University of Wisconsin-Madison

BME Mid-Semester Report

Marking of Laparoscopic Instruments for Video Recording

Authors:
Bryan Kloosterboer
Matthew Jensen
Jared Ness
Bradley Wendorff

Advisor:
Dr. John Webster
Client:
Dr. Carly Seaberg

October 25, 2011

Table of Contents

Abstract

A side effect of quality teaching methods, are students who perform the concepts they've learned at a high level. The medical field lends itself to engineers looking to improve upon current methods used to educate young doctors. Better-educated physicians generally will yield a higher surgery success rate. Laparoscopic surgeries require the use of a camera to serve as the surgeon's eyes, and recording of the surgery is often used to evaluate a resident's performance. Our client is requesting that we design an accessory-marking device to the standard laparoscopic instrument, so that when a teaching physician and resident are operating simultaneously, their instruments can be distinguishable on screen both during and post-surgery. Due to the nature of the project, we have implemented three different designs, based upon ratings illustrated in our design matrices. With the three prototypes, our future work includes vigorous testing and feedback from physicians in the field to improve upon their functionality.

Problem Statement

Laparoscopic surgeries require the use of a video camera to guide the physician's surgical maneuvers within the body. Often times, there will be a resident surgeon working side by side with a teaching physician. In this type of setting, it is ideal to be able to review film of the surgery to critique technique, but aesthetic similarities in instrument design make it difficult to distinguish which instrument belongs to whom. The goal of this project is to design a sterile accessory device to the laparoscopic instrument that makes it easily identifiable on camera, without adding any additional risk or complications to the procedure.

Background and Other Methods

Laparoscopic surgery, otherwise known as minimally invasive surgery or keyhole surgery, was first implemented on humans in 1910 by Swedish physician Hans Christian Jacobaeus. Its "minimally invasive" nickname is attributable to the small incisions that are made, which coincide with a shorter recovery time, minor scarring, and decreased risk of hernia development.

This technique is constrained to operations in the abdominal area, such as a cholecystectomy, which is a removal of the gallbladder, removal or part-removal of the colon, and various others. In order to improve on-camera visibility and maneuverability, the abdominal region is insufflated with carbon dioxide creating a dome-like workspace. Carbon dioxide is used, because tissue can absorb the gas, and then have it disposed of by the respiratory system. Rather than using one large incision common to a traditional

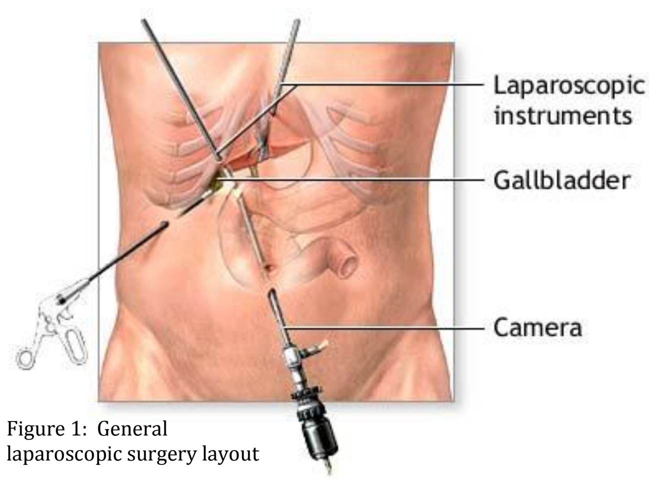

Figure 1: General laparoscopic surgery layout

open surgery, laparoscopic surgeries require three to four 0.5 mm to 1 mm incisions through which a trocar will be inserted. Trocars are the tubes through which the instruments are then inserted, leaving about 1 mm of space around the shaft of the laparoscopic instrument.

The laparoscopic instrument itself consists of a handle with a trigger like mechanism, connected to a 5 mm diameter shaft with lengths ranging from 28 cm to 36 cm depending on the patient to be operated on. A variety of tips are used as illustrated in Figure 2, some with cutting function, and others with grasping function.

There is currently no other competition on the market for this type of accessory device.

Figure 2: Variety of tip shapes and sizes used in laparoscopic surgeries

Client Requirements and Design Constraints

The client has specified several details that are necessities to be incorporated into the final design.

First and foremost, the device must be sterile and made out of a biocompatible material, to be introduced into the body. Sterility of the device may either come from the sterilization process itself if the device is deemed reusable, or by making the design sterile out of the package similar to a Band-Aid. If the final design is deemed to be reusable, it must able to withstand the sterilization process, which consists of several enzyme baths, and steam heating at about 132° C.

The hinge mechanism of the device is located at the end of the sheath, near the region of attachment.

In order for the marking to be successful, it cannot interfere with the hinge, therefore not deviating from its original position as set in pre-surgery preparation. Coinciding with that is the importance of the device maintaining a tight hold through the whole surgery. As illustrated by the region of attachment in Figure 3, the shaft doesn't have any obscure textures or notches that can be incorporated into the design aiding in a tighter fit, so it will rely solely on compression force. It is anticipated that the material the device will be made out of will be mixed with a solution of Barium Sulfate, making it radiopaque should it fall off in the body.

Figure 3: Region of attachment for marking device.

The majority of laparoscopic surgeries utilize 5 mm diameter instruments, with trocar ports that allow for ~1 mm of marker space around the shaft of the instrument. Given that, it will be necessary to design the accessory device less than 1 mm thick so that it can easily slide through the port. Lastly, the design needs to be made under a budget of $200.

Snap Clamp

Our first prototyped design was what we call the Snap Clamp, as illustrated in Figure 4. The Snap Clamp is 2.5 cm long with a thickness of approximately 1 mm. The inner diameter is 5 mm and the clip is revolved 285° around the axis. It was produced via 3D printing, from a SolidWorks drawing. The design is meant to clip onto the tip of the laparoscopic instrument, allowing it to be visible on camera. As well as securely fastening to the device, with an inner diameter equal to that of the diameter of the laparoscopic sheath.
The shape was chosen for both patient safety and ease of use. The rounded edges will prevent snagging or worse cutting the patient while in surgery. Overall, the tapered sides were chosen for a smooth contour that can move about safely in the body. It also allows for an easier entrance and leaving through the trocar. Finally, the clipping feature makes the design compatible with any laparoscopic instrument. Regardless of the tip shape on the instrument, the Snap Clamp will firmly attach as long as the diameter of the shaft remains 5 mm.

White was chosen for the color for two main reasons; it contrasts well with the black instrument as well as the internal human body. Furthermore, the default plastic of the 3D printer is ABS, a white plastic. ABS, or acrylonitrile butadiene styrene, is a biocompatible polymer, making it safe for medical grade use [1]. ABS it is relatively cheap, with the materials for the printing itself costing only $5.60. It is rigid enough to hold the shape after multiple uses, but can also bend to clip on and off of the laparoscopic instrument while retaining its shape. Putting the Snap Clamp onto the laparoscopic device requires a simple clip on, which is enough to hold it in place. The friction between the plastic and rubber of the sheath is great enough to prevent

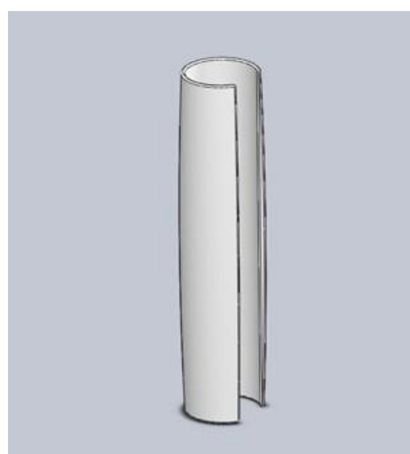

Figure 4: SolidWorks rendering of the Snap Clamp Design.

sliding or spinning. It takes a significant force to snap the marker off of the instrument, but the small size makes removal difficult.

Improvements to the current prototype include adding barium sulfate to make the plastic radiopaque. This addition will not compromise the integrity of the plastic or change the color, but it will allow the clamp to be visible with an x-ray should it fall off the instrument mid-procedure. Dr. Seaberg has also requested that we make the revolution closer to a full circumference, in order to further decrease the likelihood of detachment. An adjustment like this should be easy to do, and if needed the clamp can slip onto the end as opposed to snapping on. We are also looking to make it slightly thinner; currently going through the port makes for a snug fit. A 0.1 mm decrease in diameter of the clip is anticipated for the second prototype to remedy the problem.

Elastic Wrap

Our second preliminary design is called the Elastic Wrap, shown in Figure 5. It comes in a sterile packaging, much like a Band-Aid, and is made out of a silicone elastomer. It would then be wrapped around the shaft of the instrument just below the tip. In order to keep the wrap in place, the two pairs of ties are tightly knotted. The excess tie material can then be cut off or potentially ripped off in order to prevent any catching or pulling of the wrap. After surgery, the wrap can then be removed by using the radiopaque string as a way to tear the wrap off. The main idea of this design was to make it quick and versatile.

As with the snap clamp design, white was also chosen as the ideal color. We chose to use a silicone elastomer because the friction force between silicone and the cover material for the laparoscopic instrument was relatively high. In addition, we chose silicone because it is very biocompatible and fairly strong.

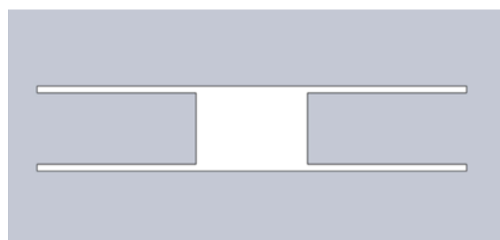

Figure 5: SolidWorks rendering of the Elastic Wrap Design.

The Elastic wrap, like any design, has many benefits and detriments. Some of the extremely useful features are worth highlighting. The most beneficial feature of this design is its ability to fit onto a vast majority of laparoscopic instruments. But for the same reason, there is a larger window of user error. Because the wrap is tied on, we as the engineers have less control over how tightly or loosely the device is secured to the instrument during pre-surgery preparation. Another major benefit is that the device can be secured to the instrument relatively quickly without the use of any other tools. Prior to surgery, the surgeon would remove the sterile packaging and be able to secure the wrap to the instrument while in a fully sterile environment. In addition to easy application, the wrap is also lends itself to an easy removal.

In terms of cost and the ability of mass production, the Elastic Wrap would be on par with the Snap Clamp. The ideal silicone for the wrap design is relatively cheap and the design is simple enough that it could be created rapidly for little to no manufacturing cost. In addition, the cost to the consumer would remain very low as well, making it an ideal solution.

Heat Shrink Wrap

Our third design idea is shown in Figure 6, the Heat Shrink Wrap design. Based solely off of heat shrink tubing, this design uses the unique qualities of the tubing to "hold" onto the shaft of the instrument. As illustrated in Figure 8, the designated length of tubing would be slid onto the ideal position of the shaft. In addition, a small piece of radiopaque thread would be slid in between the tubing and the shaft. After the thread and the tubing are in the correct positions, the tubing then has to be "set" using some method of heating. Heat guns and hot water baths are typically used to set the tubing. After the surgery is over, the radiopaque thread acts as a removal device. The thread is pulled perpendicular to the shaft in order to rip the tubing from the instrument. The used tubing is then thrown away.

The ideal color for the tubing is once again white. Because we would most likely not manufacture the heat shrink tubing from scratch, we would need to find medical grade tubing that comes in the correct color.

Figure 6: Close up of the Heat Shrink Wrap design.

The Heat Shrink Wrap design brings up many interesting pros and cons. One of obvious benefits is that it is extremely secure and would more than likely not fall off during surgery. Another advantage with this design is that it, like the Elastic Wrap design, is more versatile than the Snap Clamp due to its ability to shrink. This shrinking quality is also one of the designs biggest flaws. Shrink temperatures can vary anywhere from 90° C to 150° C. Temperatures this high can be difficult to safely achieve in an operation environment. In addition to the varying shrink temperatures, the shrink time also greatly differs. Shrink times can range anywhere from a few seconds to several hours. These two huge flaws could potentially make this design completely impractical for use during surgery.

In terms of cost, the Heat Shrink Wrap design would also be quite cheap. Because the heat shrink tubing would be bought from a third party vendor, we would have less control of the opportunity cost and the cost to the consumer.

Design Matrix

Based on our assessment of the problem, we drew up several different designs to choose from, rated on factors shown in Figure 7.

Design Possibilities							
Factors	Weight	Rating (1-10)					
		Snap Clamp	3-Piece	Elastic Wrap	Heat Shrink Wrap	Magnetic	Electric Signal
Cost	0.05	9	7	9	8	6	3
Ease of Use	0.15	8	5	6	8	8	7
Reliability	0.2	7	6	5	7	4	7
Safety	0.3	8	5	5	6	2	3
Size	0.3	7	5	8	9	5	8
TOTAL	1	7.55	5.3	6.25	7.5	4.4	5.9

Figure 7: Design Matrix

Cost was weighted lowest, due to the minimal material requirements to make each design, and an allotted $200 to cover expenses. The Snap Clamp, Elastic Wrap, and Heat Shrink Wrap were all rated highly, as their cost was relatively low. FDA approved silicone sheeting can be purchased in square 45 cm sheets at a price of $18.05. With a square 45 cm sheet and efficient usage, it is estimated that 8-10 wraps can be cut out of it. The Snap Clamp prototype is currently made out of ABS, which according to Professor John Puccinelli in the engineering department cost $5.60 to produce. Finally, medical grade heat shrink-wrap was priced similarly to the medical grade silicone sheeting. The other three designs required the previously listed material prices, with an additional cost of adding magnets, or a combination of silicone and ABS as is the case with the 3-Piece design. Finally, the Electric Signal design would have required electrical modifications to the camera to recognize the signal it gives off.

Ease of use refers to the application and removal process of using the device. The Snap Clamp and Heat Shrink Wrap were rated highest, because they both require little to be done prior to surgery in order to prepare the instrument, whereas the Elastic Wrap and 3-Piece may have application inconsistencies, depending on who applies them.

Reliability deals with the ability for the accessory to stay connected to the instrument without moving around. Snap Clamp as well as the Heat Shrink Wrap rated highly in this. The Snap Clamp uses a clamping force to demote sliding movement on the shaft. The Heat Shrink Wrap after being heated forms tightly around the instrument making movement less possible. The Elastic Wrap did not rate as high even though the material has a higher coefficient of friction than the Snap Clamp because the ties involved may not get tied as tight as they should resulting in a slipping motion of the product. The Magnet scored low because the magnet could interfere with other metal medical devices. The 3-Piece also wasn't rated to high because of the clamps holding onto the shaft are small and easily broken.

Safety is a very important factor especially when working within the body. Snap Clamp and Heat Shrink Wrap was rated high in this area because it would not easily be able to fall off the instrument as well as the material used can be biocompatible. Elastic Wrap and 3-Piece are rated next lowest due to the number of possible parts that could easily be lost within the body with the 3-Piece and the small ties that could easily rip or come undone. Magnetic and Electric Signal both are rated the lowest because magnets could easily interfere with other instruments in the body and the electric signals could easily interfere with other electronic devices such as a pacemaker.

Lastly, Size was heavily weighted, because the device must remain less than 1 mm thickness in order to fit through the trocar. The Elastic Wrap and Heat Shrink Wrap designs are extremely thin, as they don't rely on structural integrity to compress and grip the shaft of the instrument like the Snap Clamp. The 3-Piece and Magnetic designs would have required small clips and magnets respectively, both of which would have exceeded the 1 mm size limit.

Materials Design Matrix

Our materials design matrix, Figure 8, allowed us to decide between three general groups of material for which is best for the final product. The substances were graded on cost, color, manipulation, safety, and elasticity. Cost was weighted 0.1 because it plays a small role in the choice. Most materials of this size will be cheap, but availability, quality, and other factors like dyes play a factor in determining the pricing. Color must be noticeable in the body and more importantly against the black of the instrument sheath. Bright/ fluorescent colors, as well as too shiny of appearance should be avoided due to distractions. Manipulation is how well we could work with the product to make the desired shape and size; it has a high weight because if we can't work with the substance, it won't be a good product. The safety category is also very important, weighted 0.3 because it will be used in surgery. Whichever design we choose can't fall off in the patient, must be biocompatible, and should be smooth to avoid cutting internal organs while operating. Finally, elasticity is what we called the measure of how well it would hold the shape of the design. For the clip it must be fairly rigid, and able to be put on and taken off without compromising the shape, while the wraps need to be moveable and flexible enough to be taken on and off, only for one use.

Based off of our work, it was determined that polymers score the best, with elastomers at a close second, and metals trailing far behind. Metals are fairly cheap, but coloring them would include coating them with paint or a finish, or picking specific alloys, both of which are time and money consuming. The metals would also be difficult to work with; bending them would be our easiest option, however due to low elasticity, the design is unlikely to go back in to place after one or more uses. Finally, only specific metals are biocompatible and would need to be chosen and obtained by that basis. Concerns also arise from getting a magnetic or electric charge that could harm the patient or disrupt the surgery with a metal clip. Also heat from cauterizing could be retained in the metal and harm the patient.

Polymers scored highest on our matrix. Many plastics are biocompatible (ABS, PVC, etc.), making this material very safe [1]. They are also easy to work with. Since we have the ability to use 3D printers, any SolidWorks part can be made into a prototype via printing. This is why the manipulation grade is also a nine. The elasticity of polymers is a high grade, but not the highest because while the plastic will usually retain its shape it will not bend as much as elastomers. The one downfall is it could be too rigid, and break when bent too far. Colors can be added to polymers through simple dyeing processes. Overall, it scored very well in all categories, which led to it being the best material of choice. Furthermore, the use of a polymer is ideal for the one of our possible designs, the Snap Clamp, making it practical as well.

Elastomers scored second best in the design matrix. Like the polymers, there are many biocompatible elastomers that can be used for the project [1]. They are also available in a variety of colors that will distinguish them from the black instrument. This material is a bit more expensive, mainly because it could only be used once and each individual device would have to be sterilized before hand and remain sterile for the experiment. The main safety concern for elastomers is the material ripping during the procedure, causing it to fall off. However, this problem can be worked around, with thicker compounds. Elastomers are fairly easy to work with, giving them a high manipulation grade. Finally, for elasticity they get the best score. The marker could be stretched, bent, or in other ways distorted and still return to its original size because these materials are so flexible.

Material Matrix				
Factor	**Weight**	**Metal Alloy**	**Polymer**	**Elastomer**
Cost	0.1	5	8	6
Color	0.1	2	8	8
Manipulation	0.3	3	9	7
Safety	0.3	4	9	7
Elasticity	0.2	2	7	9
TOTAL	1	3.2	8.4	7.4

Figure 8: Design matrix for a variety of materials that could be used for the marking device.

Future Work

Based off of the three preliminary designs, we have much work to do. Initially we will need to heavily research what materials will be ideal for each individual project. All of the materials must be biocompatible, but some will be better suited for each devise. After determining which materials to use, we need to create a working prototype of each design. For each design we will order the necessary materials. Our Snap Clamp prototype seems to work well already however, small changes will be made to it. Each prototype will be fully functional for use in a test environment in order to determine which design will work the best. In addition to testing, we will consult with multiple surgeons to see which device they prefer and if it has all the necessary attributes.

After consultation and testing, we will pick the design that works the best and perfect it for the final product. In addition, we plan on researching methods of mass production. Alongside this, we will need an efficient, sterile packaging method for any of the designs. More research and testing will be necessary to ensure the sterility of the device.

Works Cited

- [1] "Heat Shrink Tubing - Home." *PTFE, FEP and PFA Fluoroplastic Tubing and Heat Shrink*. 2011. Web. 20 Oct. 2011. http://www.texloc.com/hs_home.html.

- [2] "Laparoscopic Colon Surgery : Laparoscopic Colon Resection." *Comprehensive Center for Laparoscopic Surgery -- White Plains, New York.* Web. 12 Oct. 2011. http://lapsurg.org/colon.html.

- [3] "SIL-TEC Medical Grade Radiopaque Sheeting from Technical Products, Inc. of Georgia, U.S.A." *Technical Products, Inc. of Georgia.* 2011. Web. 20 Oct. 2011. http://www.technicalproductsgausa.com/meddiv/radiopaq.html.

- [4] "What Is Laparoscopic Surgery." *Center for Pancreatic and Biliary Diseases*. University of California, Department of Surgery. Web. 12 Oct. 2011. <http://www.surgery.usc.edu/divisions/tumor/pancreasdiseases/web%20pages/laparoscopic%20surgery/WHAT%20IS%20LAP%20SURGERY.html>.

- [5] "FDA Approved Plastics Materials - Order Online." *Plastic Sheet, Plastic Rod, PlasticTubing - Buy Online*. 2011. Web. 16 Oct. 2011. <http://www.professionalplastics.com/FDAApprovedPlasticMaterials>.

Appendix A: Product Design Specifications

Identification Marking of Laparoscopic Instruments for Video Recording
Preliminary Product Design Specifications
Jared Ness, Brad Wendorff, Bryan Kloosterboer, Matt Jensen

Function: The function of the device being designed is to make laparoscopic instruments identifiable during surgery, without compromising the instruments performance ability. During laparoscopic surgeries, there is often a teaching physician accompanied by a resident, each having his or her own instrument. Currently, there is no way of identifying which instrument belongs to whom, which is reason for developing a type of marker to attach to the instrument.

Client Requirements:

1. Device must be sterile as to not cause infection in the patient.
2. Device must not compromise the functionality of the laparoscopic instrument.
3. Must be securely fastened on the device so it does not separate during surgery.
4. The device should be located at or near the tip of the instrument so that it shows up on the video.
5. Device needs to stay within a budget of less than $200.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements*: The device must not deviate from its original position prior to surgery. It also must not impede the functionality of the laparoscopic device, therefore not slipping over the mechanical hinge. The color of the device must be easily distinguishable while in operation.
    b. *Safety*: The device must not fall off during operation. It also must be sterile prior to operation, whether that be opening up a new device or using one that has gone through processing. Finally, there can be no sharp corners that have the potential of snagging tissue during use.
    c. *Accuracy and Reliability*: The device must be able to remain intact during surgery, meaning its strength cannot be compromised by contact with tissue or blood. If reusable, it must be able to withstand the sterilization process.
    d. *Life in Service*: The device is expected to be reusable, but could be determined to be for one time use depending on physical integrity after several rounds of processing.
    e. *Shelf Life*: The device must remain sterile while in packaging.
    f. *Operating Environment*: The laparoscopic labeling device will be used in laparoscopic surgeries, therefore within the human body. It must also be able to withstand the processing environment, which includes several enzyme baths and a steam cleaning at 270'F for 6 minutes.
    g. *Ergonomics*: The device must be easily applicable and removable from the laparoscopic instrument.

h. *Size*: Diameter will be ~5-6mm and total length will not exceed the length of the instrument shaft.
i. *Weight*: Weight is expected to be less than 20 g.
j. *Materials*: Device will be made out of a polymer to be determined based on biocompatibility. Secondary options include various types of alloys also based on biocompatibility.
k. *Aesthetics, Appearance, and Finish:* Device needs to be visually appealing. It relies on the visual appearance for functionality, so color choice will be crucial.

2. **Production Characteristics:**
    a. *Quantity:* ~10
    b. *Target Product Cost*: $1.00 per piece
3. **Miscellaneous**
    a. *Standard and Specification*: Built to United States legal standards. Must be approved by proper hospital committees and staff to comply with HIPPA and patient disclosure or release. Needs to receive FDA approval.
    b. *Customer*: Dr. Carly Seaberg and the surgery staff of the University of Wisconsin-Madison Hospital.
    c. *Patient*-Related Concerns: The device will need to receive proper sterilization between uses as laid out in operating room protocol. If necessary, use of device during surgery may need to receive patient approval.
    d. *Competition*: N/A.