



Liver Retractor

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1. Background

Liver retraction is necessary for surgeries near the gastroesophageal junction, most notably of which is Nissen Fundoplication. This procedure is a treatment for gastroesophageal reflux disease (GERD) when medications do not adequately relieve the symptoms (University, 2008). GERD affects nearly 10% of adults on either a daily or weekly basis and even more on a less frequent basis (Reflux, 2009). This disease

results from the backflow of gastric acid into the esophagus from the stomach, which causes irritation and inflammation that lead to heartburn which is visible in Figure 1. The damage caused by the acid induces a narrowing of the esophagus and eventually leads to esophageal cancer. A frequent cause of GERD, hiatal hernias, are a result of the upper stomach and esophagus slipping through the diaphragm into the chest (Dugdale, 2008). The presence of hiatal hernias increases with age, affecting up to 60% of the US population by age 60 (Hiatal, 2009).

Nissen Fundoplication is the procedure of interest for the development of a liver retractor. In this surgery, a part of the stomach known as the

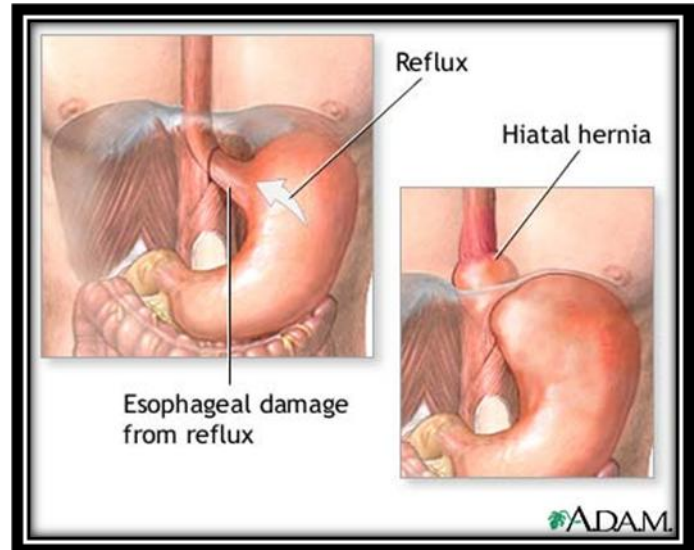


Figure 1- The white arrow shows the reflux of stomach acid into the esophagus. The hiatal hernia is a bulge of the stomach above the diaphragm (Dugdale, 2008).

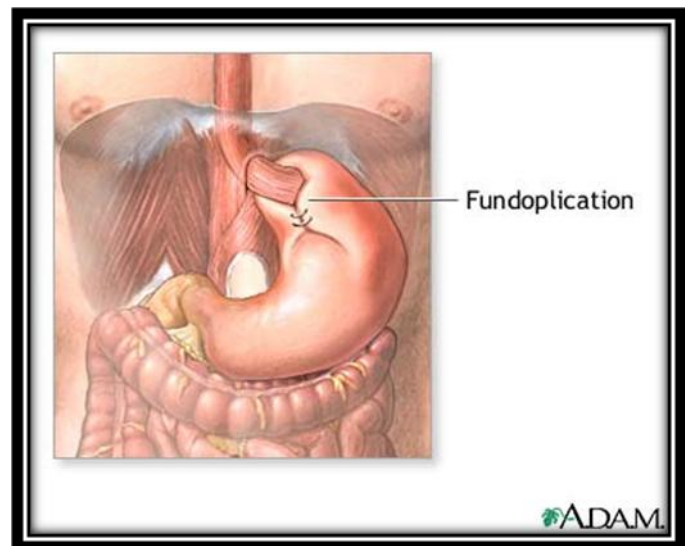


Figure 2- A fundoplication (Dugdale, 2008).

gastric fundus is wrapped around the lower esophagus to prevent the gastric acid from flowing into the esophagus as shown in Figure 2. The valve between the esophagus and stomach, the cardiac sphincter, is responsible for blocking acid from entering the esophagus and is strengthened during this procedure. Currently, laparoscopic procedures are used to perform this surgery which reduces recovery time and scarring in comparison with traditional, or open surgery (Laparoscopic,



Figure 3- A Nathanson liver retractor (Nathanson, 2006).

2008). Overall, the Fundoplication has a success rate of 90% - 95% for those with GERD who do not respond to pharmacological agents or lifestyle changes such as dietary interventions. In the laparoscopic procedures, a Nathanson retractor (Figure 3) is used to adequately expose the gastroesophageal junction in order for the surgeon to operate. This retractor is designed to support the liver during laparoscopic procedures and can be inserted in under a minute (Nathanson, 2006). The Nathanson's primary disadvantage is that it requires a dedicated port throughout the entire surgery for its use, an undesirable trait.

A number of benefits have been shown for single incision laparoscopic surgeries (SILS). Dr. Gould performed a trial on a consenting patient using a Red Rubber Robinson (Figure 4). This hollow, rubber, 6mm wide tube is primarily used as a catheter but was cut into a 10cm length for this trial. It was chosen due to its size and hollow nature – which allowed

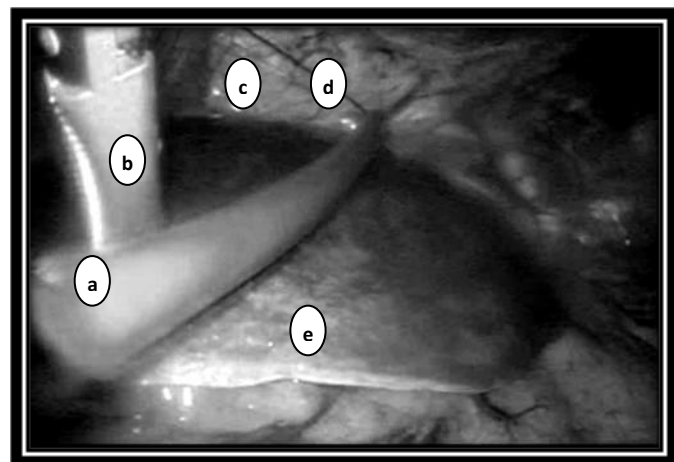


Figure 4- An attempted SILS procedure for liver retraction. Two sutures (d) were used to support (a) a Red Rubber Robinson, which was positioned using (b) the Covidien Roticulator™. Two sutures (d) were inserted through the abdominal wall (c). The left lobe of the liver (e) is visible in this image (SILS, 2008).

for easier threading with sutures. Due to the nature of the left lobe of the liver as a limp organ, it was unable to be adequately supported by the Red Rubber Robinson and slipped off during multiple attempts. As a result, a Nathanson retractor was used as the end result of the procedure (SILS, 2008).

2. Motivation

The main advantage of developing a device that will retract the liver from a single incision in the umbilicus is a decreased number of incisions. Currently, the Nissen Fundoplication requires at least two incisions: one in the upper abdomen for the liver retractor and one in the umbilicus for the rest of the surgical instruments. This new device would eliminate the need for this extra incision. With a decrease in the number of incisions there is a smaller risk of infection. In addition, fewer incisions result in fewer scars. In this case, the single incision in the umbilicus is hidden and produces a seemingly scarless surgery. This decrease in scars improves cosmetic appearance and increases patient satisfaction.

3. Design constraints

The device must adequately retract the left lobe of the liver to expose the entire gastroesophageal junction. This amount of retraction will allow the surgeon to have adequate visibility of the work area and will allow the surgeon to have enough room to maneuver the surgical instruments. The device needs to maintain this retraction for at least two hours, which is the approximate length of the surgery. It also needs to withstand the internal conditions of 37°C, 15 mmHg CO₂, and the potentially corrosive effects of the peritoneal cavity including exposure to blood.

An important constraint is that the device must fit through a 1.2 cm laparoscopic port. This port is placed in the umbilicus and is the method that all of the surgical instruments pass into the body. This requires that the device is deployable once inside the body and also retrievable through this same port

when the surgery is finished. In addition, no part of the device can remain in the port during the surgery and must be fully within the body.

The time of deployment should be under five minutes. This will ensure that the use of the device does not cause a significant increase in the length of the surgery and will make the device something surgeons are willing to use. The device can either be single use or preferably reusable. If it is reusable, it will need to be sterilizable. The device should also be easily held and used by surgeons.

Patient safety is a major consideration in the design of this device. It must not cause any trauma to the liver and should be free of any sharp edges that might puncture the lining of the peritoneal cavity. The liver should be evenly supported every time the device is used in order to distribute the weight of the liver. This will ensure that the device does not apply too much pressure to one area and induce trauma. It also needs to accommodate a variety of liver shapes and sizes. The device also needs to be non-toxic and biocompatible as it will be inside of the body. It will need to satisfy all relevant FDA standards for experimental devices including proper labeling. Possible materials include stainless steel, titanium, and Red Rubber Robinsons.

4. Ergonomics

In our design it is necessary to take into account human factors and ergonomics since our device will be used by a variety of surgeons. Most importantly, our device needs to be as simple as possible to deploy and remove from the body. The surgeon is working with his hands crossed, viewing his work through a camera, and using articulating instruments (instruments that articulate and rotate) in a small space.

Since the work is already complex, this device must not cause any further complications to the surgeon's work. The more work the surgeon has to do to correctly place our device, the more room there is for

error and possible trauma to the liver as the surgeon is moving the tools around. Increased work could also cause the surgeon frustration and make him or her more likely to make a mistake. In addition, the removal of the device needs to be a process that is as simple as possible for the same reasons as the deployment needs to be simple. Lastly, the deployment mechanism should be easy to grasp and place inside of the laparoscopic port. If these conditions are met, our device will be something that surgeons are willing to use.

5. Design Options

To solve the problem of retracting the left liver lobe with a deployable, removable device compatible with the 12mm single incision laparoscopic port, we developed the following three designs:

Procedurally, for each of the three designs, sutures are used as the general method of retraction and removal as follows: Two sutures are pre-attached to eye hooks on one end and Keith needles on the other end. The eye hooks are connected to the top portion of the designs and all suture components are enclosed by a protective capsule, potentially plastic or rubber. After insertion of the designs into their appropriate positions for retraction inside the patient, the protective capsule is removed. Next, the exposed Keith needles are punctured through the abdominal wall and pulled upward in order to provide the retracting force that is transferred from the sutures, to the folded ring, and finally to the left lobe of the liver. Once the liver is retracted, the sutures are clamped off on the outside of the body in order to hold the liver in the desired position. After the surgery is performed, the liver is lowered back into its original position, the sutures are cut, and the designs are to be folded or collapsed into their original pre-deployment configurations in order to be removed through the laparoscopic port.

6. Folded Ring

This design option is composed of four stainless steel rods connected together by four flexible rubber joints (Figure 5). The flexible joints allow the ring to be folded twice over itself in order to minimize its outer diameter for passing through the laparoscopic port. Once the device is inserted through the port with the client's graspers, the ring is unfolded inside of the patient and

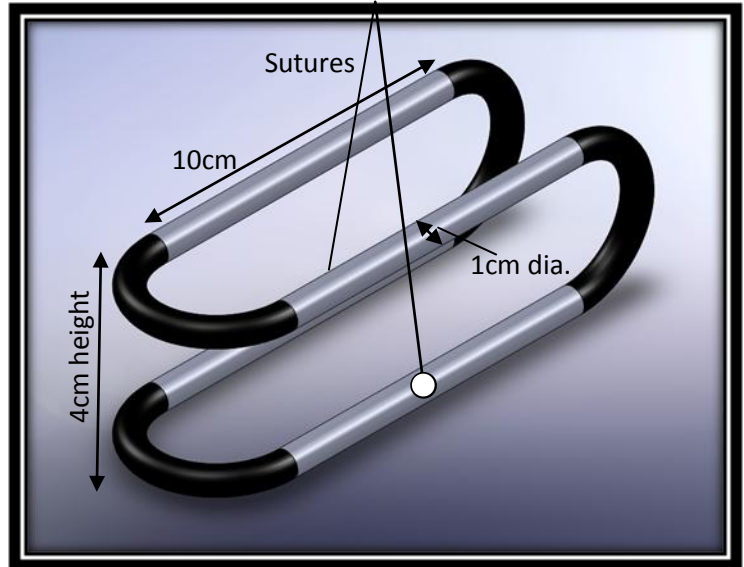


Figure 5 - Folded ring design. Light colored rods represent stainless steel. Black colored components represent flexible rubber joints.

prepared for deployment. In preparation for deployment and retraction of the left lobe of the liver, the bottom half of the ring is moved under the left lobe using the graspers. Next, the top half of the ring is folded over the top of the liver, and the protective capsule enclosing the suture components is removed.

The previously described general retraction and removal procedure is then performed.

7. Wedge

The second design option considered to retract the left lobe of the liver is the frame of a triangular prism, termed the "Wedge" (Figure 6). This design is composed of nine stainless steel rods, connected together by six flexible rubber joints. During

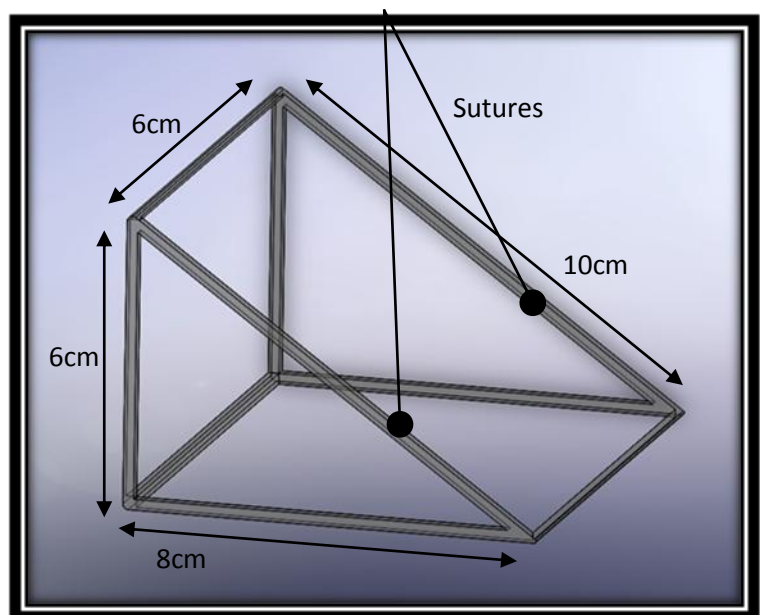


Figure 6 - Wedge design. Each stainless steel rod is connected by a flexible rubber joint on each of the six corners of the frame. The rods are each 5mm in diameter.

deployment, the wedge is collapsed and folded while transported through the 12mm diameter port. Once inside the subject, the device is opened up so the left lobe of the liver can fit through it. This leaves the two parallel rods on the bottom of the wedge (running from bottom left to top right in Figure 6) to support the left lobe, while the triangular frames on either side of the device prevent the liver from slipping horizontally out of the device. The general suture retraction and removal procedure is then performed, with the two eye hooks attached to the top corners of the wedge.

8. U-Shape

The third and final design option is a modification of the Red Rubber Robinson retraction technique that the client performed as previously described. This design is composed of a single stainless steel rod with two flexible rubber joints on its ends (Figure 7). During deployment, the rubber portions of the design are straightened out to be parallel with the stainless steel rod in order to form a single, cohesive rod with diameter less than 12mm. Once

inside the patient, the rod is positioned under the left lobe of the liver with the client's surgical graspers, and the flexible rubber ends are bent over the sides of the liver onto the top. With the flexible joints folded over the sides, the liver is less likely to slip horizontally out of the device during retraction. In order to produce a more desirable angle of retraction

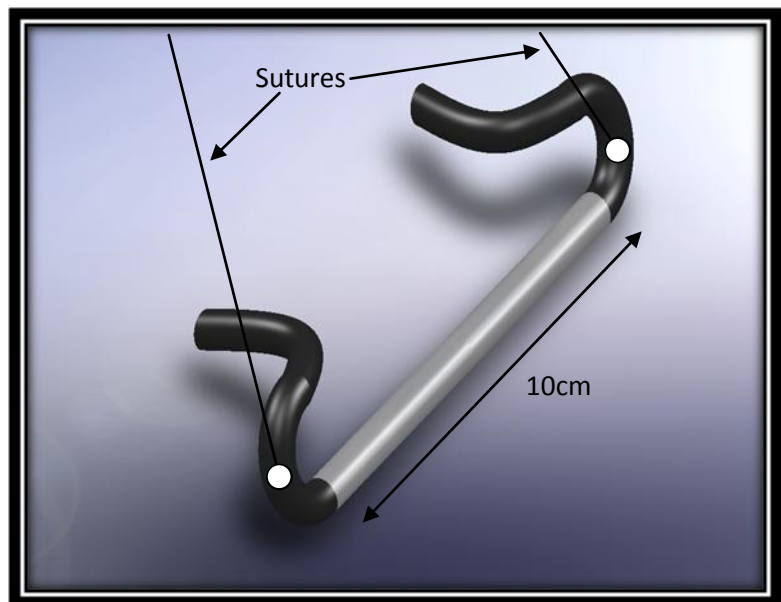


Figure 7 - U-Shape design. The light colored rod represents stainless steel. Black colored components represent flexible rubber joints. The diameter of the rod is 10mm.

force, the flexible ends where the eye hooks are attached are also bent closer to the abdominal wall. Lastly, the general suture retraction and removal procedure is performed.

9. Design Matrix

In order to assess the design options presented above, the following design matrix was created. With input from our client, five criteria were developed and weighted according to their importance to the design. Each criterion was given a score from zero (poor) to five (excellent), and the weighted average score was then calculated for each design. The device would not be used if there was a high risk for trauma, resulting in highest weight assigned to that criterion. All of our designs, however, received a five in this category since they were designed to minimize the risk of trauma.

Criteria	Weight	Wedge	U-Shape	Folded Ring
Ease of Use	10%	2.5	4.5	3.5
Support of Liver	25%	5	4.5	4
Risk For Trauma	30%	5	5	5
Time of Deployment	15%	2	5	4
Out of way of Surgical Field	20%	4.5	4.5	3
		4.2	4.725	4.05

Figure 8 - Design Matrix used to evaluate designs

The Folded Ring design received the lowest score out of the three designs, primarily due to the fact that although it could adequately support the liver, the portion of the ring that is beneath the liver would block the field of view of the surgeon during the operation. Also, it would be difficult for the surgeon to properly position the device beneath the liver and fold the top portion over top of the liver. The Wedge also scored low overall, largely due to the complexity of the design. It would be extremely complicated to design the Wedge in a manner that both provided structural support while retracting the liver and

also was able to fold down to fit through the 12 mm port. In addition, the Wedge would be difficult to deploy, because the high number of joints present would make unfolding the device difficult.

The U-Shape is the design that our team decided to develop for the semester, as it received the highest score in the Design Matrix. This device scored well in the “ease of use” category because it could easily be deployed, having only two flexible joints to position. Also, the U-Shape can be inserted easily as a straight rod and then folded up into the position seen in Figure 7.

10. Preliminary Design

In order to satisfy the design constraints, several prototypes were constructed. Due to the difficulty of creating a deployable prototype at the small scale required, both non-deployable prototypes to test the ideal shape and a deployable prototype were constructed (Figure 9). The non-deployable prototypes (B, C, and D) consisted of a 3/16” brass rod of varied lengths that was bent at two points to varied angles. Then, two holes were drilled for the suture to be threaded through; one at each of the peaks of the bends. Several lengths and arm angles were used to test which would most effectively retract the liver. In a previous trial by the client, it was determined that a 10 cm middle section length was too short for adequate retraction. As a result, the middle section lengths used were greater than 10 cm. They ranged from 12.0 cm to 13.7 cm. Without actual trials it was difficult to determine which arm angle would be most effective, so various angles were tested ranging from 37° to 90° in the deployable prototype. Lastly, the deployable prototype was made from ¼” hollow aluminum rod. At each of the bends (the ends of the middle section), a hinge was attached that could bend to 90°. These hinges were then covered with rubber tubing to prevent the sharp edges from causing trauma to the liver. Two holes were cut in the rubber in order to allow the suture to be threaded through the device.

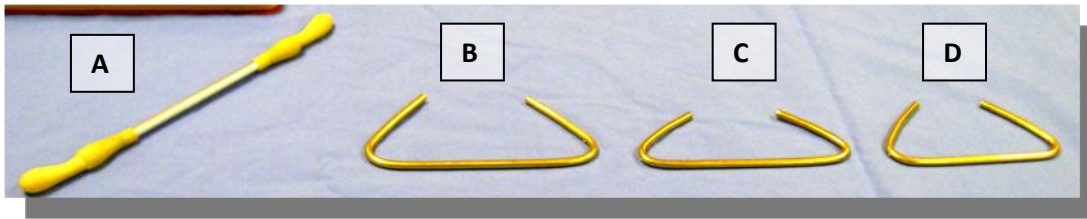


Figure 9- The four prototypes tested and their corresponding dimensions.

Prototype	Middle Section Length	Arm Angle
A – Deployment Mechanism	12.5 cm	90°
B	13.7 cm	47°
C	13.3 cm	38°
D	12.0 cm	47°

11. Deployment Procedure

In order to use and deploy these prototypes, a procedure was developed. First, the surgeon uses an Endostitch that attaches a suture to the left crus of the diaphragm. This is a section of muscle located in the abdominal cavity and very near the gastroesophageal junction. Next, the suture attached to the left crus is taken outside of the body through the 12 mm port and is threaded through the two holes in the retractor. The retractor is then inserted (in the non-deployed position) into the abdominal cavity through this same port. After insertion, the surgeon uses his or her tools to deploy the retractor arms. This is done by having one grasper tool hold onto the device and by having another grasp the arm and rotate it until it locks into position. Next, the surgeon positions the device underneath the liver. After this is complete, the suture is passed out the abdominal wall and tension is applied in order to retract the liver. Once the liver is adequately retracted, the suture is clamped in place (Figure 10).

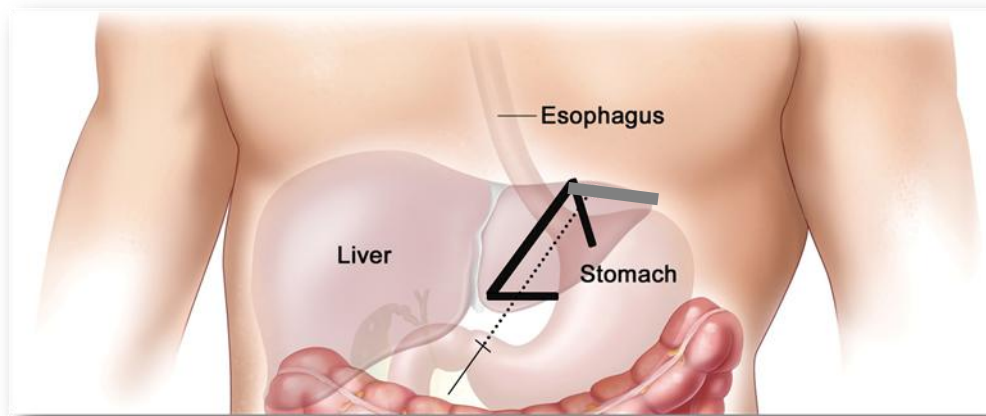


Figure 10 – In black: placement of the deployed prototype under the liver. The dotted line represents the sutures. In dark grey is the version modified according to the testing performed.

12. Testing

In order to test the efficacy of our design shape in retracting the left lobe of the liver, we executed the deployment procedure using each of the previously described prototypes in attempts to retract a pig liver. The pig was not used solely for our study; it was also used in teaching students surgical procedures. During the retraction attempts, the pig was anesthetized and connected to a respirator. Through liver retraction attempts on the pig liver, we were able to gain insight into the preferred size, arm angles, and suture attachment locations for liver retraction.

Initially, we learned that the 13.7 cm and 13.3 cm retractors were too long to fit inside the pig's abdominal cavity while positioned under the liver. We also learned that the suture exit point through the abdominal wall could be varied in location in order to accommodate different sized retractors.

In order to retract the lower portion of the liver's left lobe, the 47° arm angle was ideal as it covered a large portion of the surface area. However, for all of the prototypes that we tested, the arm angles on

the upper section of the retractor failed in retracting the upper portion of the liver's left lobe sufficiently. The failure was due to the location of the left crus.

When the suture attachment points were located at the joints of the retractors, the arms were prone to rotating downwards as the entire device rotated along the suture axis. Those prototypes with suture attachment points near the joints could not adequately retract the liver as the arms rotated downwards instead of providing the upward retraction force to lift the liver. Alternatively, when the suture attachment points were located further up the arms of the retractor, the downward rotation was eliminated and upward retraction was improved. However, the retractor arm attached to the left crus could not be positioned as far as it needed to be under the liver for optimal retraction since the attachment was located in the middle of the arm. Additionally, the torque to lift the liver was suboptimal with both suture attachment locations.

13. Modified Design

After testing the various prototypes in the pig lab, modifications were made to our design to address the results obtained. Each modification was an attempt to correct an imperfection that was exposed during the testing of the prototypes.

First, the length of the middle section of the device was set to 11.5 cm (Figure 11). This length was chosen because it is longer than the 10 cm Red Rubber Robinson, which was unable to adequately retract the liver, and shorter than the 13.3 cm prototype, which

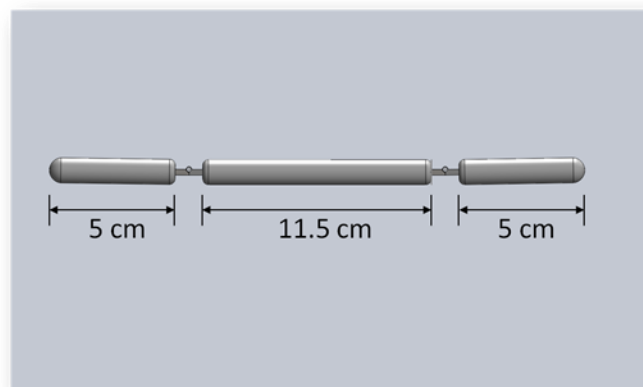


Figure 11 - Central rod length was set to 11.5 cm

was too long fit inside of the abdominal cavity. By setting the device to a slightly shorter length, we are also able to adjust the location of the suture exit point through the abdominal wall to a greater degree, giving more flexibility based upon the needs of individual surgical cases. If the device were set to a longer length, it would not be possible to get as much variation in suture exit points, as a longer device would contact the abdominal wall sooner.

As indicated in Figure 10, a portion of the left lobe of the liver extends beyond the left crus of the diaphragm. In the previous prototypes, both of the arm angles were set to be less than 90° . This is indicated by the black retractor in the image below. However, with both arms set to less than 90° , the portion of the liver that extended beyond the device was not supported.

By setting the arm that attaches to the left crus to an angle of 135° , the portion of the liver that was not previously supported can now be retracted, as indicated by the dark grey arm shown in Figure 10. It is crucial that this portion of the liver be supported properly, as it lies directly above the gastroesophageal junction, where the surgeon will be operating.

Finally, the suture attachment points were staggered on the device in order to help position the retractor underneath the liver in a way that provides the most support. Because the left crus lies adjacent to the gastroesophageal junction, placing the suture attachment point closer to

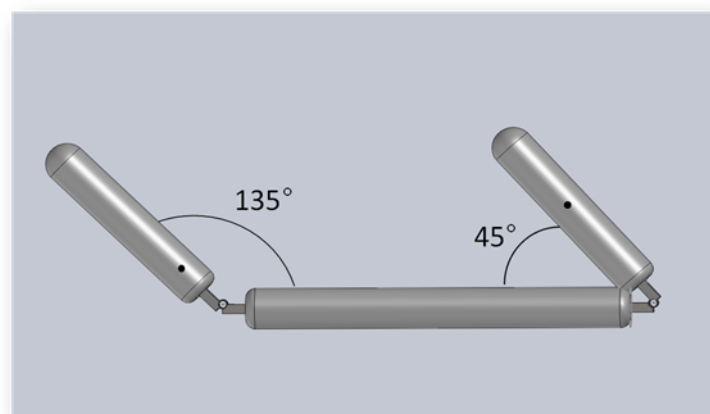


Figure 12- The modified post deployment orientation. The black dots represent suture attachment locations

the hinge for the arm attached to the left crus, it is possible to provide more support to the liver. In addition, by positioning the suture attachment points closer to the center of the device arms, the torque used to retract the liver can be optimized. In the prototypes tested, those with attachment points closer to the center of the arms did not rotate as freely, preventing them from swinging downward. Preventing the arms from swinging downward is important because the arms cannot provide support if they swing into the downward position.

14. Future Work

The first prototype has provided a lot of information regarding optimal lengths and angles. Our client is measuring the livers in human patients of upcoming procedures so that an optimal length can be determined. Nathanson retractors come in a package of three different sizes to compensate for the varying sizes of human livers. Once a functional prototype is developed, we will look into the merits and liabilities of having several sizes of retractors.

An important and crucial addition to the retractor will be the deployment mechanism. This is necessary to ensure that the device can fit through the port and be deployed from a straight, hinged rod (Figure 11) to a rod with two parallel bars extending at 45° and 135° angles (Figure 12). Due to the varying nature and sizes of human livers, it is also desirable for these angles to be adjustable into several pre-established angles. These alternate angles, along with an appropriate locking mechanism will also need to be developed.

With the implementation of these new features, the next prototype will need to be evaluated during another lab so that further improvements can be made.

15. Conclusion

The use of the left crus has demonstrated that an internal liver retractor for SILS procedures can be developed. Using this information, the original design was modified to accommodate this new attachment point. The testing of this design was very useful for learning about appropriate angles and lengths of a liver retractor. Further modification of the prototype needs to occur to adequately fit and support the liver so that the surgeon has a clear view of the work area. Another important addition will be the deployment mechanism. Through the continued refinement of this design, a device suitable for human testing and use is very feasible.

16. References

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17. Appendix A: Product Design Specifications

Function: This device is for use in a single incision surgery such as Nissen fundoplication – a process that wraps a portion of the stomach around the esophagus. The procedure is performed to treat gastroesophageal reflux disease (GERD) as well as hiatus hernias. It should retract the left liver lobe to expose the gastroesophageal junction, allowing for free access to the stomach and esophagus. It needs to be capable of being both safely deployed and removed through a 12mm laparoscopic port.

Client requirements:

- Deployment
 - In the human body (i.e. no attachments through the umbilicus / port)
 - Setup in under five minutes (current devices take one minute)
 - Should be easy due to limited mobility of instruments in the abdomen
 - Cannot rest upon the stomach or esophagus
 - Liver should be retracted within 1cm of the abdominal wall (10cm from stomach)
 - Fits through a 12mm laparoscopic port
- Materials
 - The use stainless steel or aluminum is ideal
 - Must withstand up to 15 mmHg in abdomen
 - The use of silk sutures is available
- Human considerations
 - The liver weight needs to be evenly distributed due to fragility
 - The procedure is much more difficult in the obese
 - View of the esophagus cannot be obstructed
 - A variety of liver sizes need to be considered

Design requirements

1. Physical and Operational Characteristics

a. *Performance requirements:* The device may be either single use or reusable. If reusable, it should be available for use after sterilization. The weight of the liver should be supported evenly by the retractor each time it is used. It also must accommodate a variety of human and liver sizes and weights.

b. *Safety:* The device needs to be non-toxic to humans and biocompatible as it will go inside the body. It needs to satisfy all relevant FDA standards including appropriate labeling (name, address and qualifier for manufacturer, intended use, directions for use, net quantity, warning statements of safety hazards, and contain the phrase “CAUTION Investigational device. Limited by Federal (or United States) law to investigational use”). The device also needs to be free of sharp edges that would cause significant internal trauma (including puncturing the chest cavity).

c. *Accuracy and Reliability:* The device needs to retract the liver to the top of the abdominal wall, which is an approximate distance of 10 cm from the lower edge of the liver depending on

the person. This needs to be done once during the surgery, and can be within 1 cm of the top of the abdominal wall.

d. *Life in Service*: The device will need to last the length of the surgery, which is about 2 hours. The device can either be a disposable device made for one-time use or, preferably, can be reusable.

e. *Shelf Life*: The device needs to be able to be stored at room temperature in a sterile environment for at least one year.

f. *Operating Environment*: The device should be able to:

- Withstand an environment high in CO₂ at 15 mmHg
- Be used at body temperature (37° C)
- Withstand sterilizing conditions (either steam and heat or sterilizing gas and IR)
- Be held by surgeons
- Withstand corrosion from body fluids and air

g. *Ergonomics*: The device should be easily maneuverable during deployment and removal using laparoscopic instrumentation.

h. *Size*: The device must attach to a deploying tool that together fit through a 1.2 cm diameter laparoscopic port and reach from the umbilicus to the liver. Inside the abdominal cavity, the deployed, self-supporting device must be large enough to evenly distribute retracting force on the liver without being in the way of the surgeon's tools and line of view. Average liver dimensions: greatest transverse measurement 20 to 22.5 cm, vertically 15 to 17.5 cm., greatest anteroposterior diameter 10 to 12.5 cm.

i. *Weight*: The weight of the self-supporting device inside the patient should not cause trauma to internal organs and tissues.

j. *Materials*: Must be biocompatible, non-toxic, and durable to the specified operating environment. Titanium, sutures, red rubber balloons, and stainless steel are acceptable materials.

k. *Aesthetics, Appearance, and Finish*: Device material in contact with the liver and internal tissue must be smooth to not cause injury upon friction. Device shape must be compatible with 1.2 cm diameter laparoscopic port and human anatomy in order to fit inside abdominal cavity and extend from the umbilicus to the liver.

2. Production Characteristics

a. *Quantity*: For prototype, only one necessary. If reusable, less need to be produced than if single-use.

b. *Target Product Cost*: If reusable product, target price is in the thousands. If single-use, target is in the hundreds.

Initial budget for production: ~\$500

3. Miscellaneous

a. *Standards and Specifications:*

Because this item is a “manual surgical instrument for general use,” under section 878.4800 of the FDA’s Modernization Act, this device (classified under general and plastic surgery devices) appears to be exempt from premarket requirements as defined by the FDA Center for Devices and Radiological Health. Initially, device also falls under category of “investigational device exemptions,” but if marketed for profit will no longer qualify.

b. *Customer:* Would prefer:

- Minimize work after placing device inside patient
- Open to coupling device with sutures in abdominal wall
- Open to using falciform ligament for device attachment

c. *Patient-related concerns:*

Device must be safe and cause no damage to patient during its use. With fatty livers, the liver becomes heavier, increasing the risk of “sawing” through liver with improper support from device, requiring our device to adequately distribute the load to relieve liver pressure. The operation is not usually performed on obese patients due to complications with fat deposits.

d. *Competition:*

- Nathanson Liver Retractor
 - Retracts liver during laparoscopic GI surgery
 - Requires separate incision for insertion
 - Intended for sterilization and reuse
 - ~\$500/ea
 - www.cookmedical.com
- Pediatric Liver Retractor
 - US Patent #7300400
 - Supports liver to make room for surgical procedures
 - Requires separate incision for insertion