Effect of Proximity to the Modiolus for the Cochlear CI532 Slim Modiolar Electrode Array on Evoked Compound Action Potentials and Programming Levels

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Abstract
Background: The first surgeries with CI532 showed an effect of the proximity of the electrode to the modiolus on the Evoked Compound Action Potentials (ECAPs). Objectives: Objectives of the study were to investigate the effect of the “pullback” procedure on intraoperative ECAP responses in three different electrode array positions and additionally to compare behavioral thresholds with the thresholds obtained in a group of patients using the standard insertion. The hypothesis of this study is that pullback will cause lower ECAPs and behavioral thresholds. Patients: The study included 40 patients, 20 in the pullback insertion group and 20 in the standard insertion group (without pullback). Method: During insertion of the CI532 electrode array, ECAP was performed in three different positions for the pullback group: at initial insertion, at over-insertion, and after pullback. Insertion was monitored by fluoroscopy. In the standard group, ECAP was performed at the initial position, which is also the final position. ECAP thresholds (T-ECAPs) were compared within subjects at the initial and the final position in the pullback group and between groups in the final positions of the pullback and standard groups. Programming levels (C- and T-levels) were compared between the two groups 1 year after switch-on. Results: Intraoperative measurements pullback showed lower average T-ECAPs after pullback compared to thresholds in initial position. Comparison of intraoperative T-ECAPs at the final positions showed no statistically significant difference between the pullback group and the standard insertion group. Furthermore, 1 year after switch-on there was no statistically significant difference in C- and T-levels between the two groups. Conclusion: The pullback maneuver of the CI532 electrode array after an over-insertion gave significantly lower T-ECAPs compared to the thresholds at the initial position. However, the between-groups analysis of pullback and standard insertion showed neither significantly different T-ECAPs nor different programming levels. Because T-ECAPs and programming levels vary considerably between subjects, large groups are required to detect differences between groups. Additionally, the effect pullback technique to preserving the residual hearing is not known yet.
Introduction

Cochlear implantation is the golden standard of treatment for patients with severe to profound hearing loss. Development of the electrode array is one focus of innovation of CIs. Perimodiolar electrodes were introduced in the late 1990s [Gibson and Boyd, 2016]. In 2016, Cochlear Ltd. introduced a thin precurved perimodiolar electrode, the CI532, aiming for a close-to-modiuli position, minimal insertion trauma, and stable scala tympani position [Risi, 2018]. Compared to the perimodiolar electrode Contour Advance/CI512, the volume of the CI532 electrode array is 60% reduced [Ramos-Macias et al., 2017]. Ramos de Miguel et al. [2018] showed that CI532 has a better (closer) perimodiolar position than both the CI512 and the Slim Straight CI522.

Compared to lateral wall electrodes, perimodiolar electrodes are situated closer to the target spiral ganglion cells, leading to lower current levels (CLs) required to produce a behavioral threshold [Saunders et al., 2002; Gibson and Boyd, 2016; Hey et al., 2019]. In addition, reducing the distance may provide better place-pitch spectral discrimination, resulting in improved speech perception outcome. In a prospective study with 114 postlingually deaf adults, Holden et al. [2013] identified a number of factors that correlated with outcome. Among other factors such as age at implantation and duration of hearing loss, positioning of the electrode closer to the modiolus wall positively correlated with outcome, as measured by monosyllable word recognition scores. Other authors reported as well an pitch to place improvement especially in the basal turn [Basta et al., 2010].

Although perimodiolar electrodes were developed to improve stimulation of specific neural populations and to decrease power consumption, they can cause damage to the cochlear structures [Jeong et al., 2015]. Presumably, the stylet-free insertion and the reduced bulk and stiffness of the CI532 electrode can reduce the risk of scalar translocation and intracochlear structural damage [Aschen dorff et al., 2017; Risi, 2018; Shaul et al., 2018]. Shaul et al. [2020] reported that out of 120 CI532 implantation just one was placed in the scala vestibuli, all the others fully in the scala tympani.

To reduce the distance between the electrode contacts and the modiolus, a surgical technique called “pullback” can be used [Basta et al., 2010]. In 2005, Todt et al. [2005] found that the spread of excitation (SOE) was sharper on average. The impedances remained unchanged. For SOE measurements, the Evoked Compound Action Potentials (ECAPs) are measured at different electrodes, where the probe stimulus pulses were presented at a (fixed) electrode of interest, while the electrode that presented the masker varied along the electrode array [van Weert et al., 2005]. Riemann et al. [2019] did a temporal bone study with the CI532 and showed that the pullback technique brings the electrode closer to the modiolus compared to a nonpullback method, both times with marker I (Fig. 1a) visible in the round window. A study from van Weert et al. [2005] investigated the difference before and after stylet removal of a perimodiolar electrode array and found that removal resulted in an increased SOE sharpness and that the array came closer to the modiolus. The benefits of lower behavioral thresholds and large ECAP amplitudes have been investigated, which tend to have higher speech perception scores [DeVries et al., 2016]. The same research group investigated in a later study that CT-estimated electrode positions support the hypothesis that electrodes farther from the modiolus tend to have higher behavioral thresholds [DeVries and Arenberg, 2018]. Another study pointed out, that, at least for monopolar stimulation, behavioral threshold detection and ECAP measures were dependent on medial-lateral electrode location [Schwartz-Leyzac et al., 2020].

Given the large variability of intraoperative ECAP thresholds (T-ECAPs) across subjects, measures of intraoperative T-ECAPs in different electrode array positions during the insertion of the electrode will reduce the effect of subject variability and it will require fewer subjects to detect significant differences. The pullback technique is dependent on the flexibility of the electrode array since the latest arrays getting thinner and thinner other effects of pullback outcome may can be measured. The aim of the current study was to investigate T-ECAPs at different positions during electrode array insertions which include the pullback technique. The three positions investigated were the initial position (marker I), over-inserted position (marker III), and pullback position (marker II). The initial position (marker I) corresponds to the electrode array position used in standard electrode insertion. Hence, comparing T-ECAPs at the initial (standard) and the pullback position will provide useful information. In addition, a group of patients with standard electrode insertion was compared with the pullback group both regarding intraoperative T-ECAP and T- and C-levels 1 year postoperatively.

Materials and Methods

Patients

Forty adult patients meeting auditory and medical indications for CI received a CI532 between December 2015 and September 2017. The surgeries were performed by four experienced surgeons.
Exclusion criteria were cochlear anomalies as shown on CT and/or MRI, previous ear surgeries, and auditory neuropathy spectrum disorder (see Table 1 for patient characteristics). The patient selection for each group (pullback or standard) was random.

The study was in accordance with the internal regulations at Oslo University Hospital and approved by the Regional Committee for Medical and Health Research Ethics (Reference number: 2017/1839). All patients gave their written informed consent to participate in the study.

Surgery
Following a standard mastoidectomy and posterior tympanotomy, the overhang of the round window was removed and the round window membrane was exposed and opened. A ventral extension of the round window was needed in the majority of cases to achieve an insertion along the direction of the scala tympani in the basal turn. The CI532 electrode array with sheath was inserted into the scala tympani until the sheath stopper reached the round window. The sheath handle was stabilized using straight forceps.

Fig. 1. a The CI532 electrode array (picture with courtesy of Cochlear) with the different markers I, II, and III situated in the round window. b Example fluoroscopy images in the three different positions. Marker I (left) is a standard insertion (initial), marker III (middle) is an over-insertion, which in this case caused a deeper insertion of approximately one electrode contact. After a pullback maneuver to marker II (right), the tip stays in place while the electrode array approaches the medial wall. The projected distance between electrode contact 22–16 was measured as illustrated with the straight lines in the images.

Table 1. Patient characteristics

|                | Pullback (n = 20) | Standard (n = 20) |
|----------------|------------------|------------------|
| Gender, n (female: male) | 9:11             | 11:9             |
| Age (mean, SD), years     | 58.6, 13         | 52.9, 18         |
| Surgery type, n (CI1:CI2) | 13:7             | 14:6             |
| Etiology, n               |                  |                  |
| Unknown                   | 10               | 7                |
| Meniere                   | 2                | 2                |
| Usher                     | 1                |                  |
| Familiar/genetic          | 5                | 6                |
| Otosclerosis              | 2                |                  |
| Meningitis                |                  | 1                |
| Trauma                    | 3                |                  |
| Rubella                   |                  | 1                |

CI1, first CI; CI2, sequential contralateral CI.
while the electrode was advanced slowly into the cochlea until the white marker reached the sheath marker. The sheath was then smoothly withdrawn straight back along the axis of the electrode until completely removed [Ramos-Macias et al., 2017], while keeping the array stationary. The electrode has three white markers to control insertion depth (Fig. 1a). The pullback technique for the CI532 means that the electrode is inserted to marker I at the round window level (initial insertion), then advanced to marker III at the window level (over-insertion), and subsequently pulled back (pullback) until marker II is seen at the round window level.

The effect of the pullback procedure was observed in real time by a radiograph and an audiologist on the fluoroscopy display. They informed the surgeon about the electrode movements. The surgeon must focus on the round window while performing the pullback, so this feedback is necessary to avoid backward motion of the electrode tip. When no further pullback was possible without moving the electrode array tip, the surgeon was informed to stop. Figure 1b shows examples of fluoroscopy images in the three different electrode positions.

The standard insertion of the CI532 followed the same surgical procedure, but included only the initial insertion, with a final position of marker I or II at the round window level. Surgeries of the pullback group were carried out with fluoroscopy during CI surgery in a hybrid operation room at the Oslo University Hospital Intervention Centre. The average X-ray exposure measured was 0.1 mSv, which is considered to be low and with no risk for the patient. Surgeries of the standard (no pullback) group were performed in an ordinary operation room.

**Intraoperative ECAP**

The ECAP measurements were obtained using the AutoNRT function of the Cochlear Custom Sound 5 software with standard settings. Electrode conditioning was done at 230 CL with a pulse width of 25 μs. The maximum stimulation level was 255 CL and the number of averaged sweeps per measured response was 35. The T-ECAPs were estimated from the ECAP responses using the standard Custom Sound 5 extrapolation scheme.

The pullback procedure included T-ECAP measurements at all electrode contacts, with the electrode array in three positions: (1) initial insertion with marker I at the round window, (2) over-insertion with marker III at the round window, and finally (3) the electrode pulled back to marker II/marker at the round window, aiming for closer proximity to modiolus (Fig. 1). The standard procedure included measurement of T-ECAP on all electrode contacts after insertion, with marker I and marker II at the round window.

**Projected Distances in Fluoroscopy Images**

In addition to the fluoroscopy real-time observation of the electrode insertions in the pullback group, three fluoroscopy still images from the three different positions of the electrode array were analyzed postoperatively. The images were compared in terms of projected distance between electrode contact 22 and 16 (see Fig. 1). The projected distance is the two-dimensional projection of a three-dimensional structure, as described by various authors, and their method has been used to measure between two electrode contacts [Cohen et al., 1996; Kawano et al., 1996; Xu et al., 2000; Escude et al., 2006]. The distance between electrode contact 22 and 16 was chosen to represent the proximity to the modiolus, with less distance indicating closer proximity to modiolus. Different electrode combinations were investigated, but 22–16 illustrated the pullback effect best. The difference between the projected distance in the initial and pullback positions was calculated.

**Programming Levels**

Four to 6 weeks after surgery, the patients returned for sound switch-on with the latest processor available at the time, Nucleus 6® (n = 29), Kanso® (n = 4), or Nucleus 7® (n = 7). The switch-on lasted for 2–3 days with appointments twice a day, followed by appointments at 3 months and 1 year post-switch-on. All patients could make appointments on demand in between if needed. Impedances, T- and C-levels, and AutoNRT on all electrodes were carried out, if possible both at switch-on and the two follow-up appointments. C- and T-levels were determined by psychophysical loudness scaling [Wolfe and Schafer, 2014]. For C-levels, the loudness was increased until “loud,” but not “too loud” was reached. For T-level determination, the top-down approach was used; T-levels were decreased to the lowest audible level of electrical stimulation. For statistical analysis, the 1-year programming levels were used because they reflect a more stable situation than the switch-on data.

The analysis of data from the programming levels (C and T) revealed that some patients required an increase of the pulse width during switch-on or follow-up sessions, from 25 μs to 37 μs (10 patients) or 50 μs (1 patient). Since this influences the results if the CLs are compared, recalculation into charge levels was required, using the following formula:

\[
I = 175 \times 100^{\frac{CL}{20}} \mu\text{A}.
\]

\[Q = I \times \text{pulse width}.\]

Where \(I\) is the current in units of μA and \(Q\) is charge. Charge levels were not used for programming. Therefore, a conversion model was used, where the charge levels were calculated and converted back to equivalent CLs corresponding to a standard pulse width of 25 μs, which was used for the statistical analysis.

**Analysis**

Paired sample \(t\) tests were conducted to compare T-ECAPs in two different electrode positions within the pullback group. Independent samples \(t\) tests were conducted to compare T-ECAP, C-levels, and T-levels for measured electrode contacts between groups. A two-tailed \(p\) value less than 0.05 was considered as an indicator of a statistically significant result. The statistical analyses were carried out using IBM SPSS v. 26.

**Results**

**Within-Subjects Variance of T-ECAP in Marker Position I, II, and III**

The mean thresholds of the ECAP measurements per electrode in the pullback group are shown in Figure 2 for three electrode array positions (initial, over-insertion, pullback). Three participants had no measurement from the over-inserted position.
The mean threshold of ECAP across patients was 181 CL (SD = 9) in the initial position and 174 CL (SD = 0) in the pullback (final) position. The mean difference was statistically significant ($p = 0.02$, $n = 17$).

T-ECAPs in the mid-frequency region were lower in the final electrode array position after pullback compared to the initially inserted (marker I) and over-inserted (marker III) positions. A paired sample $t$ test for T-ECAP at marker I and II showed significant differences for electrode contacts 14 ($p = 0.031$), 13 ($p = 0.033$), 11 ($p = 0.01$), 8 ($p = 0.05$), 6 ($p = 0.033$), 4 ($p = 0.045$), and 2 ($p = 0.036$). The mean differences were 9.8, 11.5, 4.1, 10.8, 12.1, 7.6, and 8.9 CL, respectively. The analysis did not show significantly different T-ECAP paired means for electrode contacts 22, 20, 18, 16, 12.

Differences in projected distance between electrode contact 22 and 16 are shown as a boxplot in Figure 3, with the exact values superimposed. The mean difference shows a reduction of distance by 0.51 mm from initial insertion to the pullback position. The variations range from no variation (or more exactly an increase of −0.06) to maximum 2.37 mm.

Comparison of T-ECAP and Programming Levels between Pullback and Standard Procedure

The mean thresholds of the final intraoperative ECAPs for the pullback and the standard group are shown in Figure 4. The standard group shows higher T-ECAPs across the whole electrode array, but this difference is not statistically significant for any of the electrode contacts. The mean T-ECAP across patients was 182 CL (SD = 18) in the standard group and 174 CL (SD = 10) in the pullback group. The difference was not statistically significant ($p = 0.945$).

Postoperative Programming and Measurements

The mean T- and C-levels per electrode for the standard and pullback groups are shown in Figure 5. After 1 year of using the CI, the mean T-level across subjects was 121 CL (SD = 20) in the standard surgical group and 113 CL (SD = 22) in the pullback groups. The mean C-levels were 184 and 182, respectively, for the standard group and the pullback group. The mean differences between the standard and pullback groups were statistically not significant regarding T-levels ($p = 0.207$) and C-levels ($p = 0.774$).

Discussion

The pullback technique has previously been described in patients with Advanced Bionics [Todt et al., 2008; Bastta et al., 2010] and Cochlear devices [Todt et al., 2005]. The aim of the current study was to investigate if the pull-
back method affects T-ECAP and/or programming levels when using the more flexible CI532 electrode. We found lower T-ECAPs in the mid-frequency region after the pullback intraoperatively. There was a tendency toward lower T- and C-levels and T-ECAP in the pullback group compared to the standard group, but the difference was not statistically significant.

Placement – Surgical Issues

The placement of the electrode was documented by intraoperative fluoroscopy in the pullback group but not in the standard surgery group. At the very first CI532 insertions in 2015, before this study, intraoperative fluoroscopy showed inadvertent back and forth movements of the array inside the cochlea while removing the sheath. This phenomenon cannot be excluded for the standard surgery group but should not occur more often than in the pullback group.

The size of the cochlea may have an effect on the placement of the electrode. A large diameter of the modiolus will cause the electrode array to be closer to the modiolus even without a pullback. An over-insertion may cause the tip of the electrode to proceed further toward the apical region or simply push the array toward the lateral wall. In this case, the pullback will not have any effect on the position of the array for the more apical region. In a small cochlea, the pullback may cause a better, medial position after pullback. The extent of the pullback needs to be further standardized and evaluated in different cochleae [Todt et al., 2008]. Figure 3 shows that from the initial to the pullback position, the change of projected distance between electrode 22 and 16 varies from none to 2.37 mm. This could be explained by variations of the cochlea size and shape. A larger cochlea with wider modiolus may have no potential for reducing the distance or getting the array even closer to the modiolar wall.

ECAP Threshold

Positioning the electrode closer to the modiolus has been discussed in the literature [Todt et al., 2005; Todt et al., 2008; Todt et al., 2011]. It is shown that a shorter distance between the electrode and the spiral ganglion cells can be a positive factor for the audiological outcome [Basta et al., 2010; Holden et al., 2013]. The analysis of the raw data revealed an interesting effect: while the T-ECAP profile for the pullback group in the initial position (marker I) appeared “smoother,” it was more zig-zag-like after the pullback to marker I/II. A possible explanation is that some electrode contacts lying particularly close to the modiolar wall stimulate the neural elements very efficiently.

Figure 2 shows the group data where the T-ECAP profile in the most lateral position (marker III) shows a large threshold difference in the mid-frequency range (electrode 16–6). The over-insertion of the array may have pushed it slightly toward the modiolus at electrode 20–18 causing a small change in T-ECAP and pushing the electrode array more lateral in the mid-frequency range leading to this drastic difference. We speculate that the movement from a medial to a lateral array position at over-insertion is the moment when the ECAPs drop and the T-ECAP levels are increasing. The most basal electrode contacts (1–6), this is due to the closer electrode contacts...
to the modiolus and the electrode array is pushed deeper inside and herewith closer to the neural elements causing an ECAP response. Different marker positions cause a difference in distance to the modiolus and T-ECAP levels. Other researchers came to the similar conclusion that perimodiolar electrodes have a better but not uniform modiolar proximity [Clark, 2003; Todt et al., 2005]. Our results support the observation that the pullback technique appears to have its greatest effect on the perimodiolar position in the mid- to basal region of the cochlea [Basta et al., 2010]. This is obviously dependent on the larger width of the scala tympani toward the basal section.
Typically, the T-ECAP rises from apical to basal electrodes, which is a result of lower responses in the basal region [Todt et al., 2005].

Figure 2 shows similar mean T-ECAP levels after initial insertion and over-insertion. This indicates that the corresponding change in lateral position has little effect on T-ECAP levels. A significant T-ECAP change occurs only after the pullback maneuver. This could indicate that direct electrode contact with the modiolus has a much larger effect on T-ECAP levels than lateral movements within the scala tympani, which do not involve direct modiolar contact.

Programming Levels

One year after switch-on, C-levels did not differ significantly between the groups. T-levels were slightly lower in the pullback group than in the standard group, but the difference was not significant ($p > 0.05$). However, the group sizes were small. Whether a more perimodiolar position has a larger effect on the T-levels and results in a larger dynamic range needs to be further investigated. Studies are also needed to elucidate the clinical value of an increase of dynamic range. Davis et al. [2016] investigated how the difference in programming levels depends on the distance to the modiolus and found just a minimal improvement of lower programming with shorter distance.

General

In our study, fluoroscopy has been used during insertion to observe the over-insertion, pullback without pulling back the tip electrode, and investigate if the tip electrode is moving further inside while doing an over-insertion. Fluoroscopy monitoring and real-time observation during the electrode insertion is not a standard surgical procedure, but is important during the experimental phase, testing new electrode types and validation of the development of new surgical procedures. Over-insertion has a risk to a deeper insertion; a deeper insertion has the risk to more trauma, especially if this is at the section between the first and second turn [Avci et al., 2014].

In this study, the lateral-to-medial movements of the electrode array were observed by fluoroscopy. CT scan was not performed postoperatively and thus a scala tympani to scala vestibuli dislocation can neither be confirmed nor excluded. Prior to this study, and whenever new electrode array is used at Oslo University Hospital, the first surgeries were done at the hybrid operation room, at the Interventional Centre to achieve the best possible insertion technique before starting a research project.

Conclusions

When analyzing the within-subjects variance of T-ECAP, we found that the pullback maneuver of the CI532 electrode array after an over-insertion resulted in significantly lower T-ECAPs compared to the initial insertion. Our findings are very similar to other studies that have used the pullback procedures with other types of electrodes [Todt et al., 2005; Todt et al., 2008; Basta et al., 2010; Todt et al., 2011] When comparing T-ECAPs at the final position in the pullback group with the initial and final position in the standard insertion group, we found no statistical mean difference in T-ECAPs. Neither did the between-group comparisons of C- and T-levels show significant differences between the pullback and the standard group. More subjects must be included to reach enough statistical power to detect group differences – if they exist – between T-ECAPs, C-levels, and T-levels since they are largely variable between subjects.

The current study showed lower T-ECAPs after over-insertion and pullback. As a next step, the effect of a surgical procedure including over-insertion and pullback on residual hearing is important to investigate. Further radiological investigations would be useful when investigating the relevance of the shape and size of the cochlea for the effect of the pullback technique. Additionally, the effect pullback technique to preserving the residual hearing is not known yet.

Statement of Ethics

The study was in accordance with the internal regulations at Oslo University Hospital and approved by the Regional Committee for Medical and Health Research Ethics (Reference 2017/1839). All patients gave their written informed consent to participate in the study.

Conflict of Interest Statement

The University Hospitals ENT-department receives research funding from Cochlear and Advanced Bionics. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Author Contributions

All authors have made substantial, direct, and intellectual contribution to the work and approved it for publication.

Data Availability Statement

The data that support the finding of this study are not publicly available due to legal and ethical reasons but are available from the corresponding author RG upon reasonable request.

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