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CLINICAL & BASIC RESEARCH

Intra-Operative Neural Response Telemetry and Acoustic Reflex Assessment using an Advance-In-Stylet Technique and Modiolus-Hugging

A prospective cohort study

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القياس عن بعد للاستجابة العصبية وردة الفعل الصوتية داخل العمليات باستخدام تقنية الإدخال بالمثبت ومعانقة عماد القوقعة : دراسة استباقية أترابية

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الملخص: **الهدف:** ركز تطوير صفائف الأقطاب في زراعة القوقعة على استخدام تقنية مبسطة يمثل أسلوب الحد الأدنى الغازي وتشمل معانقة القطب لعماد القوقعة. تهدف هذه الدراسة تقييم تقنية الإدخال بالمثبت بالمقارنة مع تقنية الإدخال بدون مثبت الموصى به من شركة كوكليار. قمنا بتقييم عتبات قياس السمع الكهربائي عندما إزيل المثبت (معانقة عماد القوقعة) ومقارنته بالقياسات التي ظهرت مع المثبت في مكانه (القوقعة الكهربائي في جهة الجدار الوحشي).**الطريقة:** تلقى 30 مريضا في هذه الدراسة الاستباقية الأترابية على التوالي زراعة قوقعة من نوع نيوكليس فريدم في أذن واحدة باستخدام تقنية الإدخال بالمثبت. أجريت قياسات المنعكس السمعي وقياسات الاستجابة العصبية عن بعد مع المثبت (القوقعة الكهربائي في جهة الجدار الوحشي) و بعد إزالته (معانقة عماد القوقعة) ثم تم مقارنة النتائج. قمنا بقياس ردود الفعل في اللفة القاعدية والوسطى والقمة في كلتا المجموعتين.**النتائج:** انتهت عملية زراعة القوقعة بالمثبت دون مضاعفات في 30 مريضا (16 من الذكور و 14 من الإناث في سن تتراوح بين 54–3 سنة [المتوسط 11]). بالاعتماد على قياس الاستجابة العصبية أظهرت أقطاب القمة فروق ذات دلالة إحصائية في العتبات، ولكن ردة الفعل الصوتي لم تختلف بشكل كبير قبل أو بعد إزالة المثبت في أي من المجموعات. **الخلاصة:** لا يبدو أن تسفر آثار تعانق عماد القوقعة عن فارق كبير في عتبات التحفيز الكهربائي، لهذا في الحالات الصعبة قد يكون ترك المثبت في مكانه لا يغير كثيرا في العتبات، ما عدا ربما في لفة القمة.

مفتاح الكلمات: زرع القوقعة، القياس عن بعد.

abstract: ***Objectives:*** The development of cochlear implant (CI) electrode arrays has focused on the use of a minimally invasive technique involving a modiolus-hugging placement of the electrode. The aim of this study was to evaluate the "advance-in-stylet" (AIS) technique compared to the advance-off-stylet (AOS) technique recommended for the current cochlear Nucleus® device. In the AIS technique, the stylet is not removed. We evaluated the electrical auditory thresholds measured when the stylet was removed (modiolus-hugging) compared to measurements taken with the stylet in place (lateral wall cochlea electrode placement). ***Methods:*** In this prospective cohort study, 30 consecutive patients received unilateral Nucleus Freedom® CIs using AIS insertion. Measurement of the acoustic reflex (AR) and neural response telemetry (NRT) were performed with the stylet in place (lateral wall placement of the electrodes) and then removed (perimodiolar placement), and the results compared. The responses were measured in the basal, middle and apical turns in both groups—with and without stylet. ***Results:*** The AIS surgery was completed without complication in 30 patients (16 males and 14 females, age range 3–54 years [mean 11]). Based on neural response telemetry, only apical electrodes showed statistically significant differences in thresholds, but the AR was not significantly different before or after stylet removal in any of the electrode groups tested. ***Conclusions:*** The effects of modiolus-hugging do not seem to result in a large difference in electrical stimulation thresholds so, in difficult cases, the stylet may be left in place without significantly changing the thresholds, except perhaps at the apical turn.

Keywords: Cochlear implant; telemetry

Advances in Knowledge

1. The effects of modiolus-hugging do not seem to result in a large difference in electrical performance in cochlear implant.

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Application to the patient care

1. The stylet in cochlear implant may be left during electrodes insertion without significantly changes in the threshholds.

The cochlear implant (CI) is a device that electrically stimulates the auditory nerve via an intracochlear electrode array placed in the scala tympani, bypassing the inner ear in subjects with severe to profound hearing loss. CI technology has improved considerably over the past decade as researchers and manufacturers have attempted to maximise speech perception. Although many advances have already been made, there are still several unresolved issues with regard to CI surgery, one of which is the utility of the advance-off-stylet (AOS) technique, with its resulting modiolar hugging array morphology. The classic straight CI electrode array slides along the lateral wall of the scala tympani during insertion, and it remains in this location. Newer designs from some companies have featured implants with a preformed shape memory, which causes the implant to spiral inwards towards the modiolus. Different manufacturers have achieved modiolus-hugging in different ways, but in this study we used the implementation developed by Cochlear Corporation (Sydney, Australia), which employs a stylet to stent a preformed coiled array into a straight shape. The recommendation is to insert this electrode to a predefined distance, and then advance the electrode off the stylet. This has two effects: first, the soft, flexible tip leads and, because the stylet has been withdrawn from the tip, the distal electrode is no longer stiff, avoiding penetration of the basilar membrane or spiral ligament; second, it allows the electrode to take up its pre-coiled shape and hug the modiolus. This is called the advance-off-stylet (AOS) technique. This can be a difficult surgical manoeuvre to perform because the whole array may be withdrawn instead of advanced when the surgeon attempts to slide it off the stylet, which is held steady. This can result in intraoperative extrusion of the array, and, if it curls with the stylet withdrawn, the stylet is not designed to be re-introduced. This could potentially waste an expensive CI because it is very difficult to insert the array once it is coiled.

Perimodiolar CI electrodes place the electrode contacts in closer proximity to the excitable neural elements. Theoretically, this offers better resolution and improved transfer of the electrical stimuli to the neural structures of the VIIIth nerve endings, where it results in more specific frequency stimulation, reduced electric current spread, increased dynamic range and reduced energy consumption.[1] These combined features result in performance gains for the listener and reduced electrical power consumption, thereby prolonging battery life. Behavioural response studies have found significant decreases in average threshold and comfort (T&C) levels across electrodes with perimodiolar placement when compared to lateral wall cochlea arrays,[2,3]and this placement may also potentially improve speech perception.[4] Additionally, facial nerve stimulation may be reduced by placing the electrode further away from the outer wall of the scala tympani.[5] Most of the early studies showing lowered thresholds and a wider dynamic range with perimodiolar arrays using electrically evoked auditory brainstem responses (EABR) in animals.[6,7] However, some newer studies have shown that these supposed benefits are variable.[8,9,10] Histological studies to assess the cochlear damage resulting from insertion of different types of perimodiolar electrodes were performed on cadaver temporal bones of normal-hearing individuals;[11,12] however, these studies did not take into account that, with time, fibrosis, scarring, and ossification resulting from insertion trauma could theoretically alter the amount of current necessary for stimulation. These factors are independent of the distance of the electrode from the modiolus and the remaining spiral ganglion cells. Therefore, the impact of localised damage to the spiral ligament during implantation in humans is uncertain.[12,13] In addition, many other studies have shown no improvement in CI performance in relation to hearing conservation or in the dynamic range. [3,14-16]

Perimodiolar AOS electrode surgery is relatively atraumatic due to the flexible tip, though it may result in lower lateral wall stress and forces. It may preserve the integrity of the spiral lamina and basilar membrane, further preventing the subsequent neuronal losses that have been reported using conventional straight electrode arrays.[11,17]As mentioned above, the impact of localised damage to the spiral ligament during implantation is uncertain and may take time to become evident.[13]

As noted above, many studies have shown that

Table 1: Characteristics of the sample

Variable	Statistic
Age	
Minimum	3
Maximum	54
Mean	11.47
Median	5.00
Mode	5.00
Standard deviation	13.68
Sex	
Male	16 (53.3%)
Female	14 (46.7%)
Site	
Right	14 (46.7%)
Left	16 (53.3%)

stimulation in the perimodiolar location using EABR results in less power consumption.[18-21] Neural response telemetry (NRT) is a system that measures electrically evoked compound action potential (ECAP) thresholds from the auditory nerve using the CI. The system applies an electrical pulse to a given intracochlear electrode, and the evoked neural response is recorded at a neighbouring electrode. The measured potentials are telemetered back to the system's interface for clinical analysis. The response is probably from the proximal auditory nerve, and this method has several advantages over EABR. One is that NRT requires a shorter collection time which is important for intraoperative use. Second, there is little need for patient cooperation or sedation, which is required to apply the EABRs' surface electrodes, because NRT uses the CI as both the stimulating and recording electrodes. Additionally, using NRT, postoperative data can be compared to intraoperative data. Moreover, NRT can be used to predict the behavioural threshold (T levels) and maximum comfort levels (C levels) to build stimulation maps for the CI patient and facilitate the postsurgical rehabilitation process. NRT provides information that reflects the activity of a smaller number of auditory neurons, thus effectively negating the influence of neural response from higher levels in the brain. EABR requires a larger number of sweeps and a longer acquisition time, it is more difficult to elicit, and it is often associated with artefacts.[22,23]

The acoustic reflex (AR) is the contraction of the stapedius muscle, traditionally in response to sound stimulation. The ipsilateral pathway for the stapedius reflex travels via the VIIIth nerve synapses in the ipsilateral cochlear nucleus, and then travels to the superior olivary nucleus and the facial nerve nucleus, which supplies the stapedius muscle by way of the facial nerve. The AR also helps to verify implant position and integrity in addition to validating the functioning of the auditory and facial nerves. To our knowledge, there has been no study to date evaluating the effects of perimodiolar positioning (by removing the stylet) compared to lateral wall placement of the array (by non-removal of the stylet) measured using the acoustic reflex threshold (ART) and neural response telemetry (NRT) performed intraoperatively for the Nucleus® (Cochlear Corporation, Sydney, Australia) electrode array. The purpose of this study was to determine this effect, within the same cochlea and using the same array. We will refer to the procedure in which the stylet is left in place as the advance-in-stylet (AIS) technique for the Nucleus Freedom® electrode array.

Methods

Thirty patients who received the Nucleus Freedom® device between April 2009 and January 2010 were studied. Inclusion criteria for this study were age greater than 2 years, no inner ear malformation, and compliance with our CI candidacy criteria. Exclusion criteria were failure of full insertion, inability to remove the stylet, the presence of a cerebrospinal fluid (CSF) gusher and intra-operative measures performed by audiologists other than our investigating audiologist.

This prospective study was performed at the King Abdulaziz University Hospital in Riyadh, Saudi Arabia. A total of 30 consecutive CI patients of a single surgeon and a single audiologist were recruited and evaluated with intra-operative CI testing (ART and NRT) after full insertion with stylet in place (AIS). Then, these test results were compared with the results of procedures performed with the stylet explanted (with perimodiolar hugging) in the same patient in a repeated measures fashion. The Freedom® CI developed by Cochlear Corporation was used in all of our patients. Our Institution Research Board (IRB) approved this study (Project No. E-10-198).

In our study, NRT responses were recorded at

Table 2: Comparison of the 30 subjects' means and standard deviations of NRT with and without stylet

		Mean difference	95% Confidence interval	
			Lower	Upper
Pair 1	NRT3 with NRT3 without	0.40	-8.79	9.59
Pair 2	NRT9 with NRT9 without	2.10	-3.00	7.20
Pair 3	NRT13 with NRT13 without	4.87	1.02	8.71
Pair 4	NRT17 with NRT17 without	5.00	-0.83	10.83
Pair 5	NRT21 with NRT21 without	5.87	1.39	10.34
Pair 6	NRT1 with NRT1 without	1.17	-6.63	8.96
Pair 7	NRT6 with NRT6 without	3.07	-3.57	9.71
Pair 8	NRT11 with NRT11 without	2.87	-9.95	4.22
Pair 9	NRT16 with NRT16 without	3.27	0.04	6.50
Pair 10	NRT22 with NRT22 without	5.20	1.38	9.02
Pair 11	Mean apical with Mean apical without	5.66	2.23	9.08
Pair 12	Mean middle with Mean middle without	1.37	-2.10	4.84
Pair 13	Mean basal with Mean basal without	1.54	-5.17	8.26

apical, basal, and middle electrodes in each patient. The stimulated electrodes ranged from 1 to 7 at the basal end, 8 to 15 in the middle, and 16 to 22 at the apex. The AR thresholds were observed by the same surgeon before and after stylet removal without knowing which electrodes were being stimulated.

In all cases, facial nerve monitoring was used, and then the mastoidectomy and transfacial recess were done. The middle ear was normal in all cases, and a cochleostomy was performed anterior-inferiorly to the round window. The electrode was inserted gently and slowly into the scala tympani without using the AOS technique, i.e. insertion with the stylet-in-place (AIS technique). This renders the array similar to a conventional straight electrode array, which will lie against the lateral cochlear wall. The cochleostomy site was sealed by muscle after full insertion of the electrodes. The ART were evaluated by the surgeon, and the lowest stimulation level at which visible stapedial contractions could be seen was recorded. The AR thresholds were measured at the electrodes numbered 1, 6, 11, 16 and 22. Then the NRT was measured at the electrodes numbered 1, 3, 6, 9, 11, 13, 16 17, 21 and 22. The stylet was then removed, allowing the electrode array to coil closer to the modiolus. The stimulation threshold measurements were then repeated. All the patients' intra-operative evaluations were done by the same audiologist. Therefore, identical stimulation and recording procedures were used for the measurements before and after stylet removal within and across subjects.

The next day, an X-ray was taken for all patients to confirm intracochlear electrode insertion. All statistical analyses were done using SAS (SAS Institute, Inc., Cary, NC, USA.). The results of t-tests having an alpha *P* value of 0.05 or less were considered statistically significant.

Results

The patient population consisted of 16 males and 14 females ranging in age from 3 to 54 years (mean 11). For 14 patients, the CI was placed on the right and for 16 placed on the left [Table 1]. All patients had full CI insertion.

All quantitative variables (except age) were proven to follow the normal distribution. The Kolmogrov test was used to test normality of data so the parametric paired t-test was used for comparison of data. The effects of changing electrode placement method from the stylet-in procedure (lateral wall

Table 3: Comparison of neural response telemetry (NRT) for each electrode with and without the stylet in place using *P* value

		Mean	Standard Deviation	*P* value
Pair 1	NRT3 with	184.07	29.56	.930
	NRT3 without	183.67	17.51	
Pair 2	NRT9 with	192.97	16.02	.407
	NRT9 without	190.87	12.38	
Pair 3	NRT13 with	191.57	16.01	.015*
	NRT13 without	186.70	12.26	
Pair 4	NRT17 with	185.73	17.03	.090
	NRT17 without	180.73	15.34	
Pair 5	NRT21 with	183.20	18.12	.012*
	NRT21 without	177.33	16.41	
Pair 6	NRT1 with	186.80	29.87	.762
	NRT1 without	185.63	22.23	
Pair 7	NRT6 with	188.30	26.35	.353
	NRT6 without	185.23	18.56	
Pair 8	NRT11 with	187.00	20.62	.415
	NRT11 without	189.87	13.92	
Pair 9	NRT16 with	185.00	16.58	.048*
	NRT16 without	181.73	15.66	
Pair 10	NRT22 with	179.67	16.76	.009*
	NRT22 without	174.47	17.47	
Pair 11	Mean apical with	184.23	15.59	.002*
	Mean apical without	178.57	13.84	
Pair 12	Mean middle with	190.51	14.48	.427
	Mean middle without	189.14	11.38	
Pair 13	Mean basal with	186.39	25.55	.642
	Mean basal without	184.84	17.69	

*Note: *Significant.*

cochlea) to the stylet-out procedure (medial wall cochlea) were characterised by comparing AR responses and NRTs between the positions. Table 2 shows the comparison of the 30 subjects' means and standard deviations of NRT with and without stylet, while Table 3 shows the threshold measures from NRT averaged across subjects for the lateral (with stylet) and medial (without stylet) placements for the apical, middle, and basal electrodes. Standard deviations and *P* values are indicated for each electrode using t-tests. Statistically significant differences were found in thresholds with medial placement for some electrodes (13, 16, 21, 22) using NRT, as indicated with asterisks [Table 3]. However, when all subgroups are collapsed into apical, middle and basal categories, only the apical electrodes showed statistically significant differences in thresholds, as indicated with asterisks.

Table 4: Acoustic reflex (AR) in electrode 1 with and without the stylet: cross tabulation

			AR1 with		Total
			No	**Yes**	
AR1 without	**No**	Count	17	3	20
		% of Total	56.7	10.0	66.7
	Yes	Count	2	8	10
		% of Total	6.7	26.7	33.3
Total		**Count**	**19**	**11**	**30**
		% of Total	**63.3**	**36.7**	**100.0**

Note: P >0.05.

The effect of perimodiolar electrode placement on neural responses was analysed across stimulation levels by cross tabulation of the AR responses for electrodes 1, 6, 11, 16 and 22, as shown in tables 4 to 8, respectively. This cross tabulation was performed for each electrode's AR with and without the stylet. Based on a t-test, there was no statistical difference between the AR results with or without the stylet across all tested electrodes. AR comparison (separately for electrode 1, 6, 11, 16 and 22) was carried out with 2 x 2 table and is presented showing odds ratio with 95% confidence in Table 9.

Discussion

In the current study, we used an efficient method to test the impact of modiolus-hugging on electrically evoked auditory thresholds in an acute intra-operative setting. This method combines intraoperative AR and NRT before and after stylet removal. The patient group studied in this analysis is very typical of the patient population at our large CI centre. Because we do not yet have a neonatal screening programme for deafness, our patients usually present late.

In this study, we used a single device (Nucleus Freedom®), which is the most common type of device used in our centre and worldwide. We expect other devices to be similar in their performance using modiolar hugging or lateral wall placement comparisons with the same stimulation parameters. There is no reported statistically significant difference among the three major manufacturers of electrodes (Cochlear Corporation, MEDEL

Table 5: Acoustic reflex (AR) in electrode 6 with and without the stylet: cross tabulation

			AR6 with		Total
			No	Yes	
AR6 without	No	Count	10	2	12
		% of Total	33.3	6.7	40.0
	Yes	Count	3	15	18
		% of Total	10.0	50.0	60.0
Total		**Count**	**13**	**17**	**30**
		% of Total	**43.3**	**56.7**	**100.0**

Note: P >0.05

and Advanced Bionics) with respect to inner ear trauma,[12] modiolar wall contact,[24,25] or facial nerve stimulation rates.[26]

Our study did not show a major disadvantage of the AIS technique. This procedure is actually easier to perform than removal of the stylet in the AOS technique. We did not observe any complications in our patients as a result of leaving the stylet on during insertion of the electrode. This may lower the learning and implementation curves for this increasingly used surgery and aid in teaching trainees in CI insertion. Moreover, the AIS technique may be suitable for some difficult cases, such as cochlear fracture, re-insertion, and fibrosis of the inner ear, where the presence of the stylet may give extra rigidity to the implant and prevent early coiling of the tip. In addition, not removing the stylet allows preservation of the uncoiled implant for a second trial if there is difficulty or malplacement of the electrode.

The NRT results only showed significant differences between the medial position (modiolar hugging) and the lateral position at the apical electrodes, which is consistent with other studies.[18,27]

Table 6: Acoustic reflex (AR) in electrode 11 with and without the stylet: cross tabulation

			AR11 with		Total
			No	Yes	
AR11 without	No	Count	7	0	7
		% of Total	23.3	.0	23.3
	Yes	Count	3	20	23
		% of Total	10.0	66.7	76.7
Total		**Count**	**10**	**20**	**30**
		% of Total	**33.3**	**66.7**	**100.0**

Note: P >0.05

This difference may be due to the larger diameter of the apical neurons,[28] the greater density of surviving neural fibres in the cochlear apex, or both.[29] Removal of the stylet also results in a deeper insertion of the electrodes because the inner circle path around the modiolus is shorter than the outer circle path around the lateral wall, so the same electrode length is able to reach further. Theoretically, this would lead to stimulation of a larger neural population along the apical electrodes. In this study, there was no significant difference between the AR thresholds in medial (modiolar hugging) and lateral positions at all location. However, Mens *et al.*[10] reported lower stapedius reflex thresholds in a modiolar hugging configuration. One point worth mentioning is that we usually turn the facial nerve monitor off after we finish the facial recess; therefore, stapedial reflexes secondary to direct facial nerve stimulation cannot be excluded completely.

A limitation of this study is its inability to ensure that the implant was inserted completely into the scala tympani and that removal of the stylet

Table 7: Acoustic reflex in electrode 16 with and without the stylet: cross tabulation

			AR16 with		Total
			No	Yes	
AR16 without	No	Count	10	0	10
		% of Total	33.3	.0	33.3
	Yes	Count	1	19	20
		% of Total	3.3	63.3	66.7
Total		**Count**	**11**	**19**	**30**
		% of Total	**36.7**	**63.3**	**100.0**

Note: P >0.05.

Table 8: Acoustic reflex in electrode 22 with and without the stylet: cross tabulation

			AR22 with		Total
			No	Yes	
AR22 without	No	Count	11	0	11
		% of Total	36.7	.0	36.7
	Yes	Count	2	17	19
		% of Total	6.7	56.7	63.3
Total		**Count**	**13**	**17**	**30**
		% of Total	**43.3**	**56.7**	**100.0**

Note: P >0.05.

Table 9: Comparison of acoustic reflex in different electrodes

Electrode	Stylet	Yes	No	Odds ratio	95% Confidence interval	
					Lower	Upper
1	With	11	19	0.15	0.04	0.56
	Without	10	20			
6	With	17	13	0.26	0.10	0.72
	Without	18	12			
11	With	20	10	0.30	0.12	0.77
	Without	23	7			
16	With	19	11	0.09	0.01	0.59
	Without	20	10			
22	With	17	13	0.15	0.04	0.55
	Without	19	11			

actually resulted in perimodiolar hugging because an electrode array that may penetrate the basilar membrane could become tethered by the osseous spiral lamina, preventing full coiling or close perimodiolar proximity.

One legitimate concern is that it is possible that sequential stimulation between the two conditions may affect the recordings, as there may be fatigue of the AR or evoked compound potentials after repeated stimulation. This is more likely to be an issue with the AR than with the evoked potentials because, in our experience, intraoperative AR and NRT recordings are usually very stable.

Although this study only shows a significant difference in thresholds at apical regions with stylus removal, the psychoacoustic and perceptual consequences of this warrant further study, and our results need to be confirmed with longer term follow-up in cases where the stylet was or was not removed to assess the effects of scarring or damage to structures such as the basilar membrane and spiral ligament.

Conclusion

According to the result of this study, removal of the stylet with the Nucleus Freedom® only results in a significant stimulation difference in the apical electrodes. We suggest this alternative technique in difficult cases and for new CI surgeons.

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CONFLICT OF INTEREST

The authors reported no conflict of interest.

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