Published in final edited form as:

Proc IEEE Sens. 2019 October ; 2019: . doi:10.1109/SENSORS43011.2019.8956820.

Sclera Force Evaluation During Vitreoretinal Surgeries in Ex Vivo Porcine Eye Model

Niravkumar Patel¹, Muller Urias^{2,4}, Ali Ebrahimi¹, Changyan He^{1,3}, Peter Gehlbach^{1,2}, Iulian Iordachita¹

¹Johns Hopkins University, 3400 N. Charles Street, Baltimore, MD USA-21218

²Wilmer Eye Institute, Johns Hopkins Hospital, Baltimore, MD 21287 USA

³School of Mechanical Engineering and Automation, Beihang University, Beijing, China, 100191

⁴Federal University of São Paulo, São Paulo, 04023-062 Brazil

Abstract

Vitreoretinal surgery is among the most challenging microsurgical procedures as it requires precise tool manipulation in a constrained environment, while the tool-tissue interaction forces are at the human perception limits. While tool tip forces are certainly important, the scleral forces at the tool insertion ports are also important. Clinicians often rely on these forces to manipulate the eyeball position during surgery. Measuring sclera forces could enable valuable sensory input to avoid tissue damage, especially for a cooperatively controlled robotic assistant that otherwise removes the sensation of these familiar intraoperative forces. Previously, our group has measured sclera forces in phantom experiments. However, to the best of our knowledge, there are no published data measuring scleral forces in biological (*ex-vivo/in-vivo*) eye models. In this paper, we measured sclera forces in *ex-vivo* porcine eye model. A Fiber Bragg Grating (FBG) based force sensing instrument with a diameter of $\sim 900 \mu\text{m}$ and a resolution of $\sim 1 \text{ mN}$ was used to measure the forces while the clinician-subject followed retinal vessels in manual and robot-assisted modes. Analysis of measured forces show that the average sclera force in manual mode was 133.74 mN while in robot-assisted mode was 146.03 mN.

I. INTRODUCTION

In a typical vitreoretinal surgery, multiple surgical instruments are inserted through the small openings made on the white part of the eye, the sclera. Performing precise tool manipulations while maintaining the sclera safety makes these procedures extremely challenging. Moreover, the tool-tissue interaction forces at the sclera are in order of 10s of mN, making the procedure more challenging. Measuring these forces could provide valuable input to the clinician. However, the tools those could be used for vitreoretinal surgeries are required to be compact ($\varnothing \sim 1 \text{ mm}$), making it challenging to integrate the force sensing capabilities. Smits et al. developed a force and distance sensing needle utilizing FBG strain sensors and optical coherence tomography [1]. Our team developed a novel eye surgery tool, which can simultaneously measure the sclera force, tool tip force and the length of the tool inside the eye [2]. A similar tool has been developed for the study presented in this paper.

Along with force sensing tools, which can measure the tool-tissue interactions, robotic-assistants could provide precise manipulation capabilities while eliminating the hand tremor. Over the last two decades, several robotic assistants have been developed for microvascular stenting in ophthalmic retinal surgery [3], intraocular automated surgery [4], and vitreoretinal membrane peeling [5]. At the Johns Hopkins University, we developed a cooperatively controlled Steady-Hand Eye Robot (SHER) [6]. Though, there are clinically validated robotic systems for vitreoretinal surgeries, to the best of our knowledge, there are no published data measuring the sclera forces in *in vivo/ex vivo* eye models. By integrating a robotic assistant with force sensing tools, sclera force information can be communicated passively to the surgeon e.g. via auditory feedback [7] or alternatively can trigger active robot control mechanisms [8], [9] to keep the forces below the safety threshold.

In prior work we have evaluated the forces applied to sclera during simulated vitreoretinal maneuvers in a benchtop setting. These tests have included but are not limited to, following realistic retinal vessel patterns applied to anatomically correct locations on the interior of a polymer eye model. In this study, we measure tool-tissue interaction forces in *ex vivo* porcine eyes at the point at which the instrument enters the eye (the sclerotomy port). The resulting forces are compared in both manual and robot-assisted modes. Fig. 1 shows the experimental setup in an operating room setting.

II. MATERIALS AND METHODS

As previously suggested by Jagtap et. al. [10], tool-tissue interactions at the sclera may play an important role in ophthalmologic procedures as well as impact the development of useful force sensing instrument tips. In this section we present the necessary components including: A) the FBG-based force sensing instrument, B) the robotic platform - SHER, and C) the experimental setup, describing the *ex-vivo* porcine eye model and the vessel following tasks studied.

A. FBG-based Force-Sensing Tool

During a typical retinal procedure, surgical openings through the sclera (sclerotomies), are utilized to provide access to the interior of the eye. Typically, two sclerotomies are used for insertion of active microsurgical instruments that perform the retinal procedure, in a bimanual fashion. A third port is present to accommodate a fluid infusion that maintains the pressure in the globe during the procedure using a vitrectomy machine. Sclerotomies today are typically sized to accommodate 23, 25 or 27 Ga trocars through which the standard tools are safely inserted and retracted during surgery. Therefore, a force sensing instrument should be able to measure forces (in range of 10s of mN) between the tool shaft and the sclera while passing through the sclerotomy port. To measure such small forces while keeping the tool shaft diameter below ~1 mm, FBG-based strain sensors are among the few feasible options for incorporation into the tool shaft, thanks to their small dimensions. As shown in Fig. 2, three optical fibers, each with three FBG strain sensors are attached around a 23 Ga stainless-steel Nitinol tool shaft at 120° spacing. By finding the linear relationship between the reflected wavelength from the FBG sensors and the strain, the forces on the tool shaft can be inferred [2]. To measure the changes in the reflected FBG wavelengths, FBG fibers

are connected to an optical sensing interrogator (si155, Micron Optics Inc., Atlanta, GA). The FBG interrogator sends reflected FBG wavelengths at a 1 KHz rate to the computer to calculate the forces in real-time. For each tool built, a calibration is necessary to determine the linear relationship between the change in reflected FBG wavelengths and the applied forces. The force sensing tool used in this study has an RMS error of 2.39 mN for sclera forces which are shown as F_{sx} and F_{sy} in Fig. 2.

B. Steady-Hand Eye Robot

SHER is a cooperatively controlled robotic assistant for retinal interventions [6]. It provides 1 μ m resolution joint motions which are cooperatively controlled by the user. To measure the user interaction forces, SHER has a 6 degrees of freedom (DOF) force/torque sensor (ATI Nano 17, ATI Industrial Automation, Apex, NC, USA) on the tool handle. As shown in Fig. 1b, SHER is operated by the clinician by holding the tool attached to the robot end-effector. Measured interaction force/torque are filtered to remove the hand tremor and then are fed as an input into the robot control system to cooperatively manipulate the tool.

C. Experimental Setup

The purpose of this study is to measure the scleral forces in a model that has similar biological properties to human sclera. Porcine eyes are known to be representative of human eyes in size and gross anatomy. They are often considered as the model of choice for mock retinal surgery due to their similar dimensions and the analogous pattern of retinal vessel distribution [11]. *Ex-vivo* porcine eyes were harvested and procured on the day of study. Eyes were immediately stored in a plastic holder with saline solution and ice to avoid direct contact between the eyes and the ice. Each eye was examined for corneal transparency and only those with sufficient corneal transparency were chosen. Out of 20 eyes procured, only 2 eyes had the desired corneal transparency. These were used as they allowed visualization of the retinal vessels and permitted performance of the desired manual tasks.

As shown in Fig. 1, experiments were performed in a clinical operating room in Wilmer Eye Institute at the Johns Hopkins Hospital. The experiment setup consists of a surgical microscope (Lumera 700, Carl Zeiss Meditec Inc., Dublin, CA, USA), a vitrectomy machine (EVA, D.O.R.C. Dutch Ophthalmic Research Center (International) B.V., the Netherlands), SHER, the force sensing tool and the FBG interrogator. To prepare each of the porcine eyes the following steps were carried out:

1. Place the eye in the orbit of the model human head, and secure the soft tissues to the foam, as shown in Fig. 3a.
2. Create sclerotomy via transscleral trocar placement in standard positions: one for the fluid infusion, and two to accommodate the active instruments. Enlarge the sclerotomy to accommodate the force sensing tool whose diameter is bigger than the 23 Ga trocar.
3. Perform vitrectomy (Fig. 1a) to remove the vitreous humor.
4. Remove the lens using phacofragmentation via pars plana in order to improve surgical viewing and to allow tools to move freely within the eye.

5. Inspect the retina to determine if the view is still suitable to perform the vessel following task.
6. With the light pipe in the non-dominant hand and the force sensing tool in the dominant hand as shown in Fig. 1b–c perform the vessel-following task: without touching the retina, start at the optic disc, follow a vessel to its end, and then retrace the path to the optic disc. Fig. 3b shows the force sensing tool following one of the retinal vessels.

Clinician holding the force sensing tool for robot-assisted and manual modes is shown in Fig. 1b and 1c, respectively. During the time that the clinician performed manipulations, the sclera forces were recorded in real-time, at 200 Hz.

A retina specialist with moderate experience with the robotic system performed the tasks. The tasks were performed in manual and robot-assisted modes in both eyes and were repeated ten times in each eye.

III. RESULTS AND DISCUSSION

Results from the experiments are summarized in Table I, while Fig. 4 shows sclera force and insertion depth trajectories for one of the manual and robot-assisted vessel following attempts. Analysis of the measured forces indicate that the average sclera forces were 133.74 ± 65.02 mN and 146.03 ± 88.73 mN in manual and robot-assisted experiments, respectively. It could be seen that the average sclera force is larger in robot-assisted attempts compared to the manual ones, this could be attributed to diminished force sensing feedback to the surgeon due to robot's stiff structure. Mean sclera force of 133.74 mN in manual attempts is larger than previously reported measurements of 87.08 mN in dry-phantoms [12]; this could be due to the compliance differences between the dry phantom and the pig eye, the pig eye was restricted via pinning of soft tissues to the Styrofoam model while the dry phantom moved more freely. Similar mean insertion depth indicates the clinician's ability to follow the vessel closely in both the modes. The shorter task duration for manual experiments could be attributed to higher manipulation skills of the clinician, which are limited by the robot's inertia in robot-assisted experiments.

IV. CONCLUSIONS

This paper presented first ever measurements of sclera forces in vitreoretinal surgery in an *ex vivo* porcine eye model. Experiments show that the sclera forces are larger in robot-assisted mode compared to manual ones. This finding may be related to the fact that the present generation cooperatively controlled robot diminishes force sensing feedback to the surgeon by virtue of a noncompliant robotic arm. In future work we will further validate these results with multiple users with varying retinal surgery experience as well as varying amounts of experience with robot use. Furthermore, we will evaluate impact of auditory feedback and robot control strategies on the sclera forces.

ACKNOWLEDGEMENTS

This work was supported by U.S. National Institutes of Health under grant number 1R01EB023943-01. The work of M. Urias was also supported by Instituto da Visão (IPEPO) and Lemann Foundation. The work of PLG was supported in part by Research to Prevent Blindness, New York, USA, and gifts by the J. Willard and Alice S. Marriott Foundation, the Gale Trust, Mr. Herb Ehlers, Mr. Bill Wilbur, Mr. and Mrs. Rajandre Shaw, Ms. Helen Nassif, Ms Mary Ellen Keck, and Mr. Ronald Stiff.

REFERENCES

- [1]. Smits J, Ourak M, Gijbels A, Esteveny L, Borghesan G, Schoevaerdt L, Willekens K, Stalmans P, Lankenau E, Schulz-Hildebrandt H, Huttmann G, Reynaerts D, and Vander Poorten EB, "Development and experimental validation of a combined fbg force and oct distance sensing needle for robot-assisted retinal vein cannulation," in Robotics and Automation (ICRA), 2017 IEEE International Conference on IEEE, 2017, p. 1.
- [2]. He X, Balicki M, Gehlbach P, Handa J, Taylor R, and Iordachita I, "A multi-function force sensing instrument for variable admittance robot control in retinal microsurgery," in Robotics and Automation (ICRA), 2014 IEEE International Conference on IEEE, 2014, pp. 1411–1418.
- [3]. Wei W, Popplewell C, Chang S, Fine HF, and Simaan N, "Enabling technology for microvascular stenting in ophthalmic surgery," *Journal of Medical Devices*, vol. 4, no. 1, p. 014503, 2010.
- [4]. Wilson JT, Gerber MJ, Prince SW, Chen C-W, Schwartz SD, Hubschman J-P, and Tsao T-C, "Intraocular robotic interventional surgical system (iriss): Mechanical design, evaluation, and master–slave manipulation," *The International Journal of Medical Robotics and Computer Assisted Surgery*, 2017.
- [5]. Edwards T, Xue K, Meenink H, Beelen M, Naus G, Simunovic M, Latasiewicz M, Farmery A, de Smet M, and MacLaren R, "First-inhuman study of the safety and viability of intraocular robotic surgery," *Nature biomedical engineering*, vol. 2, no. 9, p. 649, 2018.
- [6]. Uneri A, Balicki MA, Handa J, Gehlbach P, Taylor RH, and Iordachita I, "New steady-hand eye robot with micro-force sensing for vitreoretinal surgery," in 2010 3rd IEEE RAS & EMBS International Conference on Biomedical Robotics and Biomechatronics IEEE, 2010, pp. 814–819.
- [7]. Ebrahimi A, He C, Roizenblatt M, Patel N, Sefati S, Gehlbach P, and Iordachita I, "Real-time sclera force feedback for enabling safe robot-assisted vitreoretinal surgery," in 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC) IEEE, 2018, pp. 3650–3655.
- [8]. He C, Patel N, Ebrahimi A, Kobilarov M, and Iordachita I, "Preliminary study of an rnn-based active interventional robotic system (airs) in retinal microsurgery," *International journal of computer assisted radiology and surgery*, pp. 1–10, 2019.
- [9]. Ebrahimi A, He C, Patel N, Kobilarov M, Gehlbach P, and Iordachita I, "Sclera force control in robot-assisted eye surgery: Adaptive force control vs. auditory feedback," *arXiv preprint arXiv:1901.03307*, 2019.
- [10]. Jagtap AD and Riviere CN, "Applied force during vitreoretinal microsurgery with handheld instruments," in *The 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, vol. 1. IEEE, 2004, pp. 2771–2773.
- [11]. Menduni F, Davies LN, Madrid-Costa D, Fratini A, and Wolffsohn JS, "Characterisation of the porcine eyeball as an in-vitro model for dry eye," *Contact Lens and Anterior Eye*, vol. 41, no. 1, pp. 13–17, 2018. [PubMed: 28986008]
- [12]. He C, Roizenblatt M, Patel N, Ebrahimi A, Yang Y, Gehlbach PL et al., "Towards bimanual robot-assisted retinal surgery: Tool-to-sclera force evaluation," in 2018 IEEE SENSORS IEEE, 2018, pp. 1–4.

Fig. 1.

Experimental setup in an operating room showing: Vitreoretinal surgeon, vitrectomy machine, surgical microscope, *ex vivo* porcine eye fixed on a styrofoam manikin head, SHER, and force sensing tool.

Fig. 2.
Schematic of a FBG-based force sensing tool and its specifications.

Fig. 3.

Ex vivo porcine eye model: (a) showing porcine eye fixed on a styrofoam manikin head and (b) view from the surgical microscope while following a retinal vessel.

Fig. 4. Plot showing sclera force and insertion depth trajectories for one of the robot-assisted (top) and manual (bottom) vessel following attempts.

Comparison of sclera force, insertion depth and task duration for manual and robot-assisted vessel following tasks

TABLE I

Eye No.	Sclera Force						Insertion Depth						Duration			
	Manual			Robot-assisted			Manual			Robot-assisted			Manual		Robot-assisted	
	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	STD
	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	Mean	STD	Mean	STD
1	163.72	72.54	178.10	118.68	13.23	3.54	14.30	2.86	25.40	3.28	34.95	8.74				
2	103.76	57.50	113.96	58.79	14.25	3.87	13.98	3.46	37.82	6.35	45.87	9.53				
All	133.74	65.02	146.03	88.73	13.74	3.70	14.14	3.16	31.61	8.01	40.41	10.65				