Force-Sensing Laparoscopic Grasper

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Abstract

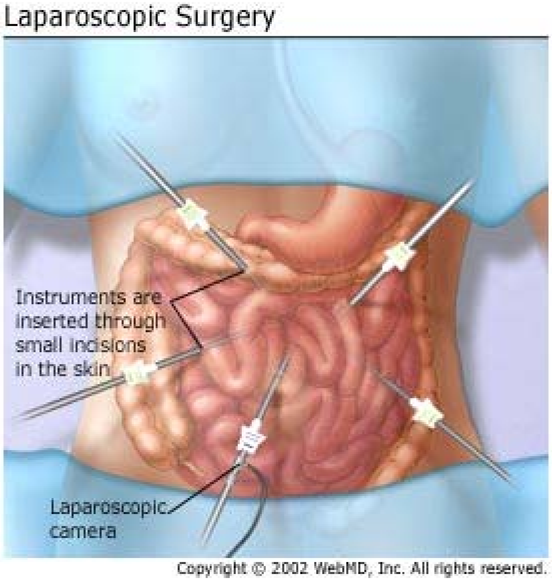
While teaching medical school students the skills necessary to utilize surgical tools, students are uninformed as to the limits of force and pressure allowed on the tissues they are working on. Two beneficial upgrades to the current tools would be a mechanism that provides feedback to the students and instructors when the limit has been exceeded and damaging force is being applied to the tissues and a jaw that reduces pinching of the tissue.

§1 Problem Statement

Laparoscopy is a method of surgery using incisions ranging from 5 mm to 10 mm for the probes and 30 mm for a camera to monitor the procedure. The instruments used must therefore fit the prescribed ports (5 mm or 10 mm). Grasping tissue in a laparoscopic procedure is important because the surgeon must be able to see around other tissues such as the connective tissue or blood vessels to view the procedure. The surgeon must firmly secure such tissues in order to cut or forcibly displace them. The goal of this project is to design and build a modified laparoscopic grasping tool to minimize tissue damage and provide feedback, auditory or otherwise. A feedback mechanism would be activated when the force applied to a piece of tissue is great enough to damage the tissue. At the end of every grasper is a jaw mechanism. Conventional jaw mechanisms have a jaw that pivots around a stationary point, similar to that of a scissors. Tissue damage frequently occurs due to the nature of the closing mechanism. The increased pressure near the pivot can puncture or otherwise damage the tissue. The jaw mechanism should be redesigned to reduce tissue damage by eliminating pinching at the pivot point of the jaws. This type of device would be an educational tool to benefit students and instructors by maintaining a defined standard force for grasping tissue and would also ensure less trauma to the patient by decreasing the risk of damaging levels of tissue compression.

§2 Background

Laparoscopic bowel surgery encompasses many diseases, including but not limited to colon cancer, colonic dysmotility (slow-transit constipation), Crohn's disease, Diverticulitis (diverticular disease), hereditary polyps, inflammatory bowel disease, rectal prolapse, and ulcerative colitis (Mayo Clinic [Online]). It is a minimally invasive surgical technique that has slowly been replacing many traditional bowel surgical procedures in the past 15 years. The procedure begins by creating a pocket of gas (usually carbon dioxide) within the abdomen. This is used to ease visibility of the site. Next, 5 or 6 small incisions are made for the introduction of the necessary surgical tools. These incisions are then secured by the use of a portal device called a trocar that holds the opening while maintaining the positive pressure within the abdominal cavity. These ports allow for repeated insertion of surgical tools . The procedure is viewed by the use of a laparoscope (a rod and lens system connected to a


Laparoscopic Surgery

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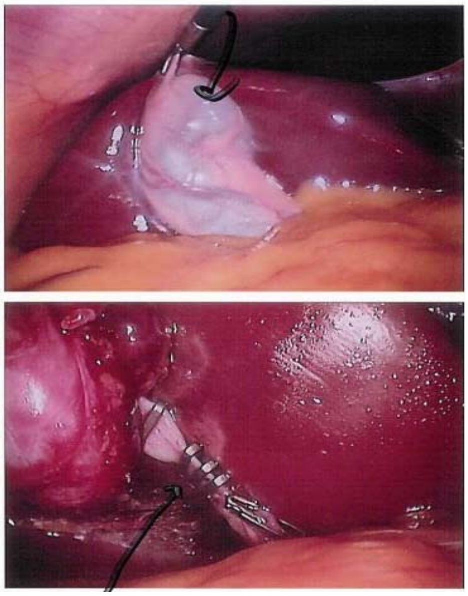
[1]Figure 1. A cutaway view of laparoscopic surgery.

video camera) (Fig. 1). An example of the view provided to the surgeon is shown in Figure 2.

Traditional surgery to the abdomen involves a large incision down the length of the abdomen and requires a long recovery period. New techniques and old surgical procedures are now being done laparoscopicly because of the many patient benefits. These benefits include reduced operative blood loss, reduced discomfort, shorter recovery periods, less pain and scarring, and less risk of infection (Cleveland Clinic [On-line]) .



[2]Figure 2. A surgeon's view using a laparoscope. The top photo is of a gallbladder. The bottom photo is a cystic duct.

With the revolution of surgery quickly taking place, surgical techniques must be reformed and students educated more effectively. One such basic educational tool is practice; but while the instructing surgeon may know the requirements and basic feeling of proper performance, conveying this information to a student is difficult. Students feel detached from the patient and the amount of pressure applied to a tissue via a grasping instrument is unknown until the tissue shows signs of damage such as leaving marks or bleeding from the point of pressure application. Minimizing damage is crucial to providing adequate treatment to patients.

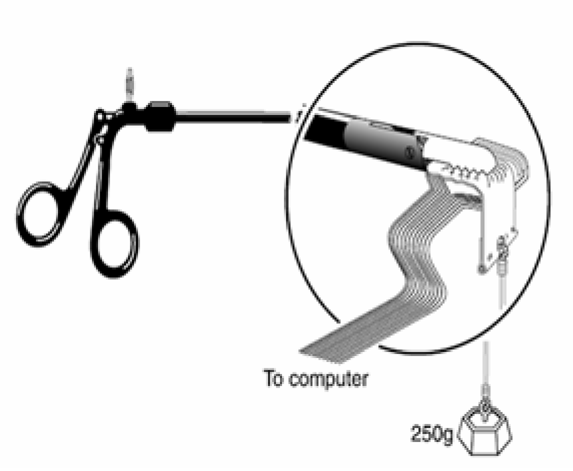
[3]Figure 3. An example of the tools available by Stryker.

Current laparoscopic graspers are made by companies including Stryker (Fig. 3), Ethicon Endo-Surgery, Inc. (Fig. 4), DuoMed and many others. The devices all have similar components: the long arm that extends into the body, the grasping claw used to grab tissue and hold it in place, and the handle used to manipulate the claw. Some of the stainless steel material can be replaced with high temperature resistant synthetic polymers to reduce weight and still remain autoclavable.

[4]Figure 4. An example of the tools available by Ethicaon Endo-Surgery, Inc.

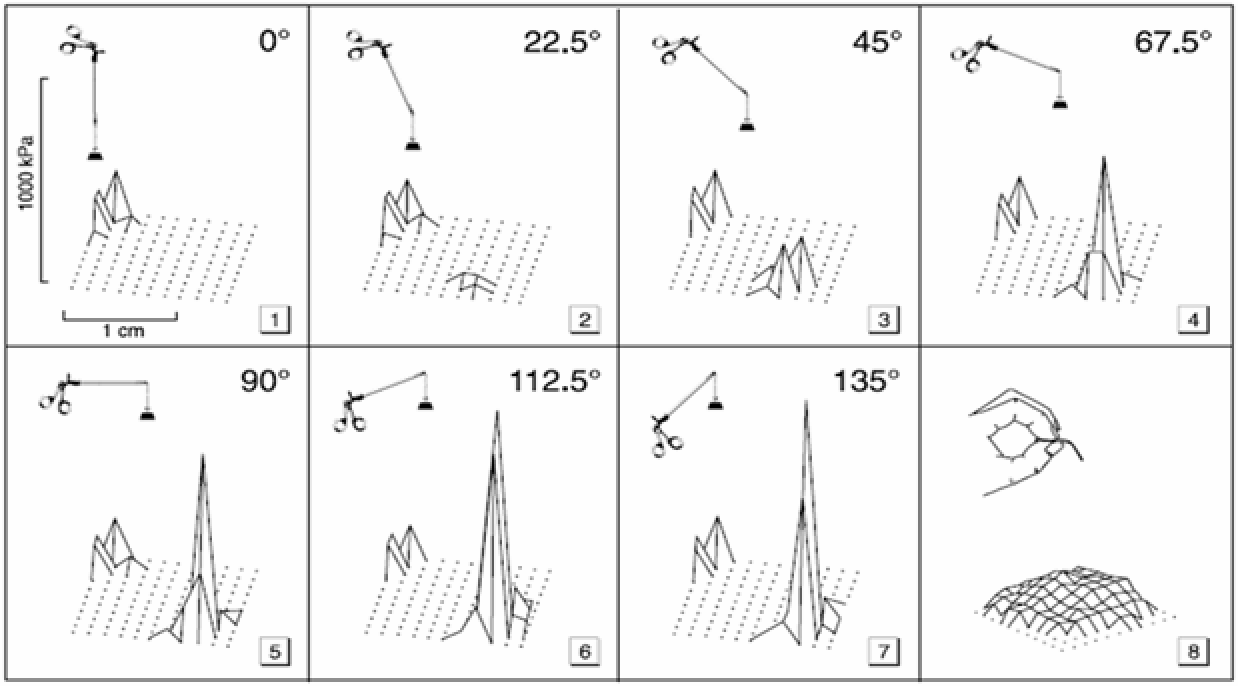
§3 Literature Search

When designing a laparoscopic grasper there are several variables that must be considered in order to result in a grasper that best services the surgeon and minimizes damage to the patient. These variables include jaw wave patterns and size, jaw pressures, and jaw surface areas. The following data was collected to determine the optimal values for these variables and engineering thought relating to the design problem is provided.



[5]Figure 5. Schematic representation of the experimental model showing the configuration of the pressure sensing transducer relative to the instrument jaw.

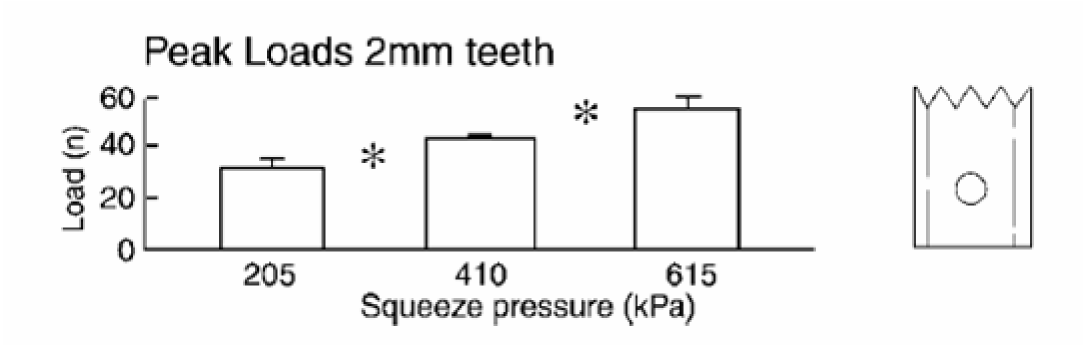
A study was done to see how the orientation of laparoscopic probes affects the pressure that is done on the tissue. A laparoscopic probe was used to grab a pressure sensor connected to a 250 g weight as shown in Figure 5 (Cartmill et al, 1999). This sensor recorded the pressure distribution exerted by the graspers. This was done at varying angles. These are shown as results 1-7 in Figure 6. Result 8 in Figure 6 is a comparison to the maximum pressure that can be produced between the index finger and thumb.



[5]Figure 6. (1-7) Data showing spatial distribution and magnitude of pressure exerted by a laparoscopic grasper as the angle of retraction increases. (8)Pressure profile of the maximum pressure generated by the pincer grip of a surgeons finger and thumb.

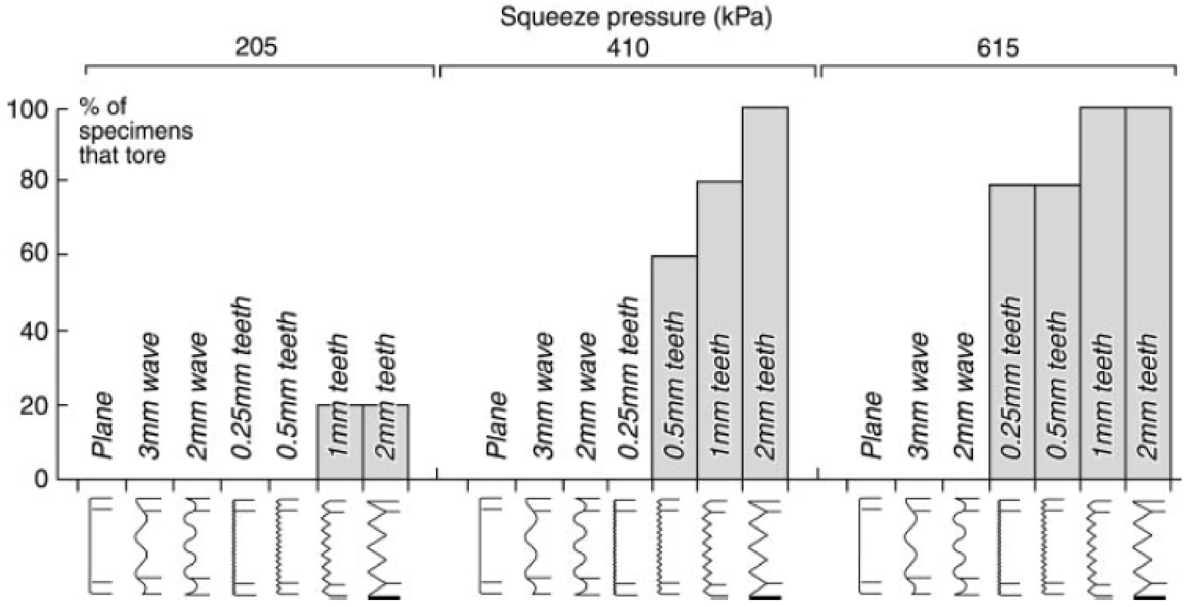
It can be seen from Figure 6 that there is always a pressure that is exerted by the jaws at the pivot point. This pressure can be reduced through an alternate design. The pressure at the tip of the jaws varies depending on the orientation in which it is used. The probe might be engineered to slightly reduce the force produced by the angle of the probe, but most of this force is incapable of being reduced from an engineering standpoint as it depends primarily on the surgeon's technique.

Another study using fresh sheep stomach was done to analyze the effect of opposing pressure on grip security (Marucci et al, 2000). It was determined that increasing the opposing pressure increased the peak load for all types. The results for a 2-mm teeth pattern is shown below in Figure 7 measured as peak load. This same trend was also shown to be true for all jaw patterns.



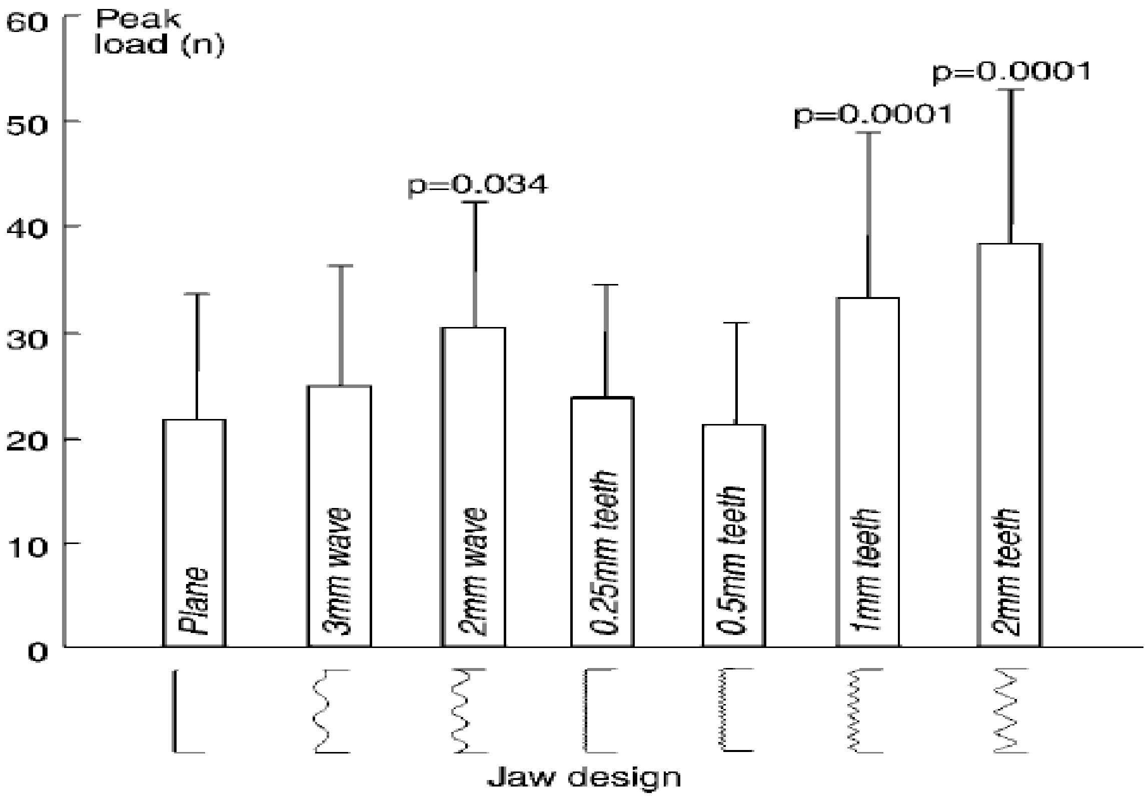
[6]**Figure 7. Graph showing the results for 2-mm teeth measured as peak load.**

Another experiment in the same study was also done on the damaging effects of different jaw patterns. Different jaw patterns were used to grasp fresh sheep stomach at different pressures. The percentage of sheep stomachs that were perforated by each jaw



[6]**Figure 8. Perforation of samples using different jaws and different pressures.**

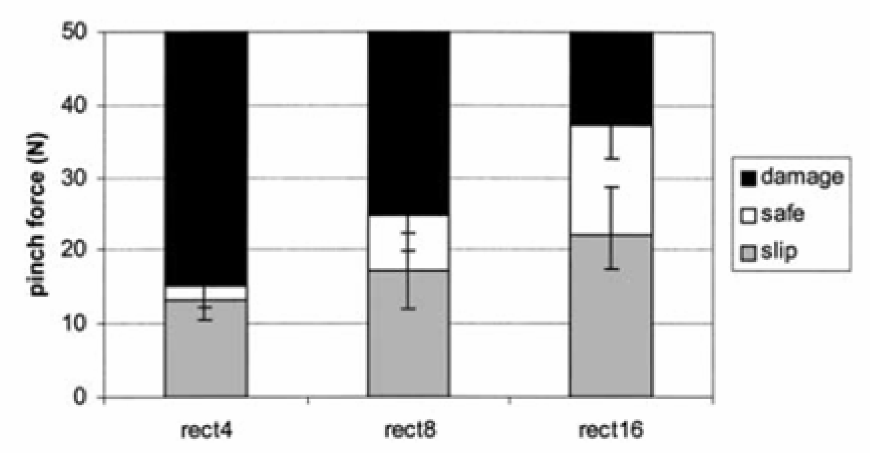
pattern at each pressure is shown below in Figure 8. From this figure, it can be seen that the only jaw patterns that did not perforate the sheep stomach at all pressures were the flat and the two and three mm wave patterns. To determine which of these patterns was more beneficial, another experiment was viewed. This study demonstrated the how the peak graspable load varied by the pattern of the jaw. This was conducted independent of squeeze pressure. The results of this experiment are shown below in Figure 9.



[6]**Figure 9. Effect of jaw design on grip security, measured as peak load. Conducted independent of squeeze pressure.**

Looking at figure 9 it can be determined that the 2 mm wave pattern is the best option for our grasping device. It does not damage the tissue compared to other patterns, and it can hold the largest load out of the patterns that do not damage the tissue.

To determine the effect of the size of a grasper on safety and efficiency, a study was conducted to compare the grasping effects of different jaw sizes on safety and efficiency (Heijnsdijk, 2004). Three flat jaw sizes were used: 8x4 mm, 8x8 mm, and 8x16 mm. The slip and damage force ranges were recorded for each pattern. These results are shown in Figure 10.



[7]**Figure 10. Damage, slip and safe ranges for jaws of varying size.**

It can be seen from Figure 10 that the safe range increase as the size of the jaw increases. One may note that the 8x4mm^2 surface area has the smallest safe range and the 8x16mm^2 surface area has the largest safe range. Maximized surface area of the jaw would result in minimized tissue damage. Another note to make is the force at which damage occurred. The 8x4mm^2 pattern had damaging force at about 15 N.

§4 Design Constraints

The client, Dr. Charles H. Heise, has expressed his wishes for the project to include several features. The first feature, and the most important, is the redesign of the jaw mechanism. Surgeons today, not just students, have witnessed the extra damage incurred to tissue by a pinching of the tissue as the closing point of the grasping claw comes together. This harmful effect needs to be minimized or eliminated completely. A second requirement is a means to provide feedback to the surgeon or student, via an auditory or tactile response to tissue-damaging force of about 10 N. This force depends on several different factors as stated in the literature search. According to the literature search, the 2 mm wave pattern afflicts the least amount of damage. Also according to the literature search, a larger grasping surface area will result in less tissue damage. However, our device must fit into a 5mm port, and therefore the grasper jaws must remain at a constant width of 5mm. According to Dr. Heise, a jaw length of 4 to 5 cm is desired. Further requirements include the other dimensions of the device: the arm housing the actuator rod must be 5 mm in diameter, which is the diameter of the port into which the grasper is inserted; the length of the device should be similar to those currently on the market, which corresponds to a length of about 30 cm. The device should provide a ratchet mechanism to lock the jaws in any position. And lastly, the device should be disposable or sterilizable by means of an autoclave at about 121ºC. Additional design constraints are provided in the Product Design Specifications (Appendix C).

§5 Design Options

Three design possibilities will be discussed and contrasted. A design matrix (Appendix A) will be used to analyze the possibilities according to cost, maintenance, sterilization ability, strength, cumbersomeness, connectivity, and accuracy. A final design will be chosen and pursued based on the outcome of the design matrix and group discretion and consensus.

Since a major factor in the re-design of the laparoscopic instrument is on reducing the jaw pressure, much focus was on creating the floating-point jaw mechanism. One jaw design was determined and maintained throughout all three design possibilities. The force-measurement and feedback options are what make each design unique.

§5.1 Jaw Mechanism

In order to minimize tissue trauma and maximize grasping security, the following jaw mechanical structure is adopted. The information found during the research phase indicates that the most desirable results stem from the wavy-patterned grip type. Four pivot points, located inside the shaft as shown, are connected to the grippers with four bars. The two parallel wave-patterned grippers are formed to ensure that the grippers always open and close in parallel positions relative to each other (Figure 11). When closing, the jaws will project forward (to the left in Figure 11).

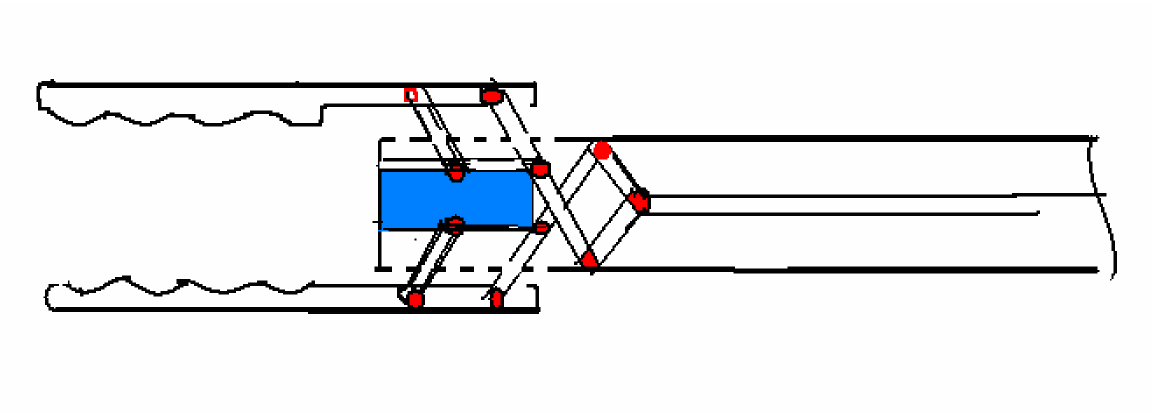


Figure 11. Figure jaw mechanical structure (cross section view) Connections highlighted in red are pivot points.

§5.2 Strain Gage on the Shaft

The first design possibility is called the Strain Gage on the Shaft, and implies directly as the name states. In this design the strain gages can be fixed on the shaft of the grasper. In this way it will measure the compression and tension stresses along the shaft, which corresponds to the pressure applied by the user at the jaw.

Strain gages are small, which will reduce obstruction to the surgeon. They are inexpensive (under 10 dollars). Certain models can withstand high temperatures that are experienced in the autoclave. Strain gages are a widely accepted method of measuring strain on bendable materials.

The principle of using strain gages as stress sensors is based on the property of the Wheatstone bridge. In this four-element Wheatstone bridge, two gages undergo compression and two undergo tension. For example, if the resistors are labeled clockwise starting at the top left, and if R1 and R3 are in tension (positive) and R2 and R4 are in compression (negative), then the output will be proportional to the sum of all the strains measured separately. Whether bending strain, axial strain, shear strain, or torsional strain is being measured, the strain gage arrangement will determine the relationship between the output and the type of strain being measured. The pressure sensor is connected to

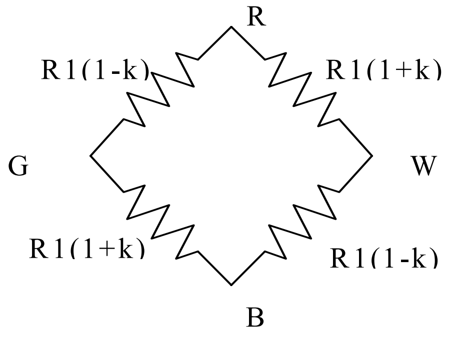


Figure 12. A Wheatstone Bridge. Output voltage changes with resistance changes due to various strains.

a conditioner in which voltage is applied onto the Wheatstone bridge. A change in resistance can be monitored as a change in output voltage.

Pressure on the grasper will be tested and calibrated to the output voltage. A threshold can be set experimentally using animal tissue. As found in the literature search, the safe range for an 8 by 4 mm flat jaw pattern was 10 N. Once this threshold is reached or exceeded, a piezoelectric buzzer alarm system will be activated.

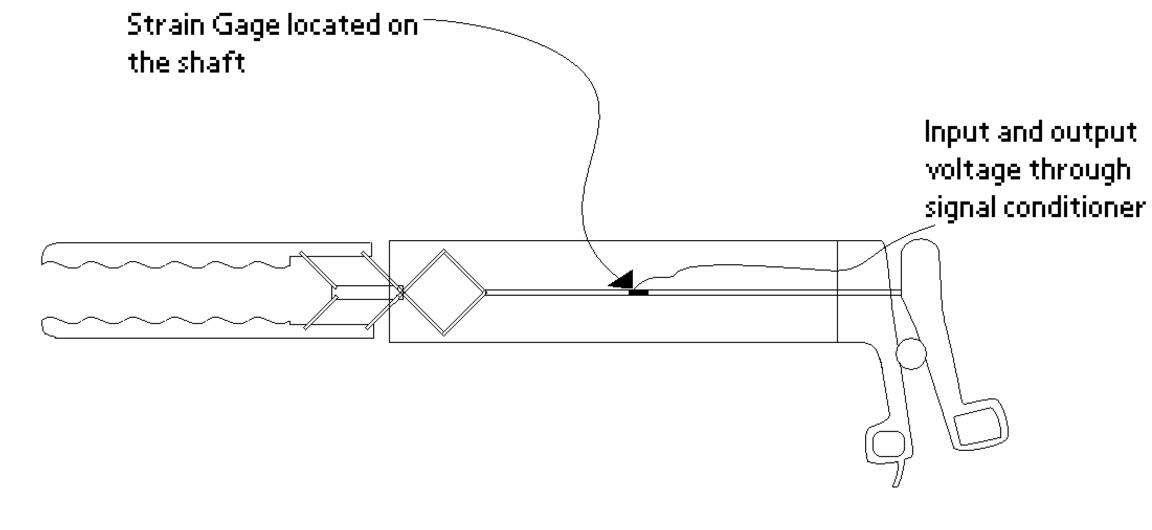


Figure 13. Strain Gage on the shaft.

Although putting the strain gages on the shaft is an intuitive solution, this design faces one major problem: In order to firmly fix a strain gage onto the equipment, the surface must be flat and large enough to accommodate the gage. The reasoning behind this came from the senior instrumentation specialist and installation expert, John Dreger, stating that custom molds would need to be made for each gage for fixation purposes. This presents a problem in that curvature of the shaft surface is not able to provide enough fixing area. The solution, designing the fixating platform for the gage to be rectangular, creates a manufacturing difficulty.

Advantages and Disadvantages

The main advantage of placing a strain gage in the shaft is that there is less clutter on the instrument, which will create a minimal nuisance to the user. The disadvantages are four-fold. One disadvantage is the manufacturing difficulty and practicality of putting the strain gages in the 5mm diameter of the shaft. A second disadvantage is the reduced accuracy of measurement. A third disadvantage is the increased cost due to using high-temperature resistant materials necessary because of routine autoclaving procedures with temperatures in the range of 130˚C. The components (strain gages, bonding agents, connecting wires, Teflon wire insulation) must remain permanently fixed to the surface, which means that they cannot be removed for other sterilization methods or when the measurement is not needed. If the gages were detached and reattached, re-calibration would be necessary. The fourth disadvantage is that an expensive signal conditioner is required to supply voltage to and monitor output from the sensor. Dreger commented that in order to use the strain gages, a device like the $10,000 conditioner must be used. A quick online search produced results of $300 conditioners, but this is still expensive. In addition, any extra unnecessary wires and equipment increases the clutter and inconveniences surgeons during operation.

§5.3 Strain Gage on the Handle

An alternative to placing the gage on the shaft is to put it on the handle to measure the bending moment produced by the user while grasping objects. The same principles of the Wheatstone bridge are applied in this case, but the strain gages are oriented

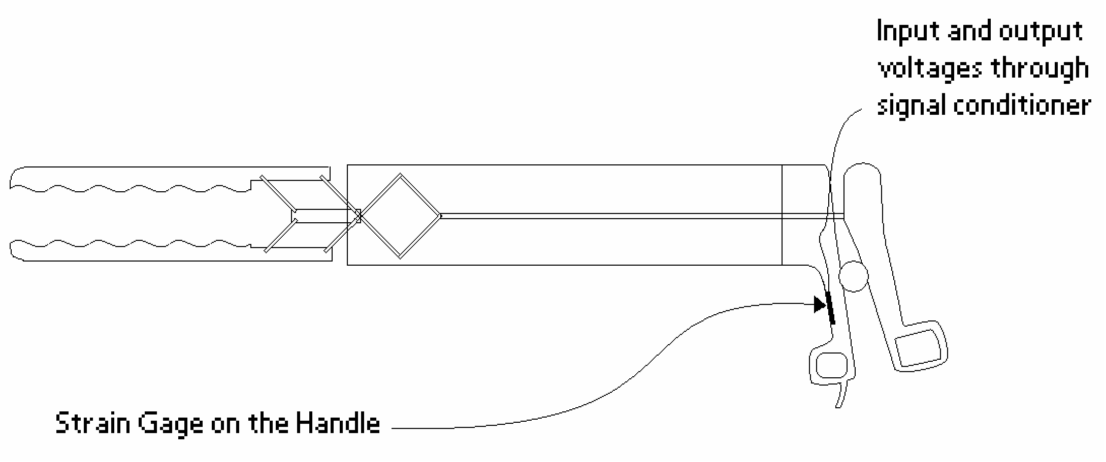


Figure 14. Strain Gages on the handle

differently to measure the bending moment as compared to the compression or tension forces.

Advantages and Disadvantages

This has a few advantages over the first design. First of all, it avoids the fixation area problem, as the handle has enough flat area for fixation of the strain gage, which needs about 5mm x 15mm. Secondly, the strain gage in this configuration is four times more sensitive to changes in bending moments. However, this design also has several drawbacks associated with the natural properties of strain gages. In an ideal strain gage situation, the change in resistances would be due only to the deformations of the surface to which the sensor is attached. The first disadvantage is that in a real application, temperature, material properties, the adhesive that bonds the gage to the surface, and the stability of the metal all affect the detected resistance. This disadvantage, in addition to the last three mentioned for the previous design, all contribute to complications with the second design.

§5.4 Microchip Force Sensor on the Handle

The third design will use a force sensor that changes resistance dependent on the magnitude of the force that is applied. Placement of the sensor will be on the inside of the handle where the surgeon places his index finger. The compressive force between the grasper that will be exerted on the intestine will be directly proportional to the amount of force that the surgeon uses to squeeze the handle of the laparoscopic instrument. From this we can measure the force that the surgeon uses and determine how much force is on the bowel. Placement of the sensor in the handle is ideal over other places such as at the hinge of the handle or where the handle pulls the shaft due to the simplicity of measurement.

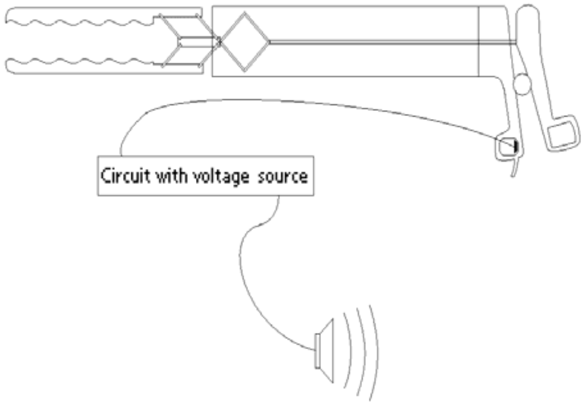


Figure 15. Force sensor schematic (not to scale).

Designing a simple interchangeable part that can fit inside the handle will be easier to design and make than fabricating an entire laparoscopic instrument. This also allows flexibility of use with other instruments. Since it will also be removable, the instrument may still be autoclaved while the sensor package itself could be rubbed down with alcohol.

The force sensor will rest against the handle on the inside of the index finger hole with a metal covering over it to focus the area that the surgeon might touch to the point of contact on the sensor. The sensor will be a 2 mm square sensor from CUI Inc. and can measure from 0 to 1500 grams with a maximum load of 3.0 kg. We expect the maximum force to be about 10 N, almost 1 kg. This is well within the limits of the sensor. There will be two wires going from the sensor to a small box containing the rest of the circuit. This box may be made to attach to the handle of the laparoscopic instrument, worn on a wristband by the surgeon, or simply set aside. The changing resistance from the sensor will be used to vary the voltage on the input of a comparator. The reference voltage input will simply be a voltage divider circuit with a potentiometer for calibration. The output of the comparator will connect to an oscillator to drive a magnetic buzzer. The circuit will run off of a 6.0 V battery with a voltage regulator to bring it down to 3.3 V. Because of this, and the fact that the components will consume less power (42mW, Figure 16), the circuit will last a long time.

P = V x A
P = 6.0 V x 0.7 mA
P = 42 mW

* The 7 mA was obtained in a trial run with the buzzer sounding

Figure 16. Calculation of power consumed with buzzer sounding.

Advantages and Disadvantages

The main advantage of this design is its simplicity and ease in design. Currently used laparoscopic instruments do not need to be redesigned to accommodate a force sensing mechanism allowing easier integration of the device into the market. Mounting strain gages and/or redesigning the handle of the instrument are costly, thus making our third design a viable solution. The next most important aspect of this design is that it will be detachable, making it possible for the instrument to still be autoclaved. This way, the preparation time for surgery will not be drastically increased. Another advantage is that the surgeon will have the option to either wear or set aside the circuit box, making as little inconvenience as possible. With the circuit running off of a battery, there will be no long wires draping across the operating room that could potentially get in the way. The circuit used for this design will not only last a long time but can be easily calibrated to buzz at whatever threshold force the surgeon thinks is appropriate.

A disadvantage of this design is the assumption that the surgeon will always squeeze the handle in the same spot. One surgeon may be different from another and may hold the instrument differently is such a way that the measured force on the sensor is not the actual force being applied. Since this device will be used for educational purposes, preciseness is not as important, yet this only serves as a guide to the students.

§6 Proposed Design

After discussing the advantages and disadvantages of our three designs, it is the most reasonable to go with our third design. The third design offers an easier solution that can be integrated into the existing market. It does not have the high cost of manufacturing as the other two designs do. It offers easier maintenance as there is only a battery that needs occasional replacement. This design makes autoclaving still possible which is a key factor in surgical equipment. It's less cumbersome as there will be few wires to deal with and the overall strength of the design is the greatest. The only assumption is that the surgeons apply all the force they used to the sensor. However, this problem can be minimized by placing the sensor in the proper place.

§7.1 Grasper Design

A prototype for the force sensor on the handle design was built along with a circuit to incorporate the buzzer and a voltage source, as well as accept input from the force sensor via a changing resistance due to force pressing on the sensor. Our initial options for design included rapid prototyping, 3D printing, and conventional metal shop hard labor. All three designs were researched and options were eliminated.

Upon looking into the biochemistry's 3d printing capabilities, it was determined that the resulting prototype would be too grainy and immovable, as the printer produces a fragile structure that is strengthened by a glue resin. In order to make moveable parts we would have needed overcome the grainy texture of the printout by creating a massive scaled assembly. With the printer costing 8 dollars per cubic inch, the 3d printer was unacceptable.

Rapid prototyping was the second option. Mechanical engineering consultant Todd Kile informed us that the department's rapid prototyper would not be able to create a moving assembly, due to the technique used by the equipment to produce an object. Also, the prototyper would not be able to construct on the scale we desired. He went on to inform us that conventional metal shop work would be the best option.

After reviewing all the options, conventional machining was the best solution. Kile made one last comment, and said that with the given budget and time frame, a large model would be the only viable outcome, as an actual-size model would have had an estimated price tag of $2,000 for labor and materials.

The large prototype was built per Dr. Heise's approval to demonstrate the feasibility of the mechanism along with the circuitry of incorporating the force sensor.

Due to the large size and availability of materials, the scale of individual parts was modified to allow for the ability to manufacture by hand. Aluminum blocks and rods and steel nuts and bolts were used to construct the mechanism. Dimensions of the prototype are not provided as it was built to provide a physical reference and demonstration of the mechanism. Actual dimensions for the recommended design are provided in Appendix A. The housing was constructed with PVC pipe to secure the central jaw block from which the bars pivot. The photo of the large prototype is provided in the following figure.

The recommended size prototype dimensions and AutoCad images are provided in Appendix C.

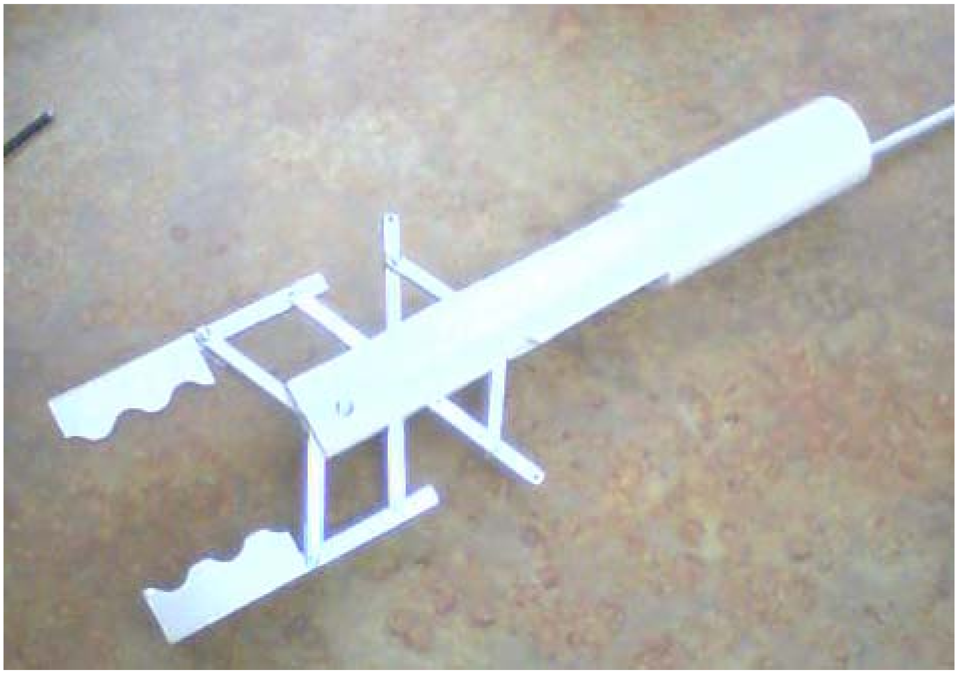


Figure 17. The large prototype is made of aluminum rods and blocks, steel screws and nuts, and PVC pipe.

§7.2 Circuit Design

The circuit was constructed and is diagrammed in the Figures 17 and 18.

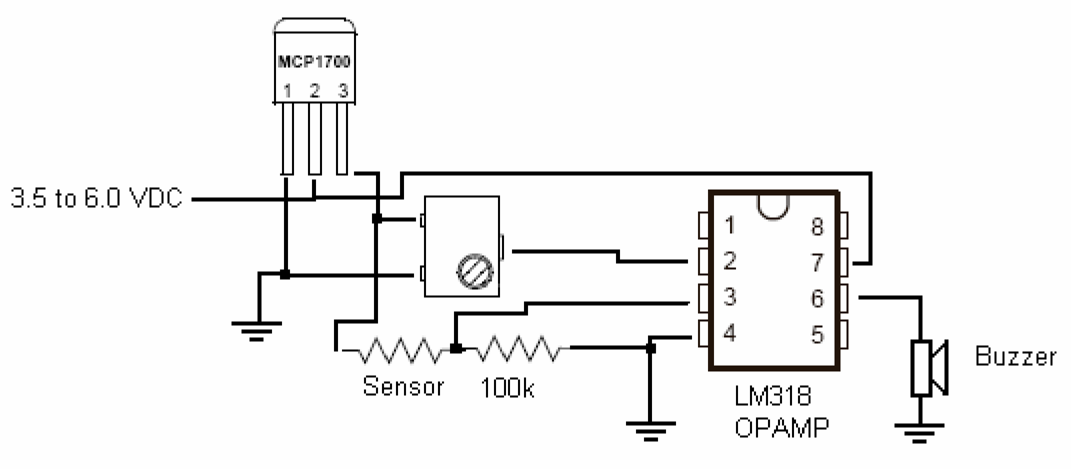


Figure 17. Schematic of the circuit.

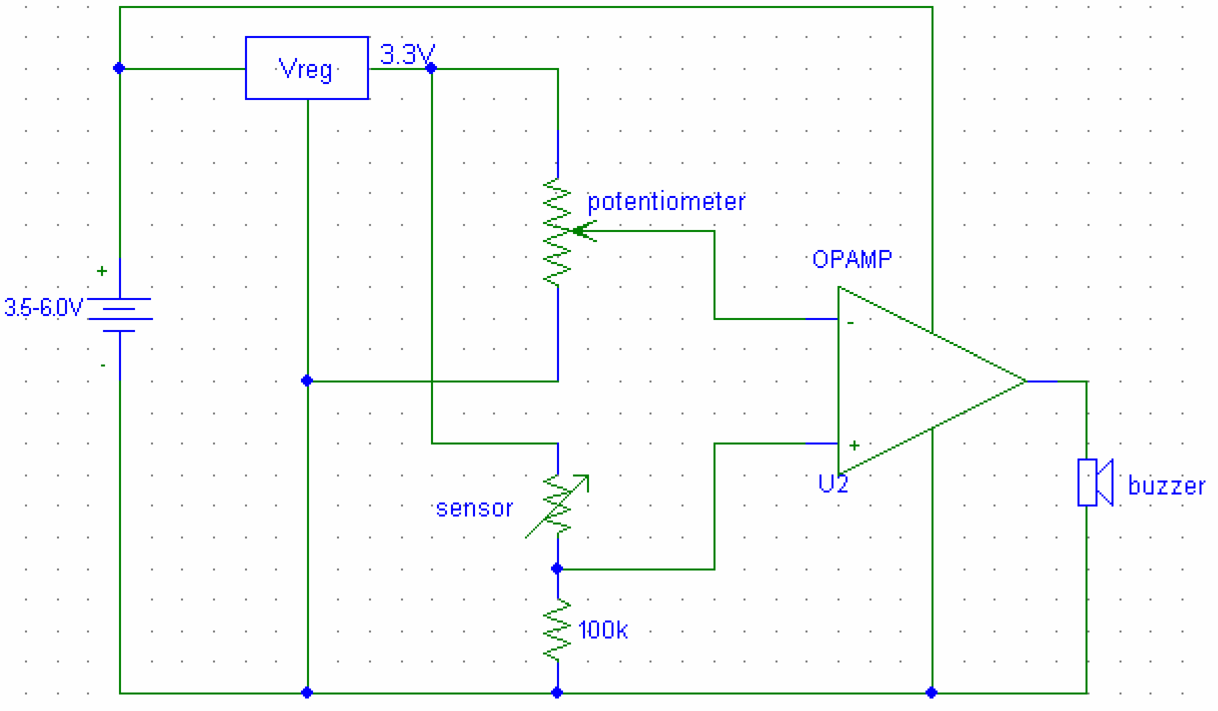


Figure 18. P-Spice representation of the circuit.

The buzzer circuit is powered by a 6.0V battery which directly drives the supply voltage of an operational amplifier and a 3.3 V voltage regulator. A potentiometer, or a variable resistor, is used to divide the 3.3 V and inputs to the inverting side of the opamp. This opamp is used as a voltage comparator which drives a buzzer if the non-inverting input voltage is higher then the inverting input, or the reference voltage. The variable voltage, or the non-inverting input, also comes from a voltage divider. Its voltage output is dependant on the force sensor. As the force sensor is compressed the voltage goes up. If the sensor is pressed too much, the voltage will rise above the reference voltage causing the comparator to output 6.0V, thus turning on the buzzer.

§8 Results

In order to calibrate the force sensor, a known force was exerted. This was done using a spring with an initial length of 2.6cm. First, a known mass (2.95 kg) was rested on a spring and the spring compression distance (1.0 cm) was recorded as Δx. The force exerted on the spring was calculated by Newton's second law, $F = m*a$. The force was calculated to be 29.03 N. Hook's law, $F = k*\Delta x$, was used to calculate the spring constant (29.03 N/cm). Using the spring constant, the force between the grasper jaws was determined by measuring the distance the spring was compressed. Using Hook's law, it was determined that compressing the spring to a length of 2.25 cm would generate a compressive force of 10 N, the threshold value. By holding the spring at this compressed length, the potentiometer was adjusted to the proper resistance in order to produce the threshold voltage of 3.8 V. This threshold voltage produced an audible sound in the buzzer.

The large prototype was tested 3 times using a spring with a spring constant of 9.74 N/cm at the two ends and the mid point of the jaws. When the springs were compressed with a tensile force of 37.58 N on the rod, equal deformations of 1mm were observed from all three springs. Using an analysis with Hook's law similar to the previous paragraph, we concluded that there was an even force distribution (0.9744 N) along the surface of the jaws.

The jaw mechanism ratio of input force on the rod to output force in the jaws was disadvantageous when we conducted the tests on the large prototype. The ratio (0.9744N/37.58N) was calculated to be 0.0259. The large input force necessary to produce the small output force would be minimized by the production of the handle with a lever mechanism, as shown in figure 19.

Figure 19. A mechanical advantage is produced by the lever.

§9 Problems

Problems that arose in the design were limited to the building of the prototype. The grasper design is sound but needs more precise, preferably computerized manufacturing. As expected, the largest problem was assuring that the assembly parts were made precisely enough that it could function normally and be assembled easily.

§10 Future Work

Further production must be done to get beyond showing feasibility of the design. An actual-size prototype should be constructed using computer controlled machine tools. This could then be tested to provide exact measurements for correlation of force at the grasper end to force exerted at the handle. Different materials should be used, such as stainless steel, for the jaws, pins, bars, and shaft. The housing and handle are recommended to be constructed from high temperature resistant polymers such as Radel R. The circuit should be printed and housed in a separate casing.

With these modifications to the final design, a reliable force-sensing, trauma-minimizing laparoscopic grasper may be produced.

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Appendix A

Design Matrix

Design	Maintenance (5)	Sterilization (5)	Strength (5)	Cumbersomeness (5)	Connectivity (5)	Accuracy (5)	Feasibility (5)	**Total (35)**
Strain Gage on the Handle	1	4	2	5	1	3	2	**18**
Strain Gage on the Actuator	2	4	2	2	1	2	1	**14**
Force Sensor	3	3	5	4	3	2	4	**24**

*Scale: 1-5

1: Poor

3: Satisfactory

5: Outstanding

Appendix B (PDS)

April 28, 2006

Atraumatic grasping instrument –Product Design Specifications

Team:

Adam Dahlen (Leader)
Darshan Patel (Communicator)
Clara Zhang (BSAC)
Andrew Eley (BWIG)

Function: Current minimally invasive laparoscopic surgical tools are insufficient in their ability to grasp and hold a large amount of the bowel without causing injury to the patient when performing surgery. A new tool suited to this task by providing feedback (auditory or tactile) to the surgeon is necessary. The goal is to reduce injury due to excessive pressure to the bowel organs during laparoscopic surgery.

Client requirements:

- "floatable" jaw to reduce pinching of bowel
- Provide feedback of pinching pressure
- must fit through 5mm port
- must be about 30 cm long
- optional ratcheting for locking
- autoclavable or disposable

Design requirements:

1. Physical and operational characteristics

a. *Performance requirements*: The design must be able to grasp a large portion of bowel without causing damage, and provide feedback of the pinching pressure. The option to lock or not lock the grasper in place would also be preferable

b. *Safety*: The design must not be hazardous to surgeons or the patient. The design must be sterilized, decontaminated, and disinfected so the risk to patient safety is minimized. The grasping end must not have separate or loose parts that could possibly get lost in the patient.

c. *Accuracy and reliability*: Accuracy is an important aspect of this design, but precision is not a major concern. It must be precise enough to ensure that no damage is done to the tissue. The grasping mechanism must be solid with little slack.

d. *Life in service*: The final design will be used repeatedly during surgery. It must be made of durable material such as stainless steel. The circuit should need little maintenance.

e. *Shelf life*: This device should last several years in a hospital environment.

f. *Operating environment*: The design must be autoclavable, and easy to use in an operating room.
g. *Ergonomics*: The handle should be easy to use and grasp by a surgeon.
h. *Size*: This device must fit through a 5mm port and measure about 30 cm. long.
i. *Weight*: The design should not be heavier then a pound.
j. *Materials*: Autoclavable parts must be used for the grasper, such as stainless steel. Other materials may be used, for parts that could be detached, as long as it can be sterilized and not compromise patient safety.
k. *Aesthetics, appearance, and finish*: The device will look like a regular laparoscopic instrument.

2. Product characteristics:

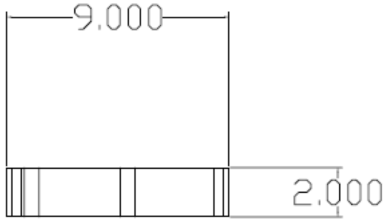
a. *Quantity*: One large model will be prototyped to show; if successful, further manufacturing of the recommended design can be done and utilized for future testing or redesign.
b. *Target product cost*: The cost of building the prototype should be under a few hundred dollars.

3. Miscellaneous:

a. *Standards and specifications*: FDA approval is not required.
b. *Customer*: The client would prefer the model to be inexpensive, and reusable.
c. *Patient-related concerns*: Sterile equipment must be used to ensure patient safety, thus the device must be autoclavable.

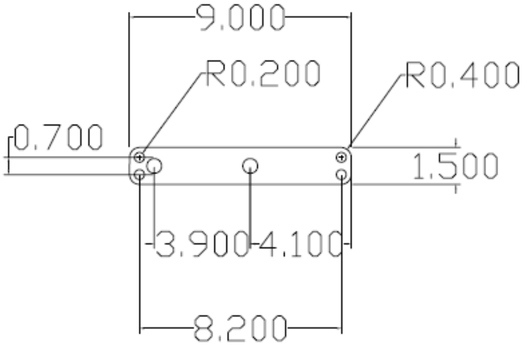
Appendix C

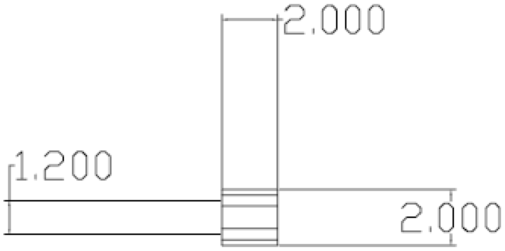
Prototype Dimensions

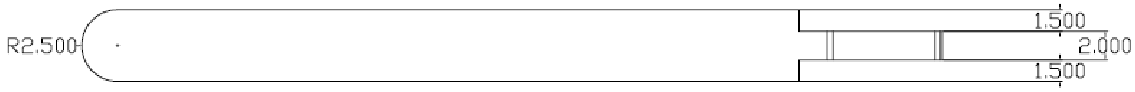


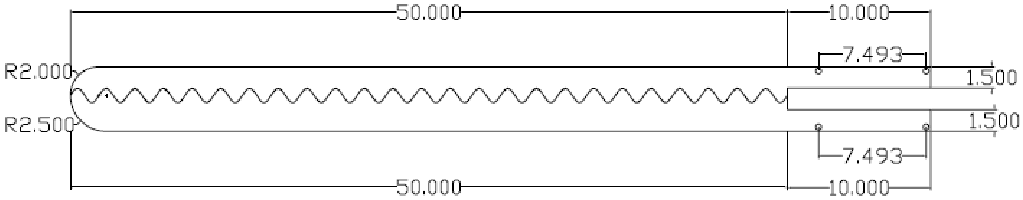
Center piece:

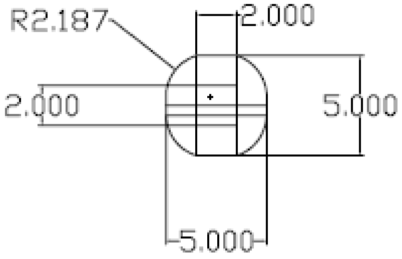
Top left drawing is top view
Bottom left drawing is side view
Bottom left drawing is front view





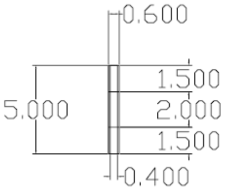


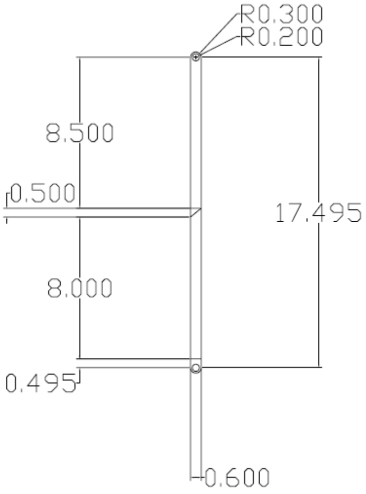




Jaws:

Top drawing is top view
Middle drawing is side view
Bottom drawing is front view

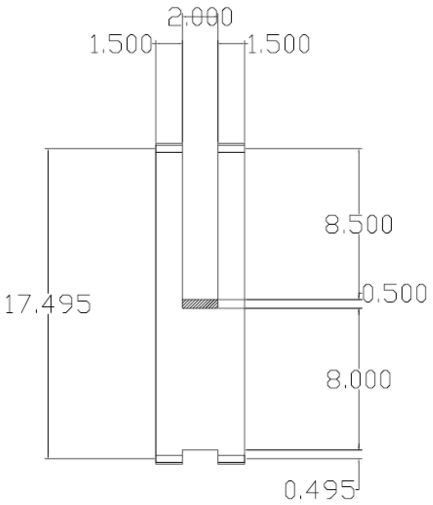


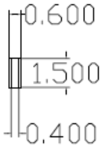


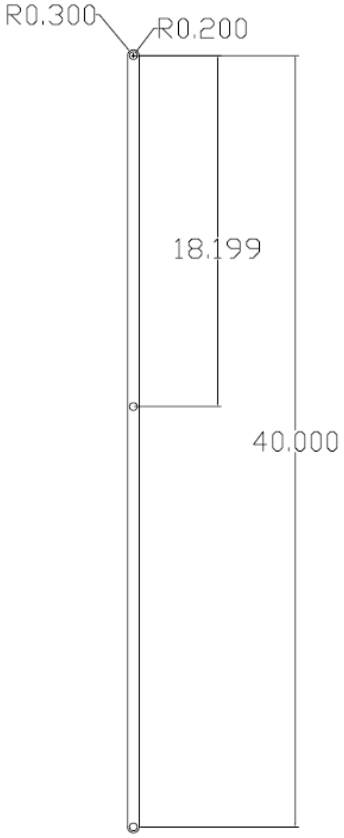
H Piece:

Top drawing is top view
Left drawing is side view
Bottom drawing is front view

*there are two in the assembly



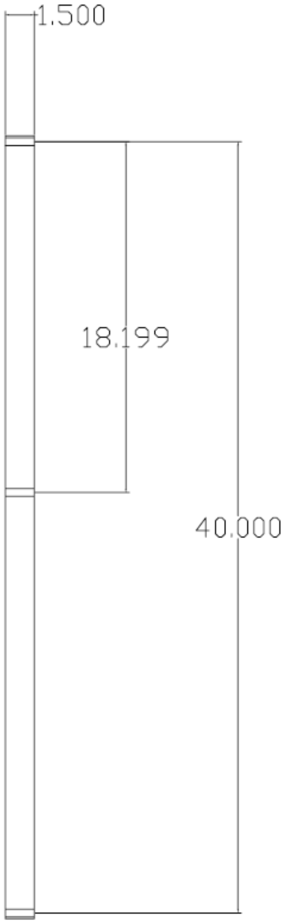


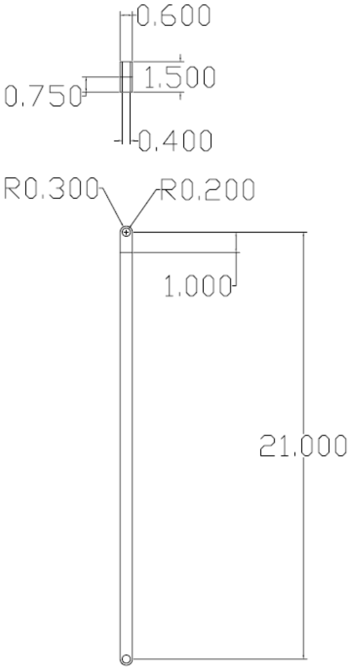


Long Middle Bar:

Top drawing is top view
Left drawing is side view
Bottom drawing is front view

*there are two in the assembly

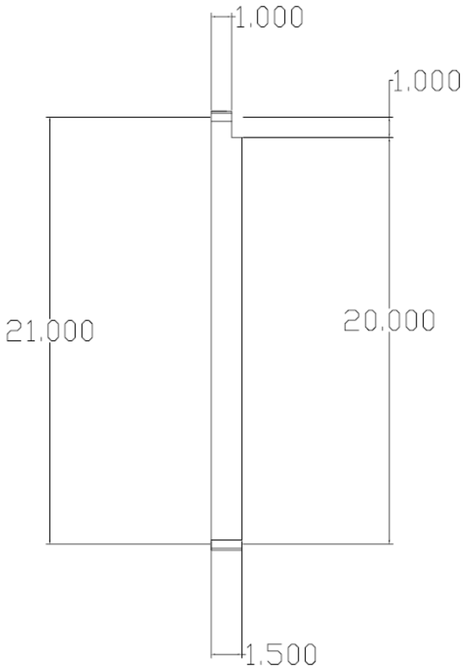


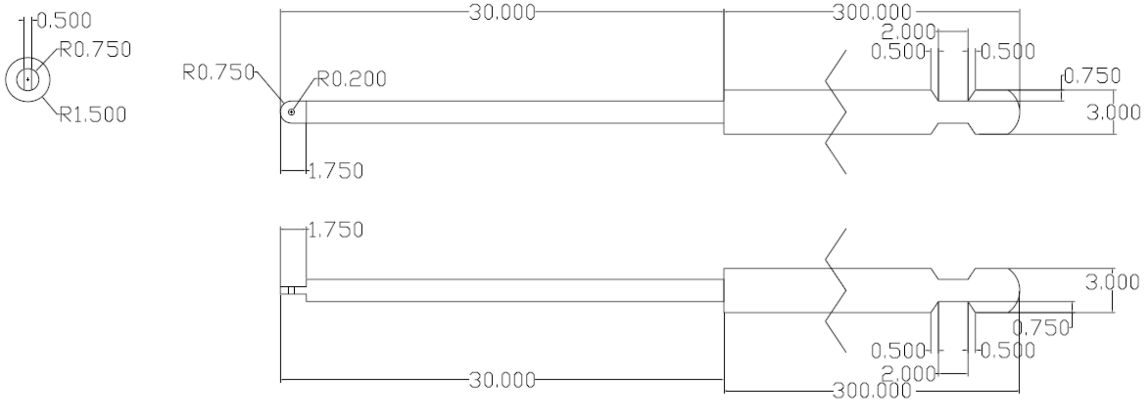


Far right bar:

Top drawing is top view
Middle drawing is side view
Bottom drawing is front view

*there are two in the assembly

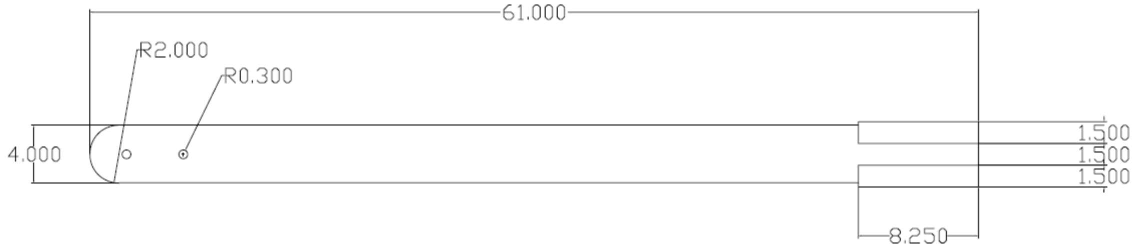


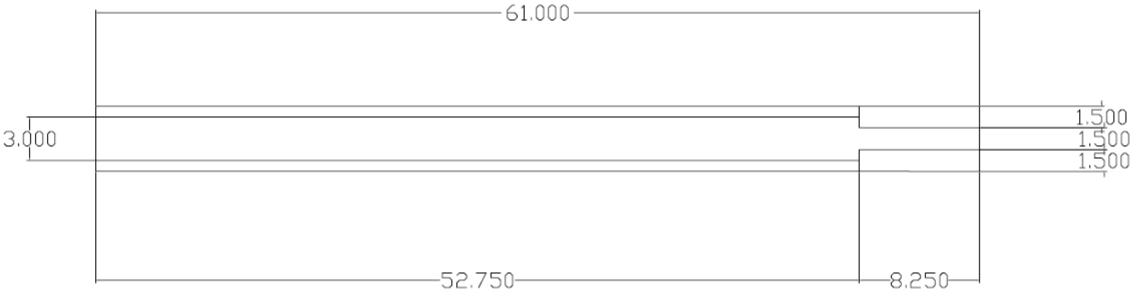


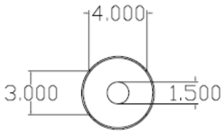
Rod:

The top left drawing is a front view
The top right drawing is a side view
The bottom drawing is a top view

*the zig zag line represents a portion of the bar not shown.

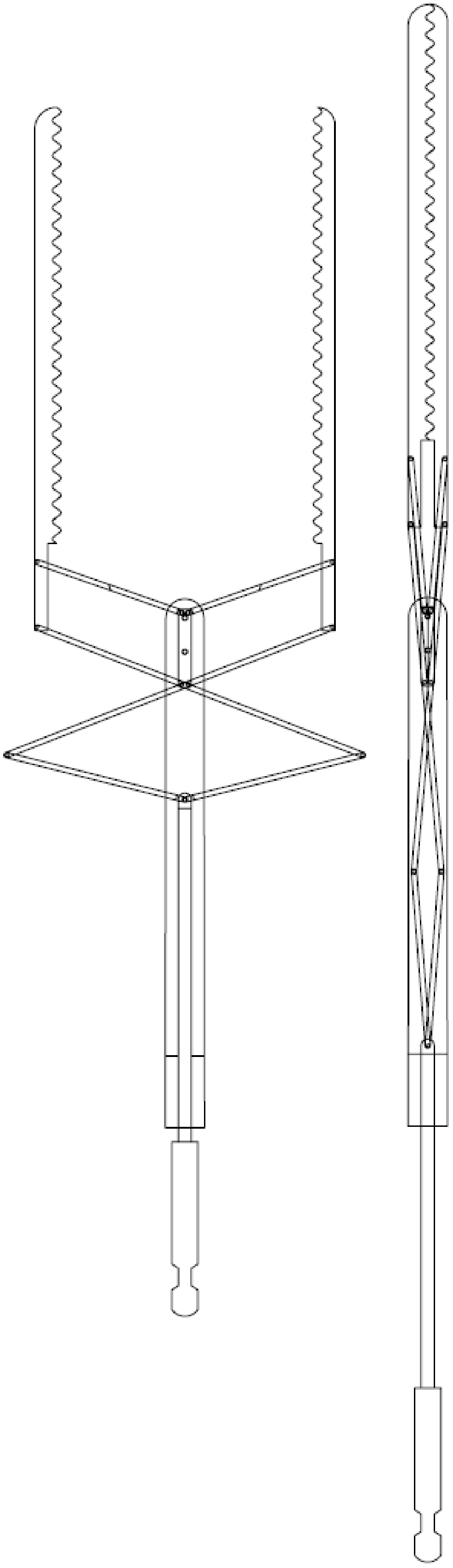






Sheath:

The top drawing is a top view
The middle drawing is a side view
The bottom drawing is a front view



The complete assembly:

The left view shows the assembly in an open position
The right view shows the assembly in a closed position.