An Optimized Robot-Based Technique for Cochlear Implantation to Reduce Array Insertion Trauma

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To compare the intracochlear trauma induced by optimized robot-based and manual techniques with a straight electrode array prototype inserted at different lengths.

Study Design. Experimental study.

Setting. Robot-based otologic surgery laboratory.

Subjects and Methods. A prototype array was inserted at different insertion lengths (21 and 25 mm) in 20 temporal bones. The manual insertion was performed with a microforceps. The optimized approach consisted of an optimal axis insertion provided by a robot-based arm controlled by a tracking system, with a constant speed of insertion (0.25 mm/s) achieved by a motorized insertion tool. The electrode position was determined at the level of each electrode by stereomicroscopic cochlea section analysis.

Results. A higher number of electrodes correctly located in the scala tympani was associated with the optimized approach ($P = 0.03$, 2-way analysis of variance). Regardless of the insertion technique used, the array inserted at 25 mm allowed complete insertion of the active stimulating portion of the array in all cases. Insertion depth was greater when the array was inserted to 25 mm versus 21 mm ($P < .001$, 2-way analysis of variance). The optimized insertion was associated with less trauma than that from manual insertion regardless the length of the inserted array ($P = .04$, 2-way analysis of variance).

Conclusion. Compared with a manual insertion, intracochlear trauma could be reduced with array insertion performed on an optimal axis by using motorized insertion and by applying a constant insertion speed.

Keywords
temporal bones, anatomy and histology, cochlea, scala tympani, scala vestibuli, cone-beam computed tomography, tomography scanners, neuronavigation, robotics

Received November 30, 2017; revised June 13, 2018; accepted July 12, 2018.

Minimizing intracochlear trauma is an essential consideration during cochlear implant surgery, especially with regard to preserving residual hearing for cochlear implant recipients.1 Despite the fact that multiple factors have been associated with outcomes after cochlear implantation,2 only some of them can be improved, such as the physical characteristics of the electrode array, the array insertion technique,1 reduction of the inflammatory response,3 and programming of the speech processor to improve signal quality.4,5

The objectives of implant surgery are to place the electrode array in the scala tympani (ST) and to avoid damaging the intracochlear structures.6 In addition to mechanical trauma, an injury to the intracochlear structures could trigger an inflammatory response and consequently lead to apoptosis,3 fibrosis development,7 and, thus, loss of residual hearing.8 One may assume that the array should be inserted into the central axis of the ST to avoid early contact with the lateral wall of the cochlea, thereby circumventing an unsuitable trajectory of the array, which could lead to damage to the intracochlear structures. However, previous studies showed that the optimal position of the insertion axis varies, depending on the cochlear anatomy."9,10 and is
seldom achievable because of the position of the facial canal. Consequently, it is not always possible for the surgeon to overcome these difficulties and achieve an optimal representation of the insertion axis. Furthermore, studies suggested that some factors can provoke additional trauma, such as insertion speed and subtle hand motions during insertion. In the light of these factors, a robot-based system entirely controlled by navigation could align an insertion tool to an optimal axis and perform the correct insertion.

Little is known about the advantages of an optimized insertion technique over a manual technique during insertion of the electrode array. Therefore, we examined the potential benefits of an optimized insertion technique consisting of an insertion tool automatically aligned with the optimal axis by a robot arm guided entirely by a tracking system, with a constant insertion speed controlled by a motorized insertion tool. The aim of this study was to compare the intracochlear trauma induced by optimized and manual insertion techniques with a straight electrode array prototype inserted at different insertion lengths (21 and 25 mm) into cadaveric temporal bones.

Materials and Methods

Temporal Bones

Twenty fresh-frozen temporal bones were used (Centre du Don de Corps, Université Paris Descartes, Institutional Review Board Inserm CAJ-2017-078). To use a tracking system, 4 fiducial landmarks were drilled at the mastoid surface with a 2-mm diamond burr. Preimplantation cone beam computed tomography (CBCT) was performed with a specific protocol (field of view, 8 × 8; interslice distance, 0.125 mm).

A mastoidectomy and posterior tympanotomy were performed and the anterior and posterior pillars of the round window (RW) niche drilled to expose the RW membrane. The crista fenestra was drilled, and an inferior extended RW cochleostomy was performed, with the endosteum opened just before the insertion. A drop of sodium hyaluronate (10 mg/mL, Healon; Abbott, Uppsala, Sweden) was placed in the RW region, and the array was inserted with a manual or optimized insertion technique according to a randomized protocol. After the insertion, postimplantation CBCT was performed according to the same acquisition protocol used in preimplantation imaging. Finally, the cochlea was removed from the temporal bone to perform a macroscopic analysis.

Preimplantation CBCT Analysis

Preimplantation CBCT images were analyzed with OsiriX 4.0 (Pixmeo, Geneva, Switzerland). The maximal cochlear diameter (distance A) was measured from the center of the RW to the lateral wall. Because a straight lateral wall array was used, the cochlear duct length at the level of the lateral wall was calculated as follows: 4.16 × A – 2.7.

As shown in previous work, it was not possible to directly reach the ST axis from the posterior tympanotomy, because of the variability of the relationship between the cochlea and the facial nerve position (Figure 1). Consequently, to have direct access to the entry point to the cochlea, an optimal axis was determined as follows (Figure 2; Supplemental Video S1, in the online version of the article): 15,17:

1. The basal turn of the cochlea was aligned with the coronal plane.
2. An inferior extended RW cochleostomy was chosen as the entry point to the cochlea.
3. The sagittal plane was aligned with the center of the basal turn and the axial plane aligned to the ST according to the entry point to the cochlea.
4. A rotation of the ST centerline was performed, centered on the entry point in the axial plane (this axis passed 1 mm from the facial canal according to the bony shell over the facial nerve and the insertion tool diameter).
5. The 3-dimensional position of 2 points were obtained: one point placed on the axis trajectory and another to the final position of the insertion tool tip (1 mm from the entry point) to build a vector.

Electrode Array

A straight array prototype (Oticon Medical, Vallauris, France) was used in all insertions. Two marks were made to provide an insertion length of 21 or 25 mm. This array had an active portion of 19.4 mm (composed by 20 electrodes) and an inactive portion (1.6 mm for the 21-mm and 5.6 mm for the 25-mm inserted array).

Insertion Techniques

The array was inserted at different insertion lengths (21 and 25 mm) with 2 techniques. The first was a manual insertion technique with a microforceps by the same ear, nose, and throat surgeon (first author; Figure 3A). The array was inserted gradually, and the goal was to perform a complete insertion. In this case, we tried to reproduce the routine surgical conditions, and the surgeon performed the insertion under operating microscope view.

The second was an optimized insertion technique composed of a motorized insertion tool, as well as a robotic arm (RobOtol; Collin, Bagneux, France) and a real-time tracking system (FasTrak; Polhemus, Colchester, Vermont) controlled by in-house software. The insertion tool comprised a rotator engine connected to a threaded screw. The rotation of the screw pushed a blunt pin into a metallic tube which pushed out the array (Figure 3B). The array was charged into the insertion tool, which was mounted on the robotic arm. The 3-dimensional position of the optimal axis was loaded on the robot software to align the insertion tool. The robot positioning was controlled by the robot software and the electromagnetic tracking system. The system would...
align the insertion tool with the optimal axis trajectory and place the tip of the insertion tool at 1 mm from the entry point to the cochlea (Figure 3C). Once the insertion tool was aligned, no modification was made of the position of the insertion tool. According to previous studies, low insertion speed is associated with lower insertion forces; thus,
the insertion speed was chosen as the lowest speed possible with the insertion tool (0.25 mm/s) to completely eject the array.

A video of the insertion procedure was acquired during each procedure to determine the duration of the array insertion. To avoid further displacement, the array was fixed with 1% cyanoacrylate.

**Postimplantation CBCT Analysis**

The depth of insertion was measured by aligning the basal turn with the coronal plane. The line between the center of the RW and the modiolus was considered to be 0° (reference line), and the angle between this reference line and the distal part of the most apical electrode was measured.

The active part of the array inserted into the ST (millimeters) was determined (with the region-of-interest tool from OsiriX following the path of the electrode array) and the functional cochlear coverage (percentage) calculated as follows: active segment of the array in the ST / cochlear duct length\(_{\text{lateral wall}}\) × 100.

**Intracochlear Trauma Analysis**

The cochlea was removed from the temporal bone; the stapes were removed; the lateral canal and apex of the cochlea were opened with a diamond bur. The specimen was then fixed in 10% formaldehyde over 24 hours. A progressive dehydration of the cochlea was performed with ethanol (50% for 3 hours, 70% for 14 hours, 90% for 3 hours, 95% for 3 hours, and 100% for 3 hours). The cochlea was then desiccated in ambient air for 16 hours. Finally, the cochlea was embedded in a crystal resin (Pebeo, Gemenos, France) and placed in ambient air for 24 hours for polymerization.

A microgrinding technique was used to determine the intracochlear trauma; the grind direction was performed perpendicular to the RW/modiolus axis and stopped each millimeter. The block was stained with Phloxine B for 15 minutes to visualize the intracochlear tissue, and the cochlea was visualized with a stereomicroscope with a ×12.8 zoom (SLM 2; Karl Kaps GmbH, Wetzlar, Germany). A trauma grading system was used to assess the trauma: 0, no trauma; 1, basilar membrane displacement; 2, basilar membrane rupture; 3, translocation of the array into the scala vestibuli (SV); and 4, osseous spiral lamina or modiolar wall fracture.

Finally, the position of each electrode was classified into 3 categories: ST electrode (grade 0, 1, or 2 trauma), SV electrode (grade 3 trauma), and extracochlear electrode.

**Statistical Analysis**

Data were analyzed by R 3.1.2 statistical software (R Core Team, Vienna, Austria). Quantitative variables were summarized by mean and standard deviation. Two-way analysis of variance (ANOVA) and Holm-Sidak post hoc test were used to determine the relationship between the length of the array inserted or the insertion technique and the insertion depth, functional cochlear coverage, and position of the electrode array. A P value <.05 was considered to be statistically significant.

**Results**

**Length of Array Inserted: 21 vs 25 mm**

The anatomic characteristics, distance A, and cochlear duct length were similar in both groups. As expected, the insertion depth was greater when the array was inserted to 25 mm versus 21 mm (P < .001, 2-way ANOVA). The functional cochlear coverage, corresponding to the length of the active portion of the array in the ST, was not associated with the length of array inserted (Table 1). However, a 21-mm inserted array was significantly associated with the number of extracochlear electrodes (P = .02, 2-way ANOVA).

Regardless of the insertion technique, when a 25-mm inserted array was used, the active portion of the array was always intracochlear (Table 2, Figure 4).

**Insertion Technique: Manual vs Optimized**

Neither the insertion depth nor the functional cochlear coverage was significantly associated with the insertion technique used (Table 1). The number of ST electrodes was higher with the optimized insertion technique as compared with the manual insertion technique (P = .03, 2-way ANOVA). The number of SV electrodes was lower with the optimized insertion technique versus the manual insertion technique (P = .04, 2-way ANOVA). However, the number of extracochlear electrodes was not associated with the insertion technique (Table 2, Figure 4). The mean ± SD duration of manual insertions was 36 ± 7 seconds; however, the insertion speed was difficult to evaluate because of the need for the surgeon to perform the insertion in 2 to 3 steps, with a small pause necessary to release and regrasp the array. The insertion time with the optimized insertion technique was 80 and 100 seconds (with the 21- and 25-mm inserted array, respectively).
Furthermore, the first passage of the array from the ST to the SV was highly variable. With a 21-mm inserted array, this first passage to the SV was 238° ± 34.1° (191°-266°) and 246° ± 91.2° (182°-311°) with the manual and optimized techniques, respectively. With a 25-mm inserted array, this first passage to the SV was 207° ± 46.3° (163°-249°) and 180° ± 69.3° (131°-229°) with the manual and optimized insertion techniques, respectively (Figure 4).

**Discussion**

Consistent with the notion that reduction in intracochlear trauma is an essential goal during electrode array insertion, cochlear trauma was assessed according to the insertion technique, optimized or manual, and the length of array inserted. Compared with manual insertion, the optimized insertion technique was associated with better functional cochlear coverage, a higher number of electrodes in the ST, and a lower risk of translocation. Moreover, the number of extracochlear electrodes was positively correlated with the 21-mm inserted array.

**Correlation between the Insertion Technique and the Electrode Position in the ST**

Because the insertion axis is an important factor associated with intracochlear trauma and the conventional technique is performed manually, a comparison of this proposed optimized technique with the conventional technique is the first stage in assessing the benefits of a robotized approach to cochlear implantation. Our results show that the use of an optimized insertion technique leads to a decrease in intracochlear trauma, which is independent of the length of the electrode array. Despite the absence of surgical robots and navigation systems in conventional cochlear implant surgery, this new optimized procedure could be an interesting way to overcome the difficulties that surgeons have in taking into account variations in cochlear anatomy and, as a result, forming a correct mental representation of the insertion axis.

Regardless of the length of array inserted, better functional cochlear coverage was obtained with the optimized insertion technique. However, the active portion of the 25-mm inserted array covered a more distal section of the cochlea, corresponding to lower frequencies as compared with those of the 21-mm inserted array. Despite the similar functional cochlear coverage with both the 21- and 25-mm inserted arrays, the functional cochlear coverage of the 21-mm inserted array depended on the translocated and extracochlear electrodes. However, the functional cochlear coverage of the array at an insertion length of 25 mm depended only on the translocated electrodes because the active portion of the array was completely inserted in all cases. Regarding the configuration of the electrode array, distal to the 21- or 25-mm mark, the array has an active part (containing the electrodes) and an inactive part. We considered a partial insertion when any portion of the active part of the array remained outside the cochlea, regardless of the insertion rate of the inactive part. The mark at 25 mm forced the surgeon to further insert the array, and despite a partial insertion of the inactive portion of the array, the active part always remained intracochlear.

Seven partial insertions were observed in the 21-mm group: 3 cases with manual insertion and 4 cases with the optimized technique (Figure 4). In 5 cases, 1 electrode remained outside the cochlea or at the level of the RW. This phenomenon was especially observed in the optimized group because the insertion tool was placed at 1 mm to the RW. In 1 case, 5 electrodes remained outside the cochlea. During the insertion, the array could not be completely inserted. Consequently, the insertion was stopped and the array fixed with the cyanoacrylate glue, and no displacement occurred after insertion. Finally, the macroscopic analysis showed a translocation of the array on the 2 apical electrodes.

**Differences between the Optimized and Manual Insertion Techniques**

To optimize the electrode array insertion, the development of an insertion tool could be an important step to performing a robot-based approach in cochlear implant surgery. Insertion speed is an important issue in cochlear implantation, and a lower risk of translocation.
and a lower insertion speed was associated with lower insertion forces and better hearing results after surgery. A manual insertion is performed in a saccadic way, and the speed is variable along the insertion. Under experimental conditions, the force sensitivity threshold of surgeons is in the range of the insertion forces during the insertion; however, it is possible that the sensitivity and reaction time after a positive stimulation would not be sufficient to detect and reduce possible intracochlear trauma during the insertion. As observed in our study, the use of an insertion tool may permit the insertion of the array in an optimized axis and in a constant speed of insertion. However, improvements will be necessary to allow insertion of various array designs and to couple a force sensor to have a haptic return.

Our findings show a higher translocation rate (optimized, 40%; manual, 80%) than that observed in previous studies. These results could be explained by the fact that the insertion tool had no haptic feedback; it was not possible to detect a resistance and stop the insertion according to the soft surgery technique. Despite the lack of haptic feedback

<table>
<thead>
<tr>
<th>Electrode Position</th>
<th>21-mm Inserted Array</th>
<th>25-mm Inserted Array</th>
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<tbody>
<tr>
<td></td>
<td>Manual</td>
<td>Optimized</td>
</tr>
<tr>
<td>Scala tympani</td>
<td>16 ± 2.0</td>
<td>19 ± 1.1</td>
</tr>
<tr>
<td>Scala vestibuli</td>
<td>2 ± 2.1</td>
<td>1 ± 0.9</td>
</tr>
<tr>
<td>Extracochlear</td>
<td>2 ± 2.1</td>
<td>1 ± 0.4</td>
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*All results are expressed as mean ± SD (n = 5).*

**Figure 4.** Intracochlear trauma according to the insertion technique and the length of array inserted. White circle, electrode in the scala tympani; light gray circle, basilar membrane displacement; dark gray circle, basilar membrane rupture; X, scala vestibuli electrode; open triangle, extracochlear electrode.
on manual insertions, the goal was to insert the entirely array during insertion. Certainly, this constraint will provoke more trauma, as seen in this study, but it allowed to compare both techniques.

Limitations of the Study and Perspectives
The location of the first translocation, the insertion depth, and the functional cochlear coverage are clearly related to the physical characteristics of the electrode array, and these values cannot be extrapolated to other arrays. Nevertheless, one can expect that the optimized technique would still improve the insertion of other straight arrays. The use of an insertion tool is a crucial point: it must fit both the array and the robot arm in view of its clinical use. The characteristics of the arrays are different, depending on the manufacturer, and it will be necessary to adapt the terminal part of the insertion tool. Finally, the addition of haptic feedback would be interesting to stop the insertion as a result of forces occurring along the array insertion. A better understanding of the insertion forces will be important to permit the surgeon to react immediately and stop insertion when these forces exceed a threshold. Then, a key step will be to build strategies to avoid or diminish the extent of the damage if the insertion continues.

A concern about this work is our definition of the optimal axis, as previously described, which corresponded to the ST centerline. However, in many temporal bones, this axis crossed the facial nerve and cannot be used to align the insertion tool. We have modified the definition of the optimal axis to take into account the facial nerve position, and a rotation of this axis was performed to avoid the facial nerve. However, we are not sure that this trajectory is the best one that would lead to the lowest trauma possible. One may presume that following the lateral wall or, in contrast, taking the bend tightly might lead to less trauma. To answer this question, the study of various trajectories or numeric simulation could provide some clues to refine the array insertion.

In view of these findings, we conclude that an optimized insertion technique allows the damage to intracochlear structures to be reduced during insertion as compared with manual insertion. Further investigations are needed to develop an insertion tool adapted to additional array designs.

Acknowledgments
We thank Guillaume Tourrel from Oticon Medical for production of the array prototypes.

Author Contributions
Renato Torres, conception and work design; data acquisition and analysis; writing the original draft and editing the final manuscript; final approval of manuscript; agreement of the integrity of the work; Huan Jia, data acquisition and analysis; revision and final approval of manuscript; agreement of the integrity of the work; Mylène Drouillard, data acquisition; revision and final approval of manuscript; agreement of the integrity of the work; Jean-Loup Bensimon, data acquisition; revision and final approval of manuscript; agreement of the integrity of the work; Olivier Sterkers, design of the work, analysis and interpretation of data; revision and final approval of manuscript; agreement of the integrity of the work; Evelyne Ferrary, conception and design of the work; analysis and interpretation of data; revision and final approval of manuscript; agreement of the integrity of the work; Yann Nguyen, conception and work design; data analysis and interpretation; revision and final approval of manuscript; agreement of the integrity of the work.

Disclosures
Competing interests: Renato Torres, currently receiving a grant (Cifre 269/2015) from Oticon Medical during his doctoral studies.
Sponsorships: None.
Funding source: This work was supported by a Cifre grant (269/2015 ANRT/Oticon Medical) and the Agir pour l’Audition Foundation (APA RD-2014-2 /R14104DD RAK14030DA).

Supplemental Material
Additional supporting information is available in the online version of the article.

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