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The Cochlea Hydro Drive. Description of a concept for hydraulically operated, automated insertion of electrodes in CI surgery.

Th. S. Rau[1], M. G. Zuniga[1], R. Salcher[1], Th. Lenarz[1]

[1] Department of Otolaryngology, and Cluster of Excellence EXC 2177/1 "Hearing4All", Hannover Medical School, Germany.

Motivation

Automated insertion of electrode arrays (EA) in cochlear implant surgery is presumed to be less traumatic than manual insertions but no tool is widely available in the operating room. We sought to design and create a simple tool able to automate the EA insertion process in cochlear implant (CI) surgery; and (2) to perform preliminary evaluations of the designed prototype.

The following requirement specifications needed to be fulfilled:

- operate at different slow and ultra-slow velocities (down to at least 0.03 mm/s)
- easy adaption to devices from different manufacturers
- meet sterility needs and regulations as it is intended for intraoperative use
- provide stable alignment along an individual trajectory without invasive procedure
- remain simple to allow its wide future use.

Methods

A first prototype of a tool with maximum simplicity was designed and fabricated to take advantage of hydraulic actuation (Fig. 1). The prototype facilitates automated forward motion using a syringe connected to an infusion pump.

Initial prototype evaluation included:

- testing of forward motion at different velocities
- evaluation of device handling, fixation and positioning using cadaver head specimens and a surgical retractor (Fig. 2)
- EA insertion trials into an artificial cochlear model with force recordings (Fig. 3)
- exploration of alignment with CT imaging (Fig. 4).

Results

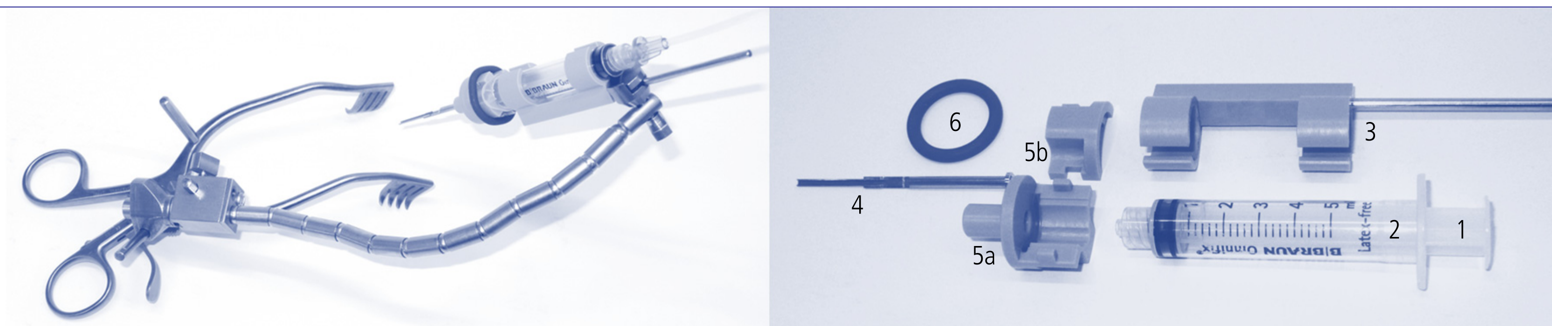

Fig. 1: The design of the CHD repurposes a commercially available, sterile, disposable syringe as hydraulic cylinder. The pressure to run the tool is delivered by an infusion pump (Injectomat 2000, Fresenius, not shown). The CHD is designed to be connected to a standard surgical retractor with a flexible arm (Codman) used to align the tool along the insertion trajectory.

The tool consists of: 1 plunger, 2 barrel with luer lock connector, 3 syringe holder with stainless steel rod, 4 u-shaped probe holder, 5a and 5b split adapter to connect the probe holder with the plunger. The two parts of the adapter are equipped with a lip feature and secured with a silicone ring (6).

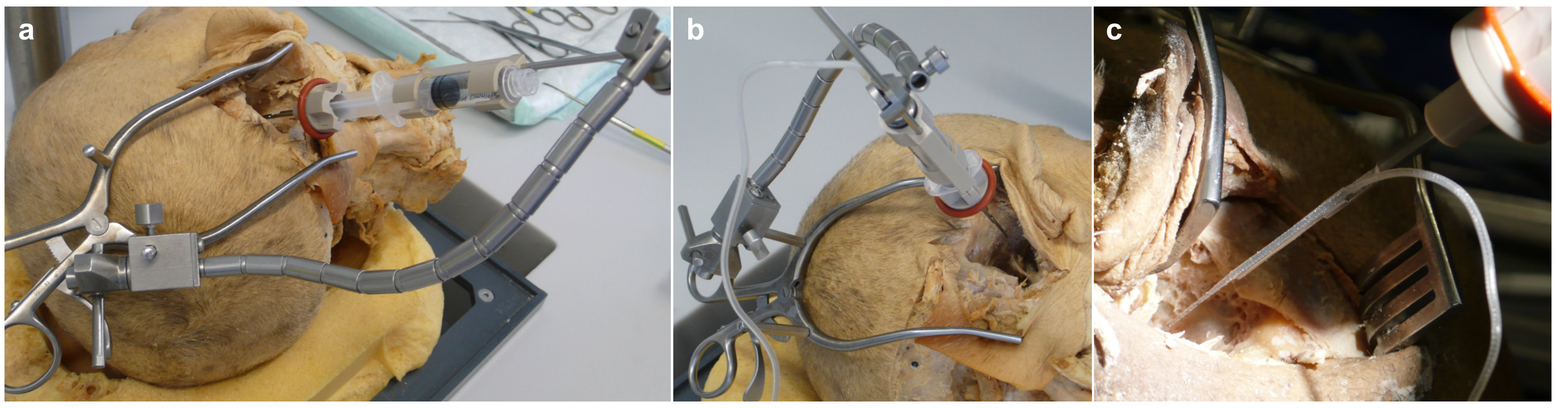

Fig. 2: Assembly of the prototype and its application on human cadaveric head specimens was easy and reproducible. **(a)** Positioning of the device along an adequate trajectory to enter the inner ear was possible for all trails and confirmed under surgical visualization using the microscope. **(b)** Different positions were tested. The flexible arm provides a sufficient stable configuration. **(c)** CHD loaded with EA.

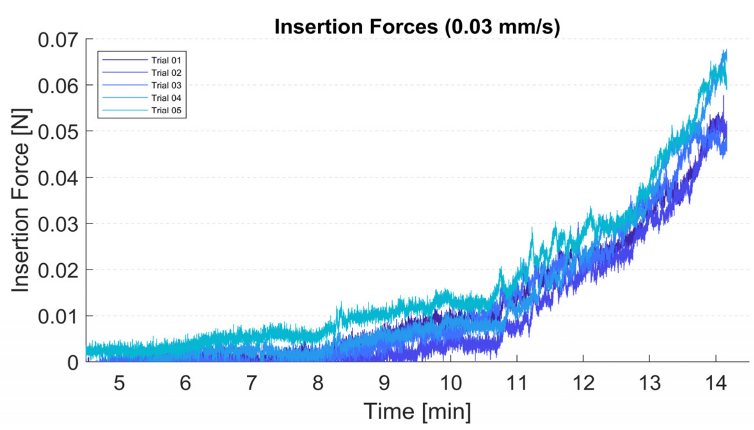

Fig. 3: Insertion forces for ultra-slow insertion velocity using the CHD. Force profiles have been synchronized for visualization based on the latest data point.

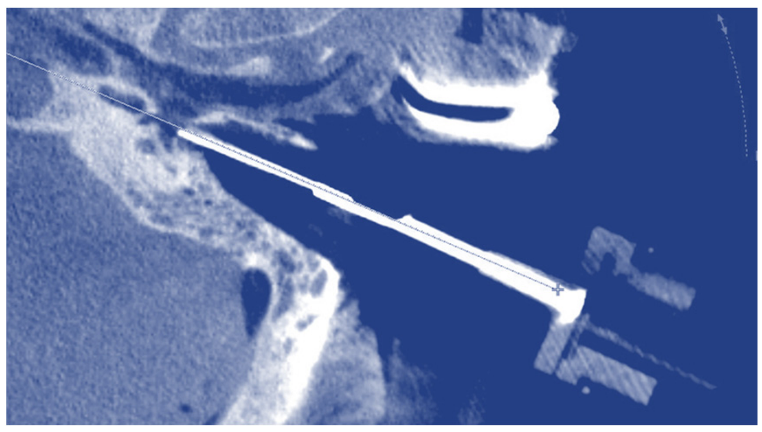

Fig. 4: CT imaging of the CHD in its final position aiming toward the cochlea.

Conclusion

Initial testing of our hydraulic insertion tool did not reveal any serious complications that contradict the initially defined design specifications. Further meticulous testing is needed to determine the safety of the device, its reliability and clinical applicability.

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Contact

Thomas S. Rau, Dr.-Ing.
Hannover Medical School
Rau.Thomas@mh-hannover.de
www.vianna.de/ags/cas