Liver Retractor

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1. Background

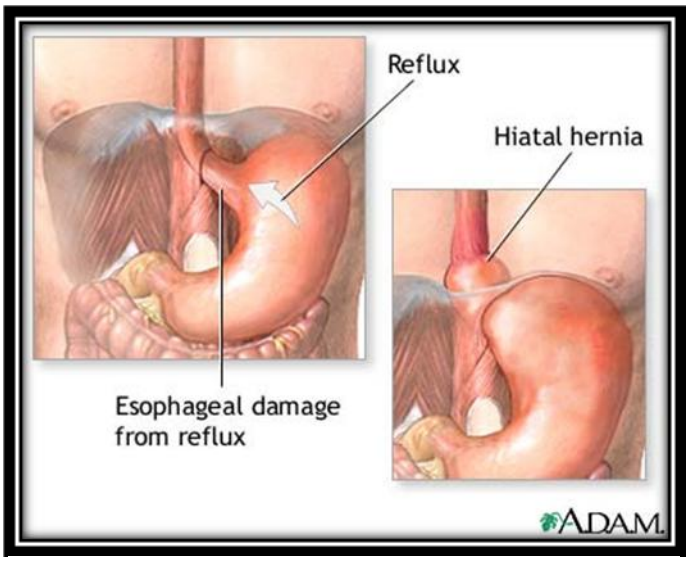

Figure 1- The white arrow shows the reflux of stomach acid into the esophagus. The hiatal hernia is a bulge of the stomach above the diaphragm (Dugdale, 2008).

Liver retraction is necessary for surgeries near the gastroesophageal junction, most notably of which is the 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). These facts contribute to its classification as "a common chronic disorder" that is increasing in prevalence with the obesity epidemic (Zhi, 2005). GERD results from the backflow of gastric acid into the esophagus from the stomach, which causes irritation and inflammation that lead to heartburn (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).

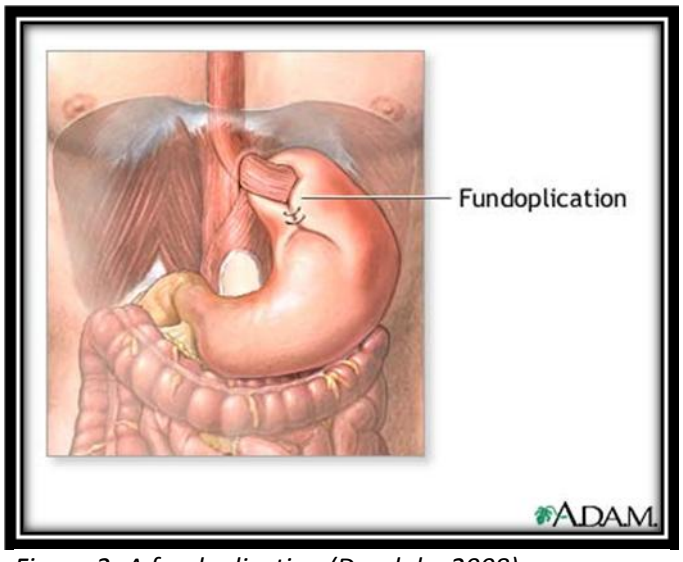

Figure 2- A fundoplication (Dugdale, 2008).

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 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, reducing recovery time and scarring in comparison with traditional, or open, surgery (Laparoscopic, 2008). Another benefit of the laparoscopic surgery is a reduced necessity of hernia repairs post-operatively (Broeders, 2009). 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.

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

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.

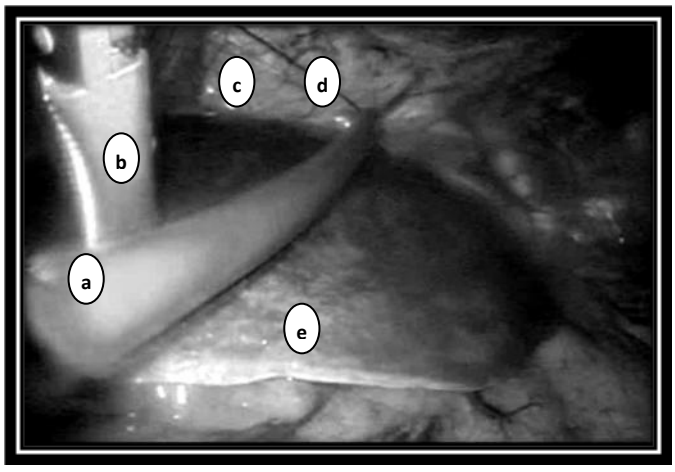

Figure 4- An attempted SILS procedure for liver retraction. Two sutures (d) were used to support (a) a Red Rubber Robinson, which was positioned using (b) the Covidien Roticulator™. Two sutures (d) were inserted through the abdominal wall (c). The left lobe of the liver (e) is visible in this image (SILS,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

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 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. The reduced number of incisions also results in fewer scars. In SILS procedures, the incision in the umbilicus is hidden and produces a seemingly scarless surgery. Overall, cosmetic appearance is improved along with patient satisfaction.

3. Design constraints

This device must adequately retract the left lobe of the liver to expose the entire gastroesophageal junction. This is defined as retracting the left lobe of the liver 10 cm vertically or retracting it within 1 cm of the abdominal wall. Since the gastroesophageal junction is where the surgery is performed, exposing this site will allow the surgeon to have adequate visibility of the work area and will provide 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. During this time, it should not change conformation unless it is intentionally manipulated by the surgeon. It also needs to withstand the

internal conditions of 37°C (body temperature), 15 mmHg CO_2 (used to inflate the abdominal cavity), and the potentially corrosive effects of the peritoneal cavity (including exposure to blood).

In order for this device to be used, it must fit through a 1.2 cm laparoscopic port. During the surgery, this port is placed in the umbilicus and is the method that all of the surgical instruments pass into the body. The use of this port also requires the device to be deployable once inside the body and also retrievable through this same port (or through the port incision) when the surgery is finished. The deployment and retrieval must be possible with the existing laparoscopic instrumentation. In addition, no part of the device can remain in the port during the surgery so the other surgical instruments can be inserted.

The time of deployment should be under five minutes. In addition, the device should also be easily held and used by surgeons. These criteria will both 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 reusable. If it is to be a single-use device, it should be made out of a biocompatible polymer so that the device remains cost effective. If it is reusable, it should be made out of stainless steel (304 or 316) for durability. In addition, a reusable device will need to be sterilized after each surgery by moist steam heating in an autoclave, ethylene oxide gas, or dry heat.

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 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 (average liver measurements: greatest transverse measurement 20 to 22.5 cm, vertically 15 to 17.5 cm, greatest anteroposterior diameter 10 to 12.5 cm). 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. As "a manual surgical instrument for general use", this device is classified under general and plastic surgery devices from section 878.4800 of the FDA's Modernization Act. This exempts it from premarket requirements as defined by the FDA Center for Devices and Radiological Health. This device falls under the category of "investigational device exemptions," unless marketed for profit. As a result, the device must satisfy the requirements for an investigational device.

4. Ergonomics

In the design of this device it is necessary to take into account human factors and ergonomics since our device will be used by a variety of surgeons. Most importantly, it should be as simple as possible to deploy and remove from the body. The surgeon is working with laparoscopic, reticulating instruments (instruments that articulate and rotate) in a small space while viewing his work through a camera. 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 the device, the more room there is for error and possible trauma to the liver. Increased work could also cause the surgeon frustration and make him or her more likely to make a mistake. As a result, it is necessary that the device is easy to maneuver so that surgeon will want to use the device.

5. Previous Work

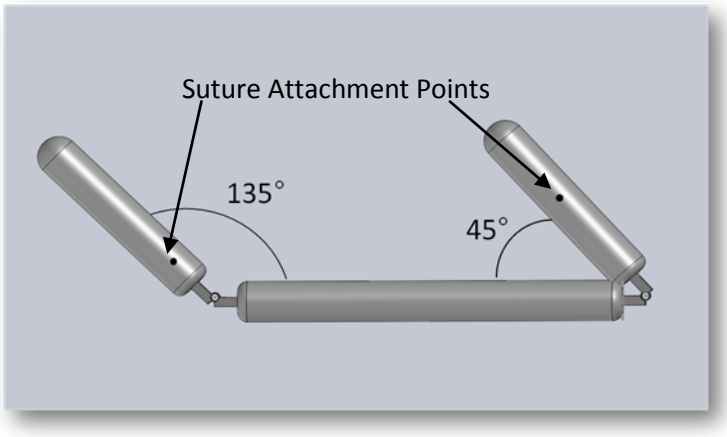

Figure 5- The modified post deployment orientation. The black dots represent suture attachment locations

In the previous semester, a device was developed to retract the left lobe of the liver through the 12 mm single incision laparoscopic port. The design consisted of a base rod and one arm attached to each end of the base rod (Figure 5). To use the device, a suture is threaded through a hole in each arm. One end of the suture is anchored in the left crus of the diaphragm and the other end is passed out of the abdominal wall. By placing the device underneath the liver and pulling up on the suture, the left lobe of the liver is retracted. The prototype developed last semester was a static, non-deployable device. The focus was on determining the optimal base rod length, appropriate angles of the arms, and optimal placement of the suture attachment points.

In order to determine these dimensions, several prototypes of various lengths, arm angles, and suture attachment points were fabricated from 3/16" solid brass rod and tested inside of a pig. After testing the various prototypes in the pig lab, the appropriate dimensions were determined. First, the length of the middle section of the device was set to 11.5 cm (Figure 6). This length was

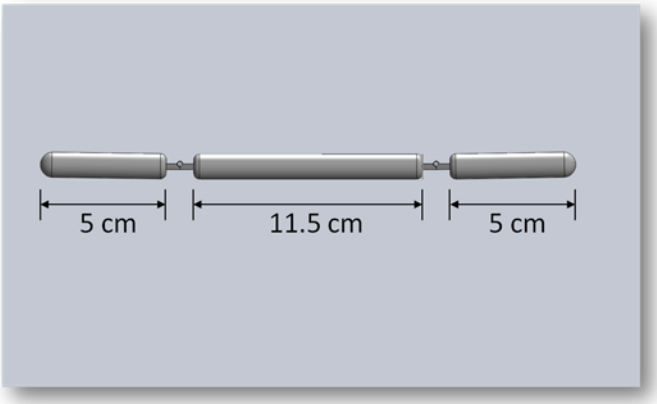

Figure 6 – The central rod length was set to 11.5 cm with two arms of 5cm in length from work performed in the Spring and Summer of 2009.

selected because it is longer than the 10cm required to adequately retract the liver and shorter than the 13.3 cm prototype, which 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.

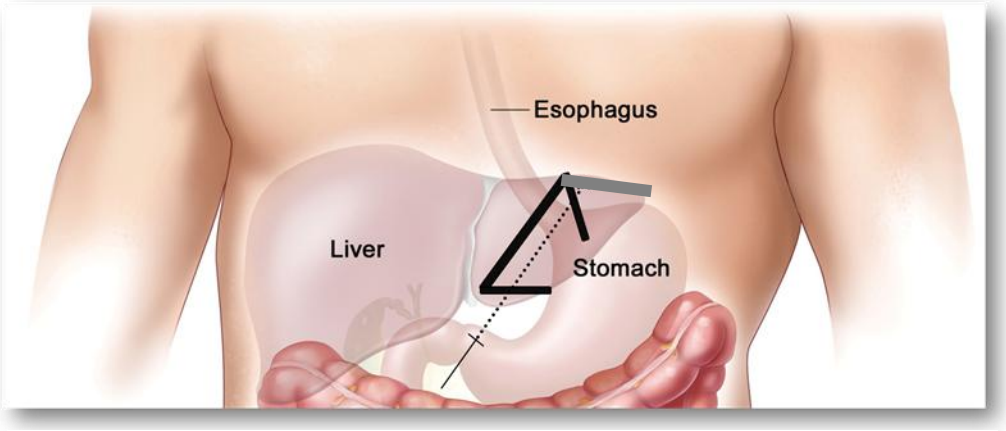

Figure 7 – In black: placement of the deployed prototype under the liver. The dotted line represents the sutures. In dark grey is the version modified according to the testing performed.

Next, the arm angles were determined. As indicated in Figure 7, a portion of the left lobe of the liver extends beyond the left crus of the diaphragm. In the prototypes, both of the arm angles were set to be less than 90°. 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 could be retracted, as indicated by the dark grey arm shown in Figure 7. 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. The other arm (the arm far from the left crus) was found to have an optimal angle of 45°.

Finally, the suture attachment points were determined (Figure 5). In testing, the points were staggered on the device in order to help position the retractor underneath the liver in a way that provides the most support. For the arm close to the left crus, the suture attachment point was found to be optimal when it was nearest the arm/base rod connection. Since the left crus lies adjacent to the gastroesophageal junction, it is possible to provide more support to the liver by placing the suture attachment point closer to the base rod. For the arm farther away from the left crus, it was found that positioning the suture attachment points closer to the center of the arm optimized the torque used to retract the liver. Attachment of the suture at the center of the arm prevented the arms from swinging downward. This is important because the arms cannot provide support if they swing into the downward position.

In summary, last semester's work helped to determine the base rod length, the arm angles, and the suture attachment points, but failed to provide an appropriate mechanism for deployment. This problem was addressed in work completed this semester.

6. Design Options

Since we validated the retractor shape, arm angles, suture attachment points, and deployment mechanism last semester, this semester's goal was to design a hinge that would allow changing the retractor shape from the deployment configuration (Figure 8) to the retraction configuration (Figure 9). Thus, the hinges located at each end of the base rod need to allow each arm to rotate between the straight configuration for insertion through the 12mm laparoscopic port and the retraction configuration for lifting the left liver lobe. In order to accomplish this goal, we developed the following three hinge designs.

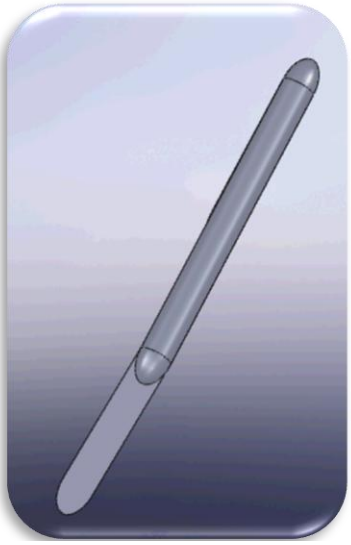

Figure 8 – Liver retractor deployment configuration for insertion through 12mm laparoscopic port.

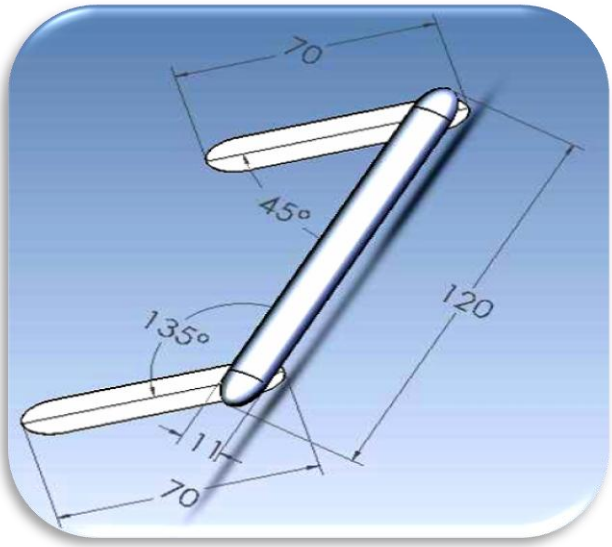

Figure 9 – Liver retractor retraction configuration for lifting the left lobe of the liver

7. Screw Hinge

This design option consists of a cylinder with male threads protruding from each of the retractor arms (Figure 10). The base rod has two corresponding holes with female threads for insertion and connection of the arms to the base rod. The threaded holes on the base rod provide the axis of rotation of the arms between the deployment and retraction configurations. For insertion through the 12mm laparoscopic port, each arm is slightly screwed into the base rod in order to remain connected throughout the deployment procedure. The arms are screwed until they reach the straight deployment configuration. After insertion through the port, the surgeon rotates the arms, screwing them tighter into the base rod. Once fully tightened, each arm is in the retraction configuration at either 45° or 135°.

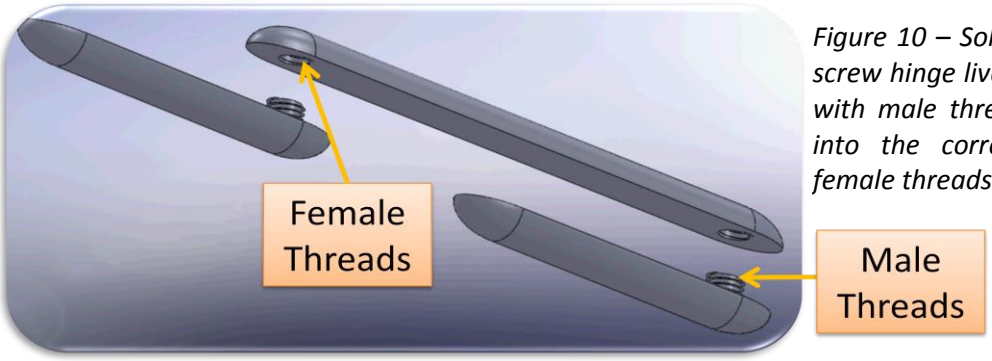

Figure 10 – SolidWorks image of the screw hinge liver retractor. Each arm with male threads is to be inserted into the corresponding hole with female threads on the base rod.

8. Detent Hinge

The second hinge design option is composed of a cylinder axle and spring-coupled peg on each arm, with a hole for the axle and two detents for the spring-coupled peg on each end of the base rod (Figure 11). The axle on each arm provides the axis of rotation of the arms about the base rod. The detents in the base rod are positioned with one detent maintaining the arms in the deployment configuration, and the other detent maintaining the arms in the retraction configuration. The peg on each arm fits into the detents for either deployment or retraction. Upon rotation of the arms, the spring located at the base of each peg is compressed, increasing the energy stored in the spring. This energy will only be released once the peg is able to fit into one of the two detents, decompressing the spring. This provides a locking mechanism for rotating the arms between the deployment and retraction configurations.

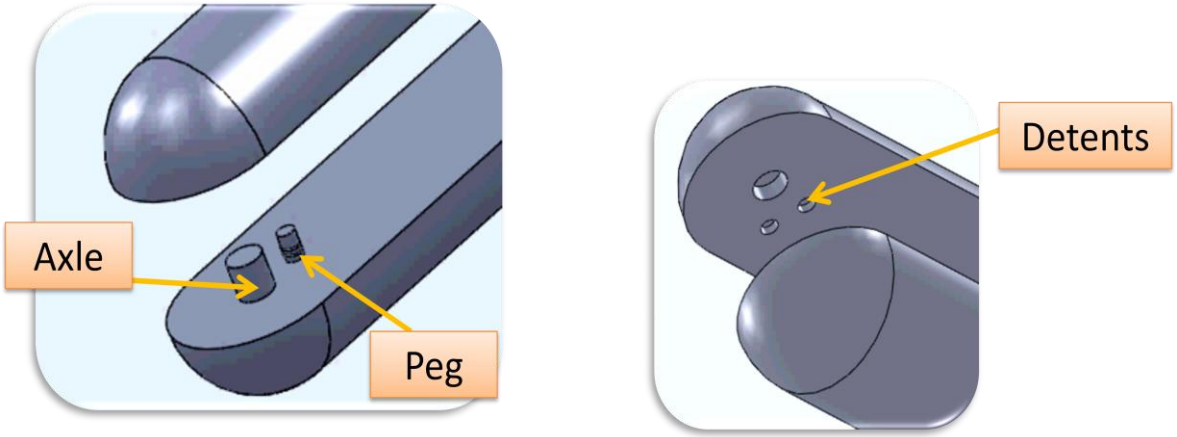

Figure 11 – SolidWorks image of the detent hinge liver retractor. A retractor arm is pictured left with a spring-coupled peg that fits into one of two detents in the base rod pictured right.

9. Spring-loaded Hinge

The third design and final hinge design option is composed of a torsional spring inserted inside a hollow cylinder axle on each arm (Figure 12). The torsional spring has two legs on each end, with one leg secured to the retractor arms and the other leg secured to the base rod. The legs of the torsional spring are positioned to be in the relaxed state in the retraction conformation with the arms at either 45° or 135°. For deployment, each arm is turned in line with the base rod, increasing the torsional energy in the springs. Thus, once inserted through the laparoscopic port, the torsional springs release the stored energy inside the abdominal cavity by rotating the arms back to the retraction configuration. For removal, the laparoscopic port is removed and the retractor is pulled out the port incision.

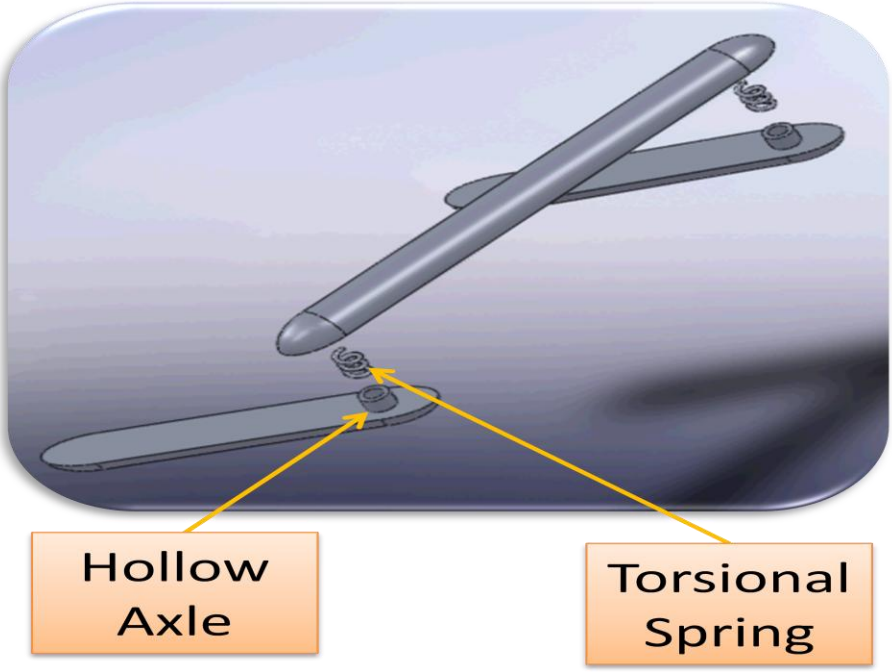

Figure 12 – SolidWorks image of the spring-loaded hinge liver retractor. A retractor arm is pictured left with a spring-coupled peg that fits into one of two detents in the base rod pictured right.

10. 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 as a percentage 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 very high scores in this category.

Criteria	Weight	Screw	Detents	Spring Loaded
Ease of Fabrication	15%	11	7	11
Ease of Deployment / Removal	25%	13	16	21
Reliability	20%	15	16	18
Cost	10%	9	6	7
Risk for Trauma	30%	29	29	28
	Total	**77**	**74**	**85**

Figure 13 - Design Matrix used to evaluate designs

A screw was selected for one of the designs since it would be relatively simple to machine. A benefit of this simplicity is the lack of moving parts or components under tension. This improves the ease of sterilization through autoclaving as well as disassembly for storage. While discussing designs with Dr. Gould, it was determined that the rotation of arms would be excessively difficult for the laparoscopic tools to maneuver.

The design with detents was ranked the lowest due to the difficulties associated with fabrication. The small peg and detents would require significant machining experience that may need to be performed by an external contractor resulting in a higher cost. The limited range of motion associated with laparoscopic instrumentation would add difficulty to moving the arms into position. Though this design was not selected for further development, a modified version of the peg and detent component has been integrated into the current prototype.

The spring-loaded design was selected for further pursuit as a result of its easy deployment. By placing the arms under tension, additional manipulation by the surgeon is minimized so that they may position the device and proceed with their surgical procedure. In its original form, components were determined to be machinable using resources available on campus. Further modification led to the incorporation of more intricate components required to maintain the desired retraction angle. Despite these complications, the ease of fabrication and deployment supported the selection of the spring-loaded design.

11. Spring-loaded Hinge Design Modifications

After selecting the spring-loaded hinge design to pursue this semester, a mechanism for attaching the spring to each rod and restricting the arms to rotate solely between the deployment and retraction configurations was developed. To attach the torsional spring to the arm and base rods, a slot was milled out of the rods to the diameter of the spring (Figure 14). Once the torsional spring was inserted into the hollow cylinder of the base rod and secured to the slot, the arm rod was placed on top with the opposite spring leg inserted into the slot of the arm. Thus, each leg of the torsional spring was secured to either the base rod or the arm, allowing a torsional force to be

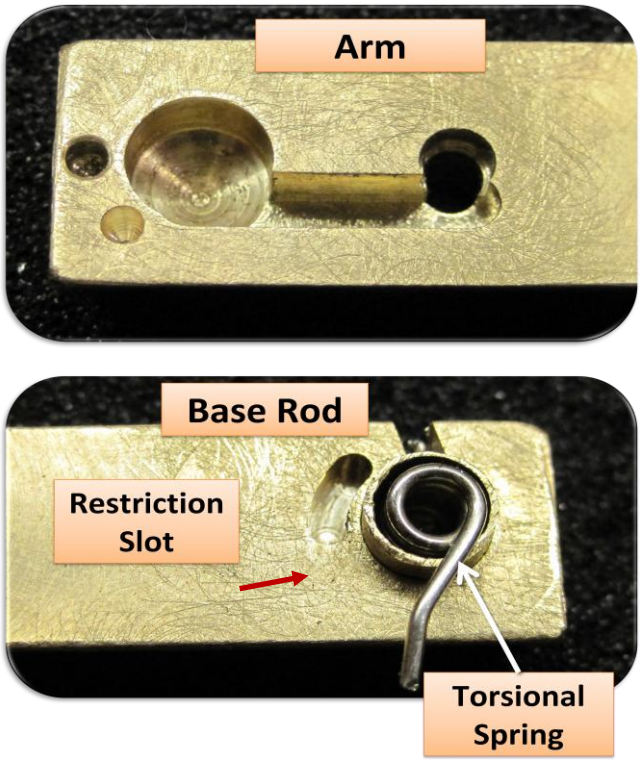

Figure 14 – Pictures of the final retractor spring-loaded hinge. Slots carved in the arm (top) and base rod (bottom) for spring leg attachment. Restriction slot carved in the base rod to restrict arm rotation.

developed in the spring upon rotation of the arm from the retraction configuration to the deployment configuration.

In order to restrict the arms from rotating solely between the deployment and retraction configurations, a restriction slot was carved out of the base rod and a peg was connected to the arms that fit into the restriction slot. Thus, the arm is restricted to rotating only with the peg in the slot, which is set between the straight deployment configuration and 45° or 135°.

12. Deployment Procedure

For proper testing of the original and future prototypes, this procedure was developed. First, the surgeon uses a laparoscopic tool, the Endostitch, to attach a suture to the left crus of the diaphragm. This is a section of muscle located in the abdominal cavity and near the gastroesophageal junction. Next, the suture attached to the left crus is taken outside of the body through the 12 mm port and 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 retractor's arms automatically deploy into position from the tension. The device is then positioned underneath the liver before passing the suture out the abdominal wall. Applying tension to this suture brings it into the retracted position. Once the adequately retracted, the suture is clamped in place.

13. Testing

Because the focus of the project this semester was the development of the hinge for the retractor, the most important element to test was the ability of the retractor to successfully deploy upon insertion through the port. To do this, we inserted the retractor through the actual 12 mm laparoscopic port that will be used during surgery, and verified that the device switched from the "deployment" position to the

"retraction" position. This test was conducted using only the surgical tools available during surgery to make our results as accurate as possible. Upon insertion, the retractor successfully assumed the "retraction" position, validating our hinge as well as the deployment procedure we developed.

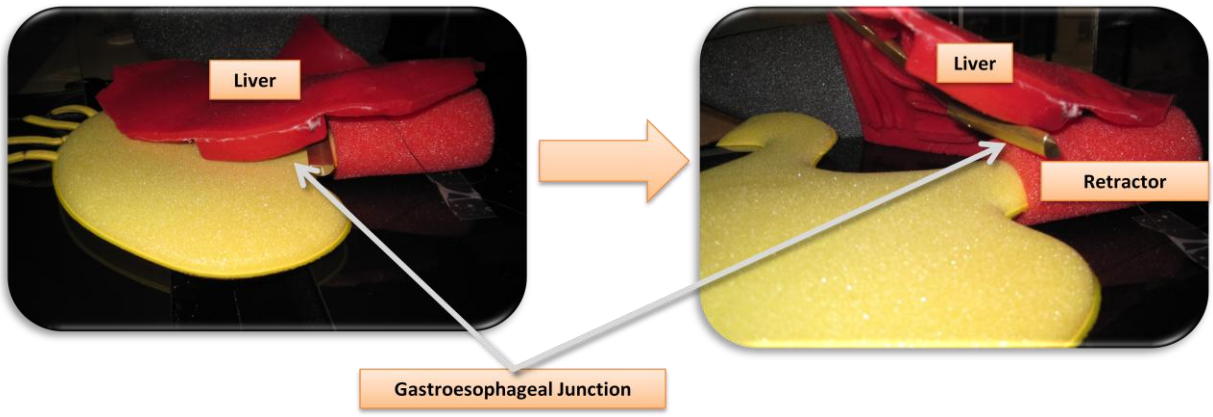

Figure 15: Testing setup: The prototype retractor was placed below the liver and lifted using a suture to assess the retraction capabilities.

Ideally, we would have preferred to test our retractor in a pig to assess its ability to adequately retract the liver. However, limited availability of pig labs near the end of the semester caused us to develop alternative testing methods. Using mock organs as shown in Figure 15 we inserted the retractor into the proper position underneath the liver but above the stomach. We then attached a suture to a location inside the testing apparatus that closely mimicked the location of the left crus of the diaphragm (the first attachment point for the retractor). The other end of the suture was threaded out of the side of testing apparatus, at a location that mimicked the abdominal wall. By applying tension to this end of the suture, we were able to successfully retract the liver, exposing the gastroesophageal junction, demonstrating the deployment and retraction mechanisms we developed have the potential to succeed inside of a live test subject.

One additional piece of information that we gained throughout the testing procedure was that the rounded shape of our retractor is not ideal for maneuverability with the laparoscopic tools available.

The laparoscopic tools, with flat surfaces used for grasping, do not have the ability to hold the curved outer surfaces of the retractor, a problem that will be addressed in the future.

14. Future Work

Now that we have validated both the deployment and retraction of our device, the next step will be to test the fully-assembled device in a pig to ensure that the retractor is equally effective using an anatomically accurate test subject rather than mock organs. While testing the device in a pig, we also plan to quantify the field of view provided by the retraction of the liver by our device. This will allow us to apply numbers to the very qualitative retraction test we performed using the mock organs, and will permit a more detailed analysis of the efficacy of the retractor.

If the device is shown to be successful in a pig, then we will need to develop a biocompatible version of the retractor. Before materials can be selected, however, we need to determine whether this product will be a single- or multiple-use device. Currently, single-use seems to be the more attractive option, since this would eliminate concerns with bodily materials becoming trapped inside of the intricate hinge, potentially inhibiting the proper function of the retractor. In addition, if the device were single-use, it would be possible to construct the device out of a biocompatible plastic, simplifying fabrication and driving down the cost of the device. As an alternative, a multiple-use device would likely be constructed from stainless steel, a heavier material that would be expensive as well as more difficult to fabricate.

Another modification we need to address is the suture attachment protocol, which will likely involve the pre-attachment of sutures to the retractor. This would eliminate the need for the surgeon to thread the sutures through the small suture attachment points in each of the arms of the device prior to deploying

the device. With this modification, we would also need to secure the sharp needle points that would be attached to the suture as to avoid the potential for the sutures to damage internal tissues during the insertion or deployment procedure.

The final modification we are considering is addressing concerns associated with liver variability (primarily liver size). If we were to develop multiple retractor sizes, we could serve a more expansive patient population than with a one-size-fits-all liver retractor. However, because the Nissen Fundoplication is not performed on obese patients, we need to more fully evaluate the merits of developing multiple retractor sizes. If the device we able to be used in more procedures than just the Nissen, however, our patient population would be expanded, potentially creating a greater need for multiple retractor sizes.

15. Conclusion

The development of a successful deployment mechanism demonstrated that an internal liver retractor for SILS procedures can be developed. Using this information, the device can be re-fabricated using biocompatible materials for further testing. Quantification of the field of view will provide details necessary for implementation in an actual Nissen Fundoplication.

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17. Appendix A: Product Design Specifications

Function: This device is to be used for liver retraction during a SILS[1] Nissen fundoplication[2].

It should retract the left liver lobe of the liver to expose the gastroesophageal junction, allowing for access to the stomach and esophagus. The device needs to be deployed and removed through a 12mm laparoscopic port

The device should:

- Insert through a 12mm laparoscopic port
- Deploy in under 5 minutes
- Maintain retracted position without:
    - additional incisions
    - use of an additional laparoscopic port
    - resting on the stomach or esophagus
    - obstructing the view of the gastroesophageal junction
    - changing conformation
- Retract the left liver lobe 10cm or within 1cm of the abdominal wall
- Evenly distribute the liver weight

Design requirements

1. Physical and Operational Characteristics

a. *Performance requirements*: The weight of the liver should be evenly supported by the retractor each time it is used and accommodate a variety of human liver sizes and weights.

b. *Safety*: The device should be free of sharp edges or other protrusions that could cause internal trauma.

c. *Accuracy and Reliability*: The device should retract the liver within 1cm of the top of the abdominal wall, about 10 cm from the lower edge of the liver. Once deployed, the device should not change conformation unless intentionally manipulated by the surgeon.

d. *Life in Service*: The device will need to last the length of the surgery, 2 hours. It should be reusable with proper sterilization procedures[i].

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

[1] SILS: Single Incision Laparoscopic Surgery

[2] Nissen: A surgical procedure 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.

f. *Operating Environment*: The device should be able to withstand surgical conditions[ii].

g. *Ergonomics*: The device should be inserted, maneuvered, and retrieved using laparoscopic instrumentation.

h. *Size*: The diameter must be less than 12mm for insertion and deploy to evenly distribute the force of the liver[iii].

i. *Weight*: The weight should be under 150g.

j. *Materials*: Stainless steel 304 or 316 should be used whenever possible. Sutures may be used for attaching the retractor.

k. *Aesthetics*, *Appearance, and Finish*: The device should appear simple to operate and smooth to not cause injury upon insertion.

2. Production Characteristics

a. *Quantity*: One prototype.

b. *Target Product Cost*: Under $500 for a prototype but up to several thousand for a reusable commercial product.

3. Miscellaneous

a. *Standards and Specifications*:

As "a manual surgical instrument for general use", this device is classified under general and plastic surgery devices from section 878.4800 of the FDA's Modernization Act. This exempts it from premarket requirements as defined by the FDA Center for Devices and Radiological Health. This device falls under category of "investigational device exemptions," unless marketed for profit.

b. *Customer*: Would prefer:

- Minimization of work required to deploy/retrieve device and retract liver
- Attachment of the device with sutures through the abdominal wall and left crus

c. *Patient-related concerns*:

This device should not be used on obese patients due to complications with high fat content around the liver. The device must adequately distribute the load of the liver to minimize pressure applied and not cause trauma to the liver. It also must not injure the patient during its use.

d. *Competition*: Cook medical supplies the Nathanson liver retractor for traditional laparoscopic Nissen procedures which requires its own incision. It is sterilizable and costs approximately $500.

[i] Sterilizing techniques include: a) moist heat by steam autoclaving, b) ethylene oxide gas, and c) dry heat.
[ii] The surgical environment will entail the human internal environment with 15 mmHg CO_2 and 37°C.
[iii] 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