

# Evaluation of the implant electrode inside the cochlea and damage to cochlear structures associated with implantation using cone beam computed tomography techniques (CBCT)

## Ocena położenia elektrody implantu ślimakowego i uszkodzeń struktur ślimaka po implantacji przy zastosowaniu technik tomografii komputerowej

### Wkład autorów:

A – Study Design  
B – Data Collection  
C – Statistical Analysis  
D – Manuscript Preparation  
E – Literature Search  
F – Funds Collection

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### ABSTRACT:

**Objectives:** The aim was to evaluate the position of the cochlear implant electrode inside the cochlea and damage to cochlear structures associated with the implantation itself using cone beam computed tomography technique (CBCT).

**Material and methods:** Nine human cadaver temporal bones were used, five were implanted with round window approach and in other four anterior cochleostomy was used for insertion. After implantation the temporal bones were scanned with CBCT scanner and the images were then analyzed. The degree of insertion damage was evaluated in two-tier scale, where the first degree included damage to basilar membrane, and the second degree covered damage associated with pushing up into the scala vestibuli.

**Results:** The first degree of cochlear damage was noted in three temporal bones implanted with the round window approach and in two with cochleostomy, and the second degree of damage was noted in two and one temporal bones respectively. The analysis did not show any correlations between depth of insertion and degree and extend of damage in both analyzed groups, also no significant differences were found between the two groups.

**Conclusions:** The good quality of the images presents CBCT as a good method for the evaluation of the cochlear implant electrode position in the inner ear structures. CBCT holds the promise for intraoperative imagining during cochlear implantation.

### KEYWORDS:

cochlear implant, earing loss, scala vestibuli, cochleostomy, temporal bone

### STRESZCZENIE:

**Cel:** Celem prezentowanej pracy była ocena położenia elektrody implantu ślimakowego oraz uszkodzeń struktur ślimaka związanych z implantacją przy zastosowaniu technik tomografii komputerowej wiązki stożkowej (CBCT).

**Materiał i metody:** Do badania wykorzystano 9 preparatów kości skroniowych pobranych ze zwłok. Na pięciu preparatach wykonano implantację przez okienko okrągłe, na pozostałych czterech przez kochleostomię. Wszystkie preparaty zaimplantowanych kości skroniowych poddano badaniu CBCT, a skany z badania dokładnie przeanalizowano. Przyjęto dwustopniową skalę określającą stopień uszkodzenia – pierwszy stopień (I°) to uszkodzenia obejmujące

uwypuklenie blaszki podstawowej, do drugiego stopnia (II°) zaliczyliśmy uszkodzenia związane z przebicciem elektrody do schodów przedsionka. Dokonano pomiaru długości odcinka elektrody od miejsca jej wejścia do ślimaka aż do jej zakończenia. Zmierzono także kąt skręcenia we wnętrzu ślimaka oraz policzono liczbę elektrod (contact points), które zostały wprowadzone.

**Wyniki:** Uszkodzenia I° struktur ucha wewnętrznego dotyczyły trzech preparatów implantowanych przez okienko okrągłe i dwóch implantowanych przez kochleostomię, natomiast uszkodzenia ślimaka II° dotyczyły odpowiednio dwóch i jednego preparatu. Nie stwierdzono ani korelacji między głębokością insercji a ilością i rozległością uszkodzeń ślimaka, ani istotnych statystycznie różnic między grupami przy porównaniu danych uzyskanych z preparatów implantowanych przez okienko okrągłe i kochleostomię.

**Wnioski:** Ponieważ jakość obrazów uzyskiwanych za pomocą CBCT jest dobra, może stanowić bezpieczną metodę do oceny położenia elektrody względem struktur ślimaka u implantowanych pacjentów. Można domniemywać, że śródoperacyjne zastosowanie CBCT może być pomocne dla otochirurga i przyczynić się do bardziej precyzyjnego umieszczenia elektrody w ślimaku oraz na korektę jej położenia jeszcze podczas tej samej operacji.

**SŁOWA KLUCZOWE:** implant ślimakowy, niedosłuch, schody przedsionka, kochleostomia, kość skroniowa

## INTRODUCTION

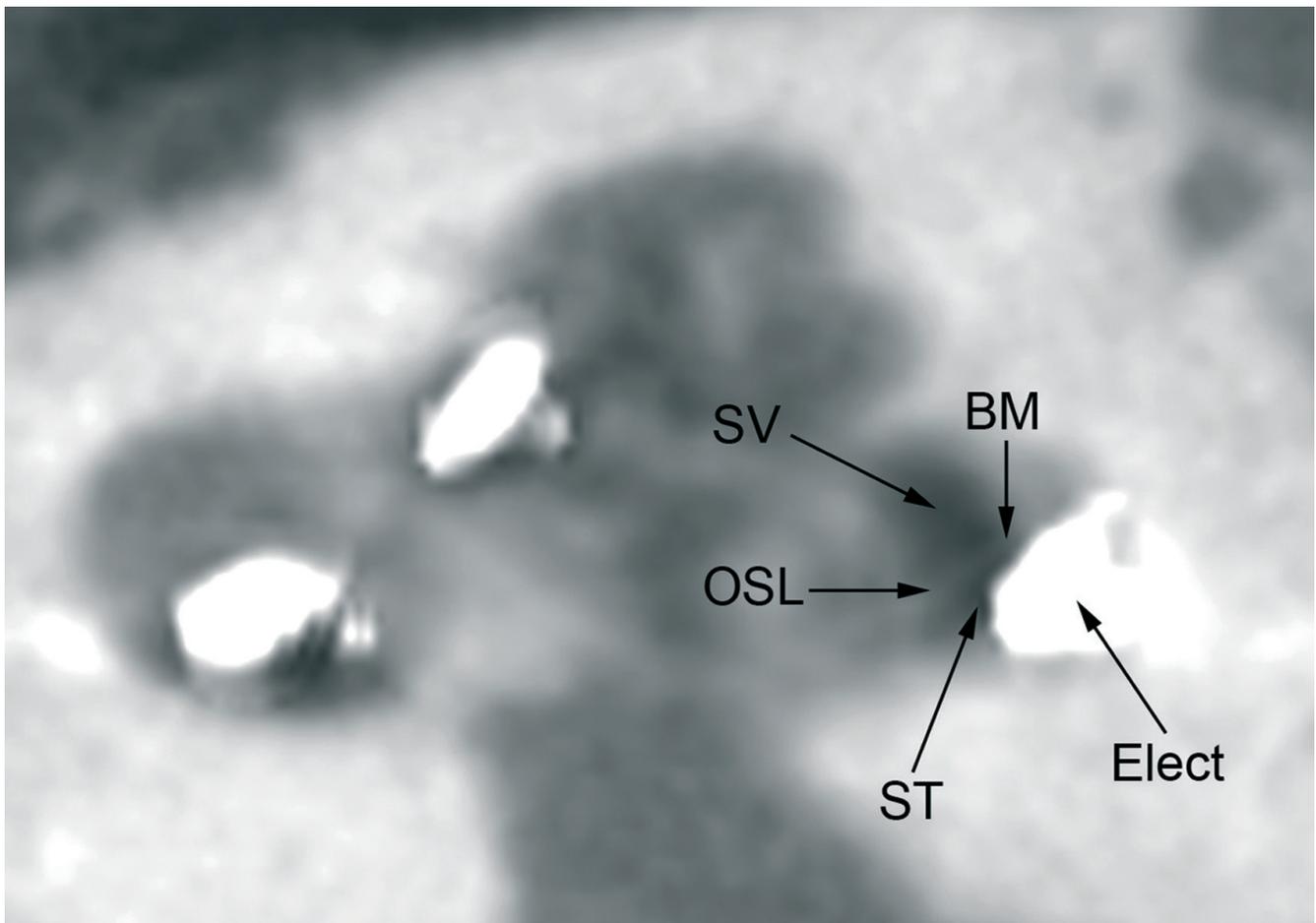
Cochlear implants (CI) are one of the greatest achievements of medicine and technology. They are considered a standard treatment procedure for patients with severe-to-profound hearing loss. Cochlear implantation procedure involves placing an electrode array in the scala tympani in the inner ear and positioning the inner coil of the implant on the bony surface of the temporal bone. By applying an electric potential to the cochlea, the cochlear implant directly stimulates the auditory nerve restoring hearing. Nowadays, the electrode arrays are designed in the way to position electrodes closer to the modiolus for more effective and selective stimulation. Both the surgical technique and the construction and properties of the implant electrodes are crucial factors regarding results. An important part of the surgical procedure is the introduction of the electrodes to the cochlea in the least traumatic way possible [1]. This is a major challenge when designing the new electrodes and developing surgical techniques.

The studies of CI electrode array placement have been conducted for many years and a number of papers have been published. Many authors evaluated the type and extend of damage to cochlear structures resulting from insertion [2-5] and pulling out the electrodes [6]. Todt et al. [6] found that removing the implant's electrodes from the cochlea did not cause any damage to the microstructure of the inner ear. According to those authors, in order to atraumatically remove the electrodes, this procedure should be performed manually.

The most common techniques used to visualize the position of the implant's electrode array are radiological and histological methods. In histological techniques freshly frozen and chemically preserved temporal bones are used [2,6]. Commonly, these samples are sectioned using a microtome, and then evaluated under a microscope [2]. The studies of cochlear

structures with electrodes placed inside the cochlea became possible due to the development of histological techniques. In the past it was required to remove electrodes from the cochlea. It was therefore not clear whether the observed changes were caused by implantation itself or removal of the electrodes [7-9]. Roland et al. [5] conducted studies on cochlear trauma in fixed cadaveric temporal bones using histological evaluation. They assessed the degree of damage to the cochlear microstructures after insertion of the implant electrode array. The most commonly described damage was related to the Reissner's membrane, spiral ligament, basilar membrane and osseous spiral lamina. The frequency and type of damage to the cochlea during implantation were dependent on the type of electrodes used which was also confirmed by other authors [3,5]. The lesions were described using a five-degree scale where "0" degree meant no lesions, and the highest degree of "4" meant severe trauma such as fracture of the osseous spiral lamina or modiolus or tear of the stria vascularis [2]. This scale was applied to analyze histologically fixed implanted cadaver temporal bones.

The histological research on the human cochlea showed differences in the level and extend of intracochlear damage depending on the electrode type. The results of these studies have contributed to the development of implantation techniques [3] and improved surgical tools [4] used for electrode array insertion. This allowed for reducing the number of cases with damaged cochlear microstructure after implantation. Stover et al. [10] used the technique of microgrinding in order to evaluate the damage to the microstructures of the cochlea resulting from the three different insertion techniques: conventional, manual AOS insertion (Advance Off-Stylet), and AOS with an insertion tool. In addition, they evaluated two prototype variants of the Contour electrode with Softip (Cochlear Corp, Sydney, Australia). The results of their study showed the conventional technique to be more traumatic causing basilar membrane



**Fig. 1.** Cone beam computed tomography (CBCT) image obtained for the temporal bone following cochlear implant electrode array insertion in one example case –modiolar scan demonstrating electrode array (Elect) and cochlear structures such as scala vestibuli (SV), scala tympani (ST), spiral lamina (OSL), and basilar membrane (BM).

perforations. The AOS technique proved to be less traumatic. The prototype insertion tool used with AOS technique showed basilar membrane perforations. However, the Advance Off-Stylet insertion technique itself provides very good and reliable electrode perimodiolar placement.

Standard X-ray diagnostics allows the visualization of the cochlea and electrode placed inside. Measurement of the depth of implantation is performed with the use of digital X-ray images analyzed with specialized software. Linear depth of implantation is usually measured from the electrode's contact point located in the apical part of the cochlea to the marked contact point placed in the round window. This method also allows for the measurement of the angular depth of implantation [3].

Roland [5] used the real-time fluoroscopy technique to evaluate the position of the electrodes during implantation. He performed the fluoroscopic recordings during the insertion

of electrodes with the use of a small fluoroscopy unit that is commonly used in hand surgery procedures. The images were recorded perpendicular to the plane of insertion. This method allowed estimating the angular insertion depth of the electrode placed inside the cochlea, as well as the degree of adhesion to the bony walls of the cochlea. Additionally, it enables evaluation of irregularities, such as bending the electrode by 180° [5]. The application of this technique required proper bone preparation. Using the diamond drill the bony wall had to be slightly reduced, which helped to increase the resolution of the observed images [5].

Noble et al. [11] investigated the micro-architecture of the cochlear structures using computerized microtome. High resolution images obtained using this type of equipment allow the evaluation of the inner ear structures with a similar accuracy that is achieved using histological methods. Such devices are not yet widely available.

Introduction of computed tomography techniques to evaluate the position of the electrodes during cochlear implantation with the high resolution images enables the assessment not only of electrode implantation depth, but also an assessment of the position of the electrode in relation to the cochlear structures (Figure 1 and 2).

## AIM

The purpose of this study was to evaluate the position of the cochlear implant electrode inside the cochlea and assessment of damage to the cochlear structures associated with the implantation itself using cone beam computed tomography technique (CBCT).

## MATERIAL AND METHODS

Nine human cadaver temporal bones were used for this study. The bones were harvested within 24 hours after death and frozen to  $-18^{\circ}\text{C}$ . After complete thawing and warming to room temperature, the antromastoidectomy and posterior tympanotomy were performed. The temporal bones were individually marked for recognition purposes.

The device manufacturer (Neurelec™, Chemin Saint-Bernard, Vallauris, France) supplied all the cochlear implant electrodes for testing. Five cochleae were implanted with round window approach and in other four anterior cochleostomy was used for insertion approach. An experienced surgeon, familiar with the device, performed all nine implantations. The surgeon was using standard techniques and tools according to manufacturer's recommendations. Photographic documentation was performed using optical microscopy.

After implantation, the electrodes were immobilized with wax for transport purposes. All implanted temporal bones were transported to the radiology department for CBCT (cone beam computed tomography), where radiographs were obtained for each implanted temporal bone and scanned using a CT scanner Planmeca Promax 3D Mid (Planmeca USA, INC, Roselle, Illinois, USA) to produce digital image files using OsiriX software (Pixmeo SARL, Bernexi, Switzerland). Images from a CBCT scanner were analyzed on the basis of sections with a thickness of 0.05 mm, in three planes: the plane of the basal turn parallel to the electrode, plane of the long axis of the modiolus, and plane of the short axis of the cochlea. The images were analyzed to identify intracochlear electrode position, insertion characteristics, and associated trauma. The electrode position and inser-

tion characteristics were evaluated using built-in features of OsiriX software.

The inserted electrode was evaluated in its full length starting from the first contact point located in the basal part of the cochlea close to the cochleostomy or round window until the last contact point located in the apical part of the cochlea. The degree of insertion damage was evaluated in a two-tier scale, where the first degree included damage to the basilar membrane, and the second degree covered damage associated with pushing up into the scala vestibuli. Insertion length (cm) and radial degrees of electrode rotation around the cochlea ( $^{\circ}$ ) (Figure 3) were measured to estimate the depth of insertion. The inserted contact points of the electrodes were also counted.

The project conforms with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

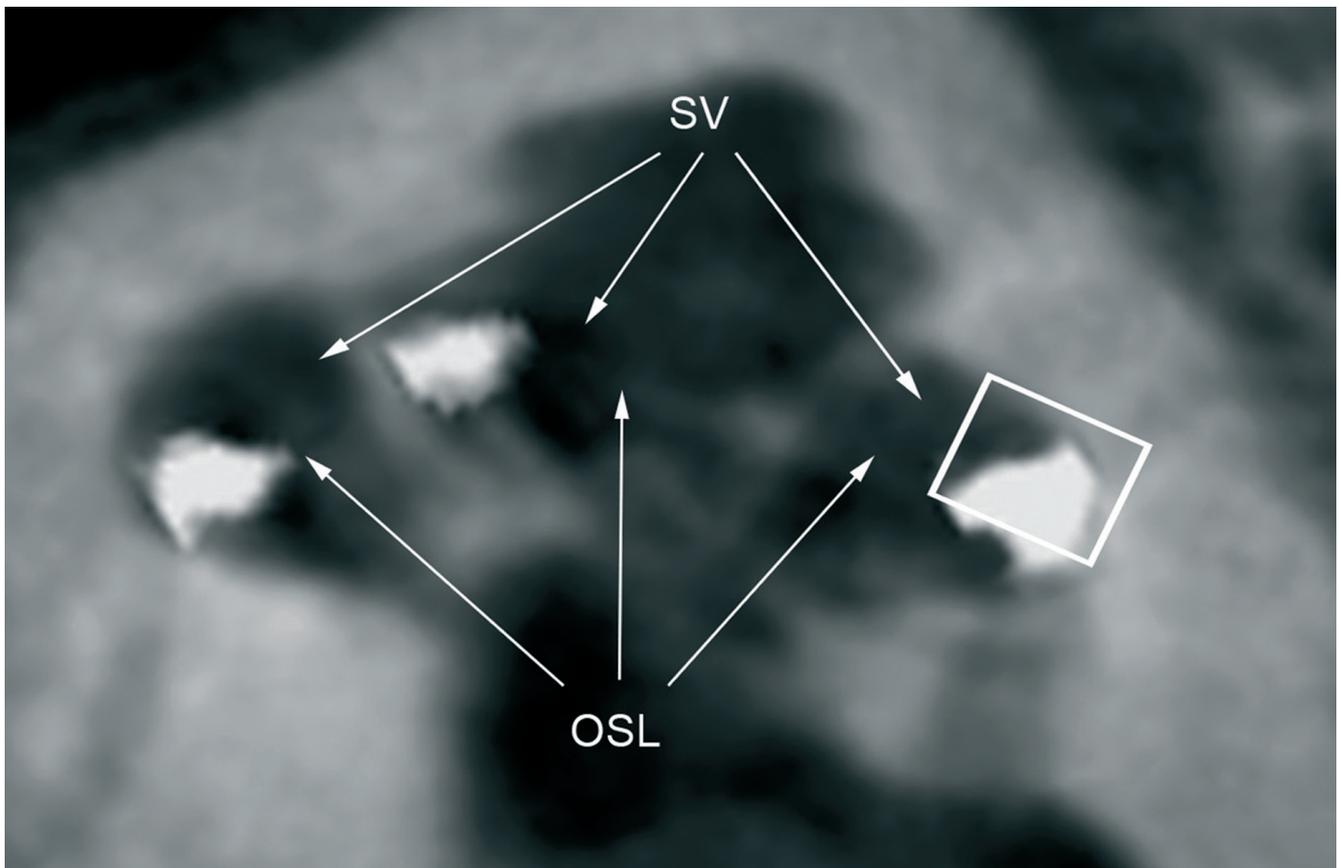
Statistical analysis of collected data was performed using Statistica software (StatSoft, Inc. 2011, data analysis software system, version 10, Tulsa, UK). The data were tested for normality, parametric and nonparametric criteria. To analyze the data the following tests were used: Fisher's test, Kruskal-Wallis test, Mann-Whitney U test, correlation analysis. P-values  $<0.05$  were considered statistically significant.

## RESULTS

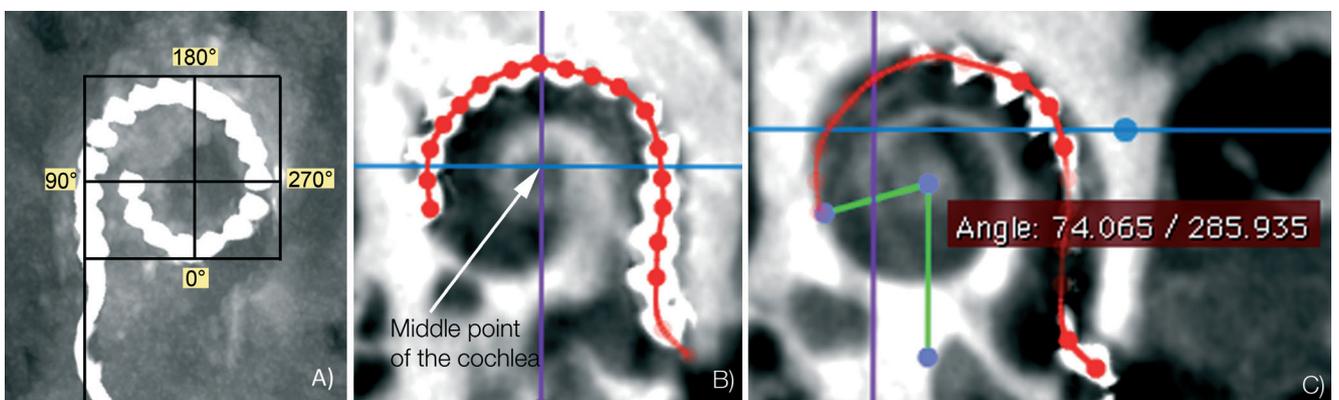
Figure 4 shows intracochlear electrode positions, depth of insertion and other insertion characteristics for each electrode separately. The mean general depth of implantation was 2.17 cm, through round window 2.57 cm, through cochleostomy 2.16 cm. General mean radial degrees ( $^{\circ}$ ) of rotation around the cochlea was  $513.30^{\circ}$ , in case of round window insertion it was  $515.80^{\circ}$ , and cochleostomy  $432.75^{\circ}$ . Counting inserted contact points of the electrode it was 21, 21, and 18.5 respectively.

The first degree of cochlear damage was noted in three temporal bones implanted with the round window approach and two with cochleostomy. In oval window cases the damage begun from the depth of 0.83 cm ( $140.37^{\circ}$ ) up to 1.27 cm ( $208.87^{\circ}$ ), and cochleostomy from 0.83 cm ( $144.60^{\circ}$ ) to 0.98 cm ( $189.30^{\circ}$ ), which makes the size (extend) of the first degree of damage 0.42 cm ( $68.50^{\circ}$ ) and 0.16 cm ( $44.70^{\circ}$ ) long, respectively.

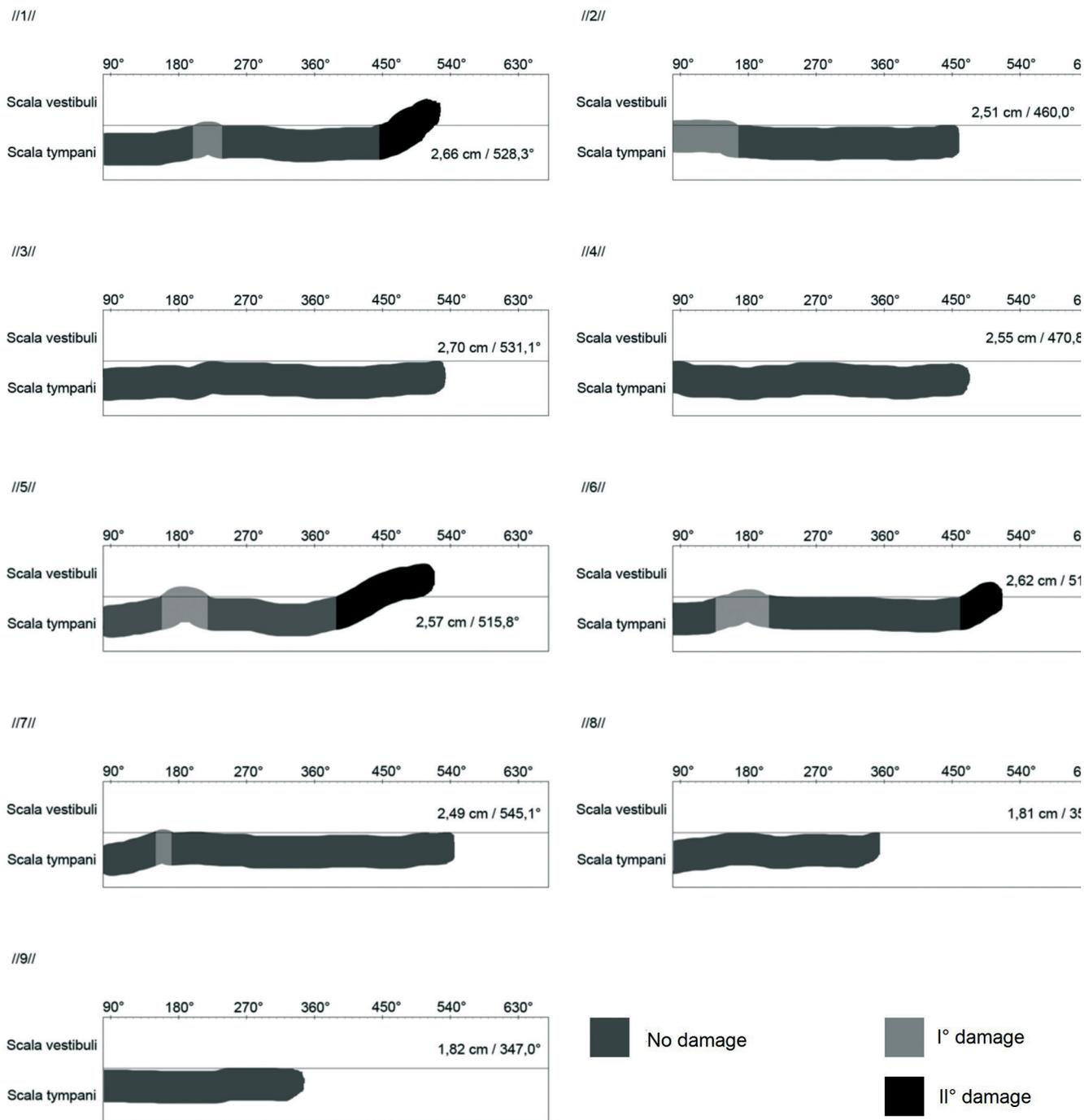
The second degree of cochlear damage was noted in two temporal bones implanted through the round window and in one through cochleostomy. In round window cases, damage begun from the depth of 2.39 cm ( $419.15^{\circ}$ ) up to 2.62 cm ( $522.05^{\circ}$ ), and cochleostomy from 2.42 cm ( $463.30^{\circ}$ ) to 2.62 cm ( $513.30^{\circ}$ ),



**Fig. 2.** Cone beam computed tomography (CBCT) image obtained for temporal bone following cochlear implant electrode array insertion in one example case – modiolar scan demonstrating puncture of the electrode to the scala vestibuli (marked by a white rectangle). Scala vestibuli (SV) and spiral lamina (OSL) are visible.



**Fig. 3.** Cone beam computed tomography (CBCT) image obtained for the temporal bone following cochlear implant electrode array insertion. The grid, as shown in panel A, was constructed around the electrode array path in order to estimate the angular insertion depth of the electrode. Panel B shows marked points corresponding to the electrode contact points and the middle point of the cochlea going through the apex. Insertion length and radial degrees of electrode rotation around the cochlea were measured to estimate the depth of insertion using the built-in features of OsiriX software (panel C).



**Fig. 4.** Graphs present the position of the electrode inside the cochlea in each of the analyzed temporal bones (n=9). Insertion length (cm) and radial degrees of electrode rotation around the cochlea (°) for each electrode array is shown. The colors in gray scale present trauma to the cochlea caused by the electrode array (light grey – no damage; dark grey – first-degree damage; black – second-degree damage). Subsequent numbers in the upper left corner //x// correspond to the number of the temporal bone specimen.

which makes the size (extend) of second-degree damage 0.23 cm (102.9°) and 0.20 cm (50,00°) long, respectively.

**Table 1 and 2** show details concerning insertion characteristics: depth of insertion (cm), radial degrees of electrode rotation around the cochlea (°), number of inserted electrode's contact points, and damage characteristics in case of round window (**Table 1**) and cochleostomy (**Table 2**) insertions. The statistical analysis did not show any correlations between the depth of insertion and the degree and extend of damage in both analyzed groups ( $p>0.05$ ). No significant differences were found between the two groups either ( $p>0.05$ ).

## DISCUSSION

In our study, the cochlear implant electrode and its position in relation to the microstructure of the cochlea and the caused damage were evaluated. Using CBCT (cone beam computed tomography) we could determine the position of each cochlear implant electrode with respect to such structures as the osseous spiral lamina and basilar membrane. However, the images did not allow for evaluation of the Reissner's membrane or spiral ligament. The Suomalainen et al.'s [12] study showed that CBCT scanner delivering considerably small effective doses to the patient provides adequate image quality assessing electrode inside the cochlea. Research on CBCT conducted by Güldner et al. [13,14] showed that CBCT is an excellent tool for the evaluation of the anatomical structures of the temporal bone. In addition, it provides a reliable post-operative control of electrode placement, especially in the basal part of the cochlea. However, difficulties were encountered when evaluating implant placement in the medial and apical turn of the cochlea due to the high rate of artifacts (50%). In our study, in some cases imaging position of the electrode in the distal part of the cochlea did not give absolute certainty as to the exact position of the implant in relation to the structures of the cochlea either.

CT technique results depend on the quality of the photographic documentation. Nowadays technological progress allows creating increasingly excellent devices for diagnostic imaging. The device used in our study provided very good resolution of the images. It allowed for the accurate assessment of the depth and length of insertion, and radial degree measurements of electrode array rotation around the cochlea as well as the evaluation of the array position in relation to the bony structures of the cochlea, basal membrane and spiral lamina.

Other authors usually used one surgical approach and more types of electrode arrays in fewer temporal bones (corresponding to one type of electrode) [2,3]. For our study we used nine

samples of human cadaver temporal bones and implanted them with one-type electrode array using two surgical approaches: round window and cochleostomy. In our study, the results did not show any correlations between the depth of electrode array insertion and the degree and extend of cochlear damage in both analyzed groups. Wardrop et al. [3] demonstrated that the extent of damage depended on the depth of insertion and happened more often when insertion depth was more than 400°. In another study, Eshraghi et al. [2] showed that about half of the implantations with insertion depth above 378° were complicated with cochlear damage. Both mentioned studies were performed using histological evaluation and microsectioning technique which is different than CBCT and might be the cause of different results from ours. In our study, despite the good resolution of the CBCT images, the damage to the structures such as the Reissner's membrane or spiral ligament were not possible to assess which could translate into final results and possible lack of correlations. However, the biggest disadvantage of histological techniques in this case is that they cannot be used intra-operatively during cochlear implantation in living subjects, and CBCT has a potential to be used in that way.

In 2010 Kurzweg et al. [15] presented results of their study on digital volume tomography (DVT) as the postoperative imaging of CI patients to identify the exact position of the implant array. The results of their study showed good accuracy, the exact position of the implant array could be recognized in 85% of cases with shifting of the electrode between the tympanic and vestibular scalae possible to identify.

The intra-operative use of computed tomography, especially CBCT, in the inner ear surgical management might be very useful allowing for verification of cochlear implant electrode placement. It would be very beneficial in case of a congenitally abnormal or ossified cochlea as was presented by Baker et al. [16] on a cadaveric ossified cochlea model. In our study, as in the majority of other studies (both using computed tomography and histological techniques) on cochlear implantation performed on human temporal bones taken from cadavers, we used a selection of temporal bone samples that come from normal hearing subjects. In patients with profound hearing loss, especially with intracochlear fibrosis or osteogenesis, the position of the implant electrode and insertion damage might significantly differ from those described so far [2]. This is an important drawback of most of the studies performed so far, including ours.

The latest study of Diogo et al. [17] was performed using a CBCT scanner on implanted complete human heads and then repeated on temporal bones after their removal. The differences between whole heads and temporal images were significant

Tab. I. Descriptive statistics for implantation with oval window approach

VARIABLE	NUMBER OF IMPLANTED TEMPORAL BONES	AVERAGE	MEDIAN	MINIMUM	MAXIMUM	SD
insertion length (cm)	5	2,60	2,57	2,51	2,70	0,08
radial degrees of electrode rotation (°)	5	501,20	515,80	460,00	531,10	33,40
number of inserted contact points of the electrode	5	21,00	21,00	21,00	21,00	0,00
number of damage areas	5	1,00	1,00	0,00	2,00	1,00
I degree damage starting from (cm)	3	0,84	0,91	0,44	1,18	0,37
I degree damage ending at (cm)	3	1,27	1,28	1,14	1,38	0,12
size of I degree damage (cm)	3	0,42	0,37	0,20	0,70	0,25
I degree damage starting from (°)	3	140,37	157,50	67,60	196,00	65,89
I degree damage ending at (°)	3	208,87	228,00	163,90	234,70	39,09
size of I degree damage (°)	3	68,50	70,50	38,70	96,30	28,85
II degree damage starting from (cm)	2	2,39	2,39	2,35	2,43	0,06
II degree damage ending at (cm)	2	2,62	2,62	2,57	2,66	0,06
size of I degree damage (cm)	2	0,23	0,23	0,14	0,31	0,12
II degree damage starting from (°)	2	419,15	419,15	389,50	448,80	41,93
II degree damage ending at (°)	2	522,05	522,05	515,80	528,30	8,84
size of II degree damage (°)	2	102,90	102,90	79,50	126,30	33,09

Tab. II. Descriptive statistics for implantation with cochleostomy approach.

VARIABLE	NUMBER OF IMPLANTED TEMPORAL BONES	AVERAGE	MEDIAN	MINIMUM	MAXIMUM	SD
insertion length (cm)	4	2,19	2,16	1,81	2,62	0,43
radial degrees of electrode rotation (°)	4	439,40	432,75	347,00	545,10	104,52
number of inserted contact points of the electrode	4	18,75	18,50	17,00	21,00	2,06
number of damage areas	4	0,75	0,50	0,00	2,00	0,96
I degree damage starting from (cm)	2	0,83	0,83	0,81	0,84	0,02
I degree damage ending at (cm)	2	0,98	0,98	0,95	1,01	0,04
size of I degree damage (cm)	2	0,16	0,16	0,11	0,20	0,06
I degree damage starting from (°)	2	144,60	144,60	138,70	150,50	8,34
I degree damage ending at (°)	2	189,30	189,30	170,50	208,10	26,59
size of I degree damage (°)	2	44,70	44,70	20,00	69,40	34,93
II degree damage starting from (cm)	1	2,42	2,42	2,42	2,42	
II degree damage ending at (cm)	1	2,62	2,62	2,62	2,62	
size of I degree damage (cm)	1	0,20	0,20	0,20	0,20	
II degree damage starting from (°)	1	463,30	463,30	463,30	463,30	
II degree damage ending at (°)	1	513,30	513,30	513,30	513,30	
size of II degree damage (°)	1	50,00	50,00	50,00	50,00	

showing greater artifacts in case of whole-head evaluation. The authors concluded that results for isolated temporal bones were not transferable to clinical situations and should be assessed critically. However, their study was performed on only three human head samples and their thesis should be verified by the studies on a higher number of samples.

## CONCLUSIONS

The good quality of the images and a relatively small dose of radiation absorbed by the tissue [18] present CBCT as a good and safe method for the evaluation of the cochlear implant electrode position in the inner ear structures. Our study results and the results of other authors so far are very encouraging and hold the promise that intraoperative CBCT might be very helpful for the otosurgeon when inserting cochlear implant electrode array. It should be very helpful for more precise placement of the electrode inside the cochlea and allow for its verification when it is required during the same surgical session. The in-

tra-operative use of computed tomography, especially CBCT, in the inner ear surgical management might be also very beneficial in case of a congenitally abnormal or ossified cochlea. However, in order to prove this hypothesis, further studies are needed, especially those comparing surgical implant insertion with and without CBCT in temporal bones but even more important in a complete head.

## CONFLICT OF INTEREST STATEMENT

The authors state that there is no conflict of interest.

## FINANCIAL DISCLOSURE

The device manufacturer (Neurelec™, Chemin Saint-Bernard, Vallauris, France) supplied all the cochlear implant electrodes for testing. The authors declare no financial support other than the mentioned above delivery of the electrodes.

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