A Novel MIS Left Lobe Liver Retractor

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Specific Aims

Minimally invasive surgery (MIS) based, upper GI procedures are often complicated by a need to retract the left lobe of the liver in order to provide an unobstructed view of the surgical area. Current methods primarily rely on the surgeon adding slings, hooks, or other apparatuses that are suspended from the surrounding tissue and loop under the left lobe of the liver to suspend it out of the way (see Figure 1). These options are effective for a majority of patients; however, they are insufficient for obese patients (who typically have enlarged, fatty livers) due to decreased intra-abdominal space and increased stress concentrations at the tissue-retractor interface (sometimes causing perforations in the tissue, as shown in Figure 2). We propose a novel device for retraction of the left liver lobe that can be used in MIS procedures for a variety of patients, including those with enlarged or fatty livers.

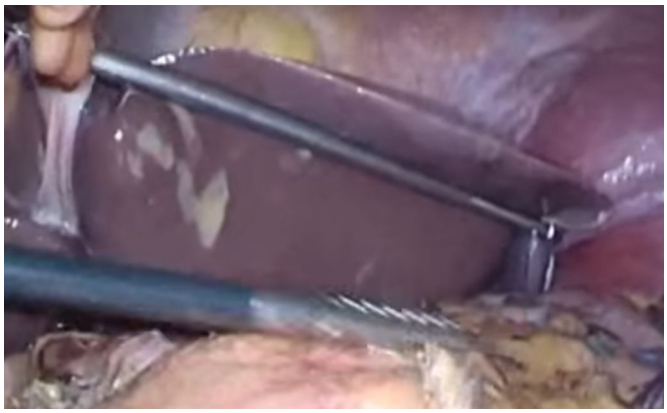


Figure 1: EndoLift Retractor being set during Left Liver Retraction

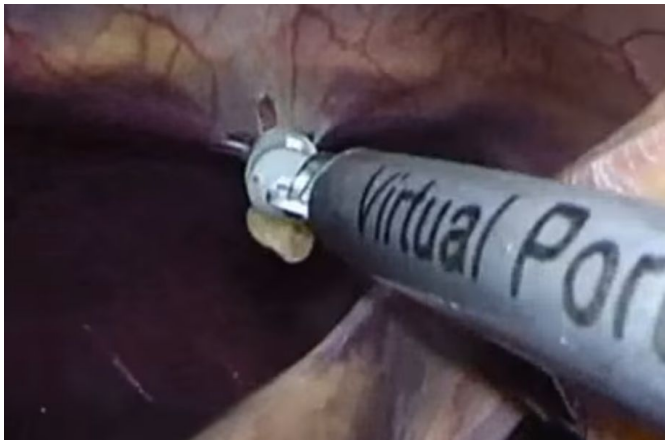


Figure 2: EndoLift Retractor Connection at Abdominal Wall

Specific Aim 1: Design a robust liver retraction device for obese patients that is capable of working within the framework of current MIS procedures.

Task 1.1: Design a bracing structure that distributes force across the peritoneum and supports the liver at least 10 cm above the hiatus.

Task 1.2: Adapt the device from Task 1.1 to ensure it is capable of fitting through a standard 10 mm MIS port.

Hypothesis 1.1: The device designed will allow for MIS insertion and setup of a pre-assembled bracing structure which can be completed by a trained surgeon in comparable or faster time than the current art of liver retraction technology.

Specific Aim 2: Integrate post-insertion control of the device so as to ensure the surgeon can optimize the shape of their desired work space.

Task 2.1: Implement remote actuation of the supporting legs of the device.

Hypothesis 2.1: The control of remote actuators integrated into the device, along with standard MIS based visual feedback, will allow surgeons to accurately adjust the dimensions of the surgical workspace and achieve a sufficient degree of hiatal exposure in the obese population.

Specific Aim 3: Develop a framework for predicting and preventing patient injury by calculating contact stress on the surrounding tissue using FEA.

Task 3.1: Generate a stress-strain model of the device proposed using Finite Element Analysis that can predict tissue damage during a MIS liver retraction procedure.

Hypothesis 3.1: The FEA model generated will accurately predict tissue strain to within accepted standards of ± 15% [1].

A. Significance

We propose a novel method of robotic minimally invasive surgery (RMIS) compatible liver retraction to address the needs of patients who are obese and have enlarged or fatty livers. In the United States, over 35.7% of adults are considered obese (BMI of over 30)[2], and up to 25% of the population has non-alcoholic fatty liver disease (NAFLD)[3]. One common procedure that requires liver retraction is laparoscopic fundoplication for relief of gastroesophageal reflux disorder (GERD) [4]. For this procedure, patient obesity and enlarged liver dimensions have been identified as the leading cause of conversion to an open procedure[5]. In this procedure, liver retraction is often the most technically demanding part of the operation and complications at this stage are linked to higher rates of morbidity[5]. The number of patients hospitalized for GERD increased from 995,402 in 1998 to 3,141,965 in 2005[6], and studies have consistently shown a positive correlation between BMI of a patient and severity of GERD symptoms[7]. Hence, our device has the potential to affect greater than 35.7% of this demographic, or 1,121,680 patients per year. Furthermore, this number is for the treatment of GERD alone, and given that this device is designed to work in any MIS liver retraction procedure, we predict that it can be used for a significant number of other procedures involving left lobe liver retraction where obese patients are currently excluded from using MIS.

There are currently several methods for surgical retraction of the liver. Some common techniques include the suspension tape technique [8], the Istanbul technique [9], Nathanson's liver retractor [10], and the Endograb[11]. These tools work by either adding an additional port to the body [10] or by securing the liver to the gallbladder and/or abdominal walls [8,9,11,12]. These techniques are generally effective for the average patient but remain severely limited in application to the obese population.

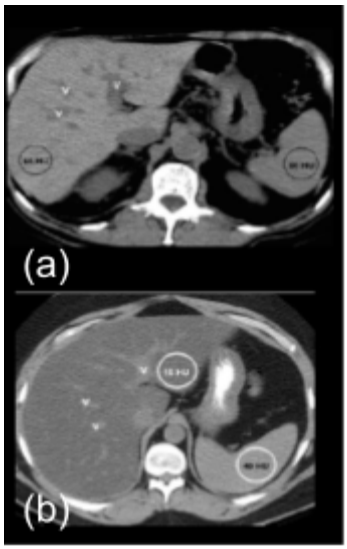


Figure 3: Enhanced CT Scan of Normal(a) and Fatty(b) Liver and Environment

There are two issues that arise for obese patients in left lobe liver retraction. First, a patient's liver size is correlated to their BMI, with obese patients having an average increase of 10.7% in liver diameter measured along the midclavicular line when compared to their normal weight counterparts [13]. This increased liver size causes more stress on the retractor and the locations it attaches to the cavity walls. These higher loads may result in a reduction of blood flow within the liver or permanent damage to surrounding tissue. Second, in many obese patients the space between the undersurface of the left lobe of the liver and the stomach can be reduced to a few centimeters or less. Figure 3 shows an enhanced CT Scan of the liver, and its surrounding environment. Figure 3b shows the lack of open space as compared to the healthy patient in Figure 3a. Hence, even if the retraction method is capable of supporting the liver weight, there may still remain significant challenges to hiatal dissection and intracorporeal suturing[5] due to the lack of necessary space in the abdominal chamber.

For these reasons, traditional retractors that attach to the abdominal walls, such as the Endograb, are only directed to be used on patients with a BMI less than 35 [11]. We plan to address these two challenges in obese patients, and create a robust liver retractor that can safely and adequately provide these patients with the opportunity to choose minimally invasive surgery instead of open surgery.

B. Innovation

To address the concern of increased liver weight, we will change the fundamental nature of the tissue-retractor interface used. Instead of attaching to distinct points on the abdominal wall or gall bladder, we will distribute the

force along the peritoneum at the bottom of the abdominal cavity. This force distribution will help minimize high stress concentrations and decrease the peak forces applied to the surrounding environment. We ultimately hope this will lead to fewer perforations and other forms of tissue damage.

To address spatial concerns which may cause visual and dexterity impairments for the operator, we hope to create a mechanism that provides bilateral force application, pushing the lower abdominal wall down while simultaneously lifting the liver. Traditionally, surgeons overcome this environmental challenge by applying a downward force to the bottom peritoneum wall[5]. Since current liver retractors rely solely on a lifting motion[14], an additional tool is required for this maneuver. However, our device is capable of achieving the same result without additional tools or surgical maneuvers. This results in the potential for fewer tools used, fewer MIS ports and fewer support staff necessary to perform this additional process.

In current procedures on obese patients, surgeons are already forced to apply a downward force to this lower peritoneum using instruments of similar surface area to that of our device [5]. Hence, we are confident this will not cause any increased stress or tissue damage.

C. Approach

We propose to design, develop, and evaluate a device that will be used to perform retraction of the left lobe of the liver for MIS procedures. We hope to create a device that is capable of working in various surgical environments, specifically patients with a BMI greater than 35 or who have NAFLD, where current devices do not have the necessary load distribution capabilities. Our device will allow for increased total force input to the liver while decreasing peak stress values on the surrounding tissue. The various design and verification steps of this process are divided into the three specific aims discussed below.

C1: Specific Aim 1: Design a robust liver retraction device for obese patients that is capable of working within the framework of current MIS procedures.

Our device will be used to perform retraction of the left lobe of the liver during surgical procedures in the upper GI tract. In order for our device to lift the liver up and away from the region of operation, the top bar must be at least long enough to accommodate the 9.6 cm average width of the left liver lobe of obese patients (measured at the midsternal line)[13,14]. In order to adequately retract the left lobe of the liver and expose the hiatus, the liver must be moved 10 cm vertically upwards from the gastroesophageal junction [15]. These dimensional requirements (Figure 4) address Task 1.1: Design a bracing structure that distributes force across the peritoneum and supports the liver at least 10 cm above the hiatus - however, we must also design our device to achieve Task 1.2: Adapt the device from Task 1.1 to ensure it is capable of fitting through a standard 10mm MIS port.

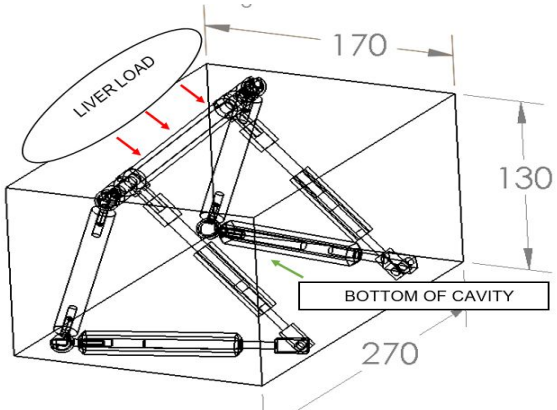


Figure 4: Dimension requirements for proposed device (mm).

Preliminary Data: Physical prototypes and CAD models

Based on the dimensional criteria outlined above, we began initial design iterations and prototyping efforts. We chose a triangular support system for its stability and flexibility, resulting in the first prototype shown in Figure 5. This prototype sought to test an initial folding geometry where the legs of the device folded inward and parallel to the main supporting bar. While this design was easily fabricated, it had multiple problems. First, the folding design required the leg lengths to be too short proportional to the primary supporting bar, and second,

the hinges used did not provide the level of support desired, particularly between the legs and primary supporting bar.

Next, we hoped to create a prototype using the desired manufacturing material to test strength and environmental interaction at 2x scale. This design was constructed out of stainless steel (Figure 6) and was manufactured with much finer tolerances and machining methods. We designed our two support triangles so that the actuated legs were significantly smaller than the other two legs. This resulted in the force application occurring parallel to the actuator and perpendicular to the lower peritoneum wall. This will reduce the potential for slippage during testing and usage of the device.

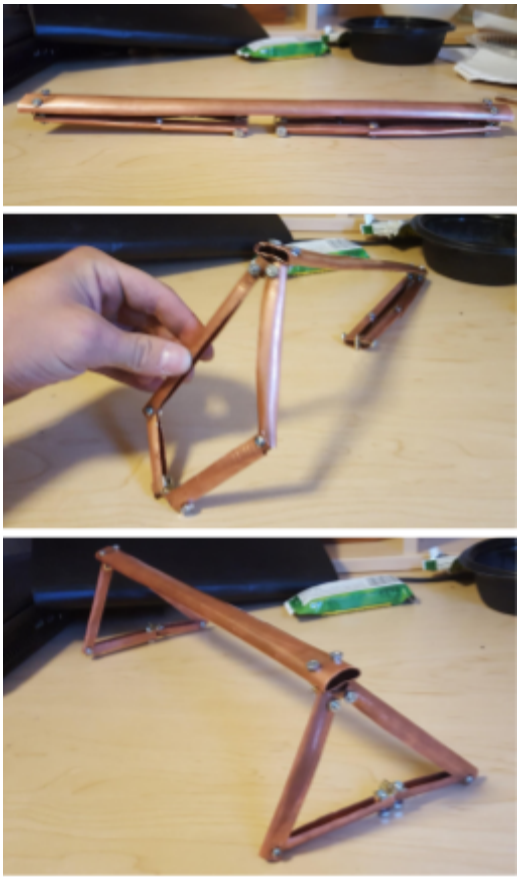


Figure 5: Folding mechanism demonstrated by first prototype.

Finally, to achieve the necessary folding functionality, we created a CAD model of a device whose design satisfied all functional requirements (Figure 7). We then used a combination of Fused Depositing Material (FDM)-printed ABS plastics and machined aluminum and steel parts to construct our third prototype (Figure 8). The device, constructed at 1.5x scale, consists of a string of components that are all 10mm in diameter, attached by a series of joints manufactured to allow for a specific range of motion.

In disassembled form (Figure 8b), the entire device can be inserted in sequence through an MIS port. Once inserted inside the body, only two maneuvers - clipping the end of the structure back to each side of the main supporting bar - are needed to secure the device in the assembled form shown in Figure 8a. This device helped validate both the structural integrity and MIS insertion capabilities of our design.

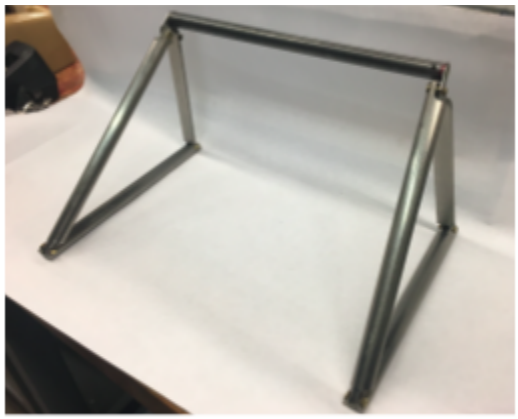


Figure 6: Geometric prototype of device, manufactured from stainless steel.

Future work:

The next major steps for this specific aim are to produce a final prototype of sufficient fidelity and reliability to allow for to-scale testing. To accomplish this, we will need to eliminate any sharp edges or areas with risk of high stress concentrations from the CAD design. Additionally, we will add a textured pattern along the bottom bars that interacts with the tissue surface to help eliminate risk of slippage under load bearing conditions. With these edits in place, a new device will be printed and assembled for usage in initial testing. Unfortunately, this specific set of dimensions was calibrated for the average liver size, and we will also need to begin fabrication of additional prototypes capable of dealing with enlarged livers. Finally, after initial testing is performed using the cheaper ABS plastic that is currently available for 3D printing, a final version will be submitted to subcontractors for to-scale, high fidelity production in medical grade 420 stainless steel.

Experimental Analysis:

To assess the validity of Hypothesis 1.1: The device designed will allow for MIS insertion and setup of a pre-assembled bracing structure which can be completed by a trained surgeon in comparable or faster time than the current art of liver retraction technology, we will test our designed apparatus in a simulated surgical environment with trained surgeons. This simulated environment will be a model of the entire surgical site, including gelatin tissue phantoms[16] for the liver and a flexible outer shell to simulate the peritoneum and abdominal walls. We will have surgeons insert our device through standard-sized MIS ports in the abdominal wall, and then have them assemble the device inside the body using traditional MIS/laparoscopic tools. We will record the time it takes surgeons to insert and assemble the device, and then compare that time to the 2.8-8.6 minute range identified as average by Palanivelu et al. in their review of existing liver retraction techniques [17].

Figure 7: CAD model of proposed device.

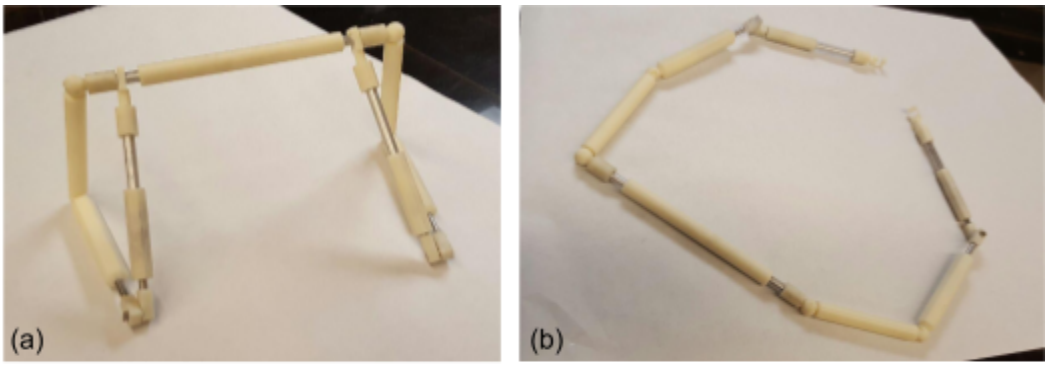


Figure 8: 3D-printed prototype in (a) assembled, and (b) disassembled configurations.

C2: Specific Aim 2: Integrate post-insertion control of the device so as to ensure the surgeon can optimize the shape of their desired workspace.

Once the device is inserted and assembled in its correct configuration inside the body, the surgeon must be able to adjust the shape of the surgical workspace based on the size of the liver and other conditions of the environment. Post-insertion control of the device is necessary for surgeons to be able to make these adjustments accurately and dynamically. To achieve this, we will perform Task 2.1: Implement remote actuation of the supporting legs of the device.

Preliminary Data: Adding actuators to prototype:

To test actuation, we attached one linear actuator (Firgelli L-16P, 50mm stroke[18]) to each side of our stainless steel prototype (Figure 9). These actuators were individually controlled using a circuit with an Arduino Uno, allowing for fine control of the position of the top bar of our device.

Future Work: In the future, we would like conduct more research into the necessary microactuators to build our design to scale. Though miniature actuators exist at the 1.5x scale that allow for a relatively large extension range (around 5 cm)[18], shrinking the maximum diameter of the actuator down to 10 mm is a significant challenge. Fortunately, high-speed linear actuation is not important to the overall success of the design, and so current ultra-small linear actuation technology should be adequate given a sufficiently high gear ratio. Nevertheless, it may be necessary to fabricate custom linear actuators for our exact design specifications.

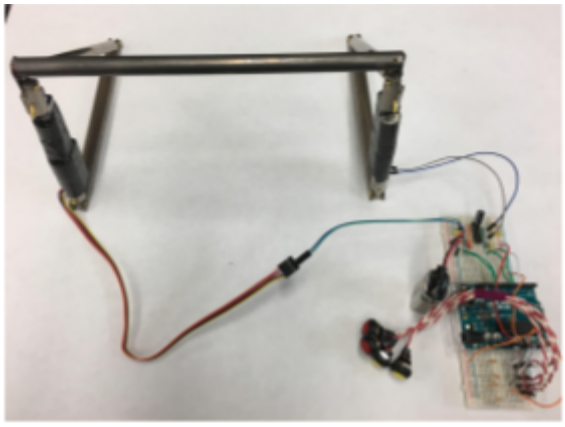


Figure 9: Steel prototype with linear actuators and control circuit.

Experimental Analysis:

Once we integrate microactuators into an appropriately scaled device, we will perform fatigue testing to analyze the strength and longevity of the actuators as well as that of the overall structure of the device. We will setup the retractor in its assembled configuration in the same surgical environment created for the testing of Hypothesis 1.1, and repeatedly extend and retract the actuators under the load of the liver phantom. This operation will be extended until device failure, forming a basic data set for the longevity and reusability of the proposed retractor.

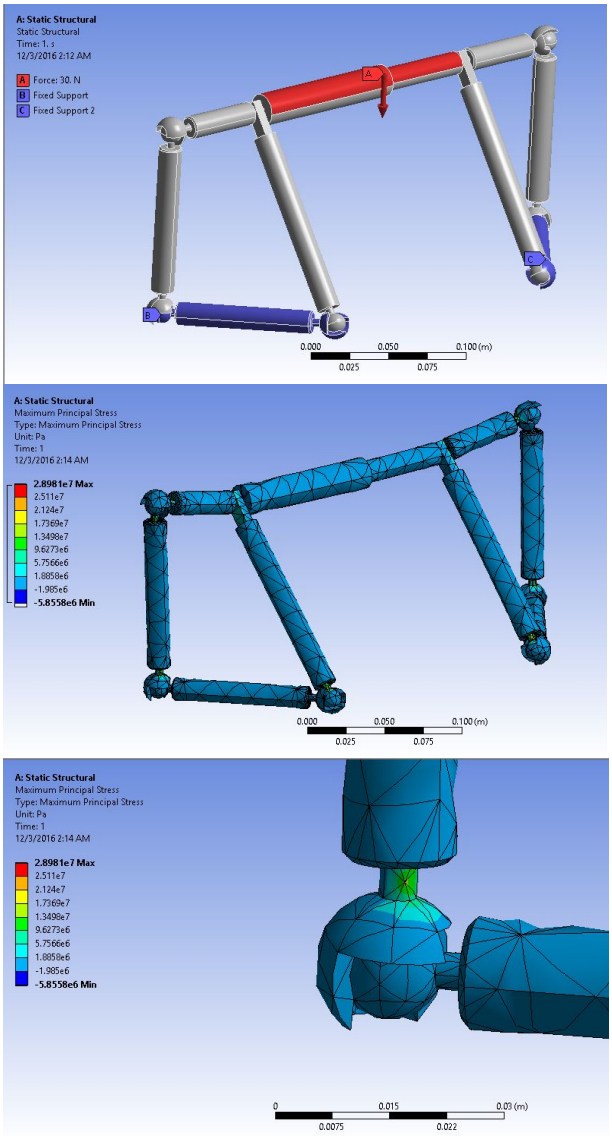
Grade	Degree of hiatal exposure
1	> 1cm exposure above anterior crura
2	< 1cm exposure above anterior crura
3	GE junction visible; no part of anterior crura seen
4	GE junction not visible

Figure 10: Levels of hiatal exposure defined by Palanivelu et al[17].

We will also perform tests on porcine cadavers in order to quantify the level of hiatal exposure achieved by our device. We will have surgeons use remote controls of the actuators and visual feedback from traditional MIS cameras to adjust and position the device to achieve what they deem to be optimal size and shape of the surgical workspace. We will review videos of these tests and use the criteria defined by Palanivelu et al [17] (Figure 10) to rate the level of hiatal exposure achieved in each sample. The average of this rating across the various trials will be compared to the results of the other liver retraction techniques to assess the validity of Hypothesis 2.1, that the control of remote actuators integrated into the device will allow surgeons to accurately adjust the dimensions of the surgical workspace and achieve a sufficient amount of hiatal exposure.

C3: Specific Aim 3: Develop a framework for predicting and preventing patient injury by calculating contact stress on the surrounding tissue using FEA.

A major challenge in the design of surgical tools for MIS procedures lies in the prediction of tissue damage. This interaction is difficult to model because soft tissue response depends on loading configuration and duration of exposure[19,20]. To tackle these challenges, we propose a framework based on Finite Element Methods that will accomplish Task 3.1: Generate a stress-strain model of the device proposed using Finite Element Analysis that can predict tissue damage during a MIS liver retraction procedure.



Preliminary Data:

Device Structural Stress Analysis

First, we had to ensure that device failure does not occur at any stage of the liver retraction procedure. To calculate the reaction loads at the support that will be used to compute the contact stresses, we subjected a CAD model of our device to FEA in Workbench (ANSYS). FEA results show that the maximum stress within the device when it is supporting the weight of the liver will be approximately 12 MPa. Figure 11 shows, from top to bottom, the loading conditions, the meshing methodology/boundary conditions, and the location of the maximum stress.

For this analysis, we model the body tissue as a linearly elastic, incompressible and isotropic material. In reality, the tissue in this region is nonhomogeneous and behaves non-linearly. This simplifying assumption is acceptable for preliminary calculations as long as it is only applied to a low-strain regime. Using previously computed reaction loads to quantify the stress the supports exert on surrounding tissue, calculations predict that the maximum stress and strain on the tissue near the supports will be 48 KPa and 14.2%.

Figure 11: ANSYS FEA Analysis

Future Work: To improve the accuracy of our contact stress analysis, we propose to incorporate constitutive models that are more representative of the non-linear behavior of soft tissue into our analysis. We will first generate stress-strain data of the target tissue using indentation tests and CT scans [21,22]. After this stress-strain behavior has been characterized, we will refine our tissue model to reflect the anisotropic, non-homogeneous and softening properties of real tissue[21,23].

Experimental Analysis:
In order to analyze the amount of tissue damage caused by our device, the porcine cadavers operated on in the experimental analysis of Hypothesis 2.1 will undergo open-cavity, postoperative analysis to accurately quantify the severity of any damage that occurs as a result of the procedures. These numbers will then be compared to average results from traditional liver retraction techniques to determine the validity of Hypothesis 3.1, the FEA model generated will accurately predict tissue strain to within accepted standards of ± 15% [1].

C4: Potential Problems And Alternative Solutions

The primary concern that may emerge with this project is the issue of device slippage relative to the supporting tissues. Though the severity of this problem could be quite high, the team has several potential methods of addressing it. First, there are a lot of different texturing and friction-enhancing patterns that could be added to the bottom of the triangular supports so as to better accommodate for shear stress. Additionally, there are lots of geometric changes that could still be made to shift the primary loading directions of the force exerted by the liver. Currently, these forces are directed along the actuated legs of the supports and orthogonally to the bottom wall of the abdominal cavity, but this may not be the most optimal load-bearing situation when tested in a real, organic environment. If slippage remains a problem even after traction enhancement patterns are added, then the team will reiterate on the design shape to further diminish shear stress and thereby eliminate this concern.

A second significant problem that may emerge is that, even with the increased surface area of our device, stress concentrations may remain high enough to inflict tissue damage on the patient. To solve this problem, we would include additional pads that fold out from the primary load-bearing tubes of the triangular supports to further increase surface area. The mechanical complexity of this solution makes it undesirable, so it will only be added if absolutely necessary. Fortunately, this problem is unlikely to occur as the surface area of our device is already orders of magnitude higher than the millimeter-scale hooks used in current liver retraction technology.

An additional, more mild concern we have is that device setup will take a longer amount of time for patients in the obese population. The same spatial constraints that make this device a necessary surgical component also may make it difficult to manipulate during setup. To solve this concern, it may be necessary to further reduce the minimum size of the actuated leg lengths so as to allow for easier alignment of the legs during the setup process. If this augmentation is still insufficient to allow for easy surgical insertion, then there is also potential to redesign the actuation procedure to be structured around a cable-based tendon network that can be tightened after insertion to achieve the desired support structure shape.

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