

ORIGINAL ARTICLE

**Perimodiolar electrode position: Effects on thresholds, comfort levels, impedance measurements, and neural response telemetry**

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**OBJECTIVE:** This multicenter study describes the effects of perimodiolar electrode position on 50 adult patients (31 with an implanted Nucleus 24 Contour perimodiolar hugging electrode array [Cochlear Limited, Lane Cove, NSW, Australia] and 19 with an implanted straight electrode array) with a severe-to-profound sensorineural hearing loss.

**MATERIALS AND METHODS:** In all patients, intraoperative impedance measurements were performed; threshold levels (T-levels), comfort levels (C-levels), and dynamic range were measured 1 and 3 months after surgery; and a real-time 3-dimensional computed tomographic reconstruction was obtained to evaluate the insertion depth and perimodiolar placement of the electrode array.

**RESULTS:** Preliminary results showed that intraoperative electrically evoked compound action potentials (ECAPs) measured via neural response telemetry (NRT) correlated better with the behavioral C-levels in patients with a Nucleus Contour cochlear implant. T-levels for the apical electrodes were statistically significantly lower in patients with the perimodiolar electrode array than in patients with the straight electrode.

**CONCLUSION:** The insertion depth of the Nucleus Contour electrode array, which was positioned near the modiolus, was greater than that of the straight electrode array. Electrode impedances uncorrected for differences in electrode surface area were relatively higher in the Contour group than in the straight electrode group. T-levels for the Contour group were comparatively lower than those in the straight electrode group, although C-levels (except for those in apical channels) were not statistically significantly different between the groups. Preliminary results indicated that intraoperative ECAPs measured via NRT correlated better with the behavioral C-levels for patients with a Contour cochlear implant.

For a number of years it has been known that the position of an intracochlear electrode array is important in the electrical stimulation of residual nerve fibers within the cochlea. In their investigation of the influence of various intracochlear electrode positions in an animal study, Shepherd and colleagues<sup>(1)</sup> measured the electrically evoked auditory brainstem responses (ABRs) in 2 groups of animals: those with normal hearing and those that had long been deaf. Statistically significant reductions in electrical ABR thresholds were noted when the electrode was repositioned from the lateral wall of the toward the medial wall. Similar results from physiologic and modeling studies have also been published<sup>(2-4)</sup>, and it has been suggested that placing the electrode array as close as possible to the spiral ganglion cells would be of benefit.

A number of advantages may result from positioning the electrode contacts near the modiolar wall. That proximity may reduce required stimulation levels, which would in turn cause a decrease in T-levels and C-levels. Lower stimulation levels can result in lower power consumption<sup>(2)</sup> and may also improve spatial selectivity and speech perception.

The development of perimodiolar electrode arrays, which are easy and safe to implant, has been technically challenging. The perimodiolar Nucleus Contour array (Cochlear Limited, Lane Cove, NSW, Australia) preserves important attributes of previous Nucleus conventional straight arrays while providing functional advantages. The electrode array contains half-banded electrodes that occupy only the inner medial surface of the carrier and are proportionally spaced along the array to better match the cochlear frequency map<sup>(3)</sup> and improve speech understanding. The Contour electrode array occupies a relatively small proportion of the scala tympani volume and does not exert static force on intracochlear structures, a factor ultimately important for long-term safety. The proximity of the Contour electrode to the modiulus may result in lower and more selective stimulation, reduced channel interaction,

enlarged dynamic ranges, and reduced power consumption<sup>(5,6)</sup>.

Our study investigates the hypothesis that a Nucleus Contour<sup>(1)</sup> electrode array placed in the modiulus would reduce stimulation thresholds and impedance and improve the neural responses shown via NRT to a greater degree than would an electrode array placed along the outer wall of the. To examine this hypothesis, we evaluated and compared the psychophysical data and clinical outcomes of 2 groups of patients: those with a Nucleus 24 Contour perimodiolar hugging electrode array and those who received a straight electrode array version of either the Nucleus CI24M or the Nucleus CI24K.

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## PATIENTS AND METHODS

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Fifty adult patients from 4 cochlear implant clinics in Spain were included in the study. The subjects selected to undergo implantation met the following criteria: age of at least 18 years, bilateral severe-to-profound hearing loss, hearing loss of less than 15 years' duration, postlinguistic deafness, patency of the cochlea, absence of any cochlear malformation or ossification, and no evidence of a retrocochlear pathologic condition or a central component to hearing impairment.

The study was performed via repeated measurements in the subjects. Thirty-one patients received a Nucleus 24 Contour cochlear implant, and 19 patients received a Nucleus 24 M or Nucleus 24 K cochlear implant.

### **Evaluation of auditory function**

Preoperative assessment for cochlear implantation candidacy was performed with conventional test materials, including unaided pure tone audiometry at 500, 1000, 1500, 2000, 3000, 4000, and 6000 Hz for both ears and aided and unaided speech audiometric testing using standardized Spanish sentence and disyllabic word materials in quiet and in noise (right, left, and binaural conditions). In addition, objective evaluations such as the

ABR test and a complete medical evaluation were performed. All speech test materials were recorded on a compact disc, and testing was administered in a calibrated sound field at 70 dB SPL with patients seated at a distance of 1 m from the loudspeakers. Before the testing was begun, the patients were asked to adjust their hearing device controls as desired for comfortable listening. Postoperative speech perception was measured 1, 3, and 6 months after device activation.

### **Psychophysical measurements**

#### **Comfort and threshold levels**

Behavioral threshold levels (T-levels) and comfort levels (C-levels) were measured along the electrode array from the basal to the apical electrodes in all subjects. One unit of current level (CL) represented 10.2  $\mu$ A. The first programming session was conducted with the patient's preferred speech processor and coding strategy. Optimization of the patient's MAP continued over the next fortnight until a stable and complete MAP was obtained. Each patient's speech processors were programmed with 1 of 2 speech coding strategies: the ACE strategy (rate, 900 pps), a more flexible spectral maxima program that allows a maximum stimulation rate of up to 14,400 pulses, or the SPEAK strategy (stimulation rate, 250 pps per channel) <sup>(4)</sup>.

#### Electrode impedance

Intraoperative impedance measurements in common ground (CG), monopolar 1 (MP1), monopolar 2 (MP2), and monopolar 1+2 (MP1+2) modes were performed in all subjects. In patients with the Nucleus Contour array, those measurements were obtained after stylet removal. Postoperative impedance measures were obtained 1 and 3 months after implantation.

In a given electrode, the impedance is directly proportional to the radial distance and inversely proportional to the geometric surface area of the

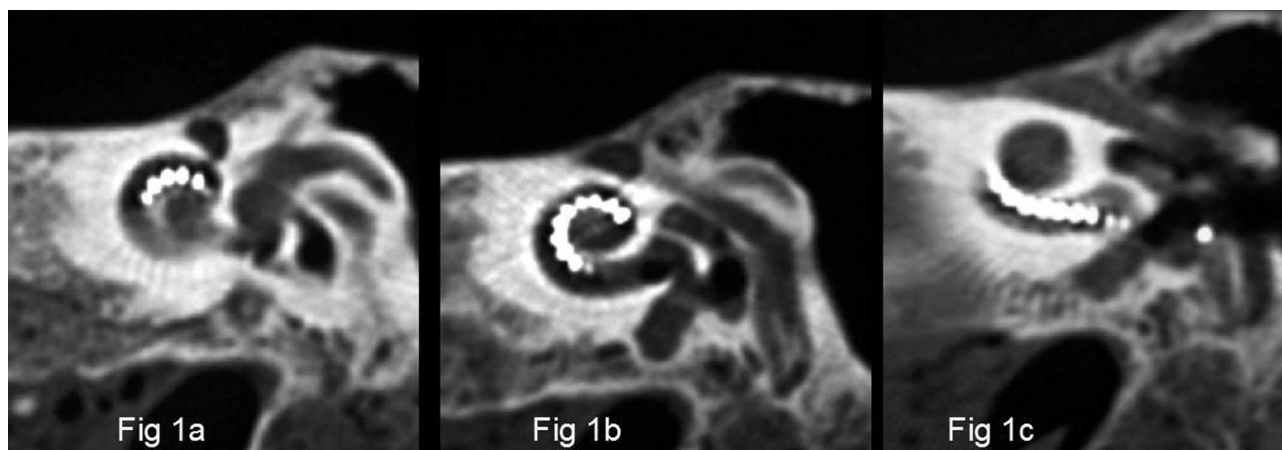
electrode. The Nucleus 24 Contour array has 22 half-band electrodes embedded along 15 mm of the silicone carrier. The half-banded pure-platinum electrode contacts occupy only the inner surface of the array, which is designed to be seated against the modiolar wall of the cochlea after insertion. Each electrode has a diameter ranging between 0.6 mm and 0.65 mm and a surface area ranging between 0.21 mm<sup>2</sup> and 0.23 mm<sup>2</sup>. The Nucleus straight electrode array has 22 full-banded active electrodes that are embedded along 17 mm of the silicone carrier. Each electrode band has a diameter ranging between 0.40 mm and 0.63 mm and a surface area ranging between 0.38 mm<sup>2</sup> and 0.59 mm<sup>2</sup> <sup>(5)</sup>. For that reason (and to eliminate the influence of the varying surface areas in both electrode arrays), the data were normalized to the area of the most basal electrode on the standard straight electrode array.

#### Image analysis

To evaluate the insertion depth and the perimodiolar placement of the electrode array in 10 patients in the Contour group and 10 patients in straight array group, high-resolution computed tomographic (HRCT) scans (Toshiba Medical Systems Corporation, Tokyo, Japan) were used. Fine 1-mm spiral acquisition axial and coronal scans were obtained, and 2-dimensional images were transferred to a workstation running a software package that generated a multiplanar analysis of the electrodes in the cochlea (Figure 1). Real-time 3-dimensional image and multiplanar (MPR) reconstructions were also obtained, as was a postoperative Stenvers view radiograph.

#### Neural response telemetry

Intraoperatively evoked compound action potential (ECAP) thresholds recorded via NRT were determined in 10 patients in the Contour group and 10 patients in the straight electrode array group. Those thresholds, which were referred to as T-NRTs, were compared



**Figure-1:** A computed tomographic scan showing the position of the perimodiolar electrode array.

with the C-levels and T-levels of the initial programming. Intraoperative NRT measurements were performed with NRT software versions 2.04 and 3.0 on odd-numbered recording electrodes.

#### Statistical analysis

Results are reported in descriptive statistics (means, SD) and were compared via the 2-tailed t test to determine whether statistically significant differences existed for each parameter in the study design. Data were entered into and analyzed via SPSS software (Statistical Package for the Social Sciences, version 11.0, SSPS Inc, Chicago, IL, USA).

In all tests, a P value of less than 0.05 was accepted as statistically significant.

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## RESULTS

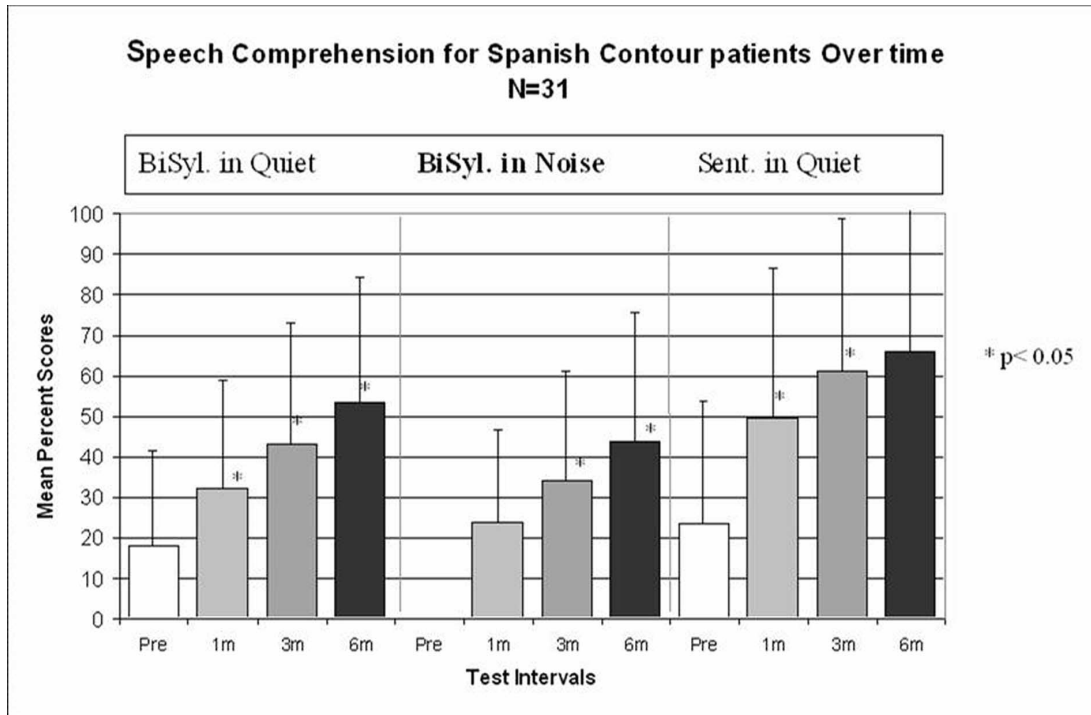
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The mean age at implantation was 51 years (SD, 14.0). The subjects consisted of 32 women and 18 men with a mean duration of severe-to-profound hearing loss of 7.4 years (SD, 4.1). No surgical complications developed in the subjects. All electrode arrays were fully inserted. Aided warble-tone thresholds

performed 1, 3, and 6 months after surgery consistently revealed thresholds between 30 and 40 dB SPL in the subjects.

#### **Open-set word and open-set sentence recognition**

A comparison of individual performance data 1, 3, and 6 months after switch-on revealed statistically significant improvements in word recognition on disyllabic words in quiet and noise and in the results of the sentence test in quiet in the Contour group. The mean score for disyllabic word recognition in quiet increased with statistical significance from 14% (SD, 8%) preoperatively to 42% (SD, 26%) 3 months after surgery. The mean score for disyllabic word recognition in noise increased with statistical significance from zero percent preoperatively to 36% (SD, 17%) 3 months after surgery. The mean correct score for Spanish sentence materials in quiet increased with statistical significance from 21% (SD, 6%) preoperatively to 62% (SD, 33%) 3 months after switch-on (Figure 2). No statistically significant differences were observed between the performance of the Contour group and that of the straight electrode group in any speech test<sup>(4)</sup>.



**Figure-2:** The results of a speech comprehension test for Spanish Contour patients over time (n = 31).

**Thresholds and comfort levels**

In both groups, T-levels and C-levels were determined 1 and 3 months after the activation of electrodes 3 to 22.

Results 1 month after activation

Mean C-levels at each electrode 1 month after activation showed no statistically significant effect with regard to electrode array type. C-levels ranged between 165 and 187 CL in the Contour group and between 168 and 196 CL in the straight electrode group. T-levels for the apical electrodes (3 through 6) 1 month after activation were statistically significantly lower in the Contour group than in the straight electrode group (P < .05).

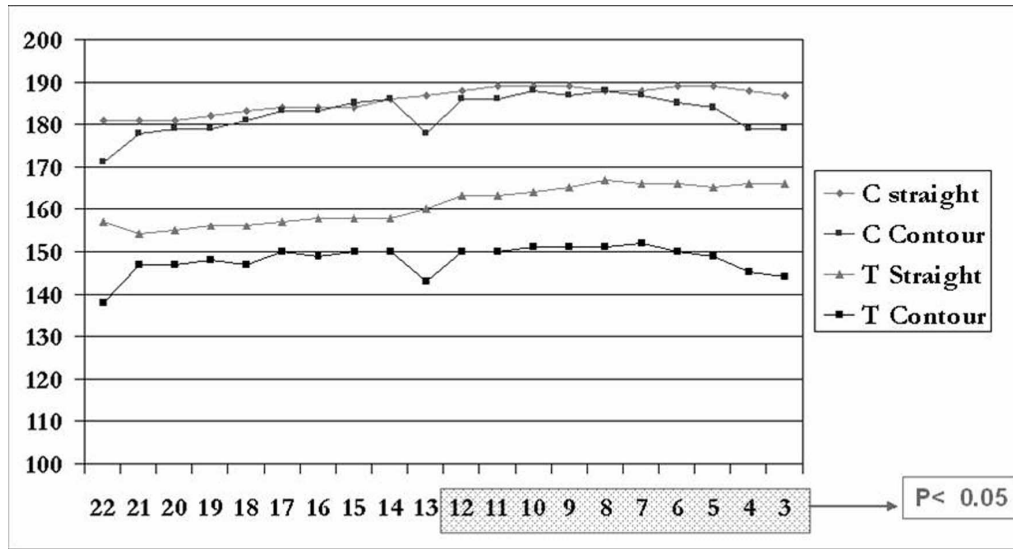
Results 3 months after activation

No statistically significant differences were observed between the patient groups for the C-levels measured 3 months after activation. C-levels ranged between 170

and 187 CL in the Contour group and between 180 and 192 CL in the straight electrode array group. The T-levels for the Contour group were statistically significantly lower than those for the straight array group (P < .05) for apical electrodes (3 through 12) 3 months after activation. No statistically significant difference between the groups was observed with regard to basal electrodes. T-levels ranged between 137 and 152 CL for the Contour group and between 154 and 168 CL for the straight electrode group. In comparison, the mean threshold in the Contour group was 12.8 CL lower than that in the straight electrode group 3 months after activation (Figure 3).

**Electrode impedance**

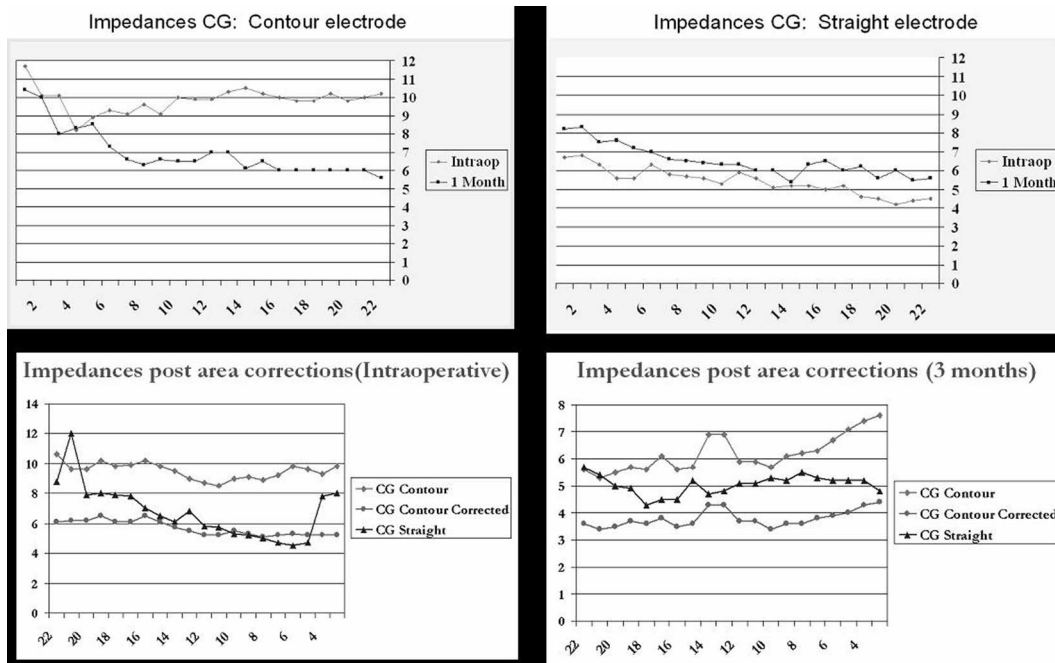
The main effects of electrode type and array type were analyzed with regard to corrected and uncorrected surface area data. It is of greater relevance to the investigation of the effect of radial distance upon impedance, however, to use area-corrected impedance values. The clinical impedance recorded intraoperatively



**Figure-3:** C-levels and T-levels with both types of electrode array.

was greater in the Contour group in than that in the straight electrode group. With regard to uncorrected impedance values, statistically significant differences were noted in the apical electrodes (electrodes 1 through 10) ( $P < .05$ ). However, when we considered the corrected values for electrode surface area versus impedance results, we found no statistically significant differences between the groups. Intraoperatively, the

clinical impedance for the Contour group varied between 8.1 kOhms and 11.2 kOhms. The corrected area impedance results varied from 5.2 kOhms to 6.4 kOhms. In the straight electrode group, the impedance varied from 4.3 kOhms to 10.1 kOhms (Figure 4). The outcomes in both groups were similar when the monopolar 1 or monopolar 2 mode was used.



**Figure-4:** Impedance in common ground for Contour and straight electrodes with electrode area corrections.

Three months after switch-on, the impedance values had decreased across all stimulated electrodes in the Contour group. The highest impedance values were found at the apical electrodes (from 1 through 7). No differences were observed in the straight electrode group. No statistically significant differences were found between the groups when clinical impedance was compared. The corrected impedance in the Contour group was lower than that in the straight electrode group, although that difference was without statistical significance (Figure 4).

### Image analysis

The Contour electrode was positioned near the modiolus at a uniform distance from the outer wall, and insertion was relatively deeper than that of the straight electrode. The mean insertion depths were 416 degrees (SD, 32) in the Contour array and 354 degrees (SD, 46) in the straight electrode. In Contour group subjects, the radial distances for the basal electrode region (electrodes 22 through 12) ranged from 0.3 to 0.8 mm. In the apical

electrode region (electrodes 13 through 1), the radial distances ranged from 0.0 to 0.4 mm (ie, closer to the modiolus). The radial distances in the straight electrode group ranged from 0.7 to 1.5 mm (Figure 5).

### Neural response telemetry

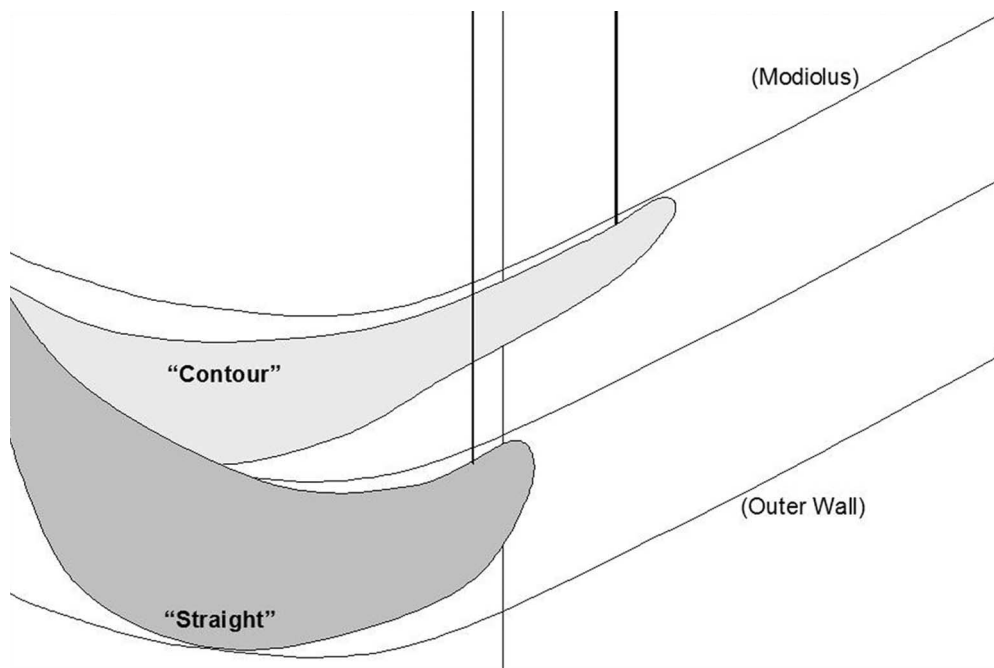
The T-NRTs correlated best with the behavioral C-levels in the Nucleus Contour group. The offset between the ECAP threshold and the C-level seemed to be more reliable in the Contour group than in the straight electrode group. The T-NRTs ranged between 166 and 178 CL units in the Contour group and between 172 and 186 CL units in the straight electrode group (Figure 6). No correlation was found between T-NRTs and the radial distance in either group.

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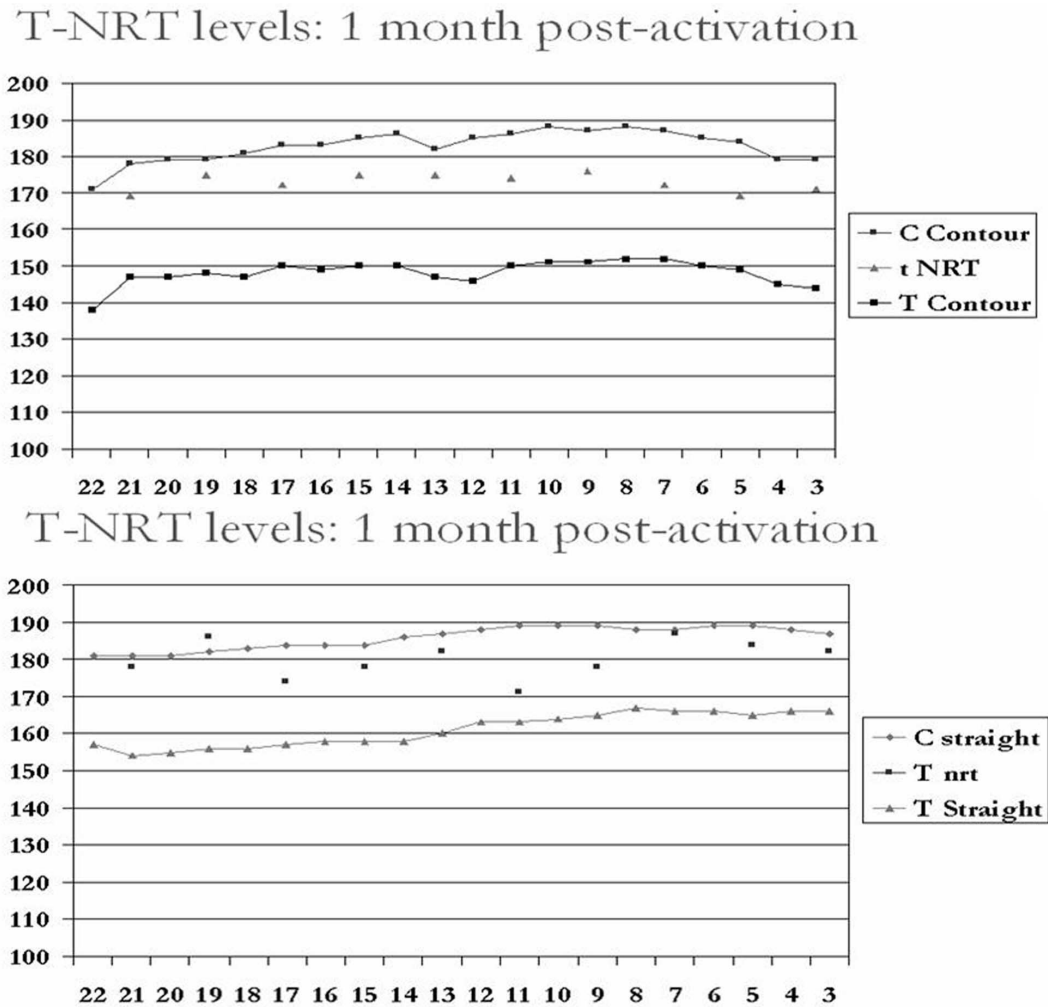
## DISCUSSION

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Our results suggest that the psychophysical behavior of 2 different Nucleus electrode designs (a perimodiolar half-banded electrode array and a straight full-banded



**Figure-5:** Comparison of the radial distance, the insertion depth, and perimodiolar position in Contour and straight electrodes.



**Figure-6:** T-NRT levels 1 month after activation in perimodiolar and straight electrode arrays. T-NRT, Intraoperatively evoked compound action potential thresholds recorded via neural response telemetry.

electrode array) differs. The perimodiolar half-banded electrode array Nucleus Contour has a passive positioning system that relies on the mechanical recoil properties of the precurved electrode array alone to find its final resting position in situ. This mechanism has been shown to reduce the potential for insertion-induced inner ear damage<sup>(7)</sup>.

The image analysis showed that the Contour electrode array was positioned near the modiolus, although that positioning was not uniform along the entire array. In our study, the apical part of the Contour

electrode array was very close to the modiolus (electrodes 1 to 12), but it separated from that structure in the basal area of the scala timpani. The design of the electrode array requires minimal restoring force when the stylet is removed; this prevents secondary damage to the modiolus wall and subsequent degeneration of the spiral ganglion cells. Among the new methods of stylet removal is the advance-off-stylet insertion technique, which involves simply pulling back the electrode array 1 to 1.5 mm after insertion; this ensures optimal positioning of the electrode array around the modiolus



wall in the basal turn area. The ability of the array to fold itself around the modiolus reduces the likelihood of basilar membrane perforation and intracochlear trauma.

Other authors have reported that electrode impedance increased when an electrode array was moved toward the modiolus wall<sup>(5)</sup>. Although the variation in the surface area of the electrodes along the array is one of the factors causing the differences in the straight electrode array group, the clinical importance of higher impedance is unknown. Some investigators have observed that other responses (stapedius reflex thresholds or ABRs) were lower in patients with a perimodiolar position of the electrode array than in those with<sup>(1,8)</sup>.

We noted statistically significantly higher electrode impedance in the Contour array group than in the straight electrode array group. The area-corrected impedance data from the Contour group suggested that impedance correlated negatively with the estimated radial distance from the modiolus for the apical electrodes (electrodes 1 to 10). For that reason, various factors (radial distance, geometric surface of the electrode contact, modifications in surgical manipulation, fibrous tissue growth) must be considered when electrode impedance is analyzed<sup>(9)</sup>. The results of our study revealed a trend toward higher impedance values in apical electrodes (ie, those shown intraoperatively to be closer to the modiolus wall). However, at the 3-month evaluation after switch-on, no statistically significant differences were found between the 2 electrode types. When the correction for surface area was applied, the impedances of the perimodiolar electrode array tended to be relatively lower than. We also noted that the T-levels for electrodes 12 to 1 (ie, the apical electrodes) correlated positively with the estimated radial distance of the electrodes from the modiolus. In our patients, lower T-levels were noted in the electrodes closest to the modiolus. In the basal electrodes, similar impedance values were noted in the straight electrode group and the Contour group, a finding consistent with the results of other studies<sup>(1,4)</sup>.

No statistically significant differences were noted among the C-levels in the groups studied. This finding suggests that the variations in C-levels may not be related solely to the radial distance. In our study, the dynamic range values were lower in patients with larger radial distances (ie, for patients in the straight electrode array group, along the length of the array; and for those in the Contour group, along the basal electrodes). The dynamic range was relatively higher in the apical electrodes in the Contour group.

As shown by Tykocinski and colleagues<sup>(5)</sup>, the progressive decrease in the mean T-levels and C-levels, as well as the slight increase in the dynamic range from the base to the apex in the straight electrode group, could be associated with the gradual reduction in the width of the scala timpani. This suggests the effect of positioning the straight electrode array in a perimodiolar position.

T-NRT values correlated better with the behavioral C-levels in the Contour group than with those in the straight electrode group. In addition, the offset between the ECAP threshold and the C-level seemed to be more reliable in the Contour group than in the straight electrode group. Although no correlation was found between T-NRTs and radial distances, other authors have suggested a pattern in the association between NRT responses and the perimodiolar position of the electrode array<sup>(8)</sup>.

In our study, then, the Contour electrode array was inserted more deeply than was the straight electrode array and was also positioned closer to the modiolus, primarily in the region of the apical electrodes (electrodes 12 through 1). The radial distance seemed to be at least 1 of the factors that affected the psychophysical outcome data in the study population. A shorter radial distance may result in lower T-levels, less impedance, and higher reliability of the offset between the ECAP threshold and the C-levels. Additional studies must be performed to assess the effects of the electrode position inside the cochlea, the psychophysical data from

the study subjects, and the results of performance measures.

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