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Dual-Stiffness Force-Sensing Cannulation Tool for Retinal Microsurgery

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Abstract

Retinal vein cannulation is a promising treatment for retinal vein occlusion that involves the injection of an anticoagulant directly into the occluded vein to dissolve the blockage. However, excessive forces applied by the injection tool during the procedure, at either the scleral incision or injection site, can result in injury to the eye. Furthermore, the force required to puncture retinal veins (around 10 mN) is well below human sensing ability and an order of magnitude smaller than those that can be safely applied at the sclera (around 100 mN). Detection and management of tool-to-tissue forces on these different scales are some of the most challenging aspects of the cannulation procedure. This work describes the development of a sensorized cannulation tool capable of detecting both tool-to-vein puncture forces and tool-to-sclera contact forces. By combining two materials, nitinol alloy for the tool tip and stainless steel for the tool shaft, to achieve dual stiffness, the tool possesses a flexible tip to capture small vein puncture forces and a stiffer shaft to maintain straightness during use. Three segments of fiber Bragg grating sensors are calibrated to measure the transverse forces at both the tool tip and sclerotomy, as well as to determine the tool insertion depth within the eye. The results of the validation experiments show that the root mean square error of the measurements for the force at the tip, the force at the sclerotomy, and the tool position are 0.70 mN, 1.59 mN, and 0.69 mm, respectively.

I. Introduction

Retinal vein occlusion (RVO), one of the most common retinal vascular diseases, arises from the formation of a tiny thrombus inside of the retinal vein [1]. Patients experience blurred or distorted vision, and in severe cases, permanent vision loss. A promising treatment for RVO is retinal vein cannulation (RVC), which directly delivers the therapeutic agent into the blocked vein to dissolve the clot. The general RVC procedure can be summarized by the following steps: (a) inserting the cannulation tool into the eyeball through a sclerotomy port ($\phi < 1$ mm), (b) accurately locating a sharp cannula needle above the occluded retinal vein,

(c) puncturing through the upper vein wall and holding the cannula tip at a precise position to avoid piercing the bottom vein wall, and (d) maintaining the cannula position inside the vein for several minutes to deliver the therapeutic agent e.g., tissue plasminogen activator (t-PA). Due to these rigorous manipulation requirements and currently unproven efficacy, RVC has not yet been incorporated into routine clinical practice. One of the greatest challenges of the RVC procedure is that the required force applied by the needle to puncture the vein (puncture force) as shown in Fig. 1 (a) is well below human sensing capability [2], which potentially could lead to unintentional, excessive manipulation forces on retinal vessel and cause further iatrogenic injury. Additionally, at the sclerotomy incision, sustained contact force between the tool shaft and the sclera (scleral force) can also potentially lead to scleral damage. Therefore, successful implementation of RVC requires not only detection of vessel puncture, but also monitoring of the scleral force in order to inform the surgeon of unsafe tool-to-tissue interaction forces and improve surgical outcome.

Surgical instruments with sensing capability have been developed to address some of the aforementioned challenges of RVC. Our group [3] developed a motorized force-sensing microneedle by incorporating fiber Bragg grating (FBG) sensors into the tool tip to detect the puncture force. Kang et al. [4] proposed a distance-sensing microinjector that used common-path swept source optical coherence tomography (OCT), for which an OCT fiber was attached to the tool tip to obtain the distance between the tool tip and the target vein wall. Ourak et al. [5] integrated both FBG and OCT and attached the fibers on the tool tip to extract both distance and contact force as indicators of vein puncture. The tool developed by Schoevaerdt et al. [6] captures the puncture event by using a bioelectrical impedance sensor. Other sensing instruments incorporate micro sensors into the tool handle [7] to measure the tool-to-tissue forces but cannot necessarily distinguish between tip and scleral forces. The sensing capability of these aforementioned tools is limited to puncture detection at the tool tip and measurement of the scleral force is not addressed. Therefore, our group [8] has previously proposed a novel dual force-sensing tool to measure the scleral force and the forces applied at tool tip (tip force), as well as the tool insertion depth from the sclerotomy port (insertion depth), by attaching FBG sensors on the multiple contact segments of the tool. However, given that vein puncture forces can be as small as a single millinewton [3] and scleral forces can reach a few hundred millinewtons [9], tools constructed with a single material are either not sensitive enough to detect the tiny forces at the tip (e.g., stainless steel) or not stiff enough to keep the tool straight in the sclerotomy port during operation (e.g., nitinol).

Our solution to the trade-off between sensitivity and stiffness as stated above is to utilize materials of different stiffnesses for the tool tip and tool shaft. This work presents the design and finite element analysis (FEA) of a new sensorized tool with dual stiffness that uses FBG sensors to detect both tip force and scleral force, as well as measure insertion depth. Tool calibration and validation were performed using a previously developed Steady Hand Eye Robot (SHER) research platform [10], and the linear correlations between the FBG wavelength readings and the measurements, i.e., the tip force, the scleral force and the insertion depth as described in Fig. 1 (a), were calculated.

As a proof of concept for RVC use, the sensorized tool was assembled with a 3D printed handle, and a motorized cannula needle was fabricated and inserted into the tool shaft. The resulting cannulation tool can be utilized to enhance RVC procedure safety by providing surgeons with essential tissue manipulation information.

II. Prototype

The mechanical design of the sensorized tool improves upon previous dual force sensing tools [8] in the material and structural properties of the tool shaft. The tool shaft consists of two distinct sections of 23 Ga ($\phi = 0.64$ mm) tubing, with a small segment of 26 Ga ($\phi = 0.46$ mm) tubing interfacing between the sections as an internal join. Medical device adhesive (Loctite 4011, Henkel, CT, USA) is used to glue all of the segments together. The tip end of the tool consists of a 8 mm length of nitinol tubing (Young's modulus = 83 GPa, under austenite status), and the remaining shaft is a 70 mm (45 mm of which is the sensing part) length of stainless steel tubing (SS304, Young's modulus = 203 GPa). In addition to the segment interfacing between the 23 Ga outer tubes, two more segments of 26 Ga tubing are utilized at the tool tip and the distal end of the tool shaft to keep the inner injection tube centered. The injection tube itself is a 31 Ga ($\phi = 0.26$ mm) tube, and a 36 Ga ($\phi = 110^{\mu}$ m) beveled microneedle is glued at the tip with adhesive to serve as the cannula needle, which is angled at 45° , as shown in Fig. 1 (b).

In order to measure transverse forces at the tool tip and sclera, three FBG fibers are arranged at 120° intervals around the circumference of the tool shaft to sense the wavelength shift due to tool deflection as shown in Fig. 1 (c). Each fiber contains three separate 3mm-long FBG sensors located at 3 mm, 28 mm, and 34 mm from the tool tip as shown in Fig. 1 (b), for a total of 9 FBG sensors. The first segment of FBG sensors (FBG-I), which is closest to the tool tip, is capable of measuring the puncture force. The second and third segments of FBG sensors (FBG-II and FBG-III) are located outside of the eye and together are capable of measuring the scleral force as well as the insertion depth [8].

The FBG fibers themselves are secured to the outside of the tool shaft using the medical device adhesive. To maintain equal spacing among FBG fibers along the length of the round tool shaft, a custom jig was created out of polymer clay to hold both the tool shaft and the fibers in place during fabrication as shown in Fig. 2. After securing the ends of the FBG fibers to the tool tip to axially align the FBG sensors, the jig is incrementally shifted down the tool shaft to allow the FBG fibers to be glued in sections. The triangular shape of the jig suspends the tool above the table and also allows the entire setup to be rotated for easier access to each FBG fiber.

The final sensorized tool is shown in Fig. 3. The outer tool shaft with the FBG fibers is assembled with a 3D printed handle and a syringe is connected to the injection tube via a catheter. To prevent damage to the microneedle during tool insertion and before vein puncture [3], the cannula needle is able to extend and retract within the tool shaft using a linear motor.

III. Finite element analysis

We hypothesized that the combination of nitinol and stainless steel tubing would create a tool shaft able to achieve higher sensitivity at the tool tip, while maintaining adequate stiffness in the remainder of the tool shaft. To assess this, FEA was performed for the following three tools with different structures as shown in Fig. 4:

- Tool A: the cannula needle covered with a 23 Ga nitinol tube,
- Tool B: the cannula needle covered with a 23 Ga stainless steel tube (benchmark tool),
- Tool C: the cannula needle covered with a 23 Ga nitinol tube at the tip and a 23 Ga stainless steel tube for the rest of the shaft (proposed tool).

The same constraints were applied to all three models, i.e., the tool end is fixed in geometry and the contact between the cannula needle and the outer tube is set as "no penetration". For Tool C, the proposed tool, the contact between the nitinol tube and the stainless steel tube was set as "bond". Two load cases were applied, and tip displacement and strain at different locations were measured.

In the first load case, a force with a magnitude of 1 mN was applied at the tips of each of the three tools. The middle plane of the FBG sensor at the tip (FBG-I) was selected as the measurement location as shown in Fig. 5 (a), and the strains at the top and bottom points of the cross section were taken as shown in Fig. 5 (b). The results showed that Tool C (the proposed tool) had the highest strain of the three models, with a strain of more than 2 times that of Tool A and 3 times of that of Tool B due to the material properties as well as the gap between the 31 Ga injection tube and the 23 Ga outer tube as shown in Fig. 5 (c). This indicates that the proposed tool improves upon the sensitivity at the tool tip by allowing for more strain for the same amount of force when compared to the benchmark tool. In the second load case, a force with a magnitude of 80 mN was applied 20 mm away from the tip for each of the three tools as shown in Fig. 6 (a), and the displacements of tool tips were analyzed (Fig. 6 (b)). For Tool C, the tip displacement is 0.78 mm, comparable with that of the stainless steel-only Tool B and about two-thirds of the tip displacement of the nitinol-only Tool A. This suggests that the shaft of the proposed tool is stiff enough to maintain small displacements at the tool tip, even when sustaining a clinically relevant scleral force [9]. For the same load case, the strain at the top and bottom points of the cross section taken at FBG-II was analyzed as shown in Fig. 7 (a) and (b). The strain of Tool C is smaller than that of Tool A but only slightly larger than that of Tool B, which indicates that the proposed tool has a comparable strain to that of the stainless steel tube for scleral force. The FEA results show that the proposed tool is comparable to the stainless steel benchmark tool in terms of its response to scleral forces, while at the same time being more flexible, and thus more sensitive, at the tool tip to facilitate the detection of small tip forces.

IV. Experiments and results

A. Experimental Setup

The experimental setup for tool calibration and validation is depicted in Fig. 8. The SHER [10] is used to hold the tool to perform loading and unloading on a custom fixture that is mounted on a precision scale with the resolution of 1 mg (Sartorius AG, Goettingen, Germany). The SHER has high motion precision with a translation resolution of 1 μ m and a rotation resolution of 0.005°. An FBG interrogator (SI 115, Micron Optics Inc., GA USA) is utilized to collect the signals of FBG sensors within the spectrum of 1525 nm to 1565 nm at a 2 kHz refresh rate. A plastic box is placed over the scale and the tool to isolate the temperature.

B. Calibration

The sensorized tool undergoes calibration using an automated calibration system to determine the relationship between FBG sensor outputs and applied force values. When the SHER translates the tool vertically, the tool comes into contact with the lower bar of the fixture, inducing an applied transverse force on the tool and a positive scale reading. When the SHER translates the tool horizontally along the tool axis, this simulates insertion of the tool to different depths relative to the sclera. The SHER is also able to rotate the tool about its axis so transverse forces can be applied from different directions.

For calibration, the tool is loaded into the lower bar until a set scale reading threshold is reached and then subsequently unloaded until the scale reading returns to zero. This loading and unloading sequence is repeated at a -90° rotation in order to collect transverse force data for the positive X and Y directions according to the coordinate system in Fig. 8 (c). For tip force calibration, the tool is loaded 1 mm from the tool tip to a threshold of 15 mN. For sclera force calibration, the tool is loaded 16 mm from the tool tip to a threshold of 100 mN.

The calibration matrices mapping the FBG sensor readings to the tip force and scleral force are obtained using the algorithm proposed in our previous paper [8]. The calibration results are depicted in Fig. 9, with the 45° line representing the ideal result of when the calculated forces equal the actual measured forces. The RMS errors of the calculated values as compared with the actual values are 0.21 mN and 0.38 mN for tip force and scleral force, respectively.

C. Validation

Validation of the calibration results uses the same experimental setup and similar loading procedures as those for calibration. To validate the full working range of the tool, data was collected from -75° to $+75^\circ$ around the tool axis at intervals of 50° . Furthermore, the upper bar of the scale fixture is also used in addition to the lower bar for loading/unloading to cover 360° of the tool range. Thresholds of ± 15 mN for the tool tip and ± 100 mN for the tool shaft are used, and tool shaft forces are applied at insertion depths of 10 mm to 22 mm from the tip at 2 mm increments. The validation results are depicted in Fig. 10. The RMS error of the calculated values as compared with the actual values are 0.70 mN, 1.59 mN, and 0.69 mm for tip force, scleral force, and the insertion depth, respectively.

V. Discussion and conclusion

During the calibration and validation of the proposed tool, the SHER was used to manipulate the tool and automatically perform the loading/unloading sequences. This approach allowed for the collection of many data points but also may have introduced random noise into the scale readings. In addition, although a customized jig was used to secure the FBG fibers evenly around the outer tube surface, the fibers still may have slipped out of alignment when applying the adhesive, which would have contributed additional noise to the FBG readings. While the RMS errors for both the tip and scleral force calibration results were relatively small in the force ranges of interest, the introduction of noise during data collection may have impacted the calibration calculations and the resulting RMS error in the validation results.

In this work, the development of a tool with dual stiffness, which allows for increased tool tip sensitivity while maintaining stiffness of the tool shaft, was achieved by combining two tubes of different materials. This dual material approach was selected over combining tubes of the same material but of different diameters in order to keep the FBG fibers straight along the tool shaft.

To the our best of our knowledge, this is the first time a cannulation tool has been built with dual stiffness in order to capture the forces at both the tip and sclerotomy port. The presented method could potentially be extended to other instrumentation applications that require tool stiffness for manipulability in addition to flexibility for increased sensitivity.

The advantages of the proposed tool are best highlighted in robot-assisted surgical applications, given that retinal surgical procedures like RVC are extremely challenging to perform freehand. However, robot assistance can also potentially attenuate the surgeon's tactile ability and lead to excessive maneuver forces due to robot inertia and stiffness [9], [11]. The measurements captured by our sensorized tool, including the tip force, scleral force and insertion depth, could not only signal the surgeon regarding unsafe manipulations (e.g. extreme forces), but also be fed back to the robot and incorporated into different control schemes (e.g. motion limits).

We presented a force sensing cannulation tool with dual stiffness that can be used in RVC to detect vein puncture force and also monitor the scleral force with FBG sensors. Two tubes of different materials, i.e., nitinol and stainless steel, are combined to provide a flexible tool tip for increased sensitivity and stiff tool shaft for manipulability. FEA was performed to simulate the performance of the combined material tool structure. The fabrication, calibration and validation of the tool are presented, and the validation measurement RMS errors of tool are 0.70 mN, 1.59 mN, and 0.69 mm for tip force, scleral force, and the insertion depth, respectively. The proposed tool could be used to provide practical tool-to-tissue interaction information during retinal surgery. Moving forward, we will focus on the evaluation of the measurement performance of the tool with phantom or animal models of retinal surgery.

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Fig. 1.

Tool illustration. (a) The cannulation tool is inserted into the eyeball to perform cannulation. The needle is used to puncture the retinal vein, and the injection tube is used to deliver the medicine. The scleral force, denoted as F_s , is the contact force between the tool shaft and sclerotomy, the tip force, denoted as F_t , is the force applied at the tool apex, and the insertion depth is the distance between the tool tip and sclerotomy port. (b) The dimensions of the cannulation tool. The tool is constructed with two materials, an 8 mm long nitinol tube at the tip and a stainless steel tube for the remainder of the tool shaft. The FBG sensors are located in three segments along with tool shaft. (c). The section view of the tool shaft. Three fibers are attached evenly around the tool shaft.

Fig. 2.

Jigs used to secure the fibers on the tool surface. (a) The tool is inserted through two jigs and (b) the fibers pass through the guiding channels. The channels are located around the jig axis at intervals of 120°.

Fig. 3. Tool fabrication. (a) The exploded view of the tool. (b) The connection of the nitinol tube and the stainless steel tube. (c) Beveled cannulation needle. (d) The assembled cannulation tool

Fig. 4.

The tool models for FEA. The structures and the dimensions of three tools are described.

Fig. 5.

FEA results: strain of the tip segment. (a) The normal forces of magnitude of 1 mN are applied at the tool tip. (b) The points at the top and bottom of the target cross section of each tool are selected, and the section plane is 4.5 mm away from the tip, which is the position of FBG I. (c) The plot of the strain of the selected points. The points of Tool C (proposed tool) have the highest strain.

Fig. 6. FEA results: displacement of the tip. (a) The normal forces of magnitude of 80 mN are applied to the tool shaft 20 mm away from the tip. (b) The tip displacements of three tools are plotted. Tool C has similar tip displacement values as Tool B (stainless steel-only tubing).

Fig. 7.

FEA results: strain of the tool shaft. (a) The normal forces of magnitude of 80 mN are applied to the tool shaft 20 mm away from the tip. (b) The points at the top and bottom of the target cross section of each tool are selected and the section plane is 29.5 mm away from the tip, which is the position of FBG II. (c) The plot of the strain of the selected points. The points of Tool C have comparable strain values to the points of Tool B.

Fig. 8.

Experimental setup. (a) The fabricated tool is attached at the end effector of the SHER and is (b) loaded/unloaded into the fixture on a scale with the precision of 1 mg to perform calibration and validation. (c) The tool frame defined.

Fig. 9.

Calibration results for (a) tip force (b) and scleral force. The RMS errors of actual force and calculated force are 0.21 mN and 0.38 mN for tip force and scleral force, respectively.

Fig. 10.

Validation results for (a) tip force (b) and scleral force. The RMS errors of actual force and calculated force are 0.70 mN and 1.59 mN for tip force and scleral force, respectively.