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Robot-Assisted Retinal Vein Cannulation with Force-Based Puncture Detection: Micron vs. the Steady-Hand Eye Robot*

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Abstract

Retinal vein cannulation is a demanding procedure where therapeutic agents are injected into occluded retina veins. The feasibility of this treatment is limited due to challenges in identifying the moment of venous puncture, achieving cannulation and maintaining it throughout the drug delivery period. In this study, we integrate a force-sensing microneedle with two distinct robotic systems: the handheld micromanipulator Micron, and the cooperatively controlled Steady-Hand Eye Robot (SHER). The sensed tool-to-tissue interaction forces are used to detect venous puncture and extend the robots' standard control schemes with a new position holding mode (PHM) that assists the operator hold the needle position fixed and maintain cannulation for a longer time with less trauma on the vasculature. We evaluate the resulting systems comparatively in a dry phantom, stretched vinyl membranes. Results have shown that modulating the admittance control gain of SHER alone is not a very effective solution for preventing the undesired tool motion after puncture. However, after using puncture detection and PHM the deviation from the puncture point is significantly reduced, by 65% with Micron, and by 95% with SHER representing a potential advantage over freehand for both.

I. Introduction

Retinal vein occlusion (RVO) is one of the most prevalent retinovascular diseases, affecting about 16.4 million people worldwide [1]. RVO occurs when there is thickening of the crossing artery, low flow, hypercoagulability, or thrombosis in the central or the branched

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retinal veins of the eye. This results in the affected retinal vein to become dilated, tortuous and to hemorrhage into the retina. In many cases, the resulting ischemia leads to macular edema. Other serious complications of RVO includes neovascularization, vitreous hemorrhage, and retinal detachment [2,3]. Patients with RVO are reported to experience blurred or distorted vision, and in severe cases blindness results [4].

Retinal vein cannulation (RVC) is an experimental surgical procedure proposed to treat RVO by direct therapeutic agent delivery methods. The procedure involves the injection of clot-dissolving tissue plasminogen activator (t-PA) directly into the occluded vein [5], which is very demanding because of the small size and fragility of retinal veins—especially if the occlusion is at a branch retinal vein (typically $\varnothing < 200 \mu\text{m}$) rather than the central vein [6].

A successful cannulation procedure requires the completion of three main steps: (1) accurately bringing the cannula onto the retinal vein of interest, (2) puncturing through the vein wall and precisely halting the cannula tip at the right depth, and (3) maintaining it inside the vein for several minutes, during which t-PA is delivered to dissolve the thrombus. There are three main challenges that may hinder the success of cannulation. First, a proper cannula is required that is not only thin enough to be inserted into the retinal vein ($\varnothing < 100 \mu\text{m}$) but can also withstand the forces while puncturing the vein and can easily be seen under the microscope. This challenge has partially been resolved by utilizing stainless steel microneedles in replacement of the transparent and fragile glass micropipettes [7,8]. The second challenge is the physiological hand tremor of the vitreoretinal surgeon, which is comparable in amplitude to the size of retinal veins [9]. To alleviate this issue, various teleoperated [10–12], cooperatively-controlled [13,14] and handheld [15–19] robotic devices have been proposed. Among the handheld devices is Micron, an actively stabilized micromanipulator which uses optical tracking and piezoelectric actuators to sense and counteract any tremulous motion. An alternative system is the Steady-Hand Eye Robot (SHER), which provides smooth tool manipulation based on a cooperative control scheme between the surgeon and a stiff non-backdrivable robot arm. Micron and SHER systems have been both shown to enhance tool manipulation accuracy in vitreoretinal surgery tasks [20]. The last challenge stems from the fact that cannulating retinal veins occurs at forces that are almost imperceptible to humans. [21]. This makes detecting venous puncture almost imperceptible without the feedback of a proper force-sensor continually monitoring tool-to-tissue interaction forces. To provide such force feedback in retinal microsurgery, our team has developed force-sensing instruments using fiber Bragg grating (FBG) strain sensors [22–26], which have been shown to accurately measure the micro-forces directly at the tool tip without significant degradation due to varying ambient temperature or the forces at the sclerotomy port.

Combining a force-sensing cannulation tool with a robotic assistant is a potential solution to overcome the challenges in identifying the moment of venous puncture, achieving cannulation and maintaining it during drug delivery in RVC. Previously we have achieved an extended period of intravenous cannula stability in a dry phantom by combining Micron with a force-sensing microneedle (Fig. 1a,1b) [27]. This study builds on our previous work, and integrates our force-sensing microneedle with another robot assistant, the SHER system (Fig. 1c) by extending its cooperative control scheme with force-based puncture detection

and position holding features to fixate the cannula after venous puncture. Then, performance in cannulation trials in a dry phantom is evaluated for different controller gains of the robot and compared to the performance provided by the Micron system. The paper concludes with a discussion of the results, current limitations and our future aims.

II. Materials and Methods

A. Micron

Micron is a fully handheld actively stabilized 3-DOF micromanipulator that is mainly designed to remove unintentional motion and enhance positional accuracy [15]. The device operates by activating three piezoelectric actuators based on the sensed motion of the handle, producing a workspace of $1 \times 1 \times 0.5$ mm. The position information is provided by optical sensors with a resolution of $4 \mu\text{m}$ at a rate of 2 kHz by tracking the LEDs mounted to Micron. After sensing its own motion, Micron separates the involuntary components, such as hand tremor, and moves its tip to actively compensate them.

B. The Steady Hand Eye Robot (SHER)

SHER is a cooperatively-controlled device where the operator and the actively controlled robot arm simultaneously hold and move the surgical tool [13]. The robot has 5 DOF, including XYZ linear stages for translational motion, a rotary stage for rolling and a tilting mechanism. While the operator is maneuvering the attached surgical tool, the forces exerted on the handle of the instrument ($\vec{F}_{\text{operator}}$) are sensed via the force sensor located at the tool mount, multiplied with a controller gain factor (K) and converted into velocity commands ($d\vec{p}_{\text{needle}}/dt$) for the robot arm. In this way, the surgical tool is moved precisely without the effects of physiological hand tremor of the operator and at a speed that is proportional to the applied force as given by eqn. (1).

$$d\vec{p}_{\text{needle}}/dt = K \cdot \vec{F}_{\text{operator}} \quad (1)$$

The gain factor in eqn. (1) can be modulated to adjust the sensitivity of the robot. Increasing the gain results in a more responsive system that feels more like a handheld instrument whereas decreasing it provides slower motion with more inertial feel on the operator's hand.

C. Motorized Force-Sensing Microneedle

■ **Mechanical Design**—In order to perform injections into thin branch retinal veins ($\varnothing < 200 \mu\text{m}$), even thinner cannulae with sharp tips are needed. In our previous work [26], we developed a motorized force-sensing cannulation tool that has a sharp beveled (15°) and bent (45° relative to the tool shaft) microneedle at its tip with an outer diameter of $70 \mu\text{m}$ (Fig. 1b). The bent tip enables approaching the vein surface at an ideal angle ($\sim 30^\circ$ [11]) for easier and safer venous puncture. However, it prevents the tool from being directly inserted through the sclerotomy port ($\varnothing < 1 \text{ mm}$). Thus, we devised a motorized mechanism (Fig. 2) that keeps the needle straight and protects it inside an outer tube during introduction into the eye. After inserting the tool tip through the trocar into the eye and upon reaching the retina

surface, the outer tube is retracted by a linear micro-motor to expose the needle tip which flexes back to its pre-bent state. Since this actuation is entirely independent from the site of attachment, the tool can be easily used on any of the existing assistive robots [10–19] without interfering with their operation. The design and control mechanism of this part are further detailed in [27].

In order to sense the very fine forces (typically less than 40 mN) associated with RVC, the use of a very sensitive force sensor with sub-mN resolution is required. In addition, since the forces at the sclera insertion port can be much larger than the typical cannulation forces at the tool tip, the force sensing elements need to fit through the sclerotomy port ($\varnothing < 1$ mm) and be located close to the tool tip and inside of the eye. FBG strain sensors (Technica, GA, USA), with their small dimension ($\varnothing = 80$ μ m), high sensitivity, biocompatibility, sterilizability, and immunity from electrostatic and electromagnetic noise satisfy these criteria. In our design we attached 3 FBGs evenly around the outer tube to sense the 2-DOF transverse forces on the tool tip, which is sufficient for our design since the tool is moved mostly laterally while inserting it into the vein due to its pre-bent tip. The resulting tool has an outer diameter less than 0.9 mm. This is sufficiently small for insertion through a 20 Ga trocar ($\varnothing = 0.9$ mm). The calibration setup and protocol of the force sensor follow [22]. In order to monitor the response of each FBG, we use an optical sensing interrogator, sm130–700 from Micron Optics Inc. (Atlanta GA), which provides a wavelength resolution of 1 pm. Combining this with the calibration matrix identified in [27] shows a resolution of about 0.25 mN for our force-sensing microneedle. The time constant is about 5 ms [28], providing a fast enough response for accurate tracking of quick force variations.

■ **Force-Based Puncture Detection and Position Holding**—Our previous work has shown that venous puncture can be detected by continually tracking the tool tip position ($\vec{p}_{\text{needle}}$) and tool-to-tissue interaction force (F_{needle}) [27]. After the needle tip touches the vein wall, as it is pushed into the vein, the tissue is gradually deformed which results in an increasing resistance force on the needle tip. If the needle is retracted back, the exerted force drops. Therefore, until the vein is punctured, the time derivative of tool tip force and the tool tip velocity vectors oppose directions and hence their dot product is always either zero or negative. At the instant of venous puncture, however, the needle tip moves forward into the vein although the force experiences a sharp drop. This results in a momentarily positive dot product. Our force sensor, with its quick response, is able to accurately capture the sharp variations in force. Using this information in combination with tool tip position data from the robotic system, we can detect the instant of venous puncture.

Following venous puncture, the operator needs to maintain the needle tip inside the vein lumen throughout the drug delivery phase. This can be up to 2 minutes or even longer [5]. Given the small puncturing force, fragility and small size of retinal veins, it is very challenging to identify venous puncture, quickly stop needle insertion and hold it fixed throughout the injection period. Robotic assistants [10–19] can attenuate high-frequency components of involuntary motion, such as surgeon's physiological hand tremor, which is beneficial for accurately positioning the needle tip on the target vein before puncture. However, they remain insufficient for identifying the instant of venous puncture or eliminating the low-frequency drift of the needle tip after the puncture. To help with this, the

operation modes of both Micron and SHER can be altered utilizing our force-based venous puncture detection as shown in Table I.

Micron normally operates in “Tremor Canceling Mode” (TCM), which attenuates physiological hand tremor by continually tracking the tool handle motion and filtering it to compute a goal position for the tool tip. Once venous puncture is sensed ($d\vec{F}_{\text{needle}}/dt \cdot d\vec{p}_{\text{needle}}/dt > 0$), Micron’s operation mode can be switched to a “Position Holding Mode” (PHM), where the goal position is constantly set to the position detected at the instant of puncture. After this point, the actuators are used to compensate any (both high and low frequency) motion to fixate the needle tip within the available workspace of Micron (± 0.5 mm along each axis). On the other hand, SHER normally operates in a “Cooperative Control Mode” (CCM), where the robot complies proportional to the user forcing. Upon venous puncture, the mode can be altered into a PHM similar to Micron by setting the controller admittance gain to zero ($K=0$) so that the needle is held fixed (unless the operator wants to disable the mode via a foot pedal, which was implemented as a safety measure). On both systems, when the PHM is activated, the user is also informed of the venous puncture via auditory feedback to signal the right time to begin drug delivery.

III. Experiments

We performed a series of cannulation experiments to comparatively evaluate the performance of Micron and SHER with the developed microneedle tool using the setups shown in Fig. 3a and 3b respectively. The experimental procedures involving human subjects described in this section were approved by the Institutional Review Board. To closely replicate the vein cannulation procedure *in vitro*, we developed an artificial phantom platform similar to the one used in [27], which is an acrylic plate with 18 circular holes covered by a thin, uniformly stretched vinyl layer emulating the retinal vein walls. The diameter of the holes on the plate is 2.5 mm, small enough to create the support for the vinyl membrane’s tension while leaving sufficient space for the user to perform several cannulations. Previous studies showed that the applied force while cannulating retinal veins can range anywhere from 5 mN to 35 mN depending on the angle of approach, the needle tip bevel, and the vein size [21]. Thus, the vinyl layer was stretched in a way that the force of cannulation fell in this range. The phantom was fixed on a light pad to clearly visualize the membrane loci under a digital microscope. The microscope view was displayed on a monitor providing only the top view of the phantom.

Tests were done by a non-surgeon subject with no prior cannulation experience, but with extensive training on both Micron and SHER systems. The task in each trial was to puncture the vinyl membrane by moving the microneedle almost entirely laterally, in the direction the needle tip is pointing, and hold the needle fixed for 45 seconds after the event of puncture.

Using Micron, two cases were experimented: only TCM, and with PHM. On SHER side, three cases were explored: only CCM with low gains ($K=2$ mm/N.s), only CCM with high gains ($K=20$ mm/N.s), and with PHM. 12 trials were completed for each case. In order to prevent significant performance degradation in time due to fatigue, tests were completed in 3 periods, each period involving a total of 8 trials for Micron and 12 trials for SHER (4 trials

per case), with a 10 minute break between the periods. During the trials, the operation mode was altered in random order for either robotic system. Since each puncture causes the membrane to lose its tension locally, every new trial was done at a sufficiently distant location from the previous puncture loci.

A detailed performance assessment on Micron trials was reported earlier in [26,27]. In this study, the focus is on evaluation of the SHER system and comparison of its performance with our earlier findings on Micron. We assess the performance based upon the recorded deviation from the point of puncture, which would be highly correlated to the trauma on the cannulated vasculature in a clinical scenario. Analyses are done by a t-test assuming unequal variance. Statistical significance is based on $p < 0.05$.

IV. Results and Discussion

As the performance metric, we assess the range of deviation from the puncture point as a function of the hold time, analyzing the acquired needle tip position data during the first 15, 30 and 45 seconds after the puncture.

A. CCM Gain Modulation for SHER

In CCM of SHER, using higher controller gains is beneficial in manipulating the tool faster, saves operational time and results in less fatigue on the operator's hand. On the other hand, using low controller gains provides a slower and safer motion if the tool tip is moving close to critical anatomical features, which is important while approaching the target vein. After the needle tip punctures the simulated vein wall, results in Fig. 4a show that with the low controller gains, the deviation from the puncture point is $459.50 \pm 181.54 \mu\text{m}$ during the first 15 seconds. This rises up to $668.54 \pm 252.69 \mu\text{m}$ for the full experiment period of 45 seconds. When the controller gains are increased, resulting in a more freely moving system similar to a handheld tool, slightly less deviation, $341.95 \pm 75.04 \mu\text{m}$, is observed for the first 15 seconds ($p < 0.05$). However for 45 seconds of hold time, the deviation rises to $625.16 \pm 280.07 \mu\text{m}$, revealing no statistically significant difference from the low gain case ($p = 0.4$). Therefore, modulating the controller gain does not produce a significant reduction in the involuntary needle motion after the puncture, especially for longer hold periods.

B. CCM vs. PHM for SHER

Shown in Fig. 4b is the comparison between the deviation obtained with regular CCM and with PHM. The force-based puncture detection and motion locking in PHM significantly reduces the motion after puncture, from $625.16 \pm 280.07 \mu\text{m}$ to $9.68 \pm 4.18 \mu\text{m}$ for the full experiment period of 45 seconds. In contrast to the gradually increasing deviation in time with CCM, the performance with PHM is not affected from the hold time, maintaining it fixed at the same level ($p < 0.05$).

C. Performance Comparison: Micron vs. SHER

When the two robotic systems are used in their regular operational modes, namely TCM for Micron and CCM for SHER, the performance difference observed in the initial 15 seconds is not statistically significant ($p = 0.10$). However, as shown in Fig. 4c, for longer hold times,

slightly more deviation from the puncture point is observed with SHER ($489.76 \pm 189.78 \mu\text{m}$ for 30 s and $625.16 \pm 280.07 \mu\text{m}$ for 45 s) than with Micron ($328.86 \pm 134.19 \mu\text{m}$ for 30 s and $367.32 \pm 113.57 \mu\text{m}$ for 45 s) ($p < 0.05$). Upon using PHM on both systems (Fig. 4d), an opposite trend is obtained with the SHER providing significantly less deviation regardless of the hold time ($p < 0.05$). Micron can attenuate the undesired motion after puncture by more than 65% (from $276.18 \mu\text{m}$ to $90.34 \mu\text{m}$ in case of a 15-second hold time for instance). However, due to its small workspace, the range of motion it can compensate is limited ($\pm 0.5 \text{ mm}$). If the tool is moved beyond this range after the puncture, the actuators will saturate and fail in fixing the needle tip position. This is why almost a linear rise in the average deviation is observed for Micron as the needle is held for longer periods (Fig. 4d). On the other hand, SHER can stop the needle motion right after the puncture and lock the position without any saturation issues. This results in an almost 95% reduction in the deviation for all hold periods as compared to regular CCM (from $75.04 \mu\text{m}$ to $4.17 \mu\text{m}$ during a 15-second hold time).

V. Conclusions

This paper has reported a performance comparison between two robotic systems for retinal vein cannulation, Micron and SHER, with or without the aid of puncture detection and position holding mode. Both robotic systems were combined with a force-sensing microneedle intended to maintain cannulation for a longer period causing less trauma on the vasculature, corresponding to minimal movement of the cannula upon venous puncture.

Micron is a compact handheld system that feels more like a standard surgical instrument. However, it provides a limited workspace. If the motion artifact is beyond a certain level, the actuators saturate and the device cannot fully compensate the undesired motion to hold the cannula fixed. The SHER system does not have this saturation issue, but it has a larger footprint than the Micron system and exerts a higher resistance force on the user's hand. The sensitivity and feel of this robot can be altered by modulating the gains on the cooperative controller. Our experiments in a dry phantom showed however that tuning this gain alone, does not lead to a significant improvement in cannula fixation after venous puncture. After activating our new position holding mode on either device, the deviation from the puncture point were significantly attenuated, 65% by Micron and 95% by the SHER representing a potential advantage for both systems.

The evaluation presented in this work is based upon a fixed phantom position. In a real clinical scenario, after venous puncture, the cannula needs to be maintained fixed relative to the tissue. Therefore it is essential to account for potential movement of the tissue, which can be detected via our force sensing microneedle, and complying with it. Our current work focuses on implementing and evaluating this technology using *in vivo* chorioallantoic membrane models.

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Figure 1.

(a) Motorized force-sensing microneedle to inject t-PA into the occluded retinal vein. The tool has a bent tip (45°) to approach the vein at the optimal angle ($\sim 30^\circ$) and can easily be integrated on (b) a handheld robot, Micron or (c) the cooperatively controlled Steady-Hand Eye Robot (SHER).

Figure 2.

Design of the motorized force-sensing microneedle and its integration with SHER. The bent needle is held straight and protected inside an outer tube while inserting the tool through the trocar. When the target vein is reached, the linear micro-motor is used to retract the outer tube and expose the needle tip. 3 FBGs on the outer tube provide force sensing. The tool is attached to the SHER tool mount and is manipulated cooperatively, moving with a speed $(d\vec{p}_{needle}/dt)$ proportional to the operator's forcing on the tool handle ($\vec{F}_{operator}$).

Figure 3.

The experimental setup for evaluating the performance of (a) Micron and (b) SHER on an artificial phantom. Stretched vinyl membranes, simulating the vein walls, were punctured open-sky using the force-sensing microneedle.

Figure 4.

Experimental results: Average deviation from the puncture point during the initial 15, 30 and 45 seconds after the puncture. The solid bars represent the mean, and the error bars show ± 1 standard deviation. (a) Changing the controller admittance gain of SHER does not create a statistically significant difference. (b) Activating the force-based puncture detection and PHM significantly reduces the deviation. (c) When Micron and SHER are used in their normal operating modes, TCM and CCM respectively, slightly larger deviation is observed in SHER trials. (d) When Micron and SHER are used with puncture detection and PHM, SHER system fixates the needle position better since Micron has a smaller workspace and its actuators may saturate.

TABLE I
Operation Mode Regulation for Micron and Sher

	Condition	Operation Mode
$\frac{d\vec{F}_{needle}}{dt} \cdot \frac{d\vec{p}_{needle}}{dt} \leq 0$

$\frac{d\vec{F}_{needle}}{dt} \cdot \frac{d\vec{p}_{needle}}{dt} > 0$