Liver Retractor

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3/10/2009

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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 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).

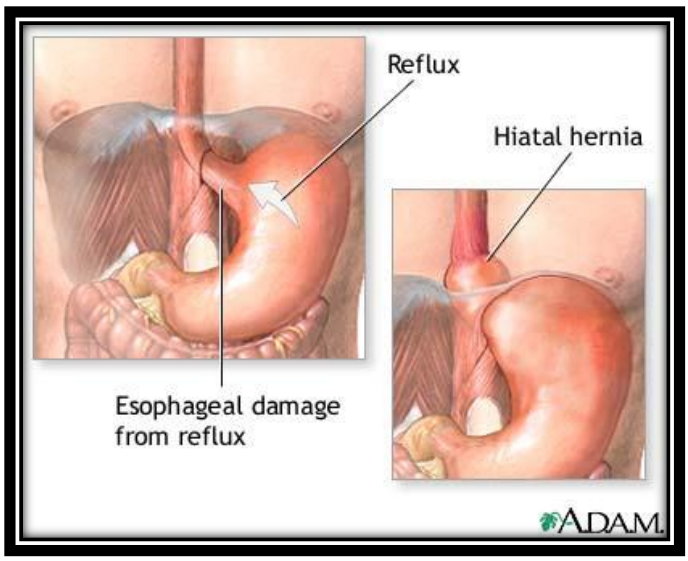

Figure 1- The white arrow shows the reflux of stomach acid into the esophagus. The hiatal hernia is a bulge of the stomach above the diaphragm (Dugdale, 2008).

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 gastric fundus is wrapped around the lower esophagus to prevent acid flow into the

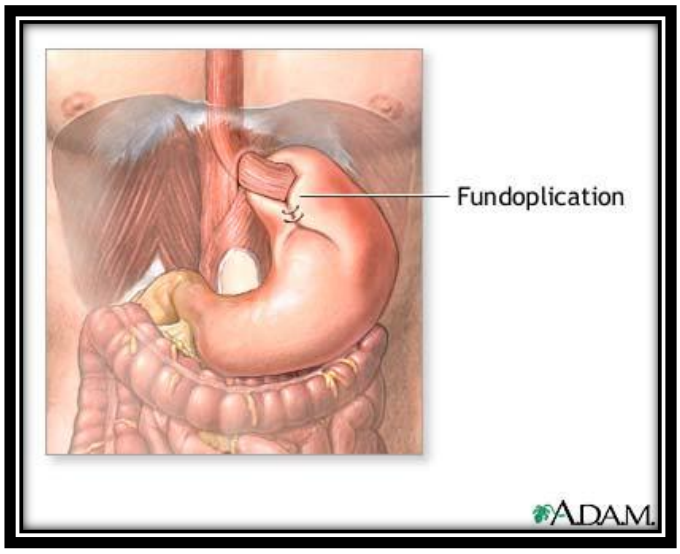

Figure 2- A fundoplication (Dugdale, 2008).

esophagus as shown in Figure 2. This also strengthens the valve between the esophagus and stomach. Currently, laparoscopic procedures are used to perform this surgery which reduces recovery time and scarring in comparison with traditional, or open surgery (Laparoscopic, 2008). Overall, the Fundoplication has a success rate of 90% - 95% for those with GERD. 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).

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

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). 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).

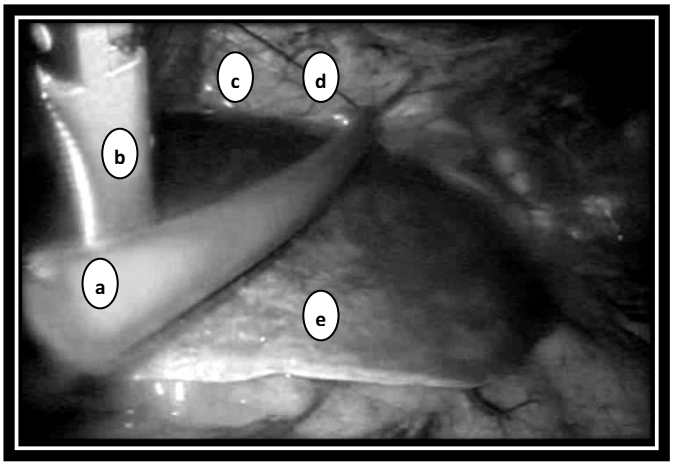

Figure 4- An attempted SILS procedure for liver retraction. Two sutures (d) were used to support (a) a Red Rubber Robinson, which was positioned using (b) the Covidien Roticulator™. Two sutures (d) were inserted through the abdominal wall (c). The left love of the liver (e) is visible in this image (SILS,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

2. Motivation

The main advantage of developing a device that will retract the liver from a single incision in the umbilicus is a decrease in the 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 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. This is defined as the liver being within 1 cm of the abdominal wall. This amount of retraction will allow the surgeon to have adequate visibility of the gastroesophageal junction and 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 CO_2, and corrosive body fluids.

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 is retrievable through this 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 chest cavity. The liver should be supported evenly every time the device is used. 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. It also needs to accommodate a variety of liver shapes and sizes.

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 already working with his hands crossed, viewing his work through a camera, and using roticulating instruments in a small space, so we don't need to cause any more 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 his tools around. Increased work could also cause the surgeon frustration and make him 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:

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 possitions for retraction inside the subject, the protective capsule is removed. Next, the exposed keith needles are punctured through the abdomenal 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 folded or collapsed into their original 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

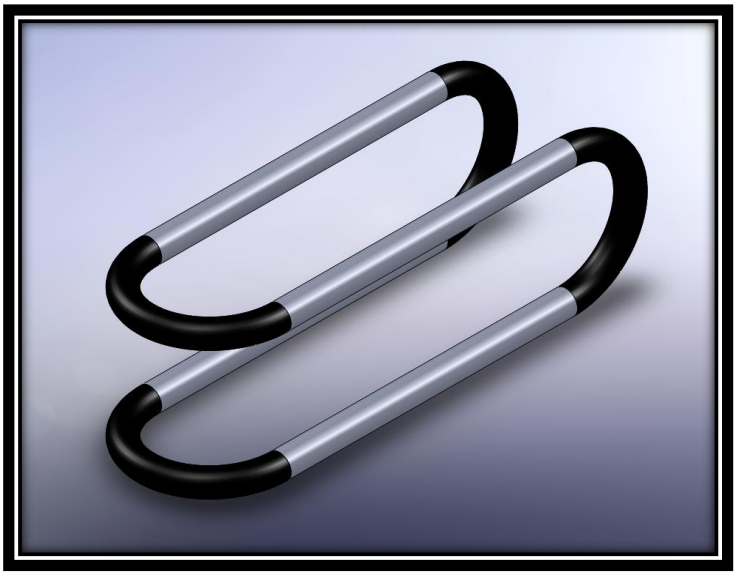

Figure 5 - Folded ring design. Light colored rods represent stainless steel. Black colored components represent flexible rubber joints.

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 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 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.

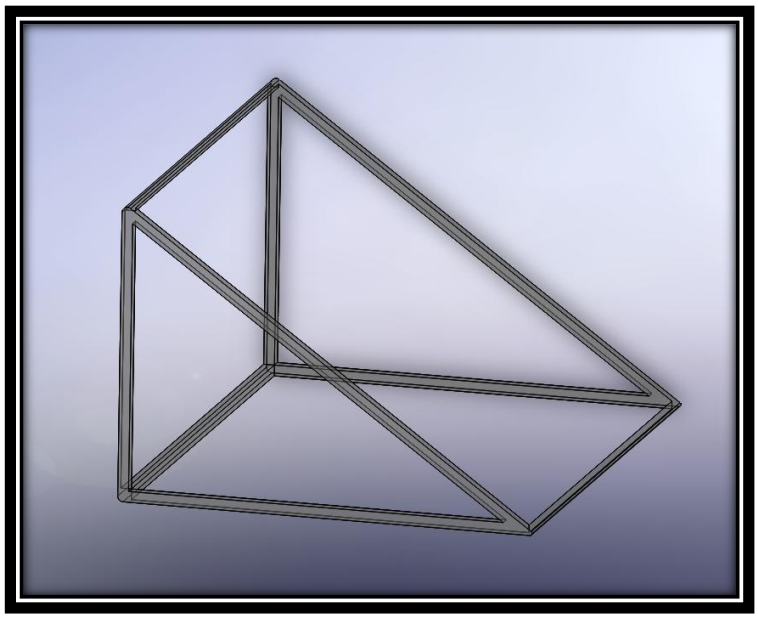

Figure 6 - Wedge design. Each stainless steel rod is connected by a flexible rubber joint on each of the six corners of the frame.

8. U-Shape

Figure 7 - U-Shape design. The light colored rod represents stainless steel. Black colored components represent flexible rubber joints.

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 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 though 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. Future Work

In order to develop the U-Shape from the simple design concept we have into a functional prototype, several tasks must be accomplished. Currently, our client is investigating the use of the left crus of the diaphragm, a tendinous structure extending inferiorly from the diaphragm to the vertebrae, as an alternate attachment point for our device. By using the left crus as a point of insertion for a suture, it could be possible to obtain a better angle with which to retract the liver.

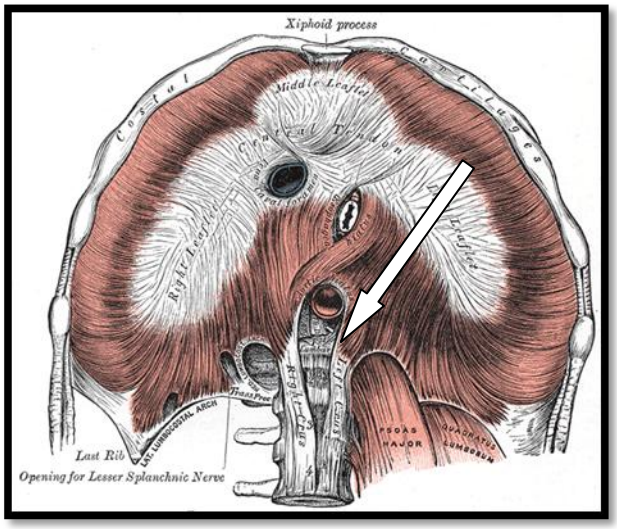

Figure 9- Left Crus of liver

In addition, a method of securing the base of the liver must be developed to prevent the liver from flopping as it did when our client attempted to retract the liver with a Red Rubber Robinson. Finally, the deployment and retrieval mechanism of our device must be expanded upon. As previously mentioned the U-Shape contains flexible joints that allow it to be straightened during insertion/retrieval and folded over the top of the liver for retraction. However, the exact design of these joints has not yet been determined.

11. Conclusion

At this point in the semester, we have created and assessed three feasible design options, and have narrowed them down to one design concept, the U-Shape. This design received the highest rating, and fulfills all of the requirements listed in our Product Design Specifications. We will continue to develop this design and create a functional prototype that will prove the concept of our design through testing

and performance evaluations. This will eventually be developed into a device that can make true Single Incision Laparoscopic Surgery a reality.

12. References

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13. 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 CO_2 at15 mmHg
- Be used at body temperature (37^o 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 robinsons, 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