

VINE Catheter for Endovascular Surgery

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Abstract—Endovascular surgery (ES) is a minimally invasive procedure used to treat diseases such as stroke, coronary artery disease, and aneurysms. Often, the vascular anatomy exhibits high tortuosity and severe angulation, which requires long procedures and significant expertise, and leads to a risk of vessel dissection. Here we introduce a soft, tip-extending robot—the VINE (Vascular Internal Navigation by Extension) catheter—that extends, or “grows,” from the tip when pressurized with fluid. It acts as an access device, pulling a standard catheter to the target site as it grows. We demonstrate how this movement via tip-extension enables the VINE catheter to easily and safely pass through tight curvatures. We also demonstrate the system’s usability in a patient-specific anatomical model under fluoroscopy, even by novices. Overall the VINE catheter has potential to: (i) increase safety, given its inherent limit to stress that it can apply to vessel walls, and (ii) decrease the time and expertise required to successfully complete complex ES cases. The results serve as a foundation for an entire class of devices capable of gaining access to difficult-to-reach locations via navigation through constrained anatomy and illustrate the potential for the VINE catheter to have a significant impact on a range of procedures.

Index Terms—Medical robotics, soft robotics, surgical instruments.

I. INTRODUCTION

ENDOVASCULAR surgeries (ES) are minimally invasive procedures performed from within blood vessels. These surgeries increasingly augment or replace traditional open surgical treatment of brain, spine, liver, heart, and vascular diseases [1]–[5]. ES are commonly performed by inserting endovascular equipment into the groin, arm, or neck, and pushing them through the vasculature to gain access to the distal arteries that are targeted for treatment. Typically, a vascular sheath is placed first to serve as a conduit through which

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smaller catheters and wires may be introduced to successfully navigate the vasculature. Arteries as distal as the small vessels overlying the surface of the brain may be accessed in this manner. These procedures are typically performed under X-ray fluoroscopy to enable real-time visualization and ensure proper guidance.

Despite the main benefits of ES compared to traditional open procedures, there remain several challenges. The vascular anatomy is highly variable and may demonstrate excessive tortuosity and severe angulation. Such challenging vascular anatomy is often encountered in elderly patients (Fig. 1), who are increasingly the target of ES for the treatment of stroke, coronary artery disease, aneurysms, and other diseases [6]–[8]. As shown in Fig. 1, difficult proximal anatomy, including the acute turn characteristic of a Type II or Type III aortic arch, can make it challenging to access the cerebral circulation. This complex anatomy requires a series of tools that must be passed in and out of the vasculature, rendering ES complicated, often necessitating an expert surgeon, and time intensive, increasing the risk to both the patient and surgeon [9]. At the same time, complex anatomy increases the chance of dissecting the vessel [10]. A device that can easily, efficiently, and safely navigate the tortuous anatomy of the body has the potential to advance the treatment of cerebrovascular and other diseases treated by ES and to improve patient outcomes.

Existing manual semi-rigid instruments used for endovascular surgeries, such as catheters, wires, and sheaths, reduce patient trauma compared to standard surgical methods [11]. Many of the more recent catheters are designed with a stiffness gradient that decreases significantly towards the tip. The advantage of the less stiff tip region is that as the catheter is pushed through winding anatomy, less force is exerted on the vessel walls compared to when using a standard push-catheter, which may reduce the risk of vascular injury during ES [12]. Despite these advancements, endovascular instruments remain difficult to use in tortuous blood vessels, and the surgeon’s ability to traverse this anatomy is limited to simple pushing and twisting of the available catheters and wires. A number of steerable catheters and sheaths have also been developed to aid in the selection of the path for intervention with the goal of reducing complications of procedures [13]. However, many of these pull-wire steerable catheters remain limited in flexibility and rely on the surgeon’s expertise to successfully navigate tight turns. Novel ES tools that are more capable of traversing the vasculature are needed.

Robotic solutions have been proposed to address the challenge of efficiently navigating surgical instruments through the vasculature. Similar to the manual steerable catheters, these robotic approaches are typically focused on methods

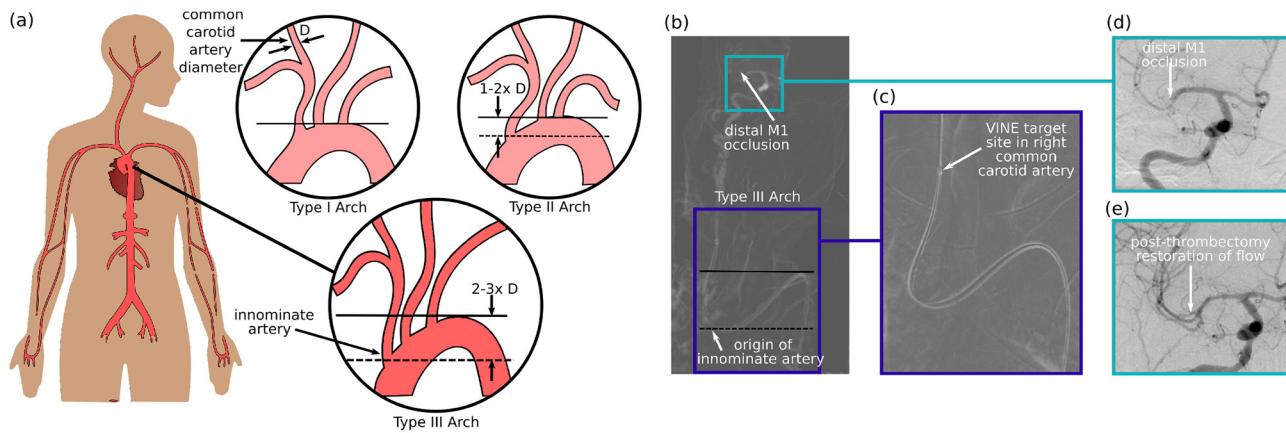


Fig. 1. Difficult proximal anatomy of older patients motivates the development of the VINE catheter. (a) The aortic arch is characterized as Type I, II, or III according to the angulation of the origin of great vessels relative to the apex of the arch curvature. (b) Intra-procedural images from an elderly patient with an acute ischemic stroke, due to a distal M1 occlusion (arrow). (c) Zoomed image of the Type III aortic arch, which causes difficulty in accessing the cerebral circulation. After the use of numerous endovascular catheters, an access catheter has been advanced into the right common carotid artery (arrow), the target location for the VINE catheter, from which a microcatheter is advanced to perform the thrombectomy. (d) Zoomed image of the occlusion of the first part of the middle cerebral artery (arrow). (e) after removal of the clot, blood flow is restored to the brain (arrow).

for controlling the steering of the instrument tip. The Amigo system, for example, enables remote steering of a commercial 3 degree-of-freedom catheter using a controller that mimics the handle of a standard catheter [14]. The Magellan is another example of a robotically steered catheter, designed to bend around tight turns with fine, controlled movement [15]. These robotic platforms, along with several others, achieve their mobility and dexterity from a set of tendons, whose relative length can be changed [13], [16]–[18]. Another popular approach to enable catheter steering has been magnetic navigation. These systems generally consist of a catheter with a magnetically responsive tip that can be controlled using an external magnetic field [19], including, for example [20], [21]. However, these robotic catheters are not yet in widespread clinical use.

Here we introduce a soft, tip-extending robot—the VINE (Vascular Internal Navigation by Extension) catheter—that grows through vessels in a manner analogous to how plants grow (Fig. 2). Pressurized fluid (water or saline) pumped into the base of the VINE catheter enables this extension, or lengthening, at the tip, while the rest of the body remains stationary with respect to the environment [22]–[24]. The result is a fundamentally different method of movement through the vasculature, which, until this point, has relied on manual and robotic instruments that must be pushed from the base.

The initial target application for the VINE catheter, neurointerventional ES, is challenging due to the high degree of miniaturization and tight curvatures required to access the cerebral circulation (Fig. 1). Although there are a number of less complicated application areas with less demanding design requirements, we chose to validate our design by targeting the brain, where this type of device could have a significant impact given recent advances in ES treatment of ischemic stroke. If successful, this demonstration would also provide strong initial evidence in its potential to improve many other procedures as well. In the remainder of the paper, we present the results from both benchtop testing and trials in a simulated clinical setting, where both expert neurointerventionalists and novices

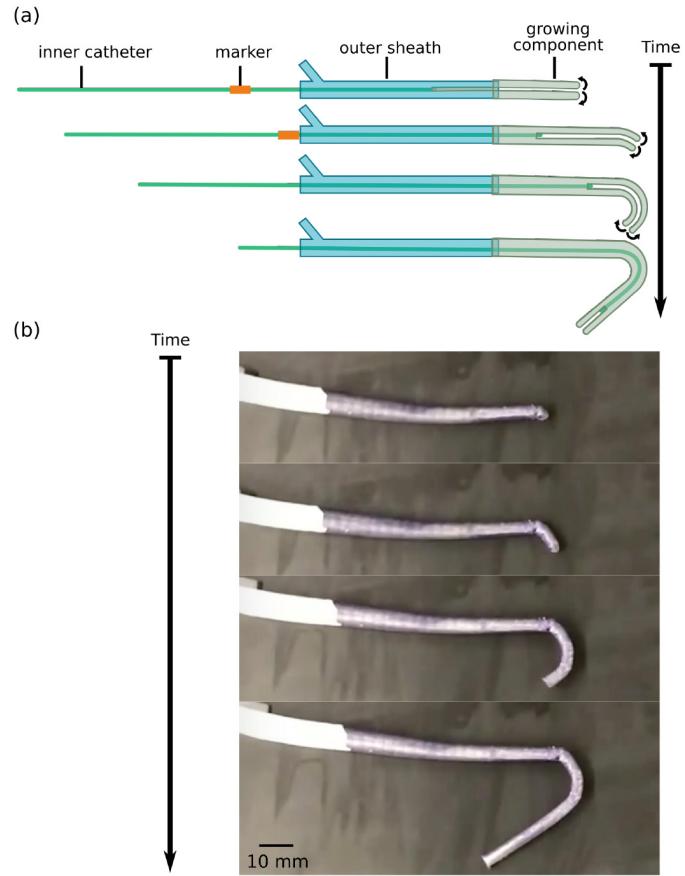


Fig. 2. (a) The VINE catheter consists of an outer sheath, an inner catheter, and a pre-curved, inextensible thin-walled tube (or growing component). As the VINE catheter is pressurized and the inner catheter is fed forward, the tip of the VINE catheter everts, resulting in a growing action. (b) Time-series of a fabricated VINE catheter during the growing process.

deployed the VINE catheter through a phantom model. The results suggest that the soft tip-extending VINE catheter could reduce the required time and expertise for a procedure while also increasing its safety.

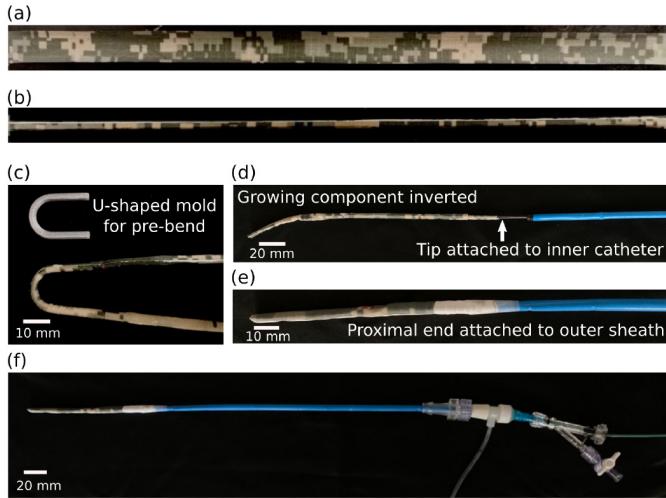


Fig. 3. The fabrication process starts with (a) cutting the urethane-coated ripstop nylon into the desired shape and (b) sealing one edge to the other in a lap joint to form a long, narrow tube. (c) A U-shaped 3D-printed mold is then used to form the pre-bent shape. (d) The tube is then inverted and the tip attached to the inner catheter. (e) The proximal end of the tube is attached to the outer sheath to form the (f) final VINE catheter.

II. SYSTEM OVERVIEW

The system presented here consists of two main components: the VINE catheter itself and its associated control system. We designed the VINE catheter to navigate from the aorta into the innominate artery, left common carotid artery, and the left subclavian artery, as well as into the more distal branches (Fig. 1). The control system has been designed to enable intuitive operation to grow the robot by only requiring the user to feed an inner catheter forward, similar to the standard operating procedure, while a closed-loop controller maintains the proper level of internal fluid pressure. We detail below the design and fabrication of these subsystems.

A. Design and Mechanism of Action

The method of movement—termed “growth” or “tip-extension”—employed by the VINE catheter is described in more detail in [22] and is illustrated in Fig. 2. Briefly, one end of a thin-walled, hollow tube is inverted (or folded inside of itself), and as internal pressure is applied, this folded material extends from inside the body of the tube out through the tip. The VINE catheter is designed with a pre-bend (Fig. 2) to enable easier navigation around the base of the aortic arch.

The VINE catheter is different from previous tip-extending devices in that the tip is not simply sealed off and inverted inside itself. Instead, the tip is attached to a 6-Fr. catheter, in this case the Sofia (MicroVention), that is commonly used for neurointerventional surgeries. As the VINE catheter traverses through the vasculature, it acts as a delivery vehicle by pulling this catheter (termed “inner catheter” here) along. This approach ensures that there is a hollow access channel to the target and sufficient stiffness for treatment to be delivered. While the distal end of the VINE catheter is attached to this inner catheter, the proximal end of the VINE is attached

to a 15-French vascular sheath (termed “outer sheath” here), which is used for introduction into the femoral artery in our model.

B. Fabrication

Because the VINE catheter can “grow” from the tip, rather than being pushed from the base, it does not need to be stiff like a standard catheter. Instead, it is fabricated using a 40 denier urethane-coated ripstop nylon (Rockywoods Fabrics) that is 0.1 mm thick and nearly inextensible (Fig. 3). The fabric is first cut into the desired shape using a custom stencil, which is designed to enable a gradual taper from a diameter of approximately 3.5 mm at the distal end to approximately 5 mm at the proximal end. A fast-cure polyurethane glue, Marine Adhesive Sealant Fast Cure 5200 (3M), is then used to seal one edge of the fabric to the other in a lap joint in order to form a long, narrow tube. After curing for approximately 24 hours, a U-shaped, 3D-printed mold with a radius of curvature of 20 mm and a diameter of 3.7-3.9 mm depending on the resulting tube diameter is placed inside the nylon tube. A thin strip of the same ripstop nylon is then glued along the inside of the U-shaped bend, in order to create a permanent pre-bent shape with the desired curvature. Once cured, the mold is removed.

The hollow, pre-curved nylon tube is then integrated with a set of existing surgical instruments (Fig. 3). First, the VINE catheter is inverted inside out by pulling the 3.5 mm distal end towards the 5 mm proximal end. Then a flexible 6-Fr diagnostic angiographic catheter (MicroVention) is fed through the sheath, and its tip is attached to the inverted VINE catheter at the 3.5 mm distal end. Next, the catheter is pulled so the distal end of the VINE catheter will slide into the 15-French vascular sheath and the proximal end, which has been designed to fit snugly around the sheath, will mate with the sheath tip. It should be noted that alternative sheaths and catheters can be used following the same procedure.

C. Control System

In order to enable the endovascular surgeon to intuitively control the growth of the robot, we designed a pressure-controlled actuation system. This system consists of a saline-filled syringe whose tip is connected to the VINE catheter, and whose plunger is connected to a linear actuator (Fig. 4). The syringe and linear actuator are rigidly mounted, such that as the linear actuator pushes the plunger forward, saline is pushed into the VINE catheter, increasing its internal pressure. A pressure sensor is connected for real-time feedback on the pressure inside the VINE catheter. To grow, a proportional controller updates the command signal sent to the linear actuator based on the difference between the current pressure and the desired pressure. The command signal takes the form of the duty cycle of the PWM signal driving the motor. If the pressure difference at a given time step is small, then the duty cycle, and therefore the voltage of the linear actuator, is small, and there is little to no forward movement of the actuator. However, if the difference between the current pressure and the desired pressure is large, then the duty cycle is also

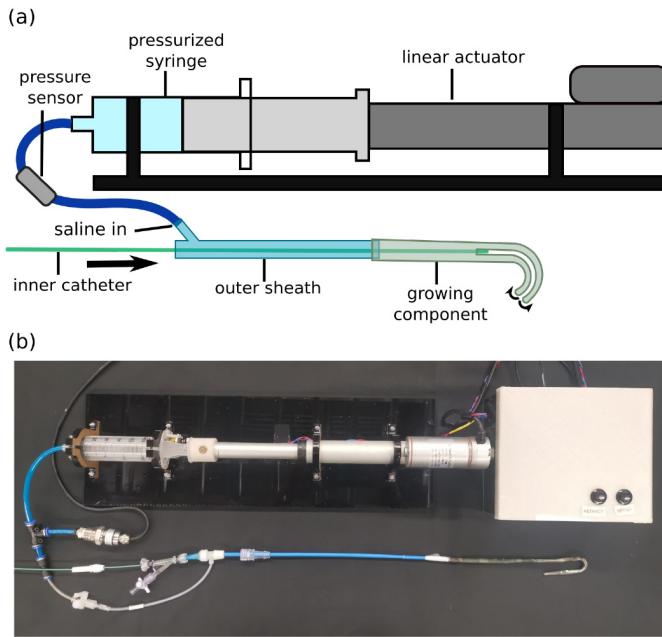


Fig. 4. (a) Schematic of the entire system, including the actuation system that controls the pressurization of the VINE catheter. (b) Image of the actuation system and closed-loop control box containing the microcontroller and electronics for driving the system.

large, causing the linear actuator to advance forward and drive fluid into the VINE catheter.

The tip of the inverted material of the growing component of the VINE catheter is attached to the distal end of the inner catheter (Fig. 2a). Therefore, if the user applies a force to the inner catheter in the opposite direction to the direction of growth, there is a resultant tension applied to the material of the growing component. When the growing force at the tip of the VINE catheter due to the internal pressure is balanced by the tension applied by the user on the inner catheter, an equilibrium is reached and no growth occurs. During operation, the endovascular surgeon manually feeds the inner catheter forward into the outer sheath. Because the inner catheter is connected to the tip of the growing component, feeding the inner catheter forward produces slack in the growing component, and therefore a decrease in the tension of the material. This decrease in tension results in a net force on the VINE catheter in the direction of growth, since the controller is designed to maintain a constant pressure inside the VINE catheter.

To notify users of when to expect the pre-bend to emerge from the tip of the VINE catheter, a marker is attached to the inner catheter, such that this marker reaches the base of the outer sheath just as the pre-bend is emerging (see Fig. 2a). The marker is designed to prevent further growth once it reaches this point, since the inner catheter cannot be fed any further. The users are therefore required to remove the marker and orient the VINE catheter by rotating the base of the outer sheath, before continuing to grow. Because the position and orientation of the outer sheath are not fixed relative to the anatomy, the user can translate and rotate the outer sheath if necessary in order to adjust the pose of the pre-curve. Once the

target location has been reached, the VINE catheter is depressurized and pulled from the base in order to retract it similar to a standard catheter.

III. EXPERIMENTAL EVALUATION AND RESULTS

To evaluate the VINE catheter system, we performed both benchtop testing, as well as an experiment under fluoroscopy using a patient-specific anatomical model. The goal was to compare the VINE catheter to standard endovascular instruments, particularly in terms of its safety, ability to navigate tight turns, and its potential to decrease the time and expertise required to successfully complete complex and emergency ES cases.

A. Benchtop Evaluation

1) *Safety Assessment:* The pressure control system described in Section II-C also serves to limit the maximum applied stress that can be induced by the tip of the robot to the surrounding anatomy. Unlike traditional push-catheters, which are relatively stiff structures pushed from the base and capable of causing dissection or other injury of the arterial vessels, the maximum stresses applied by the VINE catheter are inherently limited by the internal pressure in the soft structure to be well below a dangerous level. Arterial perforation forces have been measured at around 2 N for several 4-French catheters [25], resulting in an applied stress of around 1440 kPa. In contrast, the maximum applied stress of a 4.9 mm diameter VINE catheter, when grown through a hollow channel 12.5 mm in diameter, was measured to be 165.9 ± 8.3 kPa on average, when grown with a pressure of 200 kPa, and 234.3 ± 25.9 kPa on average, when grown with a pressure of 300 kPa. These measured stress levels are approximately 6–8 times smaller than those that have been shown to cause arterial perforation using standard catheters. Even in the case that the full internal pressure was applied to the arterial wall, the stress level would be roughly 5 times less than the perforation stress. These results demonstrate the inherent safety of the VINE catheter.

2) *Robustness to Anatomical Variations:* The current VINE catheter has a “U”-shape with a radius of curvature of 20 mm, selected to enable navigation around a range of possible angles found at the base of the aortic arch. The robustness of this single VINE catheter design to different angles was tested as shown in Fig. 5. To navigate these different paths, the VINE catheter is grown until the pre-bend begins to emerge, at which point the base of the VINE catheter is rotated to align the tip of the pre-bend in the desired direction. The VINE catheter can then continue growing, relying on interaction with the constrained environment to continue along the desired path.

The pre-curved VINE catheter was grown through an acrylic model with dimensions similar to those of the vasculature. Compared to a straight VINE catheter, which would always grow down a straight path if it exists, the pre-curved VINE catheter was able to successfully grow down an angled path, where the angle ranged from 0° (complete “U-turn”) to 180° (completely straight). The VINE catheter’s ability to grow through this range of different paths illustrates its potential in navigating varying anatomy and tight curves.

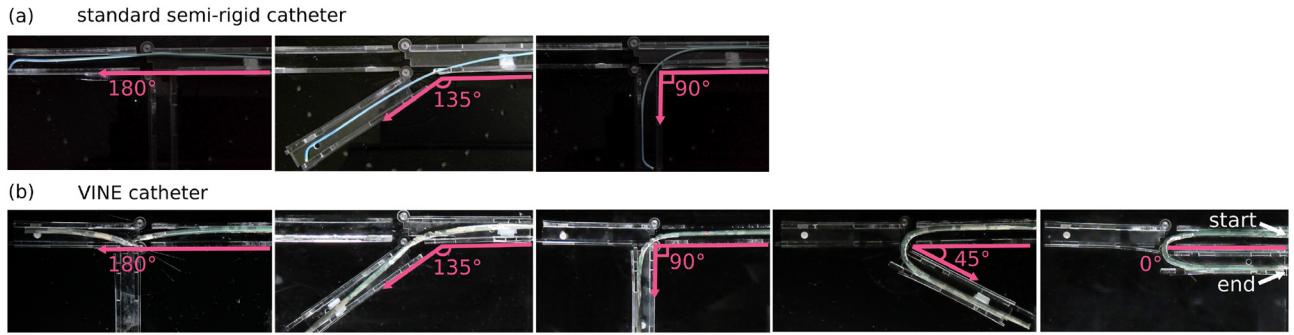


Fig. 5. (a) The standard semi-rigid catheter is only able to traverse curves as sharp as 90° . (b) Device robustness to varying anatomies demonstrated by growing the VINE catheter through channels with angles ranging from 180° (straight line on the left) to 0° (complete u-turn on the right).

As a comparison, a standard push-catheter (5-French Berenstein Catheter (Cordis, Santa Clara, CA)) was similarly navigated through the same set of acrylic models (Fig. 5a). Unlike the VINE catheter, which was able to successfully grow through all five paths, the push-catheter was only able to traverse the 180° (straight) path, the 135° path, and the 90° path. Both the 45° and 0° paths proved to have too tight a curvature for the standard push-catheter to be able to hook and translate successfully without the use of a guidewire or other tools. This test was designed as a comparison between the VINE catheter and a single standard catheter that is appropriate for this model geometry and is the most commonly used catheter to gain access to the cervical arteries during endovascular surgeries at the author's institution. It should be noted that in standard vascular interventions, a guidewire and catheters of various shapes may be exchanged in challenging anatomies. Thus our test does not show that the VINE catheter is better than combinations of standard catheters and guidewires, but only than a single tool. Using a single tool has the advantages of time savings and decreased risk associated with potential vessel dissection with a guidewire. It should also be noted that we chose the pre-curvature of the standard catheter as the best option for the geometry of the benchtop model. While a more angulated catheter might be desirable for tight turns, it is not possible to form this highly pre-curved shape in this model, because of its narrow width. To form a Simmons 1 catheter, for example, one has to navigate the catheter distally into an artery, and then push and twist to force the catheter into the aorta in order to achieve the pre-formed curve of the catheter. The small diameter of the benchtop model would not allow for the catheter to assume this pre-formed shape.

The difficulty in navigating standard push-catheters through these acute turns can be attributed to their method of movement. After they are hooked around a curve, the entire catheter body must translate forward in order to advance the tip towards the target, meaning that a bend in the catheter will no longer match the curve in the vasculature. As such, pushing forward might not result in forward motion around the curve (Fig. 6a). Depending on the curvature, this could be difficult to impossible without the use of additional instruments. In contrast, the VINE catheter can be grown with a bend in its body that roughly matches a curve in the vasculature, and this bend can then remain stationary with respect

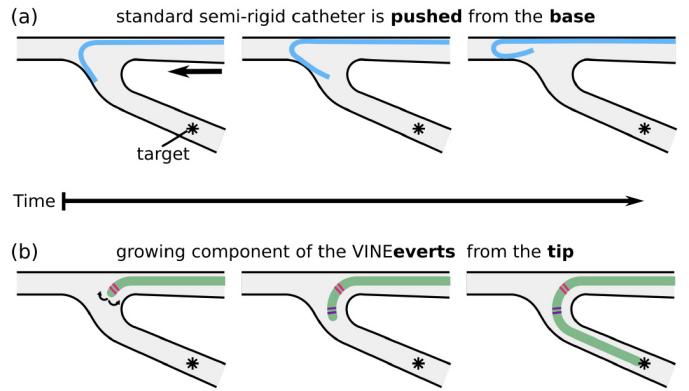


Fig. 6. Compared to (a) a standard semi-rigid catheter, which is pushed from the base, (b) the VINE catheter everts from the tip, such that the rest of the body remains stationary with respect to the environment. This method of motion enables the VINE catheter to navigate tight curves, which a standard catheter could not pass around without additional tools.

to the environment as the tip continues to advance towards the target. Accordingly, the curves in the vasculature remain matched by the bends in the body as the tip of the VINE catheter continues to advance (Fig. 6b). This ability to navigate a wide range of turns without the use of additional tools, as shown here, demonstrates the versatility of the VINE catheter compared to the standard approach, which often requires a significant number of instrument exchanges.

B. Navigation Under Fluoroscopy

Novice users and expert surgeons participated in a user study designed to compare the performance of the VINE catheter and a standard set of manual tools in a patient-specific anatomical model under fluoroscopy (see Fig. 7 for setup). The set of standard instruments included a 15-French vascular sheath (identical to the one incorporated into the VINE catheter design), a 5-French Simmons 1 catheter (identical to the catheter ultimately used to gain access in the actual procedure from which the flow model was created), and a guidewire. The goal of the task was to navigate a catheter to a target site in the distal right common carotid artery of the model.

1) *Experimental Procedure:* Each participant first read a step-by-step explanation and watched a video of how to use both the standard and the VINE catheter method. The

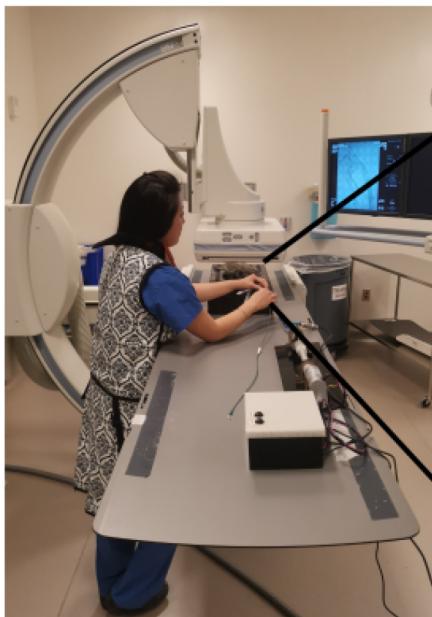


Fig. 7. Experimental setup on the fluoroscopy suite, including the external monitor for viewing during navigation, as well as a top-down view of the patient-specific anatomical model used for testing.

participants had 5 minutes to practice using each device before trying the task under fluoroscopy. The novice users did their final test session after an additional 30 minutes of training—up to 15 minutes for the standard method and up to 15 minutes for the VINE catheter method—in order to become more familiar with the devices and improve their techniques. Approval for testing the VINE catheter under fluoroscopy was given by the University of California San Diego Institutional Review Board (Protocol #190103, approved 6/4/2019). All participants took an online radiation safety training course and wore protective lead aprons and a dosimetry badge. A protective shield was also used when possible. Participants were also told that they could choose to end the study at any time.

2) *Experimental Setup:* A patient-specific anatomical model of a Type III aortic arch was used for the navigation task. CTA images from a rotational angiogram obtained from a challenging clinical case (approval given by the Stanford University Institutional Review Board (Protocol #37209, approved 10/22/2019)) were used to reconstruct a 3D model of the anatomy in the area of interest. The 2D axial slices were first segmented, and this stack of 2D segmentations was used to reconstruct a 3D volume. This 3D DICOM data was then used to generate a patient-specific model that was 3D printed using an FDM (Fused Deposition Modeling) printer. The model was then dip-coated using Silicone, and once cured, the model was removed.

This anatomical model was attached to an acrylic box, fabricated to catch any liquid that may leak from the model during the experiments (Fig. 7). The model was filled completely with water, and air bubbles were eliminated. The actuation system was clamped to the X-ray bed, and the syringe was filled with water spiked with contrast in approximately a 1:1 ratio. An external monitor was used to visualize the X-ray images in

TABLE I
COMPARISON OF NOVICES AND EXPERTS DURING NAVIGATION TASK

	Time to Complete		Radiation Dosage
	Standard	VINE	VINE
Actual Case	35 min	N/A	N/A
Novice	X	4.22±1.90 min	5.90±2.84 μ Gy
Expert	X	3.75±0.90 min	3.72±0.79 μ Gy

real time, and participants were shown on the monitor their target path and end location. All measurements of radiation dosage and elapsed-time were recorded from the monitor.

3) *Experimental Results:* All participants were able to reach the target site by growing the VINE catheter, however none—novice nor expert—was able to complete the task using the standard set of tools (see Fig. 8). Still-frame images from one novice participant’s trial can be seen in Fig 8a. It should be noted that while this participant was able to gain initial access into the innominate artery, they were unable to further advance the catheter. We found that the experts were able to navigate into the right common carotid artery much faster using the standard tools than the novices, two out of three of whom were unable to select this branch at all. On average, it took the experts 0.67 ± 0.05 min to navigate into the right common carotid artery and advance the guidewire towards the target, while the one novice, successful at this portion of the task, completed it in 8.1 min.

We quantitatively assessed the performance of novice users and expert surgeons by measuring the total times and radiation dosages. In contrast to using the standard tools, all users were able to complete the task using the VINE catheter (see video), and the non-medically trained novices had similar times to the expert surgeons. On average it took novices 4.22 ± 1.90 minutes and experts 3.75 ± 0.90 minutes, for a difference of only 0.47 minutes between the two groups. Although the power is too low to make a claim on statistical significance, these results illustrate the ease of learning to use the VINE catheter for novices compared to learning how to use standard tools. Finally, Table I also compares the time to achieve similar access in the actual procedure from which the patient-specific benchtop model was created. As seen, access using the VINE catheter was significantly faster for all study participants compared to the actual procedure with standard tools, which took approximately 35 minutes for an expert neurointerventionalist. The relatively short task time with the VINE catheter resulted in relatively low dosages of radiation, similar between the expert and novice groups. On average, novices experienced $5.90 \pm 2.84 \mu$ Gy and experts experienced $3.72 \pm 0.79 \mu$ Gy. This result is promising and suggests that use of the VINE catheter could lead to lower radiation exposure for both surgeons and patients, particularly for navigating highly tortuous anatomy.

After completing the user study, the participants responded to a survey where they compared using the VINE catheter and the standard tools by ranking statements on a 5-point Likert scale (where 1 = strongly disagree and 5 = strongly agree). Overall, both novices and experts thought the VINE catheter was easier to learn and use. For the first statement, “The VINE

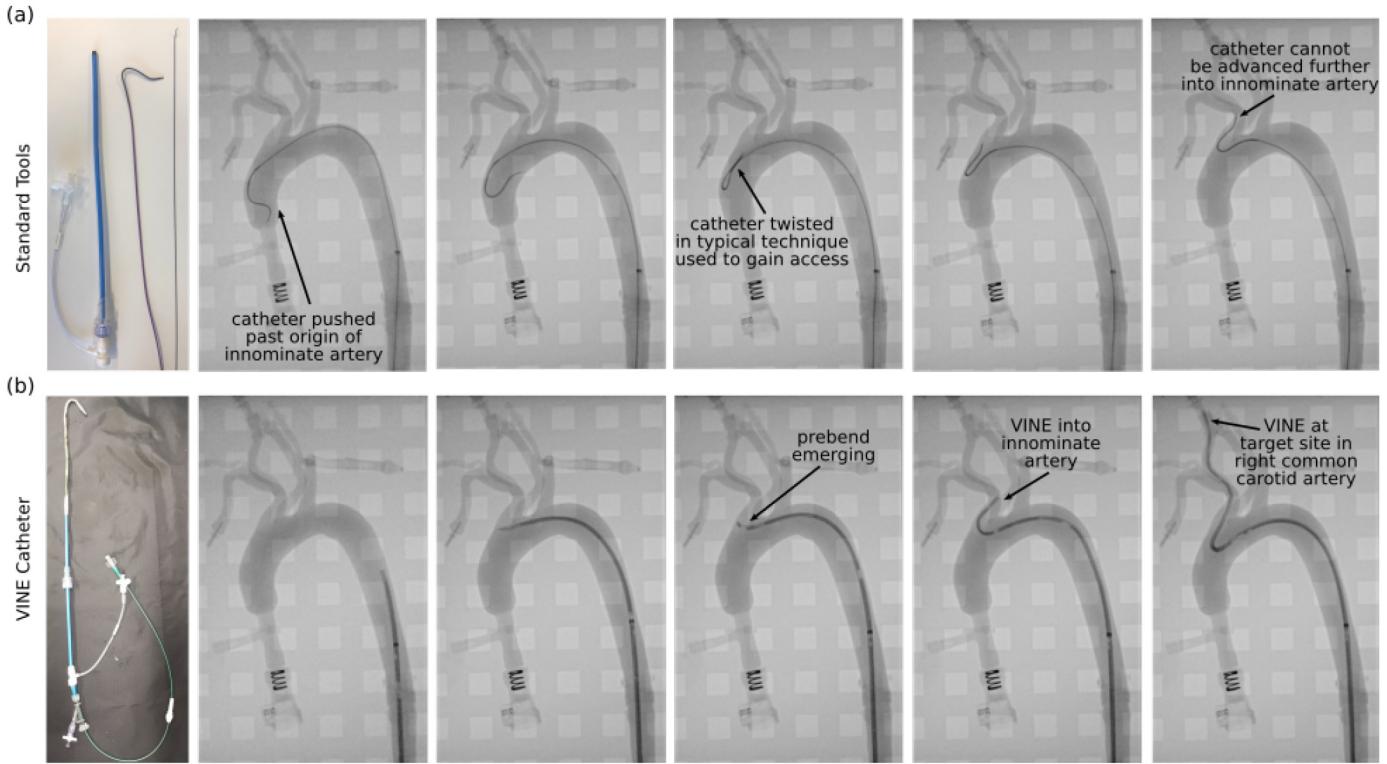


Fig. 8. Results from navigation of the VINE catheter and standard tools in a benchtop model under fluoroscopy. Still-frame X-ray images of (a) the standard tools (vascular sheath [blue] and a 5-French Simmons 1 catheter) and (b) the VINE catheter inside the model at various time points during navigation.

catheter was easier to use compared to the standard tools,” the average responses were 4.33 ± 0.58 and 4.5 ± 0.71 for the novice and expert groups, respectively. For the second statement, “The VINE catheter was easier to learn compared to the standard tools,” the average responses were 3.67 ± 0.58 and 5 for the novice and expert groups, respectively. For the third statement, “The VINE catheter would be easier for a novice to learn compared to standard tools,” the average responses were 4 \pm 1 and 5, for the novice and expert groups, respectively.

IV. CONCLUSION

We have presented a soft, tip-extending robot that extends from the tip when pressurized with fluid. The device is designed such that as it grows, it pulls a standard catheter along with it to the target site, enabling a hollow access channel required for many procedures. In addition to investigations of the robustness to different anatomy and safety during navigation, we demonstrated operation of the VINE catheter compared to standard tools in a benchtop model under fluoroscopy. Both expert neurointerventionalists and novice users participated, and while navigation using a standard set of instruments proved challenging for both groups, all participants were successfully able to complete the task using the VINE catheter. Further, the time and radiation dosage were very similar for the two groups when using the VINE catheter. The results of this work serve as a foundation for an entire class of devices capable of gaining access to difficult-to-reach locations via navigation through constrained anatomy while

maintaining an open access channel. For example, if fabricated at different scales, the VINE catheter could have a wide range of applications for other medical procedures, from percutaneous heart valve replacement to endovascular treatment of small vascular malformations and tumors in a variety of tissue types. Further, these results illustrate the potential to address cases that are not currently achievable. Since this work has demonstrated the ability of the VINE catheter to operate at the millimeter-scale, design, fabrication, and successful operation at larger scales should be relatively straight-forward.

Limitations of the presented work include the amount of manual labor, and therefore the potential for variability, involved in the current fabrication method. Future work will include the development of a more reliable and repeatable manufacturing and testing process. In addition, the VINE catheter in its current form relies on the user to manually orient the tip of the pre-bend in the correct direction. We plan to investigate the advantages of patient-specific, population-specific, or procedure-specific designs, depending on how widely the anatomy varies. And building on our initial work designing actuation methods for larger scale tip-extending robots [23], we will investigate the scalability of such methods for active steering of the VINE catheters.

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REFERENCES

- [1] J. L. Saver *et al.*, "Time to treatment with endovascular thrombectomy and outcomes from ischemic stroke: A meta-analysis," *Jama*, vol. 316, no. 12, pp. 1279–1289, 2016.
- [2] G. W. Albers *et al.*, "Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging," *New England J. Med.*, vol. 378, no. 8, pp. 708–718, 2018.
- [3] R. G. Nogueira *et al.*, "Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct," *New England J. Med.*, vol. 378, no. 1, pp. 11–21, 2018.
- [4] C. Rognoni *et al.*, "Trans-arterial radioembolization in intermediate-advanced hepatocellular carcinoma: Systematic review and meta-analyses," *Oncotarget*, vol. 7, no. 44, pp. 72343–72355, 2016.
- [5] S. Kalra, H. Bhatt, and A. J. Kirtane, "Stenting in primary percutaneous coronary intervention for acute st-segment elevation myocardial infarction," *Methodist DeBakey Cardiovasc. J.*, vol. 14, no. 1, pp. 14–22, 2018.
- [6] E. S. Sussman *et al.*, "Thrombectomy for acute ischemic stroke in nonagenarians compared with octogenarians," *J. NeuroInterventional Surg.*, vol. 12, no. 3, pp. 266–270, 2020.
- [7] B. M. Snelling *et al.*, "Unfavorable vascular anatomy is associated with increased revascularization time and worse outcome in anterior circulation thrombectomy," *World Neurosurg.*, vol. 120, pp. e976–e983, Dec. 2018.
- [8] G. Jin *et al.*, "Association between extracranial carotid artery tortuosity and clinical outcomes in anterior circulation acute ischemic stroke without undergoing endovascular treatment," *J. Stroke Cerebrovasc. Dis.*, vol. 29, no. 2, 2020, Art. no. 104512.
- [9] A. N. De Gast, A. Soepboer, M. Sluzewski, W. J. Van Rooij, and G. N. Beute, "How long does it take to coil an intracranial aneurysm?" *Neuroradiology*, vol. 50, no. 1, pp. 53–56, 2008.
- [10] B. J. Kim *et al.*, "Vascular tortuosity May be associated with cervical artery dissection," *Stroke*, vol. 47, no. 10, pp. 2548–2552, 2016.
- [11] P. Morris, *Practical Neuroangiography*. Philadelphia, PA, USA: Lippincott Williams & Wilkins, 2007.
- [12] J. J. Heit *et al.*, "Sofia intermediate catheter and the snake technique: Safety and efficacy of the sofia catheter without guidewire or microcatheter construct," *J. Neurointerventional Surg.*, vol. 10, no. 4, pp. 401–406, 2018.
- [13] Y. Fu, H. Liu, W. Huang, S. Wang, and Z. Liang, "Steerable catheters in minimally invasive vascular surgery," *Int. J. Med. Robot. Comput. Assist. Surg.*, vol. 5, no. 4, pp. 381–391, 2009.
- [14] E. M. Khan *et al.*, "First experience with a novel robotic remote catheter system: AmigoTM mapping trial," *J. Interventional Cardiac Electrophysiol.*, vol. 37, no. 2, pp. 121–129, 2013.
- [15] C. Riga, C. Bicknell, N. Cheshire, and M. Hamady, "Initial clinical application of a robotically steerable catheter system in endovascular aneurysm repair," *J. Endovasc. Ther.*, vol. 16, no. 2, pp. 149–153, 2009.
- [16] T. Kato, I. Okumura, S.-E. Song, A. J. Golby, and N. Hata, "Tendon-driven continuum robot for endoscopic surgery: Preclinical development and validation of a tension propagation model," *IEEE/ASME Trans. Mechatronics*, vol. 20, no. 5, pp. 2252–2263, Oct. 2015.
- [17] M. D. M. Kutzer, S. M. Segreti, C. Y. Brown, M. Armand, R. H. Taylor, and S. C. Mears, "Design of a new cable-driven manipulator with a large open lumen: Preliminary applications in the minimally-invasive removal of osteolysis," in *Proc. IEEE Int. Conf. Robot. Autom.*, 2011, pp. 2913–2920.
- [18] D. B. Camarillo, C. F. Milne, C. R. Carlson, M. R. Zinn, and J. K. Salisbury, "Mechanics modeling of tendon-driven continuum manipulators," *IEEE Trans. Robot.*, vol. 24, no. 6, pp. 1262–1273, Dec. 2008.
- [19] A. Ali, D. H. Plettenburg, and P. Breedveld, "Steerable catheters in cardiology: Classifying steerability and assessing future challenges," *IEEE Trans. Biomed. Eng.*, vol. 63, no. 4, pp. 679–693, Apr. 2016.
- [20] S. Ernst *et al.*, "Initial experience with remote catheter ablation using a novel magnetic navigation system: Magnetic remote catheter ablation," *Circulation*, vol. 109, no. 12, pp. 1472–1475, 2004.
- [21] Y. Kim, G. A. Parada, S. Liu, and X. Zhao, "Ferromagnetic soft continuum robots," *Sci. Robot.*, vol. 4, no. 33, 2019, Art. no. eaax7329.
- [22] E. W. Hawkes, L. H. Blumenschein, J. D. Greer, and A. M. Okamura, "A soft robot that navigates its environment through growth," *Sci. Robot.*, vol. 2, no. 8, 2017, Art. no. eaan3028.
- [23] J. D. Greer, T. K. Morimoto, A. M. Okamura, and E. W. Hawkes, "A soft, steerable continuum robot that grows via tip extension," *Soft Robot.*, vol. 6, no. 1, pp. 95–108, 2019.
- [24] P. Slade, A. Gruebele, Z. Hammond, M. Raitor, A. M. Okamura, and E. W. Hawkes, "Design of a soft catheter for low-force and constrained surgery," in *Proc. IEEE/RSJ Int. Conf. Intell. Robots Syst. (IROS)*, 2017, pp. 174–180.
- [25] T. H. Schwarcz, P. B. Dobrin, R. Mrkvicka, L. Skowron, and M. B. Cole, Jr., "Balloon embolectomy catheter-induced arterial injury: A comparison of four catheters," *J. Vasc. Surg.*, vol. 11, no. 3, pp. 382–388, 1990.