Kidney Clamp for Laparoscopic Partial Nephrectomy

Mid Semester Report

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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) are dangerous and cause harm to the kidney. 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, resulting in less complications during the surgery as well as a reduced chance of global ischemia in the kidney after the procedure is completed.

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 then temporarily occluded to control bleeding [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 30 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, Doctor 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.

Problem Statement

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. 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. Additonally, 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 is not large enough to accomadate most tumors.

Figure 0: The Satinsky Clamp is widely used in open partial nephrectomies [5].

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

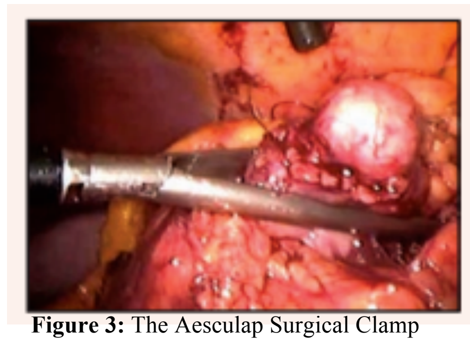

Figure 3: The Aesculap Surgical Clamp performing a LPN [7].

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.

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.

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 ®

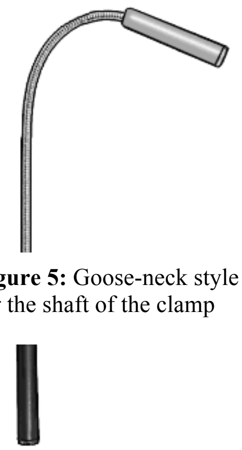

Figure 5: Goose-neck style used for the shaft of the clamp

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

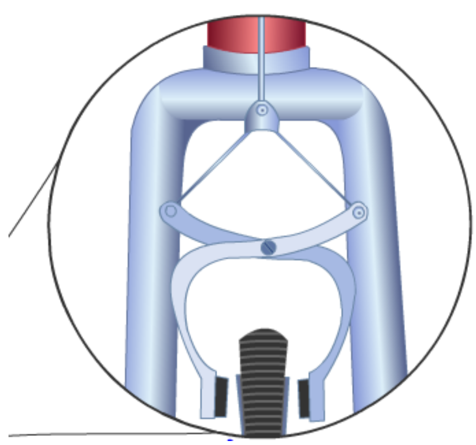

Figure 6: Bike Brake Mechanism

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

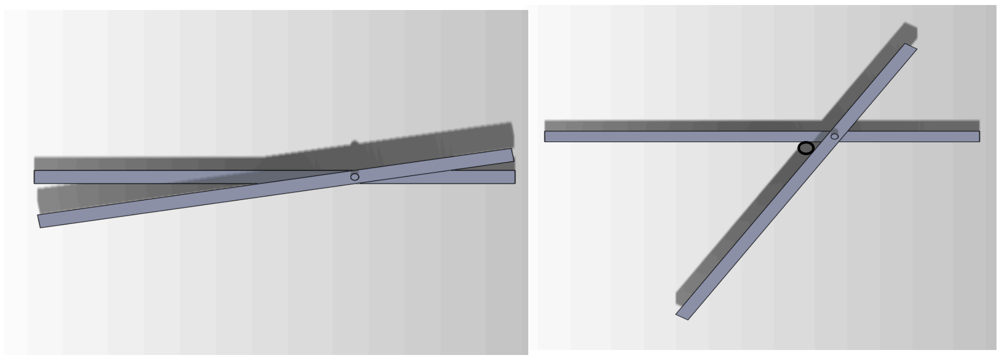

Figure 7: Straight Clamp Arms

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

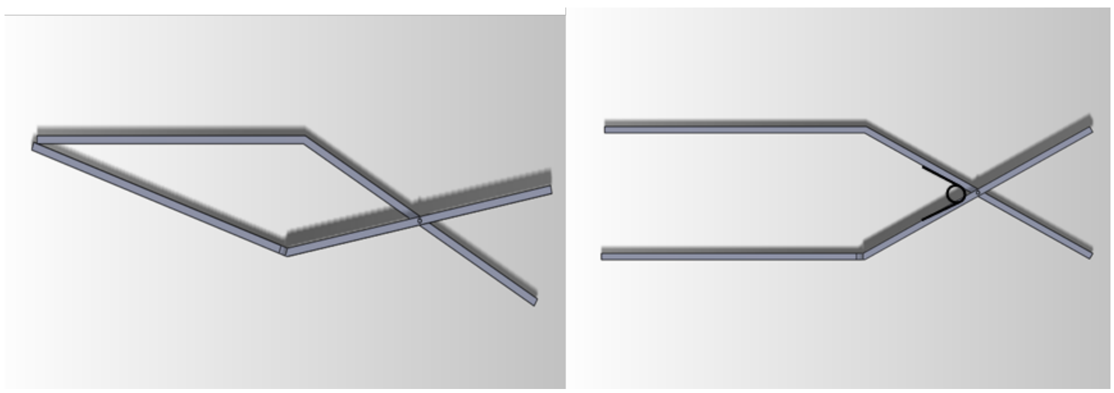

Figure 8: Angled Clamp Arms

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

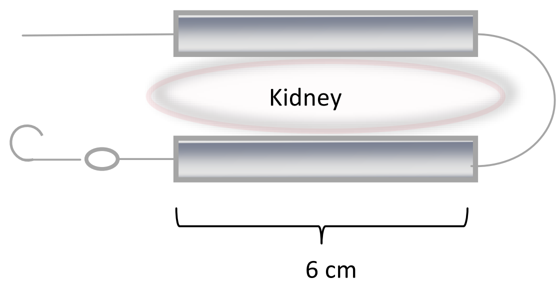

Figure 9: Loop Clamp

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 will need to be made to make the clamp satisfy all of the requirements. These modifications are further discussed in future work.

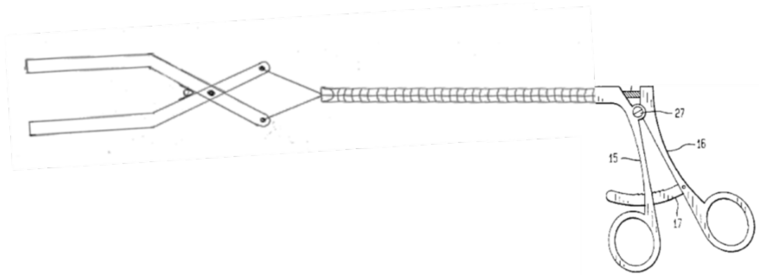

Figure 11: Final design incorporating the ratchet-style handle, the goose-neck shaft, and the angled clamp arms utilizing the bike brake mechanism to operate.

Future Work

In order to make our device feasible for use we will have to add several mechanical features. First, a metal bar will have to extend from the end of the shaft to the clamp arm connection/pivot point. This bar will provide stability to the clamp arms as well as allowing the brake mechanism to be successful. This bar will keep 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.

Second, the current dimensions of the clamp make it unable to fit through the trocar. The angle on the clamp arms needs to be collapsed in order to go through the trocar. We are currently looking at adding hinges at the angles that will keep the clamp arms parallel at all times. Thus when closed, the clamp arms will take on the shape of the straight clamp arms. Another method we are looking at for collapsing the clamp arms is using a less sturdy material for the clamp. The material would need to bend to a straight line when forced closed and would need to be able to retake its original shape when opened, while still applying enough force to the kidney when in use.

Third, the spring that keeps the clamp in the open position needs to have the appropriate spring constant for our clamp. The spring needs to have a high enough spring constant to keep the clamp open when no force is applied but should not be too big in diameter that it makes the clamp unable to fit through the trocar. The last part of our design that will need to be determined is the material the clamp will be made out of. Most surgical tools are made of either stainless steel or titanium, however if we decide to use a more flexible metal more research will need to be done. Once all of the design issues are resolved, materials for the clamp, shaft, and handle can be ordered and fabrication and testing can begin.

Testing

An essential factor of our device is the ability of the clamp to occlude blood. The amount of pressure needed to occlude blood in the kidney can be tested using compression tests in a mechanical tester. These tests can provide us with information on the amount of force needed as well as the distance the kidney needs to be compressed before blood flow stops.

Once we fabricate our preliminary device, we will be able to test it on an animal subject. Our client has informed us that we will be able to participate in a Pig Lab, where we can test our device. A Pig Lab is an open surgery on a live pig. It is an opportunity for surgeons to practice procedures, new techniques, or new tools. The pig lab will allow us to observe the human factors involved in our preliminary design, including the ease of use of our device. The pig lab also allows our client to provide us with feedback that might help in future modifications of this device.

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 will clamp the kidney at the site of the tumor removal, stopping blood flow only at the resected area. It provides 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 modifications the clamp will be able to be used in laparoscopic partial nephrectomy surgeries.

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Product Design Specifications – October 26th, 2011

A New Vascular Clamp for Robotic Partial Nephrectomy (VASCLAMP)

Members

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Advisor

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.