OtoJig

Feasibility of a Simple, Safe, and High-Precision Approach to Minimally Invasive Cochlear Implantation

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Introduction

Minimally invasive cochlear implantation, if available on the market, would certainly revolutionize the field. The de-facto standard treatment to severe to profound sensorineural hearing loss is a cochlea implant and the standard surgical procedure is a mastoidectomy with facial recess approach (MFRA) where the mastoid bone is successively removed and a passage through the facial recess is carefully identified by removing a larger volume [fig. 1]. The benefit of the MFRA approach is that a straight insertion line, tangential to the basal turn of the cochlea, is possible.

Several groups are pursuing different concepts to reach this goal in a minimally invasive manner. Among those are impressively engineered custom-made, navigated robotic setups as well as much simpler mini-stereotatic frames.

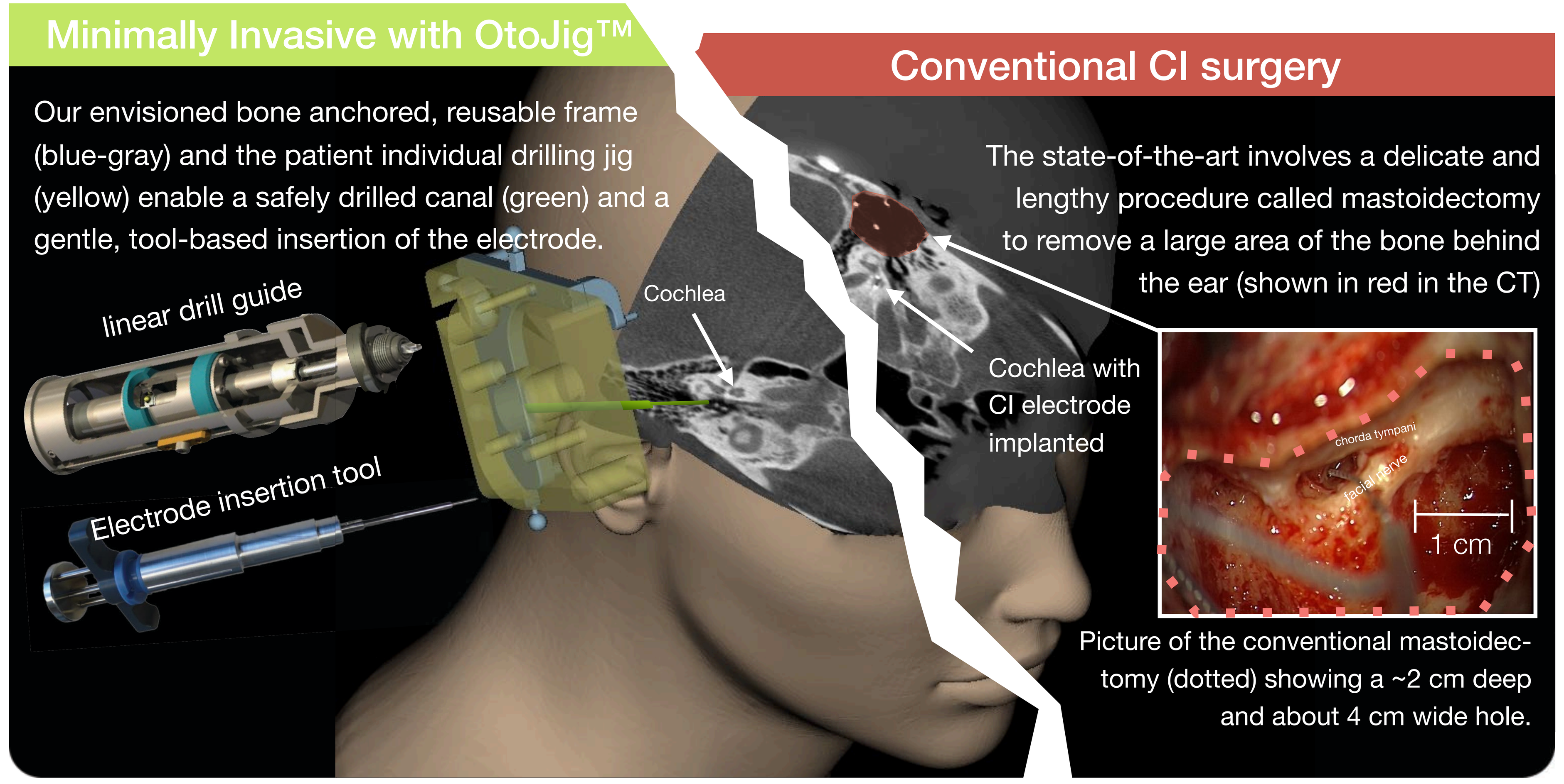
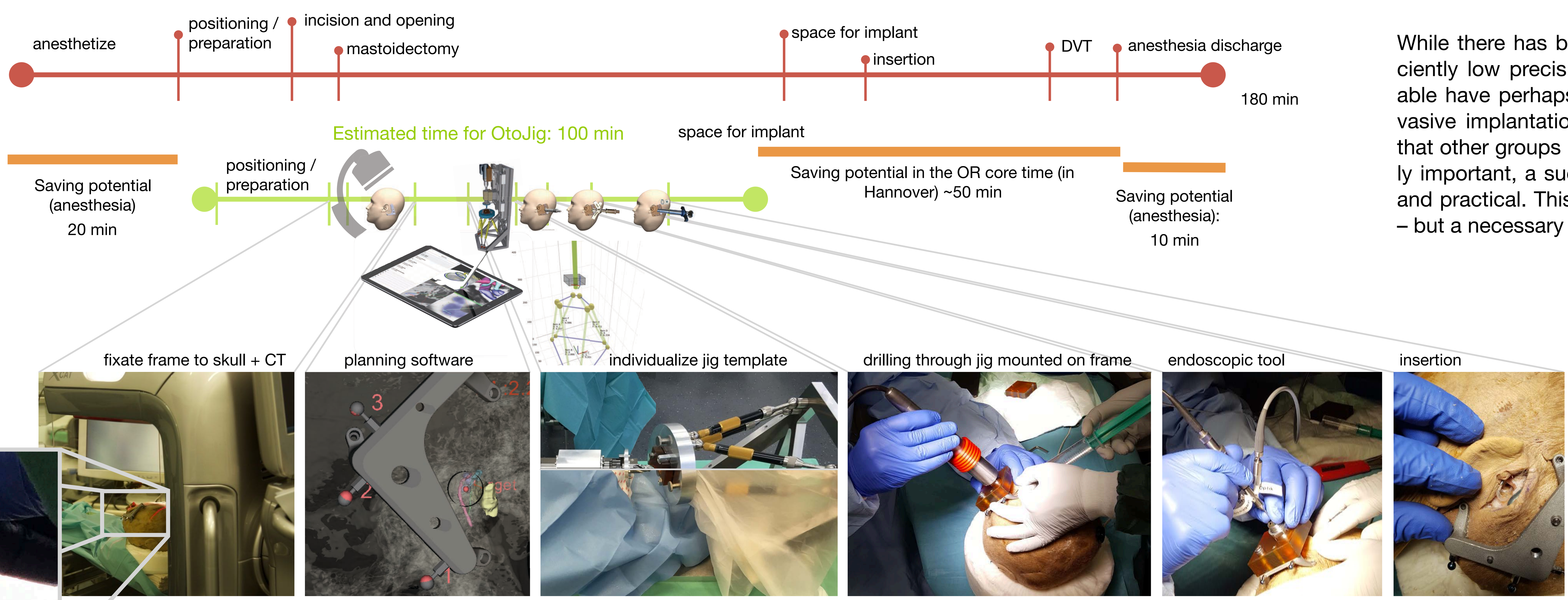


Figure 1: Illustration of the minimal-invasive approach vs. the conventional surgery.

Methods

We are developing a high-precision mini-stereotactic solution (OtoJig™) that is also practical and very cost effective by saving OR time [fig. 2]. It is based on the concept of patient individual drilling jigs that will be customized to the planned drill path right in the OR. The jig is mounted on the bone anchored frame without any movable mechanic parts. In two recent full cadaver head experiments under realistic operating theater environment conditions, we evaluated the surgical handling and (in the second experiment) the overall system precision. Here, we share the preliminary results of an ongoing evaluation of the current system. Earlier temporal-bone evaluations with an older generation of our system showed a somewhat sufficient precision of around 0.5 mm [2]. The new generation went through a complete system optimization and calibration.

Timeline of conventional and minimally-invasive surgery (estimated)



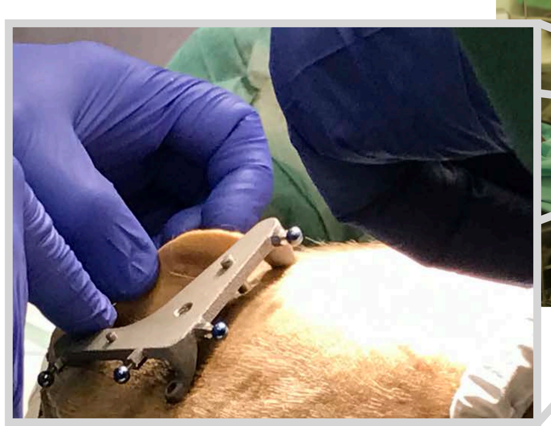


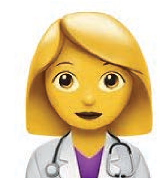
Figure 2: This graphic compares the steps and duration of a conventional surgery (MFRA) with an estimation of the OtoJig mini-stereotactic system based on our cadaver studies. The reusable frame has to be visible in an CT scan such that the planning software can compute the drill path relative to the frame. The hexapod can be operated in a sterile manner to make the individual hole into the (disposable) jig such that the planned path can be transferred to the patient. Drilling into the skull is done using the produced jig.

Benefits

The suggested minimally-invasive system has different benefits for the stakeholder groups: patients, surgeons, hospitals, and healthcare-system:

Patients

- High therapeutic safety
- Better reisdual hearing → EAS
- Treatment near home
- Outpatient treatment



Surgeons

- Standardized procedure
- Simple
- Optimal electrode insertion & placement
- Innovation → more private patients

Hospitals

- Saving time and money
- Efficient & plannable OR workflow
- Competitive advantage → more cases
- Still get full reimbursements (depending on country)

Healthcare system

- Reduced risk → lower follow up costs
- Reduced costs by shorter stay in hospital

Results

While we discovered areas where we have to make the system even more “surgeon safe” as we call it, the currently reached overall system precision (including image registration, marker detection, jig production, and drilling into the skull) was better than our post-operative DVT analysis could tell. Therefore, we estimate that the reached precision was better than or equal to 0.15 mm (half the DVT resolution). Additionally, we evaluated the drilled tunnel by a following up conventional mastoidectomy to visually measure the distances to the facial nerve and the chorda tympani. In figure 3 (left side) we augmented the microscopic image with the planning by using the scale introduced by a 1 mm drill bit head in the image. The drilled tunnel and nerve structures match exactly with the situation in-situ, therefore, we were not able to notice any deviations.

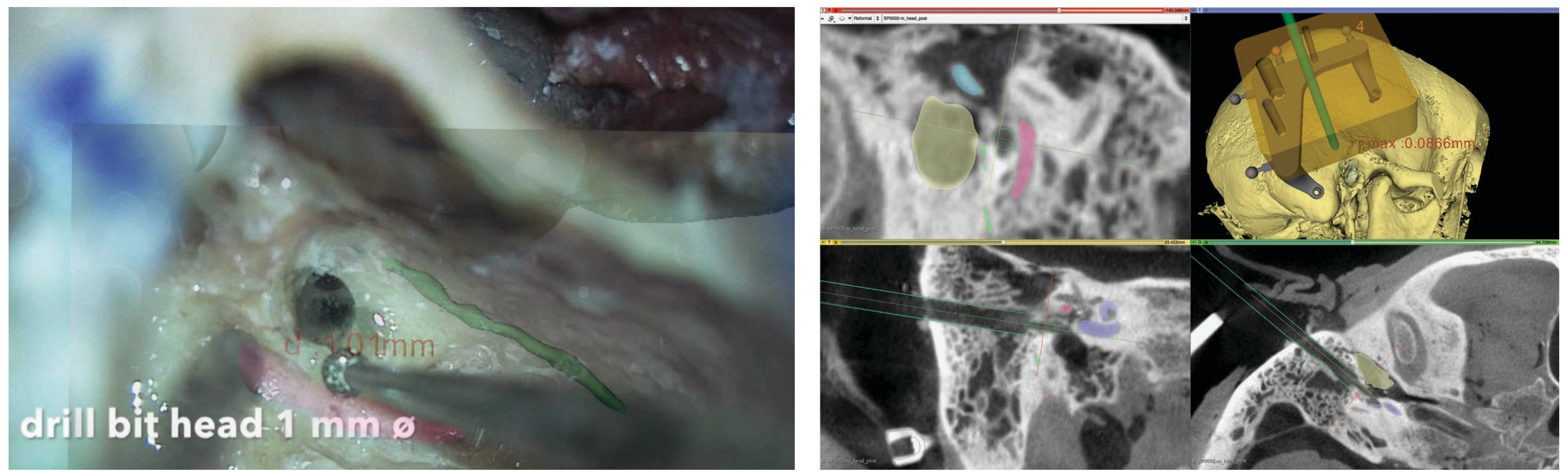


Figure 3: Evaluation of the precision of the whole head cadaver study. Left: Augmentation of the microscopic image with 3D planning on the right ear. The ext. ear canal is at the top. Right: Using the registration module in our extension to 3D Slicer [1], we are able to bring the post-operative image in the exact position with the pre-operative image that contains the planning. The removed bone and the planned drill path overlay exactly.

Conclusion

- Successful drilling of minimally invasive tunnel
- Drilled tunnel matches planned trajectory: <= 0.15 mm
- Safety margins kept as planned

While there has been a scientific competition to reach sufficiently low precision, other factors that make a system usable have perhaps gotten out of sight. Making minimally invasive implantation a reality requires not only the precision that other groups before and we have shown now, but equally important, a successful medical product has to be simple and practical. This is a multi-objective optimization; only one – but a necessary – condition is the a sufficient precision.

Literature

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Fedorov A., Beichel R., Kalpathy-Cramer J., Finet J., Fillion-Robin J-C., Pujol S., Bauer C., Jennings D., Fennessy F.M., Sonka M., Buatti J., Aylward S.R., Miller J.V., Pieper S., Kikinis R. 3D Slicer as an Image Computing Platform for the Quantitative Imaging Network. Magn Reson Imaging. 2012 Nov;30(9):1323-41. PMID: 22770690. PMCID: PMC3466397.
2. Schipper, Jörg, Antje Aschendorff, Iakovos Arapakis, Thomas Klenzner, Christian Barna Teszler, Gerd Jürgen Ridder, and Roland Laszig. 2004. “Navigation as a Quality Management Tool in Cochlear Implant Surgery.” *The Journal of Laryngology and Otology* 118 (10): 764–70. doi: 10.1258/0022215042450643.

GEFÖRDERT VOM

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