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ORIGINAL ARTICLE

ESPRESSO: A novel device for laser-assisted surgery of the anterior eye segment

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ABSTRACT

Introduction: Merging robotics with laser eye surgery could enhance precision, repeatability and automation. During some eye laser procedures the patient is awake, thus eye stabilization is desired to avoid movements that could affect the treatment. **Material and methods:** The ESPRESSO platform has a two-stage actuation system to position a stabilization tool on the eye, a proximity sensing unit to monitor the stabilization tool position, and a sensing unit to monitor the pressure exerted on the eye. The platform is tested *in-vitro* and *ex-vivo* with clinicians. A maximum pressure to be exerted on the eye is defined with expert ophthalmic surgeons to be 22 mmHg: physiological intraocular pressure (IOP) range is 10-21 mmHg. This pressure corresponds to a force of 0.3 N. **Results:** The necessary contact force to have eye fixation (according to the clinicians' feedback) is evaluated: maximum values resulted always below 0.3 N. A maximum IOP increase of 4.67 mmHg is observed, that is a slight variation with respect to the performance of other platforms (IOP elevations up to 328 mmHg). **Conclusion:** Design and initial assessment of the platform is presented. Eye stabilization is performed without exceeding the critical contact force value and causing large/sudden IOP increases.

KEYWORDS
Eye stabilization, laser-assisted surgery, ophthalmic surgery, surgical robotics

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Introduction

Robotics has strong potential to advance eye surgery by improving precision, reducing tremor, amplifying scale of motion, and automating the procedure (1). Recently, many robotic surgical platforms have been developed for eye surgery, such as: master-slave systems (2–9), cooperatively controlled robots (10–12), handheld assistive manipulators (13) and magnetic controlled microrobots (14). The daVinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) has been tested in eye microsurgery (15–17) and customized systems have been proposed (18–19). A significant advance in ophthalmic surgery is expected from the merging of minimally invasive laser techniques with robotics: This will further advance precision, reproducibility and overall automation. Laser technology is integrated by Becker et al. (20) for robotic-assisted laser retinal photocoagulation. A robotic manipulator for laser tissue welding of the sclera is presented by Garcia et al. (21). Contact transscleral cyclophotocoagulation of the ciliary body is performed by Belyea et al. (8) with the TeSS (Telepresence Surgery System) robot.

The clinical target addressed here is anterior eye segment laser-assisted surgery. Typical procedures are: corneal transplantation (22), cataract surgery (22), glaucoma surgery (23), etc. The surgical target area (Figure 1 a) comprises the cornea (approximately 11 mm in diameter) and an annulus around it, to perform scleral flaps (maximum 4×4 mm) for glaucoma surgery, resulting in an area with a total diameter of approximately 20 mm (Figure 1 b). An overview of the surgical scenario is shown in Figure 1 c and d. The focal distance (d in Figure 1d) from the laser output to the eye must be fixed. During some anterior eye segment laser procedures, the patient is awake and only locally sedated. Eye stabilization is therefore of outmost importance to avoid movements that may cause inaccurate results or permanent damage. Usually surgeons use handheld tools such as forceps or rings, for engaging and stabilizing the eye, but this can induce intraocular pressure (IOP) increase. Commercial excimer lasers for refractive surgery employ eye tracking systems to compensate for eye movements, but the precision of the eye-tracker can be affected by bubbles that may appear during laser treatment of the anterior eye segment (24). More precise

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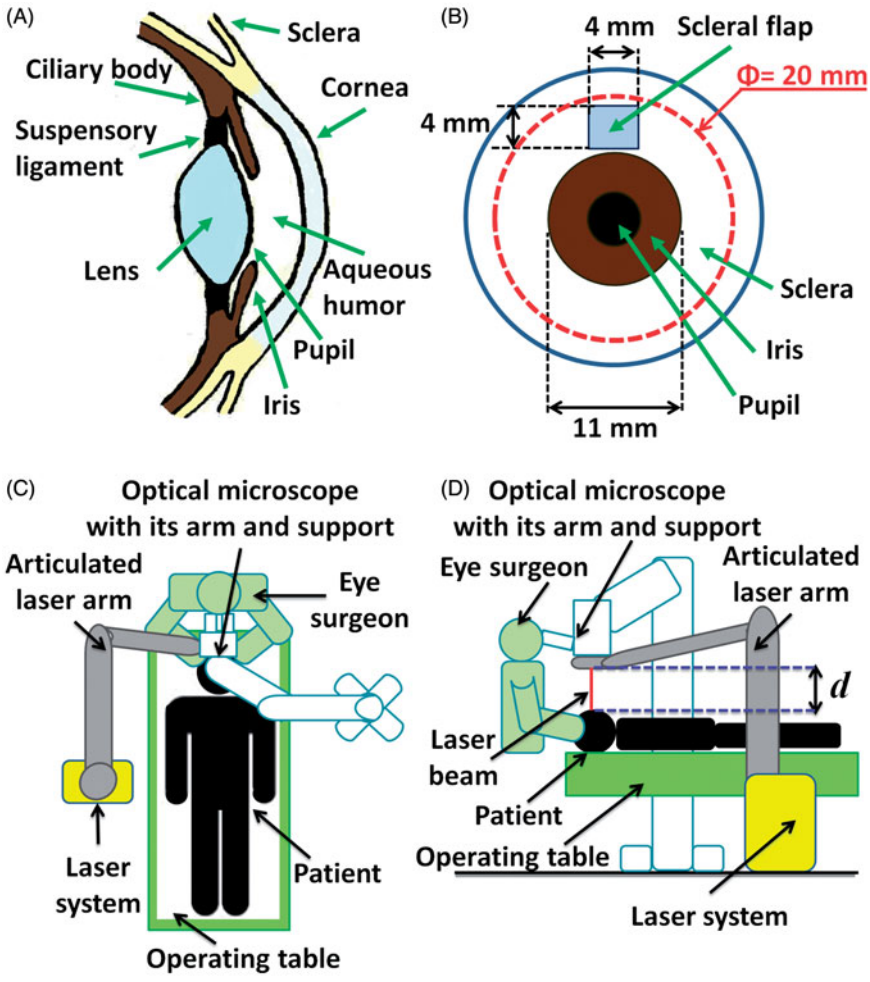

Figure 1. Clinical specifications and surgical scenario for anterior eye segment surgery: (a) anterior eye segment, (b) surgical target area (inside the red dashed circle), (c) view from above of the traditional clinical surgical scenario for laser-assisted ophthalmic surgery, (d) lateral view of the traditional clinical surgical scenario (d is the focal distance between the laser and the patient's eye, which must be fixed during surgery).

mechanical patient interfaces, based on applanating contact lenses and vacuum ports, are employed to stabilize the eye in commercial femtosecond lasers for refractive surgery. However, no precise intra-operative information about the force exerted on the eye is provided in these systems, except for an alarm that is set when an excessive force is reached. In recent studies, these platforms have been found to cause substantial IOP elevations up to 328.3 mmHg (physiological IOP range is 10-21 mmHg); high or sudden IOP changes may cause several irreversible damages in ocular structures (25).

Material and methods

In this study, ESPRESSO (Eye Stabilization maniPulatoR for lasEr aSSisted Ophthalmic surgery) system is proposed. The platform exerts a moderate pressure on the eye through a stabilization tool: This guarantees contact between the tool and the eye, stopping involuntary movements, but at the same time, avoids causing eye damages.

System design

ESPRESSO is designed to be lightweight and have a small overall encumbrance so as to be mounted to the operating table and be compatible with commercial operative microscopes and laser systems (Figure 2a). The microscope (M844F40, Leica Mycrosystems, Wetzlar, Germany) dimensions are $25 \times 35 \times 50$ mm (L × W × H), excluding arm and support. The laser system is based on an RF excited CO_2 laser (SmartXide2, DEKA, M.E.L.A. srl, Firenze, Italy), coupled with the surgical microscope. Laser spots are delivered to the target tissue inducing photothermal effects, through a scanner (HiScan Surgical, DEKA, M.E.L.A. srl, Firenze, Italy) and a

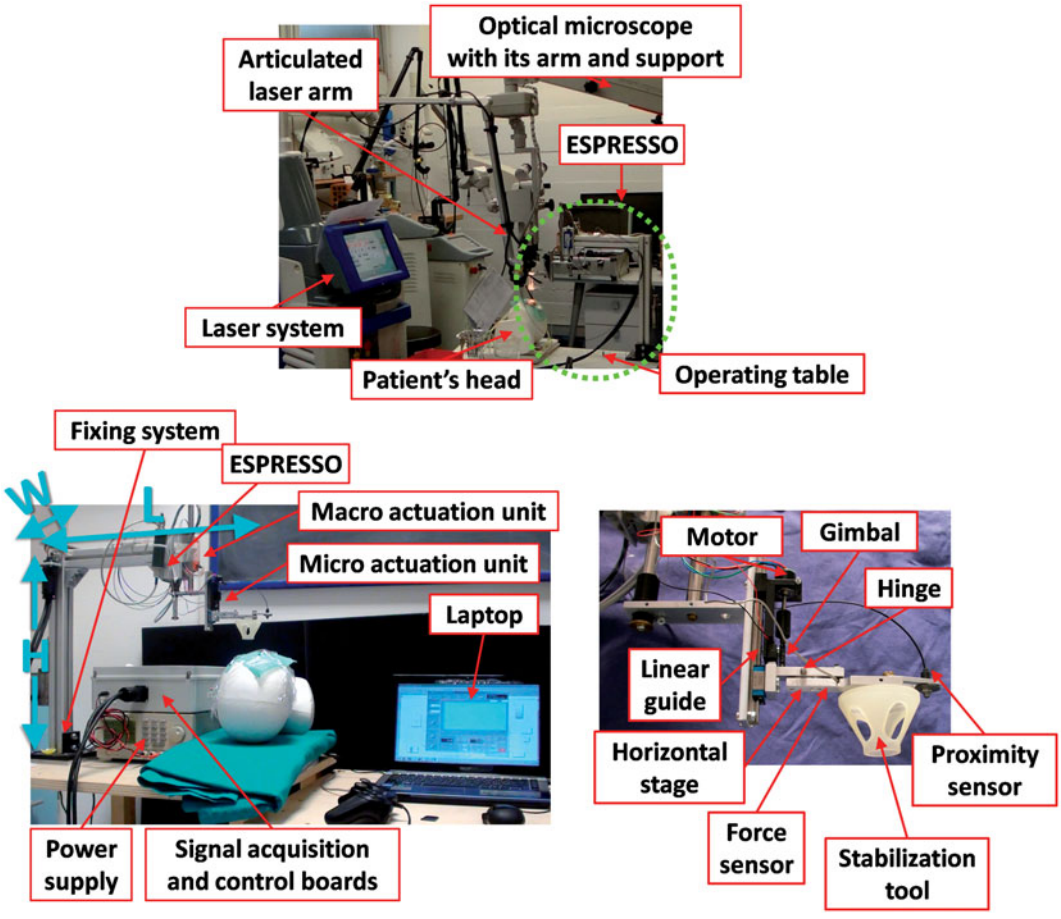

Figure 2. The ESPRESSO platform:(a) ESPRESSO platform integrated with the surgical microscope and the laser; (b) ESPRESSO platform main components, the system is lightweight (3.5 kg) and has a small overall encumbrance (55 × 8×50 cm as L × W×H); (c) a close view of the ESPRESSO platform micro actuation unit.

micromanipulator (EasySpot Micromanipulator, DEKA, M.E.L.A. srl, Firenze, Italy) (26). The focal distance with this laser has to be fixed at 200 mm.

ESPRESSO consists of the following main components (Figure 2b):

- A stabilization tool that stays in contact and fixes the eye during the treatment;
- a fixing system to the operating table;
- a macro actuation unit for coarse positioning and approaching the stabilization tool to the eye;
- a micro actuation unit for slow and precise positioning of the stabilization tool in contact with the eye;
- a proximity sensor to monitor the position of the stabilization tool during the approach phase;
- a force sensor to monitor in a continuous way the force exerted on the eye by the stabilization tool during the contact phase.

The stabilization tool is the only component in contact with the eye; it is realized by rapid prototyping (ProJet™ HD 3000, 3DSystems, Rock Hill, SC, USA) in VisiJet® EX 200 Plastic, which is sterilizable by ethylene oxide (EtO), beta and gamma rays. Most of the platform's main components are located far away from the surgical area, thus allowing an easy separation of the non-sterilized parts from the sterilized surgical area. The stabilization tool is a plastic hollow truncated cone with a height of 37 mm, internal and external lower radii respectively afterwards of 20 and 23 mm, and internal and external upper radii respectively of 49 and 62 mm. It can be tailor-made, thus internal and external lower radiuses can be adjusted if needed, allowing a better matching to the eye surface: This can be decided case by case by the surgeon, by analyzing the anatomical features of the patient's ocular structures preoperatively. The stabilization tool is provided with lateral holes that enable a better visualization of the surgical area and allow the surgeon to put water or other fluids easily on the eye, if necessary. This tool is designed to be disposable and thus it can be mounted/unmounted from the device, tightening/loosening a screw. In order to guarantee the safety of the procedure and avoid sudden or large IOP increases, the maximum pressure to

Table I. DESIGN PARAMETERS OF THE ESPRESSO MAIN COMPONENTS.

		Parameter	Value
Actuation units	Macro actuation unit	Stroke length	120 mm
		Precision	0.4 mm
		Continuous force	9.2 N
		Dimensions	218 × 20 × 28 mm (L × W × H)
		Weight	306 g
	Micro actuation unit	Stroke length	25 mm
		Resolution	0.01 mm
		Continuous torque	6 mNm
		Dimensions	45.3 × 15 mm (L × d)
		Weight	12 g
Sensing units	Proximity sensor	Range of	Up to 140 mm
		Resolution	1 mm
		Frequency	1.5 kHz
		Dimensions	13 × 5 mm (L × d)
	Force sensor	Range of	Up to 2.45 N
		Accuracy	0.70%
		Frequency	1 kHz
		Dimensions	3.3 × 9.6 mm (H × d)

be exerted on the eye is defined (with expert ophthalmic surgeons) to be 22 mmHg (physiological IOP range is 10–21 mmHg). This pressure exerted on the contact area of the stabilization tool (101.3 mm^2) corresponds to a maximum force exerted on the eye of 0.3 N. This force value is considered to be adequate to fix the eyeball with respect to vibrations and involuntary movements.

ESPRESSO can be mounted at either side of the operating table in case the operation has to be performed to the left or the right eye. The fixing system is connected to a structure made of aluminum profiles that support the actuation and sensing systems (Figure 2b).

The macro actuation unit (Figure 2b) is composed of a linear DC-Servomotor (LM2070-120-01, Faulhaber, Croglio, Switzerland) provided with analog Hall sensors. With regard to the range of motion, the anatomical characteristics of the eye have been considered as well as the variability in the configuration of the human face: A stroke length of 120 mm is estimated to be sufficient, considering the encumbrance of the overall clinical setup and the focal distance between laser and eye. The micro actuation unit (Figure 2c) is composed of a stepper motor (AM1524-2R-V-6-35-55, PreciSTEP® Technology, Faulhaber, Croglio, Switzerland) combined with a lead screw and a nut that is connected to a gimbal. The gimbal is attached to a horizontal stage (connected to a linear guide), which supports the stabilization tool and the proximity and force sensors. The horizontal stage is composed of two parts connected by a hinge. For the micro actuation unit, a stroke length of 25 mm is estimated to be sufficient (since it is comparable with the diameter of the eyeball) but, during the contact phase, higher precision is needed in order to carefully position the stabilization tool on the eye and consequently avoid sudden IOP changes. Since ocular structures are very thin (e.g. corneal thickness is approximately 0.5 mm), a positioning precision of 0.01 mm is considered to be sufficient, based on input from surgeons. The design parameters of the two actuation units are summarized in Table I.

A photoelectric proximity sensor (CF/CA1-20, Micro Detectors SpA, Modena, Italy) is integrated (Figure 2c) to monitor the position of the stabilization tool during the approach phase: It is composed of two optical fibers (emitter/receiver) and works at 660 nm wavelength, that is considered safe also if directly pointed at the patient's skin (27). The position of the sensor is shifted with respect to the central axis of the eye with an offset of 40 mm so that it is located above the cheekbone, thus avoiding interference with the laser work space and the microscope field of view. The sensor is a digital switch (returns 0 or 1) that responds above a certain distance threshold that can be set by the surgeon before starting the surgical procedure. A force sensor is integrated (Figure 2c) to monitor the force exerted on the eye during the contact phase: This is a small and compact load cell (Model 13, Honeywell International Inc, Morristown, NJ, USA) integrated close to the surgical target in order to directly measure the contact forces between the stabilization tool and the eye. The main design parameters of the sensor are summarized in Table I.

Actuation motor control is performed in Matlab-Simulink™ using commercial drivers through a graphical user interface (GUI) provided with alarms and security buttons to guarantee the safety of the procedure at any time. The alarm is set not to exceed high pressure on the eye: An emergency release mechanism lifts up the stabilization tool if the force

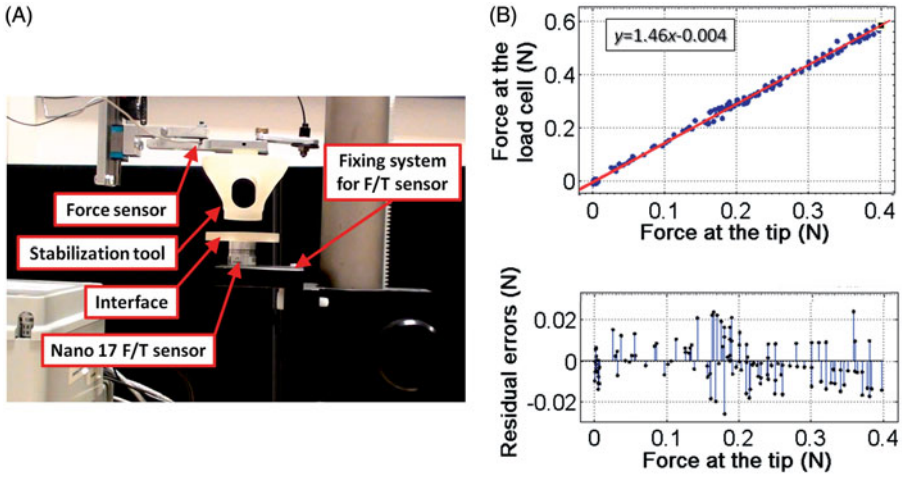

Figure 3. Calibration experiment: (a) calibration setup showing the Nano-17 F/T sensor mounted on a fixing **system** and the ESPRESSO platform stabilization tool and force sensor, (b) calibration results: linear fitting of the force measured by the subminiature load cell integrated in the ESPRESSO platform versus the force measured at the tip of the stabilization tool by the F/T sensor and its residual errors.

exerted on the eye exceeds the maximum value of 0.3 N. In case this occurs, the macro actuation unit is activated to remove the stabilization tool from the eye and the laser is turned off. The force exerted on the eye is continuously monitored and displayed to the surgeon thanks to the GUI. The stabilization tool stays in contact with the eye during the laser cut (the procedure takes usually 3–5 minutes) and it fixes the eye with respect to the laser fixing the focal distance (no motion compensation is performed), then it is removed so as to allow the surgeon proceeding with additional surgical tasks if necessary. No additional tools are inserted in or placed on the eye during the laser treatment. The patient's head is fixed between the operating table pillows.

Calibration

The ESPRESSO force sensor is calibrated in order to monitor the contact force between the stabilization tool and the patient's eye. The experimental setup (Figure 3a) consists of a force/torque (F/T) sensor (Nano-17 SI 12/0.12, ATI Industrial Automation, Apex, NC, USA) mounted on a fixing system and the ESPRESSO. The calibration is performed by moving down the micro actuation unit and positioning the stabilization tool in contact with an interface fixed on the F/T sensor (to match different diameters). The experiments are performed activating the micro actuation unit and moving the stabilization tool in steps of 0.04 mm; at each step the force is measured. The calibration range of the measured force varies from 0 to 0.4 N. Five load/unload cycles are carried out.

Eye stabilization

The eye stabilization performance of the platform is evaluated: In particular, the contact force exerted on the eye is monitored during *in-vitro* and *ex-vivo* stabilization experiments in order to verify if the contact force applied exceeds the maximum value of 0.3 N.

The experimental setup consists of a foam head covered with an ophthalmic drape (as it is usually done in eye surgery). An eye phantom made of a soft plastic ball is placed in the anatomically correct position using the foam head for the *in-vitro* tests (Figure 4a and c); enucleated porcine eyes are used for the *ex-vivo* tests (Figure 4 and d).

In both tests, ESPRESSO is used to position the stabilization tool on the eye. Forces are monitored throughout the experiments. First, the macro actuation unit is activated to approach the eye up to 1 cm distance, then the macro actuation unit is stopped and the micro actuation unit is activated until a proper stabilization of the eye is achieved. Evaluating ocular stabilization can be complex and it requires experience; so these tests are carried out with the supervision of an expert ophthalmic surgeon: In traditional procedures, the surgeon fixes the eye with handheld tools (she/he knows when the eye is stable but she/he cannot control the force exerted). The surgeon indicated when a proper stabilization of the eye was reached to stop the micro actuation unit. The stabilization tool is then kept in position for 60 seconds,

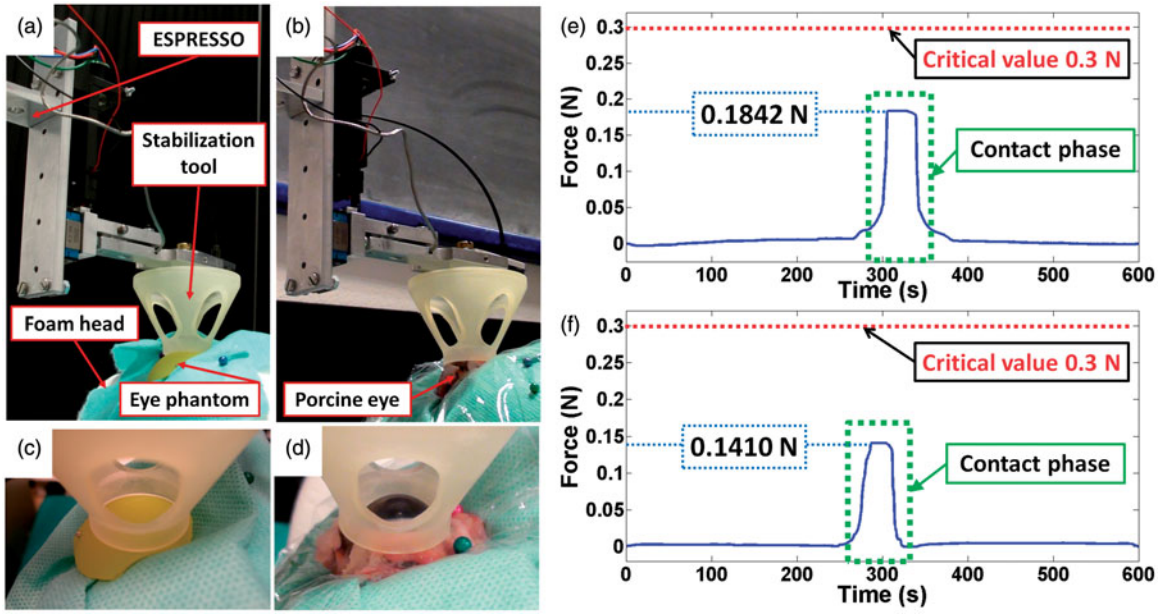

Figure 4. Stabilization of the eye and monitoring of the exerted contact force: (a) *in-vitro* experiment with an eye phantom,(b) *ex-vivo* experiment with an enucleated porcine eye, (c) a close view of the *in-vitro* setup, (d) a close view of the *ex-vivo* setup, (e) contact force between the stabilization tool and the phantom eye during an eye stabilization experiment, (f) contact force between the stabilization tool and the enucleated porcine eye during an eye stabilization experiment. In the pictures (e) and (f), the critical value of 0.3–N for the contact force is shown with a dashed red line.

after this, the stabilization tool is lifted up. Each test is repeated ten times.

IOP monitoring

IOP is monitored during eye stabilization to check for potential unexpected or substantial IOP changes when contact between the stabilization tool and the eye is established. The experimental setup is shown in Figure 5a and b. The test is repeated ten times (ten enucleated porcine eyes are used). The vitreous compartment is cannulated with two 23 gauge needles. The first is connected to a syringe attached to a stopcock and filled with saline solution, in order to adjust the baseline IOP before starting the experiment, if needed. When the IOP is in the physiological range of 10–21 mmHg, the stopcock is closed. The second needle is connected to a filter unit (16555 Minisart, Sartorius Stedim Biotech GmbH, Goettingen, Germany) and then to a manometer (9400150, Sper Scientific, Scottsdale, AZ, USA). Small amounts of glue are used around the insertion points on the sclera in order to keep the seal water tight. The test is performed by lowering the stabilization tool on the porcine eye in order to stabilize it, the force exerted on the eye and the IOP are monitored throughout the experiment lasting for five minutes. The test is carried out following the same steps as the one described above and the expert ophthalmic surgeon indicated when a proper stabilization of the eye was reached to stop the micro actuation unit. The stabilization tool is kept in position for three minutes and then it is lifted up. IOP monitoring continues for one minute after the tool is removed from the eye.

Results

Force sensor calibration

The experimental results of the calibration are reported in Figure 3b: the linear fitting of force measured by the F/T sensor versus the force measured by the subminiature load cell integrated in the platform and its residual errors are shown. The slope of the linear fitting is 1.46, the R-square is 0.99 and the root mean square error (RMSE) is 0.01 N.

In-vitro and ex-vivo stabilization tests

The maximum value of contact force registered *in-vitro* is 0.1842 N (Figure 4e), which corresponds to a pressure of 13.6 mmHg: The mean value of the force is 0.1633 N and the standard deviation is 0.0157 N. The maximum value of contact force registered *ex-vivo* is 0.1410 N (Figure 4f), which corresponds to a pressure of 10.5 mmHg: the mean value is 0.1320 N and the standard deviation is 0.0084 N.

During the *in-vitro* and *ex-vivo* tests, the contact force to reach stabilization of the eye never exceeds the critical

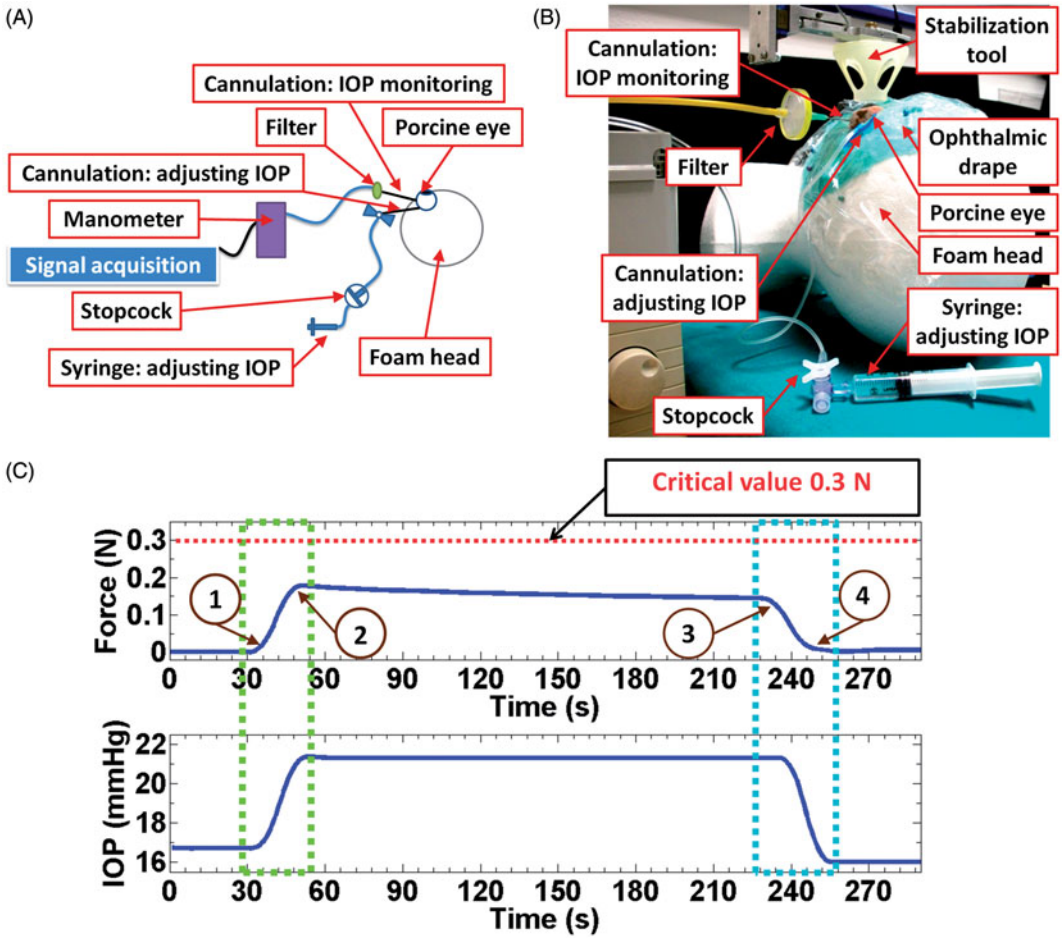

Figure 5. IOP monitoring in *ex-vivo* tests: (a) scheme of the experimental setup for IOP monitoring; (b) the experimental setup for IOP monitoring during eye stabilization with the ESPRESSO platform, (c) force exerted on the porcine eye monitored by the force sensor integrated in the ESPRESSO platform (the critical value of 0.3 N is shown with a dashed red line) and the corresponding IOP monitored during the *ex-vivo* test. In (c), four segments of the test are highlighted: (1) contact between the stabilization tool and the eye starts, (2) eye stabilization, (3) removal of the stabilization tool from the eye, (4) contact between the stabilization tool and the eye removed. Green and cyan dashed lines underline the correspondence between the applied force and the induced IOP variation.

value of 0.3 N, highlighted with a dashed line in Figure 4e and f). In both experiments, the pressure exerted is theoretically safe since the force values stay within the physiological range (10–21 mmHg).

IOP tests

The IOP variation mean value of the ten experiments is 3.2548 mmHg and the standard deviation is 0.8245 mmHg. The mean value of the force of the ten tests is 0.1686 N and the standard deviation is 0.0059 N. The dataset for which the maximum value of the force and the maximum IOP variation are reached are shown in Figure 5c.

These results show that the IOP increase, during eye stabilization with ESPRESSO is limited and slow. The contact force ranges from 0 to 0.1783 N (contact and stabilization, phase (1)–(2)) and the IOP increases accordingly from 16.7 to 21.37 mmHg in 23 seconds: 4.67 mmHg IOP variation that is a slight variation with respect to IOP physiological range (10-21 mmHg), especially if compared with the performance of other platforms (IOP elevations up to 328.3 mmHg (25)). The IOP remains almost constant during contact (phase (2)–(3)) and when the stabilization tool is removed (phase (3)-(4)), it drops a little below than its original value: it decreases down to 16 mmHg in 20 s. No other variations occur after up to one minute monitoring.

Discussion

Design and initial assessment of a novel platform for eye stabilization during laser assisted anterior eye segment surgery is presented. The system is tested *in-vitro* and *ex-vivo* by clinicians. Preliminary results show good performance: The necessary contact force to stabilize the eye with ESPRESSO never exceeds the critical value of 0.3 N and the platform capability to fix the eye without

causing large neither sudden IOP increases is proved. Stationary models are used in order to monitor IOP by eye cannulation avoiding leakage of vitreous humor and pressure loss. Additional *in-vivo* tests will be performed with clinicians in the future, focusing on performing an entire laser assisted surgical procedure (such as trabeculectomy or keratoplasty). In comparison with previous systems (24) (25), the ESPRESSO platform is provided with continuous monitoring of pressure exerted on the eye. This could help preventing high IOPs, possibly leading to an improved surgical outcome and to the elimination or at least reduction of eye damage.

Conclusion

The authors envisage that the ESPRESSO platform will pave the way to an increasingly less invasive laser surgery, as well as a treatment personalization. In fact, the contact force exerted by the stabilization tool on the eye can be directly related to the IOP if the anatomical features of the patient's eye are known (i.e. acquired preoperatively), such as done typically in tonometry.

Acknowledgements

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Declaration of interest

The authors report no conflicts of interest.

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