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Robotic milling of the electrode lead channel during cochlear implantation

Abstract: A new fixation technique for the electrode lead of cochlear implants is proposed for the robotic middle and inner ear access technique, and studied for safety and efficacy in an ex-vivo model.

Keywords: robotic cochlear implantation, electrode fixation, ex-vivo, image-guided surgery

1 Introduction

During the robotic cochlear implantation procedure, the middle ear access is drilled precisely with a robotic arm [1]. The resulting small-diameter hole does not provide enough space to store the excess electrode lead from the fixed-length cochlear implants. Surgeons usually prepare a channel before insertion of the electrode array into the cochlea. This is to avoid its contamination and to avoid manipulation of the electrode after insertion, since this could lead to more intracochlear damage and loss of residual hearing. In the conventional surgery, the excess electrode lead can be stored in the mastoidectomy cavity. The goal of this study is to further standardise the robotic procedure, ensure protection of the electrode from external trauma, and prevent fatigue fractures caused by micro-movements. We propose a workflow consisting of preoperative planning on cone-beam computed tomography and its robotic execution. The planning provides a channel with low-curvature bends and sufficient depth below the temporal bone surface, and a cross-sectional shape designed to immobilize the electrode with a slight press-fit.

2 Methods

This workflow has thus far been planned for three ex-vivo human cephalic specimens, considering a safety margin of 1.0 mm from the channel to surrounding anatomical and artificial structures. The intended sample size is twelve. The planning was then executed using a commercially available robotic system. To evaluate safety and efficacy, the lateral and depth displacement of the resulting channel, as well as the channel depth and width were measured in a micro-computed tomography scan. Additionally, the length outside the planned safety margin is determined.

3 Results

Three out of three cases were completed with successful cochlear insertions. The lateral displacement was measured to have a mean and standard deviation (SD) of -0.06 mm ± 0.08 mm. The mean depth displacement was -0.06 ± 0.14 mm (SD). The effective channel never left the planned safety margin. The mean channel width was measured to be 1.19 ± 0.06 mm (SD), where the planned channel width and tool diameter was 1.2 mm. The mean channel depth was measured to be 2.41 ± 0.13 mm (SD), and the planned channel depth was 2.3 mm. The minimal depth was 2.25 mm, still great enough to contain the full 1.3 mm diameter of the electrode used for the experiments.

4 Discussion

In this work, we have proposed a method for electrode fixation for robotic cochlear implantation, thus when the robotic system is already installed for the middle and inner ear access. The lateral and depth displacements are maximally 0.3 mm in the first three cases, and the mean and standard deviation are

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such that the risk of going beyond the safety margin of 1.0 mm is smaller than one in ten thousand patients. The channel width is mostly defined by the milling cutter shape, and the decision that the channel is milled in a singular pass. Furthermore, the channel depth is always great enough to contain the electrode, hence can effectively protect the electrode from trauma. Thus, it seems thus far that the proposed workflow and robotic system can be safely and effectively used for electrode lead channel milling.

5 Conclusion

This study proposes the robotic creation of a channel for cochlear implant electrode leads, and is thus far found to be safe and effective. The proposed procedure step could further standardize cochlear implantation and potentially decrease the risk of device failure due to trauma or fatigue from micro-movements, leading to increased longevity of the implant. Additionally, the risk of intracochlear damage is further diminished, which could result in greater residual hearing preservation.

Author Statement

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References

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