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A New Intraoperative Method for Controlling Electrode Placement in Cochlear Implant Surgeries: Nucleus® SmartNav System and Preliminary Results

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ABSTRACT

Objective: This study aimed to evaluate electrode placement in the cochlea by analyzing data from the Nucleus® SmartNav system.

Methods: Cochlear implant (CI) surgery was retrospectively reviewed. The participants including the use of CI522 Slim Straight electrodes with anatomically normal inner ear structures were selected. Intra-operative (Intra-op) and post-operative direct graphy (X-ray imaging) results were compared to assess electrode placement in the cochlea.

Results: A total of 15 ears (4 bilateral, 7 unilateral) were evaluated. The average age of the pediatric group was 38 months (6 participants), and the average age of the adult group was 39.8 years. Intra-op SmartNav measurements obtained an average angular insertion depth of 413. 86±70.9 degrees (254-480°), a mean insertion time of 89.6s±47.05 (40-173s), and an average insertion speed of 0.65±0.54 mm/s (0.1-1.17 mm/s). In the initial placement check performed with the SmartNav system, the electrodes were placed in the appropriate position in 14 cases, and only one case had a tip fold-over (TFO). The electrode was reinserted, and a second check using the SmartNav system confirmed that TFO was not present. The SmartNav system demonstrated 100% sensitivity in determining the placement of the CI522 Slim Straight electrodes in all cases compared with direct X-ray results.

Conclusion: In cases with anatomically normal inner ear structures, the SmartNav system was determined to be an effective and reliable method for Intra-op assessment of CI electrode placement, thereby reducing the need for additional Intra-op radiological imaging.

Keywords: Hearing Loss, cochlear implant, electrode placement, SmartNav system, X-ray

INTRODUCTION

Hearing, a fundamental component of communication, can be impaired by congenital or acquired causes, and permanent hearing loss of varying degrees can occur. In severe to profound hearing loss, hearing aids are insufficient for hearing restoration, and a cochlear implant (CI) may be the only option (1,2).

CI is an electronic device designed to convert mechanical sound energy into electrical signals that are transmitted directly to the cochlea, thereby providing hearing by stimulating the auditory nerve. The device consists of an internal component (electrode array) surgically implanted into the cochlea and an external component that is activated in the post-operative (post-op) period. The CI process consists of three periods: Pre-operative period, in which it is determined whether the individual with hearing loss is a suitable candidate; ıntra-operative (Intra-op) period, in which the electrodes are placed in the cochlea by microsurgical methods by otologists specialized in CI during general anesthesia; and post-op period, in which the placed electrodes are activated by experienced audiologists (3). Additionally, the post-operation period involves CI mapping (programing) at regular intervals and auditory rehabilitation sessions. Considering all these stages, the success of a CI and the patient's benefit largely depend on the placement of the electrodes during the Intra-op period.

A misplaced electrode array during surgery may not provide the desired level of benefit in hearing and receptive speech development related and may lead to side effects, such as vertigo and facial twitching, due to electrical stimulation of the

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wrong area (4). To prevent inappropriate electrode placement, some measurements are made by audiologists during the intra-op period (3). These tests can give an idea about the placement, but in cases in which a clear decision cannot be reached, the placement and position of the electrode array is tried to be determined with fluoroscopy, X-ray, or computerized tomography (CT) during surgery. Among these, X-ray is the most commonly used. If an issue with electrode placement is identified during these evaluations, the electrodes can be removed from the cochlea, repositioned, or replaced before completing the surgical procedure. However, the mentioned portable imaging methods may not always be available in clinics or operating rooms. Even if they are available, it might affect the waiting times, prolong surgery time, increase workload, and increase radiation exposure for both patients and staff. In cases where intra-op imaging is not performed due to the above-mentioned or different reasons, post-op imaging may reveal issues that necessitate revision or reimplantation surgeries. In addition, in some cases, tip fold-over (TFO) in the electrode array may not be determined during surgery. TFO is very important because it negatively affects low-frequency hearing, causes trauma to the cochlea, and causes an inflammatory response, which can disrupt the function of the implant throughout the entire cochlea, thus negatively affecting the functionality of the implanted device (5,6).

There is a need for new methods that can reduce the need for radiological evaluation during CI surgery and that can be an addition or alternative to traditional audiological tests. The SmartNav system is a new measurement method that is designed to verify the appropriate placement of the electrode array in the cochlea, thanks to the sound processor placed wirelessly inside the ear during surgery. In addition to traditional measurements (e.g., impedance testing, stapedius reflex testing, and electrically evoked compound action potentials), SmartNav reportedly assesses the angular insertion depth, insertion speed, and consistency of insertion speed during electrode placement (7). It has also been claimed that it determines whether there is a TFO by performing a placement check test after electrode placement is completed (5).

The present study aimed to examine intra-op SmartNav system data and post-op direct X-ray results to evaluate the location and position of electrodes placed in an anatomically normal cochlea during CI surgeries.

METHODS

In this study KTO-Karatay University Rectorate Dean of the Faculty of Medicine Non-Drug and Non-Medical Device Research Ethics Committee Presidency (approval no: 2024/034, date: 26.09.2024), the CI surgeries performed at the ENT department of our tertiary care hospital were retrospectively examined. Cases with anatomically normal inner ear structures and in which Cochlear® CI522 Slim Straight electrodes were placed during surgery were identified through file scanning. Among these cases, a tablet-based mobile Nucleus® SmartNav system, which included new Intra-op measurements and was left to our clinic by the same company for trial purposes, was used. With this system, the angular insertion depth, placement time, and speed of insertion during the placement of the electrodes, and whether TFO occurred after the electrode placement was completed were evaluated. In order to provide information about the placement of CI electrodes in the inner ear, the post-op first-day X-ray results, which are a part of the routine process in our clinic, were compared with the SmartNav results.

Cases in which electrodes other than the CI522 electrode model were used, cases in which the SmartNav system was not used intraoperatively, or cases in which post-op X-ray was not used were excluded from the study. 15 ears that underwent CI surgery within the scope of the specified criteria were included in the study.

In our descriptive study, Microsoft Excel was used to evaluate the data obtained. For summary statistics, categorical variables (gender, etc.) were presented as frequency and percentage values, and quantitative variables (angular insertion depth, insertion of speed, insertion time) were presented as mean ± SD (minimum-maximum) values.

RESULTS

In the present study, a total of 15 operated ears were evaluated: Four bilateral (8 ears) and seven unilateral (7 ears). The mean age of the 6 individuals in the pediatric group was 38 months, and the mean age of the adults was 39.8 years. 54.5% of the participants were female (6 individuals), and 45. 5% were male (5 individuals). According to CT reports, all of the operated ears, 8 on the right and 7 on the left, had normal inner ear structures, and CI522 Slim Straight electrodes were used during the operation in all ears. According to Intra-op measurements made with SmartNav, the average angular insertion depth of the electrodes in 15 ears was 413.86°±70.9 (254-480), and the total insertion time was 89.6±47.05s (40-173), and the average insertion speed was 0.65±0.54 mm/s (0.1-1.17). In the first placement check test, it was determined that the electrode arrays were properly placed in 14 cases, and only in one case (no: 7) did TFO occur between the 22nd and 19th electrodes (located in the apical part of the cochlea). In the ear where TFO was determined, the impedance values of all electrodes were within normal limits (6-9 kΩ). In addition, neural response telemetry (AutoNRT) data were obtained from only 2 of the 22 intra-cochlear electrodes (E2 and E3, these electrodes locate in the most basal part of the cochlea).

In this case, the surgeon removed the electrodes and re-inserted them. Then, in the second placement check performed with the SmartNav system, it was confirmed that there was no TFO and that the electrode array was properly placed. In this case, the appropriate position of the electrodes was confirmed by post-op CT. The images obtained in the Intra-op SmartNav system placement check test of the case are shown in Figure 1 A.

In our study, each case was evaluated with X-ray at the first post-op day, and according to these results, the electrodes were properly

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in the cochlea in all cases (Table 1). When the Intra-op SmartNav measurements and post-op X-ray results were compared one-to-one for each case, the SmartNav system showed 100% sensitivity in correctly determining the electrode array placement in 15 completed CI cases.

DISCUSSION

In the current study, we retrospectively examined CI surgeries and compared intraoperative SmartNav measurements with post-operative X-ray results. In our clinic, the SmartNav system detected TFO in one of the 15 ears and confirmed proper electrode placement in the other 14 ears. In the ear with TFO, the electrode array was removed and reinserted into the cochlea during surgery, and the absence of TFO was confirmed using the SmartNav system during surgery. Post-op traditional X-ray imaging showed no issue in the placement of electrode arrays in all ears. In the ear where SmartNav identified TFO, impedance values for all electrodes were within the normal range (6-9 kΩ). AutoNRT responses were obtained only from two electrodes located in the cochlea's most basal region (E2 and E3). Routine measurements such as impedance and NRT may fail to detect electrode TFO during surgery (5). Studies have demonstrated the inadequacy of these measurements in identifying TFO and determining which electrodes are affected (8,9). Intra-op imaging methods such as X-ray, CT, and fluoroscopy are commonly used to detect electrode TFO. X-ray is preferred due to its quick procedure and minimal radiation exposure. In our routine clinical practice, X-ray radiography is typically used to assess the TFO, followed by electrode removal and reinsertion based on radiological results. Radiologic imaging and traditional telemetry measurements will then be performed to ensure the correct placement of the electrode array. On the other hand, we were able to detect and visually confirm the absence of TFO using the SmartNav system within a short time after reinsertion in our case (Figure 1 B). This method verified that the electrode array was properly placed in the cochlea without the need for imaging modalities that have the potential to significantly extend operating room time and without exposure to radiation. The SmartNav system determines the TFO by using the transimpedance matrix (TIM) algorithm (10). During the TIM measurements, electrode voltage telemetry is used to analyze the Intra-op status of the electrode array. This technology measures the electrical current between the intracochlear and extracochlear electrodes and the voltage of the intracochlear electrodes to determine the position of the electrodes. These repeated measurements generate a TIM that can detect potential misplacement or TFO. These studies validated the TIM algorithm as an effective screening tool for identifying electrode TFO (10,11).

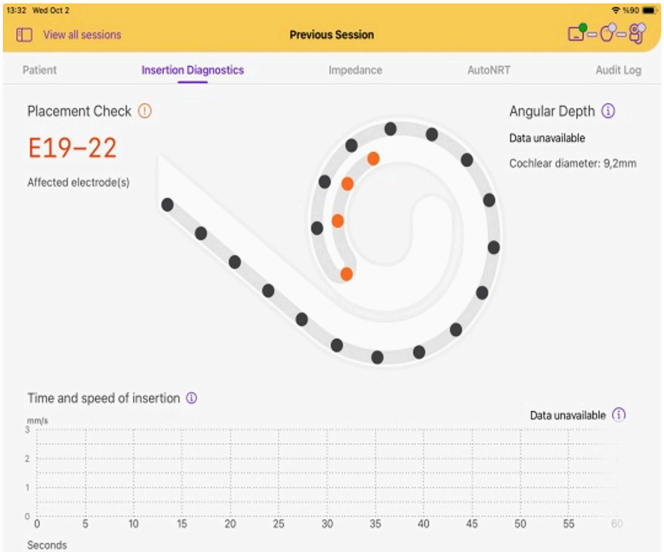

Figure 1 A. Initial placement placement check showing tip fold-over in the electrode array (involving electrodes 22, 21, 20, and 19)

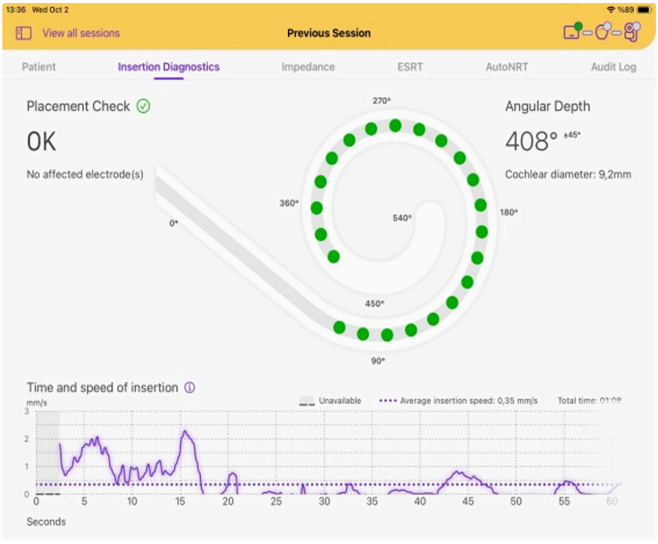

Figure 1 B: Second placement check showing all electrodes properly positioned

In a study involving different model electrodes (Slim Modiolar/CI632, Slim Straight/CI622, Contour Advance/CI612), it was reported that the Intra-op X-ray and SmartNav system correctly detected appropriate electrode placement in 47 ears and TFO in 3 ears, and the SmartNav system provided guidance in the placement of the electrode array in CI surgeries. In addition, the SmartNav system was reported to provide guidance in repositioning electrode arrays during CI surgeries (5). Kelsall et al. (12) reported that 113 out of 116 ears with slim modiolar electrodes (CI632) had proper electrode placement with Intra-op fluoroscopy and 107 with SmartNav, and 2 ears had TFO detected in the electrode array with both imaging and SmartNav, and the electrodes were then successfully repositioned. The researchers also reported that in one case, SmartNav placement could not be performed due to inconsistency in the radio frequency (RF) connection. They detected TFO only via imaging during surgery, and in a total of 4 cases, they could not perform a placement check test with SmartNav due to RF interruption (12). All SmartNav

Table 1. Demographic characteristics and clinical results

Case no	Gender	Age	Operation side	Ear	Electrode type	Cochlear anatomy	SmartNav angular depth (°)	SmartNav total insertion time (s)	SmartNav average speed of insertion (mm/s)	SmartNav Intra-op placement check-1	SmartNav Intra-op placement check-2	Post-op X-ray report
1	F	39 years	Unilateral	Right	CI522	Normal	447°	88	0.36	Normal	-	Normal and full insertion
2	F	1 year 4 m	Bilateral	Left	CI522	Normal	437°	70	2.2	Normal	-	Normal and full insertion
3	F	1 year 4 m	Bilateral	Right	CI522	Normal	451°	170	0.14	Normal	-	Normal and full insertion
4	M	20 years	Unilateral	Left	CI522	Normal	415°	67	0.61	Normal	-	Normal and full insertion
5	M	6 years 2 m	Bilateral	Left	CI522	Normal	254°	108	0.92	Normal	-	Normal and full insertion
6	M	6 years 2 m	Bilateral	Right	CI522	Normal	362°	58	0.44	Normal	-	Normal and full insertion
7	F	35 years	Unilateral	Right	CI522	Normal	408°	68	0.35	E22-E19 Tip fold-over	Normal	Normal and full insertion
8	M	1 year 2 m	Bilateral	Left	CI522	Normal	474°	68	0.5	Normal	-	Normal and full insertion
9	M	1 year 2 months	Bilateral	Right	CI522	Normal	476°	163	0.69	Normal	-	Normal and full insertion
10	M	4 years 6 m	Unilateral	Right	CI522	Normal	386°	62	0.1	Normal	-	Normal and full insertion
11	F	70 years	Unilateral	Right	CI522	Normal	400°	47	1.12	Normal	-	Normal and full insertion
12	M	4 years 4 m	Unilateral	Left	CI522	Normal	274°	128	0.44	Normal	-	Normal and full insertion
13	F	35 years	Unilateral	Left	CI522	Normal	480°	173	0.12	Normal	-	Normal and full insertion
14	F	1 year 6 months	Bilateral	Left	CI522	Normal	468°	40	1.17	Normal	-	Normal and full insertion
15	F	1 year 6 months	Bilateral	Right	CI522	Normal	476°	40	0.69	Normal	-	Normal and full insertion

CI: cochlear implant, M: male, F: female, s: seconds, °: degrees, mm/s: millimeters per second, m: month, E: electrode

tests were completed without any problems in 14 ears at our clinic. However, measurements were performed by manually applying light pressure to the sound processor to compensate for an inconsistent RF connection that we thought was related to the thickness of the scalp in a very overweight adult patient (the skin flap over the temporo-parietal area could not be measured). A stable RF connection is required to complete the tests in the SmartNav system, and the thickness of the scalp has been noted as a parameter that should be considered, especially in adults.

Atraumatic insertion of the electrode array via the round window into the cochlea can preserve residual hearing and improve auditory performance (13). Factors such as surgical approach, electrode model, steroid use, and insertion speed contribute to atraumatic insertion (14-17). The insertion speed directly affects the inner ear structures; faster speeds are associated with increased force and potential damage (18,19). To minimize risks such as membrane rupture, scalar translocation, and TFO, slower insertion speeds are recommended. Although no standard method exists for evaluating insertion speed during routine surgeries, experimental and robot-assisted insertions have enabled these measurements (17). The SmartNav system estimates insertion speed in real-time, providing graphical feedback during the insertion. The average speed and total time are displayed at the end of the insertion. This real-time feedback on insertion speed allows the surgeon to adjust the electrode insertion speed instantly while also providing a training effect that enhances surgical skills through repetition (20). In our study, the average insertion speed was 0.65 mm/s (range: 0.1-1.17 mm/s), which is consistent with the results of Concheri et al. (20), who reported an average insertion speed of 0.64 mm/s (range: 0.23-1.24 mm/s) in 65 implanted ears with CI632 electrodes. Interestingly, researchers reported that no correlation was found between electrode placement speed and

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pure tone audiometry results or word recognition scores with CI. Due to the limited number of our cases, the relationship between electrode placement speed and hearing thresholds with CI could not be evaluated. However, we believe that it would be useful to investigate the possible effect of electrode placement speed on hearing thresholds in future studies. Another important parameter is the angular insertion depth of the electrode array, both in terms of protecting the inner ear structures (21) and in terms of providing an idea about possible translocations of the electrodes between scales (22). The only real-time method to observe the angular insertion depth is Intra-op fluoroscopy. Considering the disadvantages of fluoroscopy, such as prolonged surgery time and radiation, SmartNav can be an alternative treatment. The SmartNav system angularly evaluates the Intra-op electrode insertion depth and provides real-time visual and auditory feedback (7,23). In our study, the average angular insertion depth was 413. 86° (range: 274-480°) for 15 ears. Cooper et al. (5) reported a mean depth of 307.45° (standard deviation 36.42°) in 50 ears, including nine with inner ear anomalies. Our study included only individuals with anatomically normal inner ear structures. The difference in inner ear structures may have caused the angular insertion depth measured during surgery to differ.

TFO, which affects low-frequency hearing by folding in the apical region, can impair the implant's function across the cochlea due to associated trauma (9). Therefore, detecting TFO during surgery is critical to avoiding repeat surgeries, additional anesthesia, and adverse auditory outcomes. Our results indicate that Intra-op SmartNav findings demonstrated 100% sensitivity in accurately determining the placement of the CI522 Slim Straight electrode array within the cochlea compared with post-op X-ray imaging results.

This clinical study demonstrated that the SmartNav system is an effective and reliable method for Intra-op electrode placement checks in an anatomically normal cochlea, thereby reducing the need for radiologic imaging. However, further research is needed to evaluate its efficacy and reliability in CI surgeries involving patients with inner ear anomalies.

CONCLUSION

This clinical study demonstrated that the SmartNav system is an effective and reliable method for Intra-op electrode placement checks in an anatomically normal cochlea, thereby reducing the need for radiologic imaging. However, further research is needed to evaluate its efficacy and reliability in CI surgeries involving patients with inner ear anomalies.

Ethics

Ethics Committee Approval: In this study KTO-Karatay University Rectorate Dean of the Faculty of Medicine Non-Drug and Non-Medical Device Research Ethics Committee Presidency (approval no: 2024/034, date: 26.09.2024)

Informed Consent: Retrospective study.

Footnotes

Author Contributions: Surgical and Medical Practices - S.A.İ.; E.K.; Concept - A.K.; M.B.U.; S.A.İ.; E.K.; Design - A.K.; M.B.U.; S.A.İ.; E.K.; Data Collection and/or Processing - A.K.; M.B.U.; S.A.İ.; E.K.; Analysis and/or Interpretation - A.K.; M.B.U.; Literature Search - A.K.; M.B.U.; Writing - A.K.; M.B.U.

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