From idea to clinical use

Vitreoretinal surgeries are performed by a small group of highly specialized ophthalmologists, with the majority of these intra-ocular interventions lying on or even beyond the boundaries of human skills as they pose extreme requirements in terms of manipulation and positioning precision. As a consequence, current treatments are characterized by moderate success rates and even an inability to adequately treat some common diseases. A large group of patients thus is left untreated or receives suboptimal treatment only. Robotic technology can and is likely to put an end to these current restrictions.

Supplementing the project results of the H2020 project EurEyeCase (Use Case for European Robotics in Ophthalmologic Micro-Surgery, research funded by the EU Framework Programme for Research and Innovation - Horizon 2020, H2020-ICT-2014-1 - Robotics Innovation Action), R&D activities in the framework of the ACMIT competence center aiming to transfer the robot setup into a clinically viable setup and to validate this robot-assisted operation suite in a clinical trial phase. One particular aspect for this study was to investigate a novel fiber-optical tool for integrated measurement of the distance between tool-tip and retina in order to avoid puncturing of this delicate tissue and to significantly increase patient safety. All together the research activities are completely addressing the overall goals of the ACMIT research agenda “from idea to clinical use”.

Beside of the R&D activities for qualification of the robot-suite for a patient trial and evaluation of safety & usability, performed in the framework of project MF3.1 “Human Factors in MedTech”, ACMIT also significantly contributed to the development of the aforementioned sensor tool in the framework of project MF1.1 “Robotics and Instruments”.

Main system components

The investigated setup is a tool manipulation system which basically consists of a telemanipulated robot device, a workflow monitoring and...
The developed sensorized probing instrument is being connected to the robot with a dedicated adapter. The probing tool includes a distance measurement system – with the measured value (i.e. distance between tool-tip and anatomy of interest) being connected to the robot controller and being used for additional motion control (such as motion limiting function).

The intended use of the robotic suite is to safely insert and manipulate an attached tool in the patient’s eye, i.e. to guide it along user-defined trajectories and to provide stable and safe tool positioning at the retinal wall. Definition and application of pre-defined motion parameters (like defined speed) as well as reduction of the hand tremor during tool positioning are the main supporting features offered by the robot.

**Impact and effects**

A clinical trial including five patients was conducted for validation of the robot & sensing combination. In all five cases, the optical distance sensor was successfully introduced into the patient’s eye using the robot system. Intraocular OCT scans were taken using the optical distance sensor at various defined locations at a safe distance from the retina. The retrieved OCT-based distance information was used to set a safety boundary successfully, limiting the instrument’s penetration depth.

These first clinical results are promising and it is expected that the sensor can provide benefits to peeling and other intraocular tasks. Since the retina is detected reliably, the sensor-based bound can safely be used. Exploiting the micrometer precision of the robot, the sensor allows the surgeon to comfortably maintain a fixed distance to the retina. This promises to reduce accidental tissue damage and significantly improve retinal surgeries in the future.

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**Fig. 1: Robotic system in clinical setup** (© Preceyes, 2018)

The robot system (Preceyes BV) has been designed to enhance surgical precision, specifically for vitreoretinal eye surgery. The device consists of a motion controller for hand motion input, and a table-mounted instrument manipulator holding the surgical instrument. Due to the assistive nature, the surgeon is always in control of the instrument. The system also includes an interface to the OR table as well as a head support system. For proper immobilization of the patient’s head during surgery, iFIX patient positioning and immobilization technology (iSYS Medizintechnik GmbH) has been used for the patient trial.

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**Fig. 2: Instrument approaching the retina** (© ACMIT, 2018)

**Contact and information**

ACMIT Gmbh
Viktor Kaplan-Strasse 2, 2700 Wiener Neustadt
T 43 2622 22859 - 0
E gernot.kronreif@acmit.at, www.acmit.at

**Project coordinator**

Dr. Gernot Kronreif

**Project partners**

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