Assessment of cochlear trauma and telemetry measures after cochlear implantation: A comparative study between Nucleus® CI512 and CI532 electrode arrays

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Abstract

The aim of this study was to compare the new Cochlear™ Nucleus® Profile with Slim Modiolar Electrode (CI532, Cochlear Ltd., Sidney, Australia) with the previous Contour Advance® (CI512) implant through postoperative residual hearing (RH) threshold shift and telemetry measurements as indirect measures of cochlear trauma. We compared 21 patients implanted with the CI532 and 20 patients implanted with the CI512, matching the 2 groups for age and for hearing loss etiology. All subjects received audiological pure tone average (PTA) calculation pre- and post-implant. Electrode impedance was measured, followed by AutoNRT® to measure and evaluate the Neural Response Telemetry (NRT™) thresholds. Telemetry recordings were made intraoperatively, one month after surgery and one month after activation. The NRT-Ratio was calculated to evaluate full scala tympani (ST) insertion. The results showed a higher number of patients with preserved measurable hearing with the CI532 (10/15; P>0.05) compared to the CI512 (5/14; P<0.05). A significant difference in post-operative low frequency PTA was observed between the two groups. There were no significant differences for telemetry measurements and NRT-Ratio evaluation of full ST insertion (CI512: 81%; CI532: 95%).

A significantly higher number of patients who preserved measurable hearing with the CI532, and a significantly higher post-operative low frequency PTA threshold compared with the CI512 confirmed better RH preservation and lower apical cochlear damage with the CI532. There was a high number of full ST insertions for both electrode arrays. Future studies should investigate the audiological effect of implantation in patients with higher levels of RH, correlating the results with the scalar position, to assess any lesser trauma of the CI532.

Introduction

Minimizing the trauma associated with Cochlear Implant (CI) surgery has become a fundamental concept in order to preserve residual hearing. CI indications now include patients with a greater degree of residual hearing and there is evidence that combined electric and acoustic stimulation improves the outcomes.1,2 Also in the case of electric-only stimulation, less trauma (e.g. residual hearing preservation) correlates with lower electric thresholds and better speech performances.3,4

Maintaining residual hearing is more common in patients with scala tympani (ST) insertions compared with those with electrode contacts in the scala vestibuli (SV).3 Consequently, better speech perception has been observed for electrodes residing entirely within the ST.6,7

For this reason, there has been a paradigm shift within the last decade toward the development of least-traumatic electrode designs and soft surgical techniques to improve CI outcomes.8 The impact of electrode design on intracochlear electrode location has been investigated, with lateral wall electrodes translocating into the SV less frequently than perimodiolar electrodes.5,9

As regards perimodiolar electrodes, the development of the Contour Advance® electrode CI512 (Cochlear Limited, Australia) improved intracochlear mechanical behaviour, reducing the chance of dislocation into the SV compared to the previous Contour Advance® Electrode.7 More recently, Cochlear Ltd developed a thinner, pre-curved electrode that is held straight prior to insertion by an external polymer sheath which is removed after full insertion of the array. The aims of this new Slim Modiolar electrode (CI532) were to improve the preservation of the intracochlea structures achieved by the Contour Advance®, to be even closer to the modiolus and to be reloadable into the inserter sheath to repeat the insertion, should this be necessary.

Key words: Cochlear implant; Cochlear trauma; Electrode array.

Contributions: the authors contributed equally.

Ethical statement: all procedures involved in this study comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the 964 Helsinki declaration and its later amendments or comparable ethical standards. All patients gave their informed consent. This article does not contain any studies with animals performed by any of the authors.

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Due to the close correlation between inter scalar electrode migration and post-operative residual hearing loss, Balkany et al. proposed the use of post implantation pure tone threshold shift as a surrogate marker for the prediction of acquired intracochlear trauma. A good prediction of electrode scalar position and distance from the modiolus can also be based on Neural Response Telemetry (NRT®) measurements. Our first experience with the new CI532 implant showed very good results in terms of hearing preservation and intra-operative measures.

This aim of this study was to compare CI512 and CI532 implants through the information obtained from postoperative residual hearing thresholds shift and telemetry measurements in order to verify whether there really was an improvement in terms of cochlear trauma.

Materials and Methods

Patient selection and audiological information

All procedures involved in this study comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All patients gave their informed consent. After institutional review board approval, we retrospectively reviewed a prospectively acquired database. A total of 41 adults with post-lingual deafness were included in this study. Twenty-one implanted subjects received a CI532 electrode array. A group of 20 adults, undergoing CI with the CI512 electrode array over a 7-year period (October 2009-May 2016), was selected by the clinical database; subjects were selected so that the CI512 and CI532 groups were matched for chronological age, gender, etiology and the degree of hearing loss. The following exclusion criteria were used: i) evidence of inner ear malformation on high-resolution computed tomography (CT) scan and magnetic resonance imaging (MRI); ii) neurodegenerative disorders; iii) syndromes associated with psychological, development or physical disorders; and iv) the evidence on CT and MRI of extensive ossification which could interfere with a total insertion of the multi-electrode.

All subjects received comprehensive preimplantation and postimplantation audiological evaluation including pure tone audiometry. For the study purpose we tested patients hearing level up to the maximal output level for each frequency through insert earphones (105 dB HL for 125 Hz, 115 dBHL for 250 Hz and 120 dB HL for 500, 1000 and 2000 Hz) disposable with our audiometer (Otometrics MADSEN Astera2). All patients were instructed to carefully differentiate auditory perception and vibrotactile sensation when they responded to pure tone testing. The presence of measurable hearing was defined as the presence of a clear auditory perception. A frequency pure-tone average (PTA) using the average threshold value, in dB HL, for 125, 250, 500, 1000 and 2000 Hertz was then calculated for each testing session. In the case that no measurable hearing could be detected, we use the value of the maximal output level for each frequency.

Surgery

The senior surgeon (DC) performed all surgeries included in the study. Surgical procedures were performed under general anesthesia. All devices were implanted using postauricular access through a limited mastoidectomy and facial recess approach. The receiver/stimulator was seated in a subperiosteal pocket. Although the CI532 implant electrode is compatible with both the round window and cochleostomy approaches, the round window (RW) approach was used for both devices. The RW membrane was incised or removed, checking the cochlea opening width, between 0.8-1.0mm for CI532 and 1.2-1.5 mm for CI512 implants.

The basic elements of atraumatic surgery were followed. Attempts were made to limit bone dust and blood from entering the cochlea; there was minimal or no suctioning of perilymph. Sixteen electrode arrays were slowly inserted with the Advance Off-Stylet® (AOS) technique for the CI512 and four without the AOS technique due to suspected cochlea obstruction, subsequently demonstrated not to be the case intraoperatively. All CI532 electrodes were inserted according to the manufacturer’s recommendations. Full insertion was achieved in all cases. Soft tissue was placed around the electrode to seal the insertion site.

Telemetry recordings

After complete insertion, telemetry recordings were made under sterile conditions in the operating room. Software-based impedance measurements (kOhm) were taken, followed by NRT® recordings (Current Level – CL). Cochlear’s Custom Sound® Suite 4.4 was used (AutoNRT® mode) to measure and evaluate the NRT® threshold (T-NRT). T-NRT was also measured one month after surgery (during CI activation) and one month after activation. The Impedances and T-NRT measurements were evaluated both electrode by electrode (average of all first electrodes, average of all second electrodes, average of all third electrodes, etc.) and globally as averages from the 1st electrode to the 22nd electrode. Finally, using the T-NRT measurements at one-month post-activation, the NRT-Ratios were obtained by dividing the average NRT value from electrodes 18 to 16 in the apical part with the average NRT value from electrodes 7 to 5 in the basal part of the electrode array, for all subjects in the CI532 group and for 16 CI512 group subjects in whom the AOS technique was used for electrode insertion.

Statistical analysis

Fisher’s exact test and two-tailed t-tests were used to compare categorical and continuous data, respectively. In order to verify the presence of a significant pre-post implantation residual hearing change and if such a change interacted with the type of implant (group CI532 vs CI512), the statistical Analysis of Variance (ANOVA) test, mixed for repeated measurements 2×2, was used.

Recorded residual hearing at various frequencies (125 Hz to 8000 Hz) was a continuous variable. Since the statistic test is used for repeated measurements, it was assessed whether the difference between the pre residues and the post residues moves away from a symmetric distribution, as the statistical analysis carried out (Analysis of the Variance) is especially sensitive to deviations from symmetry. To assess whether the number of subjects who maintained measurable hearing between pre and post implantation was greater in one group than in the other, the McNemar test was carried out.

The distributions of the impedance and Neural Response variables, related to the 22 electrodes, can be considered roughly normal, based on the asymmetry and kurtosis values, as well as visual inspection of histograms. Consequently, to compare the average values of the two Groups, CI512 and CI532, an independent t-test was conducted for both impedances and NRT®. In the case of positive asymmetry for any electrode, measurement was reduced through formula 1/(variable).

Finally, to check for a significant change from one month before the activation to one month after activation, both for impedance and NRT®, and whether this change interacted with the implant type (group CI532 vs CI512), the ANOVA test mixed for repeated measurements 2×2 was used. The level of statistical significance was set at P<0.01.
Results

Demographic data are shown in Table 1. The mean age at surgery was 60.1 years (sd standard deviation, s.d. 15.3) and 52.7 years (s.d. 17.4) respectively in the CI532 and CI512 patients.

Audiological results

Pre and post-operative PTA across frequencies and residual hearing for each group are shown in Table 1. There is a significant post-operative impairment of PTA in both groups. There was a statistically significantly difference (P<0.05) between the two groups in the post-operative period in the values of PTA (125, 250, 500 Hz). Statistical analysis for each frequency was carried out. Pure tone thresholds at 125 Hz worsened significantly after implantation (F=39.8; P<0.001); the threshold increase was constant for the group implanted with the CI532 and for the group implanted with the CI512 (F=2.4; P=n.s.), with no interaction between the operation (pre vs post) and the group (CI532 vs CI512). The same results were observed at 250 Hz, meaning significance for the operation, but not for the group interaction. The same was true for the 500, 1000, 2000, 4000 and 8000 Hz thresholds. Figure 1 shows pre and post-operative thresholds across frequencies for the CI512 and CI532 groups, together with the relative threshold shifts.

There were no differences in the number of subjects with residual hearing between the two groups either before or after the operation (Table 1), but the McNemar test showed that in the CI532 group, there was no significant change from measurable to non-measurable hearing, or from pre- to post-operative values (P=0.063); in fact, of the 15 cases measurable in the pre-operative period, only 5 (33.3%) mutated to non-measurable in the post-operative period. On the other hand, in the CI512 group the McNemar test showed a significant shift from measurable to non-measurable hearing after surgery (P=0.004); in fact, of 14 pre-operative measurable cases, 9 (64.3%) became non-measurable post-operatively (Figure 2).

Telemetry results

Intraoperative measurements

The average value of all 22 electrode impedances was significantly higher in the CI512 group (11.54 kOhm s.d. 3.71) than in the CI532 group (8.28 kOhm s.d. 1.85).

The electrodes were then categorized into positioning groups: BASAL (from 1st to 7th electrodes), MIDDLE (from 8th to 14th electrodes) and APICAL (from 15th to 22nd electrodes). Similarly, for all three groups, the average of the CI512 group was higher compared with the CI532 group (Table 2).

Finally, all t-tests performed to compare each electrode impedance (Figure 3A) in the two groups gave a significantly higher mean value in the CI512 group than in the CI532 group.

The average value of all 22 electrodes T-NRT was not significantly different among CI512 (181.21 s.d. 19.42) and CI532 implants (180.90 s.d. 16.77).

In none of the three positional groups were the average values of T-NRT significantly different in the CI512 and CI532 groups (Table 3).

None of the t-tests performed to compare single electrode T-NRT in the two groups (Figure 4A) showed significant differences

Table 1. Demographic and audiological data for the two study groups.

<table>
<thead>
<tr>
<th></th>
<th>CI512 (n=20)</th>
<th>CI532 (n=21)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender (M/F)</strong></td>
<td>11:9</td>
<td>10:11</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>Pre-operative residual hearing</strong></td>
<td>14</td>
<td>15</td>
<td>n.s.</td>
</tr>
<tr>
<td>PTA 125, 250, 500 Hz</td>
<td>92 s.d. 28</td>
<td>93 s.d. 26</td>
<td>n.s.</td>
</tr>
<tr>
<td>PTA 250, 500, 1000 Hz</td>
<td>100 s.d. 23</td>
<td>98 s.d. 23</td>
<td>n.s.</td>
</tr>
<tr>
<td>PTA 500, 1000, 2000 Hz</td>
<td>106 s.d. 22</td>
<td>101 s.d. 23</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>Post-operative residual hearing</strong></td>
<td>5</td>
<td>10</td>
<td>0.09</td>
</tr>
<tr>
<td>PTA 125, 250, 500 Hz</td>
<td>123 s.d. 12</td>
<td>112 s.d. 21</td>
<td>0.049</td>
</tr>
<tr>
<td>PTA 250, 500, 1000 Hz</td>
<td>124 s.d. 9</td>
<td>117 s.d. 15</td>
<td>0.08</td>
</tr>
<tr>
<td>PTA 500, 1000, 2000 Hz</td>
<td>125 s.d. 8</td>
<td>120 s.d. 12</td>
<td>0.13</td>
</tr>
</tbody>
</table>

PTA, pure tone average; s.d., standard deviation; n.s., not significant.
in their average values, except for electrode 21 (P=0.019) which showed a slightly higher average value for the CI512 group (188.50 s.d. 16.26) with respect to the CI532 group (156.43 s.d. 12.69).

Cochlear implant activation measurements

The average value of all 22 electrode impedances was no longer significantly different among CI512 (13.64 s.d. 1.20) and CI532 groups (13.50 s.d. 2.10). In both groups, impedances were significantly increased with respect to the intraoperative measurements.

In none of the three positional groups were the average values of impedances (Table 2) significantly different in the CI512 and

![Figure 2. Graphical representation of the McNemar test, showing the change after cochlear implant of previous measurable residual hearing in not measurable that is statistically significant only in the CI512 patients.](image)

Table 2. Impedance thresholds for electrode regions (Basal: 1-7; Middle: 8-14; Apical: 15-22; Global) over time in the two groups of patients.

<table>
<thead>
<tr>
<th>Impedance</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>CI512</td>
<td>10.50</td>
<td>3.34</td>
<td>15</td>
<td>0.017</td>
<td>13.66</td>
<td>1.38</td>
<td>16</td>
<td>n.s.</td>
<td>9.67</td>
<td>1.99</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>8.04</td>
<td>1.63</td>
<td>20</td>
<td></td>
<td>13.36</td>
<td>1.80</td>
<td>20</td>
<td></td>
<td>9.79</td>
<td>1.82</td>
<td>20</td>
</tr>
<tr>
<td>Middle</td>
<td>CI512</td>
<td>11.44</td>
<td>3.35</td>
<td>15</td>
<td>0.002</td>
<td>13.41</td>
<td>1.83</td>
<td>16</td>
<td>n.s.</td>
<td>8.59</td>
<td>1.49</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>8.07</td>
<td>1.71</td>
<td>20</td>
<td></td>
<td>13.27</td>
<td>2.35</td>
<td>20</td>
<td></td>
<td>8.85</td>
<td>1.62</td>
<td>20</td>
</tr>
<tr>
<td>Apical</td>
<td>CI512</td>
<td>12.54</td>
<td>3.39</td>
<td>15</td>
<td>0.001</td>
<td>13.65</td>
<td>1.98</td>
<td>16</td>
<td>n.s.</td>
<td>8.47</td>
<td>1.88</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>8.59</td>
<td>1.43</td>
<td>20</td>
<td></td>
<td>13.26</td>
<td>1.98</td>
<td>20</td>
<td></td>
<td>8.85</td>
<td>1.27</td>
<td>20</td>
</tr>
<tr>
<td>Global</td>
<td>CI512</td>
<td>11.54</td>
<td>3.11</td>
<td>15</td>
<td>0.001</td>
<td>13.65</td>
<td>1.20</td>
<td>16</td>
<td>n.s.</td>
<td>8.89</td>
<td>1.49</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>8.25</td>
<td>1.43</td>
<td>20</td>
<td></td>
<td>13.30</td>
<td>1.77</td>
<td>20</td>
<td></td>
<td>9.15</td>
<td>1.36</td>
<td>20</td>
</tr>
</tbody>
</table>

IntraOP, Intra-operative; 1M, 1 months post-surgery; 1M Post ACT, 1 month post activation; S.D., standard deviation; n.s., not significant.

Table 3. Neural Response Telemetry thresholds for electrode regions (Basal: 1-7; Middle: 8-14; Apical: 15-22; Global) over time in the two groups of patients.

<table>
<thead>
<tr>
<th>NRT</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>CI512</td>
<td>186.19</td>
<td>22.02</td>
<td>12</td>
<td>n.s.</td>
<td>162.94</td>
<td>11.96</td>
<td>15</td>
<td>n.s.</td>
<td>164.75</td>
<td>15.14</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>187.60</td>
<td>15.59</td>
<td>13</td>
<td></td>
<td>166.44</td>
<td>13.44</td>
<td>21</td>
<td></td>
<td>166.91</td>
<td>12.94</td>
<td>21</td>
</tr>
<tr>
<td>Middle</td>
<td>CI512</td>
<td>182.30</td>
<td>20.30</td>
<td>13</td>
<td>n.s.</td>
<td>173.88</td>
<td>16.88</td>
<td>16</td>
<td>n.s.</td>
<td>171.13</td>
<td>18.41</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>186.43</td>
<td>18.85</td>
<td>13</td>
<td></td>
<td>170.68</td>
<td>13.58</td>
<td>21</td>
<td></td>
<td>171.23</td>
<td>12.53</td>
<td>21</td>
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<tr>
<td>Apical</td>
<td>CI512</td>
<td>177.13</td>
<td>22.90</td>
<td>13</td>
<td>n.s.</td>
<td>163.10</td>
<td>15.74</td>
<td>16</td>
<td>n.s.</td>
<td>161.47</td>
<td>19.88</td>
<td>20</td>
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<tr>
<td></td>
<td>CI532</td>
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<td>13</td>
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<td>152.57</td>
<td>19.34</td>
<td>21</td>
<td></td>
<td>151.48</td>
<td>17.48</td>
<td>21</td>
</tr>
<tr>
<td>Global</td>
<td>CI512</td>
<td>181.19</td>
<td>19.39</td>
<td>13</td>
<td>n.s.</td>
<td>166.89</td>
<td>12.97</td>
<td>16</td>
<td>n.s.</td>
<td>165.46</td>
<td>15.09</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>CI532</td>
<td>180.91</td>
<td>16.73</td>
<td>13</td>
<td></td>
<td>162.94</td>
<td>13.82</td>
<td>21</td>
<td></td>
<td>163.00</td>
<td>11.87</td>
<td>21</td>
</tr>
</tbody>
</table>

NRT, Neural Response Telemetry; IntraOP, Intra-operative; 1M, 1 months post-surgery; 1M Post ACT, 1 month post activation; S.D., standard deviation; n.s., not significant.
CI532 groups. Impedances were significantly increased in all cases except for the CI512 middle and apical positions.

None of the t-tests performed to compare single electrode impedances in the two groups (Figure 3B) showed significant differences, with the exception of electrode 22 (P=0.029) which showed a slightly higher average value for group CI512 (14.90 s.d. 2.59) compared with group CI532 (12.70 s.d. 3.14).

The average value of all 22 electrodes T-NRT was not significantly different among CI512 (166.89 s.d. 12.96) and CI532 groups (162.94 s.d. 13.82). In both cases, T-NRT values were significantly lower than intraoperative measurements.

In none of the three positional groups were the average values of T-NRT significantly different in the CI512 and CI532 groups (Table 3). In each case, there was a significant reduction of T-NRT compared to intraoperative measurements.

None of the t-tests performed to compare single electrode T-
NRT in the two groups (Figure 4B) showed significant difference of their average values, except for electrode 21 (P=0.01) which showed a higher average value for the CI512 group with respect to group CI532.

One-month post-activation measurements

The average value of all 22 electrode impedances was not significantly different among CI512 (8.89 ± 1.48) and CI532 groups (9.51 ± 2.11). In both groups, impedances were significantly decreased with respect to the CI activation measurements.

With regard to the positional group of impedances (Table 2), a statistically significant reduction was obtained from CI activation to one month after in basal (F=165.3; P<0.001), middle (F=185.0; P<0.001) and apical (F=203.4; P<0.001) regions. This decrease did not interact with the electrode type, the difference being similar in the CI512 and CI532 groups.

Figure 4. Neural Response Telemetry® threshold measurements for each electrode in the two groups of patients. (A) Intra-operative measurements. (B) At cochlear implant activation. (C) One month post-activation.
T-tests to compare single electrode impedances in the two groups (Figure 3C) did not show significantly different average values between CI512 and CI532 groups. The average value of all 22 electrodes T-NRT was not significantly different among CI512 (165.45 s.d. 15.09) and CI532 groups (163 s.d. 11.86). In both cases, T-NRT values were similar to the CI activation measurements.

With regard to the positional group of T-NRT, no statistically significant difference was detected between CI activation and one month after measurements in basal, middle and apical regions. This T-NRT level maintenance did not interact with the electrode type, the difference being similar in the CI512 and CI532 groups (Table 3).

None of the t-tests performed to compare each electrode T-NRT in the two groups (Figure 4C) showed significant differences of their average values.

With regard to the NRT-Ratio, the number of subjects below 1.05 (meaning high probability of full insertion of the electrode array in the ST) was 13/16 (81%) for the CI512 group and 20/21 (95%) for the CI532 group, with no statistically significant difference between them ($\chi^2$=1.84, $P=0.1746$).

Discussion

There are a few studies in the literature comparing the newly introduced Cochlear\textsuperscript{19} electrode array CI532 with the immediately previous model CI512 in terms of post-operative hearing preservation and telemetry CI functionality measurement.

The main findings from this study are the following: i) a significant difference between CI512 and CI532 for the low frequencies in pre/post-operative audiometric thresholds; ii) a significantly higher number of subjects with measurable hearing in the CI532 group after the operation; iii) significantly lower electrode impedances for the CI532 than the CI512 array during the intraoperative measurement; iv) increasing of electrode impedances one month after the operation (but not in the middle and apical part of CI532) and decreasing of them one month after CI activation with no differences between the two types of electrodes; v) comparable T-NRT between CI512 and CI532 in each considered measurement, with a similar T-NRT decrease one month after the operation for both the electrodes; vi) high percentage of electrode array with full insertion in the ST for both groups (81% for CI512; 95% for CI532), with no statistically significant difference between them.

The following discussion aims to analyze the clinical and physiological implication of these findings.

Due to the direct correlation between the intracochlear trauma during surgical electrode insertion and the impairment of acoustic residual hearing, the audiometric hearing threshold shift after the operation is currently considered as a reliable marker of electrode harmfulness on cochlear structures.\textsuperscript{10}

Given this consideration, according to the result of the residual hearing threshold shift obtained in this study after the implantation in the two groups, CI532 arrays can be considered less traumatic than CI512 arrays. However, this result is limited by the high preoperative threshold of residual hearing that may hide a higher loss of residual hearing in the CI512 group. In this sense, although not highly significant, the lower degree of residual hearing decrease especially in the low frequencies together with the lower number of subjects in which measurable hearing is lost after the operation could be due to the more limited trauma of the CI532 on cochlear structures especially of the apical region, helped by a thinner array (CI512: 0.8 mm in the basal region to 0.4 mm at the tip; CI532: 0.47 mm in the basal region to 0.35 at the tip).

This consideration is in agreement with previous studies regarding the traumatism of individual electrodes. The CI512 array can lead to an average sensorineural hearing level drop of 25 dB or more and total hearing loss in some cases,\textsuperscript{14} which means a possibility of SV dislocation in 28% of cases.\textsuperscript{7} The only study conducted on the cochlear position of the experimental version of the CI532 electrode shows a ST insertion in 100% of cases.\textsuperscript{15} The analysis of the outcomes in our consecutive series of patients in whom the CI532 was implanted showed a shift lower than 10 dB HL in post-operative PTA, and a good tympanic scalar location\textsuperscript{12} predicted with NRT-ratio measurements.\textsuperscript{13} The lower postoperative threshold shift reported in our previous experience with the CI532 can be explained by the higher overall preoperative PTA in our whole CI532 patient sample, while for the purpose of this study, only patients with lower preoperative PTA, in order to be homogeneous with that of CI512 patients, were included. Despite this limitation, this study too seems to confirm more limited damage of the apical cochlea with the CI532. This is important since low frequencies are commonly more represented in the presence of residual hearing, and those which can be well exploited by an electro-acoustic strategy in the case of satisfactory hearing preservation.

Further studies are required to confirm these results, comparing the CI512 and CI532 electrode audiometric shift in patients with better pre-operative residual hearing, with reference to the radiological evaluation of the post-operative scalar position of the two electrodes and correlating these results with subsequent speech recognition outcomes.

Measurement of electrode impedance provides an indication of the electrodes’ integrity, revealing the status of the electrode-tissue interface. Initial changes in electrode impedance may be expected prior to electrical stimulation due to morphological changes at the electrode-tissue interfaces. Change is related to the resistance characteristics of fluid and tissue that involve the electrode chain.\textsuperscript{16} In this study, intraoperative electrode impedance showed significantly higher values in the CI512 group. This may suggest an initially smaller surface area between the electrode and cochlear liquid for the CI512 and consequently higher electrode impedance despite its larger physical size.

Measurements showed increased values at the initial stimulation check-up compared with those obtained intra-operatively, but not for the CI532 middle and apical regions. Typically, the electrode array is not stimulated for one month after implantation. During that time, fibrous tissue may encapsulate the electrode array and new bone growth can occur, which directly affects the access resistance component of the overall impedance. This probably accounts for the increase in electrode impedance between the intra-operative measurement and the time of activation.\textsuperscript{17} The very slim dimension of the CI532 would limit this process for its terminal part.

We also found that impedance values decreased between the initial stimulation and one month after measurement. The initial stimulation resulted in the formation of a hydride layer on the surface of the electrode, which essentially creates a rougher, uneven surface, resulting in increased surface area.\textsuperscript{16} This is in agreement with previous similar studies.\textsuperscript{18,19}

The T-NRT is the clinical parameter of most interest in the evaluation of the electrically elicited compound action potential (ECAP). An objective measure of a patient’s response to electrical stimulation obtained through NRT\textsuperscript{9} can provide information about the integrity of the patient’s auditory system, the functionality of the implanted device, and the location of the CI electrode array.

In relation to the modular distance of the array, lower T-NRT levels have been observed when the electrode is closer to the modiolus,\textsuperscript{20} for example after the internal stylet removal when a CI512 is implanted without the Advance-off technique.\textsuperscript{21}

The absence of significant differences in the T-NRT values...
between the CI512 and CI532 in every region of the array measured at different times suggests a similar distance from the modiolus in the electrode’s final position, according to McJunkin et al. The possibility of scala change position of the electrode can be presumed when the T-NRT values of the apical region are higher than those from the basal region. In this study, the results of NRT-Ratio (one-month post-activation) in the CI512 group (with AOS technique insertion) show that full insertion in the ST of the electrode array was achieved in 81% (13/16) of patients. This is slightly lower compared to the results of Mittman et al. (94%: 29/31), but there was no statistically significant difference between them (χ²=2.15, P=0.1426). The NRT-Ratio of the CI512 group (with AOS technique insertion) is lower compared with the NRT-Ratio of the CI532 group (95%; 20/21), but without statistically significant difference; this assumes that the two electrode arrays are equivalent as regards good tympanic scale positioning, provided that the array of the CI512 is inserted by AOS technique.

Similarly to previous investigations of ECAP thresholds in the CI512 patients, the T-NRT values recorded in our study were similarly lower at the time of initial stimulation than those recorded intra-operatively in both electrodes. Moreover, between the intra-operative and initial stimulation check-up values, electrode impedance in both subject groups increased whereas ECAP thresholds decreased. This inverse relationship between electrode impedance and ECAP measurements at early examinations suggests there may be a common underling mechanism affecting each of these measurements in a different way. These changes may reflect the physical changes that are probably taking place in the cochlea during this period.

However, subsequent electrical stimulation also differently affects impedances (which decrease again) and T-NRT (which remain the same) in both electrode types. This heterogeneous temporal pattern of telemetry values confirms that impedances and T-NRT values do not have a direct correlation, but there may be different variables differently affecting their values. For example, the synchronal recruitment of a progressively higher number of spiral ganglion cells induced by the electric stimulation could reduce T-NRT values regardless of impedances. However, these inner cochlear electrical events do not seem to be conditioned by the different three-dimensional features of the two electrodes studied.

Conclusions

This study shows a statistically significantly higher number of patients who preserved measurable hearing with the CI532, even with a significantly higher post-operative low frequency PTA threshold compared with the CI512. These results seem to confirm less cochlear damage with the CI532, especially in the apical part. The results did show a good rate of complete positioning in the ST for the CI512 inserted with Advanced-off Stylet technique and for the CI532. The NRT-Ratio measurements did not show significant differences. Future studies should investigate the audiological effect of implantation with both electrodes in patients with higher levels of residual hearing, correlating the results with the radiological findings of scala position, to assess any lesser traumaticity of the CI532 compared with its previous generation array.

References

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