Journal of Current Research in Otolaryngology
ISSN: 3065-6974
Academic Strive
Researcher's perception is our reality

Research Article
Volume 6 Issue 1

Evaluation of Navigation System Accuracy in Cochlear Implant Surgery

Farhad F[1], Noushin B[1], Elnaz S[1], Erfan A[2] and Seyede FE[3]*

[1]Department of Otorhinolaryngology, Hamadan University of Medical Sciences, Iran

[2]Social Determinants of Health Research Center, Hamadan University of Medical Sciences, Iran

[3]Department of Audiology, Hamadan University of Medical Sciences, Iran

***Corresponding author:** Seyede Faranak Emami, Ph.D., Associate Professor, Department of Audiology, School of Rehabilitation Sciences, Hearing Disorder Research Center, Hamadan University of Medical Sciences, Hamadan, Iran, Tel: 989188118476; Email: faranak_imami@yahoo.com

Received Date: December 19, 2024; **Published Date:** January 03, 2025

Abstract

Failure to correctly identify the anatomical landmarks of cochlear implantation (CI) challenges surgical success in conventional cochlear implantat surgery (CCIS). It seems that the use of the navigation system (NS) in CI can reduce the damage to the cochlear structures, also be effective in finding the correct location of the round window, especially in cases of anatomical differences, repeated surgeries and congenital defects. This study was aimed to determine evaluation of NS accuracy in cochlear implant surgery (CIS). In this cross-sectional survey, 20 patients who were candidates for CCIS and another 20 using the NS method were examined. First, mastoidectomy was performed, and then the correct location of CI was determined by CCIS and NS. Finally, the distance deviations of two methods were recorded. The mean (standard deviation) and minimum anatomical distance difference of CCIS and NS for the following locations were as follows: Facial nerve in the facial recess= 3.42±1.14 mm and 1.8 mm; Horizontal semi-circular canal= 2.90±1.02 mm and 1.10 mm; Pyramidal process = 3.16±1.55 mm and 1.40; mm; Round window membrane= 3.28±1.76 mm and 1.2 mm; CI location= 3.9±1.38 mm and 1.13 mm. Also, the difference in the mean duration of surgery by CCIS (73.50±20.72) mm and NS (96.25±14.59) mm was significant (P=0.001). The deviation distance for CCIS and NS was more than the expected value (1 mm), which seems that NS did not have enough accuracy to detect the anatomical landmarks of CIS.

Keywords: Cochlear Implantation; Cochlear Implant Surgery; Navigation System

Abbreviations

CI: Cochlear Implantation; CIS: Cochlear Implant Surgery; CCIS: Conventional Cochlear Implant Surgery; NS: Navigation System.

Introduction

Today, CI is increasingly used to treat severe to profound sensor neural hearing loss and is considered one of the most successful methods of hearing restoration. CI consists of two parts, the external, which processes speech and converts sound into an electrical signal. The internal, which is implanted during surgery and is considered the receptor part that obtains the electrical signals and transmits them to the cochlear nerve [1]. The surgeon faces many concerns during CIS, not only spending a lot of time to complete the mastoidectomy, but also taking care of the structures of the temporal bone, such as facial and chorda tympanic nerves, bony chain, sigmoid sinus, and etc. Consequently, a surgical method that is less invasive is more suitable for CI [2].

In recent years, minimally invasive tunnels have been designed; those are slightly larger in diameter than the CI electrode and are guided through the mastoid to the cochlea. Their micro stereoscopic frame and robotic arm are used to drill holes in a correct linear path [3-5]. The frame is anchored around the temporal bone and not only secures the drills during puncturing, but also aligns the surface markers for registration with an accuracy of 0.38 mm [6]. Currently, the micro stereoscopic frame system has not only gained extensive validation in vitro experiments, but is also applied to clinical patients [7]. In this regard, mastoid bone and air cells are carefully punctured to provide clear access to anatomical landmarks and reduce the possibility of damage to important structures such as facial nerve and chorda tympani. Then reveal the fascial recess, which is a space containing the facial nerve on the inner side, the chorda tympani nerve on the lateral side, and the cavity on the upper side, the electrode is implanted through the round window [8].

Despite the transparency of the surgical procedure, there is still a possibility of damage to related structures, including the facial nerve, and if the correct anatomy is not recognized, the possibility of cerebrospinal fluid leakage is also raised [9]. Lack of correct diagnosis of landmarks and the place of cochlear implantation challenges the success of surgery. This possibility increases in revision surgeries or in patients with congenital ear abnormalities [10,11].

Radiological imaging plays an important role in pre-surgical evaluations in all types of ear surgeries. The integration of imaging and surgical field can provide a technology that allows creating a proper view, anatomical assessment and choosing the right approach before-during surgery. This technology is known as computer assisted or image guided surgery or NS. It has been widely used for sinus and skull base surgeries and use in areas with complex anatomy that require high precision, including in other areas of the head and neck [12-14].

The use of this method in orthopedic, sinonasal, skull base and spinal surgeries is well known. But there is limited information about ear surgeries [15]. It seems that the use of NS in CIS can help to reduce the damage to related structures and also facilitate finding the correct location of round window and cochleostomy. Therefore, this study was aimed to determine evaluation of navigation system accuracy in CIS.

Methods

This survey was a cross-sectional pilot study, its sample size included 40 patients, who were candidates for CI in the otolaryngology department of university of medical sciences in 2023. The data collection tool included a checklist of information regarding patients' age, sex, implanted ear and other study data. Inclusion criteria were all candidate CCIS patients who underwent surgery from the beginning to the end of 2023. Exclusion criteria were CI revision surgeries and any underlying complications that did not allow long-term anesthesia.

Procedure

Before the surgery, written consent was obtained from the patients. Basic information including age, gender and ear of the candidate for CI were recorded in the questionnaires. For each patient, a CT scan was performed with the NS protocol and a resolution of 0.6 to a maximum of 1 mm. The surgery of the patients was performed under general anesthesia, the surgeon's view was microscopic, and a radiology operator was also responsible for the evaluation with the NS system (Compo plus). Every day, two CIS were performed, and due to the sterilization conditions, only one of them was examined with the NS. The time of surgery was recorded from the time of surgical incision to the end. The same time was also recorded for patients who were evaluated without NS at the same time.

After cutting behind the ear, performing mastoidectomy and piercing the prosthesis site, anatomical landmarks including the dome of the Semicircular horizontal canal, the location of the facial nerve in the Fascial recess, the Pyramidal process, the Round window membrane and the approximate location of the CI were determined by CCIS and NS. The deviation distances were measured by these two methods. Before the end of the operation, the correctness of the electrode placement and its function were confirmed by the audiologist present in the operating room.

Data Analysis

Quantitative information was reported numerically (percentage) and qualitative information was reported through mean (standard deviation), Mann-Whitney, Chi-square and Fisher non-parametric tests. SPSS26 was used for data analysis and Value less than 0.05 was considered significant.

Limitations

The possibility of not having access to NS during surgery was one of the limitations, which was resolved with the necessary arrangements.

Ethical Considerations

Non-participation in the study did not prevent the treatment of patients. No additional financial costs were imposed on the study participants and their names and details were kept confidential.

Results

Demographic characteristics of patients such as age, gender, cochlear implanted ear were obtained (Table 1).

Variable	Evaluation method of cochleostomy site		Pvalue
	CCIS	NS	
Age	Mean±SD	Mean±SD	
Year	9.72 ± 13.37	11.30 ± 16.34	*0.678
Gender	Number (Percentage)	Number (Percentage)	
Man	5 (0.25)	15 (0.75)	**0.002
Woman	15 (0.75)	5 (0.25)	
Total	20 (100)	20 (100)	
Ear	Number (Percentage)	Number (Percentage)	
Right	14 (0.70)	19 (0.95)	***0.091
Left	6 (0.30)	1 (0.5)	
Total	20 (100)	20 (100)	

Table 1: Demographic characteristics of the patients of this research based on conventional cochlear implant surgery (CCIS) and Navigation system (NS).

The findings showed that there were no significant difference between NS and CCIS groups in terms of age (Pv = 0.678) and cochlear implanted ear (Pv = 0.091), but gender showed a significant difference (Pv = 0.002), which was due to the asymmetric distribution of women and men in two groups. There was no significant difference between the two groups in terms of prosthesis type and CI location (Table 2).

Variable	Evaluation method of cochleostomy site		P.value*
Type of prosthesis	CCIS Number (percentage)	NS Number (percentage)	
Nucleus	9 (0.45)	11 (0.55)	0.701
Advance	7 (0.35)	4 (0.20)	
Medel	4 (0.20)	5 (0.25)	
Total	20 (100)	20 (100)	
CI location			
Round window	19 (0.95)	19 (0.95)	0.999
Cochleostomy	1 (0.5)	1 (0.5)	
Total	20 (100)	20 (100)	

Table 2: Prosthesis type and cochlear implant (CI) site of patients based on conventional cochlear implant surgery (CCIS) and navigation system (NS).

The mean and standard deviation of cochlear implant surgery time in the NS and CCIS groups were 96.25 ± 14.59 mm and 73.50 ± 20.72 mm, respectively (Figure 1).

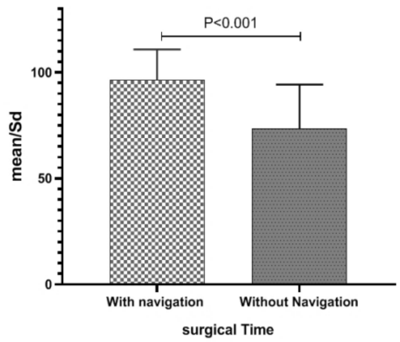

Figure 1: Mean and standard deviation of cochlear implant surgery time based on conventional cochlear implant surgery (CCIS) and navigation system (NS).

Also, the mean time of CI surgery by NS method was significantly longer than CCIS (PV = 0.001). The mean ± standard deviation and the minimum difference of the anatomical landmarks determined by CCIS and NS were as follows: Fascial nerve in the fascial recess = 3.42 ± 1.14 mm and 1.8 mm, Horizontal semi-circular canal = 2.90 ± 1.20 mm and 1.10 mm, Pyramidal process = 3.16 ± 1.55 mm and 1.40 mm, Round window membrane = 3.28 ± 1.76 mm and 1.20 mm and CI location= 3.9 ± 1.38 mm and 1.13 mm (Table 3).

Deviation distance	Mean	Standard deviation	Minimum
Fascial nerve in the fascial recess	3.42	1.14	1.8
Horizontal semicircular canal	2.9	1.2	1.1
Pyramidal process	3.16	1.55	1.4
Round window membrane	3.28	1.76	1.2
CI location	3.9	1.38	1.13

Table 3: Mean and standard deviation of navigation system deviation distance (NS) and conventional cochlear implant surgery (CCIS).

With the passage of time from the beginning of the study to the end, the deviation distance of NS and CCIS decreased, but the differences were not statistically significant, while, the reduction of CCIS surgery time or duration of surgery was significant (Pv = 0.049), which indicated the increase of the surgeon's skill over time (Table 4).

Variable	R	P.value*
Duration of CCIS time	-0.127	0.049
Fascial nerve in the Fascial recess	0.318	0.172
Horizontal semicircular canal	0.196	0.408
Pyramidal process	-0.251	0.286
Round window membrane	-0.144	0.545

Table 4: Correlation between navigation system deviation distance (NS) and conventional cochlear implant surgery (CCIS) time.

Discussion

Image-guided or NS technology is now widely used in neurosurgery and hepatobiliary surgery, allowing the surgeon to delineate the boundaries of important anatomical and surgical structures [16,17]. It can also be used in CI and is valuable as a non-invasive quality management tool. However, to maintain the accuracy of the 1-mm deviation distance, more efforts are needed to perform NS-guided CIS [18]. In our study, the deviation distance determined by NS was more than the expected value or 1 mm, which seems that NS did not have enough accuracy for its use in CIS. However, with the passage of time from the beginning of the study, the deviation distance decreased, which seems to be related to the increase in the experience of the surgeon and CT scan personnel. Another advantage of using NS is helping the surgeon to determine the correct path of CI location, reducing the possibility of facial nerve damage and reducing surgical complications [1,15,18]. Also, the target evaluated with NS has better repeatability and accuracy than CCIS [17].

In the study conducted by Zhen et al. (2023) a three-dimensional model of the cochlea, facial nerve, chorda tympani, ossicles, external auditory canal and temporal bone were manually reconstructed based on NS. The aim of this study was to optimize the implant angle, implant position and distance from the planned path to the facial nerve and chorda tympani. Then, assuming no damage to the facial nerve, tympani tendons, bones and other tissues, automatic path planning for minimally invasive CI was studied based on the damage mechanism model. The optimal implant placement angle was 23.26 degrees, the distance between the target of the planned path in Round window and the best implant axis was 0.112 mm. The distance of the path to the Fascial nerve and Chorda tympani was 0.612 mm and 0.494 mm, respectively [19]. In Shih M, et al. [20] study, 3 patients with bilateral chronic Mastoiditis, Charge syndrome, and

Treacher Collins underwent bone conduction hearing aid surgery using NS. The results indicated a reduction in surgery time and the risk of complications caused by surgery such as damage to the dura and Sigmoid sinus, and no complications related to surgery were observed during or after surgery [20].

Wang J, et al. [21] investigated the surgical accuracy of CI under the NS while accessing the relevant anatomical structures. The accuracy of the entry and the target point were 0.471 ± 0.276 mm and 0.671 ± 0.268 mm, respectively. The minimum distance from the Facial nerve was reported as 0.79 mm and from the bony chain as 1.96 mm, but in one case, the tympanum and in two cases the external ear canal were damaged during drilling [21]. In the study conducted by Al-Amro M, et al. [15] 11 patients were examined; 10 patients underwent CI surgery and 1 patient underwent surgery for Baha implantation under the guidance of the NS. The mean surgical time was reported to be 161 minutes (from 90 to 220 minutes). The results showed that none of the patients had complications and all surgery was performed successfully [15].

In the study by Chu et al. (2014), 2 patients underwent CI surgery using NS. The closest distance from the drill to the Facial nerve was measured as the main target, and the surgeon was alerted by auditory feedback, if the target was approached. Therefore, the possibility of damage to the facial nerve during surgery was reduced. If the drill is close to the scala vestibuli and as a result, the wrong path to the CI direction, the low tone signal will be heard. In case of approaching the scala tympani, as a result the correct path of the CI, the signal was announced with a higher tone, the surgeon was helped in determining the correct path of the CI and reducing the possibility of Facial nerve damage. Considering the advantages of this method and fewer complications, those researchers suggested the use of NS in CCIS [22]. Stelter K, et al. [18], in a study on a patient with sensorineural hearing loss, performed NS-guided CI. The deviation distance from the target was measured under NS observation without direct view of the surgical field. The mean deviation distance from the mastoid was 0.91 mm, from the Round window 1.01 mm and from the middle ear canal 0.9 mm [18]. In the study of Schipper et al. (2004) a deviation distance of 1.6 mm from the cochlear site in NS was observed. However, the researchers concluded that the target evaluated with the NS was better in terms of repeatability and accuracy compared to CCIS [23]. Kohan D, et al. [24] evaluated 11 patients who were candidates for glomus jugularis surgery and cholesterol granuloma using NS. The mean increase in surgical time was 36.7 minutes; the deviation distance from the desired goals was 1.1 mm at the level of the Tragus and 0.8 mm at the level of the Oval window. Overall, the mean accuracy of surgical assessment was reported to be 1 mm for 10 of 11 anatomical landmarks [24]. However, the reason for deviation distance in the results may be due to the difference in the tools used, the accuracy of the device, or the experience of the surgeon. It is hoped that by increasing the experience of surgeons and improving technology, NS guidance can be used in CI.

Conclusion

In this study, the anatomical distance difference determined by CCIS and NS was more than the expected value or 1 mm, which seems that NS did not have enough accuracy for its use in CIS. It is hoped that with the increase in the skill of specialist personnel and the advancement of technology, NS can replace CCIS, especially in cases of congenital defects and anatomical disorders.

References

1. Cho B, Matsumoto N, Komune S, Hashizume M (2014) A surgical navigation system for guiding exact cochleostomy using auditory feedback: a clinical feasibility study. BioMed Research International.

2. Wang J, Liu H, Ke J, Hu L, Zhang S, et al. (2020) Image-guided cochlear access by non-invasive registration: a cadaveric feasibility study. Scientific Reports 10(1): 18318.

3. Labadie RF, Shah RJ, Harris SS, Cetinkaya E, Haynes DS, et al. (2005) In vitro assessment of image-guided otologic surgery: submillimeter accuracy within the region of the temporal bone. Otolaryngology-Head and Neck Surgery 132(3): 435-442.

4. Labadie RF, Mitchell J, Balachandran R, Fitzpatrick JM (2009) Customized, rapid-production micro stereotactic table for surgical targeting: description of concept and in vitro validation. International journal of computer assisted radiology and surgery 4(3): 273-280.

5. Balachandran R, Mitchell JE, Blachon G, Noble JH, Dawant BM, et al. (2010) Percutaneous cochlear implant drilling via customized frames: an in vitro study. Academy of Otolaryngology-Head and Neck Surgery 142(3): 421-426.

6. Kratchman LB, Blachon GS, Withrow TJ, Balachandran R, Labadie RF, et al. (2011) Design of a bone-attached parallel robot for percutaneous cochlear implantation. IEEE Transactions on Biomedical Engineering 58(10): 2904-2910.

7. Labadie RF, Balachandran R, Noble JH, Blachon GS, Mitchell JE, et al. (2014) Minimally invasive image-guided cochlear implantation surgery: first report of clinical

implementation. The Laryngoscope 124(8): 1915-1922.

8. Caversaccio M, Gavaghan K, Wimmer W, Williamson T, Anso J, et al. (2017) Robotic cochlear implantation: surgical procedure and first clinical experience. Acta oto-laryngologica 137(4): 447-454.

9. Theunisse HJ, Pennings RJ, Kunst HP, Mulder JJ, Mylanus EA (2018) Risk factors for complications in cochlear implant surgery. European Archives of Oto-rhino-laryngology 275: 895-903.

10. Sennaroglu L (2009) Cochlear implantation in inner ear malformations–a review article. Cochlear implants international.

11. Green JD, Shelton C, Brackmann DE (1994) Iatrogenic facial nerve injury during otologic surgery. The Laryngoscope 104(8): 922-926.

12. Zimmermann M, Schulz T, Kahn T, Hofer M (2012) Imaging of the sinuses for functional sinus surgery using navigational guidance. Laryngo-rhino-otologie 91(3): 160-166.

13. Tzelnick S, Rampinelli V, Sahovaler A, Franz L, Chan HH, et al. (2023) Skull-Base Surgery-A Narrative Review on Current Approaches and Future Developments in Surgical Navigation. Journal of Clinical Medicine 12(7): 2706.

14. Gunkel AR, Freysinger W, Thumfart WF (2000) Experience with various 3-dimensional navigation systems in head and neck surgery. Archives of Otolaryngology Head & Neck Surgery 126(3): 390-395.

15. Al-Amro M, Manea MB, Shehri HAS, Hagr A (2020) Experience with the use of the navigation system for ear surgeries: A cohort study. Journal of Nature and Science of Medicine 3(4): 280-285.

16. Krohmer SJ, Pillai AK, Guevara CJ, Bones BL, Dickey KW (2018) Image-guided biliary interventions: how to recognize, avoid, or get out of trouble. Techniques in Vascular and Interventional Radiology 21(4): 249-254.

17. Schipper J, Aschendorff A, Arapakis I, Klenzner T, Teszler CB, et al. (2004) Navigation as a quality management tool in cochlear implant surgery. The Journal of Laryngology & Otology 118(10): 764-770.

18. Stelter K, Ledderose G, Hempel JM, Morhard DF, Flatz W, et al. (2012) Image guided navigation by intraoperative CT scan for cochlear implantation. Computer Aided Surgery 17(3): 153-160.

19. Zhen Y, Jianjun L, Zuo W, Yongzhen W (2023) Research on Direct Cochlear Access Planning for Minimally Invasive Cochlear Implantation.

20. Shih M, Gitomer SA, Barton G, Liu Y (2020) Image-guided surgical navigation for bone-conduction hearing device implant placement. International Journal of Pediatric Otorhinolaryngology 139: 110392.

21. Wang J, Liu H, Ke J, Hu L, Zhang S, et al. (2020) Image-guided cochlear access by non-invasive registration: a cadaveric feasibility study. Scientific Reports 10(1): 18318.

22. Cho B, Matsumoto N, Komune S, Hashizume M (2014) A surgical navigation system for guiding exact cochleostomy using auditory feedback: a clinical feasibility study. BioMed Research International 2014.

23. Schipper J, Klenzner T, Aschendorff A, Arapakis I, Ridder G, et al. (2004) Does navigation-controlled cochleostomy improve the results of cochlear implant surgery? Is it possible to improve the quality of results in cochlear implant surgery? 52: 329-335.

24. Kohan D, Jethanamest D (2012) Image-guided surgical navigation in otology. The Laryngoscope 122(10): 2291-2299.