Kidney Clamp

for Laparoscopic Partial Nephrectomy

Jeff Hlinka, Shannon Hynes, Kayla Stankevitz
Client: Dr. E Jason Abel, Department of Urology, UW- Madison
Advisor: Mitch Tyler, Department of Biomedical Engineering, UW- Madison

Abstract

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 which is risky for the patient. A new method of performing LPN surgery has been requested that would use a clamp to occlude blood flow in the kidney only to the portion of the organ being removed in an effort to maintain blood flow to the health tissue. An adjustable surgical clamp was designed and a prototype was manufactured using ABS. Preliminary testing was performed via solidworks analysis and it was determined that the device will not fail due to normal and maximum expected loading, 5 N and 20 N respectively. Further testing should be completed on a stainless steel prototype before conclusions can be drawn.

Motivation

- More than 46,000 patients undergo nephrectomy surgery each year.
- 32,000 new cases of renal cancer are diagnosed each year in the United States
- 1/3 of patients who undergo kidney resection will have a recurrence.
- Clamping times of as little as 30 minutes have been shown to cause 10% loss in kidney function post-surgery[2].
- **Market Need**: a method to increase the effectiveness & safety of surgical treatment.

Background

The Kidney:

- Filters around 20% of body's blood per minute.
- Blood flow rate essential to maintain homeostatic functions (i.e. remove wastes).

Laparoscopic Partial Nephrectomy:

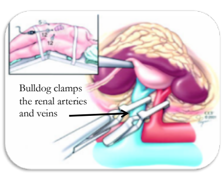
- Removal of only diseased tissue from kidney.
- Clamping needed to control blood loss and keep operating view clear.

Current Method

Occludes blood supply to entire kidney causing cell death (global ischemia) by clamping at the source of blood flow. Can cause loss of kidney function if ischemic for greater than 30 minutes.

Proposed Method

Selectively occludes blood flow to the portion of the kidney being removed (regional ischemia) by clamping around the functional part of the kidney, or parenchyma.



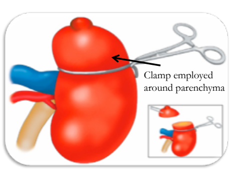


Figure 1a (left) shows the current method of tumor removal with clamps applied at the blood source. Figure 1b(right) shows the proposed method, which employs a clamp around the kidney tissue[1].

Client

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.

Design Specifications

- Must be able to fit through a 12 mm by 15 mm trocar
- Provide enough strength to occlude renal blood flow
  - Without causing harm to kidney
  - Adjustable force
  - Maintainable force
  - Evenly distributed force
  - Maintain force for 5 – 30 minutes
  - Provide force 5 N or less[3].
- Reusable
- Able to operate with one hand
- Accommodate hand breadth ranging from 6.5 – 9.5 cm
- Not exceed cost of commercially available clamps ($5000)
- Entire clamp should weigh less than 5 lbs.

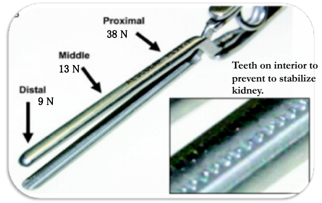


Figure 2 shows the variation of force generated by current clamps on the market. The inlaid picture shows an example of the texture desired to stabilize the kidney.

Final Design

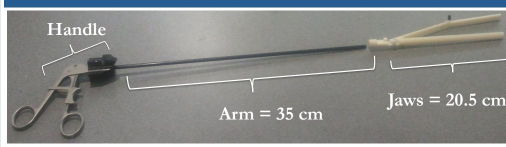


Figure 3 shows the final design fabricated out of ABS using a 3D printer.

Jaws

- Made from spring stainless-steel (prototype from ABS)
- Teeth provide grip to secure the organ
- Upper jaw has two pieces connected by hinge
  - Allows two conformations: 180° and 150°
  - Plunger deploys to lock clamp in 150° position

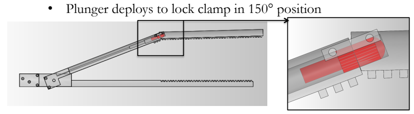


Figure 4 shows a Solidworks model of the jaws in the open position. This position allows the jaws to be parallel while clamping the kidney with 2 cm between the jaws. The enlargement shows the plunger in the deployed position to hold the top jaw in the 150° position.

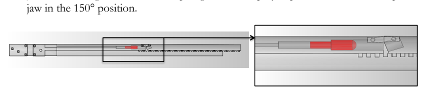


Figure 5 shows a Solidworks model of the jaws in the closed position. This position allows the jaws to be flush and fit through the trocar. The enlargement shows the plunger in the retracted position, to allow the top jaw piece to form a 180° angle.

Deployment Mechanism

- Jaws controlled via 2 wires
  - Wire to close top jaw relative to bottom jaw
  - Wire to retract plunger
- Shortened and released via handle

Arm

- 350 mm length
- 5 mm outer diameter
- 4 mm inner diameter
- Flexible

Handle

- Ratchet to lock into place
- Familiar to surgeons
- Connected to clamp through wire and bike brake mechanism

Materials

AISI 316 Annealed Stainless Steel

Yield Strength: 137.9 MPa
- 950x greater than our highest experimental stress

Young's modulus: 193.0 MPa

Ultimate Tensile Strength: 485 MPa

304 Stainless Steel Wire

- 90- 900 lbs
- .031 cm
- Corrosion resistant
- $7.99/30 ft

Analysis and Results

Solidworks Analysis

- Solidworks analysis show displacement and stress distribution

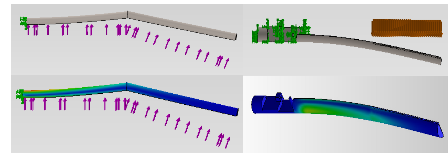


Figure 7: top images show force displacement of two top pieces modeled as one piece. Bottom image shows stress distribution from applied forces.

Yield= 137.9 MPa	Normal Loading (5N)	Max Loading (20 N)	Extreme Loading (40 N)
Base Piece	30.66 MPa	122.63 MPa	243.76 MPa
Hinge Piece	16.34 MPa	65.35 MPa	130.70
End Piece	10.66 MPa	42.65 MPa	85.31 MPa
Plunger	13.42 MPa	53.67 MPa	107.34 MPa
Single Unit	15.33 MPa	61.30 MPa	122.61 MPa

Future Work

Stainless Steel Prototype:
- Proof of concept complete
- Fabricate stainless steel prototype

Additional Function:
- Need to design and fabricate a flexible arm
- Control arm flexibility
- Incorporate RF ablation guide

Testing:
- Verify occlusion force
- Compare to pressure needed to occlude kidney
  - Ranges up to 5 N
  - Kidney ruptures at 20 N
- Check for leak point pressure
- Test final prototype in pig lab.

Acknowledgements

Dr. E Jason Abel, Department of Urology, UW– Madison
Mitch Tyler, Department of Biomedical Engineering, UW– Madison
Heidi Ploeg, Department of Mechanical and Biomedical Engineering, UW– Madison
John Puccinelli, Department of Biomedical Engineering, UW– Madison
Sam Paulsen, BME Student, Roomate
Student Shop Employees

References

[1] Landman, Jaime. "Laparoscopic Partial Nephrectomy." *Kidney Cancer Institute*. Web. <http://www.kidneycancerinstitute.com/PDFs/Aesculap-Nader-partialnephrectomy%20manuscript.pdf>.
[2] Peter L. Steinberg, Ravi Munver, and Reza Ghavamian. Journal of Endourology. September 2011, 25(9): 1525-1530.
[3] Farshad, Mehdi. "Material characterization of the pig kidney in relation with the biomechanical analysis of renal trauman." Journal of Biomechanics. 1999, 32: 417-425.
[4] Vahlensieck, W., Petrik, R. "Experiences with a new 'kidney holding and compression forceps.'" International Urology and Nephrology. 2(3). 253-260.
[5] Lee, H. Box, G., Abraham, J., Elchico, E., Panah, R. "Laboratory Evaluation of Laparoscopic Vascular Clamps Using a Load-Cell Device – Are All Clamps the Same?" *Journal of Urology*. 2008, 1267-1272.