

# Design and Development of a Tissue Retractor for Use in Minimally Invasive Surgical Procedures

by

Nikolai David Michael Begg

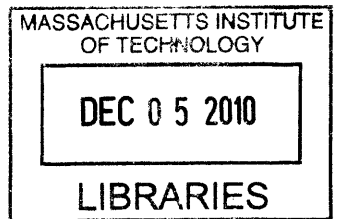
Submitted to the Department of Mechanical Engineering in Partial Fulfillment of the Requirements for the Degree of

Bachelor of Science in Mechanical Engineering  
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## ABSTRACT

Laparoscopic surgery is a widespread and rapidly growing surgical technique. One of the challenges facing surgeons performing laparoscopic procedures is the retraction of anatomical structures that restrict vision and access to the surgical site. Current solutions to this problem involve opening additional incisions, which causes increased risk and discomfort to the patient.

This study proposes a design for a laparoscopic retractor that can be inserted and operated without the need for additional incisions. The anatomical principles relevant to the design are introduced. The inventive problem is investigated and expressed as a problem statement, and the design requirements for the device are listed and explained. The processes of initial concept generation and selection are described, as well as the various stages of design refinement and prototyping performed on the chosen concept. User feedback regarding the alpha prototype of the device is presented. Finally, recommendations are made for future development of the device.

Thesis Supervisor: Professor David R. Wallace

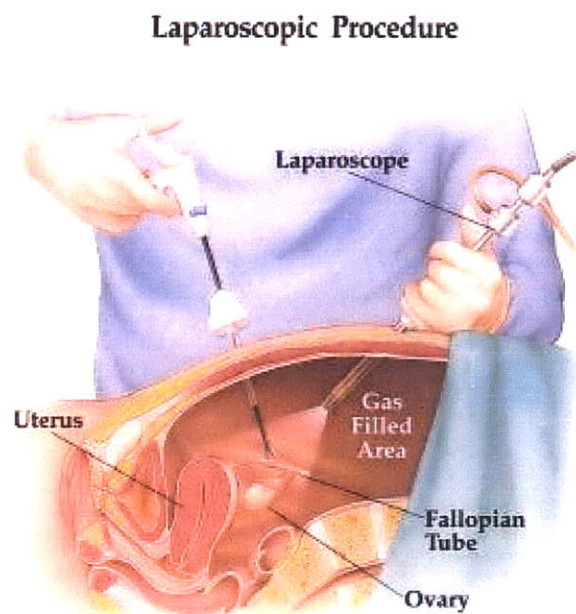
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## I. Introduction

Minimally invasive surgery (MIS) is the practice of performing surgical procedures with the goal of causing the least risk, discomfort, or lasting negative cosmetic effects to the patient. Perhaps the most widespread form of MIS is laparoscopy. Laparoscopy is a surgical technique that involves operating on the patient through small incisions and viewing the surgical field through a long, thin camera called a laparoscope. In abdominal laparoscopic procedures, the abdominal cavity is inflated using a non-reactive gas. This creates an air space inside the abdomen in which the procedure is completed. Figure 1 shows a simulation of a laparoscopic procedure, including a cross-section of the abdominal cavity showing the laparoscopic instruments performing the operation.



**Figure 1:** *Simulated view of laparoscopic surgical procedure with cross section of abdomen (From the Laparoscopy page of the Washington Center for Reproductive Medicine website).*

Because laparoscopic surgery offers many benefits over open surgery including reduced pain, recovery time, and risk of infection, laparoscopy is becoming the method of choice for many procedures in areas that can afford the advanced equipment required to perform these surgeries.

One challenge inherent to laparoscopic surgery is achieving a clear view of the target operational site. The complexity of the human anatomy often results in target organs being obstructed by other structures. As a result, surgeons must retract (move aside) these organs in order to successfully perform procedures. Currently, a variety of techniques are employed to solve this problem in laparoscopic procedures. Although diverse in their design and execution, all current solutions necessitate the creation of an additional incision in the patient. The creation of laparoscopic incisions causes additional procedural risk, pain, and long-term visible scarring to the patient. These consequences are all contrary to the original goal of minimally invasive surgery.

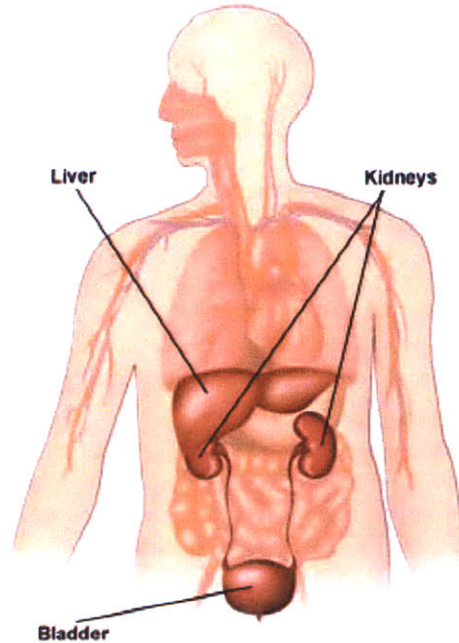
The goal of the project described in this study was to design a device to retract various anatomical structures during laparoscopic surgery that could be deployed and operated without the need to open an additional incision. Because of the limited scope of the project, the device was designed to solve the specific problem of retracting the liver during laparoscopic right kidney surgeries.

This study explains the context of the inventive problem to be solved, details the various stages of the design process, and presents recommendations for future development of the device.

## **II. Relevant Anatomy**

In the biological world, it is generally said that form fits function. The human body has evolved over millions of years to become an incredibly complex machine optimized for performing basic human tasks necessary to survival including finding and consuming food, self-defense, and healing. However, unlike the complex machines designed and built by engineers, the human body is not designed for servicing or repairs. When surgeons enter the different cavities of the body, they encounter a literal mess of structures that are stacked, tangled, glued together with connective tissue, and almost never consistent from individual to individual. It is clear from the fact that the human body was almost certainly not built to be easily disassembled for servicing that evolution has not yet caught up to surgical practice. As a result, the dissection and removal of obstructions to the target surgical site can often be one of the most complex and dangerous steps during an operation.

The human abdominal cavity contains and protects a large number of critical organs that are parts of multiple body systems. The human kidneys are located laterally, approximately a third of the way up the spine from the waist. Most laparoscopic kidney surgeries are performed with the patient in the supine (patient lying on back), lateral (patient lying on side), or prone (patient lying on abdomen) positions. Each specific procedure requires the patient to be in a certain position. In the lateral and prone positions, the kidney can be directly accessed under the lateral dorsal muscles. However, in the supine position, the upper pole of the right kidney lies under the liver. Figure 2 shows the position of the liver and kidneys in the human body.



**Figure 2:** Location of the kidneys and liver in the human body. Note that the liver covers the upper pole of the right kidney (from the National Institute of General Medical Sciences website).

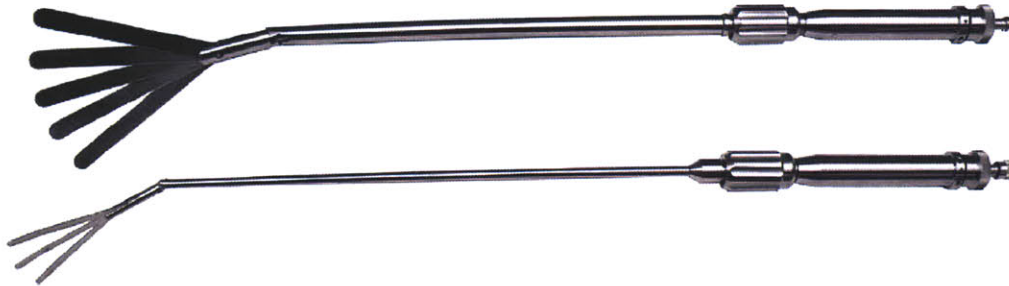
This anatomical feature causes difficulties in accessing the right kidney during laparoscopic surgery. With the patient in the supine position, the liver must be held aside for the upper pole of the kidney to be accessed.

Several considerations must be made to mechanical and surface properties of the liver. The liver is a rubbery, tough organ that will retain its shape and tend to return to its original position if moved and released. These qualities are the reason why surgeons must hold the liver aside for the duration of the procedure rather than simply moving it to one side as might be done with the small intestine. In addition, the liver is coated with moisture and bodily fluids that protect it from becoming dry, as are all of the organs in the abdominal cavity. As a result, the liver can be difficult to grasp and tends to slip away from laparoscopic instruments that do not have a firm hold on it. Finally, despite its low elasticity relative to other organs, the liver is an extremely fragile organ. As it is one of the most crucial and multi-functional organs in the human body, the liver is connected directly to the bloodstream and consists mostly of capillary beds. If the liver is punctured, it will bleed significantly and there is a high risk of injury or death due to internal bleeding. It is critical that any instrument that is used to manipulate the liver must be designed to minimize the risk of puncturing it.

### III. Current Practices

Several current practices are implemented to remove the liver from view during laparoscopic kidney surgery. Currently, no practice exists that does not require an additional incision. The difference between most current practices is the specific instrument that is inserted through the

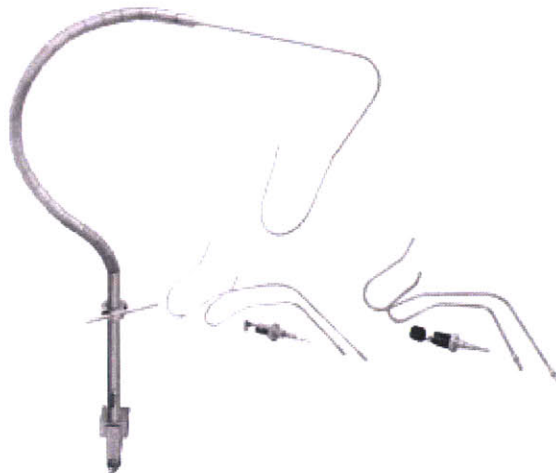
additional port to hold the liver aside. This instrument can range from a standard laparoscopic grasper to a specially designed laparoscopic retractor that expands once inserted into the body. Figure 3 shows two different types of expanding retractors that necessitate the creation of an additional port.



**Figure 3:** Several types of laparoscopic articulating fan retractors (from the online Arrow Medical Devices catalogue).

The use of a standard grasper or other laparoscopic instrument such as those shown in figure 3 to manipulate the liver through an additional trocar port is the accepted current best practice for holding the liver aside during laparoscopic surgery.

Another device that is used to hold the liver aside is a specialized retractor called a Nathanson liver retractor. This device is a curved metal hook that is threaded into the abdomen through a trocar incision. The hook is placed around the liver and pulls the liver aside. The device is then anchored to the operating table with an adjustable fixture. Figure 4 shows a standard Nathanson retractor set.



**Figure 4:** Nathanson liver retractor and fixture used in laparoscopic surgery (from the Nathanson Liver Retractor page of the Mediflex Surgical Products website).

Another strategy that is employed is hand-assisted laparoscopic surgery. In this technique, a larger additional incision is made into which a large access port with an adjustable opening size

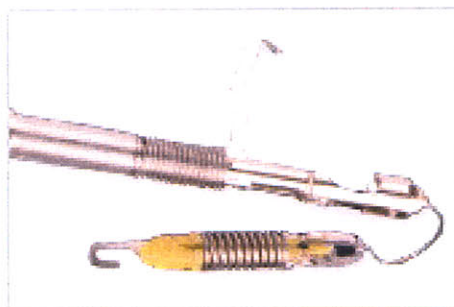
is inserted. The surgeon can insert his or her hand into the abdominal cavity and assist with the procedure while maintaining pneumostasis (no air escapes the abdominal cavity). Figure 5 shows the device that is used to allow the surgeon manual access inside the abdominal cavity.



**Figure 5:** *Device used in hand-assisted laparoscopic surgery. Tight fit around surgeon's wrist maintains pneumostasis (from the online product catalogue of the Ethicon-EndoSurgery website).*

Although this method causes a significantly greater degree of harm to the patient, it allows surgeons who are more comfortable with traditional open surgery to be able to manually manipulate various anatomical structures.

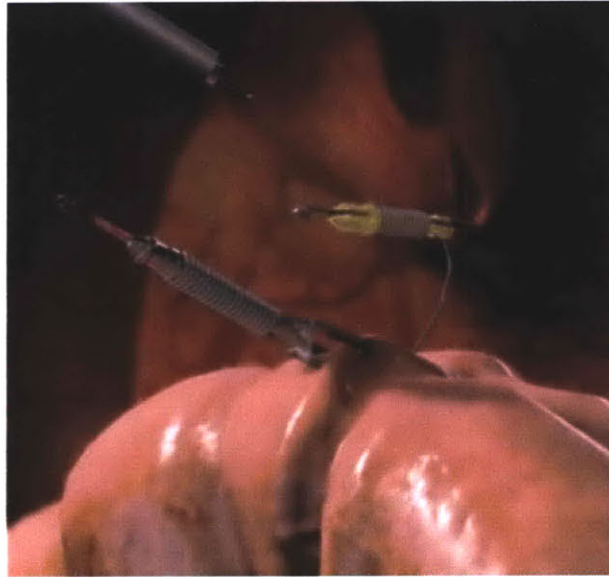
In conducting research on existing products and methods for this project, a company was discovered that claims to have invented a device that could retract abdominal organs without the need for an additional incision. The company, Virtual Ports Ltd., is preparing to market their device called the EndoGrab™. Figure 6 shows the EndoGrab™ as displayed on the company's website.



**Figure 6:** *The EndoGrab™ device as displayed on the Virtual Ports Ltd. website (from the EndoGrab™ page of the Virtual Ports website).*

The company claims that this device is inserted through an existing trocar incision with a proprietary introduction device and anchors to the desired organ and then to the abdominal wall. The method of anchoring, although not explicitly stated by the company's website, appears to be a set of clamps, one blunt clamp for the organ and one sharp clamp for the abdominal wall. Figure 7 shows a frame from a video on the company's website in which the device has been deployed and anchored to both the colon and the abdominal wall.





**Figure 7:** *Frame from Virtual Ports Ltd. website showing EndoGrab™ device fully deployed and retracting colon (from the EndoGrab™ informational video on the Virtual Ports website).*

The only organ specifically named by the website is the colon, which has substantially different mechanical properties from the liver. It would be interesting to see if this device is successful at retracting anatomical structures that are significantly less elastic, harder or less safe to grasp, or much heavier than the Colon. In addition, it would be interesting to know if the clamp that pierces and transfers the weight of the organ to the abdominal wall causes any significant trauma to the abdominal wall.

#### **IV. Problem Statement**

In laparoscopic surgical procedures performed on the right kidney, the lower right corner of the liver often obstructs the target surgical site. Currently, this situation is remedied by the insertion of a third instrument port in the patient's abdomen through which another instrument is inserted to lift and hold the liver to the side of the surgical site. However, the addition of an extra port incision increases post-operative pain, risk of infection, and residual scarring. Additional ports are opened with surgical devices called trocars. It is generally accepted in the medical world that trocar insertion is the element of highest risk during laparoscopic surgery and accounts for the greatest number of complications during laparoscopic procedures (Hashizume). As a result, this method of adding an extra port significantly increases the overall risk of the procedure and discomfort to the patient.

If a device were developed that succeeded in un-obstructing the target surgical site without the addition of another port, the benefits to the patient in terms of procedure recovery and to both the patient and the surgeon in terms of procedural risk would be significant.

#### **V. Design Requirements**

Table 1 shows a list of the design requirements derived from the problem statement for this project, including detailed definitions for each.

**Table 1:** *Design Requirements for the device in this project.*

Short Name	Description
Retract Liver (Primary Design Requirement)	The device must hold the liver out of the field of view of the surgeon for sustained periods of time.
Reduced Risk to Patient	The risk to the patient from using the device during surgery should be less than the risk from using the current best practice.
Decreased Discomfort	The discomfort caused to the patient by the device should be less than that caused by the current best practice.
No Additional Ports	The device must be deployed, operated, and removed through existing laparoscopic entry ports.
Reliability	The device must operate in a repeatable manner.
Biocompatibility	The device must follow FDA guidelines for biocompatibility.
Cost Effectiveness	The device should be cost-effective for hospitals, purchasing organizations, and medical insurance companies, and the manufacturer.
Easy to Operate	The device must be easy to operate for surgeons and operating room nurses.
Reusability	If the device is designed to be reusable, it must be compatible with common sterilization techniques.
Safe Failure Mode	If the device fails, it must not cause harm to the patient.
Easily Located	If the device is lost from view within the body, it must be easily locatable through visual or radiological search methods.

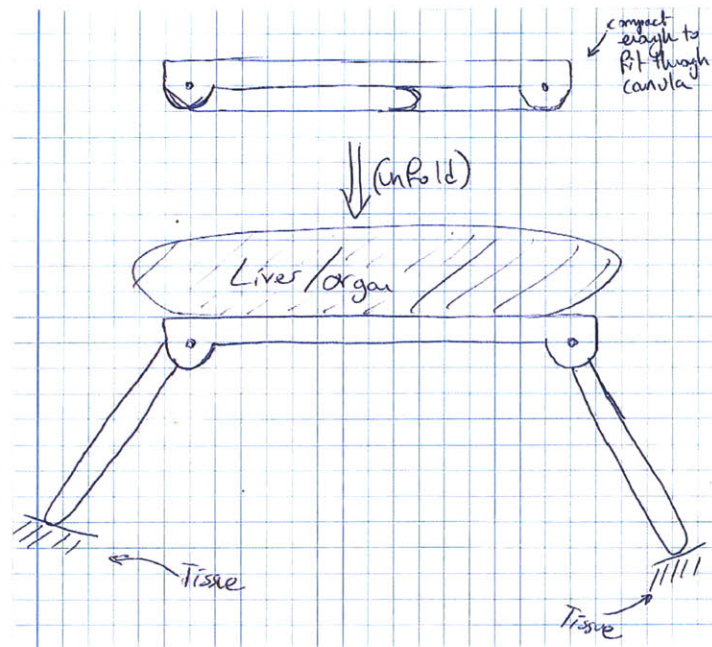
As can be seen in table 1, there is some redundancy in the design requirements. For example, the requirement of a safe failure mode can be incorporated into the requirement of reduced risk. In the case of formulating design requirements, it is most important to fully express the factors relevant to the design of the device. Therefore, some redundancy is permissible if it enhances the completeness and thoroughness of the listed design requirements. However, this redundancy must be carefully considered in choosing evaluation criteria for the concept selection phase of the design process, as described further in section VIII.

## VI. Concept Generation

In this project, general individual brainstorming was first used to develop possible concept solutions for the inventive problem. During brainstorming, the problem statement was approached as two separate design challenges. The first was the method of anchoring to the liver. This problem proved to be difficult because of the elasticity and slippery surface of the liver as described in section II. The second challenge was the method of applying a retracting force to the liver. Since an additional port could not be used, the surgeon could not simply pull

on the device holding the liver to move it out of the way as in the current best practice described in section III. Consideration of these two challenges led to the creation of six concepts.

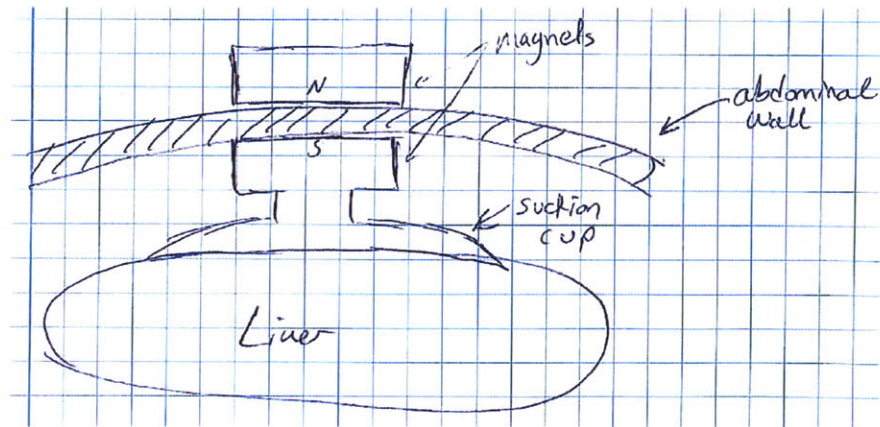
The first concept that was generated was a folding scaffold with a middle supporting section and two legs. The scaffold would be inserted through an existing trocar incision and then unfolded and placed under the liver to prop it up and out of the way of the surgical site. Figure 8 shows the “liver bridge concept” as first conceived.



**Figure 8:** Liver bridge concept as first realized.

Before other concepts were generated, several observations were immediately made about the liver bridge concept. First, this concept offered very little flexibility in positioning. In using the device, the surgeon would most likely have been constrained by where he or she could successfully position the device rather than being able to move the liver to any desired position. In addition, the legs of the device would likely experience difficulty in anchoring to the slippery walls of the abdomen. Finally, since the device could only expand to a certain height, the distance upwards to which the liver could be retracted would be limited. It was tentatively determined that supporting the liver from below was inferior to suspending it from above. As a result, most of the other concepts focused on a method of suspending the liver from above.

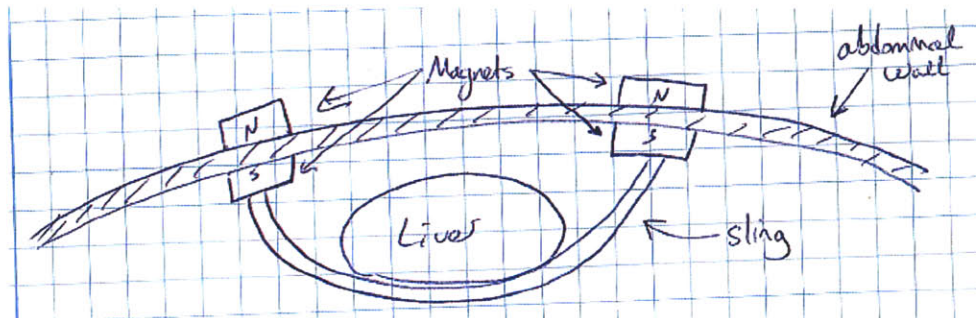
The second concept that was generated was a suction cup that anchored to the liver and then anchored to the abdominal wall by means of a set of magnets, one attached to the suction cup, and one placed on the outside of the abdominal wall. Figure 9 shows the “magnetic suction cup” concept as it was first visualized.



**Figure 9:** *Magnetic suction cup concept as first realized.*

Although not fully understood, the potential harmful effects of prolonged suction on the liver were immediately identified as a concern. In addition, it was not known whether the size restrictions on the device imposed by standard trocar dimensions would result in a small set of magnets that would apply an unsafe pressure to the section of abdominal wall compressed between them.

The third concept generated in this project was a reaction to the concerns caused by the suction employed by concept 2. Instead of one set of magnets and a suction cup, two sets of magnets would hold up both sides of a sling that could be passed under the liver. Figure 10 shows the “magnetic hammock” concept as it was first conceived.



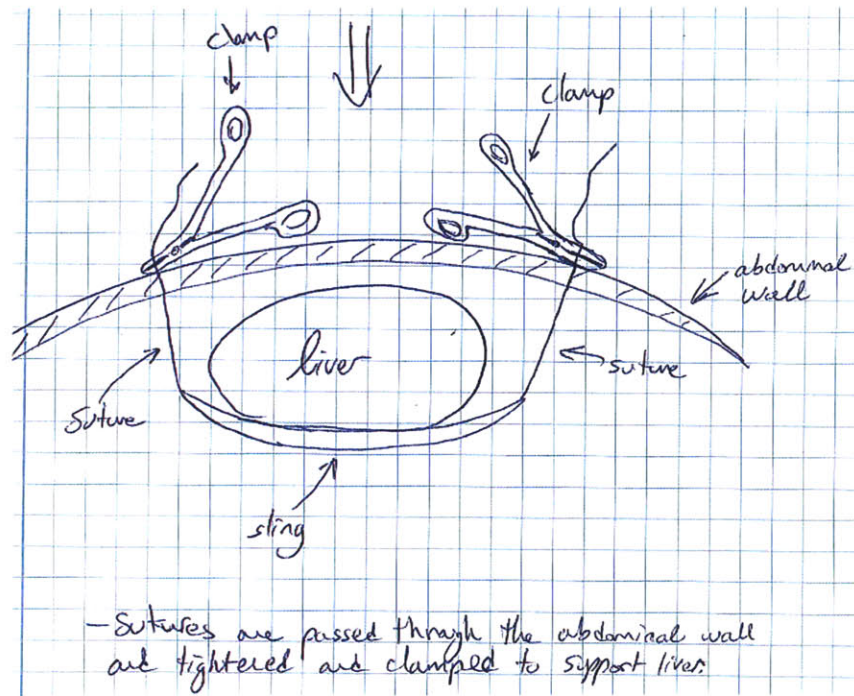
**Figure 10:** *Magnetic hammock concept as first realized.*

Although this concept resolved the concerns created by suction, the question of whether the small size of the magnets would be dangerous still remained.

The fourth concept that was generated was inspired by a previous experience of the author. During a previous design project, the author had observed urological surgeons performing a laparoscopic Pyeloplasty, which is a procedure in which the ureter (the tube connecting the kidney and bladder) is cut open to remove a blockage and then sown back together. Because this procedure is extremely delicate, surgeons must maintain complete visibility of the target surgical site. While watching the procedure, the author observed a technique to better visualize the surgical site in which the surgeon passed a suture through the abdominal wall, through the

connective tissue on the outer edge of the ureter, and back through the abdominal wall. By pulling on the suture from outside the abdominal cavity, the surgeon could suspend the ureter so that it was completely unobstructed. Since suture needles produce an essentially negligible incision, this method causes almost no risk or discomfort to the patient.

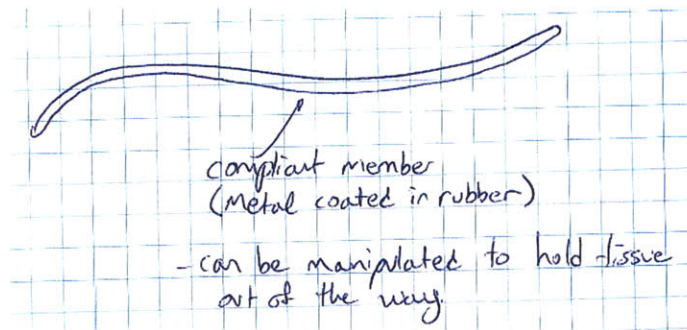
This technique was adapted in the development of the “liver sling” concept. This concept consisted of a hammock-like sling as employed in concept 3 with a suture at each end instead of a set of magnets. The sling would be placed under the liver, after which the sutures would be passed through the abdominal wall and tightened, suspending the liver much as the ureter was suspended during the observed Pyeloplasty. Figure 11 shows this concept as it was first realized.



**Figure 11:** Liver sling concept as first realized.

This concept was recognized as the first concept that did not prompt any immediate concerns. Although several design questions remained to be answered in order to make concept 4 a viable solution to the inventive problem, no apparently insurmountable barriers to the success of this concept could be identified.

The fifth concept that was conceived was driven by the discovery of the Nathanson liver retractor during research of current practices. It was noted that the Nathanson retractor had been shaped especially to fit the function of retracting the liver. Based on the examination of this retractor, the “pipe cleaner” concept was designed to allow the surgeon to create a supporting structure in any shape or orientation for the liver. This concept consisted of a ductile metal coated in rubber that could be bent by the surgeon to support the liver from below as in concept 1. Figure 12 shows this concept as first visualized.

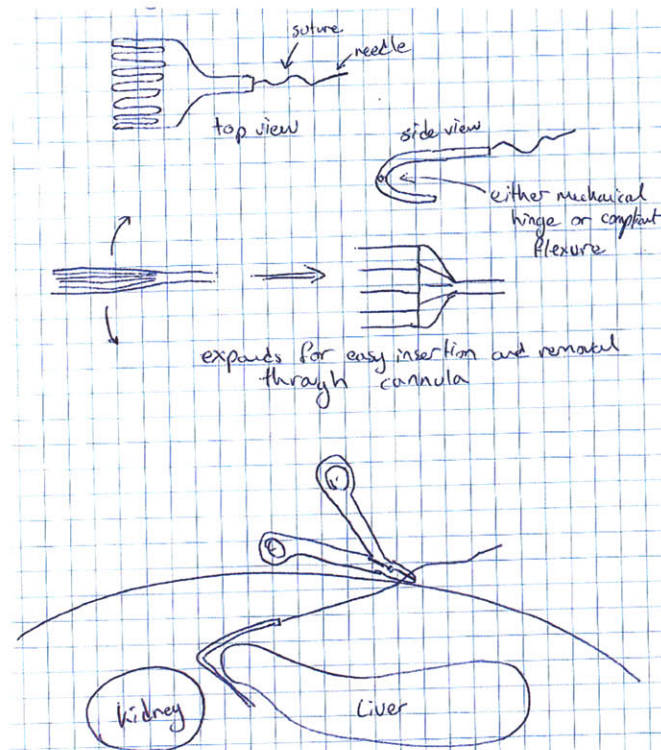


**Figure 12:** *Pipe cleaner concept as first realized.*

Although this concept offered a very simple design, the dependency on the surgeon to determine the correct orientation and form for the device caused immediate concern.

The sixth and final concept generated during brainstorming was conceived while reflecting on concept 4. The existence of two sutures in this concept had been identified as a possible concern for several reasons. Protecting two sutures so that they remained untangled and unexposed to prevent harm to the patient during insertion of the device appeared to be a difficult design challenge. In addition, it was realized that the location of the points at which the sutures were passed through the abdominal wall determined the position of the sling when the sutures were tightened. As a result, if the sutures were not positioned correctly relative to each other, the sling had the potential to slip from under the liver or not lift the liver to the desired position.

The “expanding rake” concept was conceived as a solution to the issues raised regarding concept 4. Instead of two sutures, this concept employed one suture that was passed through the abdominal wall and tightened. Instead of a sling, the suture was attached to a collapsible “rake” device with a series of bent “fingers”. These fingers would be hooked over the top of the liver and would pull the liver away from the target surgical site when the suture was tightened. Figure 13 shows this concept as it was first conceived.



**Figure 13:** Expanding rake concept as first realized.

Although this concept was more complex than the liver sling idea and involved several challenging design questions, it appeared to resolve the worries surrounding the liver sling. In addition, it did not raise any new significant concerns.

## VII. TRIZ Methodology

The “Theory of Solving Inventive Problems,” abbreviated as “TRIZ” in Russian, was developed beginning 1946 by Genrich Altshuller, a Russian Patent Inspector and Inventor (*And Suddenly*). Traditionally, invention and concept generation was thought of as a completely creative process rather than a scientific method. It was thought that skill as an inventor was driven by innate creativity and experience in necessary technical fields, and that the actual process of inventing a new concept could not be learned or understood. Altshuller believed otherwise, and endeavored to develop a specific analytical method for solving technical problems. After studying thousands of patents, Altshuller discovered patterns of technical evolution that could be generally applied. From these patterns, he developed a methodology that would lead to the formation of new concepts when applied to nearly any inventive problem. As opposed to traditional brainstorming, TRIZ is a specific sequence of steps. Subsequently, TRIZ made it possible for invention to be taught and practiced. In fact, many schools of TRIZ were founded across the USSR when the theory was first published (*40 Principles* 12).

The theory of TRIZ is based on the supposition that a true inventive problem is defined by one or more contradictions. A contradiction is the apparent inability to improve one quality of a technical system without worsening another quality. As an example, the problem of creating a

more powerful airplane engine contains the contradiction that in order to increase the power output of the engine, the weight and size of the engine, both negative attributes, must be increased (*40 Principles* 17).

In order to overcome these contradictions, Altshuller developed a set of 40 principles that could be applied to solve the given inventive problem. These principles include “Segmentation”, which is defined as separating an object into independent parts, making an object sectional for easy assembly or disassembly, or increasing the degree of an object’s segmentation (*40 Principles* 24). This might involve separating the pole of a temporary traffic sign into separate sections of shorter length that can be easily transported.

To guide the application of his 40 Principles to various contradictions, Altshuller developed the Contradiction Matrix. The matrix combines the characteristics of a system to be improved (on the vertical axis) with those characteristics that become worse as a result (on the horizontal axis). In each cell of the matrix representing a contradiction between two characteristics, several of the 40 Principles are listed that are most likely to solve the given contradiction. If the recommended principles do not produce a solution, the rest may be applied. Continuing with the example of the airplane engine described above, this problem represents a contradiction between power (characteristic 21), and volume of a stationary object (characteristic 8). In this case, the Contradiction Matrix recommends Principle 6, or Universality. Universality is defined as “an object can perform several different functions; therefore, other elements can be removed” (*40 Principles* 34). If there is a gas-powered generator in the airplane to generate electricity for the cockpit controls and other systems, the motor driving this generator could be removed and the generator could be directly coupled to the engine of the airplane. This would increase the available volume in the plane, allowing for a larger engine. In this way, the theory of TRIZ can be applied to nearly any inventive problem containing a contradiction.

In this project, the theory of TRIZ was employed following traditional brainstorming in the hope that further concepts would be generated. As dictated by the TRIZ method, the technical contradictions inherent to the problem statement were defined. Table 2 shows the contradictions that were identified for this inventive problem.

**Table 2:** *Contradictions identified for the formulated problem statement in this project.*

Characteristic Getting Better		Characteristic Getting Worse	
Name	Number	Name	Number
Safety	31	Convenience of Use	33
Safety	31	Device Complexity	36
Safety	31	Complexity of Control	37
Safety	31	Capacity/Productivity	39
Safety	31	Loss of Time	25
Loss of Time	25	Complexity of Control	37
Stationary Volume	8	Stability of Composition	13

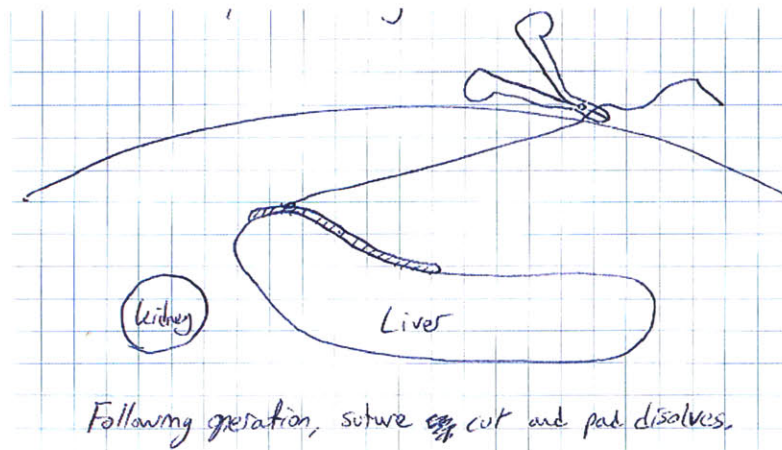
These contradictions were applied to the Contradiction Matrix. The recommended principles were identified from the matrix and are shown in table 3.



**Table 3:** Principles recommended by the TRIZ Contradiction Matrix for contradictions listed in table 2.

Principle Number	Principle Name
1	Segmentation
2	Extraction
9	Prior Counteraction
18	Mechanical Vibration
19	Periodic Action
21	Rushing Through
22	Convert Harm into Benefit
27	Dispose
28	Replacement of Mechanical System
31	Porous Materials
32	Changing the Color
34	Rejecting and Regenerating Parts
35	Transform Properties
39	Inert Environment
40	Composite Materials

Each of the principles shown in table 3 was applied to the inventive problem. The application of the principle of Rejecting and Regenerating Parts led to the idea of using a dissolvable material as a means of retracting the liver. The material could adhere to the liver and be anchored to the abdominal wall with a suture as first conceived in concept 4. This thought process led to the formation of concept 7 (dissolvable adhesive). Figure 14 shows concept 7 as it was first visualized.



**Figure 14:** Dissolvable adhesive concept as first realized.

The application of TRIZ to the inventive problem in this project resulted in the formation of one additional concept. Although this concept had positive, it was noted that the adhesive pads raised significant questions about FDA clearance of the device. Although the volume of ideas produced by TRIZ was significantly less than that of traditional brainstorming, it must be

considered that TRIZ was applied after traditional brainstorming had been attempted. It is therefore reasonable to suppose that many of the concepts produced by traditional brainstorming would have been discovered using the TRIZ methodology had TRIZ been applied first. It is also interesting to note that although it did not emerge directly from the TRIZ methodology, concept 6 (expanding rake) was conceived in a parallel thought process while applying TRIZ to the inventive problem.

## **VIII. Concept Selection**

Once the seven concepts described above had been produced and the two methods of concept generation had been attempted for the allotted time within the project, a concept selection method was applied to select the most viable concept for further development. For this project, the Pugh Selection Matrix methodology for concept selection was applied. This method involves generating evaluation criteria for a set of concepts. These criteria should capture the design requirements derived from the problem statement in order to identify the most viable concept for the given problem statement. It is important to consider eliminating redundancies present in the design requirements in order to achieve the most accurate concept ranking. Once the criteria are established, a datum concept is chosen against which to compare each concept. Either an existing solution to an inventive problem or one of the concepts to be evaluated can be chosen. With the datum chosen, each concept is evaluated against the datum for each criterion on a +1, 0, -1 scale, meaning that the given concept meets the criteria better than, as well as, or worse than the datum concept. This simple scale eliminates a certain degree of subjectivity from the concept selection process. The total score for each concept is determined, and the concept with the highest score is chosen as the most viable concept. If this concept is abandoned at a later point in the design process, the second concept in the score order is chosen for further development, and so on.

In order to pick the best concept to solve the original inventive problem, the evaluation criteria for this project were derived directly from the functional design requirements developed from the problem statement. Several design requirements were not considered in the formation of design criteria because they could not be achieved on a variable scale. For example, all the concepts formulated during concept generation met the principle design requirement of holding the liver out of view of the surgeon to an equal degree. One additional criterion was added that was not related to the design requirements. Although not significant to the design of the device, the predicted skepticism toward the concepts was considered important in choosing between them. This evaluation criterion can be called a “reality check”, in that the concept that is most viable from a technical, ergonomic, and safety standpoint may not be the one that is preferred by end users who do not evaluate the concepts in a methodical manner. It is crucial to consider such factors as important to the success of a device, which is the reason why this criterion was included in the concept selection matrix for this project.

Concept 4 (liver sling) was chosen as a datum for the selection matrix. Table 4 shows the evaluation criteria, concept scores, and score totals for the seven initial concepts developed in this project.

**Table 4:** Evaluation criteria, concept scores, and score totals for concepts evaluated in this project.

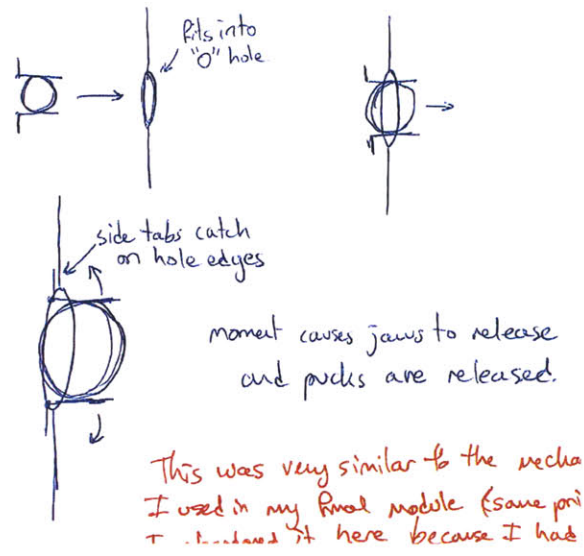
Evaluation Criteria	Concept Number:						
	1	2	3	4	5	6	7
Reduce Risk to Patient	-	-	0	0	+	+	-
Reliable (sturdy design)	0	-	-	0	-	+	-
Robust (consistent results)	-	-	0	0	-	+	-
Biocompatibility	+	0	0	0	0	+	-
Cost Effective	+	-	-	0	+	0	-
Easy to Manufacture	+	-	-	0	+	0	0
Easy to Operate	-	0	0	0	-	+	-
Safe Failure Mode(s)	-	-	0	0	0	0	-
Predicted Skepticism	0	-	-	0	-	+	-
Total Score	-1	-7	-4	0	-1	6	-8

As shown in table 4, concept 6 (expanding rake), had the highest score by a significant margin. As a result, it was chosen as the concept with which to proceed, with concept 4 (liver sling) as a second choice in the case that concept 6 was abandoned.

## IX. Concept Refinement Stage I

Following concept selection, a first level of design completion and refinement was performed for the chosen concept. Because the concepts evaluated in the selection matrix were not fully developed, several design questions needed to be answered in order to proceed with concept 6. These included determining the specific method of introduction into the body and expansion of the “rake fingers”, the actual number of fingers, and the type of joints that would be used in the device.

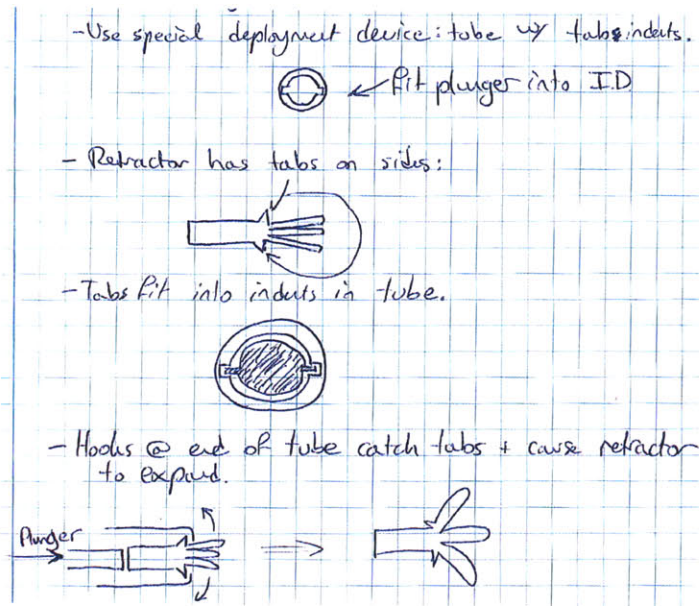
When designing the specific method of introduction and expansion of the device, a list of common objects as well as mechanisms from past experiences that expanded in the same way as the device fingers were intended to expand was considered. In developing this list, a design project from the author’s undergraduate education was recalled. In a class called “2.007 Design and Manufacturing I”, the author designed and built a robot to participate in a competition. The competition involved scoring points by moving hockey pucks and rubber balls around a playing field and into marked bins. During that design project, the author designed and incorporated a mechanism into his robot that held a stack of hockey pucks and released them when the mechanism was inserted into a hole in one of the bins. Figure 15 shows a page from the author’s design notebook detailing the design of the mechanism.



**Figure 15:** Mechanism designed to release pucks into scoring bin.

As can be seen in figure 15, the mechanism relied on spring-loaded latches that opposed the force of gravity and held the pucks inside the mechanism. When tabs connected to the latches were forced against the edges of the hole in the bin, the latches moved outwards, allowing the pucks to fall into the bin.

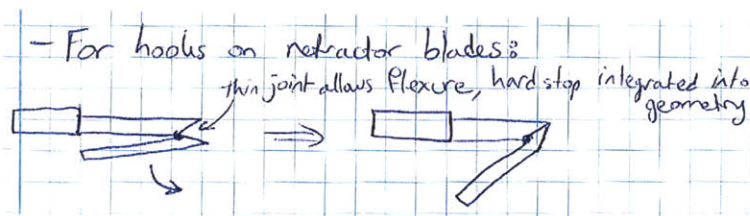
It was realized that this mechanism could be applied to the problem of expanding the device fingers in this project. The latches in the original design could represent the fingers of the device in this project, and the edges of the hole in the scoring bin could be a short section of reduced diameter at the end of an introducer device. If the tabs were shortened significantly but still extended past the reduced diameter of the end of the introducer, the fingers of the device would expand outwards as the device were forced out of the tube by a plunger or similar mechanism. In order to aid in device alignment and to ensure that the section of reduced diameter of the introducer did not catch the fingers of the device, the tabs on each finger could slide along slots along the inner walls of the introducer tube. Instead of a section of reduced diameter, the slots would end very close to the end of the tube, providing the same effect. Figure 16 shows a page from the author's design notebook for this project that illustrates the geometry of the expansion method and introducer device.



**Figure 16:** *Introducer device and expansion method for liver retractor.*

The question of how many fingers to include on the device was next addressed. When the expansion method for the device was first developed and illustrated, three fingers were included on the device as shown in figure 16. One finger remained in the same position, and one on each side expanded outwards. Although unintentional, this chosen number of fingers allowed for the desired functionality while still maintaining a simple design. In addition, since the size of the device was significantly constrained by the size of common trocars (inner port diameter of .5 inches or ~12 millimeters), each additional finger would mean a reduction in size and subsequently a worsening of mechanical properties for all fingers. As a result, the choice of three fingers for the device was maintained.

Finally, the specific design of the joints in the device was considered. Two sets of joints exist within the device. The first set allows the expansion of the fingers outwards as the device exits the introducer. The second set allows the expansion of the second section of each finger outwards to create the hook effect that can hold the liver. For this second set of joints it was noted that their design must be such that the fingers could open from their collapsed position to their open position but not past their open position. As a result, the design of the joint required a hard stop to prevent motion past the open position. This was accomplished by extending the device fingers past the joint. These material extensions acted as a hard stop for the motion of the joints. Figure 17 shows the design of the finger section extension joints as realized in the author's design notebook.

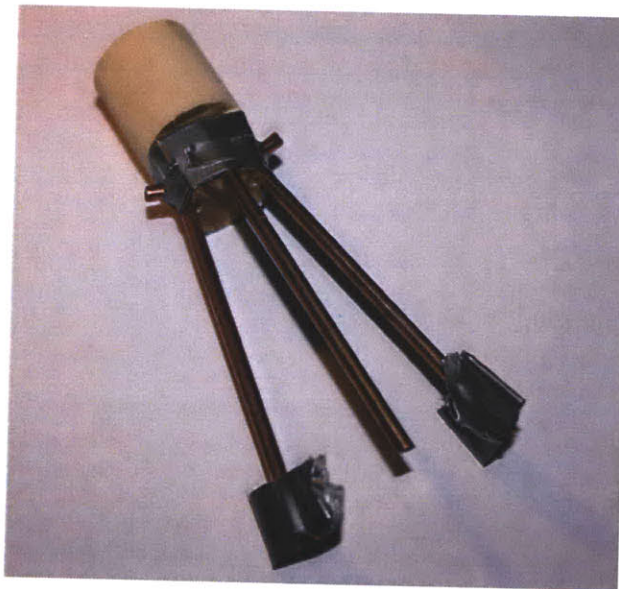


**Figure 17:** *Design of finger extension joints including hard material stop.*

Because of the very small scale of the device, mechanical joints would be very difficult to design and manufacture successfully. As a result, it was decided that all joints in the device would be purely flexural.

## X. Sketch Model

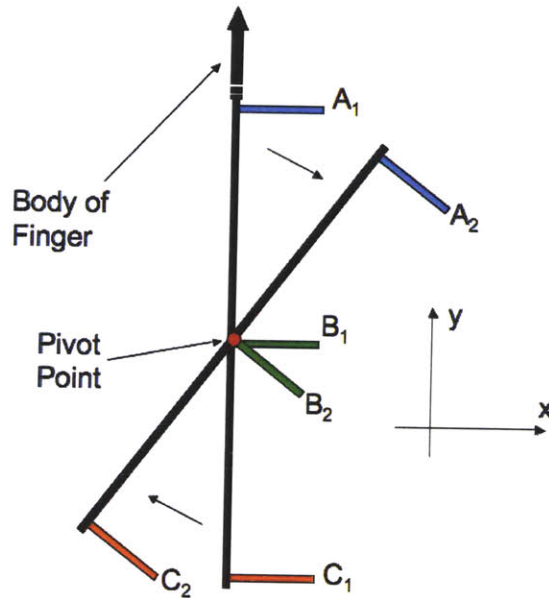
In order to prove the basic functionality of the concept as well as visualize and communicate the concept features, a set of two sketch models was built. The first model was built to demonstrate the introduction and expansion mechanism of the device as developed in the first stage of concept refinement. Using PVC tubing and wooden dowels, large-scale models of the introducer instrument and device were made. Welding rod was used to model the device fingers and was bent at the ends to model the tabs that would slide along and catch the end of the slots in the introducer tube. Figure 18 shows the sketch model that was made to simulate the introduction and expansion of the device.



**Figure 18:** *Sketch model of device demonstrating finger expansion method.*

This sketch model revealed an important geometrical condition in the proper function of the expansion mechanism. When handling the model to demonstrate its functionality, it was noticed that a surprising amount of force was required to cause the device to exit the introducer tube. In addition, the fingers expanded outwards to a much greater angle than originally intended. To further examine this observation, a geometric analysis of the tabs causing the fingers to spread was conducted. In this analysis, it was discovered that an artificial pivot point can be defined for each device finger as the point about which the movement of the finger can be described as pure rotation and no translation. In addition, the tab tip point can be defined as the point on the tab that is farthest from the pivot point for the given finger. Figure 19 shows a section of one device finger at two positions along the rotation about its pivot point. Three possible tab locations are

shown in this figure, one on the same side of the pivot point as the body of the finger (blue tab: position A), one at the pivot point (green tab: position B), and one on the opposite side of the pivot point (orange tab: position C).



**Figure 19:** Rotation of finger about pivot point with three possible tab positions shown.

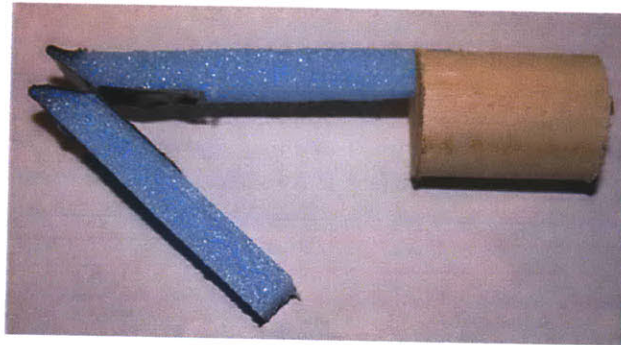
As is shown in figure 19, the tab tip points for positions B and C move inwards (in the negative x direction), while the tab tip point for position A moves outwards (in the positive x direction). Since the distance between the tab tip point and the pivot point remains constant, and since the expansion of a finger is defined as pure rotation about its pivot point, the tab tip point follows a circular path about the pivot point during finger expansion. Whenever the tab tip point is above the pivot point in the axial direction of the device (farther along the y axis in figure 19), it will move outwards as the finger expands outwards. Whenever the tab tip point is below the pivot point in the axial direction of the device (less far along the y axis in figure 19), it will move inwards as the finger expands outwards. For tab position A in figure 19, the tab tip point is initially above the pivot point which is why the tab tip moves outwards as the finger expands. However, the tab tip point will reach a point on its path where it is at an equal distance along the axial direction as the pivot point, at which point it will begin to move inwards as the finger continues to expand. For position C, the tab tip is initially below the pivot point, which is why it moves inwards as the finger expands outwards.

This phenomenon is critical in the design of the device because in order for the device to exit the end of the introducer tube, the width of the part of the device that is contained within the tube must decrease to a value less than that of the diameter of the end of the introducer tube. This width can be defined as the contained width of the device. Initially the tabs on both fingers extend past this diameter in order to catch the end of the tube and cause the fingers to expand. Following the analysis described above, in order for the device to exit the tube, the tab tip point on each finger must have moved inwards enough for the contained width of the device to be less than the diameter of the end of the tube. If the tab tip point is located above the pivot point as in

position A in figure 19, the fingers will have to expand to a greater angle outwards than if the tab tip point is located below the pivot point as in position C. Therefore, it is critical to know the desired final angle of expansion of the device fingers upon exiting the introducer tube in order to properly design the location of the tabs on the device fingers.

Aside from revealing the importance of the location of the tabs on each finger, this sketch model demonstrated the functionality of the intended method of introduction and expansion of the device.

The second sketch model was build to demonstrate the proposed joints for the device, as designed in phase I of concept refinement. This model focused on the joints between the two sections of each finger. Figure 20 shows the sketch model that was created to demonstrate the design of the device joints.



**Figure 20:** *Sketch model of device demonstrating design and functionality of flexural finger joints with hard stop. Flexural element simulated with duct tape.*

This model was successful in aiding the visualization and understanding of the motion of the finger joints. The information gained from these two sketch models made it possible to proceed to further design refinements in preparation for the construction of an alpha prototype.

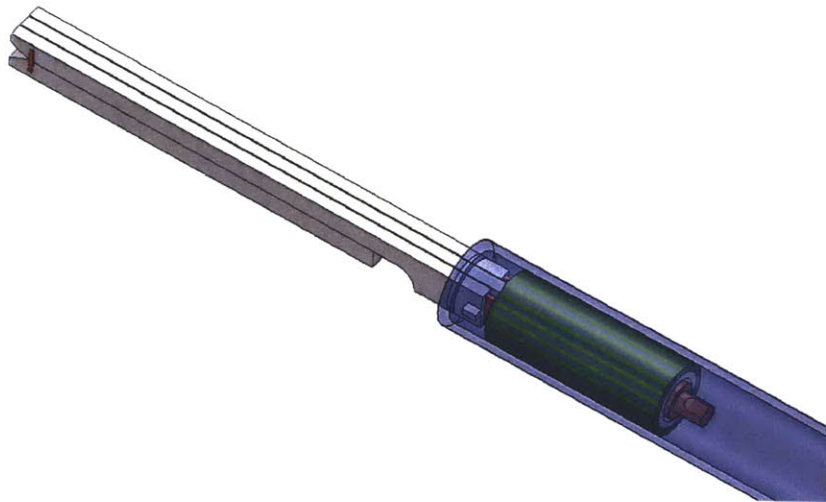
## **XI. Detailed Design and Refinement Stage II**

With the information gathered in building and studying the sketch models, a second level of design refinement was completed for the device in order to begin constructing an alpha prototype. As opposed to only solving basic design questions, this phase of refinement focused on determining the specific geometry of the device as well as design for manufacturing of the device.

Before proceeding with the detailed geometrical design of the device, an important design change was made. When considering manufacturing techniques for the alpha prototype of the device, it was realized that the slots on the inside of the introducer tube in which the finger tabs were intended to slide would be difficult to construct. In building the sketch model, these slots had been built by cutting through a PVC plastic tube with a band saw and then inserting the tube into a larger tube to simulate slots cut into the inner wall of one tube. Although this method worked for the sketch model due to its large scale and allowable dimensional inaccuracy, the



much smaller scale and necessary geometrical accuracy of the final device made this technique unacceptable. Another possible technique that was considered was to injection mold the introducer tube. Although this method would create the desired geometry with great accuracy, the costs and manufacturing time associated with machining molds made this method impractical for constructing an alpha prototype. In addition, rapid prototyping was also considered as a fabrication method. Although this manufacturing technique could also produce the required geometry, the grainy finish of 3-D printed parts raised a concern that the device would be unable to slide smoothly within the introducer tube and might get stuck. Finally, it was decided to abandon the decision to add slots on the inner diameter of the introducer tube and return to the method of creating a short section of reduced diameter at the end of the introducer tube. In order to maintain alignment of the device within the tube, the device would fit inside a sliding ring that filled the space between the outer diameter of the device and the inner diameter of the tube. The ring would be left within the introducer tube when the device exited the tube. Figure 21 shows a transparent view of the introducer tube containing the sliding ring and the device.

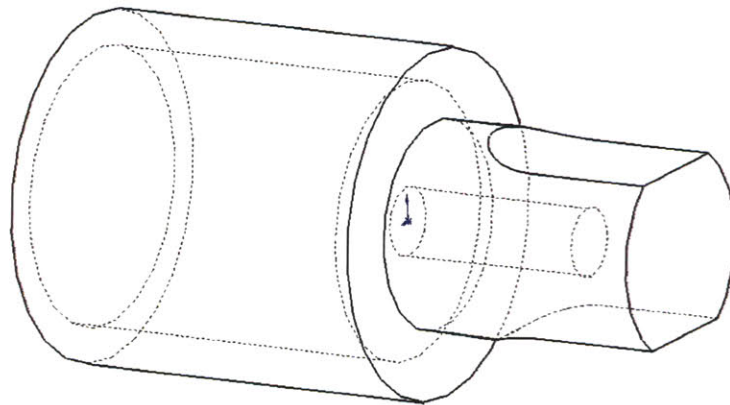


**Figure 21:** Solid model of introducer tube (transparent blue) with device (grey, red, orange) and sliding ring (green) inside the tube. Note that the fingers of the device have exited the end of the tube while the body of the device still lies inside the tube.

Several geometric constraints were important at this stage in the design of the device. First, the device had to fit inside a standard laparoscopic trocar. Standard trocars are made in two sizes, the larger with an inner diameter of 12 mm, and the smaller with an inner diameter of 5 mm. For this project, the device was designed to fit through the larger size of standard trocars in order to allow for the largest possible available device volume. As a result of this constraint, the outer diameter of the introducer tube was limited to 12 mm. Because standard metric stainless steel tubing is often made in wall thicknesses of 1 mm, an inner diameter of 10 mm for the tube was chosen. The outer edge of the device body (not including the finger tabs) was limited to 8 mm. This created a space of 1 mm around the circumference of the device for the finger tabs to extend into. The section of restricted diameter at the end of the tube was chosen to have an inner diameter of 8 mm and a length of 1 mm, so that the device would be able to pass out of the tube but the finger tabs would be caught by the restricted diameter in order to extend the fingers. In addition, the fingers were dimensioned such that they would fit through the section of reduced diameter. Finally, the fingers had to be long enough to successfully hold the liver, which, as

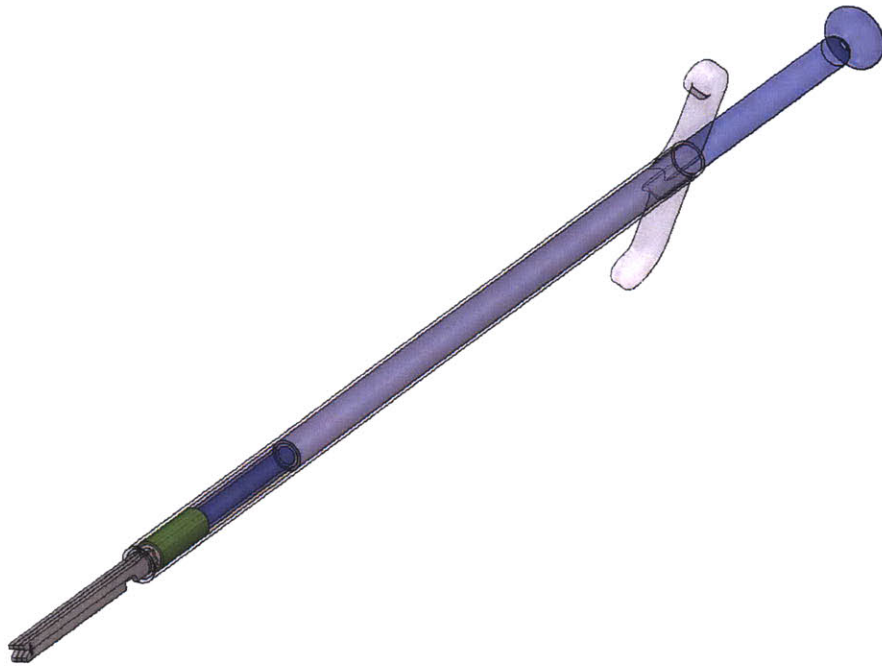
shown in figure 2, is a rather large organ. It was determined that a finger length of approximately three inches was sufficient to grasp and hold the liver.

Another design question that was answered during this stage of concept refinement was the method of storing and protecting the suture and needle during device insertion and handling. To solve this problem, it was determined that the suture should be wound and stored in a cavity within the device body. The suture would be anchored to the device at the base of this cavity. The needle of the suture would be press-fit into an end cap covering the opening of the cavity. In this way the suture and needle would be completely encased during device insertion. Once the device exited the introducer tube, the surgeon could remove the end cap by grasping it and pulling it away from the device with a standard laparoscopic grasper. The cap would separate from the device bringing the needle with it and beginning to unravel the suture. Only once the surgeon held the end cap and pulled the needle out of it would the sharp tip of the needle be exposed. The end cap would then be removed through a trocar incision with standard laparoscopic graspers. Figure 22 shows a drawing of the end cap of the device with a cavity of small diameter in which to press-fit the needle during device assembly.



**Figure 22:** *End cap for device with small cavity to contain needle.*

Once these design decisions had been made, a CAD model of the device was created to produce accurate part drawings and solid models for use in prototype construction. Figure 23 shows the assembly containing all of the device and introducer instrument components.



**Figure 23:** *Assembly of device and introducer instrument following detailed design and refinement.*

With this CAD model complete, a more complete and accurate model of the device could be constructed.

## **XII. Alpha Prototype**

In order to collect accurate user feedback and further understand the device, an alpha prototype was constructed. If the product were to ever be produced on a large scale, the parts comprising the main body of the device would most likely be manufactured using injection molding. However, due to the high cost and lead time associated with injection molding, the alpha prototype was manufactured using a rapid prototyping method known as three-dimensional printing. This method produced functional components at a very low cost. The devices were assembled using high-strength glue. The introducer components were manufactured with standard machining techniques from stainless steel and polyoxymethylene plastic. Figure 24 shows the completed alpha prototype of the device and introducer.



**Figure 24:** *Alpha prototype of device.*

Although this prototype was constructed successfully, its small size made assembly very difficult and tedious. It was noted that further design for manufacturing and assembly was necessary to allow the product to be manufactured on a large scale.

### **XIII. User Feedback**

In order to ensure that the device was not only well designed from a technical standpoint but also from an ergonomic and medical standpoint, the alpha prototype was shown to Dr. Hiep Nguyen, the Co-Director of the Center for Robotic Surgery and Director of Robotic Surgery Research and Training in the Urology Department of Children's Hospital in Boston, MA. After listening to an explanation of the device and examining the prototype, Dr. Nguyen had several comments regarding its design.

Overall, Dr. Nguyen's impression of the device was positive. He identified no significant roadblocks to further development of the retractor, and identified several key design questions for the future of the product.

There were several features that Dr. Nguyen noted as positive about the device. First, he complimented the simplicity of the design and operation of the device. The fact that the device opened on its own due to the tabs on each finger, he said, was a very positive feature. In addition, Dr. Nguyen mentioned that he liked the fact that several devices could be deployed into the abdominal cavity, allowing the surgeon to retract a larger section of the liver or even surrounding structures as well. Dr. Nguyen also identified the device end cap protecting the point of the needle as a well-designed device feature. Finally, he liked the fact that adjusting the length of suture between the device and the abdominal wall could vary the distance by which the liver was retracted.

Dr. Nguyen identified one key concern regarding the design of the retractor. Upon seeing the needle stored in the end cap of the device, Dr. Nguyen mentioned that the needle would be too small to pass through the abdominal wall of some adult patients. In adults with a high percent body fat, he explained, the abdominal wall could be up to two inches thick. In such adults, the needle presently integrated into the device would certainly not pass through the abdomen and

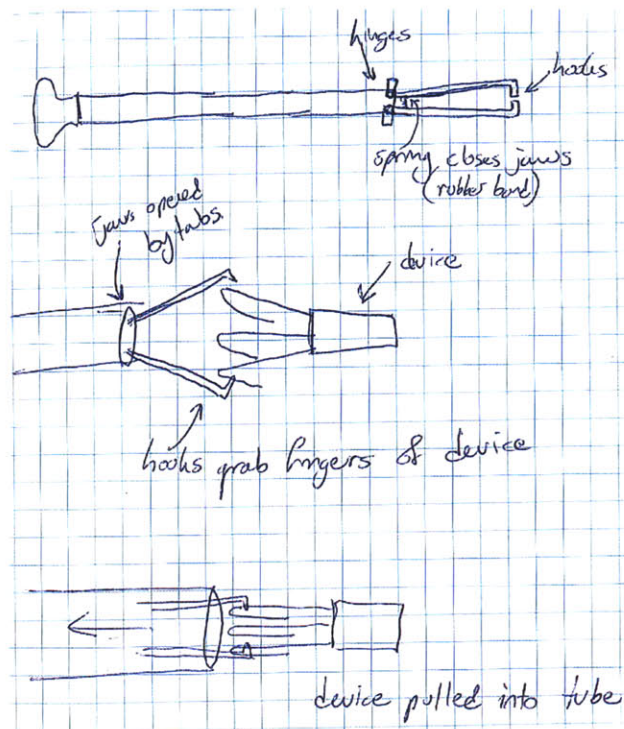
might even get lost inside the fatty tissue when the surgeon attempted to pass it through to the outside of the body. Dr. Nguyen suggested elongating the needle and creating more space for it by either extending the cavity within the body of the device or even elongating the device as well if necessary.

Dr. Nguyen also emphasized the importance of a simple and reliable method of removing the device at the end of the procedure.

#### **XIV. Future Development**

If the development of this device continues past the completion of this study, several important factors to consider and design questions to answer have been identified. First, as mentioned in section XII, further consideration must be given to design for manufacturing and assembly of the device. One potential solution that was considered following the construction of the alpha prototype was to replace the multi-component finger elements with single structures made of bent ductile metal wire. The wire could be bent to create the necessary tabs on the outer fingers, and would be joined to the body of the device simply by gluing them into holes in the body of the device. In addition this simpler design could allow for the assembly of a smaller device, potentially allowing a version of the device that could be inserted through smaller trocars (5 mm standard inner diameter). This potential design change should be considered and evaluated in any future development of the design.

Another important design decision that remains to be resolved is the method of removal of the device from the body. A potential design for a removal device was conceived following the construction of the alpha prototype. This design involves a shaft that is inserted through the original introducer tube (with the plunger removed). The shaft has a set of long grasper-like jaws at the end with a hook on the end of each jaw arm. Tabs similar to those on the device spread the jaws when the shaft reaches the end of the introducer tube. The surgeon positions the hooks around the joints on the tips of the outer fingers of the device. When the shaft is pulled back into the tube, the jaws close, collapsing the fingers of the device and pulling it back into the introducer tube and out its other end. Figure 25 shows this removal device as it was first conceived.



**Figure 25:** Proposed method of removal for device.

This removal method involves a relatively simple design and should be considered in any further development of the device.

Finally, if this design process is continued in the future, extensive testing of the device is necessary to support the design decisions made during this project. Once the design is finalized to a point that models of the design can be made efficiently and in significant quantities, the device should be tested on both simulated and actual anatomical models. Apart from testing the reliability of the device, several variable quantities regarding the design of the device could be tested to determine the ideal values for each. These include the length of the fingers as well as the angle of extension of the fingers, which can be varied by changing the specific geometry of the tabs. Because of time constraints, extensive testing was not conducted as a part of this project.

Ideally, this device could be modified for use with a variety of organ and structures besides the liver. If future development occurs, this possibility should be studied and incorporated into the final design of the device.

## XV. Conclusion

Retracting the liver during laparoscopic surgery without causing additional risk and discomfort to the patient is a significant problem that is not remedied by current surgical techniques or devices. Over the course of this project, several possible solutions to this problem were developed using different concept generation methods. The most viable of these concepts was

chosen and taken through several stages of design refinement and prototype construction. Finally, user feedback was obtained from a potential end user of the device. Although several design questions remain unanswered and further consideration should be given to design for manufacturing and assembly if the project is to be continued, the device as presented at the end of this study represents a solid foundation to a sound solution for the inventive problem.

## **XVI. Acknowledgements**

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