Review Article

Enhancement of a Master-Slave Robotic System for Natural Orifice Transluminal Endoscopic Surgery

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Abstract

Introduction: A novel robotic platform for Natural Orifice Transluminal Endoscopic Surgery (NOTES) is presented in this paper. It aims to tackle two crucial technical barriers which hinder its smooth transition from animal studies to clinical trials: providing effective instrumentations to perform complex NOTES procedures and maintaining the spatial orientation for endoscopic navigation. Materials and Methods: The technical barriers are overcome by the design of the robotic system considering size, triangulation, dexterity, maneuverability and complexity. It is also shown that haptic feedback and interventional navigation system could solve the problem of off-axis manipulation of the camera angle and loss of spatial orientation upon entering the peritoneal cavity in transgastric NOTES procedure, respectively. Results: Successful ESD (endoscopic submucosal dissection) and wedge hepatic resection have been performed on live pigs with our Master And Slave Transluminal Endoscopic Robot (MASTER) system, showing its capability to perform advanced endoscopic surgical and NOTES procedures. It is found that the MASTER exhibited good grasping and cutting efficiency. And the lesion resection time could be significantly reduced with more practice between the endoscopist and the robot operator. Conclusion: This study evaluates the feasibility of MASTER system as a platform overcoming the barriers to NOTES. It is also demonstrated that the MASTER could effectively mitigate the technical constraints normally encountered in NOTES procedures.

Ann Acad Med Singapore 2011;40:223-30

Key words: Haptic feedback, Instrumentation design, Interventional Navigation System (INS), Tracking

Introduction

Minimally invasive surgery has been widely accepted clinically and developed rapidly in the past decades. It has become the method of choice in many surgical procedures, such as laparoscopic reflux surgery, cholecystectomy, appendectomy, etc. The benefits to patients include less trauma, decreased morbidity, shorter hospital stay as well as better cosmetic results. Most recently, with the growing capabilities of therapeutic flexible endoscopy, it is feasible for surgical interventions to be performed in an even less invasive manner. This is where the concept of Natural Orifice Transluminal Endoscopic Surgery (NOTES) becomes appealing.

Ever since the feasibility and safety of transgastric peritoneoscopy in a porcine model were first reported by Kalloo et al[1] in 2004, the potential of NOTES in playing a role in future abdominal surgery has evolved from the ethereal to the tangible. There have been many publications on laboratory animal studies for NOTES.[2-12] However, NOTES is currently still being considered an experimental surgery rather than an accepted routine clinical practice in the surgical and enterological community. There are still technical challenges to the introduction of clinical NOTES.[13-15]

In this paper, we tackle the challenges from an engineering point of view focusing on the following 2 challenges:

1. Effective instrumentations for complex surgical tasks.
2. Maintaining spatial orientation in endoscope navigation.

To overcome these technical barriers, several endoscope-based systems have been developed, including the Transport™ and Cobra device (USGI Medical, USA), R-Scope (Olympus, Japan), and the Direct Drive Endoscopic System (DDES) (Boston Scientific Group, USA). By

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either providing an overtube with extra tool channels or redesigning the whole endoscope, these endoscope-based systems could provide triangulation, which is thought to be an essential feature for NOTES. However, the tools adapted by these systems still have limited degrees-of-freedom, and it is not intuitive for the surgeon to operate the tools and navigate the endoscope at the same time. Besides the endoscope-based system, with the rapid development of robotic technologies in performing minimally invasive surgery, robot-based system appears to be a promising solution to address these challenges in performing NOTES. For example, based on the technology which was originally designed for Laprotek, a tele-operated surgical robot for laparoscopic surgery, Endovia Medical developed the ViaCath system for endoluminal surgery. It enables two-handed manipulation of tissues with 2 long-shafted flexible instruments of 6 degrees-of-freedom plus gripping action. However, as reported in Abbott et al[16] the ViaCath system suffers from some major limitations, such as bulky size and insufficient lateral force of 0.5N only.

As our approach to tackle the problem, a dexterous Master And Slave Transluminal Endoscopic Robot (MASTER) has been designed and developed to enable easier and more efficient performance of NOTES. An earlier prototype of the system has been tested for its tissue dissection capability on Erlangen stomach models and on live pigs,[17] though the specifications of the system were yet to meet the requirements for performing NOTES, as commented in Karimyan et al[18] paper.

In this paper, we evaluate the performance of the latest version of MASTER in tackling these 2 technical challenges to clinical application of NOTES. For the instrument design, the following requirements and constraints are fulfilled: size, triangulation, dexterity, maneuverability and complexity. For spatial orientation, additional features are developed to enhance the performance of the system in maintaining spatial orientation, including integration of the Interventional Navigation System (INS) and provision of Haptic Feedback. The proposed robotic platform for NOTES is shown in Figure 1.

Materials and Methods

Tackling the Challenges in Design

The MASTER system consists of a master console, a tele-surgical workstation, and a slave robotic manipulator that holds 2 end-effectors: a grasper and a monopolar electrocautery hook. The fundamental principles of the design and layout of the system have been fully described in our earlier publications.[17,19] After the preliminary test on its feasibility and capability in enhancing gastrointestinal endoscopic procedures, modifications have been made to improve its performance. Adapted to a conventional dual-channel endoscope, the current version of MASTER system is capable of providing fine and dexterous motion control to perform complex gastrointestinal endoscopic surgical tasks, such as Endoscopic Submucosal Dissection (ESD),[12] and even NOTES applications such as Wedge

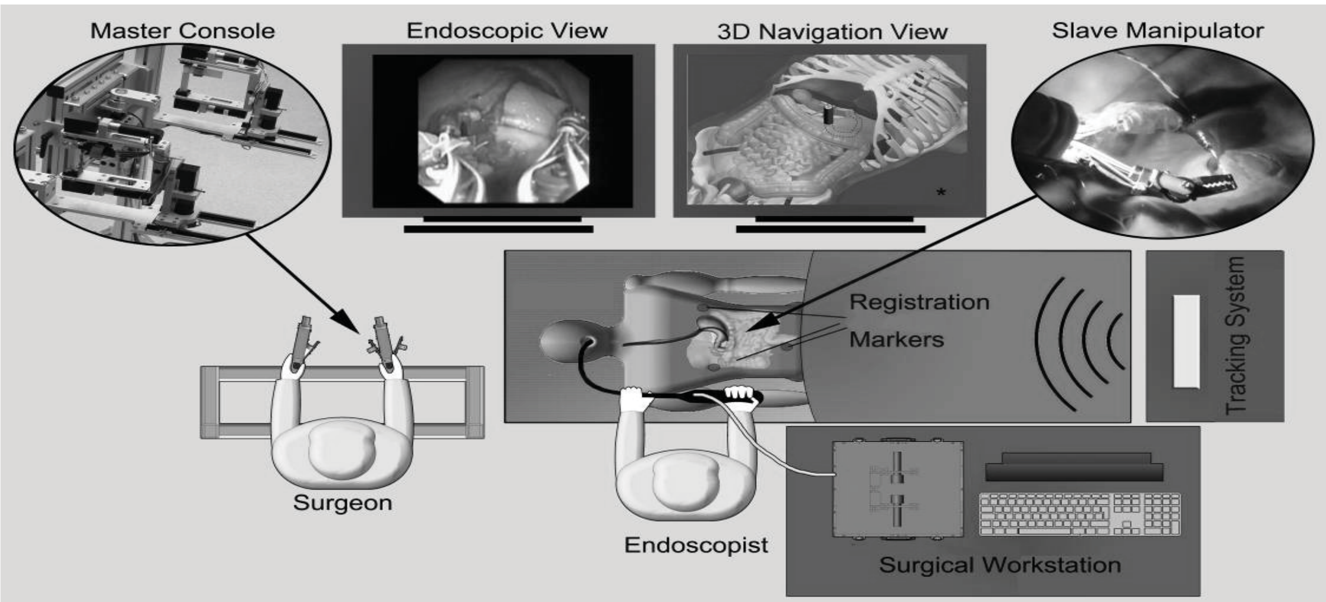

Fig. 1. An overview of the proposed robotic platform.

Hepatic Resection.[11] Following presents how the technical challenges are tackled in our latest design.

Size: The size of the instrument is a critical issue. It must allow for safe introduction to the gastrointestinal tract, while possessing sufficient degrees-of-freedom to perform the tasks. To find out the trade-off between these two factors, we purposely over-designed the manipulators with 12 and 9 degrees-of-freedom respectively to test the feasibility of the platform in our previous prototypes. The overall diameter of the slave robot at the endoscope tip was 24 mm and 22 mm respectively for the first 2 prototypes. Therefore, the whole slave robot had to be attached completely outside the endoscope to avoid acute bending in the transmission tendon-sheaths or blocking the field of view of the camera, which unavoidably made the whole attachment bulky. To further reduce the size of the platform to meet the requirement specified by Bardaro and Swanstrom,[20] which is between 18 and 22 mm, the mechanical structures of the manipulators and attachment have been completed redesigned, which can be seen in Figure 2. The overall size of the new platform is only slightly bigger than the size of the endoscope, which is able to pass through an overtube with an inner diameter of 16.7 mm.

Triangulation: As a concept concluded from laparoscopic surgery, triangulation should give the surgeon the ability to manipulate tissue with traction and counter-traction.[20] With the previous 2 prototypes, MASTER has already been able to provide triangulation. As a result of modification, the number of degrees-of-freedom of the manipulators has been reduced to 9 including 2 translation degrees-of-freedom. Without assistance from the endoscope, the maximum values of force outputs at the manipulator tip are measured to be 2.87 N for opening and closing, 3.29 N for supination and pronation, and 5.20 N for flexion and hyperextension. As tested with an explanted porcine model, the grasper is able to grasp and retract the tissue in all planes. With overlapping workspace of the grasper and hook, meticulous dissection may be performed at ease.

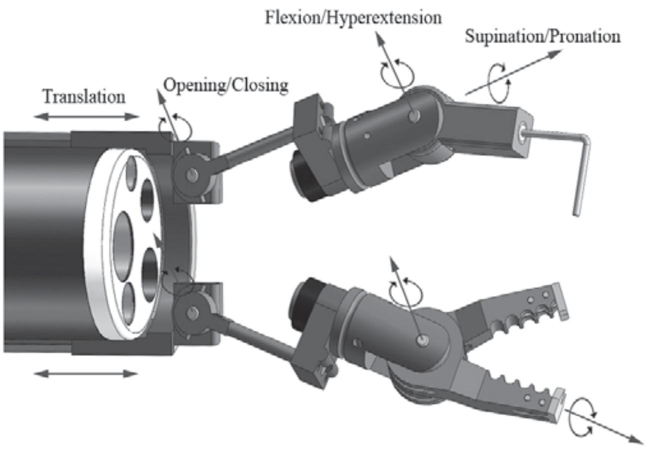

Fig. 2. Configuration of degrees-of-freedom for the robot.

Dexterity: Current endoscopic platform and instrumentations were designed for diagnostic imaging and minor interventional procedures in which the target lies in line with the visual axis of the endoscope. The lack of control precision and dexterity limits their performance in intricate intra-abdominal surgical manipulations. Thanks to its 9 degrees-of-freedom (Fig. 2), the MASTER system allows the operator to reach, position and orient the attached manipulators at any point within the workspace. Providing effective triangulation, the platform is able to not only minimise the need to maneuver of the endoscope, but also exert off-axis force on the site of interest to facilitate bimanual coordination of surgical tasks.

Maneuverability: The maneuverability of the platform includes 2 aspects: one is of the endoscope; the other is of the robotic system. Although the robotic manipulators are attached to the tip of endoscope, the maneuverability of the endoscope is not affected at all. The endoscope still has the ability to maneuver in all planes: vertical, horizontal and lateral, and the shaft can perform 180^0 retroflexion. The maneuvering of the robotic manipulators is intuitively controlled by a human-machine interface, the master console. The current version of the master console is a bilateral electromechanical device that responds to the operator's input and drives the slave robotic manipulators through a joint-to-joint control system. Newly-added haptic feedback can reflect the exerting force at the manipulator back to the operator. This feature will be expressed in details in the following section. Because of the nature of the tendon-sheath mechanism adopted in the system, accurate point-to-point mapping control cannot be applied at this moment. But with pre-stage calibration and vision feedback, the platform could allow the operator to manipulate the tissue more precisely and effectively compared with the current standard endoscopic platform.

Complexity: The complexity of the device may require a substantial learning curve for its use. To test this, a series of endoscopic surgical procedures, such as ESD, have been performed. It is found that the MASTER system requires a minimum of only 2 operators: a surgeon to control the articulating arms of the master console and an endoscopist to steer the dual-channel endoscope. The anthropomorphic design of the slave manipulators and master console and the synchronised control allows the operator to get started quickly and smoothly. Even a novice is able to operate the system with ease and comfort. With several intensive training sessions, the operator is able to perform en bloc endoscopic submocosal dissection with a segment measuring about 30 x 30 cm within minutes.

Maintaining Spatial Orientation

Two approaches are proposed to enhance the performance of the system in maintaining the spatial orientation: (i) Providing haptic feedback to deal with the prevention of damaging the adjacent tissue when manipulating the robot out of the camera view; (ii) Integrated Interventional Navigation System (NIS) to provide support for spatial orientation during transgastric access to the peritoneal cavity. The current development of the 2 approaches is presented in this section.

Haptic feedback: Due to the fixed and limited field-of-view provided by the endoscope, sometimes the surgical instruments might be working away from the axis of the camera view, especially when the instruments pull the tissue away to provide traction or encounter an obstacle; in such occasions, the surgeon is unable to precisely judge the force being applied solely by vision. Haptic feedback, or in this case force feedback in particular, would provide extra information to the surgeon about the interaction status with the environment, and thus be an additional safeguard against injury or perforation of the tissue.

However, because of the size constraints and the flexible body of the platform, up-to-date sensing technology cannot provide accurate force measurement by mounting miniaturised force sensors at the end effectors of the manipulators. A novel approach has been applied to tackle this problem. Instead of directly measuring the interaction force at the slave manipulators, load cells are placed outside the patient's body to measure the compression forces on the proximal end of the sheaths. By modeling the tendon-sheath mechanism force distribution,[21] the forces exerted on the distal end of the sheaths can be predicted correspondingly. With the knowledge of the kinematics design of the slave manipulators, the interaction forces at each joint can be obtained. The force information then can be reflected back to the operator on the master console after proper processing and scaling. The control diagram for haptic feedback is shown in Figure 3. Different from the conventional two-channel bilateral control architecture, there is an intermediate component in between the Master and the Slave. Both the position actuation and the force measurement occur at the Slave Motor Housing stage. Then, the Tendon-Sheath Mechanism Modeling fills in the gap to link the last 2 components.

By applying the force prediction method together with

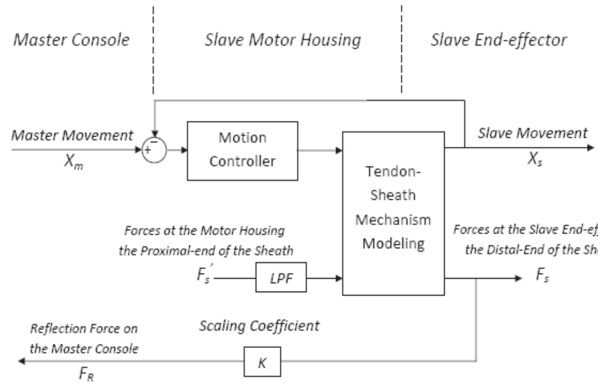

Fig. 3. Block diagram of the control architecture.

the bilateral control architecture, the system would be able to perform force tracking in both free space motion and contact motion. Using the visual feedback, the system could also provide the surgeon position tracking of the end effectors. With direct wire connection between the master console and the slave manipulator, communication latency could be minimised to be negligible. Consequently, the surgeon should be able to "feel" the environment even the end-effectors move away from the camera view during the surgical procedure.

A new grasper prototype was developed using this method. Load cells were mounted on the slave motor housing to measure the compression force in the sheath, while motors replaced encoders to make the master console an active device. The forces reflected on the master console are illustrated by virtual meters on the monitor screen. In free space motion, no artificial resistance is applied to the user; the user could feel the repulsion force when there is an obstacle blocking the slave motion or when the slave end-effector grasps an item, for instance, stretches an elastic balloon or holds a screw. The user could feel the reflection force varying as indicated by the force meter.

Interventional Navigation System: In performing NOTES, the endoscopist can only see structures of the stomach wall directly in front of the endoscope camera. The exact position of the endoscopic tip, its orientation with respect to the puncture site, and relations of other organs adjacent to the stomach, such as liver, cholecyst, colon and etc, cannot be judged intuitively and accurately. These uncertainties during surgery raise the risk of rupturing the normal organ, tissue and major blood vessels, although the uncertainties are efficiently reduced if the force feedback is present. Moreover, such knowledge could also benefit the surgical planning beforehand to figure out the most suitable puncture site to perform gastrotomy. Therefore, a complete solution for supporting spatial orientation for the surgeon during NOTES will enhance its safety and efficiency, while reducing its complication and complexity.

We have begun the development of an Interventional Navigation System (INS) to be integrated into the MASTER system for NOTES procedures. The INS will provide the surgeon with a virtual 3D model of organs and the peritoneal cavity, along with the position and orientation of the endoscope end, such that the surgeon may perform NOTES with improved safety and speed. At present, the system will be built upon open source software and commercially available electromagnetic tracking systems. Phantom and in vivo animal trials with MASTER and the navigation system are planned for validation studies. The advanced INS (Fig. 4) consists of preoperative and intraoperative modules:

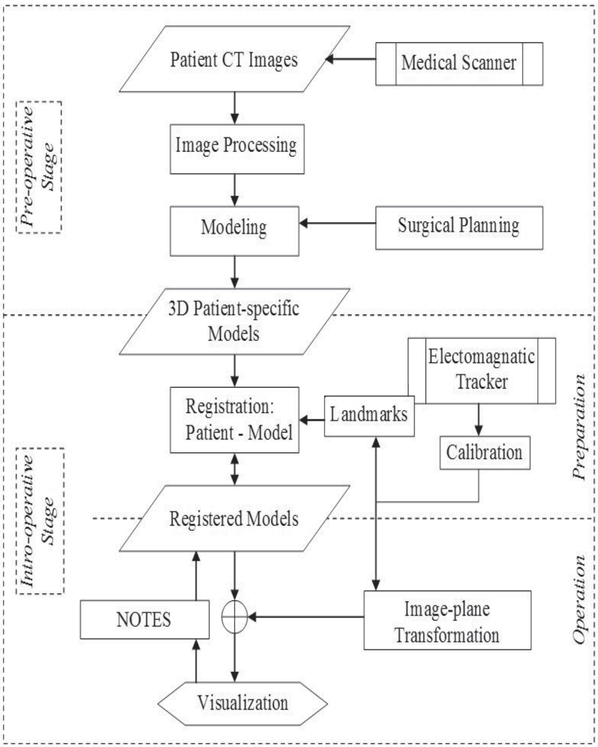

Fig. 4. Work flow of interventional navigation system.

- Preoperative Module − Medical images like computed tomography (CT) or magnetic resonance imaging (MRI) of the patient are obtained preoperatively. The target organ is the reconstructed from the image data and displayed in 3 primary orthogonal planes (axial, sagittal and coronal) as well as a three dimensional (3D) view. Three dimensional coordinates of identifiable anatomical features or fiducials are obtained for the registration procedures. Surgical planning steps including entry point and trajectory of tool are determined.
- Intraoperative Module − During the operation, registration of the patient's 3D coordinates in operating room, multi-modality images and tracking system are conducted. This is a necessary step for all INS procedures for the reliability of the surgery depends on the accuracy of the registration. The preoperatively planned surgical procedures are executed with the help of the visualisation of the target organ, the position and orientation of the surgical instruments.

The tracking system is of paramount importance since it is the crucial part that bridges the preoperative images, target organs and surgical instruments. It is used to translate the position of surgical instruments into coordinates on the preloaded preoperative CT/MRI images displayed on the computer monitor. Currently, there are mainly 3 different

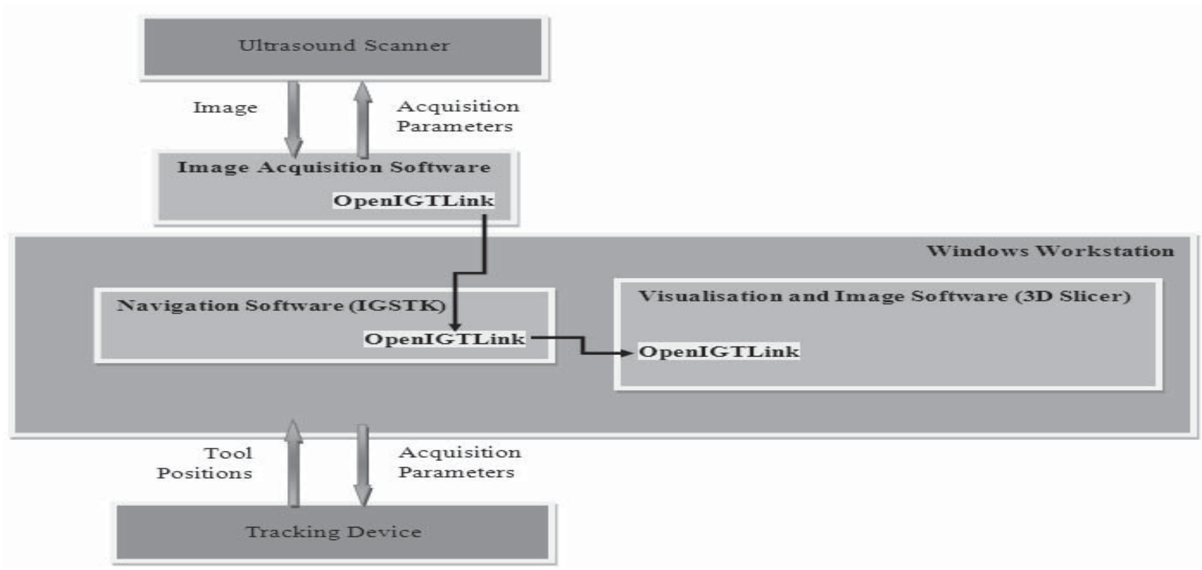

Fig. 5. Overview of the image-guided therapy platform.

types of tracking systems: optical, electromagnetic and MR gradient-based. In our platform, NDI Aurora® System (electromagnetic) and 3D Slicer are chosen to be the hardware and software used respectively. They will be integrated into an image-guided therapy (IGT) platform.

An overview of a general IGT navigation system is shown in Figure 5. OpenIGTLink protocol is an open, extensible peer-to-peer message passing mechanism for data transfer in IGT. Hence, the protocol allows 3D Slicer to communicate with external devices (e.g. imaging devices, tracking devices, medical robots, etc) and to transfer transform, image and status messages.

In 3D Slicer, OpenIGTLink IF module and NeuroNav module are used. OpenIGTLink IF module can import positions, linear transforms and image data from OpenIGTLink-compliant software to the visualis ation scene graph and vice versa. The user can choose one of the linear transforms in the scene graph to visualise its position and orientation in the 3D space, enhancing locator visualisation. NeuroNav module allows the user to perform patient-to-image coordinate system registration and surgical navigation.

The feasibility of IGT Navigation and Data Registration is being explained in a 3-part diagram, as shown in Figure 6. The first sub-diagram is the external tracked tool placement on the phantom organ. The blue wire attached to the syringe is the sensor. The second sub-diagram is the coronal view of the image body. The green-coloured rounded tip is in sync with the external tracked tool's tip, and the cylinder is in sync with the external tracked tool's tubular (syringe) component. The third sub-diagram (in orthogonal view), shows how the actual orientation of the image tracked tool is being simulated when the "Locator All" and "Orient" in 3D Slicer are checked.

Results

Endoscopic Submucosal Dissection (ESD) was performed on 5 Erlangen porcine stomach models and 5 live pigs by using the MASTER system. The lesions were made by using the saline injection method. ESD using conventional tools such as IT diathermic knife was also performed in the live pigs as a comparison. In the Erlangen stomach models, 15 simulated lesions from the cardia, antrum, and body were removed en bloc (mean dimension, 37.4 × 26.5 mm) by electrocautery excision using the MASTER. The mean ESD time was 23.9 minutes (range, 7 to 48 minutes). There was no difference in the dissection times of lesions at different

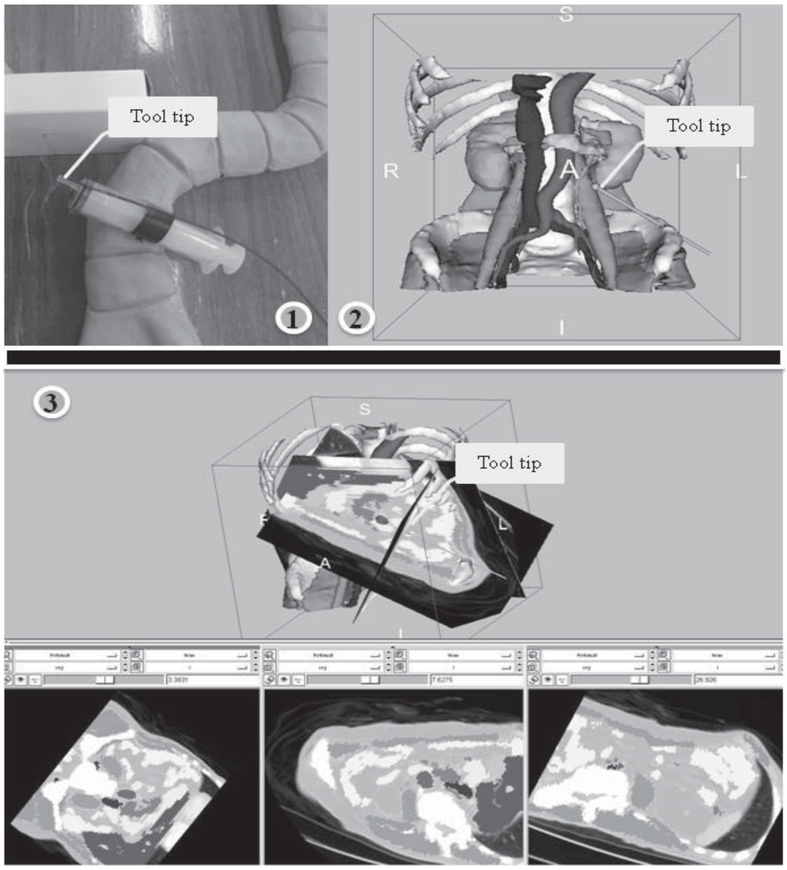

Fig. 6. Real-time tracking system in 3D interface.

locations ($P = 0.449$). In the live pigs, the MASTER took a mean of 16.2 minutes (range, 3 to 29 minutes) to complete the ESD of 5 gastric lesions, whereas the IT diathermic knife took 18.6 minutes (range, 9 to 34 minutes). There was no significant difference in the times taken ($P = 0.708$). All lesions were excised en bloc; the mean dimensions of lesions resected by the MASTER and the IT diathermic knife were 37.2 × 30.1 mm and 32.78 × 25.6 mm, respectively. There was no incidence of excessive bleeding or stomach wall perforation observed throughout the experiment.

Using the MASTER, transgastric wedge hepatic resection was successfully performed on 2 pigs without laparoscopic assistance. The entire procedure took 9.4 minutes (range, 8.5 to 10.2 minutes), with 7.1 minutes (range, 6 to 8.2 minutes) spent on excision of the liver tissue.

It is found that the MASTER exhibited good grasping and cutting efficiency. It is also investigated that with intensive practice, the operation time could be significantly shortened. This demonstrates a very steep learning curve for using the MASTER system.

With the enhancement in spatial orientation, NOTES procedure will become easily oriented and controlled by the surgeons. After the patient is registered with his own 3D model, the surgeon could clearly view the virtual organs and the endoscope in the patient's peritoneal cavity. The position of the adjacent anatomical structures could be recognised without difficulty. Iatrogenic injuries to vital organs, such as, abdominal vena cava, could be carefully avoided. Then the target organ could be accurately identified and operated. During surgical treatment of the lesion, the haptic feedback of the tissue dissection, incision, coagulation and ligation could be all sensed by the surgeon via the haptic system in our robotic platform. The surgeon conducted the surgery as if he was using extensions of his own arms. Thus, the safety and efficiency for the operation will be greatly increased.

Conclusion

This paper presents the MASTER system that tackles 2 crucial challenges to the clinical application of NOTES. It is demonstrated how these technical challenges are tackled by 2 ongoing research areas on the instrumentation design and spatial orientation support. Preliminary experiment results are also presented on the successful endoscopic and NOTES procedures by using the MASTER system. The intuitive design and control would allow the operator to get started quickly with ease and complete the surgical tasks accurately and effectively. However, the performance of the system may not only depend on the co-operation between the endoscopist and the operator, but also on the operator's extent of familiarity of the robotic system. Though intensive training may be required, for better communication between the endoscopist and the operator, the result shows that the learning curve is surprisingly steep and fast.

Another advantage of the MASTER is its designed versatility and adaptability. The robotic slave manipulator could be implemented to any standard dual-channel endoscope, and almost all the components of the platform, such as the tendons and sheaths, are commercial available except for the fabrication of the robot. With the potential of mass production, the cost of the platform could be controlled within an affordable range.

Further developments of the MASTER system involve implementing the possibility of interchanging the end-effectors during the surgical and endoscopic procedures. At the moment, the system does not allow the end-effector to be changed through extraction from the operative channel due to its size being larger than the endoscope operative channel. In the future, a further miniaturisation of the end-effector will release the constraint. Another potential solution would be to reassemble the system in a customised overtube with larger working channels, such as TransPort™ Multi-lumen Operating Platform (USGI Medical, USA). The possibility of having a variety of devices such as scissors, graspers, dissectors, and needle-holders will certainly enable implementation of a range of surgical procedures including difficult tasks such as suturing. This could bring a solution to the gastric closure problem. Survival animal studies are planned to further evaluate the system, together with the haptic feedback and INS features. With all this effort, MASTER system could be a promising platform for effective NOTES procedures.

Acknowledgements

The research was supported by the Translational Clinical Research (TCR) grants from the National Medical Research Concil (NMRC) of Singapore.

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