may lead to a gradual partial or complete loss of residual acoustic hearing [67]. This is most likely to be seen when the RW is extendedly exposed, where endothelial lesions trigger new tissue proliferation. The slightest is the tendency to harm the endocochlear structures when minimally invasive, soft surgery is applied [48].

Physical attributes of the electrode profile may also interfere with postoperative cochlear function. Theoretically, the endocochlear hydrodynamics may also be altered, as the vibration of the basilar membrane is restricted due to the

presence of an electrode array. At this point, as the traveling waves to the apical region are modified, the basilar membrane would react to sounds differently, leading to an endocochlear “conductive” hearing loss [68,69].

The new type of thin-diameter electrode arrays close to the modiolus are expected to have a lower hydrodynamic load, since the bony spiral lamina is attached from below, thus the basilar membrane vibrations remain unrestricted. However, the perimodiolar position of the electrode array allows the adjacent nerve elements of the spiral ganglion to be stimulated with a lower electrical intensity and through a smaller surface.

Cadaver experiments demonstrated that a force, applied to the basilar membrane with an average of 88mN (42-122 mN) would be sufficient to accomplish the interscalar dislocation of the electrode, of which manual perceptibility is questionable [70]. Studies with large case numbers ($n = 100$) have shown that the probability of the electrode line being located in the scala vestibuli significantly increased during CS, which also manifested itself in the absence of improvement in speech comprehension [71].

In a number of studies, intraoperatively performed electro-cochleography is used to track the electrode insertional trauma, furthermore to postoperative residual hearing follow-ups [72-74].

For the implementation of electro-acoustic (EAS) or hybrid speech processors the long-term preservation of residual acoustic hearing is inherently inevitable, thus application of atraumatic surgical techniques and electrode arrays is essential.

Our study cohort demonstrates that by the application of appropriate soft surgery techniques and atraumatic electrodes are able to retain residual hearing on a long run. The positive experience gained with the new type of CI532 Slim Modiolar electrode predicts the possibility for the preservation of structural and functional integrity of all cochlear regions. Furthermore, a prompt, definitive solution could be provided for a possible late hearing loss progression, where only a psychophysical reprogramming of the implant would be enough.

On the basis of our results, if the acoustic hearing loss can be preserved with the assurance and efficacy of the initial experience, we will be able to provide sustained prominent hearing rehabilitation even in the indication of EAS that results in significant improvement in the life quality of many implantees.

In addition, long-term residual hearing preservation follow-up could be of crucial importance in the subsequent feasibility of regenerative procedures and medical treatments [27,(ref. I., [36]) ,77,78].

VI. CONCLUSION AND NEW RESULTS

Although the Slim Modiolar electrode is significantly thinner than the Contour Advance and similar sized as the Slim Straight electrode array, the Slim Modiolar electrode provides similar or better stimulation productivity compared to Contour Advance and Slim Straight electrodes. The manufacturer's thinnest electrode array, the Slim Modiolar Electrode takes the position that is closer to the modiolus compared to the Contour Advance Electrode and the Slim Straight Electrode. Our intraoperative and postoperative measurements confirmed this showing that more effective stimulation can be achieved through the use of the Slim Modiolar Electrode.

In cochlear implantation, the use of new electrode array could play a fundamental role in minimally invasive soft surgery, taking into individual needs, and providing long-term acoustic hearing preservation. Our study demonstrates the efficacy of the Nucleus CI532 Slim Modiolar electrode profile. It has the potential to preserve residual hearing, which predicts the possible use of this configuration as part of EAS systems, and it maintains the structures availability for future treatments, i.e. the regeneration-based new therapeutic approaches of intracochlear hair-cells.

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I.

A maradványhallás megőrzésének lehetőségei cochlearis implantáció során Nucleus CI532 Slim Modiolar elektródasorral

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A hallássérült betegek rehabilitációjában alkalmazott cochlearis implantáció során a residualis hallás posztoperatív megőrzése és a hallási teljesítmény maximalizálása az elektródaprofil implantációjakor kialakult trauma minimalizálásától függ. Ennek megvalósításához minimálinvazív módszerek, továbbá vékonyabb, atraumatikus elektródasorok alkalmazására volt szükség. Célunk a posztoperatív akusztikai hallásmaradvány-megőrzés lehetőségének audiológiai nyomon követése volt. Betegünk veleszületett halláscsökkenése miatt gyermekkorától hagyományos, légvezetési hallásjavító készüléket viselt mindkét fülén. A cochlearis implantációt 6 hónappal megelőzően halláscsökkenésében mindkét oldalon kifejezett progressziót mértünk, ezért cochlearis implantátum beültetése mellett döntöttünk. A beteg a műtétet megelőzően mindkét fülén rendelkezett residualis hallással, ezért Cochlear® Nucleus CI532 Slim Modiolar implantátumot alkalmaztunk. A minimálisan invazív műtétet a beteg jobb fülén végeztük el kerekablak-behatoláson keresztül. A preoperatív hallásküszöbhez (átlag 85 dBHL) viszonyítva a 4. posztoperatív héten 0,25–1,0 kHz között 5–10 dBHL, míg 2,0–4,0 kHz-en 20–25 dBHL mértékű iniciális hallásküszöbromlást tapasztaltunk. A 6. hónapban mért hallásküszöb az 1 kHz feletti tartományban további kismértékű progressziót mutatott, ugyanakkor a 12. hónapban a hallásküszöb javult, a 4. héten kapott eredményekkel megegyezett. A cochlearis implantáció residualis hallásra gyakorolt hatásait több tanulmány is vizsgálta, melyekben számos sebészeti és technikai tényező kulcsszerepet meghatározott. A CI532 Slim Modiolar elektródaprofil modiolushoz közeli elhelyezkedése várhatóan kisebb endocochlearis hidrodinamikai terhelést jelent, mindemellett lehetővé teszi, hogy a ganglion spirale szomszédos idegelemeit alacsonyabb áramintenzitással, kisebb felületen ingerelhessük, ami neuroprotektív hatású lehet. Az akusztikai hallásmaradvány cochlearis implantáció kapcsán történő megőrzése javítja a beteg beszédértését és hanglokalizációs képességét, különösen neheztelt körülmények között. A residualis hallás hosszú távú megőrzése kiemelkedő fontosságúnak bizonyulhat továbbá a későbbi regeneratív eljárások, gyógyszeres kezelések megvalósíthatósága kapcsán is.

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Kulcsszavak: cochlearis implantátum, CI532 Slim Modiolar elektróda, maradványhallás-megőrzés, minimálinvazív sebészet

Possibilities for residual hearing preservation with Nucleus CI532 Slim Modiolar electrode array

Case report

During the rehabilitation of hearing-impaired patients, the preservation of residual acoustic hearing following cochlear implantation by minimizing the implantation trauma allows for improved hearing performance. To achieve this, minimally invasive, soft surgery methods and thinner, atraumatic electrodes were required. In our present study, we

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reported a case where Cochlear® Nucleus CI532 Slim Modiolar electrode was implanted in a patient with residual hearing. Our aim was to study the possible preservation of postoperative acoustic residual hearing by audiological monitoring. Since childhood, due to her congenital hearing loss, she has been wearing a conventional, airborne hearing correction device on both ears. Six months before cochlear implantation, we measured the progression on both sides of the hearing loss, so we decided to perform cochlear implantation. The patient had residual hearing on both ears prior to surgery thus the Cochlear® Nucleus CI532 Slim Modiolar Implant was used. The minimally invasive surgery was performed on the patient's right ear through the round window approach. Compared to the preoperative hearing threshold (average 85 dBHL) in the 4th postoperative week, an initial hearing threshold progression of 20–25 dBHL was observed between 0.25 and 1.0 kHz, while of 5–10 dBHL between 2.0–4.0 kHz. Hearing threshold measured in the 6th month showed a slight progression in the range above 1 kHz, but improved by the 12th month, to the results achieved at the 4th week. The effects of cochlear implantation on residual hearing have been studied in numerous studies, in which several key surgical and technical factors have been identified. Nucleus CI532 is a Slim Modiolar electrode profile that is close to the modiolus, so it is expected to have a lower endocochlear hydrodynamic load since it lies in the covering of the osseous spiral lamina, thus less influencing the dynamics of the basilar membrane. However, the perimodiolar location of the electrode array allows the adjacent nerve elements of the spiral ganglion to be stimulated with a lower electrical intensity and a reduced surface that may be neuroprotective. Preservation of acoustic residual hearing following cochlear implantation improves the patient's speech perception and the sound localization skills, particularly in difficult circumstances. Long-term residual hearing preservation may also be of great importance in the subsequent feasibility for regenerative procedures and drug treatments.

Keywords: cochlear implant, CI532 Slim Modiolar electrode, residual hearing preservation, soft surgery

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Rövidítések

ASSR = (auditory steady-state response) auditoros steady-state válasz; CI = cochlearis implantátum; CT = (computed tomography) számítógépes tomográfia; BERA = (brainstem evoked response audiometry) agytörzsi kiváltott potenciál vizsgálat; DPOAE = (distortion product otoacoustic emission) disztorziós otoakusztikus emisszió; EAS = (electric-acoustic stimulation) elektroakusztikus stimuláció

A legutóbbi években csaknem az összes súlyossági fokú és típusú halláscsökkenés rehabilitálhatóvá vált valamely implantálható hallásjavító rendszer alkalmazásával [1–3]. A cochlearis implantátumok (CI) évtizedek óta jó funkcionális eredménnyel biztosítják a különböző háttérű cochlearis károsodásból eredő, súlyos fokú halláscsökkenések rehabilitációját mind gyermekek, mind felnőttek esetében [4]. A CI egy műtési úton, részben beültetett hallásjavító eszköz, mely közvetlenül a csiga lumenébe vezetett, szőrsejtprotézisként működő elektródasoron át hozza ingerületbe a hallóideg még működő perifériás sejtjeit. A cochlearis implantátumok működési elve a következő: a külső beszédprocesszor a környezet hangjait elektromos jelekké alakítja át, melyeket az adótekerccs az intakt bőr alatt elhelyezkedő belső implantátumegységhez továbbít. Az elektromos impulzusok ezt követően a belső elektronikához csatlakozó elektródasoron keresztül közvetlenül a ganglion spirale sejtekhez, majd a cent-

1. ábra

A cochlearis implantátum sematikus felépítése és működése. A külső beszédprocesszor (A) a környezet hangjait elektromos jelekké alakítja át, melyeket az adótekerccs (B) az intakt bőr alatt elhelyezkedő belső implantátumegységhez (C) továbbít. Az elektromos impulzusok ezt követően a belső elektronikához csatlakozó elektródasoron (D) keresztül közvetlenül a ganglion spirale sejtekhez (E), majd a centrális hallópályán keresztül a hallókéreghez jutnak

2. ábra

A Cochlear® Nucleus CI532 Slim Modiolar elektródaprofil endocochlearis elhelyezkedése. A cochlea megnyitásának leggyakoribb sebészi kapui

(A) A sémás ábra a labyrinthus szerkezetét ábrázolja, melyen jól látható a fenestra rotundán (fekete nyíl) át bevezetett elektródasor (narancsszínű). Alternatív sebészi behatolásként, a cochleostoma furatának helyét az ábrán fekete csillag jelöli. Az ábra jobb oldalán kinagyított átmetszeti kép a csiga mikroszkopos vázlati szerkezetét, az implantáció sikeressége szempontjából nélkülözhetetlen folyadéktérjeit ábrázolja (ST – scala tympani; SV – scala vestibuli; DC – ductus cochlearis)

(B) Látható a scala tympaniba vezetett elektródasor intracochlearis elhelyezkedése két, eltérő elektródaprofil fizikai paramétereinek illusztrációjával. A CI532-es (narancsszínű, tömör átmetszetű) elektródaprofil körülbelül 60%-os relatív keresztmetszet-csökkenése, következményes intracochlearis-pozíció-változása szembevetendő a korábbi, CI512-es (narancsszínű, szaggatott körvonalú) elektródaprofilhoz képest

rális hallópályán keresztül a hallókéreghez jutnak (1/A–E ábra).

Megjelenésük óta a CI-k jelentős technikai fejlődésen mentek keresztül, ami időről időre a műtési technikák adaptációját tette szükségessé. A kezdetektől fogva jelen volt az a törekvés, hogy a beteg esetleges residualis hallását a műtétet követően is megőrizzük [5]. Ezen koncepció különösen előtérbe került minden olyan esetben, amikor a beteg mélyhang-hallása még hagyományos hallókészülékkel is rehabilitálható volt, ugyanakkor a beszédértés az egyidejűleg jelen lévő, súlyos fokú, közép- és magashang-vesztés miatt akusztikai erősítés mellett is csaknem lehetetlen volt. Ez vezetett az elektroakusztikus stimuláció (EAS) elvén működő implantátumrendszerek megjelenéséhez, melyek egyszerre alkalmaznak hagyományos, akusztikai erősítést, továbbá implantált, elektromos stimulációt [6]. Az előbbi a mély hangok tartományában nyújt erősítést, míg az utóbbi a magasabb hangok területén biztosít kellő stimulációt, így optimalizálva a beteg beszédértését.

A residualis hallás posztoperatív megőrzése ösztönözte az egyre vékonyabb, atraumatikus elektródasorok megalkotását is [5, 7]. A hallási teljesítmény maximalizálása ugyanis a beillesztési trauma minimalizálásától függ [8]. Cochlearis implantáció során károsodhatnak az endocochlearis struktúrák, melyek azonnali vagy akár késői

posztoperatív residualishallás-romlás forrásai lehetnek [9–11]. Az elektródasor bevezetése során esetlegesen kialakuló belsőfül-trauma az eredete alapján, sebészi szempontból, két csoportba sorolható. Ezek közül az első az elektródasornak a scala tympaniba történő célzott bevezetése [12]. A legelterjedtebb sebészi technikák ezt vagy a kerekablak-membránon át (úgynevezett „round window approach”), vagy egy úgynevezett cochleostomán, azaz a cochlea basalis kanyarulatának mesterséges furatán át valósítják meg [10] (2. ábra). A második jelentősebb csoportot az elektródasor minimális traumát okozó bevezetése képezi. Ebben szintén számos tényezőnek lehet meghatározó szerepe, mint például: (1) az elektróda bevezetése során keletkező közvetlen trauma; (2) az implantáció kapcsán a perilympa folyadéktérben kialakuló nyomáshullám hatása; (3) a fúró által okozott vibráció, hangártalom, esetleg hőtrauma; (4) perilymphavesztés; (5) a belső fül folyadéktereinek homeosztázisában létrejövő változások; endolymphaticus hydrops kialakulása; (6) a csiga lumenének késői fibroticus, csontos átalakulása [13, 14]. Az elektródasor hossza és keresztmetszete szintén korlátozhatja a posztoperatív elérhető residualis hallás megőrzését [15]. A közép- és a belső fül átfogó preoperatív radiológiai elemzése segíthet mind a műtési behatolás megtervezésében, mind az elektródaprofil kiválasztásában [16–18].

EAS-t alkalmazva a magashang-tartományban károsodott szőrsejtek területét, azaz a basalis régiót sok esetben egy rövid elektródasor bevezetésével fedik le, mellyel megkímélhető az apicalis cochlearis régiók szerkezete, működése. Ez esetben a kihívást a residualis hallás hosszabb távú megőrzése jelenti [19]. Ha ugyanis a mélyhang-hallásban progresszió következik be, az eredetileg optimális hosszúságú elektróda, fizikai lefedettség hiányában, már nem lesz képes pótolni a cochlea ezen régiójának funkcióját. A progresszió hátterében kiváltó okként szerepelhet késői endocochlearis fibrosis vagy csontszövetképződés is [20]. Az ebben a helyzetben felmerülő teljes belsőegység-csere, hosszabb elektródasor bevezetése ennek kapcsán akár fizikai akadályba is ütközhet. Elzáródás hiányában ugyanakkor akár több egymást követő implantáció szükségessé válhat, követve a beteg hallásának folyamatos rosszabbodását, ezzel nyilvánvaló sebészi, altatási terhet róva a betegre. Mindemellett számos finanszírozási kérdés is felmerülhet.

A cél tehát egy atraumatikus elektródasor kifejlesztése volt, mely a residualis hallás maximális megőrzése mellett képes az elektromos hallás hosszú távú biztosítására. A cochlea teljes hosszában bevezetve az elektródasort kezdetben az EAS részeként üzemelhet, majd egy esetlegesen bekövetkező mélyhanghallás-vesztés esetén, az apicalisan elhelyezkedő elektródákat aktiválva, csupán az implantátum programozásának módosításával biztosítható újra a teljes cochlea elektromos hallás lefedése. A folyamat lényege tehát egy hibrid, akusztikus és elektromos rendszerről tisztán elektromos rendszerre történő áttérés a beültetett elektródasor cseréje nélkül.

Az előbbi feltételeknek véleményünk szerint megfelelő elektródasor (Cochlear® Nucleus „CI532 Slim Modiolar”) 2015 novemberében „closed-market release” keretében a Szegedi Tudományegyetem Fül-Orr-Gégészeti és Fej-Nyaksebészeti Klinikáján került beültetésre elsőként a világon (operátor: Prof. Dr. Rovó László tanszékvezető egyetemi tanár).

3. ábra

Az elektródaprofilok csoportosítása a modiolustól való távolságuk alapján. Az elektródaprofilok modiolustól való távolságuk alapján (A) perimodiolaris, (B) mid-scala, (C) „lateral-wall” típusba sorolhatók. A jelen cikk tárgyát képező Nucleus CI532-es elektróda a perimodiolaris csoport tagja

Klinikánkon ez idáig 89 esetben (69 beteg) ültettünk be CI532-es elektródasort, melyek közül 40 fő esetében mértünk preoperatív residualis hallást. A homogén betegcsoportok adatainak részletes feldolgozása jelenleg folyamatban van.

Jelen tanulmányunkban egy olyan esetről számolunk be, amelyben Cochlear® Nucleus CI532 Slim Modiolar elektródát ültettünk be residualis hallással rendelkező betegnek. Vizsgálatainkkal arra kerestük a választ, hogy rövid vagy akár hosszú távon is megőrizhető marad-e az akusztikai hallás.

Anyag és módszer

Nucleus CI532 Slim Modiolar elektródaprofil

Az elektródaprofilokat a modiolustól való távolságuk alapján perimodiolaris, „mid-scala”, illetve „lateral-wall” kategóriákba sorolhatjuk (3. ábra) [21]. A Nucleus CI532-es elektródasor jelenleg a világ egyik legkisebb átmérőjű perimodiolaris pozíciójú elektródaprofilja. Basalisan 0,5 mm, míg apicalisan 0,3 mm átmérőjű, ezzel mintegy 60%-ban kisebb térfogatú, mint a gyártó szintén perimodiolaris elhelyezkedésű, előző generációs elektródaprofilja, az úgynevezett Nucleus Contour Advance (4. ábra) [22]. Különleges, rugalmas háromdimenziós (3D-s) konformációjának köszönhetően lehe-

4. ábra

Perimodiolaris elektródasorok összehasonlítása. Az ábrán a Nucleus CI532 vékony, perimodiolaris elektródaprofil méretei láthatók az előző, úgynevezett Contour Advance elektródaprofilhoz képest. A Nucleus CI532-es elektródasor jelenleg a világ legkisebb átmérőjű perimodiolaris pozíciójú elektródaprofilja. Basalisan 0,5 mm, míg apicalisan 0,3 mm átmérőjű, ezzel mintegy 60%-ban kisebb térfogatú, mint a szintén perimodiolaris elhelyezkedésű, előző generációs elektródaprofil, az úgynevezett Nucleus Contour Advance CI512

tóvé teszi, hogy az elektródák a lamina spiralis ossea eredése alatt helyezkedjenek el, így biztosítva, hogy a stimulációs pontok a ganglion spirale sejtjeinek közelébe kerüljenek (2/B ábra). Atraumatikus kialakítása biztosítja az endocochlearis finomstruktúrák megőrzését [23]. Egyedülálló beillesztési mechanizmussal rendelkezik, amely a sebész számára lehetővé teszi, hogy kiválaszthassa a legmegfelelőbb megközelítést a cochlea anatómiájának függvényében. A biztonság érdekében az elektróda újratölthető vezetőcszözzel rendelkezik, mely szignifikáns mértékben növeli az elektróda optimális helyzetbe kerülésének esélyét [21].

Minimálisan invazív sebési technika

A residualis hallás cochlearis implantáció során történő megőrzésének szándéka vezetett az úgynevezett „soft surgery”, azaz minimálisan invazív műtéti eljárások megjelenéséhez. Ezek alapvetően meghatározzák a cochlea megnyitásának és az endocochlearis manipulációknak minden olyan elemét, amely makro- és mikroszerkezeti károsodások által negatívan befolyásolhatja a posztoperatív elérhető hallásteljesítményt (direkt trauma és/vagy különböző anyagok bekerülése a cochleába stb.). A minimálisan invazív cochlearis implantációs eljárás tehát nem konkrét műtéti típus, hanem inkább olyan szabályok összessége, melyeket követve egyre tökéletesebb funkciómegőrzés lehetséges. A fogalmat és a főbb szempontokat elsőként *Lehnhardt* közölte 1993-ban [24], ami számos később megjelent publikáció alapját jelentette [25]. A residualis hallás megőrzésének szándéka legújabbban az EAS-rendszerekkel történő hallásrehabilitáció során merül fel [26–28].

Minimálinvazív technikát alkalmazva egyaránt választhatunk kerek ablakon, kiterjesztett kerekablak-behatoláson vagy cochleostomán át történő elektróda-bevezetést [11]. A csont szükséges mértékű elfúrásához minden esetben 1 mm átmérőjű gyémántfűrőt használunk lassú fordulatszámra, ezzel elkerülve a fúrás során keletkező hang- és hőártalmat [13, 14]. Az endosteum megnyitása előtt, annak felszínére szteroidtartalmú oldatot vagy nátrium-hialuronát-tartalmú készítményt helyezhetünk. Az endosteum megnyitásához mikrotűt vagy -horgot, továbbá különböző lézereket használhatunk. A belső fül megnyitását követően fokozottan ügyelnünk kell arra, hogy elszívás közben ne legyen perilymphavesztés okozunk. A scala tympani csupán a lehető legrövidebb ideig lehet nyitva, ugyanis azon mint behatolási kapun át primeren vagy az elektródához tapadva szekunder módon csontpor, vér vagy egyéb anyag juthat a belső fülbe, mely számos direkt és/vagy másodlagos károsodás forrása lehet, s ez végső soron a posztoperatív residualis hallás csökkenéséhez, elvesztéséhez vezethet. Bevezetése előtt, a Nucleus CI532-es elektródaszálát az implantátumhoz tervezett speciális vezetősínbe vissza kell húzni. Ez elősegíti az optimális implantációs szög meghatározását, megtartását. Az elektródaszál bevezetése a lehető legki-

sebb erő kifejtése mellett kell, hogy történjen. Minden érzékelhető ellenállás a basilaris membrán, a lateralis scala tympani fal vagy a stria vascularis kontaktusát, következményes sérülését jelezheti. Az elektródaszál bevezetését elősegítheti felszínének szteroidos oldattal vagy nátrium-hialuronáttal történő bevonása. Amint az elektróda a megfelelő hosszúságban bevezetésre került – amit markergyűrűk jeleznek –, a kerek ablakot vagy a cochleostomát autológ szövetrel (például fascia, izomszövet) lezárjuk, megelőzve a további perilymphavesztést [25].

Az implantátumtestet és a referenciaelektródát a gyártó által kiadott templát segítségével a bőr alatt kialakított zsebbe helyezzük.

Betegadatok

Nőbetegünk 1987-ben született. Veleszületett halláscsökkenése miatt gyermekkorától hagyományos, légvezetési hallásjavító készüléket viselt mindkét fülén. A cochlearis implantációt 6 hónappal megelőzően halláscsökkenésében mindkét oldalon kifejezett progressziót mérünk, így már készülékeinek viselése mellett sem volt kielégítő beszédmegértési képessége. Műtéti alkalmasságát részletes audiológiai és radiológiai tesztekkel bíráltuk el. Ezt követően az implantációt a beteg 30. életévében végeztük el általános anesztéziában. Mivel a beteg a műtétet megelőzően mindkét fülén rendelkezett residualis hallással, vékony perimodiolaris elektródaprofil (CI532 Slim Modiolar implantátum) alkalmazása mellett döntöttünk. A műtétet a beteg jobb fülén végeztük el a fentebb részletezett minimálisan invazív sebési technikát alkalmazva kerek ablakon keresztül.

Eredmények

Preoperatív hallásvizsgálatok

A preoperatív hallásdiagnosztika teljes körű szubjektív és objektív tesztekkel állt. Az elvégzett tisztahang-küszöb-audiometria a beszédfrekvenciákon (0,25–1,0 kHz) átlagosan 85 dBHL hallásküszöböt igazolt (5/A ábra), míg a beszédaudiometria az audiometer méréshatáráig nem volt vizsgálható.

Az objektív tesztek normális középfül-ventiláció mellett végeztük (normál A típusú timpanogram mindkét oldalon). A disztorziós otoakusztikus emisszió (DPOAE) méréssel egyik oldalon sem volt regisztrálható külsőszőrsejt-aktivitás, ami sensorineuralis halláscsökkenés esetében belsőfül-eredetűt igazol. Agytörzsi kiváltott potenciál vizsgálattal (BERA) nagy intenzitás mellett még éppen regisztrálható, kis amplitúdójú, ugyanakkor normál atenciájú, reprodukálható válaszokat regisztráltunk, ami szintén a Corti-szerv-eredet mellett szól. Az agytörzsi szakaszon neuralis érintettségre (úgynevezett retrocochlearis laesióra) utaló jeleket nem láttunk. Auditoros steady-state válaszok (ASSRs) vizsgálata során az

5. ábra

Pre- és posztoperatív tisztahang-küszöbaudiometriai eredmények. Az implantációt a jobb fülön végeztük el (piros görbék); az ellenoldali hallást a kék görbék jelzik. A preoperatív tisztahang-küszöbaudiometria a beszédfrekvenciákon (0,25–1,0 kHz) átlagosan 85 dBHL hallásküszöböt igazolt (A). A negyedik posztoperatív héten a beszédfrekvencia-tartományt tekintve 0,25–1,0 kHz között 5–10 dBHL, míg 2,0–4,0 kHz-en 20–25 dBHL mértékű iniciais hallásküszöbromlást tapasztaltunk (B). A 6. hónapban mért hallásküszöb 1 kHz felett ismét progressziót mutatott (C), ugyanakkor a posztoperatív 12. hónapban, javulást követően, a 4. héten kapott eredményekkel megegyező hallásküszöbértékeket mértünk (D). A 6. hónapban elvégzett szabad hangteress hallásküszöb-vizsgálat a jobb fülön viselt cochlearis implantátummal közel a szociális hallásküszöbnek megfelelő hallást igazolt, átlag 35–40 dBHL küszöbszinttel. A posztoperatív 12. hónapban mért szabad hangteress hallásküszöb további javulást mutatott, átlag 25–30 dBHL-nek bizonyult

Jelölések: –X– = bal oldali légvezetési hallásküszöb; –O– = jobb oldali légvezetési hallásküszöb; –Δ– = CI-vel mért hallásküszöb szabad hangterében

objektív hallásküszöböt mindkét oldalon nagy-súlyos fókúnak becsültük (6. ábra).

Eredményeink alapján tehát a beteg bizonyos mértékű residualis hallással rendelkezett ugyan, ez azonban a hagyományos légvezetési erősítéssel nem lett volna kellő mértékben rehabilitálható. Az objektív tesztek a nervus cochlearis retrolabyrinther károsodását nem vetették fel, melyet a preoperatív elvégzett nagy felbontású piramiscsont-CT-vizsgálat szintén kizárt. Belsőfül-fejlődési rendellenesség nem ábrázolódott.

Mivel a beteg a cochlearis implantáció audiológiai és radiológiai indikációs kritériumainak megfelelt, műtétet javasoltunk.

Posztoperatív hallásvizsgálatok

Az első ellenőrző tisztahang-küszöbaudiometriai vizsgálatunkra a negyedik posztoperatív héten került sor (5/B ábra). A beszédfrekvencia-tartományt tekintve 0,25–1,0 kHz között 5–10 dBHL, míg 2,0–4,0 kHz-en 20–25 dBHL mértékű iniciais hallásküszöbromlást tapasztaltunk. Ezt követően a posztoperatív hatodik és tizenket-

tedik hónapban újabb kontroll-hallásvizsgálatot végeztünk. A 6. hónapban mért hallásküszöb 1 kHz felett ismét progressziót mutatott (5/C ábra), ugyanakkor a posztoperatív 12. hónapban (5/D ábra), javulást követően, a 4. héten kapott eredményekkel megegyező hallásküszöbértékeket mértünk. A posztoperatív tesztek tisztán akusztikus ingerrel, a cochlearis implantátum ki- kapcsolása mellett végeztük el.

Elektrofiziológia

A Nucleus CI532 egy 22 csatornából álló vékony, perimodiolaris elhelyezkedésű elektródaprofillal rendelkező implantátum. A posztoperatív hallásvizsgálatokkal egy időben elvégzett elektródánkénti impedanciamérések számos ingadozást mutatva, a 10–22. elektródatarományban már a 6. hónapban, míg az 1–9. elektródákon a 12. hónapban válnak relatíve stabilá, kiegyenlítetté (7. ábra), ami az elektródasor megfelelő integrációjára, a belsőfül-homeosztázisnak a rendezettségére utalhat.

Megbeszélés

Az akusztikai residualis hallás cochlearis implantáció kapcsán történő megőrzése javítja a posztoperatív elérhető periodicitást és spektrális felbontást, aminek köszönhetően javul a beteg beszédértése és hanglokalizációs képessége, különösen nehezített körülmények között, ezért kiemelkedő annak megőrzése [29–35].

A cochlearis implantáció residualis hallásra gyakorolt azonnali hatásait több tanulmány is vizsgálta, melyekben számos sebészeti és technikai tényező kulcsszerepét meghatározták [10, 36, 37]. Hasonló vizsgálatok kutatják a mikrofülbészeti beavatkozások labirinthfunkciókra gyakorolt hatásait [38]. Az implantációt követő időszakban ugyanakkor számolnunk kell késői komplikációkkal is, úgymint endocochlearis kötő- vagy csontszövetképződéssel, mely másodlagosan a residualis akusztikai hallás romlásához, elvesztéséhez vezethet [20]. Erre a legnagyobb valószínűség a kiterjesztett kerekablak-feltáráskor („extended round window approach”) mutatkozik, melynek során az endosteum károsodása vált ki új szöveti proliferációt. A legcsekélyebb a károsodás kialakulásának valószínűsége minimálinvazív kerekablak-behatolás során [10]. A cochlea hidrodinamikai rendszerének károsodása ugyanakkor létrejöhet egy, az alaphártya mozgását korlátozó elektródasor jelenléte miatt is. Ekkor a membrana basilaris eltérő maximummal és helyen tér ki a különböző hangokra, így a haladóhullám terjedését befolyásoló elektródasor a mély frekvenciáért felelős apicalis régió elemeit is károsíthatja, úgynevezett cochlearis vezetékes halláscsökkenést okozva [39, 40]. Az új típusú, vékony átmérőjű, modiolushoz közeli elhelyezkedésű elektródasorok várhatóan kisebb hidrodinamikai terhelést jelentenek, hiszen a lamina spiralis ossea takarásában, az alatt helyezkednek el, a membrana basilarist nem érintik (2. ábra). Az elektródasor perimodiolaris elhelyezke-

6. ábra

Preoperatív objektív hallásküszöbértékek jobb és bal oldalon. Auditoros steady-state válaszok (ASSRs) vizsgálata során az objektív hallásküszöböt, ezzel a residualis hallást mindkét oldalon nagy-súlyos fokban emelkedettnek mértük. A hallásküszöb a jobb oldalon (A) az objektív hallásküszöb 80–90 dB corHL, míg a bal oldalon (B) 90–100 dB corHL mértékűnek bizonyult, bal oldalon 500 Hz-en relatíve megkímélt residualis hallással (corHL: hangintenzitás-korrektíós faktor figyelembevételével, mely tükrözi a beteg életkorát és a rögzítés körülményeit)

7. ábra

Posztoperatív elektróda impedancia-változások. A posztoperatív hallásvizsgálatokkal egy időben elvégzett elektródánkénti impedanciamérések számos ingadozást mutatva, a 10–22. elektródatartományban már a 6. hónapban, míg az 1–9. elektródákon a 12. hónapban válnak relatíve stabilá, kiegyenlítetté. Ez az elektródasor megfelelő integrációjára, a belsőfül-homeosztázisnak a rendezettségére utalhat. A diagram felső tengelyén a különböző elektródák frekvenciafedettség-átlagát került feltüntetése

Jelölések: —●— = posztoperatív 4. hét; —▲— = posztoperatív 6. hónap; —■— = posztoperatív 12. hónap

dése mindemellett lehetővé teszi, hogy a ganglion spirale szomszédos idegelemeit alacsonyabb áramintenzitással, kisebb felületen ingerelhessek.

Korai post mortem kadáverkísérletek során igazolták, hogy az interscalaris (azaz a scala tympaniból a scala vestibuliba történő) elektródadiszlokációhoz már 42–122 mN (átlagosan 88 mN) erő kifejtése is elegendő, mely-

nek manuális érzékelhetősége kérdéses [41]. Nagy esetszámon ($n = 100$) végzett vizsgálatokkal kimutatták, hogy cochleostoma készítése során szignifikáns mértékben nőtt a valószínűsége, hogy az elektródasor a scala vestibuliban helyezkedjen el, ami a betegek beszédértés-javulásának elmaradásában is megnyilvánult [42].

Számos tanulmányban az intraoperatív elvégzett electrocochleographiai mérések segítségével követhetőnek tartják az elektróda bevezetése során létrejövő traumát, végső soron a posztoperatív residualis hallás megőrzésének tényét [12, 43, 44].

A posztoperatív időszakban esetünkben is mérhető volt a residualis hallás küszöbértékeinek fluktuációja. A funkcionális romlás hátterében az elektródasor megfelelő integrációja, a belsőfül-homeosztázisnak a rendeződése, végső soron egy adaptációs folyamat állhat. Az implantáció által facilitált neuroregeneráció ugyanakkor a hallásküszöb javulását eredményezheti.

Az EAS megvalósításához a külső hibrid beszédprocesszorok (akusztikus és elektromos) önmagukban nem elegendőek, az elektródasornak is atraumatikus profillal kell rendelkeznie, hogy a belső fül struktúráinak megőrzése révén lehetőség legyen a residualis akusztikai hallás hosszabb távú megőrzésére [45].

Esetünk jól demonstrálja, hogy minimálisan invazív technikát, valamint atraumatikus elektródasort alkalmazva a residualis hallás hosszabb távon megőrizhető. Az új típusú CI532 Slim Modiolar elektródasorral nyert kedvező tapasztalataink előrevetítik annak lehetőségét, hogy a cochlea minden régiójának szerkezeti és funkcionális

épsége megőrizhető, ugyanakkor végleges megoldást nyújthat egy esetlegesen bekövetkező késői halláscsökkenés-progresszió kapcsán, amikor is elegendő csupán az implantátum pszichofizikai módszerekkel történő átprogramozása.

Eredményeink alapján, amennyiben a kezdeti tapasztalatoknak megfelelő biztonsággal és hatékonysággal őrizhető meg az akusztikai residualis hallás, úgy lényegesen kevesebb műtéti és altatási teher mellett leszünk képesek tartósan kiemelkedő hallásrehabilitációt biztosítani az EAS indikációjában is, ami jelentős életminőség-javulást, továbbá finansiális tehercsökkenést eredményez a beteg és a társadalom számára egyaránt.

Emellett a residualis hallás hosszabb távú megőrzése kiemelkedő fontosságúnak bizonyulhat a későbbi regeneratív eljárások, gyógyszeres kezelések megvalósíthatósága kapcsán is [46, 47].

Következtetés

A cochlearis implantáció során alapvető szerep jut, a minimálinvazív technikák mellett, az individuális igényeket figyelembe vevő, hosszú távon is biztonságos hallásmegőrzést nyújtó elektródasorok alkalmazásának. Esetünk jól demonstrálja a Nucleus CI532 Slim Modiolar elektródaprofil hatékonyságát residualis akusztikai hallás esetében, ami előrevetíti az elektródasorok ezen generációjának EAS-rendszerek részeként történő alkalmazhatóságát, hosszabb távon biztosítva egy esetlegesen a jövőben megjelenő, sejtregeneráción alapuló új terápiás módszer alkalmazhatóságának alapját.

Anyagi támogatás: A közlemény megírása anyagi támogatásban nem részesült.

Szerzői munkamegosztás: N. R.: Elektrofiziológiai mérések elvégzése, az ábrák megszerkesztése, a kézirat nyers változatának elkészítése. J. J. A.: Audiológiai leletek értékelése, a kézirat végleges szövegének megírása. D. B.: Elektrofiziológiai és audiológiai mérések elvégzése. P. Á.: A cochlearis implantációs kivizsgálás megszervezése, részvétel a műtét folyamatában. T. F.: Az elektrofiziológiai mérések értékelése, lektorálás. Sz. V.: A belső fül regenerációját vizsgáló kutatások értékelése, kéziratra adaptálása. J. J.: A kézirat lektorálása, publikációra való felkészítése. K. J. G.: Az elektrofiziológiai mérések, audiológiai vizsgálatok menetének beállítása, ellenőrzése, eredményeik értékelése, tudományos tanácsadás. R. L.: Az implantációs team vezetője, a cochlearis implantáció elvégzése, a beteg posztoperatív gondozása, a végleges kézirat lektorálása, a publikáció folyamatának nyomon követése, irányítása, lektorálás.

Érdekeltségek: A szerzőknek nincsenek érdekeltségeik.

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II.

ORIGINAL RESEARCH ARTICLE

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Electrophysiological measurements with electrode types of different perimodiolar properties and the same cochlear implant electronics – a retrospective comparison study

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Keywords: Cochlear implant, CI532, CI512, CI522, Electrode array, Perimodiolar, Electrophysiology

Introduction

There are currently different trends in cochlear implant electrode design [1]. The manufacturers provide a variety of implant configurations including different receiver-stimulators, electrode arrays (e.g. straight or pre-curved, full-length or short) and sound processors to choose from, which can facilitate decision making on an individual basis. Proximity to the modiolus [2, 3], electrical current requirements [4], energy consumption, trauma to the cochlea [5], combined electro-acoustic stimulation [6, 7]), preservation of cochlear structures with low-trauma surgical technique [3, 8–10] and hearing preservation [11–14] are important aspects of implant design which have become the focus of many discussions and studies.

For example, recent evidence suggests that speech discrimination is not improved by deep insertion, but it is significantly improved by perimodiolar position of the electrode [15].

Studies in implanted recipient groups using multiple implant types make it difficult to compare the influence of the implant electrode characteristics on outcomes in the presence of additional variables such as implant electronics, sound processors and speech coding paradigms. Hence, to reduce the number of variables, comparison

of the influence of electrode designs on outcomes could be interpreted more effectively if a consistent receiver-stimulator design and a common sound processor are used. Recent publications [16–20] represent imaging and electrophysiological results with CI532, but no comparative studies have yet been published.

Our center's postoperative radiological comparative study demonstrated that the Slim Modilar electrode array took a closer position to the modiolus than the Contour Advance electrode array [21].

As a consequence, the authors' aim in this multicenter study that is to their knowledge the first with this focus was to compare the influence of various electrode designs upon selected electrophysiological outcomes for cochlear implant recipients using the same model of receiver-stimulator, Cochlear™ Nucleus® Profile Series and sound processor in a retrospective study.

Materials and methods

Inclusion and allocation of subjects

A total of 139 consecutive subjects who were implanted between 13 June 2014 and 4 May 2017 with a Profile CI532 (CI532), a Profile CI512 (CI512), and a Profile CI522 (CI522) device manufactured by Cochlear Ltd., Australia and gave their informed consent were recruited to this retrospective study from two tertiary referral implant centers. Time periods of the study recruitment were from 13 June 2014 to 14 December 2015 for CI512, from 13 November 2015 to 4 May 2017 for CI532 and 11 March 2015 to 29 November 2016 for CI522. All subjects were examined with high resolution computed tomography

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and/or magnetic resonance imaging before surgery. Exclusion criteria were cochlear malformations, cochlear otosclerosis, obliterative postmeningitis changes and electrode tip foldover. To the authors knowledge there were no neural disorders in either group. Postoperative radiography was performed in each subject to confirm that the active electrode occupied an intracochlear position with no complications or abnormal electrode position.

The subjects were allocated into groups based on the electrode type implanted as shown in Table 1. Those who received a CI532 formed group 532, those who received a CI512 formed group 512, and those who received a CI522 formed group 522. Subjects were consecutively treated as part of routine clinical practice that was comparable at each respective implant site.

- A total of 159 ears in 139 subjects were implanted with devices, including the same implant receiver-stimulator electronics. CI532 had a 22 electrode array which was perimodiolar and with a relatively smaller diameter (named Slim Modiolar), CI512 had a 22 electrode array which was perimodiolar with a relatively larger diameter (named Contour Advance), and CI522 had a 22 electrode array which was straight, also with a relatively small diameter (named Slim Straight). A total of 54 ears were implanted with CI532 (all in Clinic 1), 54 ears with CI512 (51 in Clinic 1 and 3 in Clinic 2), and 51 ears with CI522 (47 in Clinic 2 and 4 in Clinic 1). Patients who were implanted with CI532 formed the test group. Two control groups were formed from patients who were implanted with Implants 512 and 522. The underlying causes of hearing loss were congenital, progressive, unknown and others (e.g.

cholesteatoma, infection, Meniere's disease, meningitis, ototoxic drugs, sudden hearing loss, trauma) in 29, 22, 16, and 33% for group 532, 28, 26, 28, and 17% for group 512, and 17, 23, 35, and 25% for group 522, respectively.

Implantation technique

The electrode arrays were inserted into the cochlea according to the manufacturer's instructions provided in the physician's surgical guide. The method of electrode insertion was identical in both implant clinics [22]. Full insertion was achieved via the extended round window approach with CI532 and CI512 and via the round window approach with CI522 in all ears. The AOS (advance off-stylet) technique was used for CI512 and the free-hand technique was used for CI522. Electrode choice was dependent on the actual implant pool of each center (regulated by the health authorities). The age of the patients did not influence implant choice. Discussion of hearing preservation was not an objective of this study.

Electrophysiological testing

The three different types of electrode arrays were compared with regards to outcomes from intraoperative and 3-months postoperative electrophysiological testing performed as per routine clinical protocol (Table 2).

Intraoperative electrophysiological tests were carried out as part of the regular fittings with Nucleus Custom Sound 4.4 software: Impedance was measured for each electrode, the electrical stapedial reflex threshold (ESRT) with 25 μ s pulse width for every second electrode contact (No. 2, 4, 6 etc.) and neural response telemetry threshold (T-NRT) for 6 (No. 2, 6, 10, 14, 18 and 22) electrode contacts. ESRT values were compared in

Table 1 Subject demographics for each subject group. Note: For continuous variables, the mean and + 1 standard deviation are shown in brackets

Subject group	532	512	522
Device	CI532	CI512	CI522
Electrode type	Slim modiolar	Contour advance	Slim straight
Number of patients	46	45	48
Number of ears	54	54	51
Age (year)	25.17 $\pm$ 26.29	20.80 $\pm$ 25.87	55.36 $\pm$ 28.59
Sex (male/female)	25/29	23/31	33/18
Duration of deafness (year)	2.94 $\pm$ 7.46	3.06 $\pm$ 9.34	3.13 $\pm$ 12.99
Cause of deafness			
Congenital	29%	28%	17%
Progressive	22%,	26%	23%
Unknown	16%	28%	35%
Others	33%	17%	25%

Table 2 Summary of the intraoperative and postoperative evaluation protocols and available data sets for each type of electrode. The routine protocol in Clinic 2 did not include measurement of intraoperative ESRT, and postoperative T-NRT

	Group 532 Nucleus CI532 (n/54 implants)	Group 512 Nucleus CI512 (n/54 implants)	Group 522 Nucleus CI522 (n/51 implants)
intraoperative ESRT	44	47	0
intraoperative T-NRT	50	47	43
postoperative C-level (1 month)	54	54	51
postoperative C-level (3 month)	54	54	51
postoperative T-NRT (3 month)	32	36	0

groups 532 and 512. T-NRT values in group 532 were compared with those in both control groups. A common sound processor (Nucleus CP910) was used.

The centers followed their normal routine protocol, thus the electrophysiological measurement protocol of the two centers was not identical, i.e. intraoperative ESRT testing, postoperative T-NRT measurements were not included in the routine protocol by Clinic 2, and thus CI522 was not analyzed with regards to these parameters. Furthermore, postoperative NRT was not measured for subjects in each group, where the current required to elicit a threshold response exceeded their discomfort or pain level.

The first fitting was performed 4 weeks after surgery in each case. In order to determine the electric threshold (T-levels), and comfort threshold (C-levels), the subjective fitting method was used in adults and the semi-objective NRT based fitting (based on the intraoperative T-NRT results) was applied in children [23, 24]. Default MAP parameters (25 μ s pulse width, 900 Hz stimulation rate and 8 maxima) were used. Postoperative NRT was measured 2 months after the first fitting, i.e. 3-months follow-up. C-levels at first fitting and 3-months follow-up fitting and T-NRT at 3-months follow-up were compared.

Outcomes for precurved slim perimodiolar electrode design, used at one implant clinic were compared to outcomes for two control groups of recipients implanted with precurved perimodiolar and straight electrodes in both implant clinics. Electrode designs were compared on the basis of outcomes for intraoperative objective electrophysiological measures and postoperative threshold levels and comfort levels to characterize electrode position within the cochlea.

Statistical analysis

Statistical analysis with the Student's t-test ($P < 0.05$) and one-way repeated measures ANOVA test were performed with 95% confidence interval ($p < 0.05$). Before the calculation, tests for normality of data distribution were performed. Bonferroni correction was used as needed to consider multiple variables (e.g. comparison of all three implant groups). The comparison was made on each electrode and all of the electrodes (Grand

average). The tests were performed with Microsoft Excel 2016 and SPSS for Windows.

Results

All subjects received Nucleus Profile implants. The only difference was the type of electrode. The patient groups were similar in subject numbers, etiology and duration of deafness, and indications.

Electrophysiology testing

Intraoperative measurements

Firstly, intraoperative electrical stapedial reflex threshold (ESRT, Fig. 1) and Neural Response Telemetry (T-NRT, Fig. 2), results were compared across implant groups. A stapedial reflex was tested in all subjects in group 532 and in 47 out of 54 cases in the control group (group 512). Figure 3 shows that the mean ESRTs were lower in group 532 than in group 512. This difference

was significant (t probe: $p = 0.007$) for electrode contact 2. Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between groups 532 and 512 ($p < 0.05$).

Intraoperative NRT measurements were performed in all three groups. The neural response threshold was tested in all subjects and could be elicited in 50 out of 54 (group 532), 47 out of 54 (group 512), and 43 out of 51 (group 522) cases. Repeated ANOVA analysis revealed significant difference ($p < 0.05$) between the three

groups. On examining the significance in pairs, we found that the mean T-NRTs (Fig. 2) proved to be lower in each electrode in group 532 when compared with each control group. The difference was significant in 5 measured electrode contacts when compared with CI522 and 3 measured electrode contacts when compared with CI512 (t-probe: $p < 0.05$). Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$ and Grand $T_{532-522}$) showed significant lower T-NRT values in group 532 compared with the two control groups ($p < 0.05$).

Postoperative C-levels

The subjects were scheduled for the first fitting 4 weeks after surgery. C-levels during the first fitting were compared in patient groups with different implants (Fig. 4). No significant difference in mean C-levels was seen on any electrodes between groups 532 and 512, but grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between the two groups ($p < 0.05$). C-levels were considerably higher on every electrodes in group 522 compared to groups 532 and 512, and the difference was significant for apical electrodes 2 to 12 ($p < 0.05$, Fig. 4)a. Grand average (all electrodes) statistic calculation (Grand $T_{532-522}$) showed significant differences between the groups ($p < 0.05$). However, no significant difference was present on any electrodes in C-levels 2 months after the first fitting, only the grand average statistical analysis (Grand $T_{532-522}$) showed significant differences between groups 532 and 522 (Fig. 4)b.

Postoperative T-NRT

In group 532 and 512, T-NRT measurements were attempted in all subjects at the two-month follow up fitting and the measurements were successfully carried out in 32 subjects in group 532 and 36 subjects in group 512. The intraoperative electrophysiological measurements could be performed in all subjects under general anesthesia, whereas the postoperative measurements were performed in vigil subjects. In the latter case, some of the subjects complained about unpleasant sound volume before a neural response could have been measured, for this reason the electrophysiological testing cannot be performed.

Figure 4 shows the postoperative mean T-NRT values. The mean T-NRT results in the basal section were lower in group 532 than in group 512. The difference was significant ($p < 0.05$) on two electrodes (No 14 and No 16). Grand average (all electrodes) statistic calculation (Grand $T_{532-512}$) showed significant differences between the groups ($p < 0.05$).

Discussion

A wide range of cochlear implants with different electrodes are available for rehabilitation of hearing impaired patients with severe to profound sensorineural hearing loss. Hearing rehabilitation outcomes may be influenced by optimizing device and electrode choice for the individual. Several comparative studies have been conducted including electrophysiological (ESRT, NRT) test methods to evaluate the influence of straight and perimodiolar electrode designs and their in-situ characteristics on clinical outcomes [1–3, 25–27]. Our study is unique in that it measured the influence of various electrode designs combined with a common receiver-

stimulator upon electrophysiological assessments for a relatively large routinely treated multicenter study cohort. As such, it is the first study to report on the influence of electrode design while using consistent implant receiver-stimulator electronics. The cooperation of the two clinics was established in 2017 with the aim to compare the perimodiolar and the straight electrode arrays. The study clinics followed a standard protocol enabled by the manufacturer's software, thus a conclusion from their individual results can be made. The results of Hey et al. from their multicenter study on CI532 are in good correlation with our results which proves that our methodology and results are reliable [20].

The Contour Electrode was the first perimodiolar electrode from Cochlear. As reported by researchers, some intracochlear trauma has been associated with its insertion, with a more reliable and less traumatic insertion achieved when deployed using the recommended advance off-Stylet technique [3]. This is largely due to an inherent reduction in intracochlear outer wall force generation when using this technique for this electrode [3].

The Slim Modiolar Electrode is designed for insertion with minimal cochlear trauma. It has the advantage of taking 60% less volume in the scala tympani compared to the Contour Advance Electrode and is therefore placed in a position close to the modiolus. Perimodiolar proximity is an important clinical consideration as Holden et al. [15] concluded, observing that total insertion depth was not associated with better speech discrimination outcomes, however, the distance from the electrodes to the modiolus did indicate a significant influence. The Slim Modiolar electrode array takes a closer position to the modiolus than the Contour Advance electrode array as confirmed by a comparative radiological evaluation [21].

In this retrospective study the data from recipients with the three main types of electrode arrays used in each of the two author implant centers were included. Although the electrode of CI522 was known to take the lateral wall position within the cochlea, the authors' decided to enroll those subjects who were implanted with CI522 to gain a more detailed overview. Although results of two different implant centers were combined for evaluation, upon review, the authors considered the routine clinical practices employed and device parameters used at each site as sufficiently comparable.

Results from the objective intraoperative measurements indicated that the electrode contacts of the CI532 array were located closer to the modiolus than those of CI512. A previous study found that withdrawal of the stylet in the Contour Advance Electrode resulted in better NRT and ESRT responses, than with the stylet in place. They concluded that this is most probably due to a more favorable position of the electrode array towards the modiolus within the scala tympani once the stylet is removed [26].

In our study, although the mean ESRT was only slightly lower with CI532, the difference was statistically significant at the basal most electrodes tested. However, the mean T-NRT for CI532 was significantly lower than for CI512, especially in the apical-middle section, which is considered to be indicative of closer positioning towards the modiolus. An expected rate of scalar dislocations could be 26% with precurved electrode (i.e. CI512) and 3% with straight electrode (i.e. CI522) with round window insertion technique [28] and this dislocation should have a significant impact on the NRT threshold in the apical part of the electrode. In order to minimize scalar dislocation, the extended round window insertion technique was used. Although the institutional protocols did not include post-operative computed tomography, the results from T-NRT and ESRT, both being constantly higher for CI512 when compared with CI532 and T-NRT being constantly lower for CI512 when compared with CI522 are not indicative of significant dislocations between scalae tympani and vestibuli. The sizeable reduction in both T-NRT and ESRT observed in our study are considered sufficiently large to potentially influence differences in clinical outcomes as observed for subjective comfort level [26, 29].

The surface area of an electrode is inversely proportional with the resistance, thus current is proportional with the surface area. If the electrode with a smaller surface is capable of eliciting the same response it means that it is closer to the stimulated structure. The lower objective electrophysiological thresholds of CI532 suggest that the electrodes are capable of eliciting reflex responses with lower stimulation intensity, resulting from closer proximity to the modiolus.

Conclusion

Although the Slim Modiolar electrode is significantly thinner than the Contour Advance and similar sized as the Slim Straight electrode array, the Slim Modiolar electrode provides similar or better stimulation productivity compared to Contour Advance and Slim Straight electrodes. The manufacturer's thinnest electrode array, the Slim Modiolar Electrode takes the position that is closer to the modiolus compared to the Contour Advance Electrode and the Slim Straight Electrode. Our intraoperative and postoperative measurements confirmed this showing that more effective stimulation can be achieved, through the use of the Slim Modiolar Electrode.

Abbreviations

ANOVA: Analysis of variance; C-level: Comfort threshold; ESRT: Electrically evoked stapedial reflex threshold; NRT: Neural response telemetry; T-level: Electric threshold; T-NRT: Neural response telemetry threshold

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Availability of data and material

Please contact the corresponding author for data requests.

Authors' contributions

All authors read and approved the final manuscript. AP: designed and performed experiments, analyzed data at both centers and wrote the paper. FT: designed and performed experiments, analyzed data at both centers and wrote the paper. AP and FT contributed equally to this work, thus both of them are shared first authors. BD performed experiments at the center in Hungary, provided statistical analysis and wrote the paper. RN performed experiments at the center in Hungary and provided analysis. PS: performed experiments at the center in Austria. JJ: performed experiments at the center in Hungary. JGK collected and analyzed data from the center in Hungary and provided critical revision. GS performed experiments at the center in Austria and provided critical revision. MC: proofread the manuscript. LR designed the study, performed experiments at the center in Hungary and wrote the paper.

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Ethics approval and consent to participate

The protocol of the investigation was approved by the Institutional Review Board (Human Investigation Review Board, University of Szeged, Albert Szent-Györgyi Clinical Center. Reference number: 38/2014), and the investigators obtained written informed consent from each participant or each participant's guardian. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent for publication

not applicable.

Competing interests

The authors declare that they have no competing interests.

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III.

Cochlearis implantátumok különböző, előre görbített elektródasorainak elhelyezkedése a cochlea tengelyéhez viszonyítva

Radiológiai vizsgálat a perimodiolaritás mértékének megállapítására

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Bevezetés: A cochlearis implantátumok elektródái gyártótól és modelltől függően különböznek hosszukban, vastagságukban és implantációt követően a csiga tengelyéhez (modiolushoz) viszonyított elhelyezkedésükben. Az előre görbített elektródasorok közelebb kerülnek a stimulálandó ganglion spirale sejtekhez, mint az egyenes elektródasorok, ami a stimulációban tapasztalt elektrofiziológiai különbségek mellett előnyös lehet a hangélmény minőségének szempontjából.

Célkitűzés: Előzetes elektrofiziológiai vizsgálataink eredménye szerint ugyanannak a termékcsaládnak (CochlearTM Nucleus[®] Profile) a vastagabb (Contour Advance) és vékonyabb (Slim Modiolar) perimodioláris elektródasorai közül a vékonyabbnak az elektródái hasonló töltésmennyiség átadása mellett is képesek hasonló idegi választ kiváltani, mint a vastagabbnak az elektródái. Vizsgálatunkkal arra kerestük a választ, hogy milyen jelenség áll az elektrofiziológiai eredmények hátterében.

Módszer: Betegcsoportonként 54, Contour Advance és Slim Modiolar típusú elektródasorral implantáltakat vontunk be. Az elektródasor bevezetése minden esetben a kerek ablakon keresztül történt, a kerek ablak elülső-alsó csontszélének elfúrását követően vagy a nélkül. A műtét másnapján készült, Stenvers-féle röntgenfelvételeken megmértük az elektródasorok által leírt hurok cochleán belüli legnagyobb átmérőjét. A beültetés után két hónappal megbecsültük a kétféle perimodioláris elektródasorral felszerelt implantátum energiafelhasználási mutatóit.

Eredmények: A posztoperatív röntgenfelvételeken a vékonyabb perimodioláris elektródasorral implantált csoportban az elektródasorok által leírt hurok cochleán belüli átlagos átmérője $4,2 \pm 0,5$ mm, míg a vastagabb perimodioláris elektródasorral implantált csoportban $4,9 \pm 1,1$ mm értéknek adódott. Az 'Auto power' a CI532-csoportban $44,81 \pm 5,05\%$, a CI512-csoportban $50,85 \pm 8,35\%$ volt, tehát alacsonyabb energiafogyasztást tapasztaltunk a CI532-csoportban.

Következtetés: Képi diagnosztikai módszerrel, viszonylag nagy esetszám bevonásával arra következtettünk, hogy a vékonyabb perimodioláris elektródasor még a vastagabbnál is szignifikánsan közelebb kerül a modiolushoz, ami elfogadható magyarázatot ad előzetes elektrofiziológiai mérési eredményeinkre.

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Kulcsszavak: siketség, cochlearis implantátum, elektródapozíció, modiolus, perimodioláris

The distance from the modiolus of perimodiolar electrode arrays of cochlear implants

A radiological study to evaluate the difference in perimodiolar properties

Introduction: The cochlear implants vary in electrodes in terms of length, width and proximity to the modiolus. The precurved electrode arrays could be placed closer to the modiolus and the ganglion cells compared to straight electrodes. The two types of electrode arrays provide different electrophysiological characteristics; however, proximity to the modiolus may lead to better hearing performance.

Aim: To investigate our preliminary electrophysiological results that suggest that the Slim Modiolar (SM) electrode array has the potential to elicit similar neural responses as the thicker perimodiolar (Contour Advance, CA) electrode from the same generation of implants.

Method: Subjects that were implanted either with CA or SM electrodes were enrolled, 54 consecutive subjects in each group. All electrodes were introduced into the cochlea *via* the round window. The diameter of the largest turn of the electrode arrays within the cochlea was measured through postoperative radiography. The energy consumption parameters were estimated 2 months after implantation.

Results: The mean of the largest turns of the arrays within the cochlea was 4.2 ± 0.5 mm in the SM group and 4.9 ± 1.1 mm in the CA group. 'Auto power' was $44.81 \pm 5.05\%$ and $50.85 \pm 8.35\%$ with SM and CA, respectively. Estimated energy consumption was lower with SM. The differences were statistically significant.

Conclusion: Our measurements for a large cohort in each group suggest that the SM electrode array takes a significantly closer position to the modiolus than the CA. This finding supports our earlier electrophysiological result and indicates better performance abilities.

Keywords: deafness, cochlear implant, electrode position, modiolus, perimodiolar

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Súlyos fokú sensorineuralis halláscsökkenés esetében, amikor nagy teljesítményű hallókészülékkel sem valósítható meg kielégítő hallás(re)habilitáció, cochlearis implantátum beültetése lehet indokolt. Több gyártó kínál belsőfül-implantátumot és többféle beszédprocesszor, és egyazon gyártótól is több konfiguráció áll rendelkezésre. A konfigurációk különböznek az elektródasorok típusában (például egyenes vagy előre görbített, teljes hosszúságú vagy rövid, vékony vagy vastag), ezáltal lehetőséget biztosítanak a páciensek egyéni anatómiai tulajdonságaira és igényeire szabott eszköz megválasztására. A variációk ugyanakkor megnehezítik a klinikai vizsgálatok eredményeinek összehasonlítását, értékelését. Több kutatócsoport végzett célzott vizsgálatokat a különböző elektródasorok tulajdonságaiból adódó gyakorlati következmények felmérésére, így például a stimuláló elektródasornak a cochlea tengelyéhez, azaz a modiolushoz viszonyított távolságára [1, 2] és ennek elektrofiziológiai hatásaira [3], az energiafogyasztásra, az endocochlearis struktúrák sérülésének mértékére [4], a lehető legkisebb traumával járó sebészeti technikákra [2, 5–7], a kombinált elektroakusztikus stimulációra [8, 9] és a hallásmaradvány megőrzésére [10–14] vonatkozóan. A megfelelő hangélmény biztosítását a tudományos közlemények szerzői elsősorban az elektródasor tulajdonságaiban, az elektródasor kíméletés bevezetésében és a beszédprocesszor

szor jó beprogramozásában látják. Egyes szerzők az előre hajlított elektródasorok modiolushoz közeli helyzetével, míg mások a cochlea hosszú elektródasor általi teljes lefedettségével tapasztaltak jobb eredményeket a hallásélményben [15–18].

Az elektródasorok a cochleán belül, típustól függően két „szélső pozícióba” kerülhetnek: az egyenes elektródasorok a modiolustól távoli, ún. *laterális fali* helyzetet, míg az előre görbített elektródasorok modiolushoz közeli, ún. *perimodioláris* helyzetet foglalnak el (1. ábra). Létezik még az úgynevezett *midscala* elhelyezkedésű elektródasor, amely a scala tympaniba vezetve „köztes” pozíciót vehet fel.

Bár vitatott dolog, hogy az egyenes vagy az előre görbített elektródasorokkal érhető el jobb hallásélmény, a stimuláló elektródák és a modiolus viszonyának fontosságára mutat rá az a vizsgálati eredmény, amely szerint a hangélmény és a beszédértés minőségében szignifikáns javulást eredményezhet, ha az elektródák közelebb kerülnek a modiolushoz, előre görbített elektródasorok esetében [15]. Az előre görbített elektródasorok előnye az egyenesekkel szemben az, hogy kialakított tulajdonságuknak köszönhetően az egyes elektródák közelebb kerülhetnek a modiolushoz, ezáltal az elektromosan stimulálható ganglion spirale sejtekhez is. Következésképpen a leadott töltésmennyiség – a kisebb távolság miatt – ki-

Slim Straight elektródasor

Slim Modiolar elektródasor

1. ábra

Az egyenes és a perimodiolaris elhelyezkedésű elektródasorok cochleán belüli helyzetének szemléltetése ugyanannál a páciensnél, szekvenciális cochlearis implantációt követően, Stenvers-szerinti röntgenfelvételeken. A jobb és a bal oldali cochlea szabályos alakú és azonos méretű, amit az implantációt megelőzően készült komputertomográfias felvételen, méréssel ellenőriztünk. A jobb cochleába vékony, egyenes stimuláló elektróda (Cochlear™ Slim Straight), a bal cochleába vékony, előre görbített stimuláló elektróda (Cochlear™ Slim Modiolar) került. A szaggatott fekete kettős nyílak az elektródasorok által a cochleán belül leírt hurok legnagyobb átmérőjét mutatják

sebb mértékben szóródik szét a cochlea folyadékterében, így kisebb áramerősségű impulzusok elegendőek a ganglion spirale sejtjeinek ingerléséhez [14, 19, 20]. Emiatt szélesebb a hallásküszöb és a komfortküszöb közötti dinamikai tartomány, csökken az energiafogyasztás, és nő az elem/akkumulátor élettideje [1, 21].

Cochlearis implantátum beültetését követően rutinszerűen röntgenfelvételt készítünk. A Stenvers-féle felvételen nagy biztonsággal állapíthatók meg azok a komplikációk, amelyek az elektródasor eltávolítását és újbóli pozicionálását teszik szükségessé, így például ha az elektródasor rendellenes, cochleán kívüli helyzetbe került

2. ábra

Cochlearis implantációt követően 15 évvel, recidiváló cholesteatoma gyanúja miatt készített cone-beam komputertomográfias vizsgálat, modiolusra centrál, rá merőleges síkú, a cochlea bazális kanyarulatát ábrázoló rekonstrukciója. A cochleában kiterjesztett kerek ablaki behatolásból bevezetett Contour Advance elektródasor látható. A dobüregben – hipodenz megjelenésű levegő helyett – lágyrésznek megfelelő fedettséget (műtétileletünk alapján recidív cholesteatomát és hegeket) találunk. Elkülöníthető a csontos cochleán belül a hártás cochlea, és látható, hogy az előre görbített elektródasor nagy része a hártás cochlea belső falához közel helyezkedik el

vagy a vékony, előre görbített elektródasorok esetében gyakran észlelt 'tip fold-over' (az elektródasor csúcsi részének visszahajlása) [22, 23]. A szummációs röntgenképeken a csigán belüli részletek (scala tympani, scala vestibuli) nem különülnek el. Komplikáció gyanújakor, a részletgazdagabb képi megjelenítés érdekében szóba jön a sziklacsont vékony szeletes komputertomográfiás (CT-) vizsgálata vagy még inkább cone-beam (kúpsugaras) CT-vizsgálata, amely szignifikánsan alacsonyabb effektív sugárdózissal elvégezhető, és kevesebb műterméket okoznak rajra a fémelektrodák (2. ábra) [24–26].

A hallásmaradvány implantációt követő megőrzésének kiemelten fontos feltétele az, hogy az elektródasor mind a bevezetésekor, mind azt követően a lehető legkisebb traumát okozza a cochleában. Ezért alkalmazunk vékony, hajlékony elektródasorokat, amelyeket az ún. *soft surgery* [27] technikával vezetünk a cochlea scala tympani járatába. A rendelkezésre álló vékony elektródasorokat az 1. táblázatban mutatjuk be [28–32].

A klinikai vizsgálatok eredményeinek értékelését megnehezítő variációk csökkentése érdekében ugyanannak a termékcsaládnak kétféle előre görbített elektródasorral rendelkező implantátumtípusát választottuk a vizsgálatunkhoz. Munkacsoportunk rendszeresen alkalmazza a Cochlear™ Nucleus® Profile termékcsaládot (Cochlear Limited, Sydney, Ausztrália), és széles körű tapasztalatra tett szert mindkét perimodioláris elektródával. A termékcsalád tagjai csupán az elektródasor típusában különböznek, az implantátumtestben elhelyezkedő elektronikai egység azonos. A Slim Modiolar a jelenleg elérhető egyik legvékonyabb elektródasor, amely 'closed-market release' (zárt piaci kibocsátás) keretében a Szegedi Tudományegyetem Fül-Orr-Gégészeti és Fej-Nyaksebészeti Klinikáján került beültetésre elsőként, 2015 novemberében. A Contour Advance® elektródasor mind az apicalis, mind a bazális átmérőjében (a: 0,5 mm, b: 0,8 mm) szignifikánsan vastagabb a Slim Modiolar elektródasor átmérőinél (a: 0,4 mm, b: 0,5 mm), és az egyes elektródák aktív felülete nagyobb, mint a Slim Modiolar elektródáké [31, 32]. Mivel az ingerlő elektródák felszíne és az ellenállás között fordított arányosság áll

fenn, valamint az ingerlő elektródák és a célzott idegelemek (modiolus, ganglion spirale) közötti távolság egyenesen arányos a közeg elektromos ellenállásával, ebből az következik, hogy ha a kisebb felszínű elektródák kisebb töltésmennyiséggel képesek lehetnek kiváltani hasonló mértékű akciós potenciált, akkor közelebb kell lenniük a stimulált struktúrához.

Munkacsoportunk korábbi, nagy esetszámon elvégzett elektrofiziológiai vizsgálatainak eredményei arra utalnak, hogy ugyanazon elektronikai egység mellett a Slim Modiolar elektródasor (CI532 típusú implantátum) még alacsonyabb áramerősségű impulzusok mellett is képes idegi választ, akciós potenciált generálni, mint a Contour Advance elektródasor (CI512 típusú implantátum) [33, 34]. Vizsgálatunk célja annak megállapítása volt, hogy a fenti előnyös elektrofiziológiai tulajdonságokból levont következtetést alátámasztják-e az implantátum energiafelhasználási mutatói és a posztoperatív képalkotó vizsgálatok eredményei.

Anyag és módszer

Az első 54, CI532 és az első 54, CI512 készülékkel implantált esetünket vizsgáltuk. A betegcsoportok demográfiai jellemzőit a 2. táblázatban tüntettük fel.

A műtéteket két, cochlearis implantációban jártas, tapasztalt fülsebész végezte el a nemzetközileg leginkább elfogadott és elterjedt módszerrel, posterior tympanotómias feltárásból, „soft surgery” technikával a Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központja Fül-Orr-Gégészeti és Fej-Nyaksebészeti Klinikáján. Az elektródasorok bevezetése a kerek ablak fülkáját (fossula fenestrae cochleae) képező csontos struktúrák elvétele után a kerek ablakon keresztül vagy járulékosan a kerek ablak elülső-alsó csontszélének elfúrását követően, ún. kiterjesztett, kerek ablaki behatolásból történt.

2. táblázat | A vizsgálatba bevont betegek demográfiai adatai

Betegcsoport	CI532	CI512
Az implantátum típusa	Cochlear Nucleus CI532	Cochlear Nucleus CI512
Az elektróda típusa	Slim Modiolar (vékony perimodioláris)	Contour Advance (vastag perimodioláris)
Betegszám	46	45
Az implantált fülek száma	54	54
Életkor (év)	25,17 ± 26,29	20,80 ± 25,87
Nem (férfi/nő)	25/29	23/31
A siketség időtartama (év)	2,94 ± 7,46	3,06 ± 9,34
A siketség oka		
veleszületett	29%	28%
progresszív	22%	26%
ismeretlen	16%	28%
egyéb	33%	17%

1. táblázat | A vékony elektródasorok típusa és átmérői [28–32]

Elektródasor megnevezése	Elektródasor típusa	Elektródasor átmérője (a: apicalis, b: bazális)
MED-EL FLEX24 és FLEX28	Egyenes	a: 0,3 × 0,5 mm b: 0,8 × 0,8 mm [28]
Advanced Bionics HiFocus™ Mid-Scala	Előre görbített	a: 0,5 mm b: 0,7 mm [29]
Oticon Medical EVO®	Egyenes	a: 0,4 × 0,4 mm b: 0,5 × 0,5 mm [30]
Cochlear™ Nucleus® Profile Slim Straight	Egyenes	a: 0,3 mm b: 0,6 mm [31]
Cochlear™ Nucleus® Profile Slim Modiolar (CI532)	Előre görbített	a: 0,35 × 0,4 mm b: 0,45 × 0,5 mm [32]

Contour Advance elektródasor

Slim Modiolar elektródasor

3. ábra

Perimodioláris elektródasorok helyzete a cochleán belül, ugyanannál a páciensnél, szekvenciális cochleáris implantációt követően, Stenvers szerinti röntgenfelvételeken. A jobb és a bal oldali cochlea szabályos alakú és azonos méretű, amit az implantációkat megelőzően készült komputertomográfias vizsgálaton ellenőriztünk. A jobb cochleába a vastagabb előre görbített stimuláló elektródasor (Contour Advance), a bal cochleába a vékonyabb előre görbített elektródasor (Slim Modiolar) került. A szaggatott fekete vonalak az elektródasor által a cochleán belül leírt hurok legnagyobb átmérőjét mutatják

Az első posztoperatív napon protokollunknak megfelelően digitális röntgenfelvétel készült Stenvers-nézetben [35] a beültetett implantátum helyzetének meghatározására. Jellemeztük az elektródasor és a modiolus viszonyát: a 3. ábrán feltüntetett módon a modiolus tengelyére állított merőleges egyenesen megmértük az elektródasor által leírt hurok cochleán belüli legnagyobb átmérőjét. Összehasonlítottuk az elektródahurok ezen átmérőit a két betegcsoportban. A statisztikai értékelést kétmintás t-próbával végeztük.

A beültetést követően két hónappal, ugyanannak a beszédprocesszornak (Cochlear™ Nucleus® CP910) az alkalmazása mellett, a készülék beprogramozása után megbecsültük a kétféle perimodioláris elektródasorral rendelkező implantátum energiafelhasználási mutatóit a Cochlear™ Custom Sound® Suite 4.4 verziójú szoftverrel.

Eredmények

A posztoperatív röntgenfelvételeken a CI532-betegcsoportban az elektródahurok cochleán belüli átlagos átmérője $4,2 \pm 0,5$ mm SD, míg a CI512-betegcsoportban $4,9 \pm 0,1$ mm SD volt (kétmintás t-próba: $p = 0,00136$) (3. ábra).

Egyik páciensünk esetében két különböző elektródasorral végeztünk szekvenciális bilaterális implantációt: jobb oldalra CI512 típusú, bal oldalra CI532 típusú implantátumot ültettünk be másfél év különbséggel. Az elektródák perimodioláris elhelyezkedését találtuk mindkét oldalon, ugyanakkor a Slim Modiolar elektródasornak kisebb a cochleán belüli hurokátméreje.

’Tip fold-over’-t a vizsgált 108 esetünkben nem találunk.

Az ’Auto power’ szint szignifikánsan alacsonyabbnak bizonyult a CI532-betegcsoportban ($44,81 \pm 5,05\%$), mint a CI512-betegcsoportban ($50,85 \pm 8,35\%$) ($p < 0,05$). Nagyobb ’maximaértékek’ ($7,50 \pm 0,87$ versus

$6,56 \pm 1,02$) mellett is hosszabb az akkumulátor becsült élettideje (napi élettartama) a vékonyabb perimodioláris elektródasor esetében (3. táblázat).

Megbeszélés

A nagyfokú halláscsökkenésben szenvedő páciensek (re)habilitációjára több gyártó különféle elektródasorok-

3. táblázat

Ugyanannak az implantátumcsaládnak a vékonyabb (Slim Modiolar) és vastagabb (Contour Advance) perimodioláris elektródasorával rendelkező implantátumok energiafelhasználási mutatói ugyanazzal a típusú beszédprocesszorral

Slim Modiolar elektródasor (CI532)		Contour Advance elektródasor (CI512)
$44,81 \pm 5,05\%$	<i>Auto power</i>	$50,85 \pm 8,35\%$
$7,5 \pm 0,87$	<i>Maxima</i>	$6,56 \pm 1,02$
$43,25 \pm 8,46$ h	<i>Battery</i>	$40,04 \pm 6,48$ h
$19,56 \pm 1,82$ h	<i>Standard accu</i>	$18,04 \pm 2,52$ h
$11,5 \pm 1,15$ h	<i>Compact accu</i>	$10,58 \pm 1,51$ h

Auto power: A készülékprogramozáshoz szükséges gyártói szoftver lehetővé teszi a teljesítmény automatikus vagy manuális konfigurálását minden egyes paraméterezett beállításhoz, úgynevezett MAP-hez. Ajánlott az Auto power funkció használata minden lehetséges esetben, amely hozzájárul a hangprocesszor teljesítményszintjének automatikus optimalizálásához. Miután meghatároztuk az egyes készülékbeállítás-hoz szükséges paramétereket, úgy az automatikusan számított teljesítményszint megjelenik a MAP-eken.

Maxima: A maximaérték az egyes beszéd kódolási stratégiák paramétere (SPEAK, az ACE™ és az MP3000™); az audiojel azon spektrális felbontás után frekvenciartományaira utal, amelyek a legnagyobb hangerősséggel rendelkeznek. Ez az érték adja meg az adott jelhez kiválasztott maximaértékek számát, tehát adott időpillanatban a maximaértéknek megfelelő számú legnagyobb hangerősséggel bíró, aktív elektródák számát.

Battery: hagyományos elem, vagyis kettő darab, 675 típusszámú, 1,45 V gombelem.

Standard accu: hagyományos akkumulátor.

Compact accu: kompakt akkumulátor, kisebb a hagyományos akkumulátornál.

kal ellátott cochlearis implantátuma áll rendelkezésre. A hallás(re)habilitáció eredményeire kihat a készülék és az elektróda egyénre szabott megválasztása. A perimodioláris elektródák modiolushoz minél közelebb elhelyezkedésének fontosságára hívja fel a figyelmet *Holden és munkatársainak* 2013-ban publikált eredménye, amely szerint a páciensek hangélményének és beszédértésének minősége elsősorban nem a bevezetett elektródasor hosszától, illetve a bevezetés mélységétől függ, hanem az elektródasor modiolushoz viszonyított helyzetétől [15].

A Contour Advance olyan, előre görbített elektródasor, amelyet belső fém vezetősál segítségével, kiegyenesített állapotban vezetünk be a cochlea scala tympani járatába. Az 'advance off-stylet' technika jelentős eredményeket hozott az endocochlearis struktúrák sérülésének csökkentésében, ez az elektródasor a vastagsága és a fém vezetősál miatt mégis nagyobb arányban okoz sérülést, mint a vékonyabb egyenes elektródasorok [2]. A cochleában okozott sérülések csökkentésére fejlesztették ki a szintén előre görbített, vékony és kevésbé merev Slim Modiolar típusú perimodioláris elektródasort, amelyet külső vezetőhüvely segítségével vezetünk be a cochleába. Az utóbbi a scala tympani folyadékteréből jelentősen kisebb volument foglal el a vastagabb elektródasorhoz képest, és azt is döntően a bazális membrán csontos része alatt, ami kevésbé zavarja a cochlea hidrodinamikai működését. Fontos ez a körülmény a műtét előtti hallásmaradvány megőrzésének lehetősége szempontjából [14].

A pácienseinkről rendelkezésre álló posztoperatív digitális röntgenfelvételekről határoztuk meg a stimuláló elektródák cochleán belüli helyzetét. Cone-beam CT-vel (2. ábra), rotációs tomográfiával vagy vékony szeletes CT-vizsgálattal részletgazdagabb képeket, ezáltal az egyes esetekben pontosabb távolságmérési adatokat kaphatnánk [24–26, 36]; ezeknek a vizsgálatoknak lényegesen nagyobb a pácienszt érintő sugárterhelésük (effektív dózissuk), mint a koponya-röntgenfelvételeké, és korlátozottabban juthatunk hozzájuk a mindennapi ellátásban. Ugyanakkor a standardizált protokollnak köszönhetően a direkt digitális röntgenfelvételeken [34] is jól megállapítható a különböző elektródákkal implantált betegcsoportok közötti különbség, nagy esetszám mellett. Stenvers-felvételen a centrális sugárraláb a cochleán hatol keresztül, így a röntgenteknika sajátosságaként ismert nagyítás és torzítás szerepe minden vizsgálatnál csak egyformán kis, gyakorlatilag elhanyagolható mértékben jelentkezik. A szummáció szintén elhanyagolható a fém (elektróda), a csont és a lágyszövetek eltérő sugárelnyelő képessége miatt. A páciensek életkorbeli különbségei a képalkotó vizsgálatok szempontjából elhanyagolhatók, mivel a belső fül méretei már a születéskor megegyeznek a felnőttkori méreteikkel [37–39].

A fenti vizsgálatainkkal szignifikáns különbséget találunk a kétféle perimodioláris elektródasor cochleán belüli hurokátmértékében és az energiafelhasználási mutatókban, a vékonyabb elektródasor javára.

Következtetés

Képi diagnosztikai módszerrel, nagy esetszámon megállapítottuk, hogy ugyanazon termékcsalád vékonyabb perimodioláris elektródasora a vastagabb perimodioláris elektródasornál szignifikánsan közelebb kerül a modiolushoz. A CI532 energiafelhasználási mutatói jobbakké a CI512 mutatóinál, tehát a vékonyabb perimodioláris elektródával alacsonyabb energiafelhasználás mellett is ugyanolyan hatékonyan stimulálható a hallóideg (3. táblázat).

Az elektródasor megválasztásának fontos szempontjait (a halláselmény, a beszédértés javítása, a hallásmaradvány megőrzése) figyelembe véve munkacsoportunk a perimodioláris elektródasorok közül a vékonyabb perimodioláris elektródasor alkalmazását tartja megfelelőnek és kívánatosnak.

Anyagi támogatás: A közlemény megírása, illetve a kapcsolódó kutatómunka anyagi támogatásban nem részesült.

Szerzői munkamegosztás: P. Á.: A protokoll kidolgozása, a mérések elvégzése, a kézirat megszövegezése. N. R., D. B.: Az elektrofiziológiai vizsgálatok elvégzése, a kézirat megszövegezése. Cs. M.: A kézirat megszövegezése. J. J.: Műtétek végzése, a kézirat megszövegezése. K. J. G.: A mérési módszer kidolgozása, statisztikai elemzés. R. L.: A protokoll kidolgozása, műtétek végzése, a kézirat megszövegezése. A cikk végleges változatát valamennyi szerző elolvasta és jóváhagyta.

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IV.

Long-term Hearing Preservation with Slim Perimodiolar CI532[®] Cochlear Implant Array

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Abstract

By using sophisticated surgical techniques in combination with the Slim Perimodiolar cochlear implant electrode array a hitherto unattained high rate of residual hearing preservation in cochlear implantation has been observed that makes potential for electric acoustic stimulation. One of the primary aims of cochlear implant system engineering is to promote atraumatic electrode insertion to maintain optimal postoperative hearing sensitivity by protecting and preserving the delicate inner ear structures.

The study aimed to collect pre-, and postoperative audiological and surgical results from the experience gained from the applied cochlear implant configuration.

About 30 patients (aged 43.32 ± 24 years) with partial hearing loss were supplied with this atraumatic perimodiolar thin electrode which was designed to preserve residual hearing despite intracochlear insertion of an electrode array. All patients were implanted with consentaneous CI system and surgery technique.

The use of new electrode array profiles in cochlear implantation plays a fundamental role in minimally invasive soft surgery, taking into individual needs, and providing long-term acoustic hearing preservation. Hearing preservation was achieved in most cases (partial residual hearing preservation) after a long-term follow-up period (preoperation, at least one year).

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Keywords: Cochlear implantation; Hearing preservation; Soft surgery; Perimodiolar electrode profile

Introduction

Competing companies (Advanced Bionics, Cochlear, Med-El and Oticon, etc.) provide different types of receiver-stimulators, implant electrodes and speech processors. There are several pros and cons when opting for an electrode profile (straight or perimodiolar), cochlear coverage (total or partial), receiver-stimulator (physical attributes) and speech processor (electric or electroacoustic stimulation), that meet the individual needs. One of the primary aims of cochlear implant system engineering is to promote atraumatic electrode insertion to maintain optimal postoperative hearing sensitivity by protecting and preserving the delicate inner ear structures.

Residual hearing sensitivity may deteriorate due to perioperative traumas or complications with delayed onset. The applied surgical approach (Round Window (RW), Extended Round Window (ERW), Cochleostomy (CS)) and the implanted electrode profile mainly lead to immediate or short-term damage, while delayed alteration in cochlear function usually derives from the fibrous or bony remodelling of the endocochlear compartments.

Surgically important properties are the physical attributes of the electrode configuration (perimodiolar vs. straight; rounded vs. smoothened tip; short vs. regular; with or without stylet, etc.), the type of cochlear fenestration (RW, ERW, CS), the method of electrode insertion (standard vs. soft surgery with advance-off-stylet), the use of lubricants or drugs in the cochlea (e.g. intrascler corticosteroids) and the intrascler position of the electrode array (perimodiolar, mid-scala, lateral-wall) [1-3].

However, the possible disproportion between the physical dimensions of the electrode profile and the endocochlear compartments (diameter, shape, length of scala tympani) play a significant role in preserving inner ear structures and functions, too.

Minimizing the damage in the inner ear enhances the possibility for hearing preservation, thus leading to better hearing performance. Systemic and/or intratympanic administration of steroids may contribute to hearing preservation. The beneficial effects of glucocorticoids are thought to be mediated through several different pathways: the anti-inflammatory effects; the down-regulation of production of inducible nitric-oxide synthase; and direct inhibition of the MAP/JNK cell death signal cascade [2-5].

We aimed to study long-term hearing preservation in a non-randomized, prospective clinical cohort with cochlear implant systems, limited to ones produced by Australian and Austrian leader companies, provided and fully financed by the Hungarian National Health Insurance.

Materials and Methods

Study cohort

Out of the total number of cochlear implantees with slim perimodiolar implant system (n=94) our study population was recruited on the basis of the following criteria: (1) patient with good compliance; (2) measureable preoperative hearing threshold; (3) slim perimodiolar electrode array implant system; (4) minimum one-year follow-up period. Thirty consecutive subjects were enrolled into this prospective, non-randomized clinical study. Twenty females and ten males with mean age at implantation of 43.32 years, ranged between 10 years to 77 years. All subjects were implanted at the University of Szeged from 2015 until 2017. The postoperative follow-up duration lasted 1.72 years at average (ranged between 1.1 and 2.55 years). All

subjects met the official indication criteria of Cochlear Implantation (CI). Anatomical / structural malformation was not revealed by the preoperative radiological examinations. For detailed patient data, please see Table 1.

Implant configuration

The studied cochlear implant system has a slim, full-length perimodiolar electrode (Figure 1). The thin implant body has no pedestal and it is designed to minimize bone excavation and skin protrusion. At the implant coil the implant measures 3.7 mm and the implant main body measures 3.9 mm in thickness. The side-by-side symmetrical shape makes the implantation easier for the surgeon. The titanium casing has been used for high impact resistance, and the smooth external geometry to minimize biofilm formation, that reduces the risk of infection. The 98 mm total length of electrode array helps to insert it in a better position, but the main handle assist tool is the reloadable sheath for the smooth electrode insertion. The thin electrode array allows unobstructed access to the scala tympani that has a tip diameter of 0.35×0.4 mm and 0.45×0.5 mm at the base. At the last edge of the electrode array there are three white marker rings for controlling the insertion depth that are followed by 22 half banded platinum electrode contacts. These properties make this implant configuration easier to use with shorter incision and surgery time. The insertion assistant sheath platform and the physical attributes of the electrode array facilitate to proximate the modiolus and thus prevent the electrode from dislocation into the scalae media or vestibuli [6-8].

Surgical technique

Preserving the residual hearing requires minimally invasive techniques of (1) cochlear fenestration, (2) management of endocochlear fluid compartments and (3) atraumatic electrode insertion, known as soft surgery. Thinner and atraumatic electrode arrays are also designed to accomplish these aims, as postoperative hearing performance can be maximized by minimizing the insertion trauma [3,8-11].

Several important factors contribute to intracochlear damage during implantation: (1) direct physical trauma, (2) pressure wave propagation in the perilymphatic fluid, (3) vibration and/or heat trauma from drilling, (4) loss of perilymph, (5) changes

in homeostasis/hydrodynamics of the endocochlear fluid compartments, (6) delayed fibrotic alteration and new bone formation within the cochlear lumen [3,12-16].

The physical attributes (length and diameter) of the electrode array may each limit the postoperatively achieved residual hearing [17].

Comprehensive analysis of imaging diagnostics of the middle and inner ear provide indispensable information for planning the proper surgical access route and electrode [17,18].

Soft surgery

The term soft surgery was introduced by Lehnhardt in 1993 and it provided basis for numerous publications [9,19].

Our routinely applied minimally invasive surgical technique involved electrode insertion *via* the Round Window (RW). In order to reduce bleeding and to prevent blood from accessing the cochlea, we filled the tympanic cavity with adrenaline solution after having the posterior tympanotomy been completed. To prevent bone fragments entering the cochlea, the tympanic and mastoid cavity were flushed with abundant amount of saline. To remove the bony overhang of the round window, we used a 1 mm diamond burr at low speed (max. 350 rpm) in order to avoid noise and heat injury. We opened the RW membrane with a microscopic needle or hook. After opening the inner ear, suction was applied with care in order to avoid reducing the amount of perilymph. Furthermore, the scala tympani was left

open for the shortest possible period, to prevent bone fragments, blood or other substances entering the inner ear, which might have been sources of primary and/or secondary injuries that finally would lead to loss of residual hearing. As a sort of prevention, after having opened the RW, we placed a piece of gel-foam soaked in corticosteroid solution into the RW niche.

The slim modiolar electrode of the CI532 implant was soaked into methylprednisolone solution (40 mg powder dissolved in 10 ml saline) and it was retracted into the insertion sheath. The insertion sheath together with the electrode array was inserted into the scala tympani with the lowest possible force. Any minute resistance felt by the surgeon would have indicated physical contact of the electrode array to the basilar membrane or the lateral wall of the scala tympani or stria vascularis and possible injury of these structures. After the electrode had been inserted in full length, indicated by the 1st marker ring, the RW was immediately sealed with an autologous tissue (e.g. fascia or muscle) in order to prevent loss of perilymph [9].

Radiological validation

Radiography (skull AP axial/Towne view) was performed on the first postoperative day to confirm the proper intracochlear electrode position (Figure 2).

Pure-tone audiometry

Pure-tone air-conduction thresholds were used to register residual hearing with the ascending method, with 5 dBHL intensity steps. The audiometer (GSI 61 Clinical Audiometer; Grason-Stadler, MN USA) was calibrated according to the standards of the International Organization for Standardization (ISO 389-1:2017). THD-50P (Telephonics Corporation/Griffon Company, NY USA) headphone was used for air conduction hearing measurements.

Results

Pre- and postoperative pure tone hearing threshold measurements were completed for all the 30 recruited subjects. Figure 3 frequency-dependently illustrates the number of patients pre- and postoperatively, where hearing sensitivity was measurable. It is well demonstrated that hearing is the most stable within the 250 to 1000 Hz range, and the least is beyond 4 kHz. This statement is true either pre-, or postoperatively.

Table 1: Population of study patients.

No.	Gender	Age (year)	Implanted ear	Hearing Loss w/wo genetic origin	Total Hearing Loss (THL) after implantation
1	Male	55	Left	No	No
2	Male	59	Left	Yes	Yes
3	Male	16	Right	No	No
4	Male	24	Right	No	No
5	Male	15	Left	No	Yes
6	Male	72	Right	No	No
7	Female	70	Right	No	No
8	Female	71	Left	No	No
9	Female	10	Right	Yes	Yes
10	Male	11	Right	No	No
11	Female	43	Left	Yes	Yes
12	Female	28	Right	No	No
13	Female	28	Left	No	No
14	Female	11	Right	No	No
15	Female	70	Right	No	No
16	Female	24	Right	No	No
17	Male	62	Right	No	No
18	Female	77	Right	No	No
19	Female	42	Right	No	No
20	Female	48	Right	No	Yes
21	Female	71	Left	No	No
22	Female	53	Right	No	Yes
23	Female	59	Right	No	No
24	Male	13	Right	No	No
25	Female	27	Right	No	No
26	Female	35	Left	No	Yes
27	Female	59	Left	No	No
28	Female	30	Right	No	No
29	Male	53	Right	No	No
30	Male	69	Right	No	Yes
Average	Male=10 Female=20	(Mean $\pm$ SD) 43.32 $\pm$ 24	Right=21 Left=9	Genetic disorder=3 No evidence=27	THL=7

The average preoperative thresholds of the hearing within the lower frequency range were 61.75 dBHL at 125 Hz (no response from 10 patients); 78.52 dBHL at 250 Hz (no response from 3 patients). At the middle frequency range, mean values were 88.67 dBHL at 500 Hz (response from all patients); 97.07 dBHL at 1 kHz (no response from 1 patient) and 100.50 dBHL at 2 kHz (no response from 10 patients). At the higher frequencies, the average values were 91.36 dBHL at 4 kHz (no response from 19 patients) and 84.00 dBHL at 8 kHz (no response from 25 patients).

The difference in height between the striped and checked pattern columns represents the percentage of successful hearing preservation at specific frequencies.

One year postoperatively the average values of the hearing thresholds at the lower frequency range were: 93.89 dBHL at 125 Hz (no response from 17 patients); 87.86 dBHL at 250 Hz (no response from 10 patients). At the middle frequencies mean values were 102.86 dBHL at 500 Hz (no response from 10 patients); 111.61 dBHL at 1

kHz (no response from 14 patients) and 113.75 dBHL at 2 kHz (no response from 21 patients). At the higher frequencies, average values were 115.18 dBHL at 4 kHz (no response from 24 patients) and 99.29 dBHL at 8 kHz (no response from 29 patients).

Figure 4 illustrates the preoperative (striped pattern columns) and the postoperative (dotted pattern columns) hearing thresholds in dBHL at the measured frequencies. Decrease was detected at each examined frequencies but the grade of it varied. The highest decrease was measured at 500 Hz with an average decrease of 14.19 dBHL and at 1000 Hz with an average decrease of 13.77 dBHL. At the lower frequency range, hearing remained substantially stable. At 125 Hz only 3.06 dBHL, while at 250 Hz only 7.19 dBHL loss was detected. At the high frequencies, from 2 to 8 kHz preoperative hearing sensitivity had been already proved to be rather poor, thus further loss had just little consequences.

Figure 5 frequency-specifically demonstrates the degree of loss of acoustic sensitivity grouped into dBHL ranges, while exhibiting the

number of implantees. It is clearly shown that only minute threshold decay with less than 5 dBHL loss is the most frequently found one, while prominent postoperative loss of hearing appears less often.

Subjects with complete loss of hearing following surgery

Nine implantees (9/30=30%) showed up with total loss of residual hearing at every measured frequency following surgery. Their preoperative hearing sensitivity is presented in Figure 6. It is clearly seen that within this subgroup of this cohort the measured average hearing threshold have been already poorer prior to surgery compared to those with preserved hearing. Genetic screening of the 30 recruited subjects revealed mutations in three cases in the background of hearing loss. All of these subjects suffered complete hearing loss postoperatively (3/3=100%), that genetic alteration may serve as a predictor when opting for an electro-acoustic/hybrid device, should be taken into consideration when indicating these systems [20].

Discussion

Preservation of acoustic hearing associated with cochlear implantation improves the postoperatively achievable periodicity and spectral resolution, which improves the patient's speech comprehension and the localization of the tone in particularly difficult conditions [21-26].

The effects of cochlear implantation on residual hearing have been discussed in several studies in which a number of surgical and technical factors have been identified [27]. There are some surgical techniques of approaching the scala tympani (*i.e.*, RW, ERW, CS) with varying risks of harming the fine structures of the cochlea with prompt or delayed onset [13]. Such late complications, like the appearance of endocochlear connective tissue or new bone formation, may lead to a gradual partial or complete loss of residual acoustic hearing [28]. This is most likely to be seen when the round window is extendedly exposed, where endothelial lesions trigger new tissue proliferation. The slightest is the tendency to harm the endocochlear structures when minimally invasive, soft surgery is applied [13].

Physical attributes of the electrode profile may also interfere with postoperative cochlear function. Theoretically, the endocochlear hydrodynamics may also be altered, as the vibration of the basilar membrane is restricted due to the presence of an electrode array. At this point, as the travelling waves to the apical region are modified, the basilar membrane would react to sounds differently, leading to an endocochlear "conductive" hearing loss [29, 30].

The new type of thin-diameter electrode arrays close to the modiolus are expected to have a lower hydrodynamic load, since the bony spiral lamina is attached from below, thus the basilar membrane vibrations remain unrestricted. However, the perimodiolar position of the electrode array allows the adjacent nerve elements of the spiral ganglion to be stimulated with a lower electrical intensity and through a smaller surface.

Cadaver experiments demonstrated that a force, applied to the basilar membrane with an average of 88 mN (42 mN to 122 mN) would be sufficient to accomplish the interscalar dislocation of the electrode, of which manual perceptibility is questionable [31]. Studies with large case numbers (n=100) have shown that the probability of the electrode line being located in the scala vestibuli significantly increased during CS, which also manifested itself in the absence of improvement in speech comprehension [32].

In a number of studies, intraoperatively performed electro-cochleography is used to track the electrode insertional trauma, furthermore to postoperative residual hearing follow-ups [33-35].

For the implementation of Electro-Acoustic (EAS) or hybrid speech processors the long-term preservation of residual acoustic hearing is inherently inevitable, thus application of atraumatic surgical techniques and electrode arrays is essential.

Our study cohort obviously demonstrates that by the application of appropriate soft surgery techniques and atraumatic electrodes are able to retain residual hearing on a long run. The positive experience gained with the new type of CI532 Slim Modiolar electrode predicts the possibility for the preservation of structural and functional integrity of all cochlear regions. Furthermore, a prompt, definitive solution could be provided for a possible late hearing loss progression, where only a psychophysical reprogramming of the implant would be enough.

On the basis of our results, if the acoustic hearing loss can be preserved with the assurance and efficacy of the initial experience, we will be able to provide sustained prominent hearing rehabilitation even in the indication of EAS that results in significant improvement in the life quality of many implantees.

In addition, long-term residual hearing loss may be of crucial importance in the subsequent feasibility of regenerative procedures and medical treatments [3,7,36,37].

Conclusion

In cochlear implantation, the use of new electrode array profiles plays a fundamental role in minimally invasive soft surgery, taking into individual needs, and providing long-term acoustic hearing preservation. Our study demonstrates the efficacy of the Nucleus CI532 Slim Modiolar electrode profile and it has the potential for granting residual hearing, which predicts the possible use of this configuration as part of EAS systems and makes it available for future treatments, *i.e.*, the regeneration-based new therapeutic approaches of intracochlear hair-cells.

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