INTRODUCTION

At approximately 600,000 operations per year, hysterectomy is the second-most common surgical procedure undergone by women in the United States [1]. Furthermore, there are 1-1.5 million additional diagnostic procedures each year requiring a uterine manipulator [2]. During these procedures, it is often necessary to move the uterus to a convenient location inside the body, either to allow access to a portion of the uterus itself or to provide exposure to other parts of the female anatomy.

According to a 1995 study [3] conducted at the University of Utah Medical Center comparing two commercially available uterine manipulators, an ideal device will (a) be completely safe as well as convenient and quick to use; (b) allow adequate exposure of the female anatomy by providing optimum range of motion of the uterus; (c) have the ability to inject solutions; (d) not require the use of an assistant; and (e) be inexpensive, whether the device is disposable or reusable. While many devices have been commercially developed since this study was published, there is still no uterine manipulator that satisfies all of these requirements.

Through clinical feedback and an ongoing consultation with Dr. John Petrozza, Chief of Reproductive Medicine and IVF at Massachusetts General Hospital, the authors of this paper identified five key device deficiencies. First, no current devices allow for lateral as well as vertical manipulation. Second, all devices require the operator to awkwardly hunch over the patient to reach the controls near the vagina during manipulation (as opposed to a standing position at bedside). This situation usually results in the need for a dedicated assistant to hold the manipulator in place. In this paper, we present a prototype solution that successfully addresses each of these needs: First, our manipulator allows for two complete degrees of freedom (lateral and vertical manipulation). Second, our manipulator features a cable-driven “non-local control” handle that can be clamped anywhere along the side of the operating table. With these two essential improvements, we have developed a uterine manipulator with increased functionality and enhanced physician control, which ultimately ensures patient safety and high quality of care.

PRIOR ART

A detailed search for current commercial devices was conducted. In addition, a patent review was completed to further verify that no viable solution to the problems of lateral motion and/or accessible control has been identified.

Commercial Products

Four commercial uterine manipulators were examined: the V-Care (from ConMed Endosurgery), the Advincula Arch, the RUMI, and the Pelosi (all from Cooper Surgical). In addition, two commercial mounting systems were considered: the Uterine Positioning System (UPS) from Cooper Surgical and the Kronner Sidekick from Kronner Medical.

The V-Care (Figure 1A, p. 2) and the Advincula are both designed specifically for use in laparoscopic hysterectomies.
Both are semi-rigid bodies with no mechanical actuation. The V-Care features two attachments, a cup to push the cervix away from the ureters, and a balloon to prevent loss of pneumoperitoneum [4]. The Advincula is unique in its use of an integrated, sliding cup for better visualization [5]. Both the V-Care and the Advincula provide anteversion and retroversion of the uterus, but provide no lateral movement [2].

The RUMI (Figure 1B) and the Pelosi are multifunctional manipulators used for a wider variety of laparoscopic surgeries in gynecology including diagnostic laparoscopy, myomectomy, oophorectomy, and endometriosis excision. Both are actuated using a linkage system. The RUMI provides 90° of anteversion and 50° of retroversion articulation [6]. The Pelosi is known for being simple, solid, and reliable, but only provides anteversion of the uterus [7]. Neither device provides lateral movement of the uterus.

U.S. Patents

The patent search yielded various devices, none of which successfully and practically addressed the need for lateral motion or improved doctor control. Some patents were vague, such as [9] which detailed a uterine manipulator comprising “an elongated frame presenting a proximate end and a remote end and defining a major axis aligned between said ends.” Other patents such as [10] discuss methods of obtaining tip actuation including articulated linkages, belt drives, and axle drives. However, such patents covering manipulators with pivotable tips focus only on achieving anteversion and retroversion of the uterus. There are also patents that focus on specific attachments to the manipulator, such as [11] which details an externally securable clamp for the hysterectomy cup and [12] which details a manipulator with a device for securing a tenaculum. These last two examples will be important for us to consider in future iterations of our design which may include such attachments but are not relevant to the current design presented.

FUNCTIONAL REQUIREMENTS

Our uterine manipulator should:

1. Ensure patient safety at all times
2. Provide at least 45° of lateral movement
3. Allow the surgeon to stand in a normal upright working position at the abdomen of the patient
4. Stand securely with respect to the uterus and vaginal wall without the need for an assistant
5. Provide at least 90° of anterior and 40° of posterior movement
6. Include a passive locking system to prevent unintentional uterine movement
7. Be sized for the vast majority of patient body sizes
8. Incorporate an ergonomic handle
9. Allow for the attachment of multiple cup sizes
10. Allow for injection of dyes into the uterus via disposable tubes
11. Be competitive on the price market

CONCEPT AND STRATEGY SELECTION

Early in the design process, our team selected the strategy of an internally-actuated mechanical system. This strategy is used by nearly all current commercial manipulators due to the benefits of low complexity and easy incorporation into a medical setting. Furthermore, our team chose to attain lateral manipulation by incorporating rotation into the design framework used by such devices as the RUMI and Pelosi. The addition of rotation is an intuitive and simple change that will allow surgeons to operate our manipulator in similar fashion to current devices while taking advantage of an additional degree of freedom. To allow the operator to stand in a natural position during surgery, our team devised a “non-local” control platform that would use a flexible transmission such that the uterine manipulator could be controlled away from the vicinity of the vagina. In a surgery setting, this non-local control platform would mount to the side of the operating table to give the surgeon control. Lastly, our team developed an inexpensive...
mounting system to eliminate the need for either an assistant or an expensive positioning system during operations involving a manipulator. We found that this strategy and concept would allow us to satisfy every functional requirement listed above.

In order to develop modules for our concept, our team addressed each degree of freedom in the device with a dedicated system. The \textit{tip actuation system} involves the transmission that allows for anteverision and retroversion of the manipulator end effector. This same tip actuation system may achieve lateral movement of the uterus when the actuator is in a rotated state. The rotation state of the manipulator is defined by the \textit{manipulator rotation system}. Both systems make use of braided cables for force transmission. Braided cables were chosen because of their flexibility, low weight, and high load capabilities. However, the tip actuation system makes use of positive-drive pulley systems while the manipulator rotation system makes use of capstans, as discussed in the subsequent section. It should be noted that certain aspects of this cable transmission system could be replaced with bevel gears, flexible shafts, chains, belts, or linkages. In any case, the underlying function of our device would be the same.

\textbf{DESIGN OVERVIEW}

Our uterine manipulator design consists of four main modules: (1) end effector, (2) control terminal, (3) mount, and (4) non-local controls, pictured in Figure 3. Each of these will be discussed in detail following this brief overview of system design. The end effector features a pulley-driven tip capable of 170° of vertical motion (tip actuation system). The second degree of freedom is achieved by means of a sleeve bearing surrounding the body of the manipulator, which allows the entire end effector to rotate continuously (manipulator rotation system). In this way, vertical and lateral manipulation are both possible. At the control terminal, a double positive-drive pulley is used to provide a 1:4 transmission ratio between the end effector and the non-local controls for the tip actuation system. A separate capstan at the control terminal is used to transmit rotation between the non-local controls and the manipulator for the manipulator rotation system. From the control terminal, cables run from both the double positive-drive pulley and the rotation capstan through conduits to the non-local controls. At the non-local controls, one positive-drive pulley and one rotation capstan are simultaneously manipulated by a handle to affect both degrees of freedom.

\textbf{End Effector}

The end effector module, pictured in Figure 4, consists of a plastic-covered tip, cervical push plate, tip pulley, inner tube, and outer sleeve. The tip pulley is used to manipulate the tip through one degree of freedom inside the patient’s uterus (tip actuation system). The pulley is controlled by two cables on either side of the tip, and a positive-drive system is created by wrapping each cable around the base of the tip and securing with a crimp. It is possible to obtain 170° of motion with this pulley, which is more than required by our functional requirements. Furthermore, the positive-drive system prevents slipping and ensures smooth operation.

The second degree of freedom (manipulator rotation system) is achieved through an outer sleeve surrounding the inner tube of the device. In a hospital scenario, this outer sleeve would be frictionally fixed to the vagina wall by means of inflatable balloons attached to the sleeve. The inner tube would then be free to rotate inside the sleeve (the sleeve would act as a bearing between the tube and the body and prevent deformation of the vagina wall). Since the tip pulley is attached to the inner tube, the entire tip rotates with the tube and thus lateral motion is possible. It should also be noted that it is intended for the tip to be returned back to the “start” position—pointed straight out along its neutral axis—before being rotated to prevent distortion of the female anatomy during rotation.
The tip itself is an aluminum pin that runs through the tip pulley. For demonstration purposes, a plastic sleeve cover was fabricated using a 3D printer, although the tip is compatible with a range of soft sleeves currently on the market. One new feature incorporated into our device is a cervical push plate located directly below the tip. This is used to protect the cervix from pinching by the other small parts in the end effector and also to apply an even pressure to the cervix when the manipulator is inserted into the body. It is also important to note that both the tip and the push plate are free to rotate independently about their respective axes. This prevents any distortion of the cervix or vaginal fornix as the device is being controlled.

**Control Terminal**

The control terminal, pictured in Figure 5, is located just outside of the patient’s body. Its purpose is to transmit motion from the handle at the non-local controls to the tip at the end effector. The control terminal consists of a positive-drive double pulley for the tip actuation system and a capstan for the manipulator rotation system.

The positive-drive double pulley controls the 170° of tip actuation. Positive-drive was achieved in this system by once again using two separate cables on either side of each pulley. These cables were then wrapped around the pulley, passed through a hole on the surface of the pulley, and rigidly clamped inside the pulley. This positive-drive technique eliminates the risk of slipping between the pulleys and cables. Although this technique limits the total tip actuation based on the wrapping of the cable, we were still able to surpass the functional requirement of 130° of motion with this technique. The double pulley provides a 1:4 transmission ratio between the non-local controls and the tip, which contributes significantly to the mechanical advantage provided to the operator of the device.

The rotation capstan is rigidly attached to the inner tube using a set screw and controls rotation of the manipulator. The cable was wrapped 2.5 times around this capstan to reduce the risk of slippage, while allowing for unlimited rotation of the manipulator. It should be noted that the positive-drive double pulley is rigidly fixed to the rotation capstan as in the end effector. This prevents the cables of the tip actuation system from becoming twisted during rotation of the manipulator.

Each of the four output cables from the control terminal run through conduits to the non-local controls. These conduits are resistant to axial compression but conducive to bending. To effectively use these conduits and eliminate initial slack in the cable, an adjustable tensioning system, pictured in Figure 6, was created for the cables. As you can see, each cable was fed through a bolt (with a through hole), and then the conduit was pressed up against the outside of the bolt head. With this configuration, the cable can be effectively lengthened (and thus tensioned) by loosening the bolts, which drives the non-local controls away from the control terminal. By incorporating this feature into each output cable, we were able to easily set initial tension in the cables.
Mount

The primary purpose of the mount, pictured in Figure 7A (p. 5), is to eliminate the need for an assistant to hold the uterine manipulator near the vagina of the patient throughout the duration of a procedure. The mount simply clamps to the operation table, which provides the necessary reaction force. Because mounting to the table forms a much smaller structural loop compared to the loop when the device is held by hand, the entire system also becomes more stable in this configuration. The mount controls initial positioning of the manipulator and provides three degrees of freedom: vertical motion, motion in and out of the body, and entry angle. These can easily be adjusted at any time during the procedure if necessary.

Non-Local Controls

To allow the doctor to manipulate the uterus while standing at the abdomen of the patient, a non-local control platform was necessary. During a procedure, this platform would be mounted along the side of the operation table, ideally affixed to the bed rail. We designed this platform to give the operator control over both degrees of freedom of the end effector independently with only one hand. The non-local controls also include the device locking system which prevents the manipulator tip from changing its position without the consent of the operator.

The primary concept which allowed us to develop this system was the use of flexible conduit described in the previous section. The non-local controls include a positive-drive pulley which controls the tip actuation system through rotation about the x-axis and a rotation capstan which controls the manipulator rotation system through rotation about the z-axis (see Figure 7B). As in the control terminal, it was necessary to connect the tip actuation pulley and the rotation capstan such that the wires and conduits would not twist when the controls were rotated about the z-axis. This linkage also allows both degrees of freedom to be controlled with a single handle. Rotation of the handle about the z-axis causes tip rotation and rotation of the handle about the x-axis causes actuation of the tip such that the movements of the handle are exactly mirrored by the tip.

The device locking system was designed using bevel gears, a face gear, and shaft clamps. Under normal manipulation of the uterus, the operator will both rotate the handle about the x-axis and rotate the handle about the z-axis (Figure 7B). When the lock is disengaged, the gears can spin independently from the handle. An x-axis rotation of the handle will result in no rotation of the gears whereas a z-axis rotation of the handle will result in rotation of both gears, but in opposite directions. The locking system rigidly links the rotation of the handle and both gears, therefore eliminating all degrees of freedom of the non-local controls and therefore, the entire uterine manipulator. Since the order of magnitude of the forces involved in this device are well below the forces required to shear plastic gear teeth, low-friction polyoxymethylene plastic (Delrin) gears were a low-cost method to guarantee a durable locking system.

In order to act passively, the locking mechanism was required to activate when the handle was released. Our team incorporated a lever into the handle with a spring at the top and a cable/conduit transmission to achieve this passive locking. When the handle is released, this spring activates the two shaft clamps which fix the two bevel gears to the handle and lock the uterine manipulator in place. The operator must grip this handle to compress the spring, disengage the lock, and gain control over the device.

ANALYSIS

To begin a detailed design, our team developed an analytical model of our system, beginning with the forces required to manipulate the uterus. The primary resistant forces during manipulation are created by stretching of the broad and round ligaments as shown in Figure 8. Although the broad ligament is formed of non-muscular peritoneum, we conservatively grouped the broad and round ligaments as a continuous fold of tissue with properties comparable to myometrium (myometrium is the central layer of the uterine wall and is the cause of uterine contractions during birth). With the assistance of Dr. Petrozza, we derived the mechanical properties to model the uterine system, where $E$ is the Young’s Modulus of the myometrium (1.5 MPa [14]), $t$ is the average thickness of the fold of tissue that forms the broad and round ligaments (1 mm), $L_{\text{Uterus}}$ is the length of the uterus (8 cm), and $L_0$ is the free length of the broad and round ligaments (6 cm):

![Figure 8. Uterine anatomy [13]](image)
From Figure 8 and these mechanical properties, our team formed the analytical model of the system shown in Figure 9 (p. 6), in which the broad and round ligaments are estimated by a continuous sheet spring between the uterus and the pelvis wall.

Figure 9. Mathematical model of uterine manipulation

To determine the total resistance force of the uterine ligaments, our team integrated the reaction force along the sheet spring using the concept of a distributed load, as shown in (1)-(6):

\[
\sigma_{\text{lig}} = E \varepsilon_{\text{lig}} \tag{1}
\]

\[
F_{\text{lig}} = \frac{AE}{L_0} x \tag{2}
\]

\[
\frac{dF_{\text{lig}}}{dA} = \frac{E}{L_0} x \tag{3}
\]

At 45°, \( x \approx y \tag{4} \)

\[
dA = tdy \tag{5}
\]

\[
F_{\text{tip}} = F_{\text{lig}} = \int_0^{\frac{\pi}{4}} \frac{AE y}{L_0} dy = \frac{AE \varepsilon_{\text{uterus}}}{4L_0} \tag{6}
\]

Using (6) and the mechanical properties of myometrium, our team calculated a 40 N maximum resistance force \( F_{\text{lig}} \) from the broad and round ligaments. The weight of a healthy uterus is \( \sim 1 \) N and is insignificant when compared to the resistance forces of the ligaments. However, a diseased uterus can increase in weight up to \( \sim 10 \) N, and was therefore taken into account for design purposes for a total resistance force of 50 N. Although the weight of the uterus and the resistance forces of the ligaments are not collinear and are likely supported across the length of the tip, our team assumed the worst case scenario in which the net force was applied directly orthogonal to the tip at its end. This scenario would be the most likely to induce failure.

In order to confirm our analysis, our team developed a simple spring gauge fixture and asked Dr. Petrozza to mimic the maximum force he experiences while manipulating a common uterine manipulator during a procedure. We found that he applied a maximum force of \( \sim 25 \) N. In order to build a factor of safety of 2 into our device, our team continued our detailed design assuming a maximum force of 50 N as in our calculations.

The next step in our analysis was to determine the maximum forces transferred throughout the transmission and the necessary clamping force needed to lock the system. The following figures and equations detail the analysis of the tip actuation system only. We will explain the logic we used for the manipulator rotation system at the end of this section. The force balance of the cable-pulley transmission is shown in Figure 10, in which \( P \) is the net 50 N tip force calculated above. Dimensions of our system (shown in Figures 9-11) are given in Appendix A.

The tip force must be supported by the structure of the tip when the system is locked, and the maximum bending stress in the tip was found to be \( \sim 230 \) MPa at a tip load of 50 N using (7). This value is below the yield strength of 6061 aluminum (276 MPa [15]) confirming that our chosen dimensions meet our design safety factor of 2.

\[
\sigma_{\text{max}} = \frac{32PL_{\text{tip}}}{\pi D_{\text{tip}}^2} \tag{7}
\]

The force applied at the tip also causes a moment of \( \sim 3.5 \) N-m about the tip pulley which must be balanced by a \( \sim 520 \) N tension in the cable affixed to the tip as calculated in (8). This
load is below the 700 N maximum load of the tip pulley cable. At this load, the selected steel cable will elastically stretch approximately 0.5% of its original length as shown in (9). A cable or fiber with lower elasticity would be preferable, but our team chose to work with steel cable due to availability during this design iteration.

\[
T_1 = \frac{2F(t_{\text{Tip}} + d_{\text{1}})}{D_1} \tag{8}
\]

\[
\delta_{\text{cable, max}} = \frac{T_1}{E\Delta \text{wire}} L_{\text{cable}} \approx .005 L_{\text{cable}} \tag{9}
\]

\[
T_2 = \frac{T_1 D_1}{D_2} \tag{10}
\]

In the non-local controls, the cable tension is reduced to ~130 N \((T_2)\) as the pulley size is increased through a 1:4 transmission ratio (10). This section of our device uses larger diameter cables that fit inside a conduit and are capable of supporting loads up to 1200 N. This ~130 N tension induces the original ~3.5 N-m torque about the rotation axis of the handle and the clamping system. Our team sized our handle at 20 cm such that the maximum tip force could be supported by a ~15 N reaction force by the operator at the top of the handle. This allows our device to have a net mechanical advantage of 3.5 (much of the 4:1 advantage achieved in the control terminal is canceled by the small tip pulley). However, at the level of the shaft clamp, which needed to be close to the axis of rotation of the handle to reduce the footprint of non-local controls, the required tangential force \((F_{\text{Clamp}})\) needed to resist the moment is ~700 N. The equations used to produce these numbers are given in (10) and (11).

\[
F_{\text{Hand}} = \frac{T_2 D_2}{2(D_2^2 + D_{\text{Handle}})} \tag{11}
\]

\[
F_{\text{Clamp}} = \frac{T_2 D_2}{D_{\text{Clamp}}} \tag{12}
\]

In addition to providing power transmission, the non-local control platform also includes the passive locking system, which requires two shaft clamps to prevent any relative motion between 3 collinear shafts. One half of the shaft clamp system is shown in Figure 11. Since there is only one spring to provide the force for 2 clamps, the two clamps can be grouped into the singular system depicted. In this scenario, the clamp system must resist ~3.5 N-m \((F_{\text{rest}})\) and provide a ~700N force \((F_{\text{Clamp}})\) tangential to the surface of the shaft on which the handle rotates. Using the coefficient of friction for dry aluminum contact \((\mu_{\text{static}})\) of 0.6 [16] and the equations presented in (12) and (13), we calculated that a 45 N spring force at a distance of 15 cm from the handle lever pivot would provide sufficient clamping force to lock the system. The spring and handle were sized such that the operator would be able to fully compress the spring and disengage the clamps during normal manipulation of the controls. The details of this sizing are trivial and are not included in this paper.

\[
N_{\text{Clamp}} = \frac{F_{\text{Clamp}}}{\mu_{\text{static}}} \tag{13}
\]

After the tip actuation system and the device lock were designed, our team analyzed the forces present in the manipulator rotation system. We realized that any forces transmitted tangential to the inner surface of the uterus would be relatively low (due to the low coefficient of friction between the tip and the endometrium) compared to the forces transmitted orthogonally to this surface. The only expected force is due to the weight of the uterus, which is relatively low when compared to the ligament forces. Therefore, our team was confident that the transmission system which allows for rotation of the uterine manipulator would be adequately designed (and easier to manufacture) if it used the same components and dimensions as the tip actuation system transmission. The main difference between these systems was that the rotation system used capstans in place of positive-drive pulleys. These capstans reduced the risk of slipping and lowered the required tension in the cables of the manipulator rotation system. A representation of the capstan loading is shown in Figure 12.

**Figure 12. Capstan loading diagram**

Using the coefficient of friction for aluminum-steel contact \((\mu_{\text{Cable}})\) of 0.6 [16] and the equation presented in (15), we calculated that with 2.5 wraps \((\theta = 90^\circ)\) about each capstan \((D_{\text{Capstan}} = D_2)\), the necessary torque load \((F_{\text{Applied}})\) required to induce slipping in the system is 368 times larger in magnitude than the tension in the capstan cables \((T)\). Therefore, we were confident that we could tension our capstan cables to avoid slippage in response to the ~3.5 N-m maximum loads of our system.

\[
F_{\text{Applied}} = \frac{1}{2} T (e^{\mu_{\text{Cable}} \theta} - 1) D_{\text{Capstan}} = 368[T] \cdot T[N] \tag{15}
\]

**FABRICATION AND ASSEMBLY**

Components were fabricated in a standard machine shop. A CNC mill, manual lathe, and laser cutter were used, in addition to standard hand tools. Sliding fits were used in all locations on this device, as this was simpler than ball bearings for the prototype design. Polyoxymethylene plastic (Delrin) and
bearing grade bronze alloys (936, 841, and 863) were used to achieve low friction sliding fits for rotating joints. Other components in this device were fabricated from aluminum (6061-T6) due to workability, cost, and ease of obtaining this material in different forms.

**TESTING**

A fixture was developed for testing the device in a simulated environment. A synthetic uterus with attached round ligaments and material properties similar to a human uterus was purchased from SynDaver Labs for testing. This uterus was mounted hanging in a box so it could be manipulated. The manipulator was inserted and actuated to the extreme anterior, posterior, and lateral positions. Force was applied until further deflections would cause breaking of the synthetic ligaments. Figure 13 shows the deflections achieved by the device. It should be noted that the device outside the body can obtain ~85° of motion in each direction. Smaller deflections were achieved during testing only due to constraints of motion of the synthetic uterus (mainly limitations due to the ligaments), similar to behavior in the body.

![Figure 13. A (Left) - Anterior testing of the uterine manipulator using a synthetic uterus. B (Right) - Lateral testing of the uterine manipulator](image1)

Testing was also performed to determine the effectiveness of the clamping system. A spring scale was attached to the tip, and the force was recorded when the handle began to rotate. This showed that the clamps provide about 2 N-m of locking, which is under the desired 3.5 N-m. A positive locking system is anticipated for the second iteration of this prototype.

**REFINEMENT**

Initial tests of the clamping system revealed that an all-aluminum clamp (Figure 14A) was too stiff, requiring excessive gripping force to work effectively. A new clamp was created with a spring steel hinge (Figure 14B), reducing the force required to close the clamp. This new clamp was superior to the original, transferring nearly all of the grip force directly to clamping. Nevertheless, as explained in the previous section, these clamps failed to provide the necessary 3.5 N-m of clamping (only provided 2 N-m). Therefore, we will need to revise these clamps as discussed in the subsequent section.

Tests of the capstans used in the manipulator rotation system revealed that rotational motion was quite difficult initially. The first iteration of the capstans had as many as 4.5 wraps of wire, which caused binding. The system was disassembled and the number of wraps was reduced to 2.5 as stated in the Analysis section, significantly lowering the friction. However, our team noticed minor slipping in these capstans at loads far below those calculated in the analysis section. This slippage was probably due to a lower-than-expected coefficient of friction between the cable and capstans and will be discussed in the subsequent section. In order to remedy this slippage, one of the rotation capstans was knurled, but our team noticed no significant impact as a result of this change.

![Figure 14. A (Left) - First iteration of the clamp B (Right) - Revised clamp design (right)](image2)

**FUTURE WORK**

Through testing of our prototype device, we realized a number of potential improvements that would be necessary to bring our concept to the next stage of development:

*Wire Crimps*

Wires in this device were secured (to create loops of wire and fix the cables to the positive-drive pulleys in the tip actuation system) with crimp-on fittings. Future work includes revising the attachment methods for these wires, as the crimps are fairly large and have sharp corners. These crimps could possibly be replaced with welds.

*Balloon and Sleeve*

Use of a balloon or other sealing means is desired near the tip of this device. This would maintain pneumoperitoneum in the abdominal cavity during hysterectomy, and prevent unwanted manipulator rotation or motion with respect to the vagina wall. Currently, the tip assembly presents a risk for tissue pinching near the cervix. A balloon would add the benefit of pushing the vagina wall away from the tip assembly near the cervix,
preventing the risk of tissue pinching. A protective elastic sleeve would also help to eliminate this risk.

Hysterectomy Cups and Dye Tubes
This first prototype was not designed specifically to work with hysterectomy cups, which are used to define the cut path during hysterectomy. In addition, we did not design our device for compatibility with tubes for inserting dyes during exploratory operations. However, nothing in our design precludes the use of either hysterectomy cups or dye tubes. The second iteration of this design will include compatibility with these accessories.

Flexible Tip
An aluminum and 3D printed tip were made for this prototype. A flexible tip is more desirable due to the lower risk of uterine wall perforation during surgery. Ideally, the device tip would be designed to plastically deform at loads near the perforation load. A flexible tip designed to this specification is envisioned for the second prototype.

Improved handle
Current devices typically have a small handle which is near the patient’s vagina during surgery. Our handle is significantly larger and the non-local controls allow the doctor to move the handle freely during surgery. Improvements in the handle (both in ergonomics and overall size) and the lever system which controls the device locking system are necessary for the next design iteration.

Revised Locking
The current concept uses a frictional locking system which employs shaft collars and a compression spring to initiate locking. As noted in previous sections, this device does not provide adequate force to lock the device. Although this was partially due to material limitations in our current design, a positive engagement locking system would be superior. Therefore, the next iteration of this design will include a more reliable clamping system which utilizes positive engagement.

Positive Drive for Rotation
Capstans were used for the manipulator rotation system in our device to allow for unlimited rotation (in contrast to the positive-drive system used in the tip actuation system). Testing revealed that the capstan system slips under much lower loads than expected, preventing the device from rotating as desired. A positive-drive rotation system is anticipated for the second prototype of this device due to their success in the current prototype tip actuation system.

Cable Transmission System
As described in the Analysis section, our steel cables can extend nearly 0.5% of their total length during normal operation of our device. Considering our non-local controls will require up to 2 meters of cable in the operating room, a 1 cm extension of cables could result in unfavorable movement of the uterus during manipulation. Therefore, in future iterations we will consider a fiber or cable with higher stiffness than our current steel cable.

Materials Selection
Materials in this device were selected primarily based on ease of use, both in terms of machinability and acquisition. Biocompatible materials are necessary for further refinement of the device.

CONCLUSION
The uterine manipulator designed and tested by the authors was successful in achieving two novel functional requirements: obtaining lateral motion and allowing for non-local control. With these two essential improvements, we have developed a uterine manipulator with increased functionality and enhanced physician control. Moving forward, the device will be designed and tested with hysterectomy cups, dye tubes, soft tip attachments, and biocompatible materials in order to fully verify the usability of the device. A device with these features, along with the achieved lateral motion and non-local control presented in this paper, is a new design able to meet novel requirements desired by physicians.

ACKNOWLEDGMENTS
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REFERENCES


**APPENDIX A**

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<th>Table 1. Detailed design dimensions referenced in Figures 2-4 (all units are cm)</th>
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