Assessment of Navigation Cues with Proximal Force Sensing during Endovascular Catheterization

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Abstract. Despite increased use of robotic catheter navigation systems for endovascular intervention procedures, current master-slave platforms have not yet taken into account dexterous manipulation skill used in traditional catheterization procedures. Information on tool forces applied by operators is often limited. A novel force/torque sensor is developed in this paper to obtain behavioural data across different experience levels and identify underlying factors that affect overall operator performance. The miniature device can be attached to any part of the proximal end of the catheter, together with a position sensor attached to the catheter tip, for relating tool forces to catheter dynamics and overall performance. The results show clear differences in manipulation skills between experience groups, thus providing insights into different patterns and range of forces applied during routine endovascular procedures. They also provide important design specifications for ergonomically optimized catheter manipulation platforms with added haptic feedback while maintaining natural skills of the operators.

Keywords: endovascular intervention, catheter manipulation, skill assessment, robotic catheterization, force sensing.

1 Introduction

Robotically controlled steerable catheter navigation systems have seen a growing interest in the field of endovascular surgery. These systems offer potential advantages over manual catheterization, including reduced radiation exposure, increased precision and stability of motion, and added operator comfort [1]. However, most of these systems have been designed with little consideration of underlying perceptual cues, operator-tool force interaction and behavioural patterns, thus not fully utilizing natural ergonomic skills used during conventional catheterization that are obtained through experience. A clear understanding of these force and motion patterns and manipulation skills is crucial for designing next generation intuitive catheter navigation systems by maximizing natural bedside catheterization skills of operators.

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In practice, manual catheterization is based on 2D visual guidance (fluoroscopy) and haptic cues to sense small axial forces and torques at the fingertips while manipulating catheters and guidewires. This is achieved using a combination of pushing, pulling, and twisting at the proximal end of the tools in different directions based on an implicit model of the catheter acquired through experience and a mental picture of the 3D anatomy augmented with 2D real-time image data. Understanding the forces and torques that are applied during a procedure is important to avoid injuries that can be caused by the interactions of catheters and guidewires with the vessel walls, especially in high risk areas and lesions that may lead to perforation or thrombosis.

Thus far, one of the main commercial interventional robots is the Sensei robotic navigation system (Hansen Medical, Mountain View, CA, USA), which has been successfully used in different clinical applications including cardiac ablation and endovascular aneurysm repair [2, 3]. While its efficacy in reducing radiation exposure and fluoroscopy time has been validated [2], its limitations include its large size, high cost, and longer setup times. In the research domain, different groups have also focused on telerobotic master and slave systems for catheter navigation, with added proximal or distal force sensing and haptic force feedback to the operator [4–7]. For most of these systems, the master takes the shape of a joystick or a haptic device (e.g. Novint's Falcon, Phantom Omni), therefore forgoing the natural catheter/guidewire manipulation skills and haptic cues used during bedside practice. Studies show that clinical success is highly dependent on operator experience, and endovascular procedures are associated with steep learning curves [8]. This highlights the importance of maintaining operator skills and dexterity for successful robotic catheter navigation. It also motivates the development of remote catheter navigation systems that maintain the conventional manipulation skills through the replication of motion, force and sensation during the manipulation of a local catheter.

To date, few studies have looked at operator behavioural data and catheter dynamics by mostly focusing on finger motion patterns, or measuring catheter kinematics and forces to overcome introducer sheath friction [7, 9]. Direct measurement of proximal tool forces applied to the catheter and relating these to catheter tip motion can provide critical information on endovascular manipulation skills and present useful design characteristics for improved catheter navigation systems.

The purpose of this paper is to propose an endovascular navigation platform for assessing detailed navigation cues of different operators. A novel force and torque sensor attached to the proximal end of the catheter is developed together with a position sensor attached to the tip, in order to directly relate tool forces applied by operators to catheter tip motion and path length. Performance results, including subject-specific manipulation strategies, are compared over different experience levels in a realistic endovascular setting so as to gain an understanding of force and torque patterns, haptic cues, and underlying skills that contribute to overall operator performance. The study provides important design specifications for the future development of ergonomically optimized catheter manipulation platforms with added haptic feedback, whilst taking full advantage of natural skills of the operators for endovascular intervention.

2 Materials and Methods

2.1 Force Sensor Design

The proposed force-torque (F/T) sensor measures the axial (push and pull) and torsional (clockwise and counterclockwise) loads exerted on to the catheter by the operator (Fig. 1). The sensor is miniaturized and designed to be as unobtrusive as possible to minimize the effects on catheter dynamics and operator skills; this was confirmed by the experienced operators. Instead of manipulating the catheter directly, the operator manipulates a co-axial over-tube and the force measurements are made between the over-tube and the catheter. The over-tube transmits axial and torsional loads on to a transmission component, which is seated in low friction polymer bearings within the sensor casing. The load is then transmitted on to four force sensors within the casing. A spring-loaded clamp affixes the catheter to the casing which allows the F/T measurement to be made between the over-tube and catheter. The clamp is designed so as to avoid catheter bending which would increase the friction between over-tube and catheter. By depressing the clamp, the sensor can be positioned anywhere along the length of the catheter that is comfortable to the operator.

The over-tube was chosen to have a bending, torsional stiffness, and outer diameter similar to that of the catheter so that the operator would feel as if they were manipulating the catheter directly. Additionally, to avoid errors in the measurements, the over-tube was chosen to have low friction and to have a high crush resistance, so that the user could not squeeze the catheter through the over-tube. The force sensors (FSS1500NS, Honeywell) were chosen for their compact size, low weight and linearity and were calibrated against a Nano 17 F/T sensor (ATI Industrial Automation Inc., USA).

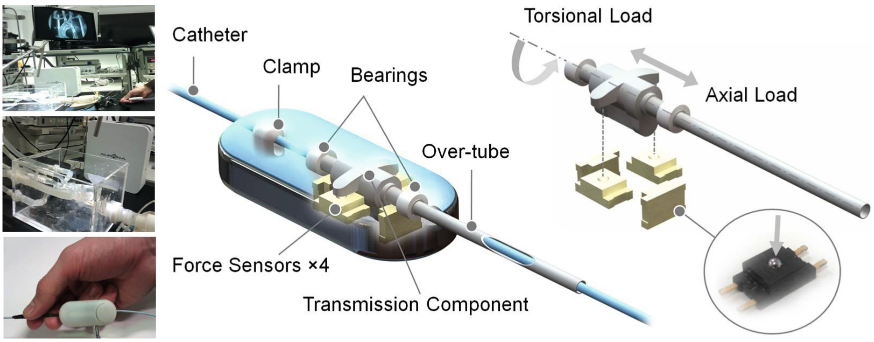

Fig. 1. Experimental setup (left) and force and torque sensor mounted on catheter with exploded view of transmission component showing the four force sensors (right)

2.2 Experimental Setup

A phantom study was performed to obtain tool force and torques applied by operators with varying endovascular skills, and to relate catheter tip motions and velocities to forces applied at the proximal end. It was also designed to extract skill related patterns and underlying factors that affect catheter navigation and overall performance within different steps of an endovascular procedure.

To obtain information on catheter tip position, velocity, and path length, a six degree of freedom electromagnetic position sensor (Aurora, ND technologies) was attached to the tip of the catheter. A silicone-based, transparent, anthropomorphic phantom (Elastrat Sarl, Geneva, Switzerland) representing a type I aortic arch was used for this study (Fig. 1). Eight subjects of varying endovascular experience were recruited and separated into two groups: experienced (n=3, more than 100 endovascular procedures) and inexperienced (n=5, 0 endovascular procedures). All operators were right-handed. Each operator was asked to cannulate the right common carotid artery of the phantom three times. Each trial was considered an independent test, thereby providing sufficient experiments for comparing the two distinct skill sets. In order to simulate 2D fluoroscopy guidance in the OR, a laparoscopic camera was mounted above the model, with the 2D image projected on a monitor to be used by operators for navigation. All operators underwent a short training session to familiarize themselves with the use of the force sensor before commencing the study. Appropriate endovascular tools, including wires and 5F shaped catheters, were available. Force measurements were read into Labview using an acquisition card (NI-USB6009, National Instruments Corp., USA) at 25 Hz.

Depending on the location of the catheter within the vasculature, force values and tip movements can vary significantly, therefore the procedure path was divided into three sections as shown in Fig. 2a : traversing the descending aorta (section A), passing through the aortic arch (section B), and finally cannulating the right common carotid artery (RCCA)(section C). Results were compared over each phase of the procedure for different experience levels.

Ten performance metrics were measured for each section of each procedure. These included median and maximum tip velocity, mean proximal forces in each axial direction, mean torques in each rotational direction, mean tip distance from the origin (catheter path length), sum of catheter tip displacements (motion efficiency), number of twists applied at the proximal end, and procedure time. To identify underlying factors that explain causalities and patterns of correlation between these observed variables, factor analysis was performed on six of these variables for each experience group. The factor loadings were extracted with a maximum likelihood estimate (MLE) for two common factors using a Varimax factor rotation. Differences between experienced and inexperienced operators were also assessed with a non-parametric Mann-Whitney U significance test on all the metrics over each section of the procedure ($P < 0.05$). Skill-related patterns of behaviour can be extracted by comparing graphs of proximal forces, torques, and catheter tip displacement between operators. Dynamic time warping was used to analyze the similarities of these parameters between an experienced and inexperienced operator over the three different sections of the procedure. The range of forces and torques applied over all procedures are also reported for the two experience groups. Statistical analysis was performed with the SPSS software (SPSS Inc., Chicago, Il) and Matlab's statistical toolbox.

3 Results

Fig. 2 depicts the path of the catheter within a mesh of the vascular model, guided by an experienced (b) vs. inexperienced (c) operator. The color gradient depicts the magnitude of the torque applied by the operator at the proximal end of the catheter, over the catheter path.

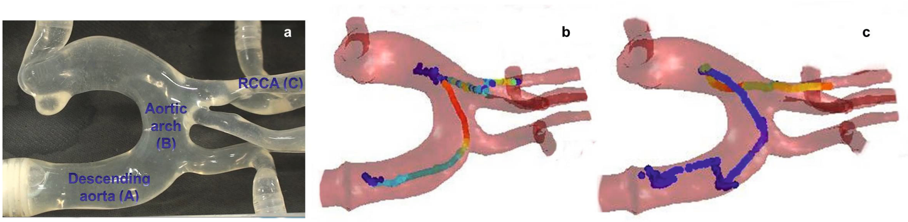

Fig. 2. Vascular phantom depicting the three sections of the procedure (a), catheter path inside the model for experienced (b) and inexperienced (c) operator, with color gradient depicting the magnitude of torque measured at the proximal end

Table 1 shows the result of the factor analysis with two extracted factors, at each section of the procedure. Each value represents the correlation between the variable and the underlying factor (the largest loadings are highlighted). For the descending aorta, mean catheter tip displacement, number of twists, and time are highly correlated for experienced operators as opposed to inexperienced operators, therefore the underlying factor could be a measure of operator efficiency and gain in motion to advance the catheter inside the aorta. In the aortic arch section, there is a high loading on torque, twisting and catheter motion for experienced operators, as compared to push force for inexperienced operators. This emphasizes trained catheter manipulation skills of operators in high-risk areas to avoid damage to the vessels. Results for the common carotid artery also depict the reliance of experienced operators on torque (rather than force) for tip displacement, in order to avoid contact with the narrow walls of the artery.

The results of the non-parametric test between experienced and inexperienced groups depict significant differences for mean displacement ($P = 0.02$), number of twists ($P = 0.02$) and time ($P = 0.05$) in the first part of the procedure (descending aorta). In the arch section, average torque was the more significant variable ($P = 0.01$), while for the RCCA section median speed ($P = 0.04$) and mean displacement ($P = 0.03$) showed significant differences between operators.

Table 2 shows the difference in performances for these significant metrics in each section of the procedure. For the descending aorta, the median values for

Table 1. Factor analysis with 2 common factors over each section of the procedure for experienced and inexperienced operators. Highly correlated factors are highlighted.

	Descending aorta				Aortic arch				RCCA			
	Exp.		Inexp.		Exp.		Inexp.		Exp.		Inexp.	
	1	2	1	2	1	2	1	2	1	2	1	2
Median speed	1.00	0.01	0.53	0.84	-0.14	-0.98	-0.59	-0.06	-0.76	0.27	-0.65	-0.60
Mean displacement	0.23	0.85	-0.26	-0.01	-0.90	0.33	0.58	0.0	0.12	0.64	0.64	-0.05
Mean push force	0.55	-0.46	0.21	-0.55	0.01	-0.31	0.37	0.47	0.33	0.19	-0.83	-0.27
Mean torque CCW	-0.87	0.05	0.17	0.20	0.44	0.82	0.04	0.35	0.13	-0.99	0.92	0.38
Number of twists	-0.19	0.63	0.75	0.13	0.68	0.33	0.05	0.93	1	0.04	0.51	0.78
Time	-0.18	0.91	0.92	0.07	0.86	0.50	0.86	0.40	0.96	0.12	-0.03	1.00

catheter displacement and number of twists show that experienced operators are more ergonomic by using less repetitious movements while achieving a higher gain in tip displacement. The difference in torque in the second part of the procedure proves our previous results that experienced operators rely much more on manipulation skills and torque when maneuvering the catheter through high-risk areas such as the arch. The difference in speed for the last section of the procedure shows cautious and smooth navigation skills of experienced operators to achieve slower yet more efficient catheter motion through narrow arteries.

Table 2. Median values of statistically significant parameters for the two experience groups at each section of the procedure

	Descending aorta			Aortic arch	RCCA	
	Displacement (mm)	Number twists	Time (s)	Torque-ccw (N.mm)	Speed (mm/s)	Displacement (mm)
Experienced	32.2	29	25	1.36	2.6	90.2
Inexperienced	20.3	70	37	0.48	5.5	82.5

Fig. 3 shows the result for force, torque and displacement of an experienced vs. inexperienced operator over the whole procedure. Distinct patterns can be detected, especially over the more complex parts of the anatomy (aortic arch and RCCA). Experienced operators rely on torque and small forces for maneuvering through these areas, and maximum torque is applied when transitioning from the arch to the artery. Overall forces applied by the experienced user are smaller and more uniform, and large forces are only used for specific controlled maneuvers such as advancing the catheter up the aorta or entering the aortic arch. Catheter displacements for experienced operators are also much smoother and contain less back and forth movement, while depicting difficulties for inexperienced operators when entering the arch as well as forcing the catheter from the arch into the narrow artery.

The similarity cost values obtained from dynamic time warping between the experienced and inexperienced operators for the three sections of the procedure

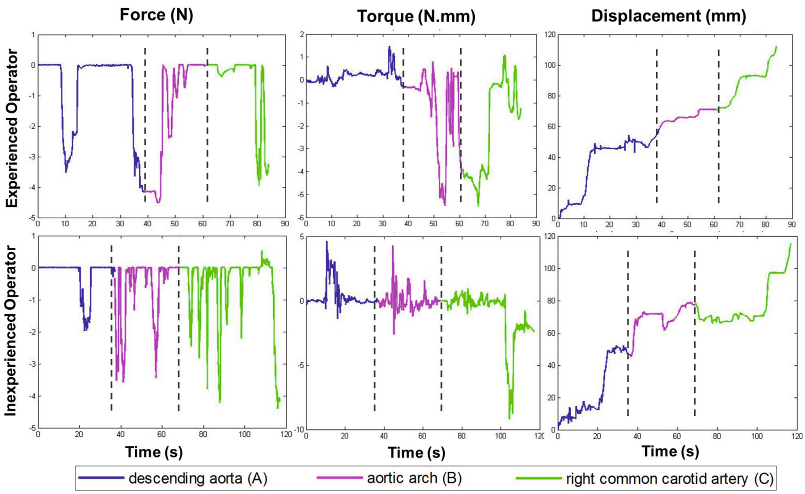

Fig. 3. Force, torque and displacement signals for experienced vs. inexperienced operator, with different colours showing the different sections of the procedure

show large differences in displacement in the first and last part of the procedure (1.55e3, 1.27e3, 1.92e3), highlighting the movement efficiency of experienced operators. Differences in torque are higher in the aortic arch and the carotid artery sections (441.18, 563.09, 894.29). There are also high differences between pull forces in the first and last part of the procedure (747.28, 351.32, 671.94), related to the back and forth movement of inexperienced operators. These findings directly map with the factor analysis results presented above.

The maximum force values (on average) in the axial direction over all procedures, for each of the three sections are 2.09 N, 3.03 N, and 2.93 N for experienced operators. The corresponding values for inexperienced operators are 2.86 N, 3.16 N, and 2.80 N. The maximum torque values for experienced operators over these sections are 2.84 N.mm, 5.26 N.mm, and 6.05 N.mm as compared to 1.87 N.mm, 2.00 N.mm and 6.71 N.mm for inexperienced users.

4 Discussion and Conclusion

A novel miniaturized proximal sensing platform is proposed to non-intrusively measure forces and torques applied during endovascular procedures and provide information on catheter dynamics and force and motion patterns used by operators over different levels of experience. A user study was performed to relate catheter tip motion to forces applied at the proximal end over different steps of a typical endovascular procedure. Different performance metrics related to catheter dynamics, proximal forces and torques, manipulation skills, and procedure time were compared for two groups of operators and patterns of correlation were extracted. It should be noted that the forces applied by the operator include forces to overcome friction from the introducer sheath as well as the vasculature.

The results highlight the importance of underlying factors and experience related skills that affect the efficiency, success and ergonomics of catheterization. Understanding these can also improve assessment and training of catheterization skills. The outcome of this research provides important insight into the perceptual cues used for optimized design of robotic catheter navigation systems while maintaining natural operator skills required for conventional catheter navigation.

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