The Journal of
Laryngology
& Otology

cambridge.org/jlo

The effect of cochlear implant insertion technique on post-operative neural response telemetry and impedance in paediatric patients

S B Hashemi[1], M Janipour[1], R Jahangiri[1] and A Babaei[1,2]

[1]Otolaryngology Research Centre, Department of Otolaryngology, Shiraz University of Medical Sciences, Shiraz, Iran and [2]Student Research Committee, Shiraz University of Medical Sciences, Shiraz, Iran

Main Article

Dr M Janipour takes responsibility for the integrity of the content of the paper

Cite this article: Hashemi SB, Janipour M, Jahangiri R, Babaei A. The effect of cochlear implant insertion technique on post-operative neural response telemetry and impedance in paediatric patients. *J Laryngol Otol* 2023;**137**: 363–367. https://doi.org/10.1017/S0022215122000901

Accepted: 21 March 2022
First published online: 21 April 2022

Key words:
Cochlear Implantation;
Sensorineural Hearing Loss; Neurotology;
Acoustic Impedance Tests

Author for correspondence:
Dr Masoud Janipour, Department of Otolaryngology and Head and Neck Surgery, Khalili Hospital, Shiraz University of Medical Sciences, Shiraz, Iran
E-mail: masood.janipoor@gmail.com
Fax: +98 713 629 1478

Abstract

Objective. This study aimed to compare neural response telemetry and impedance between the round window and cochleostomy approaches for cochlear implantation.
Methods. In this case–control study, 64 patients aged less than 3.5 years underwent cochlear implantation via the round window or cochleostomy approach. Post-operative neural response telemetry and impedance were measured.
Results. The impedance measurements at electrodes 1, 11 and 22 showed no significant differences between the two groups three months after implantation ($p = 0.90$, $p = 0.08$ and $p = 0.37$, respectively). Similar results were observed six months after implantation ($p = 0.71$, $p = 0.65$ and $p = 0.70$, respectively). There was no significant difference in neural response telemetry between the two groups after three months. The neural response telemetry of electrode 1 in the cochleostomy group (171.26 ± 19.81 μV) was significantly higher in comparison with that of electrode 1 in the round window group (161.97 ± 12.71 μV) after six months ($p = 0.03$). The neural response telemetry values for electrodes 11 and 22 did not show any significant difference after six months ($p = 0.14$ and $p = 0.48$, respectively).
Conclusion. Both approaches provide equal stimulation of the cochlear nerve and impedance.

Introduction

Cochlear implantation is a safe and beneficial procedure, even in patients with inner-ear malformation.[1] It has improved the hearing ability significantly in patients with moderate to profound hearing loss. The overall rate of complications is reported as 10.43 per cent.[2] Improvement of the surgical procedure has resulted in a decreased rate of complications.[3]

Since the introduction of cochlear implants, and Food and Drug Administration approval for their clinical use in 1985, efforts have continued to improve their efficacy.[4] Intracochlear lesions and new bone and fibrous tissue formation induced by electrode insertion can be minimised by surgical technique and electrode design.[5,6] This has led to a growing interest in performing atraumatic surgery to maintain residual hearing. Two major surgical techniques have been promoted in recent years: the round window approach and the cochleostomy technique.

Round window insertion ensures that the electrode array is placed into the scala tympani, which is advantageous compared with cochleostomy approaches. Several studies have suggested round window insertion may be less traumatic regarding scala tympani access and electrode insertion compared with cochleostomy approaches. Histological studies have confirmed the atraumatic nature of this approach.[7,8] Clinically, it reduces the risks of damage to residual hearing caused by drilling and basilar membrane perforation, which may arise if the electrode is dislocated from the scala tympani to the scala vestibuli.[8]

Anatomical variations in the round window location, such as in cases where the round window membrane faces inferiorly, can hinder access to it. In addition, if it has a more horizontal orientation, the bony cochlear hook interferes with a straight trajectory.[9] Comparison of the round window niche exposure between paediatric and adult patients revealed that full round window visibility was attained in 52 per cent versus 87 per cent of patients, respectively. Full round window exposure was achieved after facial nerve exposure at the level of posterior tympanotomy in 70 per cent of paediatric cases versus 33 per cent of adult cases.[10] In all such cases, a cochleostomy approach can become necessary, even if residual hearing preservation is targeted. The influence of the technique on post-operative complications, residual hearing and auditory nerve stimulation has been considered in previous studies.[11–13]

Post-operatively, different measurements can be used to assess the integrity and performance of a cochlear implant. Electrode impedance and neural response telemetry are common parameters. Electrode impedance determines the status of the interface between tissue and electrode and the adjacent tissue of the cochlea. Impedance is highly related to the integrity and function of a cochlear implant. In addition, impedance is used for debugging cochlear implants clinically.[14]

The Cochlear™ company designed a neural response telemetry system to measure the electrically evoked nerve potentials of the distal part of the auditory nerve without accessing the cochlea directly. The implant generates stimuli and records the responses.[15]

This study aimed to compare objective measurements for auditory nerves stimulated by cochlear implants associated with round window and cochleostomy approaches, and any relevant complications for either technique.

Materials and methods

Study design and setting

This prospective case–control study was performed on patients who underwent cochlear implantation in Fars Cochlear Implant Center, affiliated with Shiraz University of Medical Sciences, Iran.

The study protocol was approved by the institutional review board of Shiraz University of Medical Sciences, and the approval of the ethics committee was attained before the study commenced (ethics code: IR.SUMS.MED.REC.1395.10).

Participants

We included patients aged less than 3.5 years with severe to profound hearing loss (more than 70 dB hearing loss on pre-operative auditory brainstem response (ABR) testing) who underwent cochlear implantation using the round window or cochleostomy approach.

Paediatric patients were excluded from the study if they had: structural cochlear malformations; aetiologies that might cause obliteration or ossification (e.g. deafness caused by bacterial meningitis, otosclerosis and autoimmune diseases); auditory neuropathy spectrum disorder; intra-operative abnormal impedance and neural response telemetry measurements; partial insertion of the electrode array; inner-ear anomalies; syndromic causes of deafness or other co-morbidities; or incomplete follow up. Those undergoing revision surgery were also excluded.

Surgical procedures

Under general anaesthesia, a posterior auricular incision was performed. The periosteal pouch was designed for the insertion of the implant receiver. Partial mastoidectomy was then performed. Anatomical landmarks such as the posterior wall of the auditory canal, the antrum with the incus, mastoid part of the facial nerve, chorda tympani canal, semicircular canals, sigmoid sinus and sinodural angle were exposed and preserved. After that, posterior tympanotomy was created by widely opening the facial recess. Then, a bone bed was created for the insertion of the implant at 1 cm posterosuperior to the sinodural angle. After that, a connecting canal was constructed to the mastoid in projection on the sinodural angle, for the safe insertion and fixation of the electrode.

After visualisation of the round window, the round window niche was drilled with a 0.7 mm diamond burr, and then opened via incision of the round window membrane, which is called the round window approach.

When the round window could not be positively identified or accessed safely, such as in anatomical variants of the facial nerve or the jugular bulb location, or when the round window membrane angle was greater than 45° inferiorly, a completely separate cochleostomy was performed anterior and inferior to the round window niche.

Then, after partial insertion, the electrode was advanced into the cochlea, and, after full insertion, the stylet was removed. Muscle or soft tissue pieces were used around the electrode opening for secure closure of the cochlea, to avoid perilymph fistula. Intra-operative electrode impedance and neural response telemetry measurements were recorded. The incision was closed in several layers, covering the implant.

In both groups (cochleostomy and round window approach), a Cochlear Nucleus® implant (Freedom® Contour Advance® (CI24RE) implant) was used. In our centre, cochlear implantation surgery is routinely performed unilaterally. The right ear was selected in cases of symmetric sensory neural hearing loss because of the dominancy of the left brain hemisphere in speech perception and production in most patients.[16] Thus, all subjects underwent right-sided cochlear implantation. Post-operatively, a transorbital X-ray was performed to determine the proper location and full insertion of the electrode.

Outcomes

The primary outcome was the comparison of mean impedance threshold levels and neural response telemetry thresholds between the two groups (cochleostomy and round window approach), three and six months after implantation. The secondary outcome was the comparison of complications between the two groups.

Variables

Data were prospectively obtained from medical and follow-up records. Patients' records were reviewed regarding age, sex, side of surgery, manufacturer of implanted device, type of cochlear implantation approaches, post-operative complications and post-operative audiometric performance. Finally, the information from patients was collated using a data collection form.

Post-operative audiometry was performed three and six months after implantation to evaluate neural response telemetry[17] and impedance[18] measurements obtained according to previously described methods. We used electrodes 1 (proximal electrode (basilar)), 11 and 22 (distal electrode (apical)) for the analysis of low, mid and high frequencies, respectively.

Complications were classified into major and minor. Major complications included: facial nerve paralysis or paresis, cerebrospinal fluid leak ('gusher'), and significant infection (e.g. meningitis). Minor complications consisted of: vertigo or imbalance for more than 1 day, vomiting, cellulitis, ipsilateral anterior ageusia, seroma, and local infection.

Statistical analysis

Values were expressed as mean ± standard deviation for the quantitative variables, and as percentages for the categorical variables. A chi-square test was performed to compare the gender and rates of post-operative complications between the groups. An independent *t*-test was performed to compare the difference in post-operative audiometric performance. Data were analysed using SPSS statistical software, version 25 (SPSS, Chicago, Illinois, USA). A *p*-value of less than 0.05 was considered statistically significant. The effect size was

Table 1. Mean impedance measurements

Impedance measurement	Group (mean ± SD; kΩ)				95% CI of Cohen's d	
	Cochleostomy	Round window	*P*-value*	Cohen's d	Lower	Upper
3 months after cochlear implantation						
– Electrode 1	8.96 ± 1.27	8.91 ± 1.51	0.898	0.032	−0.459	0.523
– Electrode 11	7.99 ± 1.64	8.72 ± 1.59	0.078	−0.449	−0.944	0.050
– Electrode 22	9.06 ± 1.42	9.47 ± 2.07	0.367	−0.233	−0.725	0.260
6 months after cochlear implantation						
– Electrode 1	8.71 ± 1.57	8.56 ± 1.60	0.709	0.094	−0.398	0.585
– Electrode 11	8.01 ± 1.63	8.19 ± 1.44	0.646	−0.269	−0.761	0.226
– Electrode 22	8.75 ± 1.65	8.59 ± 1.73	0.696	0.098	−0.393	0.589

*Independent sample *t*-test. SD = standard deviation; CI = confidence interval

Table 2. Mean NRT measurements

NRT measurement	Group (mean ± SD; μV)				95% CI of Cohen's d	
	Cochleostomy	Round window	*P*-value*	Cohen's d	Lower	Upper
3 months after cochlear implantation						
– Electrode 1	171.26 ± 23.01	169.57 ± 15.94	0.730	0.085	−0.407	0.576
– Electrode 11	181.97 ± 18.04	178.97 ± 17.97	0.508	0.167	−0.326	0.658
– Electrode 22	166.44 ± 25.29	162.70 ± 17.89	0.502	0.169	−0.324	0.660
6 months after cochlear implantation						
– Electrode 1	171.26 ± 19.81	161.97 ± 12.71	0.028	0.551	0.049	1.050
– Electrode 11	178.97 ± 14.83	174.23 ± 14.84	0.140	0.374	−0.123	0.868
– Electrode 22	163.03 ± 25.10	159.30 ± 16.62	0.482	0.173	−0.320	0.664

*Independent sample *t*-test. NRT = neural response telemetry; SD = standard deviation; CI = confidence interval

calculated using JASP 0.14.1 computer software (JASP Team, Amsterdam, The Netherlands).

Results

A total of 64 patients were studied (34 patients in the cochleostomy group and 30 patients in the round window group). The mean age of patients was 21.94 ± 8.14 months (range, 13–42 months) in the cochleostomy approach group, and 23.63 ± 6.13 months (range, 8–34 months) in the round window group ($p = 0.357$). Of the patients, 47.1 per cent (16 of 34) and 53.3 per cent (16 of 30) were male in the cochleostomy and round window groups respectively ($p = 0.616$). All patients had pre-lingual hearing loss. Post-operative transorbital X-ray showed the appropriate location and full insertion of the electrodes in all patients.

The mean impedance values for electrodes 1, 11 and 22 revealed no significant differences between the two study groups at three and six months after implantation. Table 1 shows the mean impedance measurements at three and six months after cochlear implantation.

Table 2 represents the mean neural response telemetry values for the groups at three and six months after implantation. After six months, the neural response telemetry value for electrode 1 in the cochleostomy group (171.26 ± 19.81 μV) was significantly higher than that for electrode 1 in the round window group (161.97 ± 12.71 μV) ($p = 0.028$), with a medium effect size (0.551). Comparison of other neural response telemetry values showed no statistically significant differences between the two groups.

There were no major post-operative complications in either group. There were three patients with minor post-operative complications in the round window group. Two of them presented with cellulitis, and one presented with a local infection, which was treated by local dressing and antibiotics. No patients had any minor complications in the cochleostomy group ($p = 0.059$).

Discussion

Our results indicate no significant differences in the action potentials at the distal portion of the auditory nerve – in terms of neural response telemetry – in multichannel cochlear implant patients using the implant to elicit stimulation and record responses, regardless of whether implantation was carried out through cochleostomy or the round window approach.

Previous studies have compared the two approaches in terms of histological, radiological and audiometric findings and complications. Cochlear implant electrode impedance is defined as the resistance to current flow at the electrode. Histological studies showed that electrode impedance differs for each electrode array depending on the size, shape, constituent materials and changes in the endocochlear fluids, tissues and fibrosis. Rises in impedance are associated with increased intracochlear fibrosis and scar tissue.[19] In the present study, there were no significant differences between the two

https://doi.org/10.1017/S0022215122000901 Published online by Cambridge University Press

implantation approaches regarding the impedance measurements at three and six months after implantation. A study by Richard *et al.* demonstrated that implantation performed through the round window minimised the initial intracochlear trauma and subsequent new tissue formation, in comparison with cochleostomy.[20]

Some previous studies compared radiological findings between the round window approach and the cochleostomy approach. Minimal interscalar excursion is a key factor for a successful audiological outcome. In a study by Jiam *et al.*, it was reported that cochleostomy approaches were linked to a higher rate of interscalar excursion.[21] Another study by Jiam *et al.* showed that the round window approach was associated with a higher risk of perimodiolar placement with the Med-El® 12-electrode implant. The authors concluded that, in the round window approach, the electrodes may be placed closer to the cochlear neural substrates, minimising the current spread, in comparison with cochleostomy approaches.[22]

There are different ways to objectively measure the electrical stimulation of the auditory nerve in cochlear implant users, such as by examining ABRs, middle latency responses, late potentials and stapedial reflexes.[23] Neural response telemetry is used to measure electrically evoked compound action potentials during surgery or post-operatively in implanted patients. This is an important test for accurately monitoring the external and internal hardware function and assessing cochlear stimulation through neural responses.[24]

- Cochlear implant technique may influence post-operative auditory nerve stimulation
- No differences were observed in neural response telemetry between cochleostomy and round window approaches
- No differences were noted concerning impedance in both approaches

A systematic review of 16 studies, with a total of 170 patients, did not show any benefit of one surgical approach over the other regarding the preservation of residual hearing.[25] Residual hearing preservation after cochlear implantation performed via the round window or cochleostomy approach was also investigated by Sun *et al.*, who found no statistically significant difference in residual hearing preservation between the two groups.[26] In another study, Kang and Kim found that patients who underwent the round window approach showed similar language perception compared with the cochleostomy group.[27] A study by Adunka *et al.* investigated the effect of the surgical approach on hearing electric-acoustic stimulation of the auditory system. That study reported similar outcomes in hearing preservation rates and speech perception measures.[28] Another study compared electrode impedance values immediately after implantation.[29] The authors concluded that the mean electrode impedance values were lower in the round window group. There were statistically significant differences in the impedance values for electrodes 1 to 14. However, the difference in electrodes 15 to 22 was not significant.[29] In our study, none of the differences in measurements were significant, and there were no significant differences between the two approaches in terms of the risk of complications. This is consistent with the results of other studies.[24,30]

The limitation of this study is the assessment of neural response telemetry results just three and six months after the follow up, and we did not measure neural response telemetry immediately after the operation. Furthermore, we did not evaluate radiological findings and speech performance in the patients. Moreover, further studies could be performed with a larger sample size for a conclusively powered study, to verify these preliminary findings.

Conclusion

No differences were noted between the two approaches concerning cochlear nerve stimulation, impedance and complication rate. Surgeons need to select the procedure of their choice with a view to safety.

Acknowledgements. The authors would like to thank Shiraz University of Medical Sciences, Iran, and the Center for Development of Clinical Research of Nemazee Hospital, Shiraz, as well as Dr Nasrin Shokrpour for editorial assistance. This article was extracted from a thesis by Dr Masoud Janipour that was financially supported by the Vice Chancellor of Research at Shiraz University of Medical Sciences (grant number: 94-01-01-9323).

Competing interests. None declared

References

1 Daneshi A, Farhadi M, Ajalloueyan M, Rajati M, Hashemi SB, Ghasemi MM *et al.* Cochlear implantation in children with inner ear malformation: a multicenter study on auditory performance and speech production outcomes. *Int J Pediatr Otorhinolaryngol* 2020;**132**:109901
2 Awad AH, Rashad UM, Gamal N, Youssif MA. Surgical complications of cochlear implantation in a tertiary university hospital. *Cochlear Implants Int* 2018;**19**:61–6
3 Hashemi SB, Bozorgi H, Kazemi T, Babaei A. Cerebrospinal fluid gusher in cochlear implant and its associated factors. *Acta Otolaryngol* 2020;**140**:621–5
4 Clark GM. The multi-channel cochlear implant: multi-disciplinary development of electrical stimulation of the cochlea and the resulting clinical benefit. *Hear Res* 2015;**322**:4–13
5 Foggia MJ, Quevedo RV, Hansen MR. Intracochlear fibrosis and the foreign body response to cochlear implant biomaterials. *Laryngoscope Investig Otolaryngol* 2019;**4**:678–83
6 Li PM, Somdas MA, Eddington DK, Nadol JB Jr. Analysis of intracochlear new bone and fibrous tissue formation in human subjects with cochlear implants. *Ann Otol Rhinol Laryngol* 2007;**116**:731–8
7 Khater A, El-Anwar MW. Methods of hearing preservation during cochlear implantation. *Int Arch Otorhinolaryngol* 2017;**21**:297–301
8 O'Connell BP, Hunter JB, Wanna GB. The importance of electrode location in cochlear implantation. *Laryngoscope Investig Otolaryngol* 2016;**1**:169–74
9 Jain S, Gaurkar S, Deshmukh PT, Khatri M, Kalambe S, Lakhotia P *et al.* Applied anatomy of round window and adjacent structures of tympanum related to cochlear implantation. *Braz J Otorhinolaryngol* 2019;**85**:435–46
10 Stuermer K, Winter T, Nachtsheim L, Klussmann JP, Luers JC. Round window accessibility during cochlear implantation. *Eur Arch Otorhinolaryngol* 2021;**278**:363–70
11 Rajput M, Nilakantan A. Functional outcomes in cochleostomy and round window insertion technique: difference or no difference? *Indian J Otolaryngol Head Neck Surg* 2019;**71**:1615–20
12 Naderpour M, Aminzadeh Z, Jabbari Moghaddam Y, Pourshiri B, Ariafar A, Akhondi A. Comparison of the pediatric cochlear implantation using round window and cochleostomy. *Iran J Otorhinolaryngol* 2020;**32**:3–10
13 Elafandi H, Khalifa MA, Elguindy AS. Cochlear implantation outcomes with round window electrode insertion versus cochleostomy insertion. *Int J Pediatr Otorhinolaryngol* 2020;**138**:110272
14 Cheng X, Wang B, Liu Y, Yuan Y, Shu Y, Chen B. Comparable electrode impedance and speech perception at 12 months after cochlear implantation using round window versus cochleostomy: an analysis of 40 patients. *ORL J Otorhinolaryngol Relat Spec* 2018;**80**:248–58
15 Mittmann P, Rademacher G, Mutze S, Hassepass F, Ernst A, Todt I. Evaluation of the relationship between the NRT-ratio, cochlear anatomy, and insertions depth of perimodiolar cochlear implant electrodes. *Biomed Res Int* 2015;**2015**:706253
16 Kraaijenga VJC, Derksen TC, Stegeman I, Smit AL. The effect of side of implantation on unilateral cochlear implant performance in patients with prelingual and postlingual sensorineural hearing loss: a systematic review. *Clin Otolaryngol* 2018;**43**:440–9

17 Mittmann P, Ernst A, Todt I. Intraoperative electrophysiologic variations caused by the scalar position of cochlear implant electrodes. *Otol Neurotol* 2015;**36**:1010–14

18 Hey M, Böhnke B, Dillier N, Hoppe U, Eskilsson G, Löwgren K *et al.* The Intra-cochlear Impedance-Matrix (IIM) test for the Nucleus® cochlear implant. *Biomed Tech* (*Berl*) 2015;**60**:123–33

19 Wilk M, Hessler R, Mugridge K, Jolly C, Fehr M, Lenarz T *et al.* Impedance changes and fibrous tissue growth after cochlear implantation are correlated and can be reduced using a dexamethasone eluting electrode. *PLoS One* 2016;**11**:e0147552

20 Richard C, Fayad JN, Doherty J, Linthicum FH Jr. Round window versus cochleostomy technique in cochlear implantation: histologic findings. *Otol Neurotol* 2012;**33**:1181–7

21 Jiam NT, Limb CJ. The impact of round window vs cochleostomy surgical approaches on interscalar excursions in the cochlea: preliminary results from a flat-panel computed tomography study. *World J Otorhinolaryngol Head Neck Surg* 2016;**2**:142–7

22 Jiam NT, Jiradejvong P, Pearl MS, Limb CJ. The effect of round window vs cochleostomy surgical approaches on cochlear implant electrode position: a flat-panel computed tomography study. *JAMA Otolaryngol Head Neck Surg* 2016;**142**:873–80

23 Bayrak S, Mutlu B, Kırkım G, Şerbetçioğlu B. Examination and comparison of electrically evoked compound action potentials and electrically evoked auditory brainstem response results of children with cochlear implantation without inner ear anomaly. *Turk Arch Otorhinolaryngol* 2019;**57**:81–5

24 Hamerschmidt R, Schuch LH, Rezende RK, Wiemes GR, Oliveira AK, Mocellin M. A comparison between neural response telemetry via cochleostomy or the round window approach in cochlear implantation. *Braz J Otorhinolaryngol* 2012;**78**:71–5

25 Havenith S, Lammers MJ, Tange RA, Trabalzini F, della Volpe A, van der Heijden GJ *et al.* Hearing preservation surgery: cochleostomy or round window approach? A systematic review. *Otol Neurotol* 2013;**34**:667–74

26 Sun CH, Hsu CJ, Chen PR, Wu HP. Residual hearing preservation after cochlear implantation via round window or cochleostomy approach. *Laryngoscope* 2015;**125**:1715–19

27 Kang BJ, Kim AH. Comparison of cochlear implant performance after round window electrode insertion compared with traditional cochleostomy. *Otolaryngol Head Neck Surg* 2013;**148**:822–6

28 Adunka OF, Dillon MT, Adunka MC, King ER, Pillsbury HC, Buchman CA. Cochleostomy versus round window insertions: influence on functional outcomes in electric-acoustic stimulation of the auditory system. *Otol Neurotol* 2014;**35**:613–18

29 Liu X, Xie L, Wang Y, Yang B. Lower initial electrode impedances in minimally invasive cochlear implantation. *Acta Otolaryngol* 2019;**139**:389–95

30 Gudis DA, Montes M, Bigelow DC, Ruckenstein MJ. The round window: is it the "cochleostomy" of choice? Experience in 130 consecutive cochlear implants. *Otol Neurotol* 2012;**33**:1497–501