

Kidney Clamp for Laparoscopic Partial Nephrectomy

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Laparoscopic Partial Nephrectomy (LPN) surgery is indicated for removal of kidney tumors. The current technique involves clamping the renal artery and vein. This procedure prevents all blood from entering the kidney tissue, causing the tissue to become ischemic and putting the patient at risk. A new method of performing LPN surgery has been proposed that would use a clamp to occlude blood flow strictly in the portion of the kidney being removed, in an effort to maintain blood flow to the healthy tissue. Due to the lack of surgical clamps available for this new process, a laparoscopic clamp was designed for use in LPN surgeries that would occlude blood flow at the incision site while preserving viable tissue.

Introduction

Renal cancer is the 7th leading malignant condition for men and the 12th leading among women in the United States. [1] It is estimated that this year alone 64,770 new cases of renal cancer will be detected resulting in 13,570 deaths. [2]

Nephrectomy surgery is the initial treatment for the majority of operable kidney tumors. 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 4 cm in diameter. [1] Partial nephrectomy refers to when a surgeon removes the diseased tissue from the kidney. Partial nephrectomy can be accomplished laparoscopically through small incisions. This method is much preferable to open nephrectomy surgeries, where the surgeon must create a large incision and open the body cavity. Laparoscopic surgery results in less postoperative pain, a shorter hospitalization stay, and a quicker recovery. [3]

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. [3] During nephrectomy surgeries, the renal vessels are dissected from the surrounding tissue and 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 as little as 30 minutes have been shown to cause 10% loss in kidney function post-surgery. [4]

A new method of performing nephrectomy surgeries includes selective parenchymal clamping. This method involves clamping across the parenchyma of the kidney to solely occlude blood flow to the diseased tissue and maintain flow to the healthy tissue. [5] The new method has the potential to reduce surgical time by avoiding dissection of the renal artery and vein. Additionally, ischemia to the healthy tissue can be reduced. [6]

There is a need to develop a surgical tool to selectively occlude blood flow to the diseased tissue in laparoscopic partial nephrectomy surgery. Existing surgical clamps are not large enough to accommodate all sizes of the kidney. The Satinsky clamp, a preferred clamp for many partial nephrectomy surgeries, provides adequate jaw length to contain the kidney, but cannot be used laparoscopically. The laparoscopic Satinsky Clamp has been used to perform two successful partial nephrectomies with parenchymal clamping. [7] However, the length of the clamp, only 34 mm, is not large enough to accommodate most tumors. [2] The Reniclamp, a surgical device developed for parenchymal clamping, provides enough force to adequately suppress blood flow to the tumor but requires the use of two hands and cannot be used laparoscopically. [6] While many devices are available for use during partial nephrectomy surgery, no device has been developed to use laparoscopically to selectively clamp the parenchyma.

Methods

The engineering team worked alongside a surgeon that would use the clamp in a laparoscopic surgery. With the input of the surgeon, the team devised requirements and engineering specifications for the clamp.

End-User and Engineering Requirements

Interviews with a laparoscopic partial nephrectomy surgeon were conducted and requirements were developed based on feedback from the end-user.

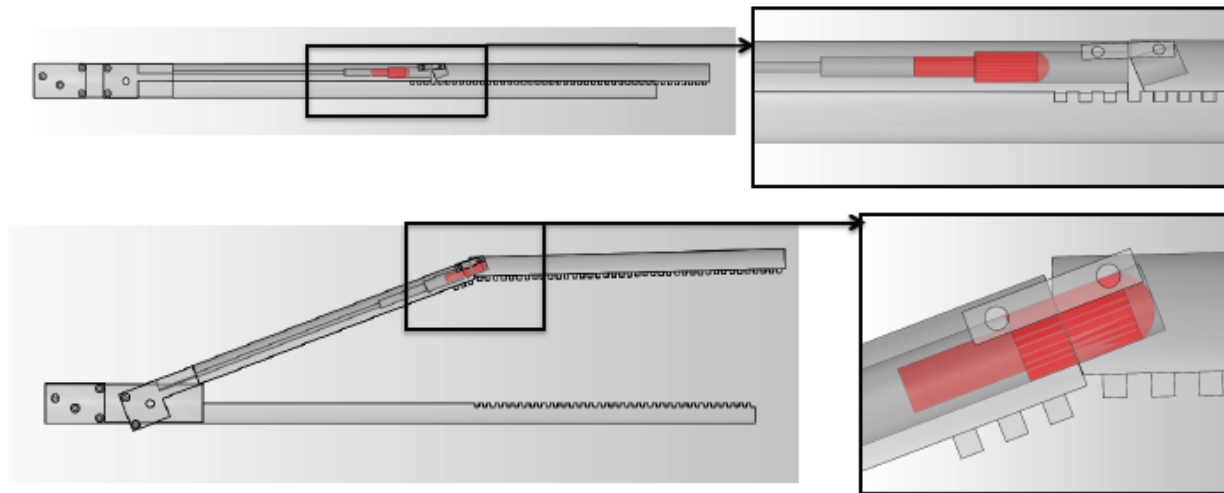


Figure 1: Final design of the clamp modeled on SolidWorks®.

Additionally, these requirements were modified by the engineering team to create the following design specifications of the device. The device needs to fit through a 12 mm trocar. 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. The neck of the clamp must be 61 cm long and 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. Additionally, the clamp must be stable and held in place for the duration of the surgery, and the entire device needs to be made of materials that will not damage human tissue.

Engineering Specifications

The device needs to be 1 mm in diameter to move easily through the trocar. The clamp needs to provide an even amount of force along the two jaws. Traditional clamps provide the most force at the proximal end of the clamp, nearest to the jaw opening, leaving the end furthest away from the opening, the distal end, providing the least amount of force. The new design has to provide the same force at the proximal and distal end as well as in the middle of the clamp. This force needs to be in the range of 5N and less than 20N. 5N will compress the kidney substantially and 20N will rupture the kidney tissue. [8] Providing this force at the handle cannot exceed the maximum force allowable by the female and male hand, 192 N and 311 N. [9] The handle also needs to accommodate hand breadth range of 6.5 to 9.5 cm so that it can be easily operated with one hand.

Results

With the requirements set forth by the surgeon a clamp was designed to meet the engineering specifications. This design was modeled on engineering software and a prototype was constructed from engineering drawings. A few different types of engineering analyses were used to determine the structural integrity of the clamp as well as the force needed to successfully compress the kidney.

Design

The final design of the clamp was modeled in SolidWorks® (Figure 1). The clamp consists of three moving parts. The base jaw of the clamp is stationary while the top jaw of the clamp is split into two halves. The two halves are connected by a plunger when the clamp is opened to at least 20°. A steel wire depresses a spring that the plunger rests on inside the proximal top half. When the wire is released the spring forces the plunger up into a hole in the distal piece. With the plunger connecting the two pieces, the distal half of the top jaw and the bottom jaw are parallel providing more uniform clamping force across the clamp.

The clamp also contains 1 mm grooves that act as teeth. When clamping the kidney may slide within the clamp, the teeth prevent this sliding and stabilize the kidney.

Prototype

The prototype consists of a clamp, arm, and handle (Figure 2). The arm and handle were repurposed from a vascular clamp donated by the University of Wisconsin-Hospital. The clamp was fabricated out of ABS plastic using a FDM Dimension Elite® printer and consisted of four pieces and three mechanisms. The

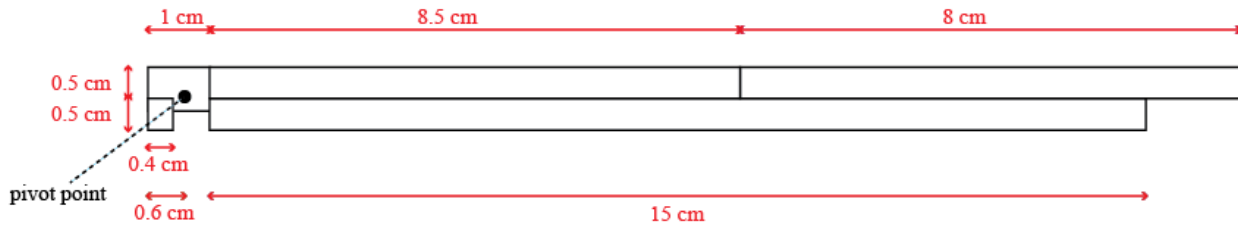
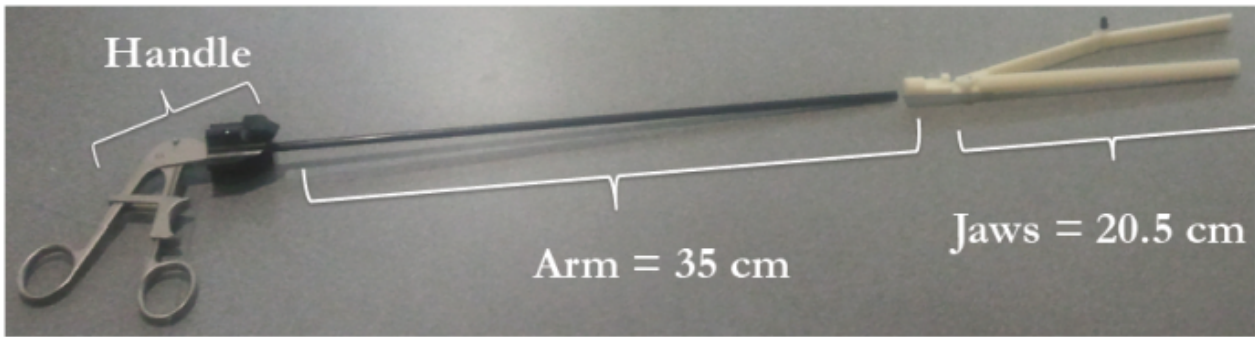


Figure 2 & 3: Prototype of the complete clamp and dimensions of the clamp jaws.

dimensions of the prototype can be seen in figure 3. The two clamp jaws are each a semicircle with a 0.5 cm radius. The bottom is 15 cm long and the top jaw is composed of two halves, the more proximal end is 8.5 cm, the distal end is 8 cm long. A hinge connects the two top jaw halves with the distal half able to rotate along the hinge. The distal piece will rotate along the hinge until making a 160 degree angle with the proximal piece. At 160 degrees the ends will rest along parallel surfaces. Once the pieces meet at the 160 degree conformation a plunger is deployed to hold the pieces together. The plunger is attached to a spring and is retracted inside the distal half when the clamp is completely closed. With the plunger retracted the clamp can collapse to a diameter of 1 cm. Once at the kidney the clamp is opened to at least 20 degrees and the spring is released, deploying the plunger from inside the proximal piece to connect the two top halves. The plunger is 2 mm in diameter and fits within a 3 mm diameter hole inside the distal piece when deployed. To control the plunger release a fishing line runs through

the proximal piece and through the clamp arm to the handle. The line is pulled to retract the plunger, to deploy, the line is released and the spring forces the plunger forward.

The remaining two mechanisms control opening and closing the clamp. To open the clamp a fishing line is connected to the end of the proximal piece and pulled. Once opened, the clamp can be placed around the kidney and the line can be released. After deployment of the plunger the clamp can be closed by pulling the trigger of the handle. The ratchet on the handle is then moved down the handle to provide more clamping displacement and force. A fishing line is connected from the bottom of the top proximal jaw to the ratchet of the handle and creates a moment along the pivot point when pulled, closing the clamp jaws (Figure 4).

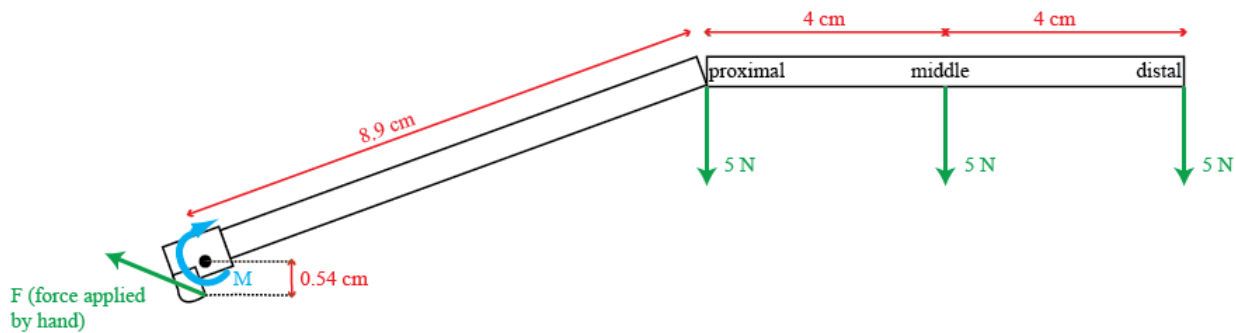


Figure 4: Free body diagram of the top jaw of the clamp.

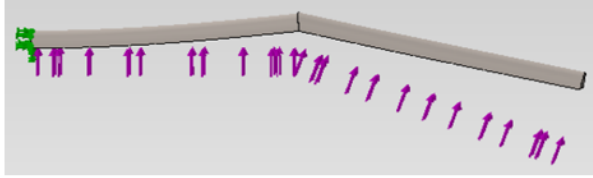


Figure 5: Deformation of the top jaw (combination of proximal and distal halves). Purple arrows represent force applied, green arrows represent the fixed location.

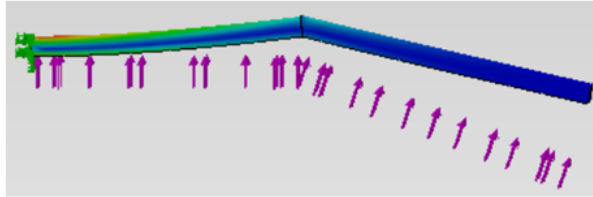


Figure 6: Stress distribution for the top jaw. Warmer colors represent areas of higher von Mises stress.

Material Selection

Surgical instruments used to clamp tissues of the body need to be compliant in order to resist recoil provided by the tissue. The instrument also must be made of a strong material that will not permanently deform under the force it applies to the tissue. Due to these specifications stainless steel (AISI 316) was chosen as the material to construct the clamp jaws. Its Young’s modulus of 193 MPa provides the steel with a spring-like nature. Additionally, it has a high Yield Strength of 137.9 MPa, which provides enough strength to maintain the structure of the clamp jaws. As well as its mechanical properties, stainless steel offers the advantage of resisting corrosion, an important feature of the clamp since it will be interacting with fluids present in the body. Corrosion resistance also allows the device to be sterilized and used repeatedly in future operations. In addition to the clamp jaws, the device will be articulated using 304 stainless steel wire. Having a diameter of 3.1 mm, these wires can support loading up to 4 kN and offer corrosion resistance.

Engineering Analysis

A free body diagram was made using the dimensions of the prototype (Figure 4). The force needed at the handle when 5N was applied at the proximal, middle, and distal positions was calculated by summing the moments around the pivot point of the clamp.

$$\sum M=0$$

Force of hand*0.54cm=5N*8.9cm (for the proximal position)

Force of hand*0.54cm=5N*12.9cm (for the middle position)

Force of hand*0.54cm=5N*16.9cm (for the distal position)

The force of the hand needed to apply 5N of force at the proximal, middle, and distal positions was 82.4 N, 119.4 N, and 156.5 N respectively. These values fit within the female and male grip force range.

In order to test the mechanics of the clamp jaws, stress analyses were performed on each part making up the jaws using SolidWorks® SimulationXpress. Each part (base, proximal half, distal half, and plunger) of the clamp jaw was modeled using AISI 316 stainless steel. Due to the fact that 5N significantly compresses a kidney and 20 N will rupture it, the device was modeled under these loads. Since 20 N causes the kidney to rupture, it is not expected that the device will exceed this limit; however, a force of 40 N was also applied as a safety measure. The parts were fixed as they are in the clamp assembly and a force of 5 N, 20 N, and 40 N was applied across the face of each piece directly interacting with the kidney (Figure 5). In addition to the four parts composing the clamp jaw, the top of the jaw was assembled by connecting the proximal and distal halves with the plunger, and tested as a unit (Figure 5). An example of stress distribution for the single unit part can be found in figure 6. The maximum von Mises stress for each part calculated from the simulation are represented in figure 7.

When the clamp jaws are used in the expected force range needed to occlude blood from the kidney, the maximum von Mises stress does not exceed the yield strength of AISI 316 stainless steel. The stress exceeded 137.9 MPa only in the case of the extreme loading placed on the base part. If the clamp jaws were to reach this level of stress, only minor deformation will

	von Mises Stress (MPa)		
	Load		
	5 N	20 N	40 N
Base	30.66	122.63	243.76
Proximal Half	16.36	65.35	130.7
Distal Half	10.66	42.65	85.31
Plunger	13.42	53.67	107.34
Single Unit	15.33	61.3	122.61

Figure 7: Maximum von Mises Stress in each of the clamp parts.

occur based on the high ultimate strength of AISI 316 stainless steel (485 MPa). However, the clamp jaws are not expected to ever experience a force of this magnitude based on the limitations of grip force applied by the human hand. The plunger also remained within the stress limits of AISI 316 stainless steel and will not deform causing the top jaw halves to separate during clamping.

Discussion

The objective of this work was to design a renal clamp for use in Laparoscopic Partial Nephrectomies. The design reported clamps the parenchyma of the kidney, cutting the circulation of blood to the tumor and tissue being removed. The clamp has adjustable and maintainable force and can provide an even amount of force across the clamp jaws, in the range of 5N, to the tissue.

The current clamp prototype is made from ABS but the final clamp will be made from stainless steel in order to be used in surgery. Based on SolidWorks® analyses, AISI 316 stainless steel is a proper material to construct the clamp jaws because of the strength of the material. Testing of the final clamp will involve using the clamp to occlude renal blood flow.

The clamp will be tested on a kidney to determine the blood occlusion force. With the current design 5N can compress the tissue, however if more than 5N is required to compress the renal tissue and arteries, a force multiplier should be added at the handle to increase the force the surgeon can apply.

Providing that the clamp proves to successfully occlude blood, it can be used in LPN surgeries. Implementation of the clamp will increase LPN surgeries, resulting in more patients with saved viable tissue and better recovery times.

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