A Collaborative Robotic Uterine Positioning System for Laparoscopic Hysterectomy: Design and Experiments

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Abstract

Background: Uterus manipulation is a lengthy and tedious task that is usually performed by a human assistant during laparoscopic hysterectomy. Note that the performance of the assistant may decrease with time. Moreover, under this approach, the primary surgeon does not have direct control over the uterus position. He/she can only verbally request the assistant to place it on a particular configuration. **Methods:** A robotic system composed of a 3 degrees-of-freedom

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uterine positioner is developed to assist in changing configuration of the uterus during laparoscopic hysterectomy. The developed system has a remote centre of motion (RCM) structure; independently controlling the uterus motion with one joint at the time is allowed.

Results: From the lab experiments, it is found that the robot shows better performance in retaining the uterus position and shows quicker response to the surgeon's instruction. Cadaver studies have been conducted to evaluate the feasibility of the robot. The robot was also applied to real patients in a clinical study.

Conclusions: The robot is capable of assisting in uterus manipulation during laparoscopic hysterectomy. However, it's user friendliness can be improved by simplifying the docking procedure. Furthermore, a more ergonomic user interface is desired.

KEYWORDS

Surgical manipulator, hysterectomy, uterus manipulation, surgical robots

1 Introduction

Hysterectomy is a commonly performed gynaecological procedure that removes the patient's uterus; common diagnoses which lead to the necessity of hysterectomy include uterine leiomyoma (fibroid tumor), endometriosis, prolapse, cancer of the reproductive tract, menstrual bleeding disorders, chronic pelvic pain, etc. [1, 2, 3, 4, 5]. In laparoscopic hysterectomy the procedure is performed with the image feedback from the laparoscope [6] , the general setup in the operating theatre is as illustrated in Fig. 1(a).

To facilitate the surgical procedures, an assistant is assigned to manipulate the patient's uterus [7] from the end of the operating table. This practice is also a common practice when the procedure is performed in a robot-assisted approach (e.g. using the daVinci surgical system [8, 9, 10, 11, 12, 13], see Fig. 1(b)).

Uterus manipulation during laparoscopic hysterectomy is lengthy and tefigures//tra_setup_.eps

Figure 1: Illustration of the setup in the operating theatre during total laparoscopic hysterectomy; (i) traditional laparoscopic hysterectomy; (ii) robot-assisted laparoscopic hysterectomy (e.g. with the daVinci system). In the figures, (a) is the primary surgeon, (b) is the assistant responsible for the laparoscope, (c) is the assistant responsible for uterus manipulation, (d) is the anaesthetist, (e) is the patient, (f) and (g) are the laparoscopic monitors, and (h) is the scrub nurse

dious. According to Shimizu [14], it takes around 120 minutes to complete a traditional laparoscopic hysterectomy in general; in [15], it is reported that the mean duration for completing a laparoscopic hysterectomy was 131 minutes. For robot-assisted hysterectomy, it is reported that it takes no less than 190 minutes to complete the procedures [9, 8]. Though the total operating time of laparoscopic hysterectomy has been shorten with the improvement of technology in recent years [16, 17, 18], uterus manipulation is still lengthy and tedious for a human assistant.

This human-based uterus manipulation approach causes certain issues: (1) The primary surgeon has no direct control on the uterus' position; the manipulation performance of the assistant may not always satisfy his/her needs, (2) the manipulation performance of the assistant may decline due to the fatigue caused by the long period of continuous manipulation; this affects the manipulation stability. Therefore, it is clear the need to develop a robot which can overcome these issues. With the robot, it is expected that the assistant can be free from the uterus manipulation task, hence valuable manpower in the operating theatre can also be saved.

In this work, we present a fatigue-free robot assistant which can be directly controlled by the primary surgeon to take up the task of uterus manipulation during laparoscopic hysterectomy. The robot can be applied to both the traditional laparoscopic hysterectomy and robot-assisted laparoscopic hysterectomy using general purpose surgical systems (e.g. the daVinci robot).

1.1 Related Works

Surgical robots exist in various forms; for example, surgeon extenders such as the daVinci surgical system (Intuitive Surgical, USA), the Zeus Robotic Surgical System (Computer Motion, USA), the Sensei robotic catheter system (Hansen Medical, USA), and ARTEMIS [19, 20, 21, 22, 23] that supplement the surgeon's ability (e.g. reducing hand tremor, increasing dexterity, etc.) in tool manipulation [24]. The daVinci surgical system has been successfully employed to perform robot-assisted hysterectomy [25]); however, uterus manipulation is still performed by a human assistant in this robot-assisted approach. Manual devices such as the ALLY Uterine Positioning System (Cooper Surgical, USA) and SurgiAssist Uterine Positioner (SurgiTools, Australia) are developed to assist in retaining the position of the uterine manipulator; these devices help to reduce the bedside involvement from the surgical team [7]; however, it still requires a human operator to change the position of the uterine manipulator manually when the desired retaining position changes.

To address the necessity of an autonomous uterus positioner, ViKY UP (Endocontrol Medical, France) was introduced to the market. It is reported that ViKY UP has been successfully applied to assist in uterus manipulation during hysterectomies in [26]. In [27] and [28], it is reported that two ViKY systems, one for laparoscope manipulation (ViKY) and one for uterus manipulation (ViKY UP), are used concurrently to completed gynecologic laparoscopic surgeries. However, as ViKY UP is designed based on the light endoscope robot (LER) [29] which is designed for endoscope manipulation, when applied to uterus manipulation, it arises the following concerns. In its design [30, 31, 32, 33], it provides a remote centre of motion (RCM) centered at the ring which acts as the base when it is used for laparoscope manipulation; when applied to uterus manipulation, the RCM would locate at the entrance of the patient's vagina. However, putting the RCM at the cervix is more desirable due to the anatomic constraints as suggested by the local medical experts; and the ViKY system could not provide such an in-body RCM due to its mechanical structure. Furthermore, the joint motions are coupled together when it generates the necessary motions for lateral manipulation of uterus, antevertion/retrovertion, and exerting tension to the uterus; it is more desirable to have decoupled joint motions as this could enhance confidence in terms of safety [34]. Nevertheless, the system is lack of safety mechanism.

A three degree-of-freedom (3-DOF) robotic uterine positioner leading to a partial spherical workspace centred at its remote centre of motion (RCM) was developed for the captioned purpose in [35]. However, under-bed space is needed to install the robot. In addition, the rigidity of the system needs to be improved. Moreover, it lacks safety mechanisms.

In this work, a new robotic system was designed and developed to provide the primary surgeon a tele-controllable "third hand" to manipulate the patient's uterus from the end of the operating table. The robotic system adopts a bottom-up structure; the configuration of the robot is in particularly designed for the purpose of uterus manipulation. At the same time, it overcomes the drawbacks of the above prototype. The originality of this work includes (1) a linearly-actuated arc-guided (LAAG) RCM mechanism which strengthen the robot's rigidity; (2) a 3-DOF RCM mechanism which allows an in-body RCM located at the patient's cervix and gives decoupled joint motions while uterus manipulation that can reduce control complexity; (3) the introduction of passive safety mechanisms which limit the interaction force between human and the robot; and (4) a detailed experimental evaluation of the robot using a female pelvic manikin, human cadavers, and clinical trials.

2 Methods

2.1 Design of the Robot

The robot is designed to provide the following features:

- Three degrees of freedom for uterus manipulation in three commonly used directions, (1) lateral manipulation, (2) antevetion/retroversion, and (3) exerting tension.
- An in-body remote centre of motion (RCM) located at the cervix to avoid excessive motions.
- Decoupled joint motions to reduce control complexity, and
- Passive safety mechanisms to enhance safety during physical human-robot interaction.

A collaborative robotic system consists of (1) a uterine manipulator positioning arm, (2) a positioning platform, and (3) a user interface is developed for this purpose. Fig. 2 shows the CAD model of the system with (1) and (2) illustrated. The uterine manipulator positioning arm has three degrees of freedoms, yaw, pitch, and insertion; each of these degrees of freedom corresponds to a specific manipulation direction for laterally manipulate the uterus, antevertion and retroversion of uterus, and exerting tension to the uterus, respectively.

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Figure 2: (a) CAD model of the robot; (b) The developed prototype

2.2 The Linearly-Actuated Arc-Guided Mechanism

To enhance the rigidity, and hence the stability of the system, the linearly-actuated arc-guided (LAAG) mechanism is implemented to the pitch joint of the robotic uterine manipulator positioning arm. It is an one-degree-of-freedom (1-DOF) remote centre of motion (RCM) mechanism which provides a virtual pivot point for manipulation. It is capable of giving the output motion as its equivalent 1-joint-2-link arc-based RCM mechanism.

The LAAG mechanism is a 4-joint-4-link 1-DOF linkage system with one revolute joint and three prismatic joints (see Figure Figure 3(a)). The prismatic joint (a) acts as the input while the prismatic joint (b) acts as the output. Joint (a) is connected to joint (b) via the revolute joint (c) and figures//kin_LAAG_3D.eps

Figure 3: Kinematic diagrams of (a) the LAAG RCM mechanism and (b) the robot

prismatic joint (d). Joint (c) and joint (d) compensate the motion difference between joints (a) and (b). That is, joint (b) is driven by joint (a) via joints (c) and (d). If a rod-shaped surgical tool is mounted to the output joint with its axial direction aligned with the normal of the arc of link 1, the surgical tool would always pass through the centre of the arc, that is, the RCM.

In [36], the LAAG RCM mechanism is proven to be back-drivable, which is an important safety feature.

2.3 Robot Mechanism

The kinematic diagram of the robotic uterine manipulator positioning arm is shown in Figure 3(b). It has three degrees of freedom which enable uterus manipulation in the yaw, pitch, and insertion directions about a common RCM. The insertion, yaw, and pitch motions are given by a liner prismatic joint, a 1-joint-1-link arc-based RCM mechanism and the LAAG RCM mechanism presented in Section 2.2, respectively.

Prior to this work, a prototype was developed for uterus manipulation in [35]. The yaw, pitch, and insertion motions are enabled by a revolute joint, a 1-joint-1-link arc-based RCM mechanism and a liner prismatic joint, respectively. The prototype serves its purpose, however, in order to give an in-body RCM, under-bed space is needed to install the robot. Nevertheless, vibration occurs at the pitch joint.

With the newly proposed mechanism in this work, under-bed installation space is no longer needed; this is done by replacing the revolute joint with an arc-based RCM mechanism. Moreover, stability of the robot is improved by replacing the 1-joint-1-link RCM mechanism in the pitch joint by the LAAG mechanism (see Section 2.2).

2.4 Kinematic Properties

With reference to the kinematic diagram in Figure 3(b), define the tip of the surgical tool (i.e. the uterine manipulator) as the end-effector and assume the origin of the right-handed coordinate frame is located at the common RCM of the system. In the Cartesian space, the position of the end-effector $\mathbf{p}_t$ can be expressed as follow:

$$\mathbf{p}_t = \begin{bmatrix} -(d_{t0} - d_3)\cos\theta_2\cos\theta_1 \\ -(d_{t0} - d_3)\cos\theta_2\sin\theta_1 \\ -(d_{t0} - d_3)\sin\theta_2 \end{bmatrix} \tag{1}$$

where θ_1 is the angle of rotation of joint 1; d_2 is the displacement of link 2; D is the distance between the RCM and the axis of translation which link 2 moves along; $\theta_2 = \tan^{-1}(\frac{d_2}{D})$ is the angle of rotation of joint 2; d_3 is the displacement of joint 3; and d_{t0} is the initial distance between the end-effector and the RCM. This gives a partial spherical workspace centred at the RCM with its radius $d_{t0} - d_3 \leq r \leq d_{t0}$, azimuthal angle $\theta_{1min} \leq \theta_1 \leq \theta_{1max}$, and polar angle $\theta_{2min} \leq \theta_2 \leq \theta_{2max}$, where θ_{1min} and θ_{1max} are the limits of the moving range of joint 1 while θ_{2min} and θ_{2max} are the limits of the moving range of joint 2.

From the kinematic equations, it can be observed that though joint motions of the robot is coupled in the Cartesian space, it gives decoupled joint motions under the spherical coordinate system. That is, only one joint has to be actuated to give a motion in the yaw, pitch, or insertion direction.

With equation 1, the Jacobian matrix $\mathbf{J}(\mathbf{q})$ can be obtained by $\mathbf{J}(\mathbf{q}) = \frac{\partial \mathbf{p}_t}{\partial \mathbf{q}}$, where $\mathbf{q} = \begin{bmatrix} \theta_1 & d_2 & d_3 \end{bmatrix}^T$. The determinant of the Jacobian matrix be expressed as follow:

$$|\mathbf{J}(\mathbf{q})| = \frac{(d_3 - d_{t0})^2 (D^2 + d_2^2)}{[D^3 (D^2 + d_2^2)/D^2]^{5/2}} \tag{2}$$

As D is always greater than zero, $[D^3(D^2+d_2^2)/D^2]^{5/2}$ and $(D^2+d_2^2)$ are hence also always greater than zero. Thus, $|\mathbf{J}(\mathbf{q})| = 0$ only when $(d_3 - d_{t0}) = 0$, that is, at the position where the end-effector coincides with the RCM, which is not allowed. Thus, there is no singularity in this mechanism.

2.5 Mechanical Safety Measures

Safety of the robotic system is emphasized from a mechanical perspective. In the robotic uterine manipulator positioning arm, compliant actuators are used to drive the yaw and pitch joints. The working principle of the compliant actuator is illustrated in Figure 4. Define the input part as the DC motor which generates the motion and the output part as the part which eventually drives the robot links. The input part is coupled with the output part via a compliant mechanism. When the force which opposes the motion of the output shaft is within the pre-defined threshold determined by the spring, the roller will stay inside the slot of the output part. This allows motion figures//csj_principle.eps

Figure 4: Working principle of the compliant actuator

transmission from the input part to the output part. When the force which opposes the motion of the output shaft exceeds the pre-defined threshold, the roller will detach from the slot and move along the helicoid surface of the output part. This cuts off the motion transmission from the input part to the output part and provides the compliance. When the opposing force falls back to the limit range, the spring will push the roller back to the slot and motion transmission between the input and output part is restored. More detailed descriptions of the behaviour of the compliant actuator can be found in [37].

In the insertion joint, a linear passive safety mechanism is implemented. The working principle is illustrated in Figure 5. In normal condition, the locking pin with a spherical tip is pressed into the slot of the shaft by the spring. However, when the interaction force exceeds the pre-defined threshold, the spring will be compressed and the locking pin will detach from the slot. Thus, the gripper will slide along the shaft and motion transmission between the gripper, and hence the uterine manipulator, would be cut off.

Ball plungers are used as the locking pins with a spherical tip pushed by springs. The triggering threshold of the mechanism can be adjusted by using different combinations of ball plunger. Experiments were conducted to obtain the triggering thresholds of seven ball plunger combinations. For figures//psj3_principle.eps

Figure 5: Working principle of the linear passive safety mechanism implemented to the insertion joint

each combination, 12 sets of measurements were taken to compute the median value of its triggering threshold. The results are presented in the box and whiskers plot in Figure 6. The combinations under test are as follow:

1. Light load ball plunger with M5 thread
2. Extra heavy load ball plunger with M4 thread
3. Heavy load ball plunger with M4 thread
4. Light load ball plunger with M4 thread
5. Extra heavy load ball plunger with M3 thread
6. Heavy load ball plunger with M3 thread
7. Light load ball plunger with M4 thread and heavy load ball plunger with M3 thread

2.6 The Prototypes

Two prototypes were developed based on the above basic design. Figure 2(a) shows the CAD model of the first prototype. Joint 1 of the robotic uterine figures//trigger_force.eps

Figure 6: Box and whiskers plot showing the triggering threshold of the passive safety mechanism of joint 3

manipulator positioning arm is realized by a pinion and rack mechanism. It is actuated by a 20W DC motor (RE25, Maxon Inc. Switzerland) with a compliant mechanism (see Section 2.5). Joint 2 is built on top of the output element of joint 1. The vertically moving element of joint 2, which drives the output element moving along an arc-shaped rail, is actuated by the same compliant actuator via a belt-and-pulley mechanism. Joint 3 is built on top of the output element of joint 2. It is actuated by a 6W DC motor (A-max 22, Maxon Inc. Switzerland). Its motion is realized by a pinion and rack mechanism with two parallel shafts guiding its motion. The gripper for holding the uterine manipulator is mounted to the shafts via a passive safety mechanism (see Section 2.5). The moving ranges of the yaw, pitch, and insertion joints are $-32° \leq \theta_1 \leq 32°$, $-23° \leq \theta_2 \leq 30°$, and $-32mm \leq d_3 \leq 0mm$, respectively.

The positioning platform which allows the user to adjust the position of the robotic uterine positioning arm has three degrees of freedom when the casters are locked. All three degrees of freedoms are unactuated. It adopts the structure of an X-Y-Z table; all the three axes have the self-locking property. The user can adjust the position by using the hand-turn knob on each axis. The moving ranges the positioning platform are $77mm$ for the x-axis, $59mm$ for the y-axis, and $116mm$ for the z-axis.

The second prototype (see Fig. 7(a)) is built with reference to the same mechanism. However, the moving ranges of the joints of the robotic uterine manipulator positioning arm are modified to $-37° \leq \theta_1 \leq 37°$, $-38° \leq \theta_2 \leq 34°$ and $-85mm \leq d_3 \leq 0mm$. The actuator of joint 3 is changed to a 20W DC motor (RE25, Maxon Inc. Switzerland). A plastic housing which shields the core components of the robot is included.

In general, the robotic uterine manipulator positioning arm adopts a human-in-the-loop motion control approach. It receives commands from the user through a user-interface (e.g. a joystick) and covert these commands into corresponding joint velocities. For safety sake, the system is restricted to that only one joint can be moved at one time and the joint should move at a constant velocity with a relative slow speed.

To control the motions of the robotic uterine manipulator positioning arm, a control system composed of a low-level industrial motion controller with embedded amplifiers (DMC-4040, Galil Motion Control, USA) and a high-level PC-based controller (i5-3550S CPU, 4GB RAM, Intel H61 Chipset) is used. The low-level controller reads feedback from the motor encoders and regulates the output of the actuators. The Linux-based high-level controller tackles external sensory feedback (e.g. user interface) and computes the corresponding motion control algorithms. Communication between the high-level and low-level controllers is established via a high-speed Ethernet connection. In general, the joint velocities of the robot are regulated by figures//gen3_pedal.eps

Figure 7: (a) The second prototype; (b) the foot-controlled interface; the joystick pedal (set 1) controls the pitch joint of the uterine manipulator positioning arm, the green buttons in set 2 controls the yaw joint, while the foot pedals in set 3 controls the insertion joint

standard PD-control; it regulates a constant joint velocity output. Fig. 8 illustrates the architecture of the robot motion control system described above.

The robotic system is compliant with the electric safety standards provided in IEC60601-1.

In general, the robot can be setup following the procedures below:

1. Insert the uterine manipulator into the patient's body as usual.

2. Move the robot joints to the home position (i.e. $\theta_1 = 0$, $d_2 = 0$ and $d_3 = 0$). The illustrations in Figure 9 show the configuration of the robot in its home position.

3. The distance D_b between the entry point of the patient's vagina and the edge of the operating table is known (or it can be measured). The

desired distance D_{r2} between the edge of the operating table and the vertical guide of joint 2 can then be calculated by $D_{r2} = D_{j2} - D_c + D_b$ and the desired distance D_{r1} between the edge of the operating table and the edge of the arc-shaped guide of joint 1 can be calculated by $D_{r1} = D_{j1} - D_c + D_b$ (see Figure 9).

4. Roughly move the robot to the desired position by using one of the above distance relationships. Then, lock the casters of the positioning platform.

5. Manually manipulate the uterine manipulator to a position in which it is horizontally parallel to the ground and its axial direction is perpendicular to the edge of the operating table.

6. Fine-tune the robot's position with the positioning platform. Adjust the x-axis of the positioning platform until D_{r1} or D_{r2} is reached; adjust the y-axis of the positioning platform until the central axis of the gripper is parallel to that of the uterine manipulator; and adjust the z-axis of the positioning platform until the central axis of the gripper aligns with that of the uterine manipulator.

7. Grasp the uterine manipulator with the gripper. The robot is then ready for use.

In the cadaveric and clinical studies (see Section 3.2), a uterine manipulator as shown in Figure 10 is used. The uterine manipulator has interchangeable tips which adapt to patients with different uterus size. A stopper between the tip and the handle of the uterine manipulator stops at the cervix; this avoids the uterine manipulator from getting through fundus.

The motions of the uterine manipulator positioning arm can be controlled by different user interfaces (e.g. joysticks). Different user interfaces can be integrated to the robotic system. In the cadaveric and clinical studies (see Section 3.2), a foot-controlled user interface (see Fig. 7(b)) is used. Three active joints of the positioning arm are controlled by three sets of switches;

the joystick pedal in the middle controls the pitch joint; the green buttons on the sides controls the yaw joint; the foot pedals at the bottom controls the insertion joint.

3 Results

3.1 Evaluation of the Robotic System

3.1.1 Mechanical Accuracy of the RCM

The uterine manipulator positioning arm is designed to have a common RCM. In this experiment, we evaluate the mechanical accuracy of the RCM of the first prototype.

A motion capturing system (OptiTrack, USA) is used to obtain the position of the rod mounted to the robotic uterine manipulator positioning arm. Infrared reflective markers are attached to the two ends of the rod as the reference tracking points. The position of the markers are recorded while the robot joints are moving.

The results are shown in Figure 11. In the figure, the rod at each instant is represented by a line joining the position of the two markers. The plot at the top left-hand corner shows the result of overlapping the position of the rod over a period of time while only the yaw joint is moving. It can be observed that the line segments intersect roughly at a point, which is the RCM point. The position of this intersection point, defined as the estimated RCM, was estimated by the least-square method. The results obtained by moving only the pitch joint and the insertion joint are presented in the plot at the bottom left-hand corner and the plot on the right, respectively. The average absolute error between the estimated RCM and the line segments in these three sub-plots are $0.89mm$, $0.33mm$ and $0.04mm$, respectively.

The plot in the middle of Figure 11 is obtained by overlapping all the line segments in the three sub-plots on the sides. It can be observed that all the line segments intersect roughly at the same point. This shows that the robot has a common RCM. The overall absolute error between the estimated common RCM and the line segments is $0.63mm$.

3.1.2 Simulation Experiment

The robotic system is designed to assist in uterus manipulation during laparoscopic hysterectomy. In this experiment, we compare the performance of traditional uterus manipulation with uterus manipulation with assistance of the robot in a simulated environment. Here, the first prototype is used.

The setup to emulate these two manipulation approaches is as follow. In the experimental set which emulates traditional uterus manipulation, one of the participants plays the "surgeon" role while the other plays the "assistant" role. A female pelvic model (Limbs and Things, UK) is used as the simulated environment. The pelvic model is observed by a USB webcam (Point Grey Research, Canada); the acquired image feedback is shown to the "surgeon" and "assistant" via two monitors. This emulates the image feedback obtained through the laparoscope in a real laparoscopic procedure. A marker is attached to the uterus of the pelvic model for visual tracking purpose. On the monitor of the "surgeon", the marker's position, starting position and desired target position are shown (see Fig. 12); on the monitor of the "assistant", only the raw image feedback from the camera is shown. In this experiment, the "assistant" has to manipulate the uterus manually from the starting position to the desired position based on the verbal instructions given by the "surgeon".

In the experimental set which emulates robot assisted uterus manipulation, only the "surgeon" is involved; the "assistant" is replaced by the robotic system presented in this paper. The "surgeon" controls the robot to manipulate the uterus from the starting position to the desired position.

In both experimental sets, data are recorded once the marker reaches the starting position. The target position appears after a certain period of time when data recording is started. The "surgeon" should then guide the "assistant"/the robot to manipulate the uterus to the target position. Once the target position is reached, the "assistant"/the robot should retain that position for a while (e.g. 10 seconds). The time taken to complete the task and the marker's trajectory are recorded.

The results are presented in Figure 13 and Figure 14. Ten "surgeon-assistant" combinations have participated in the experiment. For each experimental setting, ten sets of data are collected. In this experiment, all participants have an engineering background.

In Figure 13, the sub-plots on the left present the results of the experimental set which emulates traditional uterus manipulation while the sub-plots on the right present the results of the experimental set which emulates the robot assisted uterus manipulation approach. The sub-plots at the top show the pixel error in the x-direction, the sub-plots in the middle show the pixel error in the y-direction, and the sub-plots at the bottom show the overall pixel error between the marker and target position. In the plots, the black lines represent the target position while the coloured lines represent experimental data.

The close-ups of the bottom sub-plots in Figure 13 are presented in Figure 14. The sub-plots on the left present the results of the first 11 seconds of the experiments. In this period, the "assistant"/the robot should retain the marker at the starting position. The mean standard deviation (SD) from the average retained position is 1.3 pixels for the traditional uterus manipulation set while for the robot assisted set, the mean SD is 0.05 pixels. It can be observed that the robot shows better stability in retaining the marker's position, as expected.

The sub-plots on the right present the results of the period after the first 9 seconds of the experiments. The target position appears at the 10th second; this creates the sudden increase in the overall pixel error in the plot. It can be observed that the response time in the robot-assisted approach is faster than the one in the traditional manipulation approach in general, as expected.

3.2 Cadaveric and Clinical Studies

3.2.1 Cadaveric Study

A cadaveric study was conducted at the Minimally Invasive Surgical Skills Centre (MISSC), Prince of Whales hospital (PWH) with the second prototype. In this study, we evaluate the feasibility of the robot, that is, whether the robot is capable of performing uterus manipulation. The robotic system is setup as presented in Section 2.6 and a laparoscope is used to acquire image feedback from the cadaver as traditional laparoscopic hysterectomy does. The feasibility of performing the following manipulation tasks are tested: (1) manipulate the uterus in the lateral direction, (2) antevert/retrovert the uterus, and (3) exerting tension to the uterus by insertion.

Snapshots obtained from the laparoscope are shown in Figure 15. In Figure 15(a)-(c), the cadaver's uterus is moved by the robot from the right to the left; the yellow arrow in Figure 15(a) indicates the moving direction. In Figure 15(d)-(f), retroversion of the uterus is performed; similarly, the yellow arrow in Figure 15(d) indicates the moving direction. In Figure 15(g)-(i), the uterus is pushed inward; again, the yellow arrow in Figure 15(g) indicates the moving direction.

A laparoscopic hysterectomy is performed with the assistance of the robot afterwards. The setup is as shown in Figure 16(a). As in a traditional laparoscopic hysterectomy, the primary surgeon is responsible for the cutting procedures and an assistant is responsible for operating the laparoscope. However, the assistant who is responsible for uterus manipulation is replaced by the robotic system presented in this paper. The primary surgeon controls the robot via a foot-controlled interface (see Figure 16(b)). The primary surgeon's control commands and the joint responses of the robot are recorded throughout the experiment.

Figure 17 shows an example of the data recorded. It presents the commands given by the surgeon to control the yaw joint of the robot and the corresponding joint response of the robot. It can be observed that the robot follows the surgeon's commands. Noted that for safety reason, programmed "soft limit" is applied to stop the robot from moving when the limit of the allowed moving range is reached. The robot joint would not move further when this limit is reached, even when the user commands it to move (see the highlighted regions). This would help to protect the patient from injuries due to excessive manipulation.

3.2.2 Clinical Study

The prototype tested in the cadaveric study (see Section 3.2.1) is applied to a clinical study conducted at PWH. Female patients who have benign gynaecological disease and need to be treated by laparoscopic hysterectomy are recruited. The uterus of the patients should be sized smaller than 10 weeks. Patients with malignant disease, aged over 60, or have previously undergone uterus-related surgery are excluded from the study.

In the study, three camcorders and microphones are used to record the surgery. The camcorders are arranged as illustrated in Fig. 18. Two camcorders are used to record the overview of the surgery while one focuses on the primary surgeon; it records how he/she controls the robot using the foot-controlled interface. Among the camcorders, one of the them (or more) should have the laparoscopic monitor captured in its field of view. All camcorders are synchronized before recording; this helps to guarantee that the videos recorded could be refereed to each other.

The general flow of the robot assisted laparoscopic hysterectomy is as follow. Fig. 20(b) shows the overview of the setting in the operating theatre. The upper part of the figure shows the scrub nurse, the assistant surgeon who operates the laparoscope, and the primary surgeon (from the left to the right); in the lower part, from the left to the right, it shows the robot and the assistant surgeon standing by for uterus manipulation. Before the surgery, the uterine manipulator is sterilized. The surgeon then and insert the assembled uterine manipulator into the patient's body after the patient is anesthetized and well positioned (see Fig. 19(a)). The robot covered with a sterilized X-ray bag is then moved close to the operating table (see Fig. 19(b)). It is roughly set to a proper position and then the casters are locked. Then, the position of the uterine manipulator positioning arm is further adjusted with the positioning platform. Followed by this, the uterine manipulator is then connected to the robot. To avoid contamination, the foot-controlled interface is wrapped with a plastic bag. It is placed next to the primary surgeon (see Fig. 20(a)). The primary surgeon controls the robot to manipulate the patient's uterus to the desired positions. He/she then continue on the procedure; the robot retains the position of the patient's uterus. The robot is moved away when it is not needed.

The surgeons participated in the study addressed the following comments. First, the docking procedure can be more user friendly. To adjust the height of the uterine manipulator positioning arm, we can use the hand-turn knob in the positioning platform. However, in the current design, worm drive is used to provide self-locking ability in the axis. Due to the high reduction ratio in the worm drive, it is rather time consuming for height adjustment. A more efficient way for adjusting the relative position between the patient and the robot is desired. A wider and more flexible range for height adjustment is also expected.

Second, a more ergonomic friendly user interface is preferred. This would help to enhance the long-term usability of the system. The foot-controlled interface presented in this paper serves its purpose in enabling robot control using foot motions; however, it is commented that it is not very comfortable to use the device for a long period of time with a standing posture. And this uncomfortableness mainly comes from the ball-shaped joystick pedal for controlling the pitch joint.

4 Discussion

In this paper, a robotic system for uterus manipulation during laparoscopic hysterectomy is presented. The system can be applied to collaborate with both human surgeons during traditional procedures and general purpose surgical robotic systems during robot-assisted laparoscopic hysterectomy. Design of the robotic system is discussed. Experiments, including cadaveric and clinical experiments are conducted to evaluate the feasibility of the system.

It is proven that the design can be mechanically realized. A mechanical common RCM is attained with reasonable accuracy. The tele-controlled uterine manipulator positioning arm gives decoupled joint motions; that is, one actuator controls an independent manipulation direction. And, the resulting robotic system can be applied to uterus manipulate.

The developed prototype has been applied to a clinical study. It is tested under a real clinical environment. It is proven that the prototype serves its purpose in changing the uterus position according to the surgeon's commands; however the following improvements are desired. For example, a more user-friendly and intuitive positioning platform can help to ease the docking of the robot. Also, the foot-controlled user interface can be further improved with consideration of ergonomic factors to reduce fatigue when using for a long period of time.

When compared to tasks like endoscope or other laparoscopic tool manipulation, uterus manipulation may require a higher payload from the robot. It is challenging to keep the robot compact while providing enough output to achieve its development purpose. For machines/devices developed for medical purpose, safety is in particularly important. While increasing the robot's payload, it is important to make sure that it should not harm people; this include both the patient and the medical staff. Note that in the experiments, we focus on smaller uteruses; in the clinical study, only patients with uterus size smaller than 10 weeks are included, and results shows that our prototype can be applied in such cases. In future developments, we suggest that in addition to safety and enhancing the user-friendliness of the robot, reducing the size of the robot while guaranteeing a secure payload for uterus manipulation should also be one of the focuses.

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ETHICAL APPROVAL

The clinical study is approved by The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC) with the reference number 2016.461.

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Figure 8: Architecture of robot motion planning and actuation

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Figure 9: The desired position for registering the robot to the patient. The robot is in its home position. (a) Top view; (b) Side view

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Figure 10: The uterine manipulator used in the experiment; the tip of the uterine manipulator can be changed to adapt to different patients' size

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Figure 11: Results showing the existence of RCM in the robot: the RCM of joint 1 (top left), RCM of joint 2 (bottom left), RCM of joint 3 (right) and common RCM (middle)

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Figure 12: Visual feedback given to the “surgeon”; the green dot indicates the marker, the blue circle indicates the starting position and the red circle indicates the target position

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Figure 13: Experimental results of the manipulation experiments. Results of the traditional approach (left) and the robot-assisted approach (right)

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Figure 14: Close-ups of the overall pixel errors of the traditional approach (top) and the robot-assisted approach (bottom)

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Figure 15: Image feedback from the laparoscope during the cadaver experiment. (a)-(c) The uterus was manipulated from the right to the left by the robot using joint 1; (d)-(f) the uterus was manipulated from the lifted up position to the pressed down position by the robot using joint 2; (g)-(i) the uterus was pushed inward by the robot using joint 3

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Figure 16: (a) Setup of the cadaver experiment and (b) the robot was controlled by the primary surgeon via a foot-controlled interface

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Figure 17: The user input to and the joint response of Joint 1. From the highlighted regions, it can be observed that the robot would never go beyond the programmed joint limit

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Figure 18: Position of the camcorders which record the experiment; here, (h), (i) and (j) are the camcorders, (a) is the primary surgeon, (b) is the assistant surgeon responsible for the laparoscope, (c) is the assistant surgeon responsible for the uterine manipulator when the robot is not used, (d) is the anaesthetist, (e) is the patient, (f) and (g) are the laparoscopic monitors, and (k) is the robot

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Figure 19: Setting up the robot in the clinical trial; (a) assemble the uterine manipulator; (b) dock the robot

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Figure 20: The robot in action; (a) the primary surgeon controls the robot with a foot-controlled interface; (b) overview of the robot-assisted surgery