COMPUTER AIDED METHODS FOR ASSISTING COCHLEAR IMPLANT SURGERY

PhD Thesis booklet

Bence Horváth, MSc

University of Szeged, Faculty of Medicine

Szent-Györgyi Albert Clinical Center, Department of Otorhinolaryngology, Head and Neck Surgery

Supervisor:

József Géza Kiss, CSc, PhD

Co-supervisor:

Ádám Perényi, MD, PhD

Doctoral School of Clinical Medicine

Chair: Prof. Lajos Kemény MD, DSc

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II. Perényi Á, Nagy R, **Horváth B**, Posta B, Dimák B, Csanády M, Kiss JG, Rovó L. Új műtéti képalkotó lehetőség a belsőfül-implantátum elektródasorának dinamikus helyzetmeghatározására [A novel intraoperative imaging tool to follow the cochlear implant electrode array insertion dynamics]. Orv Hetil. 2021 May 30;162(22):878-883. Hungarian. doi: 10.1556/650.2021.32085. PMID: 34052802.
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I. INTRODUCTION

As one of our most important senses, the ability to hear enables us to connect to the world. Most importantly, hearing connects us to people, enabling us to communicate in a way that none of our other senses can achieve. Prelingual hearing impaired people are either born with or develop profound hearing loss before the period of speech development. These are the patients who if completely lack the experience of hearing, would never learn to speak. However, advanced equipment and surgical techniques enables these patients to hear. Our research focuses on the use of cochlear implants which are the most modern implantable devices of the inner ear.

I.1. Cochlear implant (CI)

The cochlear implant directly stimulates the auditory nerve which creates a hearing experience for the patient. This means that the device takes over the role of the inner hair-cells.

The implant's internal unit contains the electrode array (EA) which is surgically inserted into the scala tympani of the cochlea. The most common procedure to insert EA into the scala tympani via the round window (RW) is a partial mastoidectomy followed by a posterior tympanotomy. The RW anatomy is variable among individuals which in some instances requires its widening ("extended RW approach"). The electrode is placed near to the auditory nerve, so the nerve undergoes directs stimulation. For this reason, maintaining the integrity of the auditory nerve is essential.

I.1.1. Cochlear implant electrode arrays

Average length of the cochlear duct is approximately 35 mm, and the diameter of the basal turn measures approximately 2 mm. The cochlear implant EA dimensions should be matched to the size of the cochlea, when choosing the EA for a given patient.

I.1.1.1 Straight electrode array (SEA)

SEAs have been designed by multiple CI manufacturers (Cochlear™ Ltd., MED-El® etc.). The long lifetime and the large number of implanted devices show the clinical efficacy and reliability of SEAs. These EAs are located near to the lateral wall of the cochlea. SEAs have also been used in a significant proportion of patients with different anatomical variations, particularly when the cochlear structure is not suitable for perimodiolar electrode placement.

I.1.1.2 Perimodiolar electrode array (PEA)

PEAs have been designed to be placed near to the modiolus of the cochlea therefore, the electrodes are in closer proximity to the auditory nerve than the straight EA. There are many positive effects, such as the stimulation takes place closer to the auditory nerve, which can be reflected in both more effective electrophysiological parameters and improved hearing experience. The PEA begins to take on the twisted shape of the cochlea as soon as it leaves the EA insertion tool which can reduce the risk of damage to the cochlea's inner structures. PEAs (Slim modiolar by the Cochlear^{TM} Ltd.) have been the most commonly used electrode arrays for patients who experienced severe to profound sensorineural hearing loss at our Department.

Besides the many advantages of the delicate and slim EA, it has a significant draw-back: tip fold-over (TFO), when the EA turns back inside the cochlear duct. This phenomenon should be avoided or corrected immediately because it can cause implant failure and a need for removal.

I.1.1.3 Half-banded and full-banded EAs

In the half-banded EAs, the electrodes are located only in the half part of the silicon coat's cross-section. The half-banded design enables the electrode insertion direction critical, because it can only twist in one direction. This is unlike the full-banded electrodes, where the electrodes fill the entire cross-section of the silicone case. For this reason, half-banded EA's insertion tool is equipped with an orientation marker (OM) to align the implant to the correct trajectory.

I.2. Medical imaging

In line with the international guidelines, our patients who are candidates for cochlear implantation, undergo imaging with Computed Tomography (CT) and/or Magnetic Resonance Imaging (MRI).

Pre-operative imaging is essential to diagnose any type of inner ear malformations and to identify other abnormalities in the temporal bone. Post-operative imaging is important to confirm the correct electrode position and to investigate for any abnormality such as interscalar dislocation or electrode TFO, which can be a potential source of CI malfunction.

I.2.1. Magnetic Resonance Imaging (MRI)

During MRI, the patient is placed into a strong magnetic field. Because the principle of the procedure, this scan is best used to image proton-rich areas, such as tissues with high water and/or fat content, for example: the brain. On a T2 sequence the channels of the cochlear duct:

the scala tympani and the scala vestibule are well recognized. A pre- and postoperative MRI scan can be immensely helpful in assessing whether there is damage in the cochlea and to ensure that the EA is inside the scala tympani and has not caused any damage inside the cochlea. The majority of implants on the market are suitable for MRI scan under certain circumstances. However, the image may be profoundly distorted by metal artifacts.

I.2.2. Computed tomography (CT)

CT, which is an X-ray based imaging technique, shows mainly bones (where most of the rays are absorbed) and air-filled cavities (where there is no absorption, the area is a well-defined and therefore pure black) with good resolution. A CT scan taken before implantation can be used to determine if the patient is suffering from any anatomical malformation and can establish the necessary electrode type. Postoperative CT can assess the positioning of the EA inside the cochlea to rule out TFO or other defects (tear, incomplete insertion). Usually in practice, high resolution CT scan is made in the axial and coronal sections, with 0.4 to 0.6 mm thickness.

I.2.3. Fluoroscopy (FL)

Fluoroscopy is another X-ray imaging technique that allows visualisation of moving internal organs (for example the heart) by taking a continuous X-ray image on a monitor. Fluoroscopy is used in a wide range of diagnostic and therapeutic tests and procedures, such as radiological examinations (to visualise the gastrointestinal tract), intravascular catheter insertion and manipulation (to guide the catheter through the blood vessels). In CI surgery, the surgical team can follow on real time the insertion of the EA, and can check the result of the surgery, such as the final location of the EA.

I.2.4. Human error factor in digital image processing

In most cases, the recordings that are created of the patient require further processing. These can be manual or automatic measurement tasks. Measurements (length, angle, area etc.) and segmentations (labelled parts of the image) can greatly facilitate the planning of surgery and the success of the intervention itself.

Determination of the cochlear duct's length and/or the length of the electrode array's inserted section, as well as the shape of the cochlea, typical measurements before CI surgery. In order to examine the cochlea in 3D view, we need to segment it from the CT or MRI scan. Segmentation can be performed manually, but there are also a number of automatic, semi-automatic methods for it. Packing the created segments together can be reconstructed into a 3D model, so that the parts considered important can be examined in a 3D environment.

In medical image processing the human factor is not negligible. It is important that these tasks are carried out by a specialist or someone who is thoroughly familiar with the anatomy of the examined area. If we intend to use the images for surgical planning, it is crucial that the necessary measurements be correct.

II. OBJECTIVES

1. To investigate the extent of human error in the manual processing of medical images, in order to decide whether the measurement work can be carried out by students.
2. To develop and implement a measurement algorithm to calculate the correct alignment of the electrode array, especially for Cochlear^{TM} Ltd.'s Slim Modiolar electrode.
3. To validate the developed method on a large number of patients and evaluate the results statically.
4. To create digital 3D models of the cochlea and surrounding structures (bony structure, auditory bones, semicircular canals). To plan CI implantation for a cochlea malformation patient and monitoring the insertion of the electrode array during surgery using fluoroscopy.

III. MATERIALS AND METHODS

III.1. The measurement procedure

Ten students assisted on this study at University of Szeged. 3D Slicer (Win10, v4.11) was used to mark several anatomical landmarks and point-like structures. One point had to be marked on a 3D model created by the students. From the measured and reference points, we calculated nine anatomy planes. This dataset was used to measure the precision of the students by comparing it with reference measurements.

The measurements have been carried out on skull CT scans of patients of different age groups (1, 4 and 27 years old). We received 15 measurements from each student. Before the test, the volunteers received a basic training (3 hours long) about the usage of 3D Slicer, and recognition of the anatomy points and landmarks on CT records. After each measurement day, the students had the opportunity to ask whether they had marked the points correctly.

In our study, we observed how the accuracy of the measurements varied between measurement occasions, and we also observed the effect of age. The anatomical planes and angles defined by the points were calculated and compared with the reference dataset. .

III.2. Method to measure the correct alignment of the electrode

Half-banded electrodes, such as the Slim Modiolar array from Cochlear^{TM} Ltd., must be inserted in a specified direction (corresponding their curvature). This places the electrodes close to the modiolus and TFO may be avoided. We developed a semi-automatic algorithm to perform the measurements related to visible surgical landmarks that estimates the correct electrode alignment. For algorithm development, we used 3D Slicer to process preoperative CT scan (slice thickness 0.6 mm, no gap, bone kernel) of one of our cochlear implanted patients.

III.2.1. The manual measurement step-by-step

1. On the axial slice, the user marked the incus short process (ISP). The ISP was chosen as a clear anatomical landmark, due to the fact that it is a clearly visible point-like landmark during routine cochlear implant surgery via posterior tympanotomy.
2. The user created the cochlear view, with rotation of the coronal slice.
3. Creating two perpendicular lines starting from the round window (RW): first represent the insertion guide of the EA (IG), the second is the orientation marker (OM). The length of the IG line is similar to the real device's parameter (~6.5 mm). The OM line's length was not essential for the measurement. 3D Slicer has a built-in angle measurement tool, to create perfect perpendicular lines.

Thus, three parameters were observed: 1 point (ISP) and 2 lines (IG and OM).

III.2.2. Scripted module to 3D Slicer

To obtain the correct alignment of insertion from the above three parameters, complex mathematical calculations are required. Since we needed calculations that are not in the core program, for this reason we had to implement a separate module for the 3D Slicer. Firstly, the module defines the plane defined by the lines IG and OM. This is the cochlear view itself, which is the ideal plane for the EA insertion. Then this plane was rotated 90 degrees along the line of OM to obtain the plane perpendicular to the cochlear view. Although the surgeon is able to visualize the depth (3D view) with the surgical microscope, estimation of angles and planning the surgery is easier and more accurate in one plane (2D view). For this reason, the program projected the ISP into the previously mentioned plane of cochlear view rotated by 90 degrees. Finally, the angle between OM and a virtual line connecting the ISP to the RW is defined.

III.3. Validation and processing of the data

After applying the algorithm on one patient's imaging data, we have collected the last 3 years of all our implanted patients who had preoperative CT scan. From these, we selected those that met our requirements: high resolution temporal bone CT, malformation-free and implanted with Slim Modiolar array. A total of 80 CT scans were used. The results obtained were subjected to statistical tests using R-Studio (R version 3.6.3, Windows 10).

III.4. Real time insertion recording

Since the measurement method was developed for non-malformation cases, a different method was chosen for our next presented patient. The patient is a 1-year-old boy with bilateral hearing loss, whose CT and MRI scans revealed type III cochlear hypoplasia of both cochleae. Patients with this lesion have a normal basal turn of the cochlea that is followed by a vestigial second turn, making only half a turn, and the third turn is absent. The internal structure (scala tympani, media and vestibuli) is not damaged. This cochlear malformation may be associated with a malformation of the organ of balance, in our case, a partial absence of the lateral semicircular canals. The cochlear implantation of both ears was performed at the Szent-Györgyi Albert Clinical Center of University of Szeged, the electrode used was the Cochlear™ Ltd.'s Slim modiolar perimodiolar electrode (CI532). The intraoperative imaging was performed by Siemens Artis Pheno (Siemens Healthcare GmbH, Erlangen, Germany) robotic DSA system.

IV. Results

IV.1. Distance between measured and reference point-like landmarks

We measured the distance between point-like objects on both sides: mastoid process, nasal peak, back pole of rostrum and inion. The results are mostly similar (SD ~2 mm) of the 1 and

4 years old patients. On the 27 years old patients' scans the students achieved larger inaccuracy, so we concluded that age represents a slight influencing factor in this examination. The measurements were the most inaccurate at inion. There, the average distance between the references was 15 mm, but there were outstanding values: 30-35 mm. The other problematic point was the back pole of rostrum, there we measured approximately 5 mm difference from the reference data. The most accurate results, that were closest to the reference data, were achieved on the mastoid process and nasal peak, there the distance from the reference data was 0.5-1 mm.

Since it was possible to check their results between the measurement occasions, we examined whether there was a change between the results of the 3 measurement days. A minimal improvement was obtained (average improvement of 0.1-0.2 mm), but the selection on the 3D model did not improve significantly between occasions.

IV.1.1. Angles enclosed by the calculated and reference planes

We examined the angle between the planes calculated from the students' results and the reference values. Ideally the planes would overlap completely so the result would be approximately 0 degrees. This is closely achieved in the case of the "Mastoid process - *Nasal peak – Back pole of Rostrum"* lines (the differences are mostly 0.5-1.5°), as the students were able to mark these points with highest confidence.

The volunteers achieved similar results, but there was a greater variance between their measurements for the semicircular canals (SD ~ 4-6°) for all cases. For the centroid line (*Nasal peak – Back pole of rostrum – Inion*), the difference was large for patients aged 4 to 27 years, 10-15° difference was measured. The reason of this large inaccurate results may be, that this line also contains the inion, which was the most problematic point in the measurements.

IV.2. Correlations of electrode insertion alignment

Using the method developed by us, we determined the correct angle (mean: 45,0°±11° SD), from the measurement data of 80 different patients using our custom-made python scripted 3D Slicer module. The results obtained by the program were checked by manual counting in the first few cases. The mean age of our cohort was 22.7 years± SD 24.8 years. In this study, the ratio of female to male patients was nearly 1:1. The youngest patient in our study was 12 months old. For the statistical analysis we used the free-to-download R statistical package (R version 3.6.3, IDE: R Studio, platform: Windows 10).

IV.2.1. Correlation with sex

Previous studies have raised the possibility of the differences of the cochlea anatomy between females and males. Before a two-sample t-test, it is necessary to check the equality of the variance. The p-value of the variance test was 0.135 on the left side and 0.084 on the right side ($\alpha=0.01$). The equality of variance was accepted due to the $p>\alpha$ on both sides. Then a two-sample t-test was performed which included the angle and the sex of the patient ($\alpha=0.01$). The p-value on the left side was 0.124 and on the right side it was 0.115. The p-values were higher than 0.01, therefore the sex of the patient had no statistically significant effect on the size of the angle.

IV.2.2. Correlation with age

We examined, whether the age of the patient has any effect on the calculated angles. Since age is a discrete variable, a one-way Anova test was used. The p-value on the left side was 0.712 and on the right side it was 0.160. Because the p-values were higher than 0.05, age has no statistically significant effect on the size of the angle.

IV.2.3. Correlation with measured side

Finally, we examined whether there are any linear connections between the measurements on the left and right sides. For this a Pearson's correlation test was used. This correlation test requires a normal distribution of the data set. To check this requirement, we performed a Shapiro-Wilk test ($\alpha=0.05$).The p-value was 0.187 on left side and 0.133 on the right side. Because the p-values were higher than 0.05, it was accepted that the angles the follow normal distribution on both sides. The Pearson's correlation coefficient was 0.513.

A significance test was performed for this correlation coefficient. The Student's t-distribution value was 5.271 and $t_{78,\ 0.05} = 1.99$ (df=78, $\alpha=0.05$, p= 1.172e-06). Because $|t| > t_{78,\ 0.05}$ and $p<\alpha$ the correlation coefficient is significantly different from zero, so there is a very weak positive linear correlation between the measured side and the size of the angle.

IV.2.4. Electrode insertion angle in known tip fold-over patients

The insertion angles of the EA were compared in our 80 patients and to five TFO cases that occurred in our clinic. We determined also the insertion angle (44.9°, 46.9°, 34.2°, 54.3° and 55.9°) of these patients using their preoperative CT scan. The insertion angle was then compared to cases where a TFO occurred to the measured average angle. Although angles of two patients are very close to the mean value, the other three patient's results are close to the endpoint of SD range.

IV.3. Imaging during cochlear implantation surgery

The process of electrode array insertion into the cochlea was monitored by a C-arm DSA device on both sides, using it in fluoroscopic mode. After implantation of the second implant, a cone beam CT scan was taken with the same C-arm DSA device. No complications were detected by video fluoroscopy and cone beam CT scan. During the first programming of the external speech processors for the implant, which was performed four weeks after surgery, the child had a clear auditory experience. The child listened with interest to the electrical signals perceived as sound on both sides of each electrode.

V. DISCUSSION

V.1. Human error factor

Measurement accuracy is one of the cornerstones of our research, so we observed the accuracy of the anatomical structures identification on the provided CT scans by medical students. We used anatomical points that are relevant to the field of otolaryngology. To simulate the changing anatomy with increasing age, the students performed measurements on CT scans of 3 patients of different ages. Overall, we found that age was not a determinant factor in the recognition and assignment of the landmarks. We found that there was no significant positive change (0.1-0.2 mm) in the accuracy of the measurements between the 3 measurement sessions. The accuracy may be potentially improved if measurements are taken more than 3 sessions or after a more detailed training.

V.2. Definition of the correct insertion angle

The next stage of the research was to investigate the average correct orientation of the CI electrode array's OM relative to anatomical landmarks. For this, we developed a new, custom python scripted module into 3D Slicer, and we made the measurements on 80 cochlear implanted patients' preoperative CT scans. We carried out statistical analysis on the results, and this indicated that the correct alignment of the OM in a successful CI insertion is approximately 45.0°±11° SD. We investigated also the impact of the age and the sex of the patients on the correct insertion angle, and the statistical results did not show any connection between them. However, there was a weak positive linear correlation observed between the measurements on the left and right sides.

The angles were calculated with the electrode arrayinside the insertion tool. In this position the insertion tool prevents the electrode array from moving away. Once the electrode is inserted into the cochlear duct and the insertion tool is removed, the electrode reaches a more "comfortable" position, which is not equivalent to the position it takes with the insertion guide. Therefore, we did not perform the measurements on the postoperative scans because the resulting angle would not be authoritative.

V.2.1. Calculation of the insertion angle

Our study measures the correct orientation of the Slim Modiolar electrode's OM, but the method can be adopted to other half-band electrodes e.g. the Cochlear™ Ltd.'s Nucleus® Slim Straight and Contour Advance. In case of half-banded electrodes, the position of the OM related to the position of the modiolus is to be considered and the calculated angle is to be corrected accordingly (e.g. 180° should be added if the marker or guide wire is to be positioned caudally). For the other type, the so-called full-band electrodes do not require such measurements, because this electrode design allows their insertion in any orientation angle (e.g. MED-EL®: FORM® Series, CLASSIC® Series). Based on our experience, other contributing factors are likely to include: i) too fast or forced insertion of the very delicate electrode array, ii) incomplete loading of the array with the tip remaining and curving already outside the IG, iii) incorrect loading of the electrode array which causes the array to stuck in the slot of the IG, iv) incorrect insertion trajectory vector for example if the array is directed too much towards the medial or lateral wall of the cochlea which also may cause bending of the IG. In this situation the deformed IG's slot may expand which results in electrode array insertional failure. It is assumed that incorrect insertion trajectory can also be caused by a narrow or insufficiently extended RW or the presence of a *crista fenestra cochleae*.

V.2.2. Insertion angle in tip fold-over cases

Until recently, TFO of the electrode array was only a small probability (~0,80%) seen in lateral wall electrodes. However, with the new generation of the CI, thin perimodiolar electrode model, TFO can occur in ~4.7% of cochlear implanted cases.

In this study we calculated that the average angle of the orientation marker to the ISP in successful implantations is approximately 45.0° ± 11° SD which was verified with a confidence interval of 98%. We determined also the insertion angle on five known TFO case's preoperative CT scans, and we foundm that only some of the angles fell outside the average range, which suggests that the TFO was caused by other factors (too fast insertion, improperly loaded electrode, forced insertion) not the orientation of the marker, for which our method was designed. Although the values suggested that the further the diversion from 45.0°±SD, the increased chance of TFO.

V.3. Monitoring the electrode insertion

Our method presented here, real-time tracking of the electrode array's within the cochlear duct is possible. The membranous labyrinth that contains the functional system of the cochlea is surrounded by compact bone, for which the array cannot be visualized inside the cochlea with the operating microscope. Therefore, the abnormal position of the array is not detected by the operating surgeon. Real-time imaging, enables immediate detection of the electrode array if it leaves the vicinity of the modiolus, turns back, or enters the balance organ.

In our case with type III cochlear hypoplasia, the basal turn was of average size and shape. In cochlear hypoplasia malformation, implantation of a short straight electrode array is recommended. Nevertheless, we chose a thin, pre-curved electrode because we considered it important for the speech development of our 1-year-old patient to position the electrode array closer to the modiolus and to minimize trauma to the cochlear structure.

VI. CONCLUSIONS

VI.1. Examination of human error factor

The investigation concluded that volunteers can reliably recognize point-like structures such as the mastoid process and the back pole of the rostrum. We noticed small differences between the students inside of inion, but the 3D model processing caused big inaccuracy. The largest deviations were found in the semicircular canals, which can be explained by the fact that very small volumes had to be marked and in such dimensions an error of up to 1 mm can cause large deviations and that one or two students did not select the canals correctly. The results showed that this type of work should only be given over to students and young professionals under the supervision of an experienced professional. With our research, we hope to have been able to help research groups who do image processing work with students.

VI.2. Finding the optimal insertion orientation of CI electrode array

Due to the differences in the individual anatomy, this ~45.0° ± 11° SD angle range is not suitable for all cases. Although there is a weak positive correlation between the angles of the left and the right side, it is necessary to take measurements bilaterally if both sides are to be implanted. Our results can serve as valuable additional information for the surgeon in planning and performing the implantation procedure. During electrode array insertion, the plane of the basal turn of the cochlea is not visible. The 3D models and this calculated angle provide deeper knowledge of the individual anatomy pre-operatively. Before the insertion of the electrode array into the RW, the surgeon can align the OM towards the ISP using the patients' preoperative calculated angle. This angle considers the individual anatomy of the patient, thus by using it the surgeon does not have to rely exclusively on intuition of the cochlear basal turn during EA's alignment. Furthermore, consideration of cochlear anatomy during electrode array orientation potentially reduces complications such as TFO and interscalar dislocation.

VI.3. CI implantation in a hybrid operating room

We recommend the introduction of intraoperative imaging for cochlear implantation centres to ensure well-controlled, minimally invasive procedures. We expect new innovations from the developers of C-arm X-ray fluoroscopy equipment in the routine, easy use of the devices, even in the specific field of head and neck surgery. Intraoperative imaging replaces routine radiographic examination in multiple views on the first postoperative day, which may be of limited value in age-related non-cooperation due to motion artefacts and may require repeated imaging. By using these C-arms CT devices in a protocol-based manner, correction can be performed in one sitting due to an abnormally positioned electrode array, consequently avoiding the need for a post-operative radiographic examination and avoiding revision with additional anaesthesia and surgical stress.