

Minimally Invasive Surgery Tool

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Team Members:

Sujan Bhaheetharan (BWIG)
Ashley Huth (BSAC)
Max Michalski (Communicator)
Brenton Nelson (Leader)

Client:

Aimen F. Shaaban, M.D.
Assistant Professor of Surgery
University of Wisconsin Medical School

Advisor:

Willis Tompkins, Ph.D.
Professor at the University of Wisconsin-Madison
Department of Biomedical Engineering

Introduction:

Minimally invasive surgery is a technique that has become increasingly popular practice. This method is chosen because of the many advantages that it provides patients in comparison to traditional surgery. Advantages for patients include reduced hospital stay, shorter recovery time, less scarring, and reduced postoperative pain. In some cases, minimally invasive surgery can reduce the severity of complications that arise during traditional open surgery.

Minimally invasive surgery is performed through small incisions at the site of surgery. Typically three holes are made. A laparoscope, a device similar to a camera, is inserted through one incision which transmits two-dimensional images to a viewing screen. Surgical instruments are inserted into the other two incisions. The surgeon then uses the viewing screen to monitor his/her maneuvers inside the patient. Due to the complexity of this technique and current instrumental limitations, minimally invasive surgery is not suited for all operations. Further research can be done on surgical instruments to increase the efficiency and potential applications.

This report will address the current problems that are associated with minimally invasive surgery. First, the limitations of commonly used surgical tools will be investigated. Then the report will focus on solutions that are currently being employed, as well as mention additional areas in which improvements can be made. New designs which can improve current surgical tools will be proposed, and to conclude, future work to be done on this topic will be the discussed.

Background:

Minimally invasive surgeries are most commonly performed using mechanical laparoscopic tools. These instruments are hand operable, similar to that of a scissors or pliers (depending on function of the instrument) and a long thin shaft (approximately 5mm in diameter) which connects the tool to the handle. Depending on the specific design, some instruments have different control features such as a spin wheel that controls x-axis rotation or ratcheted handles that can secure tools in different positions.

Despite the variety of features, current hand-held minimally invasive surgical instruments have limitations that are impeding surgeons' ability to perform various procedures. One of the major constraints is that these tools are only able to rotate around the x-axis, and when doing so the control is uncomfortable, physically taxing, and difficult to use in tandem with other controls. The restriction of motions in the y-z direction makes it impossible to achieve "wrist-like" motion that would allow surgeons to more efficiently complete certain tasks such as sewing. Another major limitation of the current hand-held products is their inability to provide accurate feedback. Due to the seriousness of these surgical procedures, it is imperative that the surgeon is able to sense how much tension or pressure is being applied to the operation site. Depth perception is another major concern, because the two-dimensional images that are transmitted to the screen lack depth, providing insufficient means to facilitate accurate hand-eye coordination. The current problems associated with hand-held instruments have been addressed by Intuitive Surgical in their design of the *da Vinci*[®] Surgical System. The *da Vinci*[®] is an extremely sophisticated surgical robot that enables surgeons to



Figure 1: *da Vinci*[®] Surgical System allows surgeons to operate from across the room.

perform laparoscopic surgery without direct patient contact. The design consists of four main components including a patient sidecart, surgeon console, insite viewing, and endowrist instruments. Combined these components offer solutions to the current problems associated with minimally invasive surgery. The insite viewing displays a three-dimensional image that enhances the surgeon's depth perception by virtually replicating true-life images. This feature is found within the surgeon console, along with the controls for the robotic arms and endowrist instruments that perform the physical operations inside the patient. Endowrist refers to the ball and socket joint that connects the tools to the shaft and provides seven degrees of motion which effectively mimic the movements of a human wrist. Although endowrist instruments and hand controls are linked by means of robotics, they have been designed to provide advanced tactile feedback.



Figure 2: Endowrist instruments mimic wrist motions.

The *da Vinci*[®] Surgical System offers solutions for current tools' limitations, yet the system poses problems for minimally invasive surgery. First, purchasing a *da Vinci*[®] is a costly investment for any medical institution costing approximately 2 million dollars. Depending on how often the system is utilized this investment could potentially be uneconomical. Time is also an issue with the *da Vinci*[®], as additional training must be done for surgeons to learn how to use the system. Extra time is also required for the set up of the robot before each surgery. The advanced features of the *da Vinci*[®] model, although convenient, have drawbacks. The surgical console separates the surgeon from the patient, which may be uncomfortable for some surgeons who prefer proximity to their patients. Likewise, the patient sidecart with four robotic arms are rather cumbersome, taking up space above the patient and limiting patient access. Lastly, as with any new instrument, there is always a possibility for the system to have needs for costly updates.

Current handheld designs are sufficient for performing limited surgical operations; however, other operations require greater mobility. While the *da Vinci*[®] offers solutions to problems associated with current hand-held instruments, they present additional problems to surgeons. Our intent is to create a device that incorporates the current hand-held device mechanics and the design features that produce the “wrist-like” motion in *da Vinci*[®]. By doing so, we will be able to help surgeons to overcome the difficulties they are currently experiencing while performing minimally invasive procedures.

Problem Specifications:

To further specify areas of improvement, a problem statement has been crafted to focus the work:

A more efficient surgical instrument for minimally invasive surgery is desired. The instrument must be operable by hand and optimally will mimic the motions of the human wrist. Improvements of various factors for convenience are necessary and include, but are not limited to: applied force feedback, reusability, and simple operation for new users.

These goals were kept in mind while designing the prototypes described in the following section.

To define areas of specific concern, the following constraints will be applied. The instrument will be used in a surgical setting and must simulate the surgeon’s hands. A tool that is able to mimic the dexterity of a human wrist, allowing simultaneous rotation and bend, is necessary. It is essential for the tool to provide adequate tactile feedback, to indicate the pressure or stress being applied to the operation site. Accuracy is another key component; surgeons must be able to operate the tool with exact precision. Since the instrument will be used in a surgical setting, it is imperative that complete sterilization of

the tool is possible after each use. To offer the same size minimally incision as current tools, the instrument must be no more than 5 millimeters in diameter. Reduction of the shaft's diameter is desirable, but not necessary. Finally, the instrument must be intuitively designed to minimize the time it would take for a person to acclimate themselves to the use of the tool.

Design 1: Joystick Control

Overview

The joystick control design utilizes a thumb-maneuvered joystick for smooth movement of the serrated graspers. The joystick control method is very similar to motion simulated by the *da Vinci*[®] Surgical System with an added trigger to open and close the graspers.

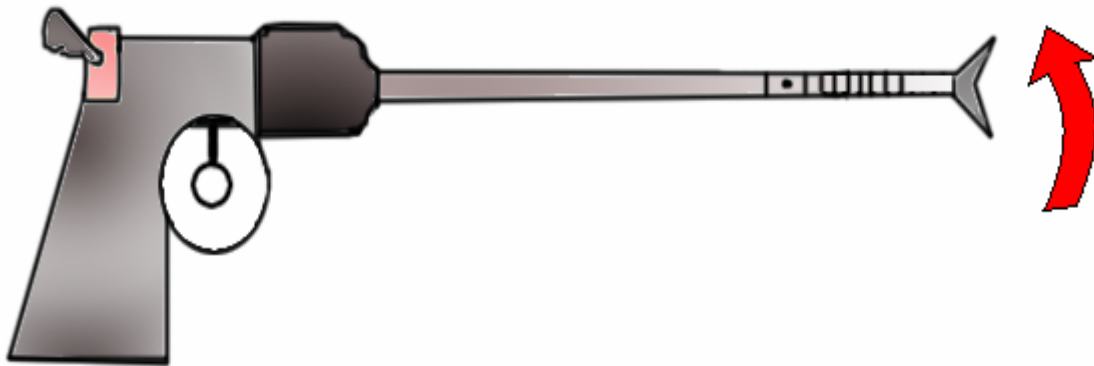


Figure 3: The joystick controlled device. Simultaneous shaft bend and rotation through motion translated to ball and socket joint from thumb-controlled joystick. Trigger mechanical linkage opens and closes the serrated graspers.

Common application of this instrument is as follows:

The operation is initiated by inserting the closed graspers into the patient to the approximate location of operation. The graspers is opened and closed through a simple trigger mechanism. In order to keep the graspers closed the surgeon pulls back and holds the trigger in the position needed to clasp the needle or organ required to perform the operation.

Movement of the graspers is then initiated by the joystick. The joystick movement is

directly translated to the ball and socket

joint in the shaft of the forceps. The ball and socket joint provides seven degrees of

freedom similar to the *da Vinci*[®] Surgical System. As illustrated in Figure 3, the joint also provides surgeons the ability to bend and rotate the graspers and shaft simultaneously. The joystick movement of the shaft can easily be stabilized through use of guided tracks. When the joystick is positioned into the guided tracks illustrated in Figure 4, it provides a smooth sweeping motion of the graspers. The guided tracks reduce the affect of hand tremors which are minimized in most robotic surgical instruments. The guided track system of the joystick pad has grooves at the end of each track which allows the surgeon to lock the shaft at a desired angle.

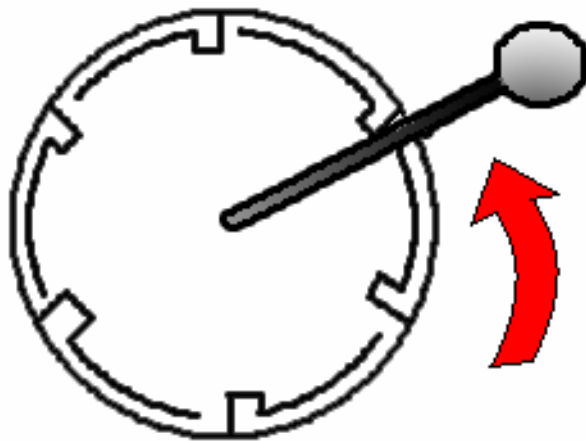


Figure 4: Joystick guide track. Numerous tracks around the perimeter of joystick pad allow for the joystick to be locked at angles in the grooves as well as smoothly swiveled around.

Pros

The joystick controlled device has many benefits derived from simultaneous bending and rotating of the shaft and the ability to operate all functions with only 2 digits. Simultaneous bending and rotating allows for wrist-like motion providing an easy means of sewing with laparoscopic graspers. The ability fully operate the device with 2 fingers reduces hand fatigue and increases ease of clutching the handle.

Cons

Although the joystick controlled mechanism has advantages there is one major disadvantage which cannot be easily avoided. The purpose of the project is to create a device which can replicate the complex movement of the *da Vinci*[®] Surgical System with a simple hands-on approach. The joystick controlled device lacks the tactile feedback surgeons need to safely and accurately perform an operation. In order to provide the necessary feedback a complex computer aided system must be implemented in the design which would lead directly back to original robotic surgery devices. Another disadvantage of this method is the inability to reuse the device which increases cost for medical institutions because the tool must be disposed after each patient. The instrument must be disposed after each use because of an inability to sterilize the ball and socket joint. A minor drawback to this design is the need for continuous force applied to the trigger in order to keep the graspers closed which quickly causes hand fatigue.

Design 2: Trigger Control

The trigger controlled graspers is a laparoscopic surgical tool adapted to bend and rotate the shaft to mimic human wrist-like movement. A rear “pen click” switch controls the opening and closing of the graspers. As shown in Figure 5, the Trigger Control, as with all of the prototypes, is a modified version of the original laparoscopic graspers.



Figure 5: Trigger Controlled surgical forceps. This design allows synchronized shaft bending and rotating which closely replicates human wrist maneuvers. The red “pen click” switch located on the top of the handle allows for locking the graspers in the open or closed position.

The method followed to operate with the trigger control design is similar to that listed below:

The closed graspers are inserted into the patient. Once in position to maneuver the graspers the “pen click” switch, located on the rear top region of the handle, is pressed once with the thumb to open the graspers. The next step in operation is to move the forceps to the desired location, followed by clicking of the switch to grasp the object. Once grasped, the surgeon may then manipulate the trigger mechanism that allows for simultaneous bending and rotating of the

end of the shaft and graspers. As the trigger is pulled back, the end of the shaft begins bending until the trigger stops. The shaft is bent by an accelerator cable, extending and contracting accordingly to shifting of trigger. As seen in Figure 4, there are numerous notches where the trigger can be placed to lock the graspers at various bent angles. The trigger returns to the initial position by means of a spring pulling the trigger forward. As the trigger spins the solid rod attached to the handle and the top of the shaft begins to cause rotation in the shaft. Synchronized spinning and pulling of the trigger closely replicates the movements of a human wrist allowing surgeons an easy means of sewing.

Pros

The trigger control design has the ability to provide spinning and bending movements in unison, mimicking wrist motion. These two functions operate through direct mechanical linkages providing surgeons the ability to receive tactile feedback, indicating the magnitude of the force that is being applied on the operation site. The “pen click” switch locks graspers in place simplifying surgical operations. As shown in Figure 3, the various functions of this device can be easily performed while holding the device in one hand. The arrangement of the apparatus needed for operation reduces hand fatigue which is essential in longer surgical procedures.

Cons

While there are many advantages to this design there is a minor limitation. The bent shaft leaves an opening in the tool making sterilization nearly impossible. Inability to sterilize the device makes it a non-reusable tool and therefore becomes costly for

hospitals and other medical institutions. This design will also include multiple ball bearings involved in the spinning trigger and shaft which cannot be easily sterilized due to the grease needed for smooth movement.

Design Prototype 3: Double Trigger

Overview

The double trigger prototype manipulates the mechanism of Ethicon's[®] laparoscopic linear staplers. Minimally requiring only one hand for operation, graspers of the double trigger design can maneuver in all degrees of freedom by means of use of grasper trigger, secondary bending trigger, rotation knob, and pivoting graspers horizontally during laparoscopic surgery.

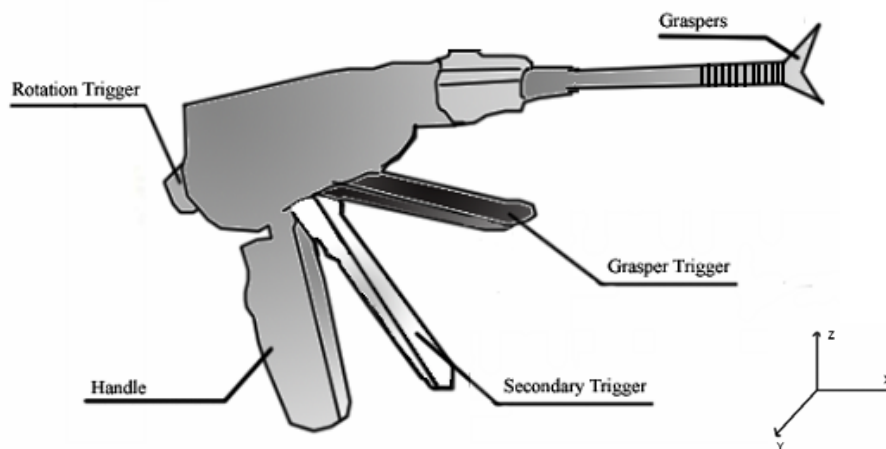


Figure 6: Double trigger control. The double trigger control utilizes many tools in order to perform the necessary wrist-like motion.

To emulate wrist mechanism during suture, secondary trigger is clasped towards handle, stimulating negative vertical displacement of graspers. The secondary trigger is spring-loaded, and requires continuous applied force. The more force applied to secondary trigger, the greater the angle displacement graspers is. Releasing the secondary trigger causes graspers to displace back into original position. Rotating the rotation trigger/knob in

clockwise or counterclockwise direction translates respected movement to graspers about its axis. Clasp Grasper Trigger towards Secondary Trigger clamps graspers. Grasper trigger is moved in opposite direction in order to release clamping of graspers.

Simultaneous application of secondary trigger and rotation knob allows graspers to move about vertical and horizontal plane, depending on force applied to secondary grasper. The enablement of maneuvering graspers in degrees of freedom afore mentioned, allows the user to perform stitching in wrist-like motion.

The gears and internal parts which stimulate and translate trigger movement to grasper will be covered by an outer layer which is thin, yet durable. Handle will consist of thin black foam grip, increasing comfort when prototype is used over extensive periods of time. The length of prototype will be the same as current laparoscopic graspers. Movement of graspers will be highly sensitive to movement of triggers, thus maximizing the amount of feedback.

Pros

Primarily the prototype provides tactile feedback, allowing the user to know how much pressure is being applied to specified area. The simultaneous application of secondary trigger and rotation knob allows graspers to move with respect to horizontal plane; such mechanism minimizes the amount of wrist motion. The prototype will be reusable due to the amount of material necessary to build a single prototype. In addition, the prototype satisfies ergonomic use, providing a handle grip. The double trigger design only requires a single arm for operation; it does not require immense work compared to current laparoscopic graspers.

Cons

The prototype's internal mechanical parts will require the design to receive complex sterilization techniques. In addition, without testing our prototype we will be unable to find whether the directions to use the control are possibly confusing. The addition of springs in secondary trigger requires force; however, there is no lock mechanism in which surgeons can lock the trigger at specified position. Applying constant pressure to trigger is impractical, and compromises the advantage of this design, precision of laparoscopic surgery. Further research must be made to conclude if the placement of the spring will be beneficial, and, if so, the optimal location and spring constant to assure accurate precision when constant applied force is desired over long duration.

Design Matrix:

In the design matrix, we felt that the two most important factors to be considered are feedback/reliability and wrist-like motion. The Trigger Control design won in both of these categories as seen in the total score. The other categories that we included in our design matrix were price, ergonomics, and ease of production. We have decided to pursue the Trigger Control design, although we will have to research further in order to construct a valid mechanism.

Factor	Weight	Joystick	Trigger	Double Trigger
Price	3	2	3	3
Ergonomics	4	1	4	3
Ease of Production	2	1	4	3
Wrist-like Motion	5	5	5	4
Ease of Use	4	4	5	3
Feedback/ Reliability	5	1	5	4
Total		58	103	79

There are many parts of the project still left for us to do this semester. We have to finalize the dimensions that we want to start building our prototype with, and then start by building a preliminary prototype, possibly with the Rapid Prototyping technology that we have available to use here on campus. Once completed and changes are made which we see fit, we will have to perform final tests to see if the different pieces in our designs can stand up to the sheer and strain forces that will be acted on them throughout their use. When we have decided on everything to be in the final design, we will make a working prototype and test it to see if what we have done will work out during operation.

Final Design

Based on the design matrix one design was selected to be further researched and improved. Emphasis of selection was placed on the simplicity of the mechanism and the extra degree of freedom it would provide. After carefully reviewing this design, minor changes were made to the trigger mechanism. In order to simplify the instrument we combined the three necessary motions in two controls. The trigger control and the flip switch are the two mechanisms that control all movements of the shaft and the graspers which allow the tool to imitate the motions of the human wrist and hand. The following breaks up each component of the final design.

Clamp and shaft:

The clamp utilized was obtained from a current laparoscopic model. The clamp must perform the same functions as before so modification from current designs is not

needed. The clamp was attached to a hollow aluminum shaft (shaft A, as pictured in figure 7) of about 10 cm. A second aluminum shaft (shaft B) of about 40 cm was attached to shaft A by a hinge. The hinge fits on the inside of the shaft with two torsion springs mounted to the

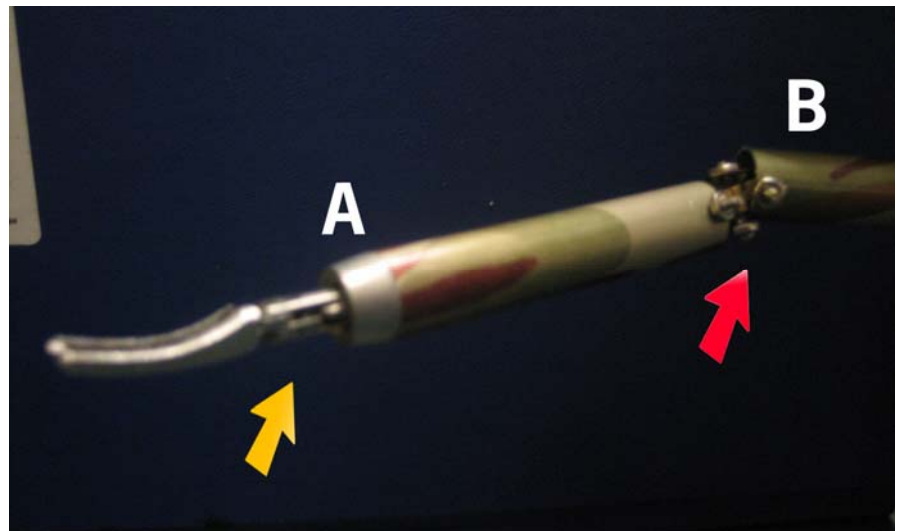


Figure 7: Shafts labeled A and B, respectively. Orange arrow points to the clamp and the red arrow points to the area where the hinge and torsion springs are located.

hinge by a small bolt and nut. The torsion springs were set to have force that kept shaft A at a 45 degree angle with respect to shaft B. Two accelerator cables were run through shaft B toward the hinge region. One accelerator cable was attached to the clamp which operates the opening and closing of the clamp. The second cable is attached to shaft B, with its insertion point opposite to the hinge. As the second wire is pulled taught toward the handle, shaft A extends until it is parallel to shaft B and rests end to end.

The Handle:

An ergonomic handle was designed to alleviate the discomfort of the original designs. The basic configuration resembles that of a handgun, which rests in the hand comfortably allowing easy movement of

digits while holding the handle. The inside of the handle was left hollow to allow the addition of the mechanism that rotates the entire shaft. The shaft was inserted into the “barrell” side of the handle, with a mount that is able to rotate freely. This mounting is controlled by a simple bevel gearbox that is enclosed in the handle. The bevel gears had a 1 to 1 ratio and operate at a 90

degree angle to one another, with the second bevel gear pointing down the handle. The cables continue through the bevel gear which has been drilled out to allow the cables to pass to the back of the gearbox. These cables then separate; one follows a path routed out

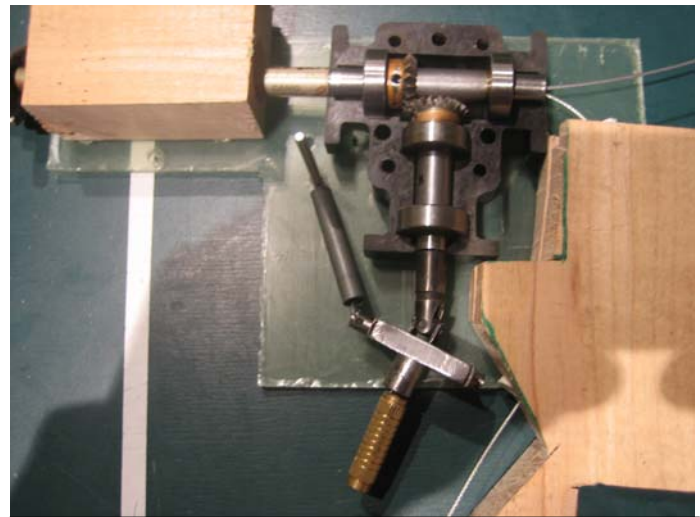


Figure 8: Beveled gears with 1:1 ratio. Trigger rotation translates to shaft rotation.

of the handle towards the trigger and the other through a routed path towards the back of the handle where it can be easily accessed with the thumb.

The Trigger:

The bevel gear perpendicular to the aluminum shaft was attached to a shaft that proceeds down and is located to act as a “trigger” for the apparatus. The trigger is made of the shaft taken from a dart which is then pin-mounted to a universal joint connected to the gearbox. The rotation of the trigger rotates the bevel gear and thus translates rotation 90 degrees to rotate the entire shaft. Using a universal joint, the trigger is connected to the gearbox shaft and allowed to move parallel with

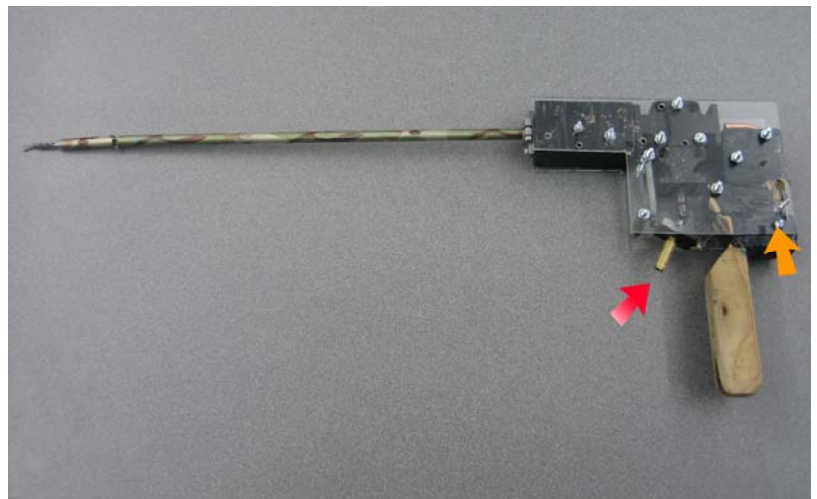


Figure 9: Depicted above is the prototype of the laparoscopic grasper. The red arrow points to the trigger and the points to the switch.

the aluminum shaft. The accelerator cable connected to the shaft was connected to a bearing which moves with the trigger but allows the trigger to spin without the cable wrapping around it. An extension spring which a greater spring constant force than that of the torsion springs is used to keep the trigger forward and the shaft straight when at rest. Extension of the trigger spring allows the torsion spring to rotate the shaft about the hinge, allowing the desired extension and contraction motion of the shaft while keeping the shaft fully capable of rotating about its axis.

The Clamp insertion:

Extension springs oriented away from the motion of the accelerator cable keep the clamp closed at rest. The extension of these springs forces the accelerator wire toward the clamps and open the clamps. This simple mechanism is operated by thumb and controls the grasping motion of the clamp.

Conclusion

In completing the prototype, we are pleased with the results, nevertheless further design is necessary to bring size of the prototype down to actual proportion. The system mechanically works well. It allows the user to manipulate the trigger, causing the graspers to imitate wrist motion. The final prototype seems efficient, and is extremely convenient. We believe that our design has improved upon the mechanics of current laparoscopic grasper designs; however, the prototype should undergo further design to meet surgical operation and sanitary requirements. Following this, testing should be conducted.

Future Work

Due to time restrictions and the complexity of the mechanical design of our project, we were unable to construct a prototype that met all design specifications; however, we have detailed plans on the future work that must be done in order to meet all design requirements. Work would focus the materials, minor design modifications, and testing to guarantee that the design is safe for use in surgical procedures and fulfills all necessary FDA requirements for medical devices.

Materials:

Since the laparoscopic grasper is designed for use in human surgery it must be constructed of materials that can be easily sterilized or disposable. Desirable materials would also be lightweight for ease of use and durable enough to withstand human elements during surgery. Materials used for the handle control which will not come in contact with human matter, could consist of a combination of hard or soft plastic for a disposable design and stainless steel for reusable designs. Materials used for the shaft and graspers would be stainless steel.

The design of this laparoscopic grasper features an extra joint, which could pose potential problems with sterilization and safety if left exposed. Ideally a thin flexible casing would enclose this portion of the shaft preventing human contact with the mechanical inter-workings of the instruments. The material of this casing must be able to withstand the stress of frequent bending and straightening, however an ideal material would not impede the shaft's ability to bend. A possible material for such a casing would consist of a flexible plastic that meets sanitary requirements. The current prototype has many small openings that could pose as another potential problem for sterilization and patient safety. Future designs would be sealed well to close any openings that pose potential threats.

Design Modifications:

Other design improvements that would be made would concern the ergonomics and aesthetic appeal of the instrument. Overall the instrument would be downsized. In

particular the shaft of the instrument should have a diameter of approximately 3mm to minimize the invasiveness of surgery. The handle of the laparoscopic grasper would be slightly smaller in circumference and the switch to open to the graspers would be placed closer to the handle. These changes would make the instrument easy to use for all hand sizes and increase comfort. Future design's bodies would resemble that of the current laparoscopic graspers to be more visually appealing and to minimize the excess weight of the handle. Other minor modifications should be made to enhance all motions making them as smooth as possible.

By employing these changes in our current design we will meet all design specifications. These changes will also increase the safety of our instrument, but further testing will still be necessary to confirm that the instrument is reliable to for use in surgical procedures.

Testing:

Testing must be done in order to improve the precision, accuracy, and durability of our design. To test the accuracy and precision of our design we use our instrument in the surgical simulator that is currently used to practice minimally invasive surgery techniques. Tests would concentrate on monitoring the tactile feedback given by the instrument, as well as how precise the control movements are translated to the shaft.

To test the durability of our design standard durability tests would be performed. If the materials chosen were to be reused we would need to perform many tests to confirm that the instrument can be sanitized and will operate like new. We would also test how effective different sanitation methods are at killing all bacteria present. Potential

tests would include testing on animals prior to use in humans, so all training for proper animal testing would be necessary. Additional testing must also be done to insure that our design meets all FDA standards for medical devices in the general surgery category.

Appendix

PDS

Sujan Bhaheetharan
Brenton Nelson
Max Michalski
Ashley Huth
September 16, 2005

Problem statement:

Our client desires a more efficient surgical instrument for minimally invasive surgery. The instrument must be operable by hand and optimally will mimic the motions of the human wrist. Improvements of various factors for convenience are necessary and include, but are not limited to: applied force feedback, reusability, and simple operation for new users.

Physical and Operational Characteristics

- a. *Performance requirements:* The instrument, used for surgical operation, should simulate human wrist motion while being capable of ambidextrous use. Operational conditions require a device sensitive to movement and touch that precisely replicates tensions and pressures applied.
- b. *Safety:* The surgical instrument should maintain the current safety precautions that don't allow the instrument to slip, allow it to lock into place, and minimize uncontrolled motion. There must be simple sterilization techniques for instrument if not disposable.
- c. *Accuracy and Reliability:* The device must maintain the reliability of current product. It must be extremely reliable and durable. The new mechanism should improve the inadequate current accuracy due to poor visual images in 2-D.
- d. *Life in Service:* The product will have a temporary life in service; it will be either disposed of after its operation, or after number of years.
- e. *Shelf Life:* The product's energy source, if operated robotically, is an outlet. Simultaneously, it can be manually used.
- f. *Operating Environment:* The product will experience various surgical operative conditions. All device mechanisms will be exposed to patient's anatomy.

g. *Ergonomics*: One essential feature of our product will be convenience. The device must have clear instructions, simple to use, and single-arm operation in the case surgeon needs to use other equipment simultaneously.

h. *Size*: The current length and radius of the device, which is submerged into the patient, should be maintained; handle and parts not exposed to patient's anatomy can be increased in size.

i. *Weight*: Lighter products are favorable.

j. *Materials*: Durability, strength, and sterility are the only limitations on material. Steel is currently used for reusable model, but its prices are again rising; it may be worthwhile to explore other options.

k. *Aesthetics, Appearance, and Finish*: Not of importance but different colors between handle and parts that are inserted into patient could be used.

Production Characteristics

a. *Quantity*: It will be mass produced; however, our goal is to achieve a working prototype.

b. *Target Product Cost*: Maintain prices at or near cost currently used.

Miscellaneous

a. *Standards and Specifications*: Convenient for surgeons. There should be no confusion over instrument instructions.

b. *Customer*: None currently known; this requires further research.

c. *Patient-related concerns*: None.