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An MR Fluids-based Master Haptic Interface with Adjustable Protection Threshold for Endovascular Catheterization

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***Abstract*- Insufficient force feedback and collision warning of teleoperation surgical tools increase the risk of endovascular catheterization. This paper proposed a master haptic interface with the adjustable threshold that takes advantage of a surgeon's natural manipulation skills obtained through experience, as well as generates collision warning with haptic cues to ensure safe operation. The experiments for performance evaluation regarding the haptic force assessment and the real-time adjustment of threshold are conducted. Results show that the magnitude of the instantaneous haptic change in the haptic interface is sufficient to elicit the operator's response, even for novices. Furthermore, for the setting thresholds after adjustment, the operator has a fast reaction to distinguish whether the catheter tip collides with blood vessels or not by collision warning with haptic cues, thus achieving the goal of safe operation.**

***Index Terms* - Master haptic interface, Magnetorheological fluids, Endovascular catheterization, Safe operation, Vascular interventional surgery**

I. INTRODUCTION

Many cardiovascular diseases including atherosclerosis, thrombosis, and aneurysms formation have been the main cause of death in the world, even in developed countries [1]. Historically, vascular surgeons have solved these diseases through "open surgery". It was not until 1963 that the field of interventional radiology was first proposed by Dr. Charles Dotter and other pioneers through advanced medical imaging and catheterization techniques laid a solid foundation for the development of endovascular procedures [2]. With the rapid development of medical technologies, endovascular interventional procedure, due to its smaller incisions, quicker recovery and fewer complications, is found to be the most effective treatment method for vascular tumors, thrombosis, vascular malformations, vascular contractions, vascular sclerosis, and other vascular diseases. It is performed under the help of imaging technologies (most commonly X-ray 2D fluoroscopy) for diagnosing and treating the abnormalities of blood vessels [3]. During this procedure, the catheters and guidewires are operated into the lesion target along the human blood vessel through a small incision in the arm or groin. The surgeon achieves this operation through the combination of insertion, retraction, and twisting at the proximal end of the tools in different directions according to the real-time image data. Nonetheless, several potential clinical challenges also have been introduced: repeated exposure to X-rays causes occupational hazards for surgeons [4, 5]; for the novices, inadequate force feedback while operating surgical tools (catheter and guidewire) increase the risk of Vascular interventional surgeries [6].

As a result, numerous research and commercial organizations have turned towards robot-assisted technologies to improve the status of endovascular therapy and more recently the imaging and navigation with computer-assisted interventions are achieved to provide pre-operative diagnosis and intra-operative guidance for endovascular procedures. Among commercialized commercial robotic catheterization systems, the Amigo TM remote catheter operating system (Catheter Robotics, Inc., NJ, USA) can locate the mapping catheter to the right atrium and ventricle. The performance and safety of the system are evaluated by the clinical trials [7]. The Sensei X robotic catheter system (Hansen Medical, Inc., Mountain View, CA, USA) combined with three-dimensional visualization technology is a combination of collaborative technology, providing better accuracy and stability for physicians [8, 9]. The CorPath® 200 robotic system (Corindus Vascular Robotics, MA, USA) is another remote-controlled robotic system to address some procedural challenges and enhance the degree of precision and control for endovascular procedures. The robotic system can synchronously operate guidewires and stent/balloon catheters during the endovascular procedure [10, 11].

Researchers around the world have also developed numerous other devices and have contributed significantly to

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improve the technology for endovascular procedures. Thakur et al. proposed a new type of long-distance catheter operating system. The system can reduce the physical stress and radiation of operators as well as achieve image guidance by the X-ray 2D fluoroscopy. And it can perceive and reproduce motion in the range of 1 mm and 1 degree in the axial and radial directions, respectively [12]. A new type master-slave catheter operating system was proposed to train the novices to have the minimally invasive surgery for vascular disease with visual feedback [13]. The dynamic and static performance and synchronization of the robot-assisted catheter system were evaluated [14]. Bao et al. proposed an electromagnetic clutch-based tele-operated vascular interventional robot to perform the catheter insertion. Also, two identical slave manipulators were in series to achieve the coordinated motion of a catheter and a guidewire [15]. Furthermore, the operation evaluation in-human of this proposed system was performed [16].

Fiber-optic based sensors have been applied on the tip of a catheter to realize force feedback to the operator [17, 18]. Fu et al. embedded four micro force sensors (FSS1500NS, Honeywell) into the active wheel in a master-slave catheterization system to obtain the advancing force assisted surgeons to operate the catheter under the 3D guiding image [19]. J. Payne et al. developed a novel master-slave operating system with force feedback by using two strain gauges close to the tip on opposite sides of the catheter and two micro force sensors (FSS1500NS, Honeywell) on the master actuator, and In accordance with the force feedback in simulating intravascular procedure, it decreased the magnitude and duration of reaction forces applied on the vessel walls [20]. In order to realize the purpose of measuring the force information directly by force-sensing unit, the compact and economical strain gauge-based force-sensing unit was designed, which is directly in contact with surgical tools, thus improving the accuracy of force measurement [21, 22].

Numerous endovascular robotic systems have been successfully developed and demonstrated to perform various stages of studies with phantom, animal and clinical trials [6, 16]. However, the behavior patterns of operators are hardly taken into account when designing these systems, thereby not fully taking advantage of natural manipulation skills which are obtained through practice and experience [23, 24]. In addition, the collision during the endovascular procedures leading to vascular injury or even perforation has been a concern of surgeons. Despite the growing interest of endovascular robotic systems in the safety of catheterization, these systems have mostly focused on force feedback [25-29] and haptic feedback [6, 30-34]. They are very useful and have important guiding significance for experienced surgeons to make correct judgments. However, for novices, their contributions are diminished because novices do not respond quickly enough and are not sensitive enough to haptic changes as well as lack of experience [24]. Thus, in order to reduce further collision damage and effectively avoid a vascular puncture, it is essential to provide a clear collision warning with haptic cues, especially for novices. Since haptic cues could make it easier and faster for operators to respond accordingly.

II. DESIGN OF MASTER HAPTIC INTERFACE

In recent years, some intelligent materials-based haptic devices have been utilized to increase the effectiveness of human-machine interfaces. The magnetorheological (MR) fluids are the most typical representative because of high permeability and low hysteresis. Combined with the motion input device, the MR fluids-based haptic interface is preferred to achieve a clear collision warning in haptic cues.

Fig.1 describes the magnetic field characteristics of MR fluid [30]. Normally, MR fluids are in a state of fluid-like due to the magnetorheological particles suspended in the nonmagnetic liquid medium. However, the structures under the action of the magnetic field can be transformed from a fluid-like to a solid-like state rapidly and reversibly within milliseconds [35]. The stronger the magnetic field, the greater the strength of the solid-like state is.

In combination with the characteristics of the MR fluids in a magnetic field and the haptic desire of the robot-assisted catheter system, it will generate a resistance force between the MR fluids and the catheter when a rigid catheter is inserted into the MR fluids with a magnetic field (see Fig.2). Magnetorheological particles rapidly form the chain structures along the direction of the magnetic field. Therefore, the operator will feel a slight resistance due to the viscosity of magnetorheological fluids. The MR fluids generate viscous resistance force to the catheter when the catheter is inserted through the MR fluids (applied external magnetic field), in addition, the magnitude of viscous resistance varies with the intensity of the magnetic field.

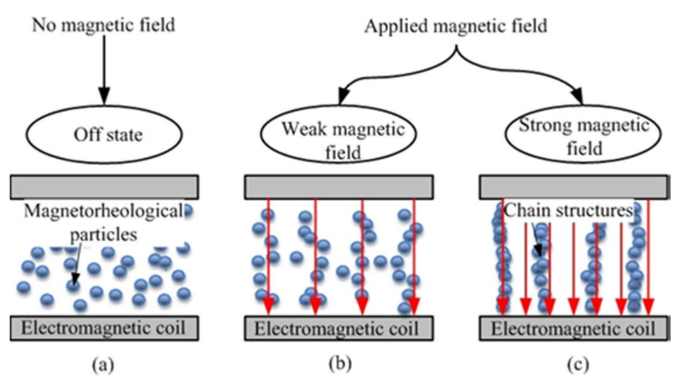

Fig.1 The magnetic field characteristic of magnetorheological particles: (a) magnetorheological fluid no magnetic field, (b) magnetorheological fluids applied weak magnetic field, and (c) magnetorheological fluids applied strong magnetic field [21, 30]

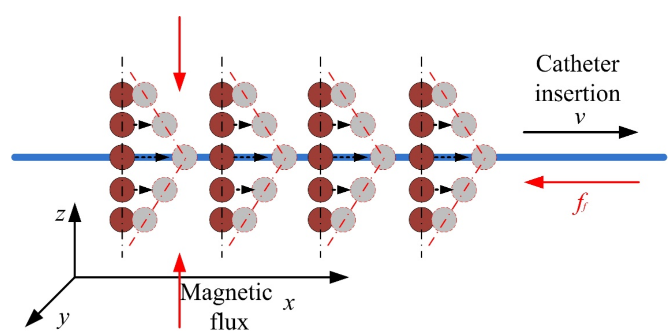

Fig.2 The process of haptic generation in the case of the magnetic field [30]

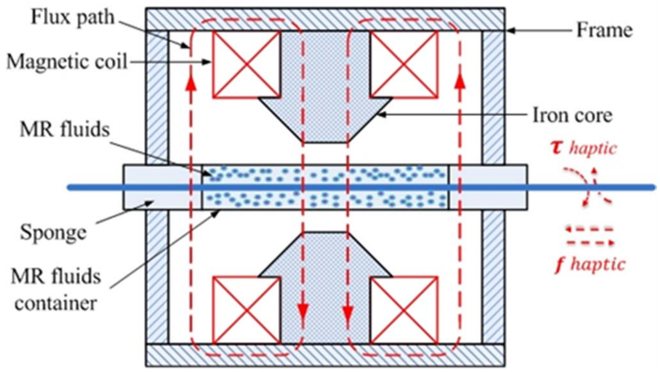

Fig.3 Schematic of the haptic master device [21, 36]

On the basis of analyzing the characteristics of the MR fluids and the haptic desire of the robotic catheter operating system, an MR fluids-based master haptic device was proposed in our lab as shown in Fig.3, which can realize haptic sensation [25]. Since the viscous resistance force can be adjusted by the intensity of the magnetic field which is controlled by a current.

The prototype of the master haptic interface, shown in Fig.4, is composed of two parts: the haptic interface and motion transmission unit. The haptic interface consists of two electromagnetic coils with two iron cores and an MR fluids container as well as coil support. In addition, four permanent magnets and two sponges were applied into both sides of the MR fluids container to prevent the overflow of MR fluids from the small holes of the container and reduce the friction caused by the edge of the holes (see Fig.4). The detailed design specifications for the haptic interface had been introduced in [25]. A pinion and rack mechanism coupled to two rotary encoders (MTL, MES020-2000P, Japan), Encoder (E1) and encoder (E2) with 2000 counts/revolution, is mounted on a linear slide as the motion transmission unit to transmit and feedback the motion signals. The encoder E1 and E2 are for capturing and transmitting translation and rotation singles during the procedures, respectively. A surgeon operates a rod attached with the motion transmission unit and passed through the haptic interface to perform the actions similar to a conventional endovascular procedure. The actions captured by rotary encoders are converted to command signals for the slave manipulator. When the catheter collides with the vascular wall and the contact force measured at the slave platform exceeds the corresponding threshold, the master haptic interface will quickly generate resistance as the collision warning to remind the operator of the collision, thus avoiding the vessel puncture.

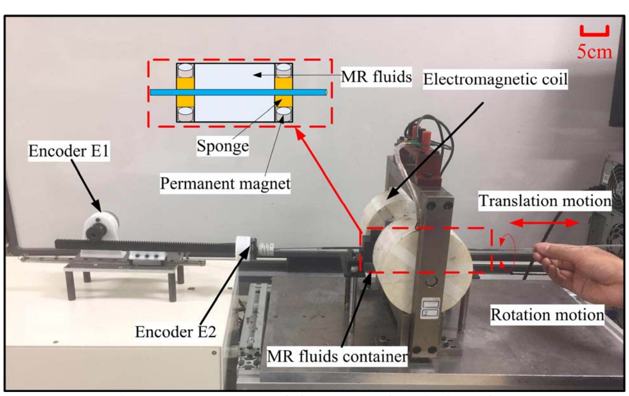

Fig. 4 A prototype of the master haptic interface

III. Haptic Force Assessment for the Collision Warning

The block diagram of the operation for collision warning is shown in Fig.5. When the actions of the surgeon are transmitted to the slave robotic platform to do the insertion/rotation motion in the vasculature, the force sensor will detect the reaction force and feedback it to the controller in the master side. If the feedback force (F_{fd})is smaller than the threshold value ($F_{th,v}$), the surgical tool will continue to be inserted until the target position. Contrarily, the collision warning mechanism will be triggered to remind the surgeon of tip collision. At the same time, the resistance of the haptic interface will also hinder the insertion motion. Then the corresponding motion adjustment will be completed by the operator to perform further actions until task accomplishment.

For the sake of evaluating the effectiveness of collision warning with haptic cues, the assessment experiment is performed to obtain the magnitude of the haptic force. The experimental setup as shown in Fig.6, a rigid rod is fixed with a load cell (TEAC, TU-UJ, Japan) which is mounted on a sliding table and passes through the haptic interface to do the insertion motion. The experimental conditions are as follows: (1) the sliding table with the load cell do the insertion motion at 5mm/s; (2) the maximum current provided by the power supply is adopted to generate the maximum haptic force, thus achieving the maximum warning effect. During the insertion motion, the duration of the electromagnetic field for opening and closing is 5 seconds and 3 seconds, respectively. At the same time, the PC will record and display the haptic force information with and without magnetic fields.

The experimental results are summarized in Fig.7. From the results, we can see that the initial haptic force is 0.2N caused by the friction between the rod and the container as well as the MR fluids. After applying the magnetic field, the haptic force will quickly change from the initial value to the maximum value (0.8N). The instantaneous change of haptic

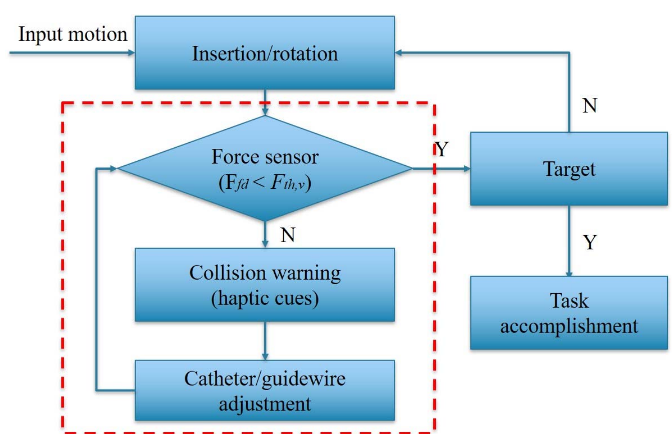

Fig.5 Block diagram of the operation for collision warning

force reaches about 0.6N, it is much greater than 19mN (human's finger detection resolution, i.e. just notice difference (JND)) [37]. Therefore, this instantaneous haptic change can quickly trigger the operator's response and achieve the goal of collision warning, even for novices.

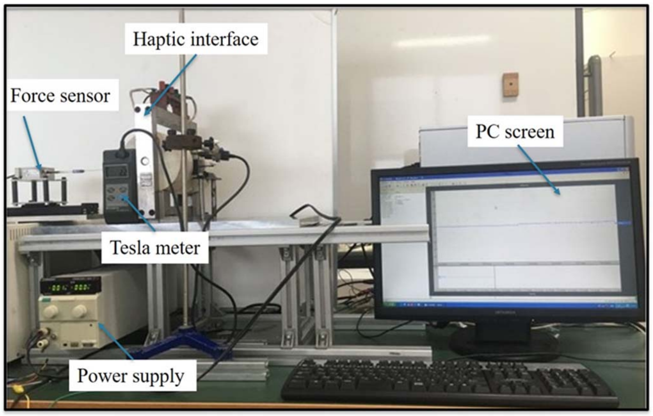

Fig.6 The experimental setup for the haptic force assessment

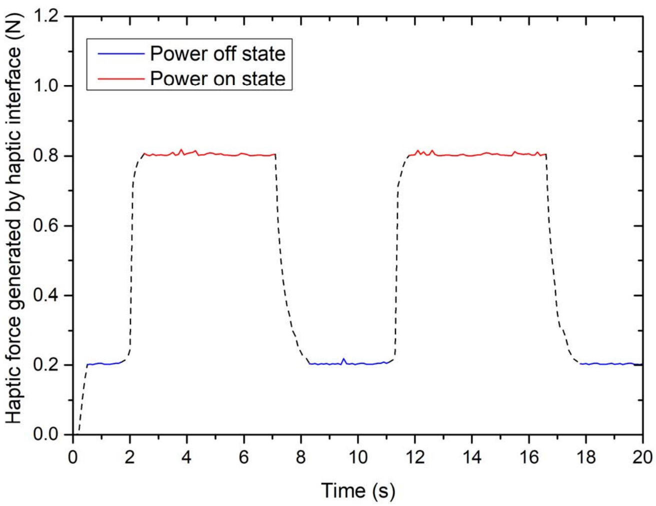

Fig.7 The experimental results for the haptic force assessment

IV. Real-time Adjustment of Threshold for Collision Warning with Haptic Cues

The trigger of the collision warning mechanism is achieved by a relay which is connected with the haptic interface and power supply in a state of constant open. The state of the relay will be changed from "open" to "close" to form a current loop and an external magnetic field is generated around the MR fluids container when the feedback force measured by the load cell is greater than the threshold value.

During endovascular interventional procedures, the catheter/guidewire usually needs to pass through multiple curved areas continuously to reach the lesion target area. In order to prevent any bending areas from being punched, it is necessary to adjust the threshold for collision warning in real-time according to the surgeon's experience combined with vascular characteristics. Motivated by such consideration, a threshold adjustment device in real-time is integrated into the master haptic interface as shown in Fig.8. This device is based on a potentiometer to adjust the threshold value, and the adjustment range is from 0N to 5N.

To evaluate the performance of real-time adjustment threshold for collision warning, the experiment was conducted by one non-medical operator. The load cell is mounted on a sliding table with a step motor, and a fixed rigid plate is contacted with the force measuring the end of the load cell. The operator operates the rod to do the insertion motion, the action signal is captured by the motion transmission unit to control the step motor [38]. In this experiment, the threshold values for collision warning are pre-adjusted to 0.2N, 0.4N, 0.6N, 0.8N and 1.0N, respectively. Some studies have shown that when the contact force between the tip of the catheter and vessel wall was greater than 0.12N, the vascular wall is at risk of perforation [39, 40]. Therefore, the safety thresholds relative to the setting threshold are 0.32N, 0.52N, 0.72N, 0.92N and 1.12N, respectively. When the measured force exceeds the setting threshold, the haptic interface generates the haptic force to remind the operator, and he/she stops doing the insertion motion. The maximum measured force is recorded by the PC in the meantime. The experiment for each setting threshold is carried out ten times.

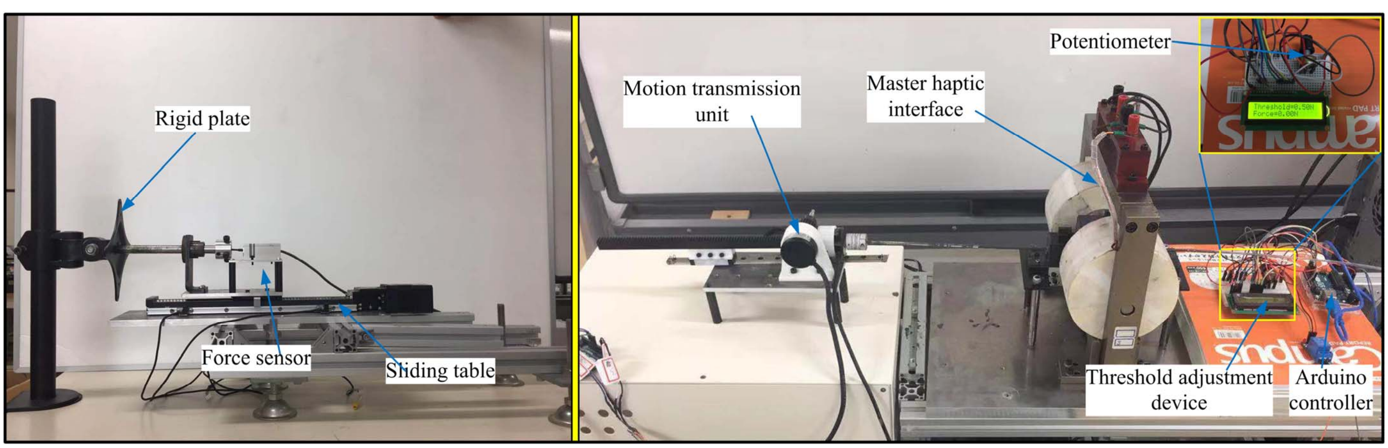

Fig.8 The experimental setup for threshold adjustment in real-time

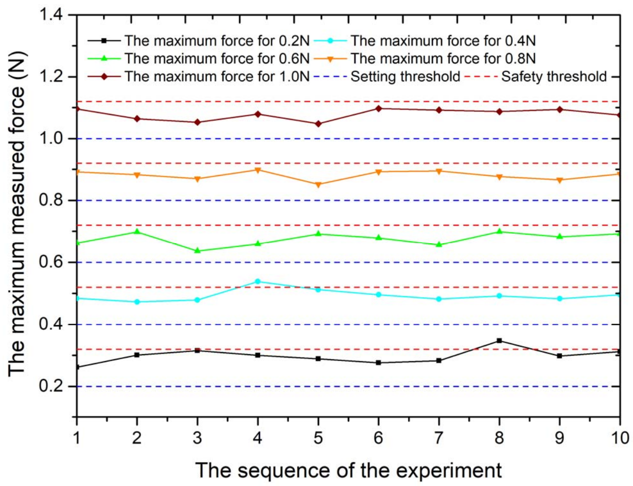

Fig.9 Experimental results for collision warning with haptic cues after threshold adjustment

The experiment results are summarized in Fig.9. From the results we can see that, when the threshold is set at 0.2N and 0.4N, the measured force slightly exceeds the safety threshold once time, respectively, potentially due to a little tremor in the operator's fingers. For the subsequent setting threshold, the measured forces are within their respective safety thresholds. Results show that this method can enable surgeons to distinguish whether the catheter tip collides with blood vessels or not more easily.

V. Conclusions

In this chapter, an ergonomic master haptic interface is proposed to transmit conventional actions of a surgeon while operating a catheter/guidewire. The application of the master haptic interface based on magnetorheological (MR) fluids and high-precision force sensor makes the obvious collision warning in haptic cues possible. To verify the validity of collision warning in haptic cues, the magnitude of the haptic force is evaluated by the experiment. The results show that the change of haptic force is much greater than the human's finger detection resolution. Therefore, it can clearly remind the operator of a collision, even for novices. In addition, a threshold adjustment device is integrated into the master haptic interface to adjust the threshold for collision warning according to the surgeon's experience combined with vascular characteristics, the experimental results show that this method can enable surgeons to respond quickly to collisions. The design of the proposed master haptic interface provides significant insights for the future development of ergonomically optimized endovascular robotic systems incorporating force feedback, haptic feedback and collision warning, whilst taking full advantage of natural manipulation skills of the operators for endovascular procedures.

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