

A NOVEL UTERINE MANIPULATOR INCORPORATING NON-LOCAL
CONTROLS AND LATERAL MOTION

by

Wan-Ni Tsai

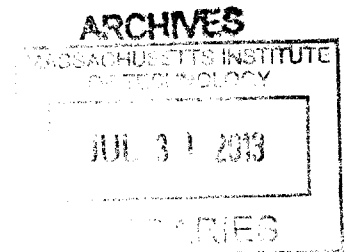
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by

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ABSTRACT

The work described in the paper was driven by a clinical need for a better uterine manipulator during laparoscopic gynecological procedures, including both hysterectomy and hysteroscopy. The primary purpose of the uterine manipulator is to provide a convenient means for the operators to position the patient's uterus from outside the body. Currently available manipulators are not adequate in two respects. First, no device allows for lateral as well as vertical manipulation. The lack of lateral motion often limits the surgeon during operations. 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 improved the features from the last prototype; addresses two essential 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. Besides these two essential improvements, the surgeons are able to adjust the in and out motion of the manipulator from the foot pedal. With the improved end effector, it incorporates industry standard tips, cups and balloons. We have developed a uterine manipulator with increased functionality and enhanced physician control, which ultimately ensures patient safety and high quality of care.

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I. 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 six key device deficiencies. First, no current devices allow for lateral (combined with vertical) manipulation. Second, the length and control mechanism of many devices do not allow the user to remain in an upright position at the abdomen of the patient, as is typical during laparoscopic procedures. Third, the geometry and attachments of current manipulators are not always suited for all body types, especially patients with higher body mass indices. Fourth, manipulator handles are often too small and non-ergonomic. Fifth, current manipulators are often not adaptable to be used for both hysterectomy and diagnostic procedures. Sixth, foot pedal control for in and out motion to improve better visualization. These considerations, along with the aforementioned metrics for an ideal manipulator, were used as the basis for the uterine manipulator design presented here.

In the fall of 2012, an initial prototype was developed which provided two degree of freedom motion but had several major drawbacks. This paper addresses the improvements that were made to this device with the

inclusion of a third degree of freedom (in-out motion) as well as major improvements to the handle and manipulator.

1.1 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.

1.1.1 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) 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.



Figure 1 A (Top) - ConMed Endosurgery V-Care
B (Bottom) - Cooper Surgical RUMI

The UPS (Figure 2) and Kronner Sidekick are designed to mount, position, and secure the manipulator in place during laparoscopic surgery. Both use a foot pedal to release the manipulator for repositioning [8]. Although both may serve as a solution to assistant fatigue, neither the UPS nor the Kronner completely removes the need for an assistant, as neither can be controlled from the surgeon's position. In addition, the physicians we interviewed had no prior knowledge of these devices, suggesting they are not commonly found in practice.



Figure 2. Cooper Surgical Uterine Positioning System

1.1.2 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.

1.2 FUNCTIONAL REQUIREMENTS

Our uterine manipulator should:

1. Ensure patient safety at all times
2. Allow the surgeon to stand in normal upright working position at the abdomen of the patient
3. Be sized for the vast majority of patient body size
4. Provide at least 90° anterior, 40° posterior motion
5. Provide 45° total lateral motion
6. Allow the surgeon control at surgical table height with 3” of in and out motion
7. Provide total length greater than 13”
8. Allow for injection of dyes into the uterus via disposable tubes
9. Allow for the attachment of multiple cup sizes
10. Incorporate ergonomic handle

11. Include a passive locking system in both the foot pedal and non-local controls to prevent unintentional uterine movement
12. Be cost competitive

1.3 CONCEPT AND STRATEGY SELECTION

Last semester, the strategy of an internally-actuated mechanical system was selected. 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 *tip actuation system* involves the transmission that allows for anteversion 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 *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. The tip actuation system and manipulator rotation system makes use of positive-drive pulleys. 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.

II. DESIGN OVERVIEW

Our uterine manipulator design consists of six main modules: (1) end effector, (2) local control (3) mount, (4) non-local controls, (5) in-out motion, and (6) foot pedal, pictured in Figure 3. Each of the modules will be discussed in detail following the 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 the means of a sleeve bearing surrounding the body of the manipulator allowing for rotation of the tip (manipulator rotation system) up to 360° in either direction. These two mechanisms allow for both vertical and lateral manipulation at the tip. Standard, commercially available tips and cups can attach to the end effector assembly. 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 turnbuckle is incorporated into the non-local controls in order to prevent any slack in this transmission. A separate positive drive pulley at the control terminal is used to transmit rotation between the non-local controls and the manipulator for the manipulator rotation system. From the local controls, 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, the two positive-drive pulleys are simultaneously manipulated by a handle to affect both degrees of freedom.

The local controls also interface with the in-and-out mechanism. The outer ring of the control terminal is fixed to a linear bearing, which in turn is connected to the foot-pedal. Pulleys translate the forward and backwards movement of the foot pedal on a fulcrum into three inches of translational movement of the manipulator into and out of the body through the use of cables routed through conduits and tensioners.

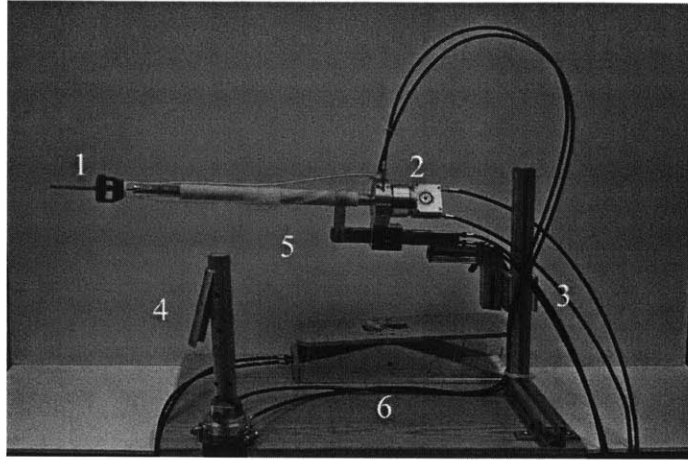


Figure 3. Six Modules: (1) End Effector, (2) Control Terminal, (3) Mount, (4) Non-Local Control, (5) In-Out Motion and (6) Foot Pedal

2.1 End Effector

The end effector, depicted in Figure 4, consists of an outer sleeve, inner tube, and tip pulley. The tip pulley allows for the control of the tip actuation system allowing for the first degree of freedom of the manipulator. The pulley is controlled by two cables that wrap around the either side of the pulley and are secured in place, thereby creating a positive drive system. One of the functional requirements for this prototype was to entirely seal the end effector assembly to prevent pinch points and access to the control wires. This was accomplished by moving the control wires off axis from the center of the pulley where the tip is inserted. A cable runs up one side of the pulley, loops around a tightened bolt, and runs down the other side of the pulley, eliminating the need for wire crimps in the tip assembly. These cables are routed from the control terminal to provide vertical motion of the tip. It is possible to obtain 170 degrees of motion with this system, more than specified by our functional requirements. Furthermore, the positive drive system works to prevent slipping allowing for smoother overall operations. Lastly, the tip pulley is designed to interface directly with standard manipulator tips and cervical cups often used in diagnostic and surgical procedures.

The second degree of freedom, the manipulator rotation system, is accomplished through the interaction between the inner tube, outer sleeve, and local controls. The outer sleeve, composed of Delrin, is frictionally

fixed to the wall of the vagina during surgical procedures via an attached medical balloon. The inner tube is free to rotate within the outer sleeve allowing for the rotation of the end effector via rotation of the local controls providing the desired and novel lateral motion. Furthermore, the outer sleeve acts as a bearing between the vaginal wall and the manipulator preventing harmful distortion of the vagina.

This prototype significantly improves on the prototype presented in fall of 2012. The wires are entirely contained and are not exposed, significantly reducing pinch points and minimizing risk to the patient. The diameter of the manipulator has been reduced to 0.75 inches for the outer sleeve, which is comparable to other devices on the market. This also allows for use of commercially available balloons. The tip pulley has also been redesigned to allow for use of commercially available tips and cups; a simple press fit allows for use of a variety of tip sizes.

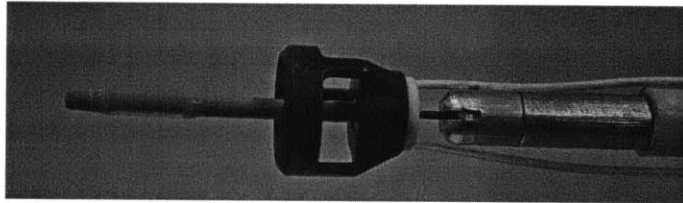


Figure 4. End Effector Module

2.2 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 positive drive pulley 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 170° of motion with this technique. The double pulley provides a 1:4 transmission ratio between the non-local controls and the tip, decreasing the force in the wires from the non-local controls.

The rotation pulley is rigidly attached to the inner tube and controls rotation of the manipulator. The cable is wrapped in a similar manner to achieve positive drive while still allowing for 360 degrees of motion in either direction. 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.

The control terminal has been significantly redesigned. All of the wires are now contained internally and none of the pulleys are exposed. This is beneficial since there is no longer access to the wires or the internals of the device. The added turnbuckle addresses a major issue we encountered with tensioning for the wires running to the tip. The entire module is significantly smaller and is a much cleaner, more manufacturable design.

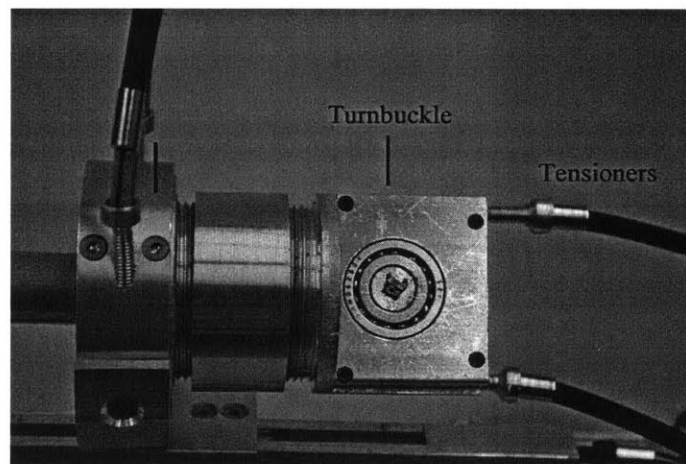


Figure 5. Control Terminal Module

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 5, 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.

One issue that was also resolved with this prototype was tensioning of the wires between the control terminal and the tip pulley. A turnbuckle was added to allow these wires to be tensioned after crimping. This effectively lengthens the entire device while preventing the wires from becoming tangles inside the inner tube.

2.3 Mount

The purpose of the mount, pictured in Figure 6 is to eliminate the need for an assistant to hold the uterine manipulator near the vagina of the patient during the procedure. The mount connects the in-out motion piece with two screws and is clamped to the operation table. By mounting to the table, it forms a smaller structural loop compared to holding by physicians, and it also becomes more stable in this configuration. The mount controls the initial positioning of the manipulator and provides two degrees of freedom: vertical motion and entry angle. The incorporated in-out system provides foot pedal controlled in and out motion of the device. These two degrees of freedom can be easily adjusted at any time during the procedure.

The next version of the mount which has been partially designed, but not built for this prototype will consist of a bedside clamp and three degree of freedom joints which will allow for easy positioning adjustment in a manner similar to other equipment often found in an operating room. It will consist of a quick release for the in-out module which will allow it to be easily attached to the mount, and quickly released and removed in the case

of an emergency. The doctor will position the manipulator in the patient and bring the mount up to the device. It will then simply click in place to the in-out module and the mount will be fixed in position.

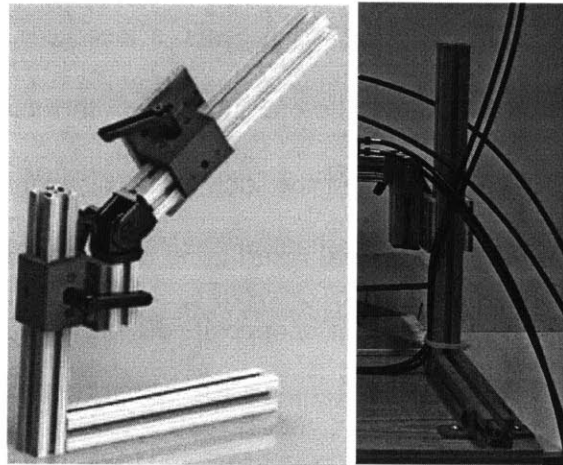


Figure 6. Mount Module

2.4 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 pulley which controls the manipulator rotation system through rotation about the z-axis (see Figure 7). 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 locking gears with a custom profile. 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 7). 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. The gears which lock the device are a custom profile which allows for minimal separation forces. Using a 6 degree taper prevents the locking wedge from sliding out due to separation force. When the handle is released, this wedge meshes with the teeth of this 6 degree taper gear and prevents relative motion, locking the handle.

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 an internal spring internal linkages. When the handle is released, this spring pushes down the locking mechanism, which engages with the custom gears. This fixes the two bevel gears to the handle and locks the uterine manipulator in place. The operator must grip this handle to compress the spring, disengage the lock, and gain control over the device.

The new handle for this device is not significantly improved from last semester. Much smaller bevel gears have been used for the locking. Internal actuation for the locks has been added, meaning there are no external cables for actuating the locks as were found on the previous prototype. Positive engagement locks in the form of custom gears with very low separation forces have been added which when manufactured with a better method will allow for significantly improved locking. A cover can now be easily added to hide all of the internal components of the handle since it is significantly smaller.

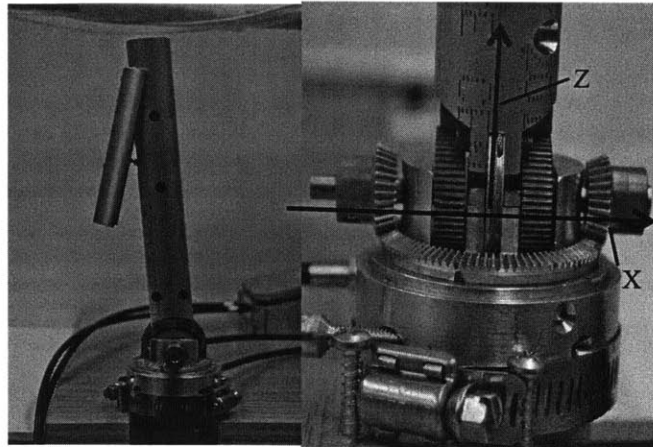


Figure 7. Non-Local Control Module

2.5 In-Out Motion

The in-out motion system, pictured in Figure 9, is attached to the mount for controlling three inches of end effector travel. It consists of a pulley, linear bearing, sleeve support and the manipulator support. The cable goes into the top tensioner on the in-out module, connects to the sliding segment where the manipulator is mounted. It wraps around a pulley at the front of the device and travels out the bottom tensioner and to the foot petal. This front pulley design allows for in and out motion through pulling of wires. See Figure 8 for clarity.

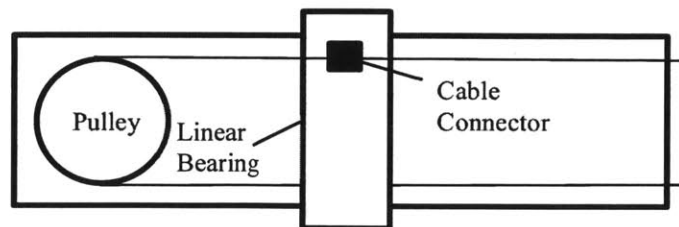


Figure 8: Sliding Mechanism Layout

The manipulator is attached to a linear bearing which moves it in and out. It has internal Delrin pieces which allow for low friction sliding. The wire is connected to this bearing and causes motion when it is actuated.

A sleeve holder (shown in Figure 9) was designed which prevents rotation of the manipulator sleeve but allows for in-out motion and rotation of the inner tube.

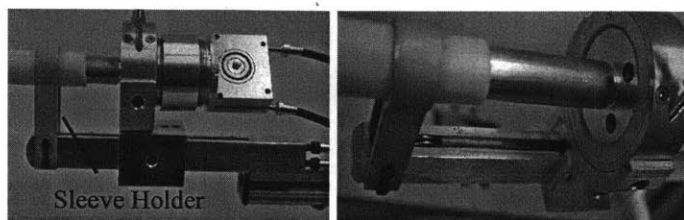


Figure 9. In-Out Module

2.6 Foot Pedal

The foot pedal, pictured in Figure 10, is connected to the in-out motion piece and placed on the floor; its purpose is to allow the surgeon to control in and out motion. When the foot pedal is tilted forward, the end effector extends into the patient; when the foot pedal is tilted backward, the end effector retracts back. Stepping on the front of the foot pedal creates tension in the rear wire. This wire is passed through the bottom tensioner of the in-out module, resulting in forward motion.

The foot pedal consists of a passive locking system. The passive locking system prevents in-out motion of the device during the procedure. The locking flap includes two pairs of ratchets and pawls, and two torsion springs. Two opposing ratchets prevent motion of the in-out system in either direction. The torsion springs cause the system to lock when the pedal is not stepped on. Stepping on the pedal disengages the ratchets and allows motion of the foot pedal.

Conduits and tensioners are employed in the same manner as in the manipulator and handle and run between the foot pedal and in-out motion system.

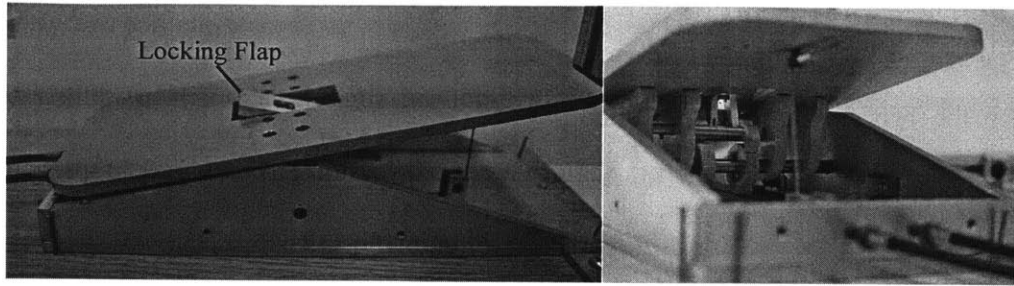


Figure 10. Foot Pedal Module

III. 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 11. 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_{Uterus} is the length of the uterus (8 cm), and L_0 is the free length of the broad and round ligaments (6 cm):

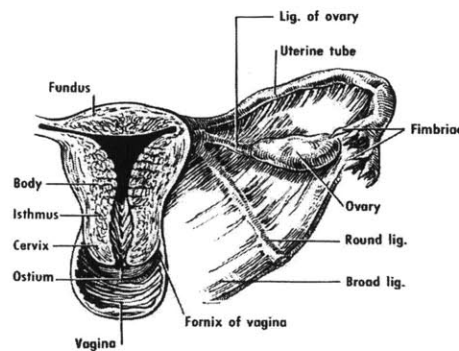


Figure 11. Uterine anatomy [13]

From Figure 11 and these mechanical properties, our team formed the analytical model of the system shown in Figure 12, in which the broad and round ligaments are estimated by a continuous sheet spring between the uterus and the pelvis wall.

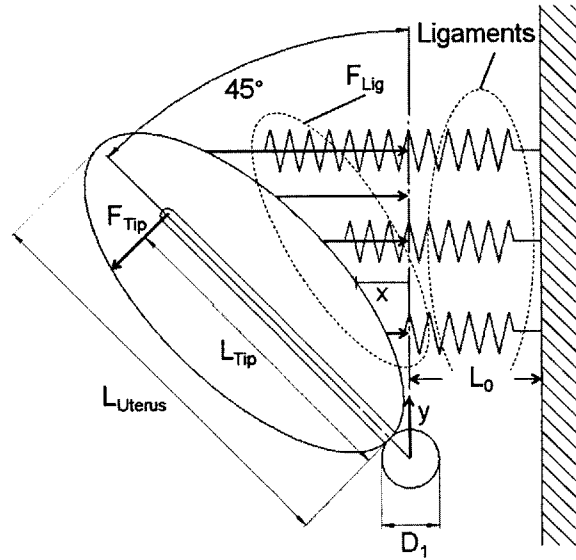


Figure 12. Mathematical model of uterine manipulation

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):

$$\sigma_{lig} = E \varepsilon_{lig} \quad (1)$$

$$F_{lig} = \frac{AE}{L_0} x \quad (2)$$

$$\frac{dF_{lig}}{dA} = \frac{E}{L_0} x \quad (3)$$

$$\text{At } 45^\circ, x \approx y \quad (4)$$

$$dA = t dy \quad (5)$$

$$F_{tip} = F_{lig} = \int_0^{\left(\frac{\sqrt{2}}{2}L_{Uterus}\right)} \frac{Et}{L_0} y dy = \frac{EtL_{Uterus}^2}{4L_0} \quad (6)$$

Using (6) and the mechanical properties of myometrium, our team calculated a 40 N maximum resistance force (F_{lig}) from the broad and round ligaments. The weight of a healthy uterus is ~ 1 N and is insignificant when compared to the resistance forces of the ligaments. However, a diseased uterus can increase in weight up to ~ 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 ~ 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.

Shafts in the device were sized and material selected based on the requirements for strength in each component. The most critical component was the main shaft for the foot pedal, which must resist the weight of the surgeon at a maximum. A simply supported beam analysis was performed, and a 0.25 inch diameter hardened steel shaft was selected for this application. All other shafts were well above their threshold for strength, so sizing was not critical.

Forces transferred in the device were similar to the previous prototype, thus the analysis has not been repeated here [17]. The only significant changes were the use of a commercially available tip which is assumed to be strong enough and the use of ratchets instead of shaft clamps for the locking.

Ratchets and locking gears were made from hardened steel and are all 1 inch in diameter.

$$F_b(N) = \frac{\sigma_b * b * e^2}{6h * S_f} \quad (7)$$

$$\Gamma = F_b * r_f \quad (8)$$

Where σ_b = bending stress

b = face width E (mm)

h = depth of teeth (mm)

$$e = \text{root length} = (\text{depth of teeth}) * \tan\left(\frac{60n - 360}{n}\right)$$

n = number of teeth

S_f = safety factor of 2

$$r_f = \text{tooth root radius (m)} = \frac{(\text{outside diameter}) - 2h}{2000}$$

48 tooth ratchets which are ¼ inch thick and have 2mm of pawl travel are sufficient to hold 150N at 1 inch.

IV. FABRICATION AND ASSEMBLY

Components were fabricated in a standard machine shop. A CNC mill, manual lathe, and a waterjet cutter were used, in addition to standard hand tools. Polyoxymethylene plastic (Delrin) and Teflon filled Delrin was used to achieve low friction sliding fits for rotating and sliding joints. Other components in the device were fabricated from aluminum (6061-T651) and 304 stainless steel due to workability, cost, and ease of obtaining the material in different forms.

V. 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.

Improved Rotation Pulleys

Many of the rotation components in the manipulator have small errors which significantly increase friction in the device. This was due to 2 or 3 thousandths of an inch of circular interpolation error on the mill used to make many of these components. Since there are two rotating parts sliding on a ring we also made on the mill, these errors can stackup and increase friction in certain spots during rotation of the handle.

Revised Locking

The locking components in the handle and foot pedal were made on a waterjet which has taper and quite a large kerf, or width which is cut by the water stream. This process significantly distorted the geometry of the gears which we made, creating issues with the locking and decreasing its effectiveness. Making these components on a wire edm or through another method would improve the functioning of the locking 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.

Larger External Handle Rings

Larger rings are needed for the handle and manipulator. The tensioners are threaded in at the extremes of this part, and due to the angle, there is little material that the threads can engage. Thickening these parts will allow for better tensioner engagement and increase the amount these tensioners can be extended to take slack out of the system.

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.

Additional Testing

Due to limited time this semester and some aspects of the device that need to be tweaked, testing of this device in a synthetic uterus or cadaver was not feasible. Additional testing is needed to determine the functionality of the locking and the forces it can withstand. Additional testing under load is desired to experimentally how much the wires stretch and how well the device functions in the body, a different set of parameters than when moving in free space.

VI. CONCLUSION

The latest version of the uterine manipulator designed and tested by the authors was successful in improving functions from the previous version. An ergonomic handle with improved locking has been added, as well as in-out motion controlled by a foot pedal. The new end effector allows injection of dyes into the uterus via disposable tubes and attachment of multiple cup sizes. Moving forward, the device will be tested again in a simulated environment to ensure the effectiveness of ratchet systems. Biocompatible materials will be used in the device and a standard sterilization process will be performed. A device with these features, along with lateral motion, non-local control and in-out motion presented in this paper, is a new design able to meet novel requirements desired by physicians.

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