

Next Level Retina Surgery



Welcome to the age of robot-assisted surgery. Learn where this technology may apply in the field of ophthalmology.

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Advances in ophthalmic surgery (loupes, microscopes, vitrectomy machines, fine surgical tools) have extended the reach, safety, and success of standard vitreoretinal procedures. Despite these advances, retina surgeons, being limited by human physiology, continue to cause unavoidable traumas during the most intricate surgical maneuvers, such as internal limiting membrane (ILM) peeling and epiretinal membrane removal.¹

TO TREMOR IS HUMAN

All humans have a baseline physiologic tremor of around 100 μm . This limits the ability of retina surgeons to cannulate fine retinal vessels or to accurately position a catheter tip in the subretinal space with concomitant infusion.^{2,3} The tremor increases significantly when switching from active to static tasks, such as attempting to slowly inject a vector into the subretinal space. Robotics can dampen this tremor and improve precision 10-fold over manual surgery, to a range of 10 μm to 20 μm .

The resolving power of our vision is also a limiting factor, particularly regarding, but not restricted to, depth perception in performing both manual and high-precision robot-assisted tasks. However, integrating distance sensing into a feedback loop can improve robotic precision to the range of 1 μm to 2 μm .

Robotics can overcome human limitations by delivering accuracy and precision at unparalleled levels. Several approaches exist, with varying levels of sophistication and cost.

Hand-Stabilizing Strategies

These strategies maintain the surgeon's freedom of movement by providing an instrument that directly compensates for tremor and jerks.

Comanipulation

This approach allows the surgeon to maintain intuitive direct control over an instrument during delicate dedicated tasks. It introduces increased friction or motion resistance during dynamic, prespecified intraocular movements, but it would be difficult to integrate with many modern intraocular imaging techniques such as intraoperative OCT.

Telemanipulation

Engineered for remote control of robotic instruments, telemanipulation allows the surgeon to perform surgical tasks via a motion controller or console. Decoupling the manipulation of an instrument from the surgeon's direct grip not only enables tremor filtering, but it also provides an opportunity to introduce a variety of other external

AT A GLANCE

- ▶ Humans have a baseline physiologic tremor that limits the ability of surgeons to perform certain precise tasks with accuracy.
- ▶ Robotics can overcome these limitations by delivering accuracy and precision at unparalleled levels.
- ▶ The Preceyes Surgical System robot was designed to be a compliant and safe assistant rather than a replacement for the surgeon.

enhancements, such as motion scaling, positional feedback, setting fixed or relative boundaries to intraocular movements, and providing a platform for surgical automation.

PUT TO THE TEST

The first human clinical trial of a telemanipulation system in eyes using the Preceyes Surgical System (PSS; Preceyes), was recently completed, and demonstrated the feasibility and safety of robot-assisted membrane peeling and subretinal injections.¹ Limiting reach along the z-axis and allowing advancement by incremental steps enabled surgeons to engage the ILM safely without disturbing deeper retinal tissues. This led to less surface hemorrhages, as demonstrated clinically.

The advantage of a robotic assistant was also demonstrated with use of a simulator at this year's Euretina congress. An Eyesi Surgical (VRmagic Holding) dedicated instrument was coupled to the PSS. Eyesi provides a number of metrics on surgical performance and complications. A virtual boundary was established at the retinal surface, and comparisons were made between manual surgery and robotically

controlled surgery (Figure 1). None of the 24 surgeons who participated had prior training with the robot or with the Eyesi simulator.

After a 10-minute training period, surgeons were asked to perform a peeling task, first manually and then robotically. Despite the stressful congress hall setting, only micro-

hemorrhages occurred at the initiation of an ILM peel during the robotic simulations, whereas additional foveal hemorrhages, extrafoveal hemorrhages, and eight retinal tears were induced in the manual approach.

Initiation and completion of the peel took an average of 4 minutes manually and 9 minutes with robotic assistance. The variation was much greater in the robotic arm, with

younger, less experienced surgeons able to perform the task faster. Such results are not surprising. The use of surgical robotics in other fields of medicine has mostly been favored by younger surgeons, who gain a level of dexterity and precision comparable to those of their mentors after a short training period.

A PLACE FOR ROBOTICS IN SURGERY

Membrane peeling is frequently performed during vitreoretinal surgery. Although the procedure requires good dexterity, it is not a “killer indication” for use of robotics—that is, an indication so desirable that it makes the availability of robotics an absolute necessity in retina surgery. Robotics is more likely to be required for subretinal procedures, where its precision can guarantee placement of biologically active products at their optimal location while avoiding a breach of the blood-ocular barrier. Absolute stability in the robot's standby mode ensures that a prolonged subretinal injection can be carried out safely without the surgeon's tremor or

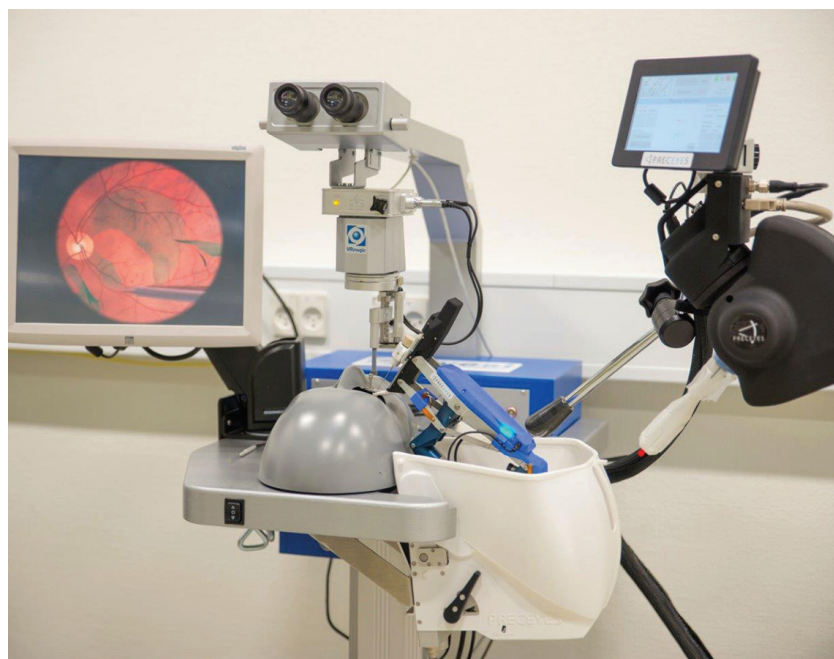


Figure 1. Setup of the PSS coupled to the Eyesi simulator. This provides an ideal platform to train surgeons and to test functionalities.

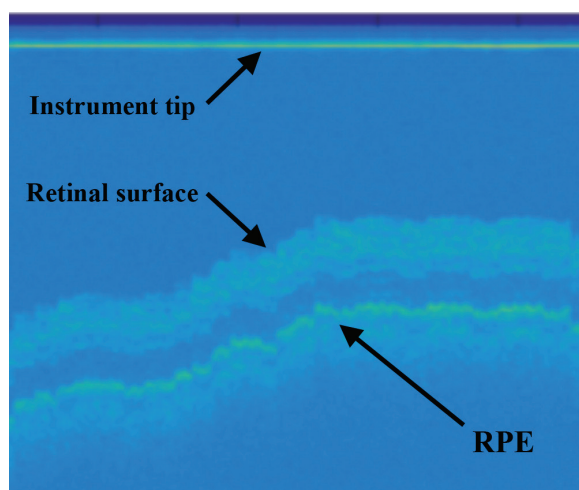


Figure 2. OCT angiography scan recording from an intraocular probe placed in the vitreous cavity of a patient and progressively advanced in the direction of the retina. Details of retinal layers are clearly visible on the recording.



Figure 3. Typical OR setup. The micromanipulator arm is positioned at the edge of the surgical site in an unobtrusive position that is easy to reach and easy to position when required.

microjerks causing enlargement of the retinotomy.

With the help of robotics, reflux can be minimized, delivery can be controlled, and the appropriate performance of critical steps can be carried out by skilled surgeons with minimal additional training. This is particularly true if visualization, in the form of an OCT scan, is built directly into the delivery instrument and used to guide the position of the instrument tip. Preceyes is currently working on developing such an integrated approach (Figure 2). Retinal thickness and subretinal structures can be visualized with the OCT scan.

Although the PSS is not commercially available yet, one can imagine that robotics could also be of assistance in more common vitreoretinal procedures, particularly because the system has been designed to integrate with existing OR equipment.

When visualization is limited or poor, the intended surgical step can be carried out robotically with greater safety, provided a boundary has been set at the retinal surface. Consider tasks such as fluid-gas exchange, removal of staining dyes, site-specific illumination, induction of posterior vitreous detachment, and laser photocoagulation; all of these could be carried out without having to worry about damaging the retinal surface. A robotic

approach could increase efficiency for steps that require steady positioning at a fixed distance from the retina and the ability to pause and exchange instruments without losing track of the site of interest. Peeling membranes could be simplified by improving illumination at the site of surgery or by providing a third arm to elevate the membrane.

MORE TO COME

True automation of tasks, although theoretically possible, requires the integration of video or image feedback into the robot at a high refresh rate and the development of appropriate fallback and safety protocols for each procedure, as the surgeon would be located at a distance from the patient. An easier, safer, and more intuitive solution is to unobtrusively place the robot adjacent to the surgical site so that it can be positioned and removed from the site as necessary (Figure 3).

Multiple fail-safe mechanisms are built into the mechanics of the PSS robot and its software and use protocols. These are designed in such a way that each level of automation falls back to a lesser level, down to standard manual surgery. The fail-safes ensure that the surgeon remains in control of the whole surgical process so that the procedure is executed safely and efficiently.

Robots can and should be designed to be compliant and safe assistants when most needed, not a replacement for the surgeon. The PSS is now commercially available as a clinical investigational device. It does not have the CE Mark or US FDA approval. Preceyes hopes to obtain the CE Mark in 2019 and to broaden commercial distribution of the PSS in 2020. ■

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