Kidney Clamp for Laparoscopic Partial Nephrectomy

Final Report

14 December 2011

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Abstract

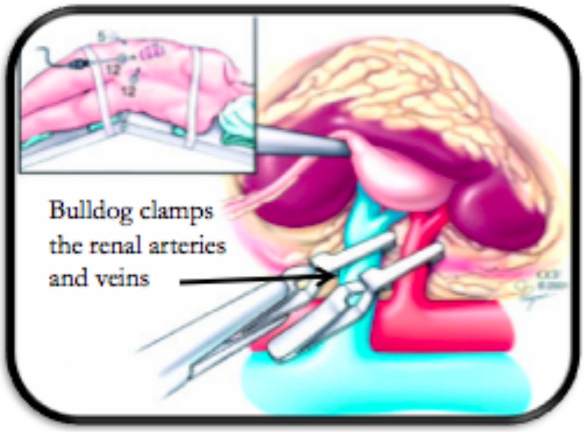
As a result of new imaging methods over the past few decades, there has been an increase in carcinoma detection in the kidneys resulting in an overall increase in nephrectomy surgeries. Recently, surgeons are performing more partial nephrectomy surgeries versus radical nephrectomy surgeries in order to spare viable and functioning tissue. In addition, these surgeons are switching over from open surgeries to laparoscopic surgeries in order to decrease post-operative complications. However, current methods of blood flow occlusion for laparoscopic partial nephrectomy (LPN) create global ischemia to the kidney that may lead to long term loss of renal function. Our client, an LPN surgeon, would like us to develop a device that can occlude blood flow in the kidney at the site of the partial nephrectomy, in efforts to simplify the procedure and prevent tissue damage. The device will clamp across the kidney in order to occlude renal blood flow to the tumor, reducing the chances of global ischemia in the kidney, therefore resulting in less complications.

Introduction/Background

Renal cancer is the 7th leading malignant condition for men and the 12th leading among women in the United States [1]. Nephrectomy surgery is the initial treatment for the majority of kidney cancers. In the past, radical nephrectomy (RN), or removal of the entire kidney, was considered the standard therapy. However, partial nephrectomy (PN) is quickly becoming the standard care in the United States for renal cortical tumors smaller than 4cm in diameter [1]. Partial nephrectomy refers to when a surgeon removes only the diseased tissue from the kidney. This can be accomplished laparoscopically, through small incisions instead of opening the body cavity. Laparoscopic surgery results in less postoperative pain, a shorter hospitalization, and a quicker recovery [2].

The kidneys play a critical regulatory role in the human body, filtering around 20 percent of the body's blood per minute. This blood flow rate is essential to maintain homeostatic functions and needs to be present to keep the kidney cells alive. During nephrectomy surgeries, the renal vessels are dissected from the surrounding tissue and then temporarily occluded to control bleeding, as shown in Figure 1a [1]. Unfortunately, dissection of the artery is difficult and time consuming, and loss of blood flow from vessel clamping causes ischemia across the kidney. Renal clamping times of as little as30 minutes have been shown to cause 10% loss in kidney function post-surgery [3].

It is desirable to find a method of occluding blood flow from the surgical site without reducing flow to the surrounding, healthy tissue. This could prevent the need for dissection of the vessels, as well as reduce ischemia in healthy cells. Our client, Dr E. Jason Abel at the University of Wisconsin – Madison Hospital, specializes in localized advanced kidney cancer. His philosophy, to "provide maximal quality of life to patients by using minimally invasive approaches to cancer therapy," has prompted the idea for a new, laparoscopic tool to aid in partial kidney removal. This tool would selectively occlude blood flow to the portion of the kidney being removed, around the parenchyma or kidney tissue, as shown in Figure 1b.



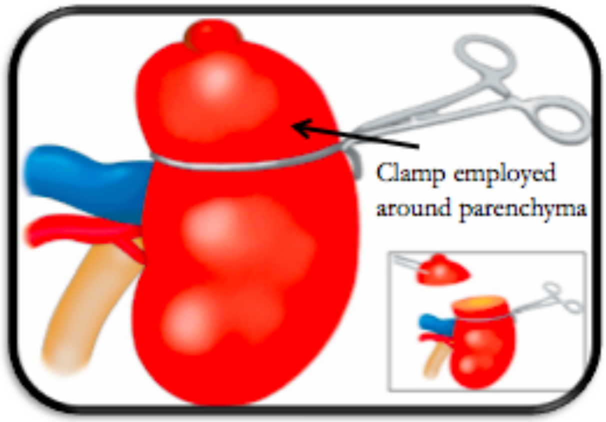


Figure 1a (left) shows the current method of tumor removal with clamps applied at the blood source. **Figure 1b** (right) shows the proposed method, which employs a clamp around the kidney tissue.

Problem Statement

A device needs to be created for use in a laparoscopic partial nephrectomy surgery to selectively occlude blood flow to the portion of the kidney being removed, while still allowing blood to reach the remaining tissue. This will reduce cell death and therefore reduce the occurrence of kidney failure post-surgery.

Design Specifications

The device needs to fit through a 12 mm trocar to be inserted into the body cavity. The handle of the device must be ergonomic, and comfortable for the surgeon to use for an extended period of time, as long as 30 minutes. Additionally, the neck of the clamp must be 61 cm long and be pliable, so that it can be moved out of the path of the camera and other surgical tools used during the surgery. The clamp must apply enough force to completely occlude renal blood flow, 3.85 kg of force [4], and must provide the same force at every position on the clamp. Additionally, the clamp must be stable and held in place for the duration of the surgery. The entire device needs to be made of materials that will not damage human tissue and they must be able to be sterilized, so as to make the device reusable.

Current Devices

Satinsky Clamp

The Satinsky Clamp is one of the most widely used surgical clamps on the market. The Satinsky Clamp is not a laparoscopic clamp, but rather it is used to perform open partial nephrectomy surgeries as shown in Figure 1. The clamp portion of the device is curved inwards, which is a preferable design for our client. Additionally, the handle of the clamp is comprised of a ratchet that can lock the clamp into different configurations. However, this ratchet is hard to unlock using only one hand and can become uncomfortable for the user. Furthermore, this design lacks the flexible shaft our client desires. There is a laparoscopic version of the Satinksy Clamp which has been used to perform two successful partial nephrectomies with parenchymal clamping [5]. However, the length of the clamp, only 34 mm, is not large enough to accomadate most tumors[5].

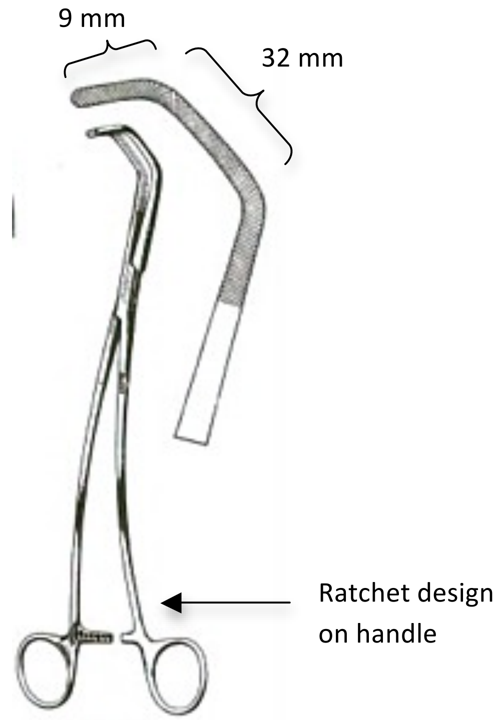


Figure 1: The Satinksy surgical clamp is widely used in open partial nephrectomies. [5]

Reniclamp

The Reniclamp is another surgical clamp, shown in Figure 2. In one study, it was successfully used to clamp the parenchyma of the kidney around the tumor site during open partial nephrectomies [6]. The two handed grip provides better control of the kidney once clamped, and is used to position the kidney for easy dissection. Although successful, the Reniclamp lacks many of the attributes our client is looking for. The size of the clamp prevents it from being used in laparoscopic surgeries. Additionally, it requires two hands to operate and is lacking a flexible shaft.

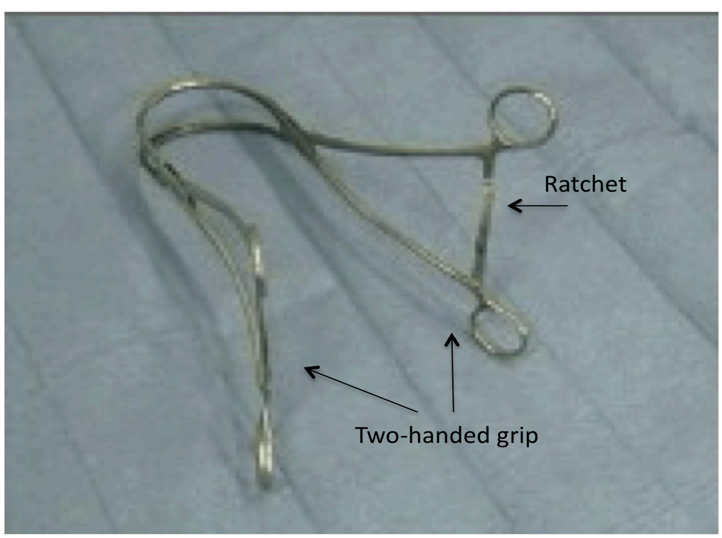


Figure 2: The Reniclamp has been used to perfrom two successful OPNs [6].

Aesculap Surgical Clamp

The Aesculap Surgical Clamp has been used to perform laparoscopic partial nephrectomies with parenchymal clamping (Figure 3). It consists of a 10 mm clamp and a small shaft that can fit through a 10 mm trocar [7]. However, this design is also lacking some proponents that our client desires. The shaft is rigid and its length is shorter than our client requires.

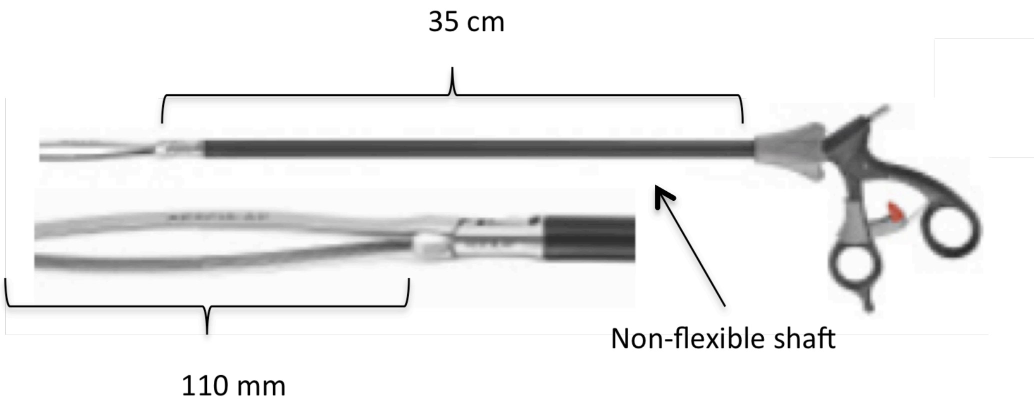


Figure 3: Aesculap surgical clamp has been used to perform a LPN [7].

Previous clamps on the market do not meet the requirements of our client. Although the Satinsky clamp provides the clamp shape our client is looking for, it cannot be used laparoscopically and is not long enough to accommodate the kidney. The Reniclamp provides enough force to adequately suppress blood flow to the tumor but requires the use of two hands and cannot be used laparoscopically. Laslty. The Aesculap Surgical Clamp has a comfortable handle and provides enough force when used laparoscopically, but the shaft is not long enough or flexible. We plan to improve upon these clamps by creating a clamp with an adjustable force handle, flexible shaft, and laparoscopic clamping mechanism to provide adequate force, as demonstrated by previous clamps.

Clamp Design

We decided to break our design into three parts: the handle, the shaft, and the clamp with the mechanism to apply force.

Handle

The handle needs to accommodate a variety of hand sizes in order to be used by all surgeons. It also has to be easy to operate and needs a way to provide different amounts of force. Furthermore, the handle needs to be able to lock in those force amounts so that the force applied can stay constant over the duration of the clamping time. Handles with all of our specifications are currently in the market and we will be purchasing one for our clamp design. Our client specified that he would prefer the ratchet style handle and we found designs from Aesculap (Figure 4) and McMaster-Carr that would work for the clamp.

Figure 4: Renal pole clamp handle from Aesculap Surgical Technologies ®

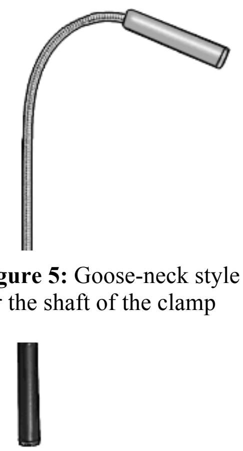


Figure 5: Goose-neck style used for the shaft of the clamp

Shaft
The shaft of the clamp needs to have enough flexibility to be able to bend out of the way of the surgeon's work area as well as the view of the camera if it is obstructing the view. It needs to be 61 cm in length and the diameter needs to be less than 12 mm to fit through the trocar. From these specifications we found a goose-neck style shaft available at McMaster-Carr (Figure 5). The shaft is less than ten dollars and is rigid enough to direct the clamp to the tumor site, but can be bent when needed.

Clamp
The clamp and the mechanism to control the clamp were further researched and the following three designs were made based off that research and our design specifications.

Design Alternatives
Design 1: Bike Brake Mechanism

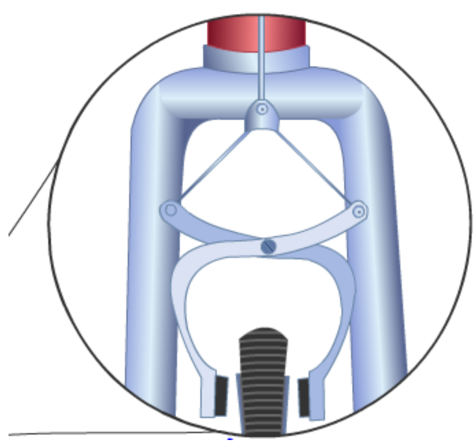


Figure 6: Bike Brake Mechanism

The first two design alternatives use the same mechanism to operate. The mechanism, similar to that used to brake on a bike, is a system of wires used to close a clamp (Figure 6). On a bike the clamp stays open while riding, when the rider needs to stop they pull on the brake handle. This handle pulls a long wire that leads to the clamp on the bike tire. When the wire is pulled it shortens the distance between the handle and the clamp and the clamp arms are forced together. The clamp then causes friction with the bike tire which eventually brings the bike tire and the bike to a stop.

Bike Brake Design A: Straight Clamp Arms

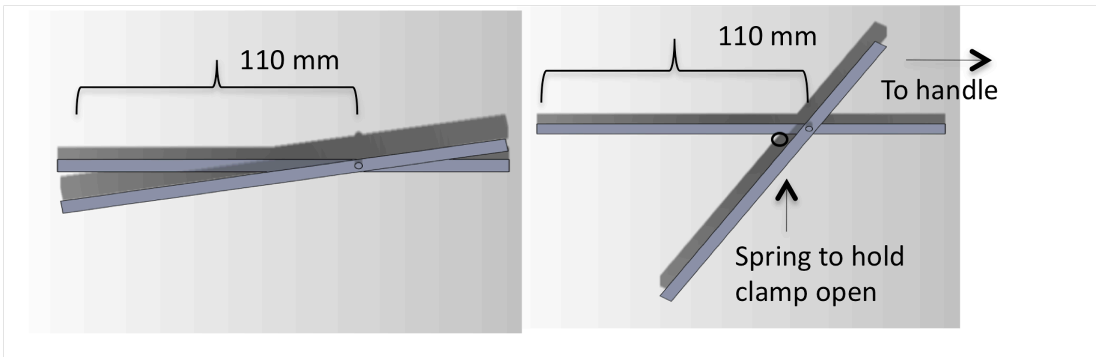


Figure 7: Straight Clamp Arms

The first clamp design that uses the bike brake mechanism has straight clamp arms (Figure 7). There is a torsion spring near the jaw opening of the clamp. This spring keeps the clamp in the open position until the clamp handle is pulled. To insert the clamp into the body the handle must be pulled, once at the site of the kidney the handle can be released, opening the clamp, making it ready for use. The straight arms ensure that the clamp will fit through the 12 mm diameter trocar. However, having the straight arms causes problems with the amount of force the clamp applies at different locations along the clamp. More force is applied at the proximal position on the clamp compared to the medial position, and the distal position provides the least amount of force. This is due to the shorter distance to the moment arm (jaw opening) of the clamp at the proximal position.

Bike Brake Design B: Angled Clamp Arms

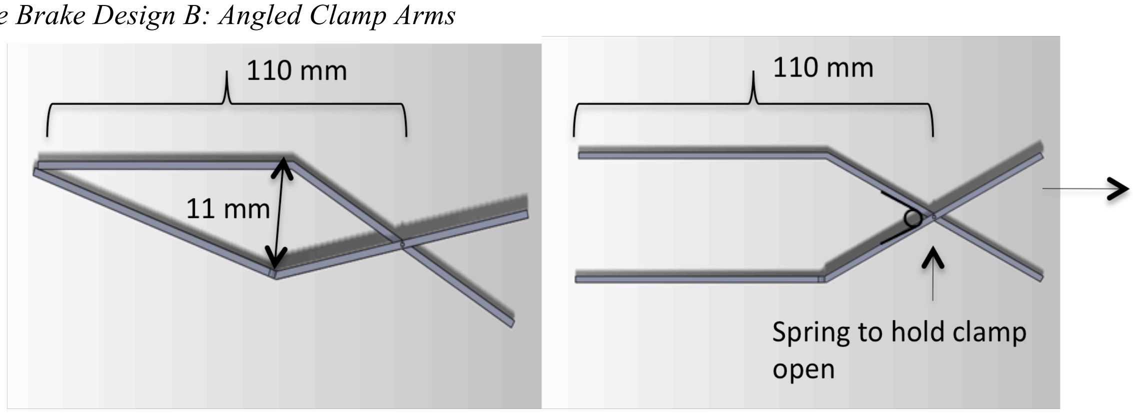


Figure 8: Angled Clamp Arms

The second clamp design that uses the bike brake mechanism is very similar to the first design (Figure 8). It uses the same mechanism and also includes the torsion spring to keep the clamp open. The difference with this clamp is that the clamp arms are angled instead of straight. The angled arms allow for a more even distribution of force along the clamp arms. However, the angled arms make the clamp width bigger than the trocar diameter. This clamp would need modifications before it could be used.

Design 2: Loop Clamp

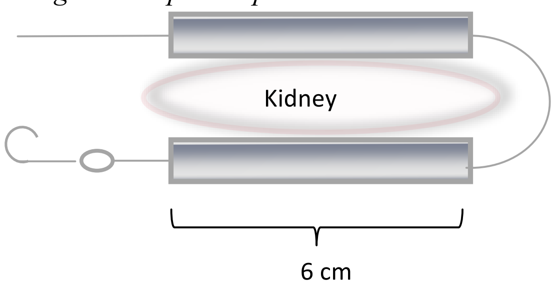


Figure 9: Loop Clamp

The last clamp design utilizes a wire that be connected in a loop using a hook and eye closure (Figure 9). There are two clamp arms with the wire running through them in series. The clamps would be placed on opposite sides of the kidney. Once in position the hook on one side of the loop would encircle the wire on the opposite side and hook back into the closure thus creating a closed loop. The wire can then be tightened, making the loop smaller and closing the distance between the parallel clamp arms, causing more force to be applied to the kidney. The force distribution would be even and the clamp would fit through the trocar. The issue with this style of clamp is that it would be more difficult to use. Another tool would have to be used to hook the loop into position.

Design Matrix

In order to quantify our decision on which design alternative to pursue in the future we created a design matrix (Figure 10). We judged each design based on five design criteria: fabrication, price, ease of use, stability, and force distribution. Fabrication was calculated by how easy it would be to put together or fabricate each design. Price was determined by the future expense of each design and ease of use was based on the difficulty to operate the device. The stability category determined how well the device would stabilize the kidney and keep it in its original orientation. Force distribution based its category on how evenly the clamp arms applied force to the kidney. Each criterion was given a weight based on importance to the design, and all of the criteria added up to a score of 100.

Criteria	Weight	Design Alternatives		
		Bike Brake Mechanism		Loop
		Straight	Angled	
Fabrication	10	10	8	5
Price	10	8	8	8
Ease of Use	25	25	25	15
Stability	25	20	23	25
Force Distribution	30	22	29	30
Total	**100**	**85**	**93**	**83**

Figure 10: Design matrix weighing design alternatives on a scale out of 100. Angled bike brake mechanism scored the highest with a total of 93.

Ease of use, stability, and force distribution were the three most important design criteria based on client input and our research. Because the straight bike brake mechanism would not apply even force across the kidney due to the geometry of the clamp heads, it only received 22 out of 30 points. As for the loop design, it lost points in the ease of use category because it would require an additional tool to place the device into position in order for it to function. Therefore, this design only received 15 out of 25 points in the ease of use category. Our client also specified that he would prefer a parallel clamp design and not a loop, so that was taken into consideration.

Due to the fact that the angled clamp arms utilizing the bike brake mechanism received high points in all categories, totaling 93 out of 100, it was chosen as our final design.

Final Design

We decided to pursue the angled clamp arms using the bike brake mechanism for our final design as seen in Figure 11. This design was chosen because it can apply force evenly across the kidney. The device will utilize the goose-neck shaft, so that the device can be flexible within the body cavity, and will also use the ergonomic ratchet-style handle, with a locking mechanism, in order to apply variable and consistent force. A few modifications to the design were needed to be made to make the clamp satisfy all of the requirements. These modifications are further discussed in the next section.

Prototype Design

We built a prototype based on the final design we had chosen. In order to make our device feasible for use we added several mechanical features. First, a metal bar was extended from the end of the shaft to the clamp arm connection/pivot point. This bar provides stability to the clamp arms as well as allows the brake mechanism to be successful. This bar keeps the distance of the clamp arms, relative to the shaft, constant while only the wires are pulled. This allows the clamp arms to open rather than to move back with the wires toward the shaft.

In order to fit through the trocar we decided to eliminate the angle on the clamp arms and make the clamp arms curved. We will be using a spring steel in our final clamp construction that can deform to the needed width when the maximum amount of force is applied to the clamp. The curved arms will also better distribute the force along the length of the arms compared to having completely straight clamp arms seeing as the kidney is not a flat organ.

The prototype made for this semester (Figure 11) incorporated the new clamp design as well as the goose neck shaft and handle. It was created using a handle from a grabber, a gooseneck from a flashlight and the clamp was made from a set of eyebrow tweezers (Figure 12). The clamp mechanism used bike wires to connect the handle trigger to the clamp moment arms and a picture hanger and nail provided the pivot point and metal bar for stability.

A cost analysis of the prototype is provided in the next section.

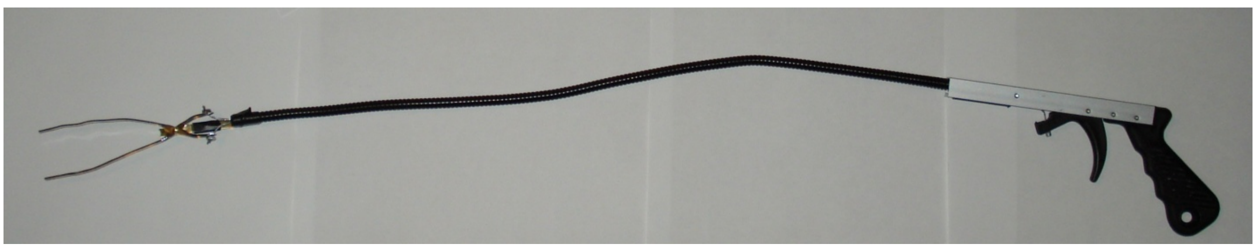


Figure 11: Final design incorporating the ratchet-style handle, the goose-neck shaft, and the curved clamp arms utilizing the bike brake mechanism to operate.

Figure 12: Close up of the prototype clamp

Cost Analysis

The budget of this project was to create a device that cost less than commercially available clamps, which cost upwards of $5000. The prototype cost a total of $16 to construct. The most expensive item incorporated into the clamp was a Reacher Medical Aid, which was repurposed for use as the handle of the prototype. However this item was donated and did not cost the project any money. The flexible flashlight was used for the shaft of the device and was purchased from a local hardware store. A bike brake cable was used to attach the handle to the clamp, and was purchased from a Budget Bicycle Center. Lastly, Revlon Perfect Tweeze tweezers, purchased from Target, were reshaped with a hammer to create the clamp. Super glue, electrical tape, a picture hanger, a nail, and two small nuts were also used to create the prototype, but were not purchased. A cost analysis is shown in table 1.

Description	Vendor	Cost
Flexible Flashlight	Northern Tool and Equipment	$8.00
Reacher Medical Aid	Featherlite	$18.50 (donated)
Bike brake cable	Budget Bicycle Center	$3.50
Revlon Perfect Tweeze	Target	$4.50
Total		$16.00

Table 1: Prototype Cost Analysis

Future Clamp

A SolidWorks Design of our final clamp (Figure 13) was created using dimensions we found of a vascular clamp (Figure 14) that is used in non-laparoscopic procedures but has effectively performed partial nephrectomies. [8] The clamp will ultimately be made of spring steel that will be able to deform to a diameter less than 12 mm when enough force is applied to the clamp. The clamp would also need to be able to retake its original shape when opened while still applying enough force, between 5 N and 20 N, to the kidney when in use. [9] A design analysis was done in SolidWorks to prove that our design was feasible.

Figure 13: SolidWorks Design of final clamp

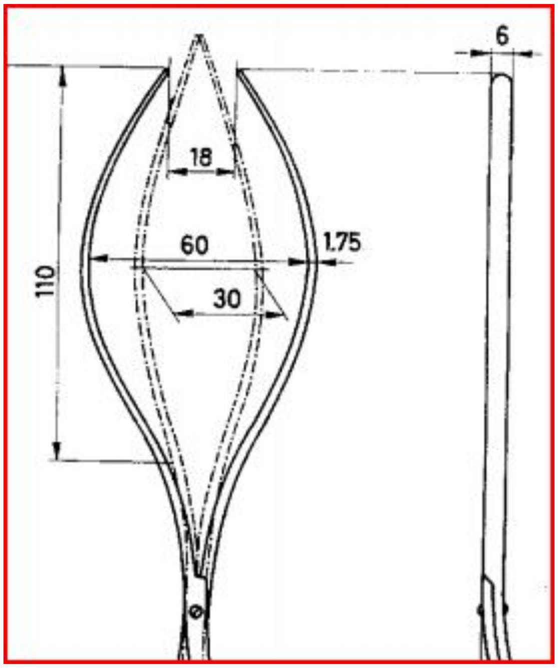


Figure 14: Dimensions used for Solidworks design. Dimensions are in millimeters. [8]

Design Analysis

To test the functionality of our clamp design, including whether or not it will fit through the 12 mm trocar diameter, a SolidWorks stress analysis was performed. In order to subject the curved clamp to the mechanics it would experience in normal use, one end was fixed as a pin and the other as a roller. Stainless steel (ferric) was used as the material for the analysis. Two trial stresses, 5 N and 20 N, were applied to the clamp to test it against the loading it will undergo in normal use. According to Farshad *et al.* 5 N of force is sufficient to substantially compress the kidney. 20 N represented the max force our clamp would withstand because the kidney begins to rupture at this force. [9] Additionally, compressive and tensile loads were applied evenly across the clamp in separate analyses. The compression mechanics model how the clamp responds to a clamping force supplied by the operator, while the tension mechanics model the forces the kidney applies during a partial nephrectomy. The SolidWorks stress analysis constraints and tensile and compressive loading can be seen in Figure 15.

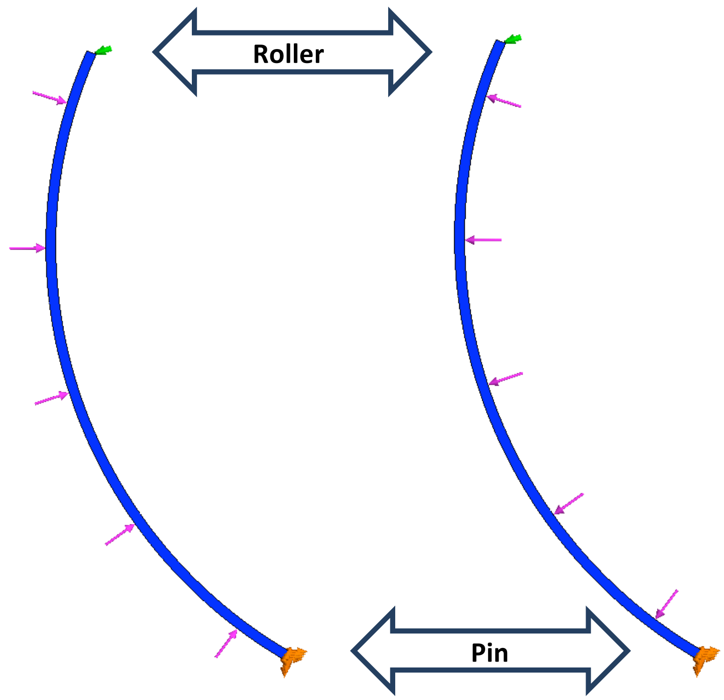


Figure 15: SolidWorks stress analysis setup for compression (left) and tension (right) trials

Results of Analysis

The deformation and stress distribution results from the SolidWorks stress analyses can be found in Figure 16. The values from these analyses are represented in Table 2**.**

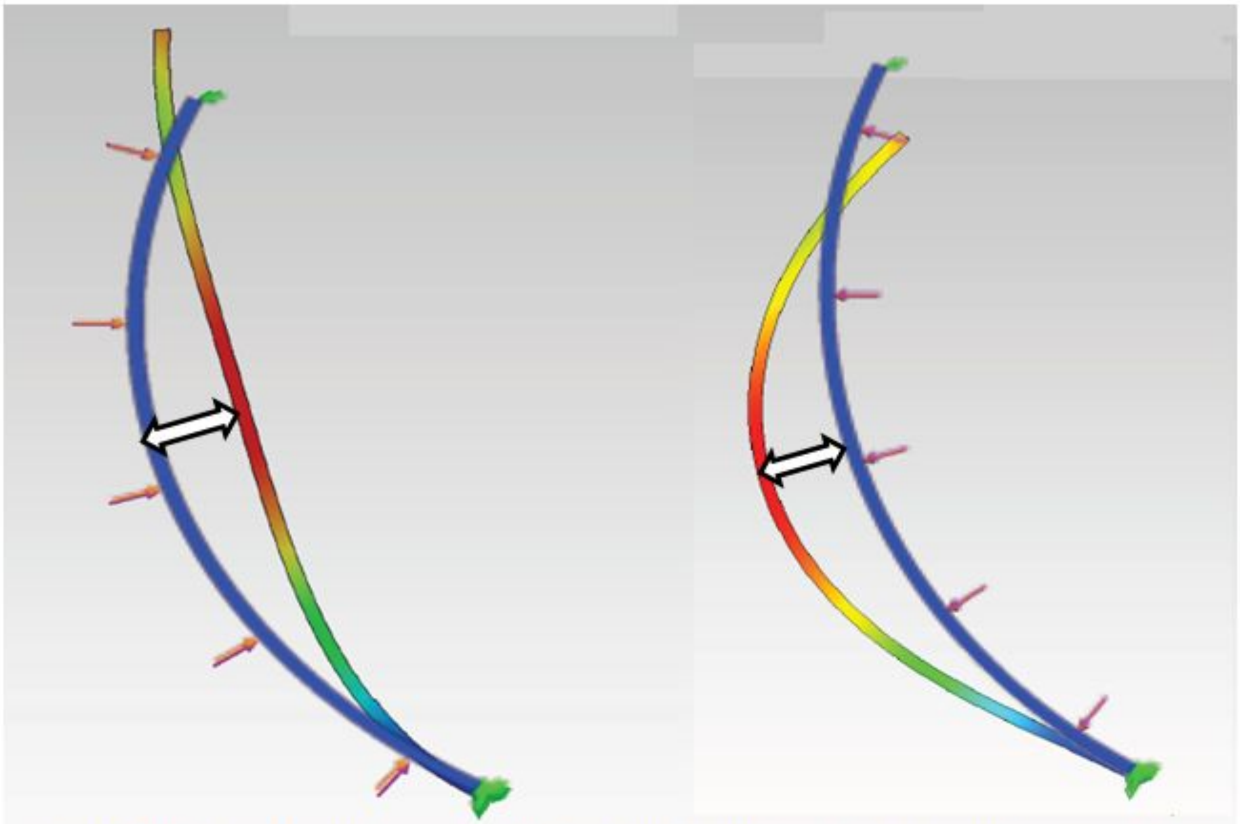


Figure 16: Results from 5 N and 20 N compression (left) and tension (right) loading results. Arrows indicate where deformation was measured. Red indicates where the highest amount of stress occured, while blue indicates regions of low stress on the deformed clamp. The two loading trials, 5 N and 20 N, had the same deformation but recorded different stresses.

5 N Load		
	Deformation (mm)	Stress (kPa)
Tension	12	44
Compression	11.5	45
20 N Load		
	Deformation (mm)	Stress (kPa)
Tension	12	179
Compression	11.5	181

Table 2: Results of the 5 and 20 N load trials from SolidWorks stress analysis.

On the deformed piece, the red indicates areas of max stress, while the blue indicates regions of least stress. Both the 5 N and 20 N trials deformed the same in their respective loading configuration: compression and tension. However, their stresses did not match each other. The 20 N trials were subjected to higher amounts of stress.

As previously mentioned, the material used to model the clamp was stainless steel (ferric). The stainless steel used in this analysis has a yield strength of 172 MPa, which is over 950 times greater than the highest stress observed in our SolidWorks analyses (181 kPa in the 20 N compression trial). Therefore, the clamp will not fail remotely close to its highest compression force in use.

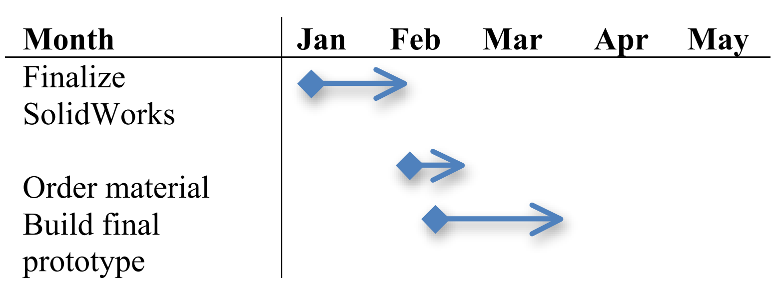
The maximum deformation that was found at the center when compressing one arm of the clamp was 11.5 mm. Before compression, the one arm has a max diameter of 22 mm; consequently, when the clamp is compressed by the operator its diameter will shrink down to 10.5 mm. With the addition of the thicknesses from each clamp to the diameter when compressed, the entire clamp diameter is 24.5 mm wide**.** Because 24.5 mm is twice the diameter we need to be able to fit through the trocar we had to make one of the clamp arms straight to fit through the trocar (Figure 17). In the future we will not be using the steel we did our analysis on. We will choose a spring steel that can have larger deformations in diameter.

Figure 17: Modification of the two curved arm clamp in order to make the clamp fit through the trocar

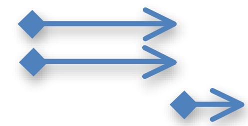
Future Work

At this point, the team has fabricated a prototype to demonstrate proof of concept and conducted SolidWorks analysis on the max stress applied and max deformation at 5 N and 20 N. With the deformation data obtained from the SolidWorks analysis, the clamp will fit through the trocar with the specified arc dimensions, given that only one clamp branch is curved and one clamp branch is straight. Testing will need to be performed to assure that evenly distributed forces are applied along the parenchymal of the kidney.

First, more accurate materials will be ordered: 1.75 mm spring stainless steel for clamp branches and a 600 mm stainless steel arm, as specified in the final design. Once this second phase prototype is constructed, manual testing will be conducted to provide additional data about pressure generation and clamp deformation. The last step will be experimenting with a flexible arm, as recommended by our client. The following is a timeline of the team's goals for the next four months.



Testing
Instron
Pig Lab



Testing of the final prototype will be performed according to the method of Lee. Briefly, the occlusion force will be measured along 5 evenly distributed points along the clamp. Data will be collected using a 2.2 mm button style compression load cell transducer (Interface Advanced Force Measurement) as seen in Figure 18. Testing will simultaneously completed on the Satinsky clamp for comparison. Pressure will be additionally monitored for a period of 45 minutes to note any variances with respect to time.

In congruent to this testing, Instron testing may be performed to measure the pressure and deformation of the kidney. In order to do this testing, the Instron grips will be modified to resemble the 6 mm by 1.75 mm bar width. Lastly, the clamp will be tested *in vivo* during a pig kidney removal.

Conclusion

With an increase in cancer detection, surgeons are leaning toward performing partial nephrectomy surgeries versus radical nephrectomy surgeries in order to spare functioning tissue. Surgeons are also leading towards laparoscopic procedures due to fewer post-operative complications. Current methods of blood flow occlusion for laparoscopic partial nephrectomy cause permanent damage to the kidney. Therefore a device needs to be created for use in a laparoscopic partial nephrectomy surgery to occlude blood flow to the portion of the kidney being removed, while still allowing blood to reach the remaining tissue. Our group looked at current clamps used in partial nephrectomy surgeries and researched ways to create a better clamp. Three design alternatives were created and weighed based on design specifications, with one being selected as the final design. The final design was modified to be able to successfully clamp the kidney at the site of the tumor removal, stopping blood flow only at the resected area. It will provide a consistent amount of force at the different positions along the clamp and the force can be varied using a ratchet handle with a lock. With some more design work, fabrication, and testing the clamp will be able to be used in laparoscopic partial nephrectomy surgeries.

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Product Design Specifications – December 14th, 2011

A New Vascular Clamp for Robotic Partial Nephrectomy (VASCLAMP)

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Professor Mitch Tyler

Problem Statement

Due to new imaging methods over the past few decades, there has been an increase in carcinoma detection in the kidneys resulting in an overall increase in nephrectomy surgeries. Recently, surgeons are performing more partial nephrectomy surgeries versus radical nephrectomy surgeries in order spare any viable and functioning tissue. In addition, these surgeons are switching over from open surgeries to laparoscopic surgeries in order to decrease post-op complications. However, laparoscopic partial nephrectomy (LPN) is a technically challenging procedure with a steep learning curve. There is an unmet need to make the procedure less technically demanding for surgeons. Our client, a LPN surgeon, would like us to develop a device that can occlude blood flow in the kidney at the site of the partial nephrectomy, in efforts to simplify the procedure. The device should clamp across the kidney in order to occlude renal blood flow to only the tumor section resulting in less complications during the surgery as well as a reduced chance of global ischemia in the kidney after the procedure is completed.

Client Requirements

- Device must be able to provide enough strength to occlude renal blood flow.
- Device must be a laparoscopic instrument.
- Device must be reusable.
- Surgeon must be able to operate the device with one hand.
- Clamp neck must be flexible.

Design Requirements

1. Physical and Operational Characteristics

a. Performance Requirements: The product must be able to be applied during the duration of the surgery (5- 30 minutes) and must be reusable for future laparoscopic procedures.

b. Safety: The product cannot cause any harm to the operators or the kidney and the surrounding tissue.

c. Accuracy and Reliability: The device must be able to apply 8.5 lbs 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 5 – 30 minutes).

e. Shelf Life: The product 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 tissue.

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. In addition the device must have a flexible shaft

h. Size: The device must be able to fit through a 12 mm by 15 cm laparoscopic trocar and the arm should be 61 cm in length. The clamp should be 5 cm long to occlude flow to a 4 cm tumor.

i. Weight: Weight should not exceed one pound.

j. Materials: The device should be made of materials that are sturdy and do not deteriorate or infect the tissues of the patient.

k. Aesthetics, Appearance, and Finish: For this project the client emphasized functionality over appearance and therefore this category is not applicable to our design.

2. Production Characteristics

a. Quantity: One device 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 our client; however, it has the potential to be integrated into other laparoscopic procedures that involve the kidney or similar organs.

c. Patient-related Concerns: The device is intended for use on patients needing laparoscopic partial nephrectomy. The device will need to be sterilized to be used on the next patient.

d. Competition: There are no commercially available clamps designed solely to clamp the kidney parenchyma that are also laparoscopic. The Satinsky laparoscopic clamp has been used in this manner, but it doesn't provide the flexible shaft our client desires.