

Aus der Klinik für Hals-Nasen-Ohrenheilkunde, Kopf- und Halschirurgie
im Klinikum Bielefeld Mitte

DISSERTATION

**“Die pull-back Technik für die 532 slim modiolar
Elektrode”**

**“The pull-back technique for the 532 slim modiolar
electrode”**

zur Erlangung des akademischen Grades
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Abstrakt (Deutsch)

Einleitung: Der Abstand zwischen Modiolus und dem Elektrodenarray ist ein Faktor, welcher im Mittelpunkt vieler Diskussionen und Studien steht. Das Einbringen des Elektrodenarrays näher zum Spiralganglion, mit dem Ziel die Stromausbreitung zu fokussieren, konnte bessere Hörergebnisse demonstrieren. Perimodioläre Elektrodenarrays können durch ein dezidiertes chirurgisches Manöver, die sogenannte “pull-back” Technik, ergänzt werden. Diese Studie konzentriert sich auf die neu entwickelte 532 slim modiolar Elektrode.

Objektiv: Die Evaluation der intracochleären Position der 532 slim modiolar Elektrode unter Anwendung der “pull-back” Technik.

Studiendesign: Experimentell.

Einrichtung: Krankenhaus der Maximalversorgung.

Material und Methoden: In 5 humanen Felsenbeinen wurde ein sogenanntes Decapping-Verfahren zur Darstellung der Scala tympani durchgeführt. Die Elektrodenarrays wurden eingeführt und die intracochleären Positionsänderungen wurden mikroskopisch und digital erfasst. Drei unterschiedliche Insertionskonditionen wurden analysiert: die initiale Insertion, die Überinsertion und die “pull-back” Position. Die Position der drei weißen vorgegebenen Markierungen der Elektrodenarrays in Bezug auf das runde Fenster wurde während der Durchführung diese drei Konditionen untersucht.

Ergebnisse: Die initiale Insertion erreichte eine perimodioläre Position des Elektrodenarrays. Es findet sich, jedoch eine Distanz zwischen dem mittleren Bereich des Arrays und dem Modiolus (1. erste Markierung im runden Fenster). Die tiefere Insertion der Elektrode führt zu einer Zunahme der Distanz zwischen Modiolus und Elektrode (2. zweite und dritte Markierung im runden Fenster). Die Anwendung der “pull-back” Technik führt zu einer maximalen Annäherung der Elektrode an den Modiolus. Diese Technik führte zu einer engen perimodiolären Position (3. erste Markierung wieder in rundem Fenster sichtbar).

Fazit: Mittels der erfolgten Felsenbeinuntersuchung konnte belegt werden, dass die Anwendung der “pull-back” Technik für die 532 slim modiolar Elektrode, die engste Beziehung zum Modiolus erreichen lässt, wenn die erste weiße Markierung des Elektrodenarrays in dem runden Fenster wiederum sichtbar wird.

Abstract (English)

Introduction: The distance between the modiolus and the electrode array has become the focus of many discussions and studies. Positioning the electrode array closer to the spiral ganglion with the goal of reducing the current spread has been shown to improve hearing outcomes. Perimodiolar electrode arrays can be complemented with

an extremely careful surgical maneuver called the pull-back technique. This study is focused on the recently developed 532 slim modiolar electrode.

Objective: To investigate intracochlear movements and pull-back technique for the 532 slim modiolar electrode.

Study design: Experimental.

Setting: Tertiary referral center.

Material and Methods: A decapping procedure was performed on five temporal bones. The electrode array was inserted and the intracochlear movements were microscopically examined and digitally captured. Three situations were analyzed: the initial insertion, over-insertion and pull-back position. The position of the three white markers of the electrode array in relation to the round window was evaluated when performing these three actions.

Results: The initial insertion achieved an acceptable perimodiolar position of the electrode array, but there was still a gap between the mid-portion of the array and the modiulus (the first white marker was visible in the round window). When we inserted the electrode a little deeper, the mid-portion of the array was pushed away from the modiulus (the second and third white markers were visible in the round window). After applying the pull-back technique, the gap observed during the initial insertion disappeared, resulting in an optimal perimodiolar position (the first white marker was once again visible in the round window).

Conclusion: This temporal bone study demonstrated that applying the pull-back technique for the 532 slim modiolar electrode allowed a closer proximity to the modiulus when the first white marker of the electrode array was visible in the round window.

Introduction

Cochlear implants are electrical stimulus prostheses for the functional replacement of the inner ear. Thanks to the positive results of technical advances, cochlear implants have been established as the standard therapy for sensory deafness. The intracochlear position of the electrode allows for differentiated stimulation of the hearing nerves and thus the transmission of various perceptions of pitches. The stimulation of the frequency organization of the inner ear leads to complex sound signals, such as speech, being transformed into a differentiated neuronal stimulation pattern of the hearing nerve, which is the basis for speech understanding with a cochlear implant. Today, the indications for cochlear implantation are bilateral sensory hearing loss and deafness in children as well as adults, single-sided deafness and high-frequency hearing loss¹. In 1963, Zöllner and Keidel formulated the basic principles of intracochlear multichannel stimulation, which is the basis of today's cochlear implant systems, with up to 20 electrode contacts in the scala tympani for simulation of the tonotopy by use of various stimulus modalities². The first clinically applicable systems were developed by House and Urban; Hochmair and Hochmair designed later systems, as well as Clark and Patrick, Merzenich in the USA and Chouard in Paris³. Since the initial introduction, there have been more than 500,000 implantations worldwide⁴. The electrode array in a cochlear implant system is the central factor of hearing performance, as it is the interface between the device and the auditory pathway of the recipient⁵. Specially designed thin electrodes are used for cochlear implant surgery intended to preserve hearing, being most frequently placed on the lateral wall and advanced depending on hearing loss. Perimodiolar electrodes are inserted with the aim of achieving selective stimulation with low stimulation current, but generally, this approach is less likely to preserve residual hearing¹. Currently, there are the two commercially available electrode arrays (Fig. 1)⁶. Apart from electrical current requirements, energy consumption, trauma to the cochlea, combined electro-acoustic stimulation, preservation of the cochlear structures with low-trauma surgical techniques and hearing preservation, proximity to the modiolus is one aspect that has gained recent attention among researchers⁷.

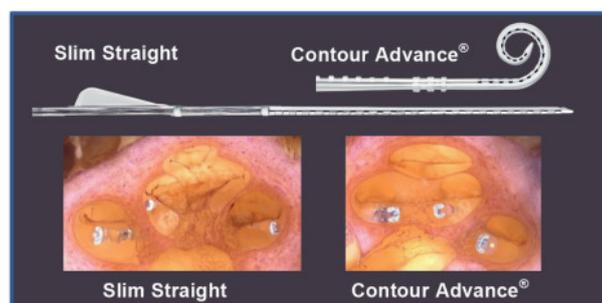


Fig. 1. Slim straight and Contour Advance electrodes. Bone histology courtesy of The HEARing CRC, Melbourne⁶.

Positioning the electrode array closer to the spiral ganglion with the goal of reducing the current spread during electrical stimulation has been shown to improve hearing outcomes⁴. Sheperd established the scientific foundations of perimodiolar

placement in 1993, demonstrating reduced electrical auditory brainstem response thresholds while positioning the electrode array closer to the modiolus. The closer the stimulated electrode was to the nerve terminals, the lower the current levels needed to elicit a stimulus⁸. Further clinical studies have proven that the perimodiolar electrode position decreases channel interactions and neural response telemetry thresholds and leads to better speech understanding. The distance to the modiolus can also influence comfort levels and dynamic range^{9,10}. The comfort levels among users implanted with a perimodiolar electrode array seem to be higher than among users implanted with a straight lateral wall array¹¹. Another benefit of this array is lower power consumption¹². Perimodiolar proximity is an important consideration, as Holden et al. concluded that the total insertion depth was not associated with better speech discrimination outcomes; however, the distance from the electrodes to the modiolus did indicate a significant influence¹³.

However, perimodiolar electrode arrays also have disadvantages, as they are much more traumatic and tend to deviate into the scala vestibuli more often than lateral wall arrays. The trauma to the cochlea produced by perimodiolar arrays led to the development of specific insertion techniques and tools to minimize it, such as the development of the advance off-stylet system¹⁴. Those with profound sensorineural hearing loss make up the largest group of candidates for cochlear implants. This group requires optimal electrical stimulation, which is best provided by perimodiolar electrodes. Therefore, any surgery technique or strategy that prompts better perimodiolar positioning with reduced insertion trauma of the electrode array could lead to better hearing outcomes⁵.

Intraoperative interventions regarding the position of perimodiolar electrodes can further reduce the distance between the electrode contacts and modiolus. The perimodiolar position of the array inside the cochlea can be complemented with a surgical maneuver called the pull-back technique. This technique was first described by Todt in 2005 and combines a deep insertion of the electrode with a subsequent pulling back until the first white marker of the array becomes microscopically visible within the cochleostomy opening. This maneuver allows for a better perimodiolar position of the electrode¹⁵, bears no serious risks to the cochlear microstructures and has shown to be reliable and reproducible¹⁶.

Electrophysiological changes have also been reported in other studies applying this intervention. In one study with the Nucleus-24 Contour Advance array, the spread of excitation was significantly reduced at basal, middle and apical electrodes in the electrode pull-back group¹⁷. Another study with the same electrode demonstrated a significant decrease of the spread of excitation at stimuli electrodes 5, 10 and 15 compared to recordings after the primary normal insertion procedure¹⁵. The array inside the scala tympani is invisible to the surgeon, so the proximity of the electrode array to the modiolar wall is generally unknown during surgery⁴. Because the pull-back technique can be performed in various ways (e.g., modifications in insertion depth and amount of pull-back) and the size of the human cochlea varies, surgical guidelines are required for each electrode array¹⁸. Clear surgical guidelines have been published for the Nucleus-24 Contour Advance electrode and the Advanced Bionics Helix

electrode^{19,20}. Therefore, the purpose of this research is to determine that, after applying the pull-back technique for the 532 slim modiolar electrode in temporal bones, the distance (measured in mm), between the modiolus and contact eleven of the electrode, is less than the distance generated after a regular insertion, as well as after an over insertion. Various scientific studies, as mentioned above, have shown that the shorter the distance between the modiolus and the electrode, the better the hearing outcomes in terms of speech understanding.

Materials and Methods

In our hospital (Klinikum Bielefeld Mitte), we are lucky to have a temporal bone laboratory. Each doctor has the option of drilling temporal bones in their free time. From time to time, we receive new temporal bones from unknown donors. Five random temporal (three left and two right) bones treated in formaldehyde were assigned to conduct this investigation as approved by the hospital's ethic commission.

The electrode we used was the new slim pre-curved perimodiolar electrode (CI532) developed by Cochlear Ltd. (Fig. 2). This electrode is held straight prior to insertion by an external polymer sheath, which is removed after full insertion of the array. This is intended to allow closer placement to the modiolus by eliminating the internal stylet and surrounding silicone rubber, reducing the electrode volume by 60% compared to with the previous perimodiolar CI512 device. This results in the CI532 being equivalent in dimension to the CI522, a lateral wall electrode that has demonstrated useful low-frequency hearing preservation. The CI532 has 22 platinum electrode contacts spread over 14 mm of active length. 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 mm X 0.5 mm and at the apical end of 0.35 mm X 0.4 mm^{21,22}. This electrode also has a higher degree of curvature in comparison to the Nucleus Contour Advance electrode and has three white markers for its insertion, as the human cochlea varies in size.



Fig. 2. The CI532 Slim Modiolar Electrode. Courtesy of Cochlear Ltd. (Sydney).

The temporal bones were freshly harvested and subsequently worked up. A conventional mastoidectomy with a posterior tympanotomy was performed first, followed by a decapping procedure of the cochlea. This procedure consisted of removing the roof of the scala vestibuli to allow a full visual assessment of the basilar membrane. The basilar membrane was also removed to obtain a panoramic view of the intrascalar position of the array in the scala tympani. A modified round window approach was performed for the insertion of the electrode array; this approach consisted of removing the promontory's lip, preparing the round window membrane, opening it and performing an inferior enlargement of the window. All of these procedures were carried out under moisturized conditions (0.9% NaCl) and

microscopic control to simulate a real-life situation. The microscope used was the Zeiss OPMI Pentero 900 and the drilling system was the Micro Drill- and Shaver System (DT55) from Spiggle & Theis. The distance from the round window to the furthest part from the lateral wall of the cochlea was measured using a paper wound ruler (Distance A). These procedures and measurements were done on different days, since the drilling of the temporal bones lasted several weeks. The same surgeon performed all of the drilling work.

Because the human cochlea varies in size, the 532 slim modiolar electrode has three white markers to guide its insertion. The marker closest to the round window is called number one, the following number two and the final marker number three. The maximal recommended insertion depth for this electrode is reached when the third white marker is visible in the round window²³. The electrode array was inserted following the surgical guidelines published by Cochlear Ltd. as follows: The white sheath handle must be aligned such that it is oriented toward the modiolus (in the plane of the basal turn). This ensures that, as the electrode advances, it follows the curvature of the cochlea. Guide the loaded sheath into the cochlea until the sheath stopper reaches the opening of the cochleostomy or round window. Insert and stabilize the sheath handle using straight forceps until the sheath stopper is against or flush with the opening. With the sheath stopper resting against or flush with the opening, slowly advance the electrode with forceps. The first white marker on the electrode will approach the white marker on the sheath. When the two white markers align, the electrode is fully inserted. After the electrode is inserted smoothly, grasp the white sheath handle firmly with straight forceps and slide the sheath straight back along the axis of the electrode until it is completely removed²⁴.

Three situations for the five temporal bones were analyzed and microscopically digitally captured. These were the initial insertion (insertion to the first white marker), over-insertion (insertion up to the third white marker) and pull-back position (pull-back to the first white marker once again). The position of the three white markers in relation to the round window was also evaluated when performing these three actions. The changes in distance between the center of the modiolus and contact eleven were measured based on the digitally captured images; contact eleven was appropriate because it is the middle of the electrode array. The images were captured using Karl Storz's AIDA documentation system connected to the microscope. The same experienced surgeon performed the insertion, over-insertion and pull-back for the five temporal bones on the same day. Fifteen insertions were performed—three for each temporal bone. The electrode array employed in this study was provided by the manufacturer.

It is a pilot experimental biometric laboratory study. The null hypothesis and the alternative hypothesis are as follows:

- H0: The distance between the modiolus and contact 11 of the electrode is equal or greater after performing the pull-back technique.
- H1: The distance between the modiolus and contact 11 of the electrode is less after performing the pull-back technique.

As this is a pilot study, since it is the first time that the pull-back technique has been applied in the new 532 slim modiolar electrode, no previous information was found for the estimation of the sample size. Thus, the number of samples for pilot studies is based on the experience and assessment of the tester. The sample size estimation follows the standard recommendations of using at least five samples, each analyzed in the three different situations, giving a total of fifteen analyzes. The differences among the distances of the three scenarios were calculated and statistically analyzed using a paired t-Test with a significance level < 0.05 (p-value). An experiment of this type in people was unethical, due to the risk of damaging the microstructures of the patient's cochleas.

Results

The average size of the temporal bones/cochleas was 8.64 mm. The longest Distance (A) was 9.5 mm, and the shortest was 8 mm (SD 0.5) (Fig. 3).

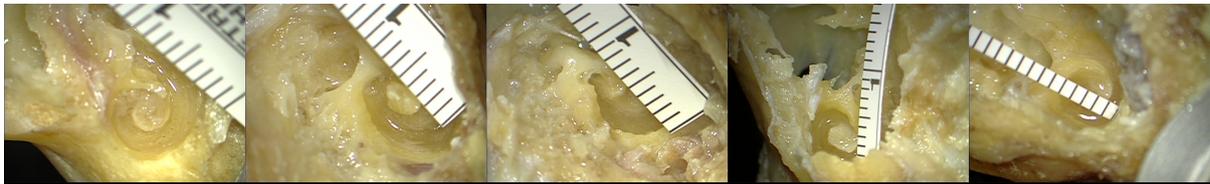


Fig. 3. Sizes of all five temporal bones.

The same pattern was observed in all five temporal bones when analyzing the three situations, as previously described. The initial insertion achieved an acceptable perimodiolar position of the electrode array, but a gap was still visible between the mid-portion of the array and the modiulus (Fig. 4). In this scenario, only the first white marker was visible in the round window.

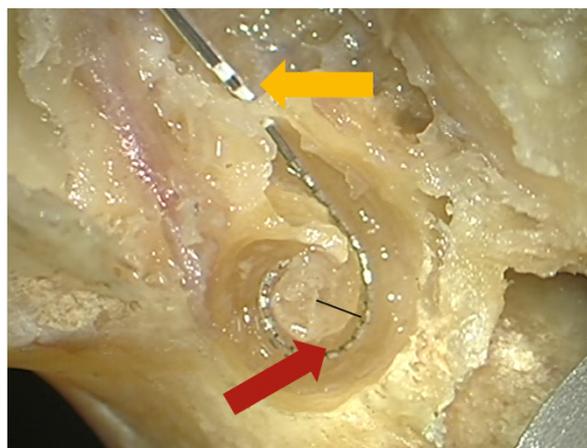


Fig. 4. Initial insertion of the electrode up to the first marker (yellow arrow) with distance of the electrode from the modiulus (red arrow). The black line indicates the distance between the modiulus and contact eleven.

When the array was inserted more deeply, the mid-portion of the array was pushed away from the modioli, resulting in an unfavorable perimodiolar position (Fig. 5). In this case, the third white marker was visible in the round window.

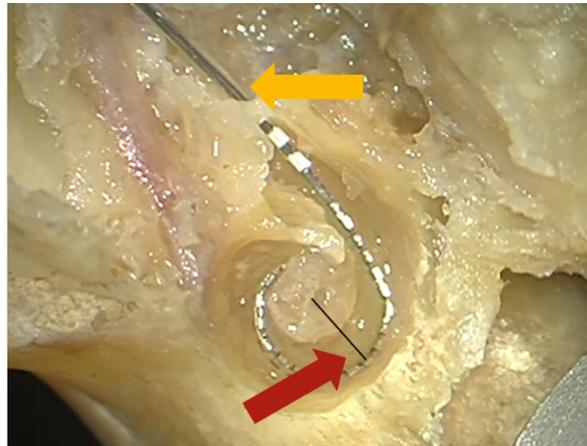


Fig. 5. The over-insertion of the electrode up to the third white marker (yellow arrow) with distance of the electrode from the modioli (red arrow). The black line indicates the distance between the modioli and contact eleven.

Finally, the pull-back technique was applied, resulting in an optimal perimodiolar position of the electrode array. When applying this technique, we found that the gap observed during the initial insertion disappeared, and the first marker of the electrode array was already visible in the round window. No electrode tip movements were detected during this procedure. There was a good correlation between the visually controlled and performed pull-back and the known electrode marker distances. The same situation repeated while applying this technique to each of the five temporal bones. We did not find a correlation between the size or side (left or right temporal bone) of the cochlea and the amount of pull-back applied. Considering the given data, the videos were reevaluated in all cases to increase the sensitivity of the method. Figures 4 to 6 show typical calculations. Analysis of the cochlear microstructures revealed no major changes or damage in any of the temporal bones, particularly at or around the modiolar wall.

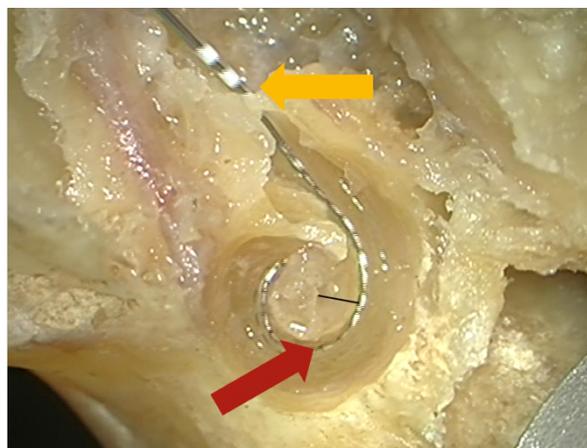


Fig. 6. The pull-back position of the electrode up to the first white marker (yellow arrow). The gap observed during the initial and over-insertion disappeared (red arrow). The black line indicates the distance between the modiolus and contact eleven.

The mean initial distance between the center of the modiolus and contact eleven was 1.9 mm (SD 0.2 mm). The over-insertion resulted in a distance of 2.5 mm (SD 0.4 mm), and the pull-back technique resulted in a distance of 1.5 mm (SD 0.2 mm). Table 1 shows results for each temporal bone.

in mm	TB 1	TB 2	TB 3	TB 4	TB 5	$\bar{\sigma}$	SD
<i>Initial Insertion</i>	2	1,9	2	1,5	2,1	1,9	0,2
<i>Overinsertion</i>	3,1	2,5	2,4	2,1	2,4	2,5	0,4
<i>Pull back</i>	1,4	1,5	1,5	1,2	1,8	1,5	0,2

Table 1. Distance in mm between the center of the modiolus and contact eleven, after applying each insertion in the five temporal bones.

When comparing the initial insertion with the pull-back position the p-value was 0.002. In the remaining two scenarios (initial insertion/over-insertion and over-insertion/pull-back position) the p-values were 0.01 and 0.005, respectively. These results demonstrate that the H0 (null hypothesis) is rejected with a significance level < 0.05.

Discussion

Since its introduction, each component of cochlear implants has been the subject of continual research and innovation to achieve the best performance in speech perception and production. In particular, special attention has been paid to electrode placement and design.

Another important feature is atraumatic insertion. To limit trauma during electrode insertion, the array should be positioned entirely within the scala tympani²⁵. Advantages and disadvantages have been described for each type of electrode array. One disadvantage—and perhaps the most important of the straight electrodes—is their final position, as they lay at the lateral wall of the cochlea, which is far away from the neural elements in the modiolar area. In contrast, preformed electrode arrays are fabricated in a spiral configuration and adjusted to the cochlea’s modiolar area. These electrode arrays were designed for intracochlear placement next to the modiolus²⁴. This position leads to a narrower electric stimulation, a lower current spread to the adjacent neural population, lower channel interaction and a reduced risk of facial nerve stimulation. As a consequence, the behavioral and electrically evoked compound action potential thresholds are reduced, with a wider dynamic range²⁵. For example, Esquia Medina found a statistical correlation between monosyllabic word scores and electrode contacts being closer to the center of the modiolus—higher scores were demonstrated when the contacts were closer to the modiolus²⁶. However, these perimodiolar designs also have disadvantages; until recent redesigns, these electrodes had a larger diameter and were associated with a higher risk of insertion trauma. Although Ramos-Macias stated that the 532 slim modiolar electrode seems to

be reliable for atraumatic intracochlear placement, a certain degree of trauma is to be expected with all of the currently available electrode designs²⁴. Another problem with perimodiolar electrodes to date is that, with these pre-curved arrays, dislocation occurs in up to 26% of the cases. Dislocation in to the scala vestibuli is associated with poorer hearing outcomes. With straight flexible electrode arrays, the incidence of dislocation has been found to be lower^{23,24}. Additionally, tip fold-overs can occur. In a study by Zuniga, tip fold-overs occurred in 8% of the patients implanted with the 532 slim modiolar electrode²⁷.

It is technically challenging to develop an electrode array that lies close to the modiulus, can be inserted with minimal trauma to the delicate cochlear structures and stays within the scala tympani¹¹. To achieve these objectives, a thin, pre-curved electrode was recently developed by Cochlear Ltd. and approved for clinical use in 2016^{25,28}. The 532 slim modiolar electrode is held straight prior to insertion by an external polymer sheath, which is removed after full insertion of the array. This new kind of electrode can be placed even closer to the modiulus. The elimination of the internal stylet and surrounding silicone rubber reduces the electrode volume by up to 75%, resulting in dimensions equivalent to that of the current lateral wall electrodes²⁵. In comparison to the Nucleus Contour Advance, the new 532 slim modiolar electrode has a diameter of 0.5 mm at the position of the most basal electrode, decreasing to 0.4 mm at the apex (the corresponding dimensions of the Nucleus Contour Advance are 0.8 mm and 0.5 mm). This gives the 532 slim modiolar electrode a cross-sectional area of about 40% of that of the Nucleus Contour Advance²³. Potential advantages of this new design include minimal insertion trauma and consistent perimodiolar location within the scala tympani²⁸. A study by Aschendorff found that the 532 slim modiolar electrode achieved the design goal of producing no trauma, as indicated by 100% scala tympani placement, while achieving consistent close modiolar proximity²³. However, McJunkin reported that 13% of 532 slim modiolar implants dislocated into the scala vestibuli²⁸. The dislocation rates of the 532 slim modiolar electrode are lower than those reported for the previous Nucleus Contour Advance.

An intraoperative intervention regarding the position of perimodiolar electrodes can further reduce the distance between the electrode contacts and modiulus¹⁷. This intervention, called the pull-back technique, has shown favorable results for the Nucleus Contour Advance and the Advanced Bionics Helix electrode¹⁹. The pull-back technique seems to encourage a better perimodiolar position of the electrode arrays¹⁵. Basta proved that the excitation spread was significantly reduced at basal, middle and apical electrodes in the electrode pull-back group using the Nucleus Contour Advance, while a significantly smaller frequency difference limen was observed with 4 kHz. This means that the pull-back technique has the greatest effect in the basal region of the cochlea¹⁷. The optimum pull-back distance for the Nucleus Contour Advance is between 1.37 and 1.5 mm¹⁹.

Another study using the Advanced Bionics Helix electrode showed similar results in applying the pull-back technique. The excitation spread showed a significant decrease in the intracochlear field in all three contacts (basal, middle and apical). The recommended pull-back for the Advanced Bionics Helix electrode was about 1 mm²⁰.

As the pull-back technique can be performed in various ways (insertion depth, amount of pull-back and variability of human cochleas), surgical guidelines are required for each electrode array¹⁹.

Therefore, it was the goal of the present study to estimate the change in position of the 532 slim modiolar electrode while being pulled back in a series of temporal bones with the aim of establishing clear surgical guidelines. The best pull-back distance is defined as the point where the tip is in an unchanged apical position and the middle part of the electrode is maximally approximated to the modiolus²⁰. We observed and digitally captured this situation in all of the temporal bones in which we performed the procedure, and we did not see any tip fold-over. This was not the case in another study, in which tip fold-overs occurred at a noteworthy rate of 1 to 8% in 532 slim modiolar implants^{28,29}.

Direct measures of electrode-to-modiolus distance, even from the best-quality CT imaging available, are problematic due to residual electrode artefacts blurring the boundary between the electrode and the medial wall of the modiolus²³. This is why studies on temporal bones, such as ours, provide the best way to assess the electrode-to-modiolus distance. Aschendorff came to similar conclusions; in her study, the electrode-to-modiolus distance was evaluated using computed tomography. As in our study, advancing the 532 slim modiolar electrode array past the first white marker position into the cochlea opening was undesirable, as it does not result in greater total insertion depths and only serves to increase the insertion depth of the first electrode contact and move basal electrodes away from the modiolus²³. Ramos-Macias also evaluated the distance between the electrode and modiolus using computed tomography and demonstrated that it was constant in all electrode arrays at less than 0.3 mm²⁴. Unfortunately, the pull-back technique was not performed in either of the studies.

The 532 slim modiolar electrode combines important electrode characteristics: a position closest to the modiolus, limited insertion trauma and positioning within the scala tympani²⁵. Adding a surgical technique modification called the pull-back technique to this array could be of interest in terms of frequency discrimination and number of virtual channels^{17,20}.

Conclusion

This temporal bone study demonstrated that applying the pull-back technique for the 532 slim modiolar electrode allowed closer proximity to the modiolus, indicated when the first white marker of the electrode array was visible in the round window. Our results show that this novel surgical technique, first described by Todt in 2005, is reproducible with the new 532 slim modiolar electrode. This technique places the electrode in a better perimodiolar position, and we can assume that when used in patients, hearing outcomes (in terms of speech understanding) will be better. We assume this because favorable results have been published for the Nucleus Contour Advance and Advanced Bionics Helix electrode when applying this technique in patients. As not all surgeons use this technique (sometimes due to unfamiliarity or fear of damaging the cochlear structures) and it is not applicable to all electrodes, clinical

results are insufficient. In future work, we aim to make measurements in patients implanted with the 532 slim modiolar electrode using this technique. This will take a couple of years, since not all patients are eligible to receive 532 slim modiolar electrodes, and hearing outcomes are first evaluated at least 6 months after surgery.

This experimental research was conceptualized by Ingo Todt. My job was to drill and measure the temporal bones as well as finding and analyzing the few published articles about the relatively new 532 slim modiolar electrode. I made adjustments to perform the insertions consisting of preparing the microscope and AIDA documentation system. The electrode insertion and the pull-back technique require a lot of expertise, which is why this part was the only aspect of the study in which I did not take part. Because Ingo Todt is an experienced surgeon and the creator of the pull-back technique, he performed the insertions. While he was performing the insertions, my duty was to manage the microscope, focus the image and record the procedures. Afterwards, I measured the distances between the center of the modiolus and contact eleven during the three actions previously described. I also completed all of the writing. Holger Sudhoff and Ingo Todt provided support of the conceptual discussion and certain corrections.

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Eidesstattliche Versicherung

„Ich, Conrad Josef Riemann Torres, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: “Die pull-back Technik für die 532 slim modiolar Elektrode” “The pull-back technique for the 532 slim modiolar electrode” selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe. Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.org) zur Autorenschaft eingehalten. Ich erkläre ferner, dass mir die Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis bekannt ist und ich mich zur Einhaltung dieser Satzung verpflichte.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst.“

Datum

Unterschrift

Anteilerklärung an den erfolgten Publikationen

Conrad Josef Riemann Torres hatte folgenden Anteil an folgender Publikation:

Publikation: Riemann C, Sudhoff H and Todt I. BioMed Research International, 2019

Bohrungen der Felsenbeine, Messungen der Felsenbeine, Literaturrecherche, Auswertung der Daten, digitale und mikroskopische Erfassung der Insertionen, Messungen der verschiedenen Abstände zwischen der Mitte des Modiolus und der Elektrode, Ausarbeitung und Verfassung des Manuskripts.

Unterschrift des Doktoranden/der Doktorandin

Auszug aus der Journal Summary List

Journal Data Filtered By: **Selected JCR Year: 2017** Selected Editions: SCIE,SSCI
 Selected Categories: **"BIOTECHNOLOGY and APPLIED MICROBIOLOGY"**
 Selected Category Scheme: WoS
Gesamtanzahl: 160 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	NATURE REVIEWS DRUG DISCOVERY	31,312	50.167	0.054410
2	NATURE BIOTECHNOLOGY	57,510	35.724	0.161460
3	TRENDS IN BIOTECHNOLOGY	14,746	13.578	0.019170
4	GENOME BIOLOGY	34,697	13.214	0.118500
5	BIOTECHNOLOGY ADVANCES	15,722	11.452	0.021940
6	GENOME RESEARCH	38,842	10.101	0.105060
7	CURRENT OPINION IN BIOTECHNOLOGY	14,009	8.380	0.024860
8	BIOSENSORS & BIOELECTRONICS	48,853	8.173	0.069510
9	METABOLIC ENGINEERING	6,384	7.674	0.014000
10	MOLECULAR THERAPY	16,013	7.008	0.029180
11	Annual Review of Animal Biosciences	582	6.775	0.002460
12	PLANT BIOTECHNOLOGY JOURNAL	6,544	6.305	0.014270
13	BIORESOURCE TECHNOLOGY	101,191	5.807	0.109450
14	REVIEWS IN ENVIRONMENTAL SCIENCE AND BIOTECHNOLOGY	1,941	5.716	0.002740
15	STEM CELLS	21,694	5.587	0.035680
16	Biotechnology for Biofuels	7,769	5.497	0.020590
17	BIOINFORMATICS	95,300	5.481	0.201110
18	JOURNAL OF NANOBIOTECHNOLOGY	3,004	5.294	0.005360
19	Journal of Biological Engineering	756	5.256	0.001600
20	CRITICAL REVIEWS IN BIOTECHNOLOGY	2,831	5.239	0.003810
21	MUTATION RESEARCH-REVIEWS IN MUTATION RESEARCH	3,440	5.205	0.003220
22	Nanomedicine	7,253	5.005	0.012950
23	HUMAN GENE THERAPY	5,559	4.241	0.007690
24	npj Biofilms and Microbiomes	183	4.128	0.000690

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
25	FOOD MICROBIOLOGY	9,325	4.090	0.012400
26	Journal of Tissue Engineering and Regenerative Medicine	3,963	4.089	0.006640
27	CANCER GENE THERAPY	2,928	4.044	0.003610
28	Current Opinion in Chemical Engineering	1,381	4.033	0.004340
29	CYTOTHERAPY	5,589	3.993	0.009020
30	EXPERT OPINION ON BIOLOGICAL THERAPY	4,426	3.974	0.008370
31	BIOTECHNOLOGY AND BIOENGINEERING	24,560	3.952	0.020170
32	Microbial Biotechnology	2,741	3.913	0.005610
33	SYSTEMATIC AND APPLIED MICROBIOLOGY	5,083	3.899	0.005450
34	Microbial Cell Factories	6,026	3.831	0.013090
35	Briefings in Functional Genomics	1,557	3.783	0.004130
36	Algal Research-Biomass Biofuels and Bioproducts	3,273	3.745	0.008100
37	New Biotechnology	2,343	3.733	0.004740
38	BMC GENOMICS	37,516	3.730	0.099740
39	APPLIED AND ENVIRONMENTAL MICROBIOLOGY	100,091	3.633	0.071890
40	MOLECULAR PLANT-MICROBE INTERACTIONS	10,099	3.588	0.010270
41	INTERNATIONAL BIODETERIORATION & BIODEGRADATION	9,237	3.562	0.011120
42	TISSUE ENGINEERING	21,530	3.508	0.023730
43	Biotechnology Journal	4,515	3.507	0.008950
44	Biofuels Bioproducts & Biorefining-Biofpr	2,918	3.376	0.004340
45	BIOMASS & BIOENERGY	19,706	3.358	0.023220
46	APPLIED MICROBIOLOGY AND BIOTECHNOLOGY	39,010	3.340	0.048620
47	BIOCHEMICAL ENGINEERING JOURNAL	9,231	3.226	0.009570
48	GENE THERAPY	7,733	3.203	0.007690
49	JOURNAL OF INDUSTRIAL MICROBIOLOGY & BIOTECHNOLOGY	7,516	3.103	0.007670
50	Artificial Cells Nanomedicine and Biotechnology	1,344	3.026	0.001810
51	DISEASE MARKERS	3,183	2.949	0.007020
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Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
53	GM Crops & Food-Biotechnology in Agriculture and the Food Chain	220	2.913	0.000700
54	GENOMICS	8,930	2.910	0.008140
55	Advances in Biochemical Engineering-Biotechnology	1,978	2.795	0.002180
56	BIOFOULING	4,011	2.786	0.004600
57	FOOD AND BIOPRODUCTS PROCESSING	3,356	2.744	0.005040
58	MAMMALIAN GENOME	2,665	2.687	0.004400
59	OncoTargets and Therapy	5,065	2.656	0.012570
60	PROCESS BIOCHEMISTRY	16,572	2.616	0.011380
61	FEMS YEAST RESEARCH	3,940	2.609	0.006070
62	BMC BIOTECHNOLOGY	3,214	2.605	0.004860
63	JOURNAL OF CHEMICAL TECHNOLOGY AND BIOTECHNOLOGY	10,516	2.587	0.009450
64	Biomed Research International	31,694	2.583	0.103050
65	JOURNAL OF BIOTECHNOLOGY	14,647	2.533	0.016990
66	JOURNAL OF GENERAL VIROLOGY	19,016	2.514	0.018360
67	MICROBES AND ENVIRONMENTS	1,388	2.476	0.002480
68	BIODEGRADATION	2,838	2.410	0.002140
69	JOURNAL OF APPLIED PHYCOLOGY	7,972	2.401	0.008290
70	MUTATION RESEARCH-FUNDAMENTAL AND MOLECULAR MECHANISMS OF MUTAGENESIS	7,799	2.398	0.004960
71	ENGINEERING IN LIFE SCIENCES	2,027	2.385	0.002770
72	OMICS-A JOURNAL OF INTEGRATIVE BIOLOGY	1,625	2.370	0.003560
73	JOURNAL OF BIOMOLECULAR SCREENING	3,213	2.355	0.006320
74	Probiotics and Antimicrobial Proteins	449	2.345	0.000760
75	MARINE BIOTECHNOLOGY	2,820	2.328	0.003120
76	Human Gene Therapy Methods	389	2.300	0.001580
77	YEAST	4,339	2.283	0.002470

Research Article

The Pull-Back Technique for the 532 Slim Modiolar Electrode

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Introduction. The distance between the modiolus and the electrode array is one factor that has become the focus of many discussions and studies. Positioning the electrode array closer to the spiral ganglion with the goal of reducing the current spread has been shown to improve hearing outcomes. The perimodiolar electrode arrays can be complemented with a surgical manoeuvre called the pull-back technique. This study focuses its attention on the recently developed 532 slim modiolar electrode. **Objective.** To investigate the intracochlear movements and pull-back technique for the 532 slim modiolar electrode. **Material and Methods.** A decapping procedure of the cochlea was performed on 5 temporal bones. The electrode array was inserted, and the intracochlear movements were microscopically examined and digitally captured. Three situations were analysed: the initial insertion, the overinsertion, and the pull-back position. The position of the three white markers of the electrode array in relation to the round window (RW) was evaluated while performing these three actions. **Results.** The initial insertion achieved an acceptable perimodiolar position of the electrode array, but a gap was still observed between the mid-portion of the array and the modiolus (the first white marker was seen in the RW). When we inserted the electrode more deeply, the mid-portion of the array was pushed away from the modiolus (the second and third white markers were seen in the RW). After applying the pull-back technique, the gap observed during the initial insertion disappeared, resulting in an optimal perimodiolar position (the first white marker was once again visible in the RW). **Conclusion.** This temporal bone study demonstrated that when applying the pull-back technique for the 532 slim modiolar electrode, a closer proximity to the modiolus was achieved when the first white marker of the electrode array was visible in the round window.

1. Introduction

Cochlear implantation is the treatment of choice for severe to profound hearing loss. Since the first nonexperimental cochlear implantations, there have been more than 500,000 implantations worldwide. In recent years, the design of cochlear implant arrays has changed [1]. One notable innovation was the introduction of perimodiolar electrodes in the late 1990s. The electrode in a cochlear implant system is the central factor for hearing performance, as it is the interface between the device and the auditory pathway of the recipient [2]. Current commercially available electrode arrays can be divided into two classes: straight lateral wall electrode arrays and precurved perimodiolar or midmodiolar electrode arrays [3]. The distance between the modiolus and the electrode array has become the focus of many discussions and studies for a variety of reasons.

Positioning the electrodes closer to the spiral ganglion with the goal of reducing the current spread during electrical stimulation has been shown to improve hearing outcomes [1]. An electrophysiological effect was demonstrated for the first time by Shepherd, who reported reduced electric auditory brainstem response thresholds while positioning the electrode array closer to the modiolus [4]. Further studies have proven that the perimodiolar electrode position decreases channel interactions and neural response telemetry thresholds and leads to better speech understanding [5, 6]. Some other benefits, like a decrease power consumption and an increase in the dynamic range, have also been reported [5, 7]. The comfort level among users implanted with a perimodiolar electrode array seems to be higher than among users implanted with a straight lateral wall array [8]. Holden et al. concluded that total insertion depth was not associated with better speech discrimination outcomes;

TABLE 1: Temporal bone specific effect of insertion, over insertion and pull back on distance between modiolus center and contact I1.

in mm	TB1	TB 2	TB 3	TB 4	TB 5
Initial Insertion	2	1,9	2	1,5	2,1
Over Insertion	3,1	2,5	2,4	2,1	2,4
Pull back	1,4	1,5	1,5	1,2	1,8

however, the distance from the electrodes to the modiolus did indicate a significant influence [9]. Any surgery technique or strategy that prompts a better perimodiolar positioning of the electrode array could therefore lead to an increase in hearing outcomes.

The perimodiolar electrode arrays can be complemented with a surgical manoeuvre called the pull-back technique. This technique consists of a normal insertion of the electrode with a subsequent pulling back until the first white marker of the electrode array becomes microscopically visible in the round window (RW). A better perimodiolar position of the electrode is achieved by this manoeuvre. The pull-back technique is assumed to bear no serious risks to the cochlear microstructures and has shown to be reliable and reproducible [10]. Electrophysiological changes have also been reported in different studies applying this intervention. In one study, the spread of excitation decreased significantly in the medial and basal part of the cochlea after the pull-back technique was applied [11]. Another study demonstrated that electrically evoked action potential amplitudes at a fixed stimulus level increased after implementing this procedure [12]. The array inside the scala tympani is invisible to the surgeon, so the proximity of the electrode array to the modiolar wall is generally unknown [1]. The variable amount of pull-back and the variability of sizes of the human cochlea make this procedure different for each electrode array [13]. Clear surgical guidelines have been published for the Nucleus Advance electrode and the Advanced Bionics Helix electrode [14, 15]. This study focuses its attention on the recently developed 532 slim modiolar electrode.

The 532 slim modiolar electrode allows closer placement to the modiolus due to a higher degree of precurvature in comparison to the Nucleus Contour Advance Electrode [16]. Therefore, the goal of this work is to investigate the intracochlear movements and pull-back technique for the 532 slim modiolar electrode.

2. Material and Methods

A decapping procedure of the cochlea was performed on 5 randomly chosen human formaldehyde treated temporal bones (3 left and 2 right). This consisted of removing the roof of the scala vestibuli until a full visual assessment of the basilar membrane was possible. The basilar membrane was also removed to obtain a panoramic view of the intrascalar position of the array in the scala tympani. A RW approach was performed for the insertion of the electrode array. This procedure was made under moisturized conditions and microscopic control to simulate an authentic situation. The sizes of the 5 temporal bones/cochleas (distance from the RW to the furthest part from the lateral wall of the cochlea,

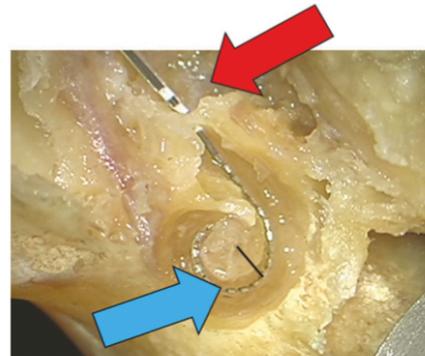


FIGURE 1: Initial insertion of the electrode up to the first marker (red arrow) with distance of the electrode at the modiolus (blue arrow). Black line indicates distance between modiolus and contact I1.

Distance A) were measured. Because human cochleae vary in size, the 532 slim modiolar electrode has three white markers for insertion. The marker closest to the RW is called number 1, the following number 2, and the final marker number 3. The electrode array was inserted with the recommended sheath insertion and removal technique. The intracochlear movements were microscopically examined and digitally captured (Zeiss OPMI Pentero 900). Three situations for the 5 temporal bones were analysed and digitally captured: initial insertion (to the first marker), overinsertion (up to the third marker), and the pull-back position (to the first marker). The position of the three white markers of the electrode array in relation to the RW was also evaluated when performing these three actions. The change in distance between the center of the modiolus and the contact I1 was measured based on the digital capturing (Table 1).

3. Results

The mean size of the temporal bones/cochleas was 8.64mm, the longest Distance A was 9.5mm, and the shortest was 8 mm. For all 5 temporal bones, the same pattern was observed when analysing the three situations, as previously described. The initial insertion achieved an acceptable perimodiolar position of the electrode array, but a gap was still observed between the mid-portion of the array and the modiolus (Figure 1). In this scenario, only the first white marker was observed in the RW. When the array was inserted more deeply, the mid-portion of the array was

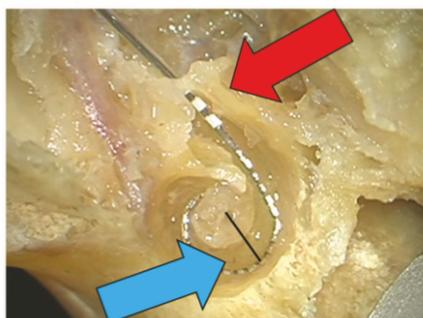


FIGURE 2: Overinsertion of the electrode up to the third marker (red arrow) with distance of the electrode at the modiolus (blue arrow). Black line indicates distance between modiolus and contact II.

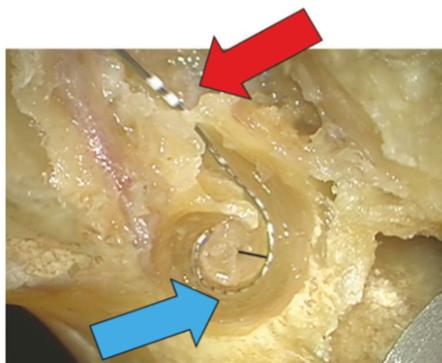


FIGURE 3: Pull back of the electrode up to the first marker (red arrow) with close position of the electrode at the modiolus (blue arrow). Black line indicates distance between modiolus and contact II.

pushed away from the modiolus, resulting in an unfavourable perimodiolar position (Figure 2). In this case, the third white marker was seen in the RW. Finally, the pull-back technique was applied, resulting in an optimal perimodiolar position of the electrode array. When applying this technique, we found that the gap observed during the initial insertion disappeared and that the first white marker of the electrode array was already visible in the RW. No tip movements were detected during this procedure. The same situation repeated itself while applying this technique to the 5 different temporal bones. We did not find a correlation between the size or side (left or right temporal bone) of the cochlea and the amount of pull-back applied. The closest perimodiolar position for all 5 temporal bones was attained when the first white marker of the electrode array was visible in the RW after applying the pull-back technique (Figure 3). Measurement showed a mean initial distance between modiolus center and contact II

of 1,9 mm (SD 0,2mm). Overinsertion resulted in a distance of 2,5 mm (SD 0,4 mm). The pull-back finally resulted in a distance of 1,5 mm (SD 0,2 mm).

4. Discussion

Since its introduction, each component of the cochlear implant has been the subject of continual research and innovation to achieve the best performance in speech perception and production. In particular, special attention has been paid to electrode placement and design. Another important feature is atraumatic insertion. To limit trauma during electrode insertion, the array should be positioned entirely within the scala tympani [17]. Advantages and disadvantages have been described for each type of electrode array. One disadvantage of the straight electrodes is their final position, as they lay at the lateral wall of the cochlea, which is far away from the neural elements in the modiolar area. By contrast, preformed electrode arrays are fabricated in a spiral configuration and adjusted to the human cochlea's modiolar area. These electrode arrays were designed for intracochlear placement next to the modiolus [18]. This position leads to a narrower electric stimulation, a lower current spread to the adjacent neural population, a lower channel interaction, and a reduced risk of facial nerve stimulation. As a consequence, the behavioural and electrically evoked compound action potential thresholds are reduced with a wider dynamic range [17]. However, these perimodiolar designs also have disadvantages, as these electrodes, until recent redesigns, have had a larger diameter and were associated with a higher risk of insertion trauma. Another problem with perimodiolar electrodes until now is that, with these precurved arrays, dislocation occurs in up to 26% of the cases, which is associated with poorer outcomes [16]. Additionally tip foldovers can occur [19]. With straight flexible electrode arrays, the incidence of dislocation has been found to be lower [18].

The development of an electrode array that lies close to the modiolus, which can be inserted with minimal trauma to the delicate cochlear structures and which stays within the scala tympani, is technically challenging [8]. In an aim to achieve these objectives, a thin, precurved electrode was recently developed by Cochlear Ltd. and approved for clinical use in 2016 [17, 20]. The CI532 is held straight prior to insertion by an external polymer sheath, which is removed after full insertion of the array. This new kind of electrode is even closer to the modiolus. The elimination of the internal stylet and surrounding silicone rubber reduces the electrode volume by up to 75%, resulting in dimensions equivalent to that of the current lateral wall electrodes [17]. In comparison to the Nucleus Contour Advance, the new CI532 has a diameter of 0.5 mm at the position of the most basal electrode, reducing to 0.4 mm at the apex (the corresponding dimensions of the Nucleus Contour Advance are 0.8 mm and 0.5 mm). This gives the CI532 a cross-sectional area about 40% that of the Nucleus Contour Advance [16]. Potential advantages of this new design include minimal insertion trauma and consistent perimodiolar location within the scala tympani [20]. A study by Aschendorff et al. found that the CI532 achieved the design goal of producing no trauma, as

indicated by 100% scala tympani placement, while achieving consistent and close modiolar proximity [16]. However, a study by McJunkin et al. reported that 13% of the CI532 implants dislocated into the scala vestibule [20]. These results for the CI532 are lower than those reported for the previous Nucleus Contour Advance.

An intraoperative intervention regarding the position of perimodiolar electrodes can further reduce the distance of the electrode contacts to the modiulus [11]. This intervention, called the pull-back technique, has shown favourable results for the Nucleus Contour Advance and the Advanced Bionics Helix electrode [14]. The pull-back technique seems to cause a better perimodiolar position of the electrode arrays [12]. Basta et al. proved that the spread of excitation was significantly reduced at basal, middle, and apical electrodes in the electrode pull-back group for the Nuclear Contour Advance, while a significantly smaller frequency difference limen was observed with the 4 kHz. This means that the pull-back technique has its greatest effect in the basal region of the cochlea [11]. Another study using the Advanced Bionics Helix electrode showed similar results after applying the pull-back technique. The spread of excitation showed a significant decrease of the intracochlear field in all three contacts (basal, middle, and apical). The recommended pull-back distance for the Advanced Bionics Helix electrode was about 1 mm [15]. As the pull-back technique can be performed in different ways (insertion depth, amount of pull-back, and variability of the human cochlea), surgical guidelines are required [14]. Therefore, it was the goal of the present study to estimate the change in position of the CI532 while being pulled back in a series of temporal bones. The best pull-back distance is defined as the pull-back distance while the tip is still in its unchanged apical position and the middle part of the electrode is maximally approximated to the modiulus [15]. This situation was observed and digitally captured in all of the temporal bones where we performed the procedure. In our study, we did not see any tip foldover. This was not the case in another study where tip foldovers occurred in 1% to 8% of the CI532 implants, which is noteworthy [20, 21]. Direct measures of electrode to modiulus distance, even from the best quality CT imaging available, are problematic due to residual electrode artefacts blurring the boundary between the medial and medial wall [16]. This is why cadaveric studies like ours provide the best way to assess the electrode to modiulus distance. The study by Aschendorff et al. came to similar conclusions as ours. In their study, the electrode to modiulus distance was evaluated using CT. As in our study, advancing the CI532 electrode array past the first white marker position into the cochlea opening was undesirable, as it does not result in greater total insertion depths and only serves to increase the insertion depth of the first electrode contact and move basal electrodes away from the modiulus [16]. Ramos-Macias et al. also evaluated electrode to modiulus distance using CT and demonstrated that it was constant in all electrode arrays and less than 0.3 mm [18]. Unfortunately, the pull-back technique was not performed in either of the studies.

The CI532 combines important electrode characteristics: a position closest to the modiulus, limited insertion trauma,

and positioning within the scala tympani [17]. Adding a surgical technique modification called the pulled-back to this array could be of promising interest in frequency discrimination and number of virtual channels [11, 15].

5. Conclusion

This temporal bone study demonstrated that when applying the pull-back technique for the 532 slim modiolar electrode, a closer proximity to the modiulus was achieved when the first white marker of the electrode array was visible in the RW.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Acknowledgments

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Lebenslauf

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

Publikationsliste

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Felsenbein MRT zur Beurteilung der Position der CI-Elektrode (Vortrag): **Riemann C**, Sudhoff H und Todt I.

- CI2021 Cochlear implants in children and adults – American Cochlear Implant Alliance, 28.04-01.05.2021 (Online): Influence of intracochlear air on experimental pressure measurements. **Riemann C**, Sudhoff H and Todt I.
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