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DESIGN AND ANALYSIS OF A 2-DOF UTERUS MANIPULATOR FOR USE DURING TOTAL LAPAROSCOPIC HYSTERECTOMY

Nicolette Fournelis
Department of Mechanical and Aerospace Engineering,
University of Central Florida
Orlando, FL

Sang-Eun Song
Department of Mechanical and Aerospace Engineering,
University of Central Florida
Orlando, FL

ABSTRACT

Uterus manipulators are one of the most useful tools utilized while performing Total Laparoscopic Hysterectomy (TLH). While highly convenient, there are many issues that are presented when using this surgical tool. Slipping, mobility, and the overwhelming varieties of manipulators all create a stressful environment for a surgeon performing this delicate procedure. This suggests that there is room for the development of a robust, multi-functional uterus manipulator that can minimize these issues, and thus create a safer and more effective surgical procedure in the operating room. As a proof-of-concept development, a 3-D Computer-Aided Design (CAD) model was produced and then simulated such that it could be tested for determining key parameters of deformation, degrees of freedom, and range of motion. From Finite Element Analysis (FEA), it was found that the suggested design can reduce slippage, has comparable range of motion to that of uterus manipulators on the market, and has increased flexion within the vaginal canal. These results encourage further development and testing to enhance the safety and efficacy of this new design.

Keywords: Uterus manipulator, laparoscopic hysterectomy, surgical instrument, CAD, FEA.

NOMENCLATURE

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TLH	Total Laparoscopic Hysterectomy
CAD	Computer Aided Design
FEA	Finite Element Analysis
DOF	Degrees of Freedom
FOS	Factor of Safety
Disp.	Displacement

1. INTRODUCTION

The laparoscopic hysterectomy is a minimally invasive surgical technique that was developed in the late 1980s, and later successfully performed in 1993, has since grown to be a largely accepted method of conducting hysterectomies due to its quick recovery rate and patient pain reduction [1]. This integration allowed for surgeons to pursue the design and development of tools to increase the safety and speed of which the hysterectomy is performed.

Of these tools, the most utilized during Total Laparoscopic Hysterectomy (TLH) is the uterus manipulator. The uterus manipulator enables the user to maneuver the uterus such that the surgeon performing the TLH can have a better field of vision, minimizing potential trauma to the uterus and surrounding areas. There are several iterations of uterus manipulators on the market that can be selected due to their catering of the specific procedure, as shown in Figure 1.

FIGURE 1: A small variety of current uterus manipulators on the market [2].

While this tool is successful in controlling the movement of the uterus, there is significant concern for overall safety of this mechanism. It was reported that there is no clinical evidence proving the efficacy of uterus manipulators with respect to the prevention of complications inherent to laparoscopic surgery [3]. Additionally, it is found that an assistant, usually a nurse or other surgical assistant, is assigned to equip the uterus manipulator and guide the uterus according to surgeon instruction. This positioning can be visualized in Figure 2.

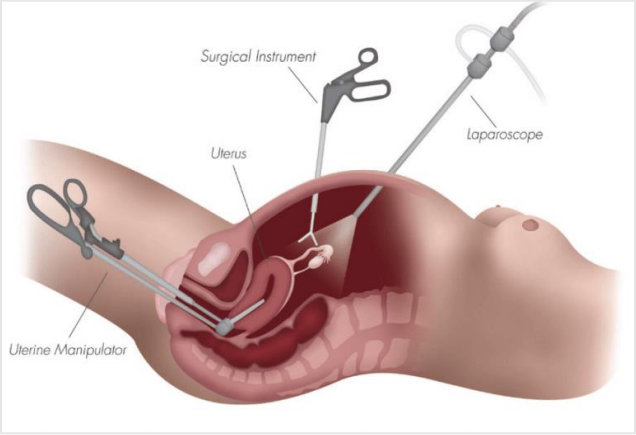

FIGURE 2: Illustration of the setup in the patient during total laparoscopic hysterectomy [4].

During the duration of the surgery, which typically lasts between 1-3 hours, the assistant must brace the manipulator by hand, causing fatigue and slipping of the mechanism [5]. This is both inefficient and unsafe for both patient and surgical staff, and there has not been much headway in the creation of a better manual uterus manipulator. Thus, it would be important to design and implement a new uterus manipulator that increases overall safety while maintaining efficacy for both the patient and surgical staff.

2. MATERIALS AND METHODS

2.1 Design of Model

The model was designed to provide the following features:

- Two degrees of freedom for uterus manipulation in two common directions, coronal (along the x-axis), and anteroposterior (along the z-axis).
- Wide range of motion in the coronal and anteroposterior directions while inside the uterus
- Flexibility and durability of the body whilst inside the vaginal canal, and
- Unique body shape to reduce slipping.

These parameters then helped to define the final model consisting of a smaller intrauterine ball-jointed arm, a cap for cervical attachment, a specialized curved body, and a ball-jointed handle to maneuver the manipulator within the uterus, which can be seen in Figure 3.

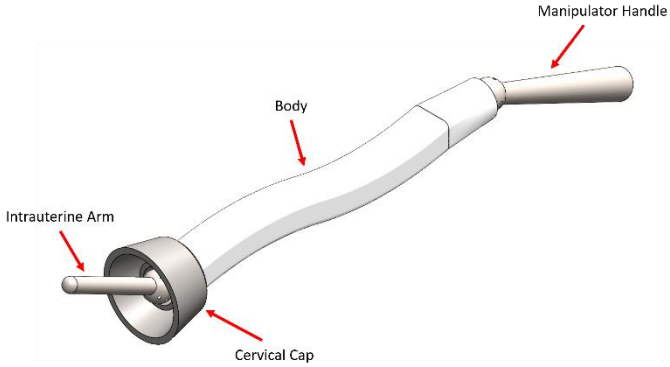

FIGURE 3: CAD model of the proposed uterus manipulator design.

2.2 Intuitive Mechanism

The interior mechanism of the manipulator consists of wire connecting the ball joint of the intrauterine arm and the ball joint of the handle. These joints have curved holes measuring 1 mm in diameter, shown in Figure 4, and allow for the two to parallel the others' motion from a distance. That is, while the handle is pushed downward, the intrauterine arm is moved upward, and the same for downward, left, and right motions. While rudimentary, this provides 2 degrees of freedom for the arm, and a range of motion of 58 degrees from the center in 4 directions.

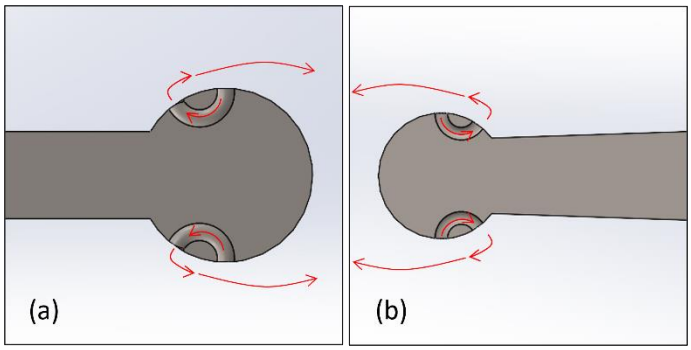

FIGURE 4: Cross-sectional view of the ball joint hole curvature in the intrauterine arm (a), and handle (b).

2.3 Design Specifications

In order to specify the required dimensions for the model design, a literature search was conducted to justify appropriate lengths and widths for the uterus manipulator. According to [6], dilation of the cervix is achieved when the cervix dilates to 10 cm. Additionally, [7] states that the length of the cervix is averaged to be 25mm and the uterus length to be 30mm. This information allowed for a diameter of 5mm and a length of 50mm to be selected for the intrauterine arm. The cervical attachment cap has a diameter of 25mm to accommodate for the outer cervical diameter and create a snug fit to prevent external air from creating pressure within the uterus.

The body of the manipulator was designed with curvature such that slipping would be reduced during surgery. This curvature was implemented throughout the length of the body, and a rounded rectangular shape was utilized as the profile, i.e., cross-sectional shape, instead of a cylindrical shape. This unique body design also abided by internal constraints, such as vaginal canal diameter and length. In a study conducted by [8], baseline information collected from five clinical trials using magnetic resonance imaging (MRI) was combined to quantify distribution of a vaginal gel. Seventy-seven MRI scans were performed on 28 women before gel application to establish baseline vaginal measurements. It was found that mean vaginal length from cervix to introitus was 62.7 mm. Vaginal width was largest in the proximal vagina (32.5 mm), decreased as it passed through the pelvic diaphragm (27.8 mm) and was smallest at the introitus (26.2 mm). These measurement restrictions were then applied to the design of the body, resulting in a length of 100mm, a width of 9.75mm, and a height of 7mm. When taking the curvature into account the maximum height of the body became 13mm.

For the manipulating handle, an ergonomic grip was created that increased the size of the shaft gradually to fit more comfortably within the user's hand. Additionally, another ball joint was implemented to intuitively translate the motion from handle to the intrauterine arm.

2.4 Material Selection

The following materials were selected for the proposed design as they compare to the materials that are used in current uterine manipulators, suggesting these materials are safe for use in patients [2].

2.4.1 Body

There are various medical grade materials that can withstand constant usage and still provide a safe and sterile environment for the patient. However, due to the simulation software limitations, it was decided that cross-linked polyethylene (XLPE) would be the best candidate to test for flexion. Cross-linked polyethylene is a versatile, durable thermoplastic that has a high impact resistance and is resistant to chemicals. Furthermore, its low moisture absorption makes it a choice medical grade plastic. It does not fade nor retain dangerous bacteria, can withstand harsh cleaning agents, and it is a porous synthetic polymer that is biologically inert and does not degrade in the body [9].

2.4.2 Cervical Cap

The cervical cap material was chosen with malleability as a priority. It needed to be flexible to be comfortable for the patient and provide a seal for sterility. That in mind, it was determined that the cup be made of a stiff silicone rubber to keep its shape while in the vaginal canal. This unique material is favored across industries because it is skin-contact safe, durable, soft, and flexible [10].

2.4.3 Intrauterine Arm and Handle

Material specifications for the intrauterine arm were difficult to facilitate due to its purpose within the uterus. There are several reasons a patient would be receiving TLH, and one of the biggest reasons is excessive menstrual bleeding and pain. Additionally, uterus fibroids are also large cause for women to undergo TLH. Fibroids are benign (noncancerous) tumors that grow in the muscle of the uterus and can cause pain, bleeding, and other intrauterine problems [11]. Knowing this, a careful selection needed to be made in order to provide a safe surgical tool that would not accidentally perforate on of these tumors or the uterus. Thus, it was decided that a medical-grade stainless steel (UNS S43000), that was carefully rounded for ease of insertion at the tip, would provide overall comfort for the patient while keeping original function. This material was also selected for the manipulator handle for consistency.

2.5 Simulation Methods

After development, in order to verify the performance of the proposed model, the final uterus manipulator model was translated into a 3D CAD model using SolidWorks (Dassault Systèmes SolidWorks Corp., MA) finite element analysis (FEA) analysis. The material data for the previously discussed material specifications was used as seen in Table 1.

TABLE 1: Material properties of the materials used in the uterus manipulator design [12].

Material	Polyethylene	Silicone Rubber	Stainless Steel
Young's Modulus (GPa)	600	0.05	205
Tensile Strength (MPa)	18	5.5	600
Compressive Strength (MPa)	14	30	370
Poisson's Ratio	0.33	0.49	0.285
Shear Modulus (GPa)		0.02	81
Elastic Limit (MPa)	23	5.5	370

This data was used to calculate the stress, strain, and total displacement when forces were applied to the body, intra uterine arm, and handle, which would be receiving the most amount of contact forces and pressures during TLH.

A combination triangular and square mesh was then generated to adhere to the large amounts of curvature along the entire uterine manipulator. This type of mesh has small inaccuracies; however, it was ultimately selected due to its overall flexibility and production of closer results to real world experiments.

2.6 Anticipated Contact Forces

After selection and application of materials, a literature search was conducted in order to find appropriate values of

contact forces to apply to the manipulator. It was determined from [13] that 3.20 N of force should be applied to the body to exhibit vaginal wall contraction. Additionally, an intravaginal pressure of 26.8 kPa was applied, as it was found that the vaginal canal can apply this pressure at rest, or under anesthesia during TLH. These parameters were applied concentrically around the arm, similar to how the vaginal canal would be surrounding the arm during surgery.

According to [14], it was found that on average it is about 1.5 to 6.5 N worth of force to insert an intrauterine device depending on type in nulliparous and low parity women. Knowing this, the maximum amount of force was applied to the tip of the intrauterine arm. For the arm to penetrate through the cervical canal, it would need to overcome these forces without causing damage to the cervix, thus creating the need to test how this force would affect the manipulator. In this case, the force was applied to the tip of the arm, normal to the cervix entrance, to simulate breach of the external opening to the uterus.

When considering the forces applied to the handle, it was found that in a study done in [15], where 566 male and female patients, aged 20-94 years were recruited to establish reference values of grip force and pinch grip in 10-year age-spans of an adult population, the average maximum grip force measured between both males and females was 313.8 N. While this amount of grip strength is not necessarily what would be used while performing TLH, it is important to test maximum values to have a range for deformation. The forces here were applied in the same fashion as the arm, as they compress the handle while the manipulator is being used.

3. RESULTS AND DISCUSSION

To verify the design of the model, three experiments were conducted. Each experiment was an application of force on individual sections of the uterus manipulator: the intra uterine arm, the body, and the handle of the mechanism. The selected outputs for these experiments were: stress, strain, and displacement measurements. These were chosen in order to create a baseline for overall design durability and flexibility, and to verify the design parameters stated earlier.

3.1 Stress

Figure 5 shows where the largest amount of von Mises stresses occurs on the intrauterine arm, body, and handle, respectively. Von Mises stress is a value used to determine if a given material will yield or fracture.

These results are valuable in that they allow for visualization of where failure can occur at different areas on the device, and thus allow for improvement such that the potential for failures decreases overall. Fortunately, the outputs were all roughly in the same blue to green margin, resulting in little deformation and very minimal, if any, extreme values for stress.

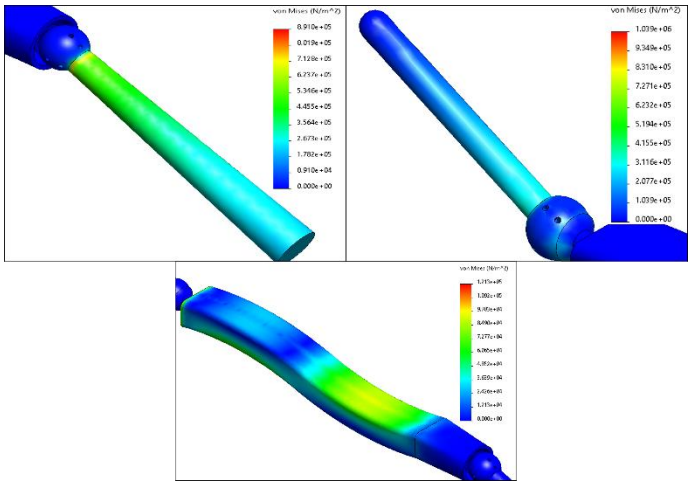

FIGURE 5: Stress analysis results of intrauterine arm, body, and handle (from top to bottom), showing where the most amount of deformation can occur at each tested part.

Additionally, the results for strain correlate to the output for stress as the occur in the same areas and the values for the minimum and maximum are shown in Table 2. Strain is a useful output because it enables the understanding of the total amount of stretching that can occur and allows for the detection of fragile points in the structure. Specifically, a point of fragility can be seen in the intrauterine arm near the ball joint, which could bend to failure with a large enough force applied. This implies that there is a possibility of the arm bending and failing during a cervical breach, which would cause internal complications. Bending points can also be seen at the body (indicated by the green color), where bending is able to occur at the valleys of the curvature; however, this indicates flexibility of the body and, in turn, a higher amount of comfortability for the patient due to is conformation of the shape of the vaginal canal.

3.2 Factor of Safety

Figure 6 displays where the minimum and maximum values for Factor of Safety (FOS) occur, which is a parameter that expresses how much stronger a system is than it needs to be for the intended load. Thus, the parts are still determined to be safe due to the minimum value for FOS being above the allowable limit of 1. However, the minimum values for each part are still very far from the allowable limit at 4.706e +02 for the intrauterine arm, 1.335e +02 for the body, and 1.934e +02 for the handle, indicating that, while these parts do not reach the highest FOS, they are still able to achieve their intended goal without deformation.

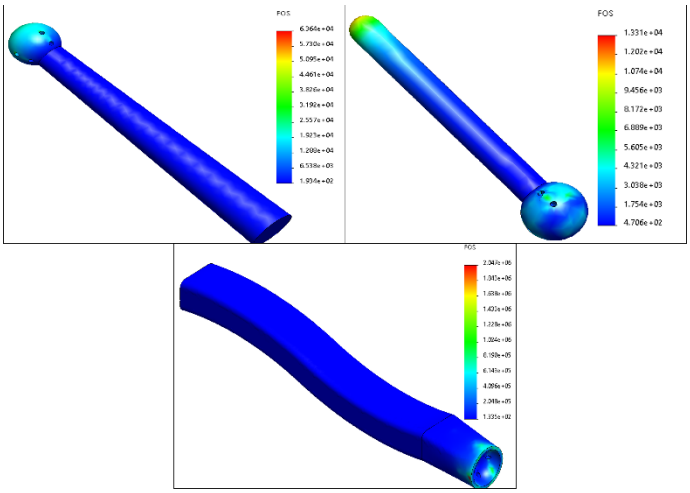

FIGURE 6: Factor of Safety analysis results of intrauterine arm, body, and handle (from top to bottom), showing where the most amount of deformation can occur at each tested part.

The minimum and maximum resultant values for stress, strain, displacement (disp), and Factor of Safety (FOS) can all be seen in Table 2, where the minimums and maximums correlate respectively to the blue and red colors in Figures 5 and 6.

TABLE 2: Minimum and maximum FEA result values for the intrauterine arm, body, and handle.

Property	Intrauterine Arm	Body	Handle
Min Stress (N/m^2)	0.000e +00	0.000e +00	0.000e +00
Max Stress (N/m^2)	1.039e +06	1.213e +05	8.910e +05
Min Strain	0.000e +00	0.000e +00	0.000e +00
Max Strain	1.428e +06	1.010e -04	3.346e +06
Min Disp. (mm)	1.000e -30	1.000e -30	1.000e -30
Max Disp. (mm)	6.059e +05	3.217e -02	8.778e -05
Min FOS	4.706e +02	1.335e +02	1.934e +02
Max FOS	1.331e +04	2.047e +06	6.364e +04

While the experiments were successful in displaying the resultant stresses, strains, and displacements of the selected parts, this is still a need for more in-depth testing of the proposed uterus manipulator to gauge if this new design is feasible and safe for the intended application. It would be beneficial to create a physical prototype of this device to fully visualize how the internal mechanism functions and how the proportions of the individual parts relate to one another. Additionally, it can be safely assumed that some of the measurements for the features can be increased to allow for more stability and a more ergonomic structure.

4. CONCLUSION

This work presents the design and FEA testing of a uterus manipulator that was created to incorporate 2 DOF in its range of motion, decrease slipping, and increase safety and efficacy in comparison to current models on the market. The results of the FEA tests found that there were small amounts of mechanical stress and strain resulting from the expected maximum value of applied forces. Additionally, the FOS for each part was above the allowable limit, indicating minimal displacement of each part.

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