December | 2012

Renal Occlusive Clamp for Laparoscopic Partial Nephrectomy

Kelsey Duxstad, Naomi Humpal, Andrew Pierce, Mike Stitgen

Client: Dr. E Jason Abel, UW Hospital

Advisor: Paul Thompson, University of Wisconsin – Madison

December 7, 2012

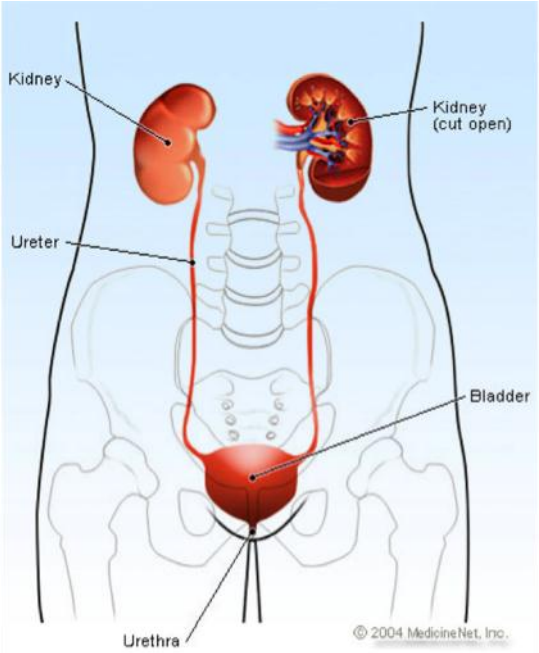
ABSTRACT

Our client, Dr. Abel, has requested that our team develop a selective renal occlusive clamp for robotic, laparoscopic, partial nephrectomy surgery. Partial nephrectomies are becoming more popular to surgeons in order spare functional tissue. Our product will optimize the partial nephrectomy by selectively occluding blood flow to part of the kidney, while allowing normal blood flow in the other parts of the kidney. This clamp will prevent global kidney ischemia which can lead to tissue damage and complications. This semester, the design will focus on the clamp end of the surgical instrument, with the laparoscopic arm being designed in future. Four different designs were developed: loop, modified bulldog, zip-tie, and crisscross. These designs were analyzed with criteria from the client and from published data about partial nephrectomy. The final design chosen from these criteria was the loop design. This design was partially modified by adding a stiff back plate, and a prototype was constructed. Three different experiments were completed with the prototype; clamp force testing, excised porcine kidney testing, and texture testing. Additionally, compression testing on excised porcine kidney was completed to determine the material properties of kidney. Next semester, testing will be completed in a live porcine model to receive feedback from the client on how the clamp performs in a surgical setting. The laparoscopic arm and handle will also be developed and tested.

Table of Contents

BACKGROUND

Partial nephrectomy is used as a treatment for renal cell carcinoma ("Renal Cell Carcinoma," 2012), which affects 32,000 people in the United States every year (Landman, 2006). The surgery is necessary because larger renal cell carcinomas do not normally respond to treatment by other methods such as chemotherapy.



http://images.emedicinehealth.com/images/illustrations/urinary_structures.jpg

Figure 1. Anatomy of the kidneys.

Currently, there are two procedures for partial nephrectomy surgery: open and closed. The open surgery is conducted through a six to seven inch incision within the lateral abdominal region (Landman, 2006). The blood flow to the area of operation in the kidney is occluded using a Satinsky clamp (Abel, 2012). The tumor is then excised and the incisions are closed.

The closed surgery is performed using laparoscopic tools. To begin the laparoscopic procedure, three to four one centimeter long incisions are made in the abdomen (Landman, 2006). After the incisions are made, the abdominal cavity is inflated to create a workspace. A laparoscope is inserted in order to identify the tumors on the kidney. At this point, the renal artery and vein are clamped using laparoscopic bulldog clamps (Martin, 2012). After the occlusion has been performed, the tumor is then excised with the goal of a negative margin, meaning all of the cancerous tissue has been removed (Landman, 2006).

The current procedure for laparoscopic partial nephrectomy requires the use of bulldog clamps to occlude blood flow of the renal artery and vein. This causes global ischemia within the kidney tissues, leading to the release of cytokines (Abel, 2012). The cytokines will induce an inflammatory response within the surrounding tissues (Furuichi, 2002), which may cause further tissue damage.

In order to prevent global, renal ischemia, a partial clamping technique may be used. The open nephrectomy surgery currently uses a Satinsky clamp to apply pressure directly

onto the kidney to occlude blood flow only to the areas of operation (Abel, 2012). However, this clamp is not compatible with the laparoscopic procedure.

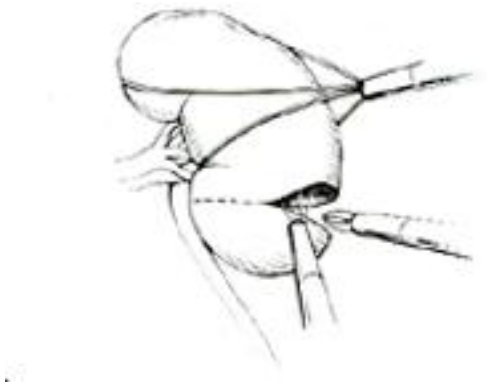


Figure 2. Illustration of a partial nephrectomy.
http://wuphysicians.wustl.edu/graphics/assets/images/FileUpload/3863image.jpg

CLIENT INFORMATION

Our client is Dr. E Jason Abel, who is a surgeon and assistant professor at UW-Madison Hospital**.** He specializes in the surgical treatment of urological malignancies and has advanced training in many types of cancer including: prostate, bladder, testis, penile and kidney. He is certified by the American Board of Neurology and performs open, laparoscopic and robotic surgeries. He has special interest in the treatment of localized and locally advanced kidney cancer.

PROBLEM STATEMENT

Our client, Dr. Abel, requests that our team develop a selective renal occlusive clamp for robotic, laparoscopic, partial nephrectomy surgery. Surgeons are performing more partial nephrectomy surgeries in order spare functional tissue. Our product will optimize the partial nephrectomy by selectively occluding blood flow to part of the kidney, while allowing normal blood flow in the other parts of the kidney. This clamp will prevent global kidney ischemia which can lead to tissue damage.

COMPETITION

Our team came across three methods that compete with our design: traditional open surgery clamps, laparoscopic vascular clamps, and the Simon Renal Pole Clamp.

Clamps such as the Nussbaum, Guyon-Pean Kidney Clamp, and Payr Pulorous Clamp are suitable for obstructing blood flow to the kidney during a partial nephrectomy open surgery. These are all suitable methods, but are not suitable for laparoscopic or robotic surgical techniques (Thompson, 2010). Due to the decrease in complications and postoperative recovery time of the laparoscopic procedure, a feasible option for clamping must be used within the realm of laparoscopic or robotic surgery.

Figure 3. Nussbaum clamp. http://www.rak-phoenix.com/prod_zoom/3107.jpg

For laparoscopic and robotic surgery there are several vascular clamps on the market. These clamps can be purchased from several different companies and work well in their application (Kobayashi, 2008). These clamps are used to occlude blood flow to the entire kidney, which is undesirable due to the risk of ischemia in kidney tissue that is not being removed, as mentioned previously.

Figure 4. Laparoscopic Vascular Clamps. http://www.aesculapusa.com/default.aspx?pageid=85

Finally, there is one product on the market, the Simon Renal Pole Clamp that combines the qualities of both the laparoscopic suitable and partial kidney clamps. This clamp permits normal blood perfusion of the non-clamped kidney during the procedure, which reduces the risk of ischemic damage. It has flexible jaws and linear grooves for safe and atraumatic grasping of the kidney. Its working length measures 37 cm and is attached to a laparoscopic ratchet handle. This product is made by Aesculap (Aesculap Surgical Technologies, 2012). However, our client does not like that the force is concentrated at the base of the clamp rather than distributed across the kidney.

Figure 5. Simon Renal Pole Clamp. http://www.tmml.com/Catalogue/SellSheets/A19_INFO_Simon%20Renal%20P

DESIGN ALTERNATIVES

Through research and multiple brainstorming sessions, four design alternatives were created. Two of the designs, modified bulldog clamp and the crisscross, are modifications of current medical devices. The other two designs, the loop and the zip-tie, are novel designs and would be fabricated out of stainless steel.

MODIFIED BULLDOG CLAMP

The modified bulldog clamp would be an attachment that connects to the Aesculap Articulating Applicator for Temporary Endoscopic Vascular Clips . The vascular clips already have a bulldog clamp attachment, but it is too small for nephrectomy surgery. A bulldog clamp opens by applying force to the handle against a spring. It closes by removing the tension and letting the spring close the clamp. Three modifications would be performed to make the device meet the client's needs. The length of the clamp would become longer so it can clamp across the length of the kidney. The spring that keeps the clamp closed would have greater stiffness. This would increase the amount of force the clamp can apply. Lastly, a bend in the metal would be added so the force is applied to the right area of the kidney. This clamp would use the vascular clips preexisting mechanisms to open and close the clamp. It would also utilize locking mechanism similar to current vascular clamps to secure the modified clamp to the top of this laparoscopic instrument (See Figure A6).

CRISSCROSS DESIGN

The crisscross utilizes the mechanism of the Johns Hopkins Bulldog Clamp. The Johns Hopkins bulldog clamp works similarly to a bulldog clamp. When a force is applied to the base of the device, the clamp opens. It closes by a spring that is produced by crossing pieces of metal. This design would attach the Johns Hopkins bulldog clamp to a piece of wire that has loose fitting metal tubing surrounding it. The tubing would then be slid down the wire until it applies force to the base of the clamp causing it to open. When the clamp is in the correct position, the tubing is pulled back off the clamp causing it to close. The tubing is removable so that the surgical field can be cleared of additional obstructions (Figure A7).

ZIP-TIE DESIGN

The zip-tie design uses the laparoscopic instruments used in other portions of surgery to thread a wire that is attached to a laparoscopic handle around the kidney. The wire will be a piece of metal modeled after plastic zip-ties. Once the wire has been wrapped around the kidney, it would be placed inside a locking mechanism, which prevents it from sliding back out and allows the wire to be tightened through the handle. As the design is tightened, increased pressure would be placed on the kidney. The handle will also have a quick release function that will release the locking mechanism (Figure A8).

LOOP DESIGN

The loop design will release a metal loop from a shaft once inside the body cavity. The loop will have a rigid piece of plastic at its tip to encourage the force to be applied against the coronal plane of the kidney. The metal band will have ridges in it to prevent it from slipping once it is secured around the kidney. The bands on each side of the plastic tip will be able to be tightened independently. The loop will also have a quick release function that will release tension in the band immediately (Figure A9).

DESIGN MATRIX

Each design was compared against the others through a design matrix to determine the best design. They were compared on the grounds of safety, ease of placement, force distribution, cost, maintenance, manufacturability, and client preference. Each of these categories were weighted on a percentage of 1. Each design was then graded on a scale from one to five with five being the best. Each graded score was multiplied by the weighting factor and summed.

Safety was given the second largest weighting factor of 0.2 because the device will be used during surgery. The device should never add complications to an already tough procedure, because a person's life is at risk. The loop and zip-tie designs ranked highest in this category because they will both have a quick release mechanism. The crisscross did poorly because, in order to remove the force of the clamp, the tubing needs to be slid down the wire. This may take too long and complications could arise.

Ease of placement is important because once the device is in the body cavity, it should be able to quickly and easily secure the kidney. The zip-tie got the lowest score in this section because its design required the surgeon to thread a zip-tie around the kidney. With such a tight space and limited vision, this can be difficult for the surgeon. The loop scored highly because the loop's size can change to any size needed to accommodate any kidney.

Force distribution was weighted the highest for this design matrix. Existing devices lacked the correct amount of force at the proper place on the kidney (Abel 2012). Most of the existing devices applied most of the force at the beginning of the clamp nearest the hinge. This would result in the majority of the force being applied to the edge of the kidney rather than the middle. The client would like the force evenly distributed across the kidney. The loop and the modified bulldog clamp both received a three because modifications need to be made to the design. The loop has a rigid tip that helps open the

loop and keeps it in an elongated shape that keeps the clamp from applying force in the wrong direction. The modified bulldog clamp needs a bend in the metal to insure that the first point of contact isn't at the edge of the kidney. The other two designs received a two because they will not be able to apply enough force.

Cost received the lowest rating in the design matrix. This low rating comes from the cost of existing medical clamps. Existing laparoscopic medical clamps cost upwards of $1000, and these designs are estimated to be in the same price range. The zip-tie received the highest score because it requires very little material, making it easier to produce. The modified bulldog clamp is the most expensive because it needs to be specially manufactured to attach to the Aesculap Articulating Applicator.

Maintenance ranks the designs on their ability to be cleaned. This is important because during surgery a doctor needs to use sterile instruments to prevent infections or other complications. The devices need to be disposable or easily sterilized. The loop received a high score because it would be able to be stripped down to it basic elements then sterilized in an autoclave. The wire would also be replaceable. The crisscross received a low ranking because the hinges of the Johns Hopkins bulldog clamp are difficult to clean.

Manufacturability ranks the design on the team's ability to actually create the prototypes. The loop and zip-tie received high scores because those designs can be built using simple parts and little machine work. The crisscross received the lowest ranking because it would be very difficult to create a Johns Hopkins bulldog clamp with the right force distribution at such a small scale.

Client preference was also evaluated in the design matrix. The team needs to deliver a product that meets the client's specifications, so the client was included in the decision process. The loop received the highest score because the client liked the novelty of the design. The client believed this was the new solution that could solve the poor force placement of existing designs. The lack of poor force placement is also the reason that the modified bulldog clamp received the lowest score.

	Weight	Modified Bulldog	Loop	Zip-tie	Crisscross
Safety	.20	3	**4**	4	2
Ease of placement	.15	3	**4**	1	3
Force distribution	.30	3	**3**	2	2
Cost	.05	2	**4**	5	3
Maintenance	.10	3	**4**	3	3
Manufacturability	.10	3	**4**	4	2
Client Preference	.10	2	**5**	3	4
Total:	1.00	2.85	**3.8**	2.8	2.5

Table 1. Design Matrix

FINAL DESIGN

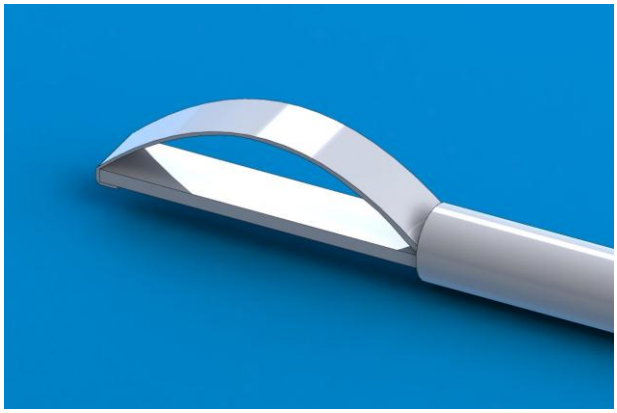


Figure 6. Image depicts the final prototype of our renal occlusive clamp.

After completing the design matrix, it was determined that the loop design would be the most successful for completing our projects goals. The original loop design was composed of three main parts. There was a shaft, a loop, and a control system. The control system will be developed and constructed next semester. After our first iteration of this design, it became apparent that changes needed to be done to this initial design.

The shaft of the renal clamp has remained the same after the first iteration. It is composed of a single piece of stainless steel tube with outer dimensions of 1.1cm x 61cm. These dimensions allow the shaft to fit inside the trocar during the placement of the device.

In the original design the loop was to be composed of two pieces of stainless steel ribbon. These pieces would have the dimensions of .8cm x 0.0254cm x 55cm. These dimensions would have allowed the loop to be within the shaft during insertion through the trocar. At the distal end of the clamp, the two ribbons would have been attached to an equilateral triangular block, which is also constructed from stainless steel. This block will be 1cm wide and 1cm tall. The proximal end of the ribbon will be welded to the control system. The two ends would have been attached at a 30º angle in order to achieve a ballooning effect within the ribbon.

While testing the loop design, problems arose. Constructing an equilateral triangle to hold the two ribbons 30º apart was difficult to create given the size constraints of the trocar and body cavity. In addition, it failed at inducing the ribbons to be 30º apart. Once the ribbon was placed inside the tube, the ribbon would bend and it would not open into a loop upon exit of the tube. The stainless steel ribbon was not elastic enough to conform to this design. Lastly, as the ribbon is pulled into the tube, pinching of the kidney could occur. This could cause unnecessary damage to kidney.

To solve these problems a new looping mechanism was designed. Two different thicknesses of stainless steel metal were used: a base plate and flexible ribbon. The thicker piece of metal, called the base plate, it is .8cm x .2cm x 70cm and the thinner metal is .8 x .0254 cm 70 cm. The two pieces of metal are welded together at the distal end. The thicker base plate allows the metal ribbon to bend into the proper confirmation for placement around the kidney.

Most aspects of the surgical procedure will remain the same as the traditional laparoscopic procedure; however, in order to achieve proper placement of the parenchymal renal clamp, it is imperative that the connective tissue around the kidney has been

sufficiently removed. As the clamp is placed inside the body cavity both pieces of metal are inside the tube lying on top of each other. Once the clamp is inside the body, the base plate and the thin metal ribbon are deployed outside of the sheath. When reaching the desired position, the base plate stops moving and the thin ribbon is pushed forward. Since the two are welded together at the end, a loop is formed as the thin ribbon is pushed. The loop can then be maneuvered around the peripheral ends of the kidney. The flexible ribbon is retracted to cause occlusion of blood flow in the kidney.

When the surgery has been completed, the clamp will be removed from the kidney. The ribbon and base plate will be retracted into the shaft. Then the entire clamp can be removed from the trocar.

The cost of the materials used in prototype fabrication is listed in Table 2.

Component	Price
Base Plate	$5.25
Steel Ribbon	$2.43
Stainless Steel Tubing	$4.99
Total:	$12.67

Table 2. Cost of prototype components.

DESIGN SPECIFICATIONS

The clamp will be a selective renal occlusive clamp for robotic laparoscopic partial nephrectomy surgery. As there is no device that meets the design criteria for laparoscopic partial nephrectomy, a clamp must be designed that successfully occludes blood flow within the kidney and works with a laparoscopic arm. The client has requested that the arm be designed so that it is not in the way during surgery. This semester will focus on designing the clamp mechanism, and next semester will focus on designing the shaft and control mechanism for the clamp.

Most importantly, the clamp cannot cause any harm through its operation to either the operators or the patient, including the kidney and surrounding tissue. To properly occlude the kidney, the clamping end must be able to be apply the necessary pressure of 60mmHg for the duration of the surgery, 3.5-4 hours. It must also reliably provide this force for at least 100 applications.

The clamp will be used in an operating room, in a laparoscopic cavity in contact with carbon dioxide gas and living tissues. Since surgical devices are stored and transported before they reach the hospital, and may be stored once they reach the hospital, in a sterile

package the device should have a shelf life of at least 10 years without corroding. To be reusable, it must be sterilizable, made with durable and biocompatible materials. For marketing purposes, the device should be aesthetically pleasing.

To ensure that the device can be used in laparoscopic surgery, the clamp end and the laparoscopic pole must fit through a 12mm by 15 cm laparoscopic trocar, and the arm should be 61.00 cm in length. It must be operated with one hand, and the laparoscopic handle should not be in the way after being applied. The laparoscopic handle must be comfortable for surgeons with handbreadth ranging from 6.5-9.5 cm. The weight of the entire device must be comfortable to use, and should not exceed one kilogram.

For proof of concept, only one prototype is required. This prototype for delivery to the client must not cost more than $500. The market price for the device should not be greater than $10,000. The device must adhere to FDA medical device guidelines so that it can be tested in pig models and eventually human patients.

MATERIALS

For our final prototype stainless steel alloys were used. The bottom piece is made of 304-2B alloy and the top piece is made of 430 alloy. Only the bottom piece is medical grade but in future we will construct the whole prototype out of 304-2B alloy (Newson, 2002).

304 is a Cr-Ni stainless steel alloy and is one of the least expensive medical materials. The nickel is used to provide a smooth and polished finish. This alloy is used for its excellent strength and high ductility. The maximum carbon content is .08%. This means there is less carbide buildup when the metal is welded. This alloy is typically used for catheters, wire guides, springs and needles (“Alloys”, 2012).

430 does not contain any nickel and is one of the most widely used stainless steels. Due to the fact it doesn’t contain any nickel or molybdenum it is cheaper than the 300 series alloys (“Alloys”, 2012).

TESTING

We completed 4 different experiments to test our prototype. First, we did compression testing on porcine kidneys to determine their mechanical properties. Second, we analyzed the clamp force of our design. Third, we conducted tests on excised porcine kidneys to compare our prototype with the current clamp and determine internal applied pressure. Fourth, we tested various texture finishes on the metal ribbon to determine the required active force. In the future, we plan to conduct tests on our prototype during live

porcine surgeries. Summaries of our testing procedures are listed below, but please reference Appendix B for the full protocols.

To begin the compression testing, 2 porcine kidney cross-sectional samples were created from each of the 2 porcine kidneys using a scalpel. These samples had an approximate area of 1cm x 5cm. One cubic sample was harvested from each of the 3 kidneys using a scalpel. The cubic samples were approximately 1cmx1cmx1cm. The height, width, and length of each of the samples were measured and recorded using a caliper. Each of these samples was placed in a load frame. The frame was lowered at a rate of 6mm/min. The force and displacement were recorded. This data was used to generate a stress-strain curve for each of the 7 samples in MatLab. Based on these plots, the Young's modulus was determined from the linear section of the stress-strain plot. Additionally, the strain at the point of failure was recorded.

To measure the force the clamp exerts at different lengths, we used the bulb and gauge from a blood pressure cuff. First the back plate was set to one of three lengths. The bulb, with the one-way valve plugged and attached to the gauge, was inserted in between the back plate and the flexible ribbon of the clamp. Then the flexible ribbon was set to a baseline length where the pressure was zero but the ribbon was not loose around the bulb. The flexible ribbon was pulled to increase its length by increments of 0.5 cm from the end of the tube, and the pressure at each length was measured. The procedure was repeated for 3 trials with at least two different students, then the back plate was set to a new length and the process repeated.

To begin the excised kidney testing procedure, 6 porcine kidneys were cut in half with a scalpel on the frontal plane. A latex balloon was inflated with air to a size of approximately $2cm^3$. This balloon was placed on one section of the kidney, and then the corresponding kidney section was placed on top, with the two hollowed kidney sections being filled by the balloon. The balloon was then attached to a blood pressure monitoring gauge, using a 1.27cm tube, which outputs in mmHg. The renal occlusive clamp was fastened around the kidney section and tensioned until the top, stainless steel ribbon in contact with the kidney and the pressure gauge readout was recorded as the baseline. The top stainless steel ribbon was pulled through the stainless steel tubing, until the pressure of the balloon reached a maximum. This was repeated three times on each of the six kidneys. The test was repeated with the Satinsky clamp for three repetitions. Data was analyzed by

subtraction of the baseline pressure from the maximum pressure. The standard deviations were calculated and the differences between the two clamps were analyzed using a t-test.

To minimize the risk of the kidney slipping out of the clamp, testing was done on different textures to determine the best texture to add to the metal ribbon. The test was performed with a MTS load frame, fishing wire, 200 g weight, a chicken breast, and five textured pieces of stainless steel. The five textured patterns consisted of raised bumps, perpendicular ridges, angled ridges, crisscross ridges, and a normal piece of smooth stainless steel. Each piece was placed between the weight and chicken breast. The MTS was then raised, and through a pulley system, pulled the metal plate horizontally. The force was recorded when the metal plate first slipped. This was done five times with each sample. The results were then averaged and standard deviations were calculated.

Next semester we plan to test our device during one of our client's live porcine tests. Due to the timing of this previously scheduled trial we could not complete the test during this semester.

RESULTS

PORCINE KIDNEY COMPRESSION TESTING

Using the data collected from compression testing, a stress-strain plot was created for each of the 7 samples (Appendix B1). The Young's modulus was then measured as the linear region on each of the stress–strain plots (Figure 7 and Figure 8). The average Young's Modulus was 1411.8565 ± 574.2461KPa (n=5). Two samples were excluded from the calculation of the average because of behavior that was uncharacteristic of the other samples. These samples may have been taken from an area closer to the renal pelvis than the other samples. The strain of failure for each of the samples was also recorded with an average value of 0.344±0.05094032.

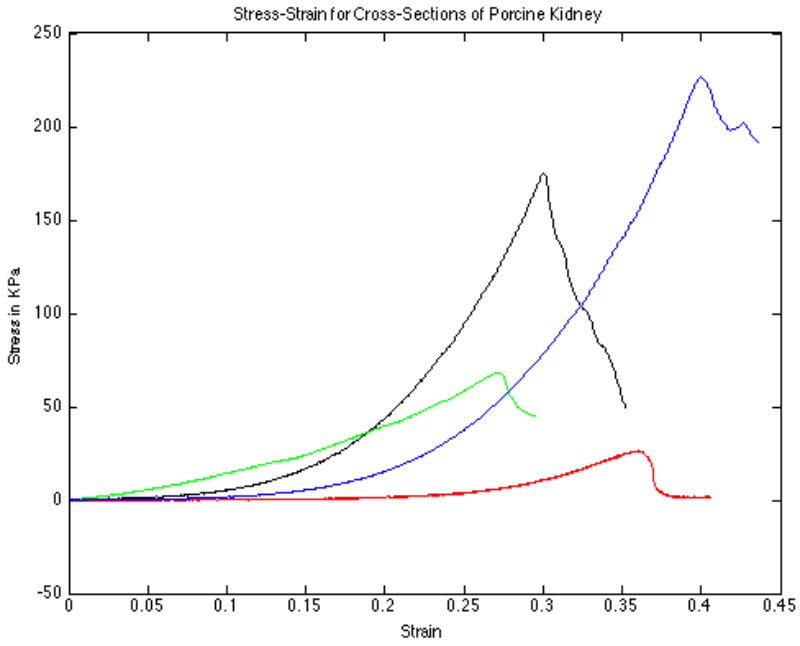


Figure 7. Stress-strain plots for the four cross-sectional samples with approximate areas of 1cm x 5cm. The red and green samples were excluded from the Young's modulus calculation due to greatly different behavior from the other samples.

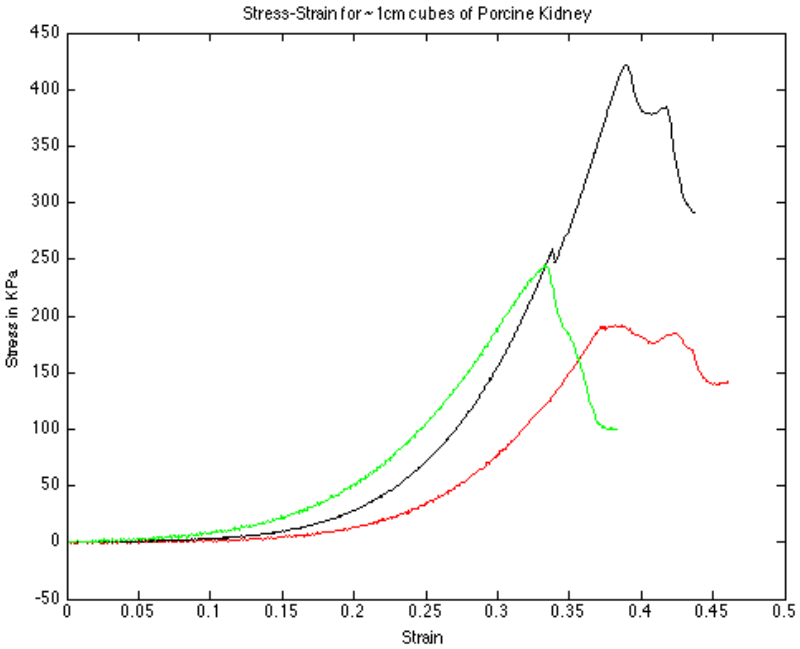


Figure 8. Stress strain plots of the 3 cubic samples with approximate dimensions of 1cm x 1cm x 1cm.

CLAMP FORCE TESTING

Using the data collected from Clamp Force Testing, a plot was created for each of the 3 trial runs (Appendix B2, and Figures 9, 10, 11).The longer the back plate was set, the faster the pressures increased. This is because, with a longer major axis to the ellipsoidal shape formed by the clamp, the faster the minor axis changes with a change in the length of the flexible ribbon. This change in length of the minor axis increases the pressure that the clamp exerts on the pressure bulb.

Error was an issue due to the difficulty holding the clamp at exact lengths without shifting or slipping during the measurement. This was especially the case for the longest length at the highest values of pressure, where the back plate tended to shift to a shorter length due to the increase in pressure. This problem will be rectified in future prototype iterations by adding a locking mechanism to hold the back plate in place.

A polynomial regression line was fitted to the data values, as it was found to most closely resemble the trend. It was most accurate at lower values, most likely due to the error described above. The 8.5 and 9.0 cm back plate length trials both had R^2 values of 0.9584 and 0.9471, respectively. The 9.5 cm back plate trial had an R^2 value of 0.8894, mostly due to the error at longer lengths. The experiment should be repeated once locking mechanisms are in place to determine if the results are more accurately predictable.

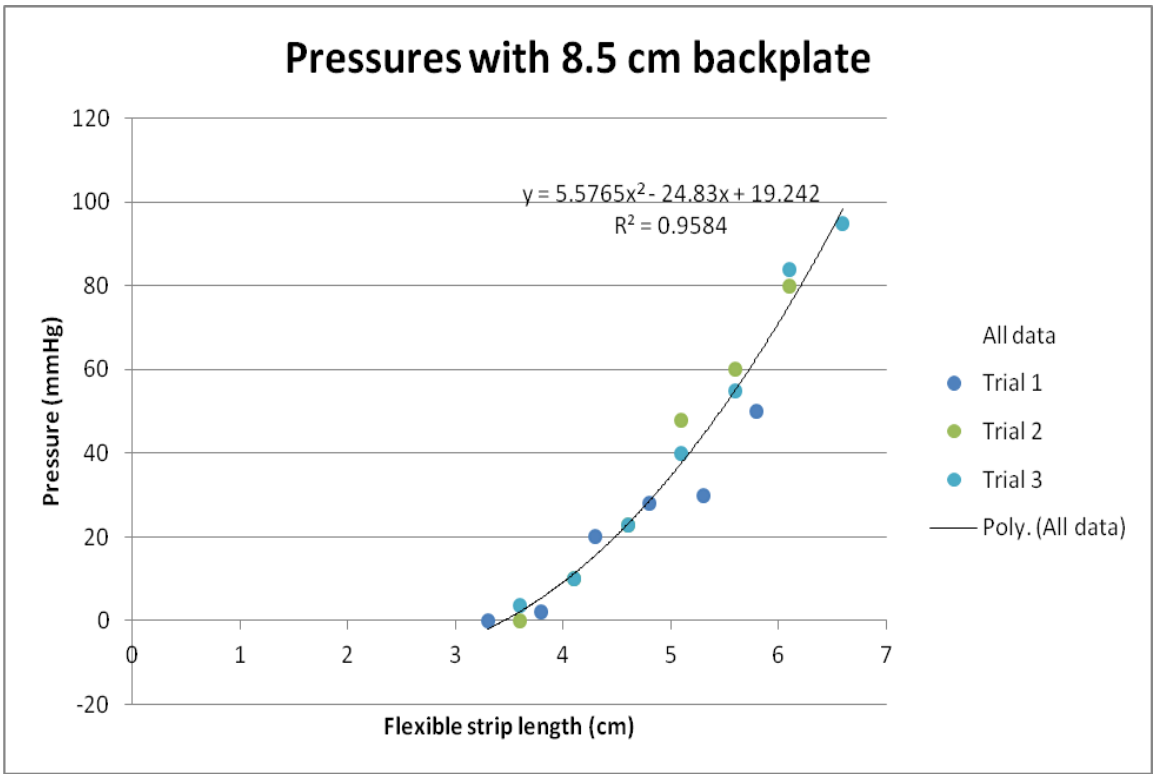


Figure 9. Clamp Force Testing with 8.5 cm back plate.

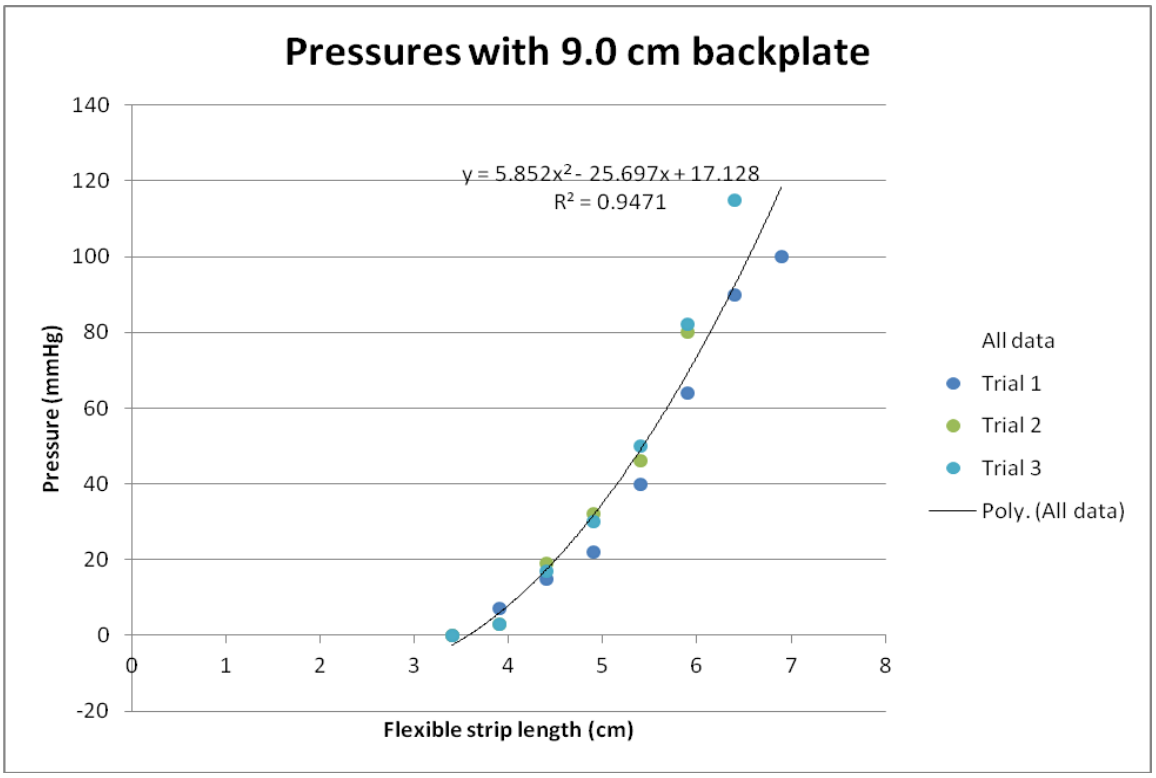


Figure 10. Clamp Force Testing with 9.0 cm back plate.

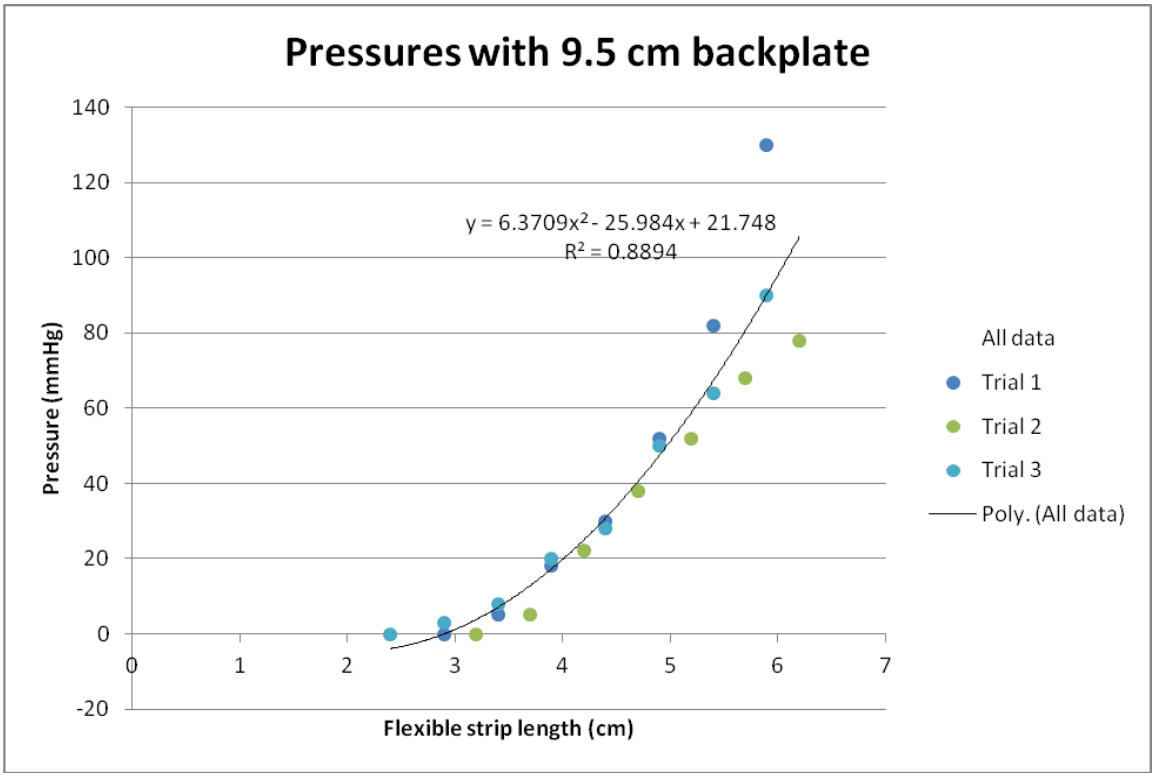


Figure 11. Clamp Force Testing with 9.5 cm back plate.

EXCISED PORCINE KIDNEY TESTING

Testing was performed on six porcine kidneys using both the prototype renal occlusive clamp and the Satinsky clamp (Appendix B3). The prototype clamp generated an average internal pressure of 60.055± 23.71mmHg (n=6), whereas the Satinsky clamp applied an average internal pressure of 70.083±18.6204mmHg(n=5) (Figure 12).

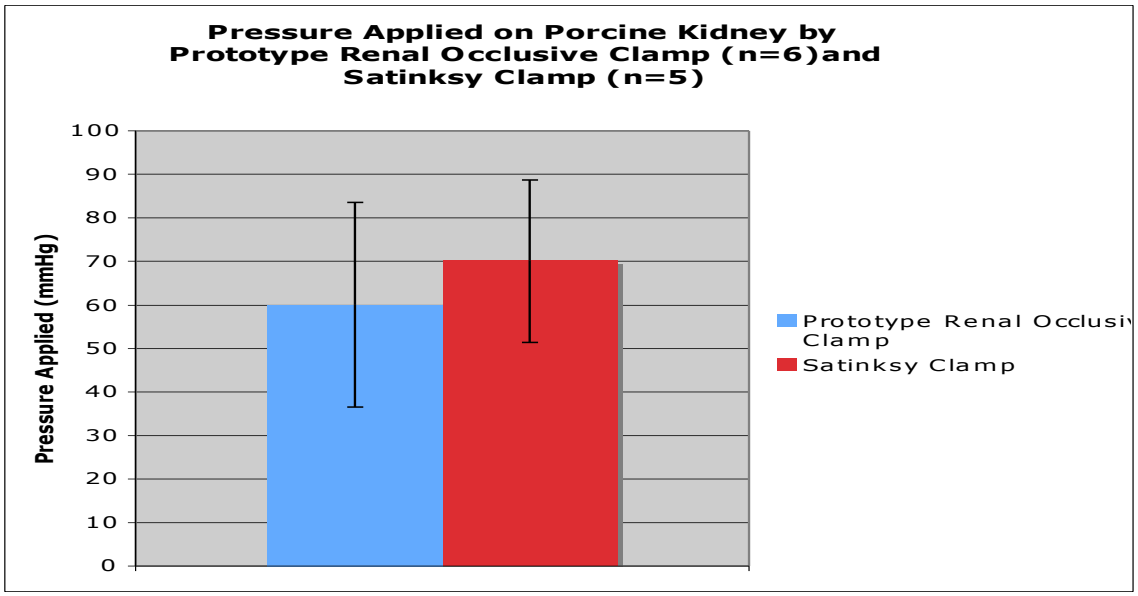


Figure 12. Average for applied pressure by prototype clamp was 60.055± 23.71mmHg (n=6) and the average pressure applied by Satinsky clamp was 70.083±18.6204mmHg (n=5).

The results of a two-tail t-test show a p-value of 0.45356, which signifies that there is no significant difference between the internal pressure generated by the two clamps. However, a difference can be seen in qualitative observations from the experiment. During testing, the Satinsky clamp caused visible damage as seen by tearing of the parenchyma of the kidney (Figure A3 E&F). One of the kidney samples for the Satinsky clamp was excluded because immediate damage caused by the clamp prevented the recording of the internal pressure. The prototype clamp did not cause any visible tears on the surface of the kidney.

TEXTURE TESTING

For texture testing, it was determined that perpendicular ridges required the largest amount of force to cause a slip (Appendix B4). The ridges create large valleys that the tissue forms to, causing a large obstacle that the pulling force has to overcome. However, texture won't be implemented into our final design. The indents from the ridges might cause the thin sheet metal to bend in unfavorable ways. In addition, texture might not be needed.

From preliminary pressure testing, there was no indication that slipping occurred. Further testing needs to be done on the actual clamp prior to adding texture to the final design.

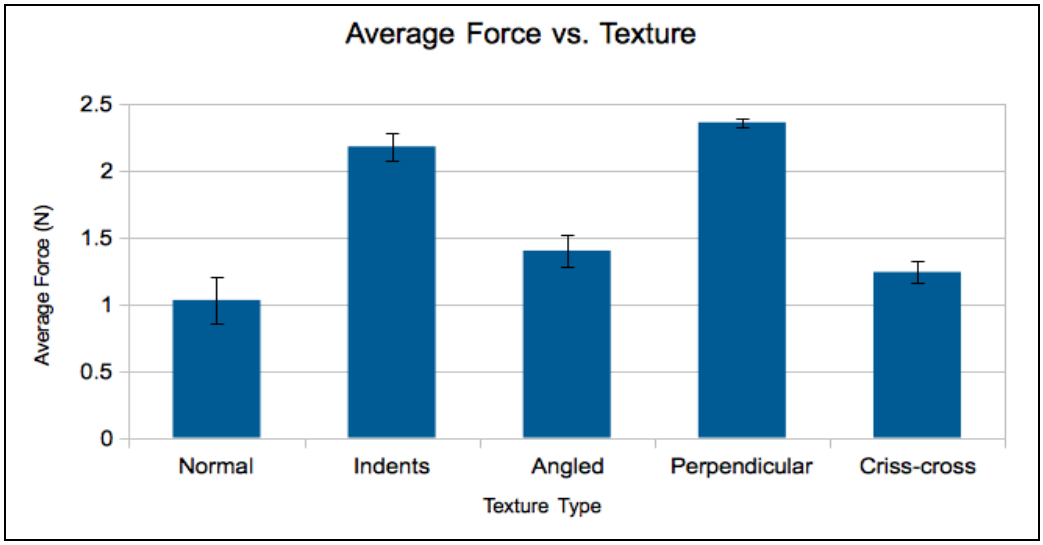


Figure 13. Texture testing results for 5 different surface textures. Normal is the current smooth strip.

CALCULATIONS

The results of the porcine kidney compression testing were applied to generate an estimate of the pressure needed to cause renal tissue failure. To perform this estimation, the kidney is idealized as a spring with only two points of contact, one with the top ribbon of the clamp and one contact with the base plate (Figure 14).

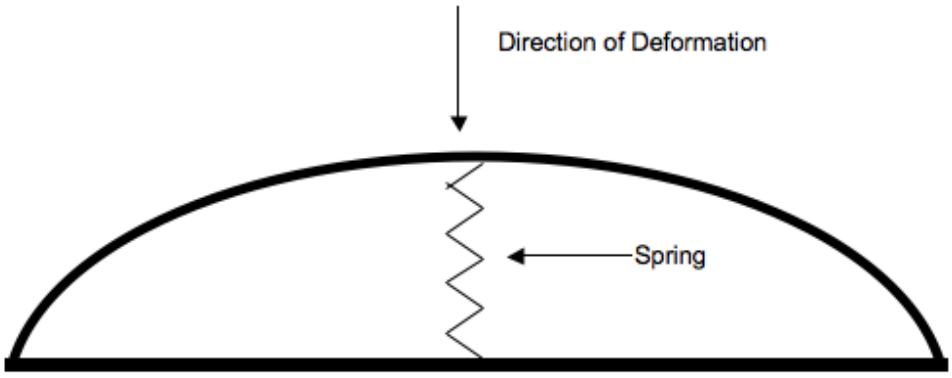


Figure 14. Idealization of the kidney as a spring with only a negative vertical displacement.

As the kidney is being idealized as a vertical spring, it is assumed that the material follows a Hookian behavior. The force, F, needed to cause tissue failure was calculated to be 272.865±29.2291N, using an average area, S, of $5.6117*10^{-4}$ m^2, an average strain of failure,

ε, of 0.3444± 0.05094, and an average Young's Modulus, Y, of 1411.865± 574.2461KPa (Eq1).

$$F/S = Y * \varepsilon \quad \text{(Eq.1)}$$

This force to needed to cause failure was then used to determine the pressure needed to cause tissue damage using the prototype renal clamp. The contact area between the clamp and kidney is $9x10^{-4}m^2$. Therefore, the pressure that our clamp needs to generate to a cause renal tissue failure is estimated to be 303.183± 32.476KPa (Eq2).

$$\sigma = F/A \quad \text{(Eq.2)}$$

ETHICAL CONSIDERATIONS

The information gathered for the presentation of this paper was done ethically. The thoughts and knowledge that were taken from previously reported studies are given credit via citations when appropriate. The authors of this paper are appreciative for the previous knowledge that allowed us to create the design proposed in this report.

Further ethical considerations should be carefully evaluated during testing. Our client currently does research on pigs and would like us to test our prototype during a live surgery. We will be conducting this testing as part of an existing IRB. It has been decided by our client and team that the proposed methods of testing are appropriate.

FUTURE WORK

To continue with the project many goals need to be accomplished. Further testing needs to be completed on our current design before work continues on the actuator end of the laparoscopic device. The client has suggested that the device be tested in a one of his animal trials. Then, the laparoscopic actuating end of our device needs to be designed, built, and tested.

To conduct testing of our device on porcine animal trials there are several steps that need to be completed. Investigation into the clients IRB or obtaining a separate IRB needs to be done to ensure we can legally use the device in trials. A testing protocol for live porcine testing can be found in Appendix B. Testing on humans also needs to be completed

before the device would be approved for the market, but this needs to be done under IRB guidelines as well. Eventually using the device in actual surgery will provide the team with the best feedback, but IRB approval must be obtained first.

Next semester our main goal will be to produce a complete prototype of our device for laparoscopic surgery. An actuator end needs to be integrated onto our current clamp so that it can be used through the trocar. We will investigate the actuator ends of current laparoscopic instruments, brainstorm, and produce a shaft and controller for our device. This new, complete prototype will be tested to ensure that it retains the clamping force obtained this semester. Also, we will test the ergonomics of our prototype.

Once arriving at a final design, streamline production of the device needs to be performed. Manufacturing at a large scale will lower the cost of the device, making it more competitive with other devices. This will also allow the device to get to a large market.

CONCLUSIONS

The creation of an innovative clamp that evenly distributes force during a partial laparoscopic nephrectomy is needed in the surgical field. This design will allow kidney tissue to be preserved without ischemia and lessen surgical recovery time. Dr. Abel is optimistic about our loop design and feels that with further calculations, prototyping, and testing a novel clamp can be created by the end of the year.

REFERENCES

Abel, E. 2012. Personal Communication

Adam, K. 2005. "Critical Care Nursing: Science and Practice" p. 572. OUP Oxford.

"Aesculap Bulldog Clips," Oct. 1, 2012. http://www.endoscopy catalog.com/images/content/en/c61111_bulldogclips.pdf

"Aesculap Surgical Technologies Simon Renal Pole Clamp," Oct. 1, 2012. http://www.tmml.com/Catalogue/SellSheets/A19_INFO_Simon%20Renal %20Pole%20Clamp_brochure_2010.pdf

"Alloys," Dec. 4, 2012. K-Tube Technologies. http://www.k-tube.com/alloys.html
Furuchi, 2002. "Role of Cytokines and Chemokines in Renal Ischemia – Reprofusion Surgery."

Kobayashi, Y., Saika, T., Manabe, D., Nasu, Y., and Kumon, H. "The Benefits of Clamping the Renal Artery in Laparoscopic Partial Nephrectomy." *Acta Medica Okayama,* 62(4), 269-273. 2008. http://www.lib.okayama- u.ac.jp/www/acta/pdf/62_4_269.pdf

Landman, Jaime. "Laparoscopic Partial Nephrectomy," Oct. 1, 2006. http://www.kidneycancerinstitute.com/PDFs/Aesculap-Nader-partial nephrectomy%20manuscript.pdf

"Laprascopy- Vascular Clamps". Aesculap. Oct. 14, 2012. www.Aesculapusa.com.

Martin, G.L., Warner, J.N., et. al. "Comparison of Total, Selective, and Nonarterial Clamping Techniques During Laparoscopic and Robot- Assisted Partial Nephrectomy" Journal of Endourology. February 2012, Vol. 26, No. 2: 152-156

Nephrectomy. *European Urology*, *58*(3), 340–345. doi:10.1016/j.eururo.2010.05.047

Newson, T. "Stainless Steel – A Family of Medical Device Materials." *Business Briefing.* 2002.

"Optimizing Selective Renal Clamping in Nephron-Sparing Surgery Using the Nussbaum Clamp," Oct. 1, 2012. http://www.sciencedirect.com/science/article/pii/S0090429507025216

"Renal Cell Carcinoma - PubMed Health", Oct. 1, 2012. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001544/.

"Satinsky Clamp". Biomedical Research Instruments, Inc. Oct 14, 2012. Biomedinstr.com.

Thompson, R. H., Lane, B. R., Lohse, C. M., Leibovich, B. C., Fergany, A., Frank, I., Gill, I. S., et al. (2010). Every Minute Counts When the Renal Hilum Is Clamped During Partial Nephrectomy. *European Urology*, *58*(3), 340–345. doi:10.1016/j.eururo.2010.05.047

APPENDIX A. PROJECT DESIGN SPECIFICATIONS

OPTIMIZING SELECTIVE RENAL OCCLUSIVE CLAMP FOR ROBOTIC SURGERY

Function

Our client, Dr. Abel, requests that our team develops a selective renal occlusive clamp for robotic, laparoscopic, partial nephrectomy surgery. Surgeons are performing more partial nephrectomy surgeries in order spare functional tissue. Our product will optimize the partial nephrectomy by selectively occluding blood flow to part of the kidney, while allowing normal blood flow in the other parts of the kidney. This clamp will prevent global kidney ischemia which can lead to tissue damage and complications.

Design Requirements

1. Physical and Operational Characteristics
    a. Performance Requirements: The product must be able to be applied for the duration of the surgery (3.5-4 Hours) and must be reusable for future laparoscopic procedures.
    b. Safety: The product cannot cause any harm to the operators nor the kidney and the surrounding tissues
    c. Accuracy and Reliability: The device must be able to apply 10-15 N of force across the entire kidney for a maximum time of 30 minutes. Additionally, it must reliably provide this force after at least 100 applications.
    d. Life in Service: The device must be able to operate for the duration of the surgery (approximately 3.5-4 Hours)
    e. Shelf Life: The device must be able to remain in storage in a sterile package without corroding for at least 10 years.
    f. Operating Environment: The expected environment for use is in an operating room in contact with living tissues.
    g. Ergonomics: The device must be easily sterilized, operated with one hand, accommodate hand breadth ranging from 6.5-9.5 cm, and not cause discomfort to the user.
    h. Size: The device must be able to fit through a 12 mm by 15 cm laparoscopic trocar and the arm should be 60.96 cm in length. The clamp should be 5 cm long.
    i. Weight: Weight should not exceed one kilogram
    j. Materials: The device should be made of materials that are durable and biocompatible.
    k. Aesthetics, Appearance, and Finish: For marketing reasons our final design should be aesthetically pleasing.
2. Production Characteristics
    a. Quantity: One prototype is required
    b. Target Product Cost: The marketable price for the device should not exceed the cost of a commercially available surgical clamp, $10,000. Our prototype should not exceed $500.
3. Miscellaneous
    a. Standards and Specifications: The device should adhere to FDA medical device guidelines.
    b. Customer: The final product is intended for use by Urologists performing Laparoscopic Partial Nephrectomies.
    c. Patient-related Concerns: The device is intended for use on patients needing laparoscopic partial nephrectomy. The device will need to be sterilized before use on subsequent patients.
    d. Competition: There are no commercially available laparoscopic, kidney parenchymal clamps. The Satinsky laparoscopic clamp has been used in this

manner, but it is only designed for arterial clamping.

APPENDIX B. TESTING PROTOCOLS

1. PORCINE KIDNEY COMPRESSION TESTING EXPERIMENTAL PROCEDURE

Purpose:

The purpose of this experiment is to determine the Young's Modulus and strain of failure for porcine kidney samples.

Materials:

Load frame, scalpel, 2 porcine kidneys, caliper

Procedure:

To begin the procedure, 2 porcine kidney cross-sectional samples will be created from each of the 2 porcine kidneys using a scalpel. Theses samples will have an approximate area of 1cmx5cm. One cubic sample will also be harvested from each of the 3 kidneys using a scalpel. The cubic samples will be approximately 1cmx1cmx1cm. The height, width, and length of each of the samples will be measured and recorded using a caliper. Each of these samples will be placed in a load frame. The frame will lower at a rate of 6mm/min. The force and displacement will be recorded. This data will be used to generate a stress-strain curve for each of the 7 samples in MatLab. Based on these plots, the Young's modulus will be determined from the linear section of the stress-strain plot. Additionally, the strain at the point of failure will be recorded.

2. CLAMP FORCE TESTING EXPERIMENTAL PROCEDURE

Purpose:

The purpose of this testing is to test our prototype to determine the force it is capable of exerting at different lengths of the back plate and flexible strip

Hypothesis:

There will be a direct correlation between the length of the back plate and a greater increase in force with an increase in flexible strip length.

Materials:

-Prototype

-Blood pressure cuff and bulb with one way valve plugged

-Ruler/measuring device

-2 students

Procedure:

1. Set the back plate of the clamp at 85mm from the end of the tube.

2. Tighten the flexible strip so that it is around the bulb without measurable pressure. Measure this length from the end of the tube as the initial length.
3. Pull the end of the strip 5mm from the initial length, and record the pressure on the gauge. Repeat in intervals of 5mm.
4. Repeat the previous steps with back plate lengths of 90mm and 95mm

3. EXCISED PORCINE KIDNEY TESTING EXPERIMENTAL PROCEDURE

Purpose:

The purpose of this testing is to test our prototype on excised porcine kidneys in order to determine the viability of our device and measure the pressure it exerts. Our device will be tested along with the traditional Satinsky clamp in order to compare the devices.

Hypothesis:

Our prototype will apply sufficient clamping force on the kidneys that is comparable to the Satinsky clamp.

Materials:

Prototype, Satinsky clamp, 6 excised porcine kidneys, Sutures, Suturing tools, Blood pressure gauge, Water balloons, Zip ties, and tape

Procedure:

To begin the procedure, 6 porcine kidneys are cut in half with a scalpel on the frontal plane. A latex balloon will be inflated with air to a size of approximately 2cm3. This balloon will be placed on one section of the kidney, and then the corresponding kidney section will be placed on top, with the two hollowed kidney sections being filled by the balloon. The balloon is then attached to a blood pressure monitoring gauge, using a 1.27cm tube, which outputs in mmHg. The renal occlusive clamp will be fastened around the kidney section and tensioned until the top, stainless steel ribbon is in contact with the kidney and the pressure gauge readout will be recorded as the baseline. The top stainless steel ribbon will then be pulled through the stainless steel tubing, until the pressure of the balloon reaches a maximum. This is repeated three times on each of the six kidneys. The test will then be repeated with the Satinsky clamp for three repetitions. Data will be analyzed by subtraction of the baseline pressure from the maximum pressure. The standard deviations will be calculated and the differences between the two clamps will be analyzed using a t-test.

4. TEXTURE TESTING EXPERIMENTAL PROCEDURE

Purpose:

The purpose of this test is to determine the pattern, imprinted onto the renal clamp, which will result in the highest force required to make the textured steel move. The higher the force, the less likely the clamp will slip when the device is clamping the kidney.

Hypothesis:

The higher the topography is on the piece of metal, the larger the active force requirement will be.

Materials:

-Chicken breast
-5 pieces of metal with different texture
-Fishing Wire
-200 grams
-MTS Load Frame

Procedure:

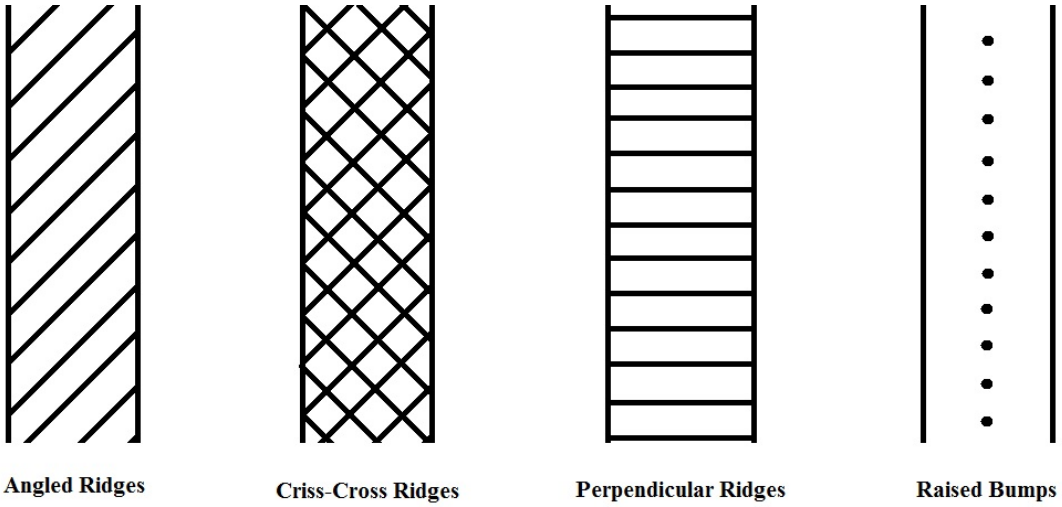


Figure A1. Surface patterns tested in texture testing. Not shown is the smooth current texture.

There will be five patterns that will be tested. The first will be the normal metal with nothing done to it. It will act as the control. The remaining patterns will be perpendicular raised ridges, angled raised ridged, crisscross ridges and a series of indents. The patterns will be attached to fishing wire that is connected to the MTS load frame through a pulley system. The textured pieces of metal will be placed on the chicken and the weight will be placed on top of the piece of metal. A pulling force will be applied to the piece of metal as the MTS moves upwards. At the first instance that the metal slides forward, the force will be recorded from the MTS system. This will be repeated five times for each sample. The results will be averaged.

5. LIVE PORCINE EXPERIMENTAL PROCEDURE

Purpose:

The purpose of this testing is to test our prototype during a porcine surgery in order to test its ability to cause ischemia to a portion of the kidney. The device will also be rated by the surgeon to determine its ease of use and effectiveness.

Hypothesis:

Our prototype will sufficiently stop blood flow to the intended area in the kidney. There will be a small learning curve but then the device will be implemented successfully by the surgeon.

Materials:

-Prototype

-6 surgically prepped pigs

-Surgical devices

-2 surgeons

Procedure:

During the regularly scheduled porcine surgeries performed by Dr. Abel we will insert a few testing steps after the incision is made but before any cauterization or cutting begins. We will ask the doctor to clamp the kidney with our device and comment on its ease of use and ability to cause proper force and ischemia on a 0-5 scale (0 being the worst and 5 being the best). We will also ask for any general observations, problems with the device and possible improvements. This process will be repeated by two doctors on six different specimens. Data will be collected and analyzed. Our device should operate above a level 3.5 and with no problems.

APPENDIX C. PICTURES

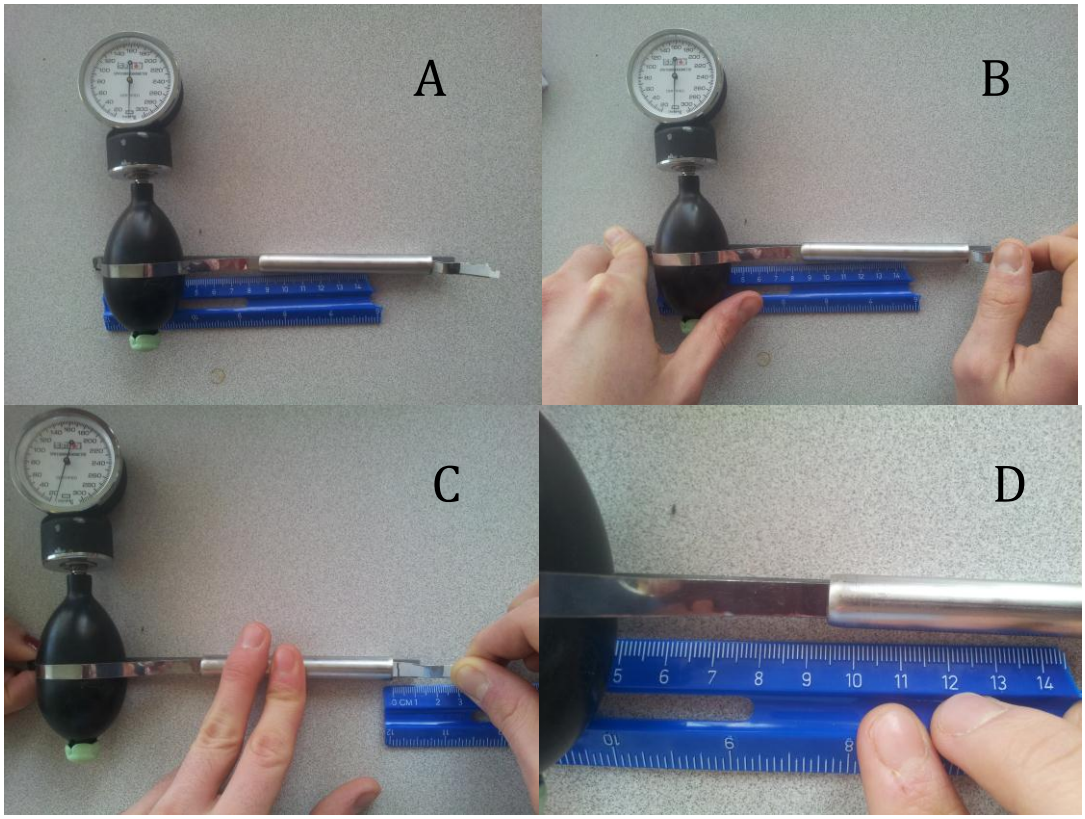


Figure A2. Pictures from Clamp Force Testing on blood pressure cuff. The general setup (A), pulling motion (B), distance pulled (C) and stick out length (D) are shown.

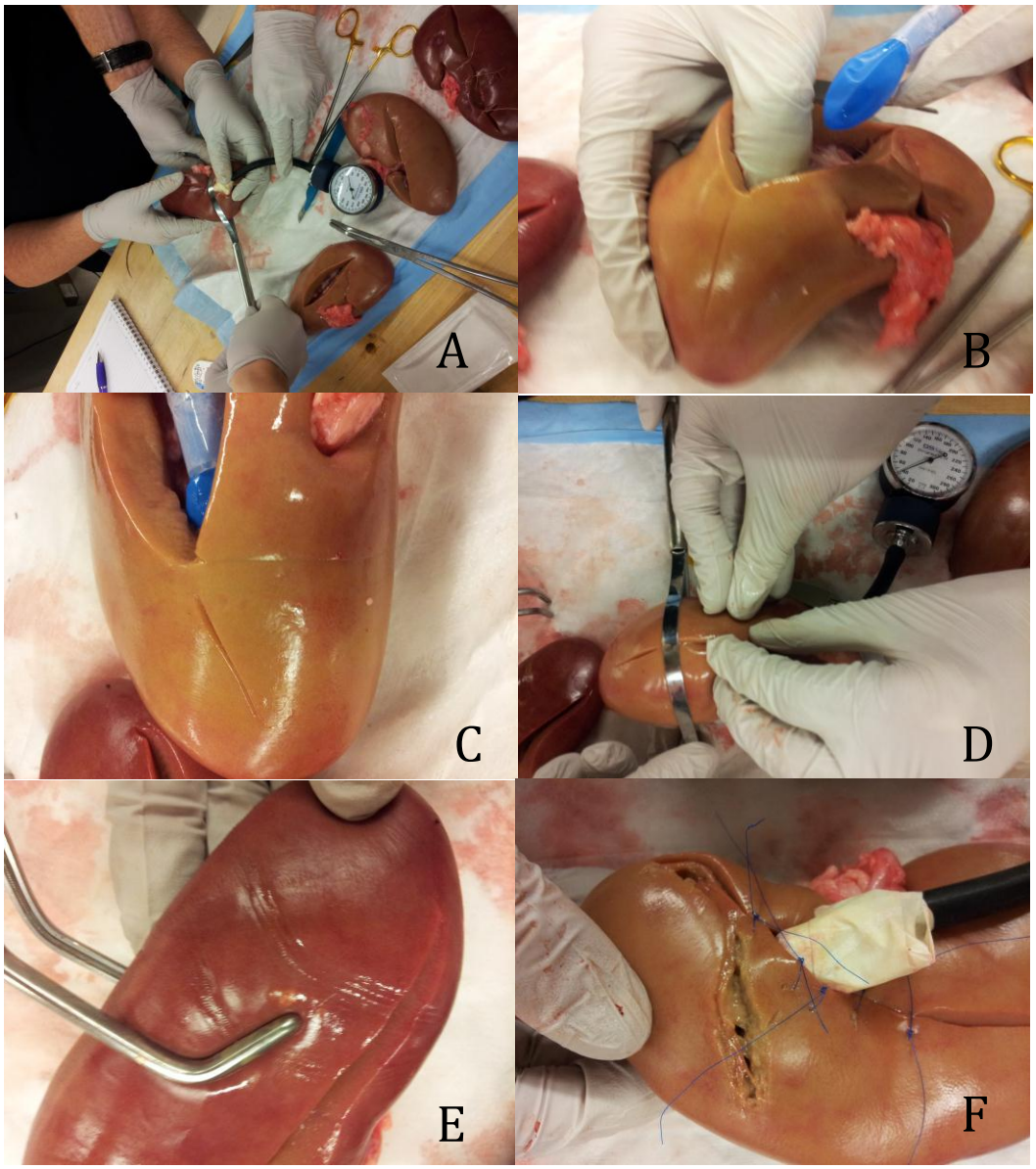


Figure A3. Pictures from Excised Porcine Kidney testing. The general setup (A), insertion of balloon (B), kidney with pressure gauge balloon inside (C) our device clamping the kidney (D), and damage left by Satinsky clamp after testing (E,F) are shown.

Figure A4. Porcine Kidney Compression Testing.

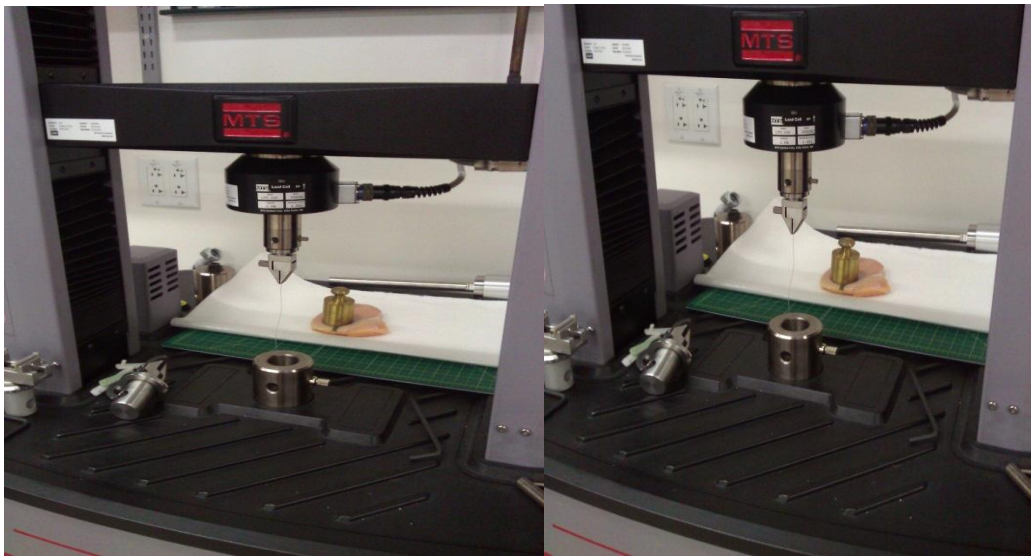


Figure A5. Texture Testing in the load frame with chicken breasts, 200g mass, and pulley system.

APPENDIX D. TESTING RESULTS

Table A1. Results of Clamp Force Testing.

Back plate (cm)	Trial 1		Trial 2		Trial 3	
	length (cm)	pressure (mmHg)	length (cm)	pressure (mmHg)	length (cm)	pressure (mmHg)
85	3.3	0	3.6	0	3.6	3.6
	3.8	2	4.1	10	4.1	10
	4.3	20	4.6	23	4.6	23
	4.8	28	5.1	48	5.1	40
	5.3	30	5.6	60	5.6	55
	5.8	50	6.1	80	6.1	84
					6.6	95
90	3.4	0	3.4	0	3.4	0
	3.9	7	3.9	3	3.9	3
	4.4	15	4.4	19	4.4	17
	4.9	22	4.9	32	4.9	30
	5.4	40	5.4	46	5.4	50
	5.9	64	5.9	80	5.9	82
	6.4	90			6.4	115
	6.9	100				
95	2.9	0	3.2	0	2.4	0
	3.4	5	3.7	5	2.9	3
	3.9	18	4.2	22	3.4	8
	4.4	30	4.7	38	3.9	20
	4.9	52	5.2	52	4.4	28
	5.4	82	5.7	68	4.9	50
	5.9	130	6.2	78	5.4	64
					5.9	90

Table A2. Results of Texture Testing

Texture	Trial 1	Trial 2	Trial 3	Trial 4	Trail 5	Average Force	Standard Deviation
Normal	1.41	1.11	0.96	1.23	1.03	1.148	0.1775387282
Indents	2.13	2.2	2.4	2.22	2.18	2.226	0.102859127
Angled	1.68	1.39	1.42	1.49	1.4	1.476	0.1205404496
Perpendicular	2.39	2.43	2.38	2.34	2.36	2.38	0.0339116499
Criss-cross	1.38	1.2	1.31	1.18	1.24	1.262	0.0825832913

APPENDIX E. ALTERNATE DESIGNS

Figure A6. The Modified Bulldog Clamp, an attachment that connects to an existing bulldog clamp applicator. It is larger than existing bulldog clamps, which allows it to clamp around the kidney.

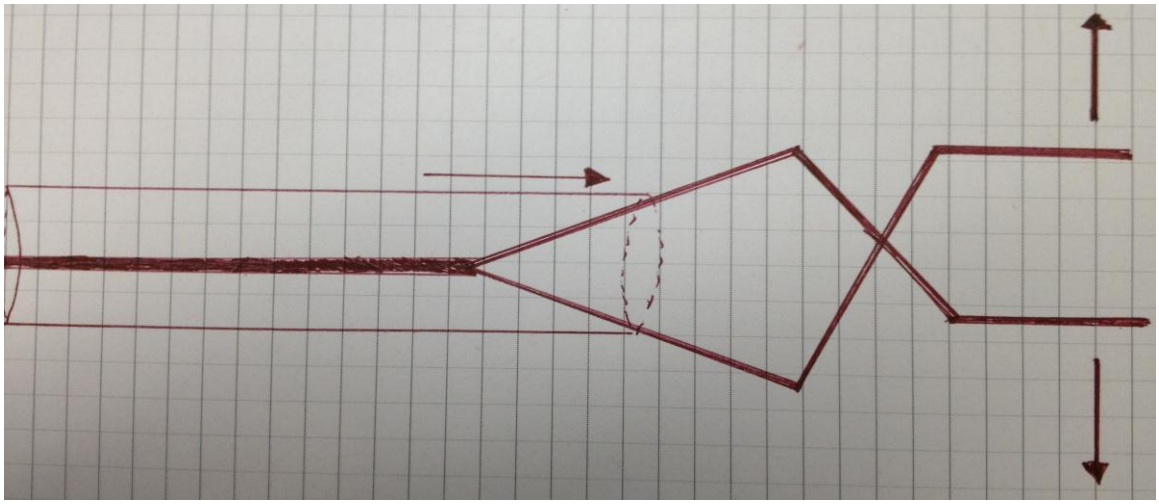


Figure A7. The Crisscross design uses the same mechanism as the Johns Hopkins Bulldog Clamp. The laparoscopic tube is pushed down to open the clamp, as shown by the arrows above.

Figure A8. The Zip-Tie design consists of the laparoscopic tube, attached to a zip-tie like strip and locking mechanism (shown on the top-right). The surgeon would use a forceps to loop the strip around the kidney, and push it into the locking mechanism at the desired length.

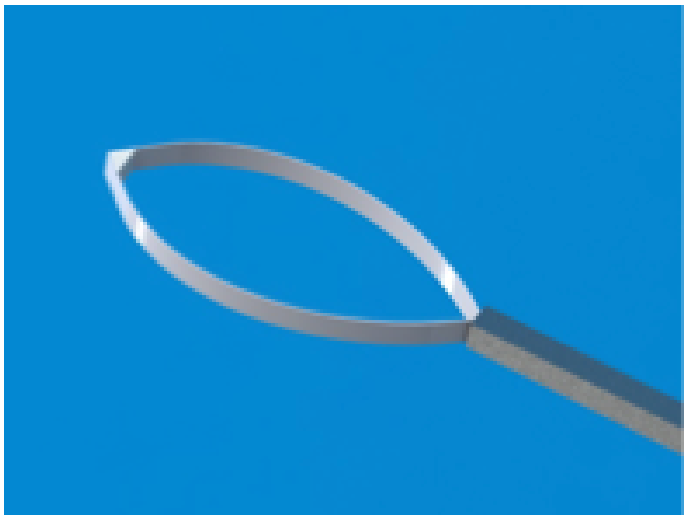


Figure A9. The original loop design worked similarly to the current clamp design, but had two equally thin steel ribbons, and a steel triangle at the end to act like a spring to push the ribbons apart, as they were pushed out of the tube. The tube as shown above was also a square instead of round.