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Illustrating orientation changes of the insertion trajectory during cochlear implant electrode array insertion

Abstract: *Introduction:* Recent investigations focused on the optimization of atraumatic cochlear implant surgery have highlighted the relevance of the electrode array (EA) insertion trajectory. This is particularly studied in the context of minimally-invasive “keyhole” and robotic-assisted approaches, e.g. to avoid injuring structures inside and outside the cochlea. However, little is known about the natural, manual movements and trajectory followed during the insertion process. The present work illustrates the orientation changes within the trajectory a surgeon follows during insertions of EAs into a human cadaveric cochlea. *Methods:* An EA insertion tool equipped with a gyroscope was developed in our laboratory. During the insertion trials, the gyroscope captures the tool’s spatial orientation. A human head specimen and a single EA were used to perform insertions into a cochlea. A cochlear implant surgeon performed all insertion trials. The recorded orientations were compared to the initial orientation upon cochlea entry to assess the surgeon’s range of motion by calculating the angle between orientation vectors. *Results:* Fifteen EA insertions were performed with a median maximal deviation from the initial orientation of 7.2° ($5.3 - 11.1^\circ$) across trials. The largest orientation changes were seen towards the last half of each insertion trial. A negative relationship between degree of axis change and number of insertion trial was observed ($r = -0.5$). *Conclusion:* Manual EA insertions into a cadaveric cochlea revealed an insertion trajectory with maximum orientation changes of approximately $\leq 10^\circ$ degrees. The observed trend on decreasing range of motion with increasing number of insertion trials may be attributed to surgeon’s familiarization with the insertion trajectory for this

specific specimen but other contributing factors (e.g. EA softening) need to be further elucidated with several EAs. Future evaluations can help determine if this orientation change is influenced by surgeon expertise.

Keywords: cochlear implant, automated, soft surgery.

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1 Introduction

Contemporary cochlear implant (CI) surgery is highly characterized by efforts that seek to minimize intracochlear trauma, as different investigations have shown that atraumatic CI surgery may lead to superior postoperative outcomes. This is especially true in patients with some degree of residual hearing, in whom an atraumatic insertion of the electrode array (EA) facilitates preservation of intracochlear structures and their remaining natural hearing. As a result, different variables that may have a significant impact on trauma have been identified in the past couple of decades and more importantly, several strategies have been proposed to optimize the so called soft CI surgery or atraumatic surgery. Recently, attention was brought to the insertion trajectory for the introduction of an EA into the cochlea, as a variable that may impact intracochlear trauma. In brief, the standard trajectory is considered to go through the facial recess into the round window and aiming at the scala tympani – the compartment within the cochlea that represents the target EA location [1-2].

However, the description of EA insertion trajectories has been mainly studied in the context of minimally invasive CI surgery. This is an approach that aims to provide patients with their surgical implant by means of a personalized trajectory that reaches the inner ear while avoiding relevant surrounding structures like the facial nerve. Such a trajectory is typically linear, with a small diameter (< 2 mm) and can be drilled as a single tunnel from the lateral surface of the skull down to the round window for the subsequent EA insertion [3-4]. During the insertion, there is then no room for pivoting movements

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and only rotations within the drilled trajectory are possible. The traditional approach is in contrast performed manually, and recent evidence has encouraged this insertion process to be performed as slow and continuous as possible for trauma reduction. During the insertion process trained surgeons are able to perform small adjustment in the trajectory based mainly on visual and haptic feedback almost intuitively. These so-called manual adjustments have not been studied in detail and it is unclear to what extent surgeons adjust the EA insertion trajectory, as the hand travels deeper into the mastoid cavity. A better understanding of the manual proceeding during EA insertions may facilitate different innovations that could further improve this process in the future. The present work illustrates manual orientation changes a surgeon makes during insertions of EAs into a human cadaveric cochlea.

2 Methods

A previously-anonymized human head specimen, a flexible straight EA (STANDARD, MED-EL, Innsbruck, Austria) and an in-house built insertion tool were used to perform manual insertions into a human cadaveric cochlea. All insertion trials were performed by a board-certified otolaryngologist with training in CI surgery.

The insertion tool was designed to hold the EA proximally (i.e. behind the basal portion), allowing the tip or apical end of the EA to be introduced into the cochlea. The handheld tool was equipped with a gyroscope to capture its special orientation throughout an insertion trial.

Figure 1: Insertion of an EA into the cochlea through a standard surgical approach. The insertion tool (\$, blue) houses the gyroscope and the metal tip holds the EA. A parallel microscope camera (*) records the trial.

Each insertion trial was started with the tip of the EA positioned at the level of the round window for a predetermined, standardized insertion of 18 mm into the cochlea. The recorded orientation changes were compared to the initial orientation to assess the surgeon's range of motion by calculating the angle between orientation vectors.

3 Results

Fifteen EA insertions were performed with a median maximal deviation from the initial orientation of 7.2° ($5.3 - 11.1^\circ$) across trials. A negative relationship between degree of axis change and number of insertion trial was observed ($r = -0.5$). Figure 2 illustrates these results and reports also the orientation change in relationship to the initial insertion axis, and the two maximum deviation points within a trial. The latter then gives an idea of the overall position change of a surgeon's hand throughout an insertion trial.

Figure 2: Maximal orientation change ($^\circ$) throughout an insertion trial relative to the initial insertion axis (dark color) and calculating the angle between the two maximum deviation points within a trial (light color)

Since some insertions were completed earlier than others, insertion times were normalized to facilitate further orientation comparisons across trials. Although the largest

Figure 3: Time at which the maximal orientation change was recorded.

orientation changes were seen towards the second half of each insertion trial across all trials (Figure 3), a definite consistent pattern of orientation changes during the insertion trials was not clearly identified (Figure 4).

Figure 4: Orientation change (°) during EA insertion: raw data per insertion trial reveals no consistent pattern.

Figure 5 depicts the median trial (#6) as example on these orientation changes, providing both time and anatomical references. The warmer colors indicate the angle changes observed toward the end of the insertion. In general, the trials illustrated a manual adjustment anteriorly and cranially as the EA continued its insertion.

Figure 5: Sample orientation change during a manual EA insertion (trial #6).

4 Discussion

Insertions of an EA into the human cochlea were characterized by an overall small pivotal orientation change of less than 10 degrees. Although each trial differed from others regarding the onset of larger orientation change, in general the largest adjustments occurred towards the latter half of an insertion trial. These findings indicate that the insertion trajectory undergoes minor adjustments as the EA reaches a deeper

location within the cochlea. Whether or not these changes occurred as a result of a path of less resistance or simply due to manual comfort cannot be determined with the methodology used in the present experiments.

Finally, the observed trend on decreasing range of motion with increasing number of insertion trials may be attributed to surgeon's familiarization with the insertion trajectory but other contributing factors (e.g. EA softening) need to be further elucidated with several EAs. Of note, only one type of EA design was studied, so it remains to be shown if different EA designs impact these orientation changes. A study evaluating a larger number of insertions with more specimens available but also more than one surgeon can help better demonstrate the usual patterns and adjustments of the manual insertion trajectory applied by surgeons.

5 Conclusion

The manual trajectory for the insertion of EAs into the human cochlea undergo variable but small ($\leq 10^\circ$) movement changes mainly towards the end of the insertion. Further evaluations are needed to determine if these orientation changes represent a desired correction on the insertion trajectory based on haptic feedback or if these are simply the result of manual ergonomics or even surgeon's experience.

Author Statement

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