Automated Uretero-Intestinal Anastomosis with Absorbable Staples

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Advisor: Dr. Wan-Ju Li **Client:** Dr. Tracy Downs

Abstract

The goal of this project is to improve the procedure to secure ureter tissue to a neobladder. A neobladder is formed from intestinal tissue after a cystectomy surgery has been performed to remove the original diseased bladder. Our client requested that our team design and build a stapler that could safely and effectively attach the two tissues together in a single action. The stapler must be safe and easier for the surgeon than suturing. It must also create a water-tight seal between the two tissues. Additionally, we will develop bio-degradable staples to be used in the stapler. After several stapler design iterations, we selected and fabricated our final stapler prototype. We are in the process of testing the stapler and the staple polymer composites.

Bladder Cancer

- 5th most common cancer in US [1]
- 70,530 new cases and 14,680 deaths in 2010[1]
- Radical cystectomy
  - Required when muscle layer is invaded
  - Need to restore urinary system function - urine storage:
    - Urostomy bag
    - Neobladder

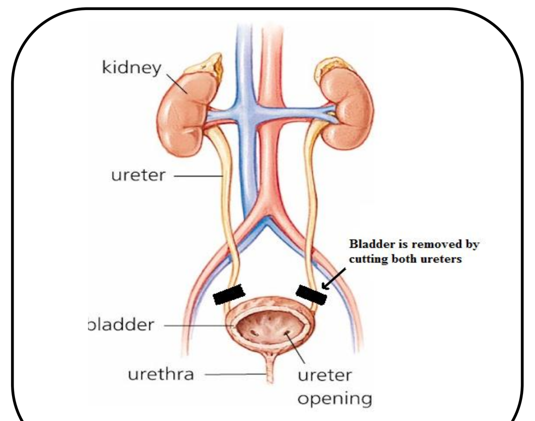


Fig 1. Urinary system

Problem Statement

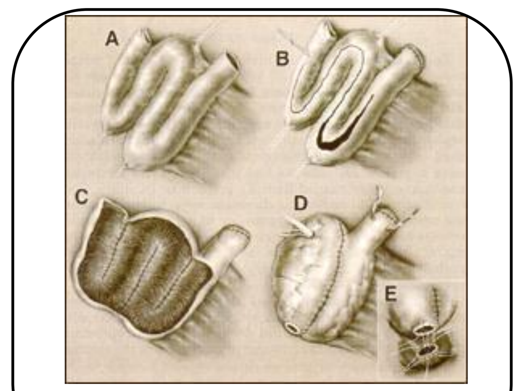


Fig 2. Neobladder formation

- Currently: Ureters connected to neobladder via suture
- Lengthy/Intricate procedure
- Need stapler for more efficient surgery
- Metal staples => stones
- Goals
  - Semester 1: Stapler design
  - Semester 2: Continued stapler work with staple research and testing

Client Requirements

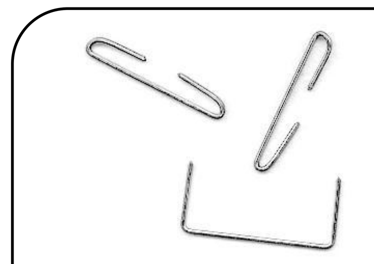
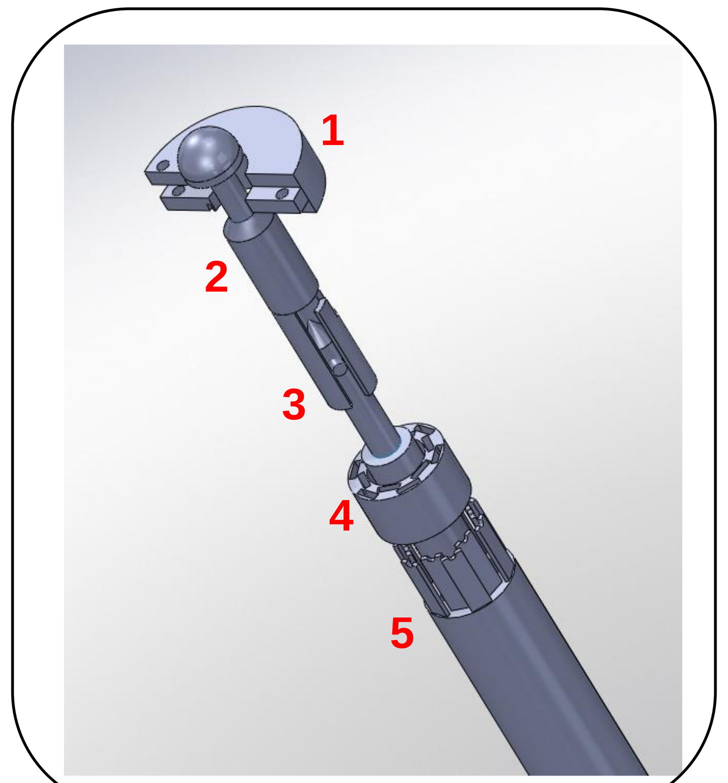


Fig 3. Traditional staples

- Usable in open surgery
- Sterile
- 10mm diameter at ureter connection
- Can operate with a single motion
- Can create a water tight seal
- Will mitigate tissue damage

Final Design

Stapler Head



Staple head function:
- Mechanism involves an anvil, ring clamp, needle, staple cartridge, and firing teeth
- Ureter secured to anvil via ring clamp
- Anvil secured to firing mechanism via the needle using a locking mechanism
- Firing mechanism pushes staple firing teeth through staple cartridge, forcing staples against ring clamp
- Ring clamp serves as an anchor and causes the staples to bend.

Fig 4(left): Stapler head exploded view
1. Ring clamp(one half);
2. Anvil;
3. Needle(inside anvil, continuous with inner rod);
4. Staple cartridge;
5. Staple firing teeth (continuous with outer rod)

Firing Mechanism

Firing mechanism function:
- Mechanism involves a pin, handle, and actuator in order to perform translational movement
- Plastic casing surrounds and encapsulates the trigger components
- Translates ~1.2cm
- Cannibalized the Ethicon® stapler for casing and handle components

Fig 5(left): Firing mechanism internal view
1. Compressive springs;
2. Washers;
3. Outer rod/flange translator (continuous with firing teeth);
4. Lever and pin(handle);
5. Inner rod (continuous with needle)

Cost Analysis

C.ideas
proto labs
Real Parts. Really Fast.

- Budget = $3000 - $5000
- Protolabs metal parts = $360.76
- Polymer components = $321.50
- **Total expenditures = $682.21**

Testing

PLA %	PCL %	DCP (PHR)	Brittle?	Tensile	Compressive
50	50	10	Yes	Fair	Fair
70	30	0	VERY	Crumbles to touch	
70	30	0.1	Yes	Bad	Fair
70	30	10	Yes	Fair	Fair
70	30	20	No	Stretchy	Poor
90	10	0	Very	Crumbles to touch	
90	10	0.1	Yes	Fair	Good
90	10	10	No	Good	Fair
90	10	20	NO(bendy)	Poor	Poor

Fig 6. Qualitative observations of polymer qualities

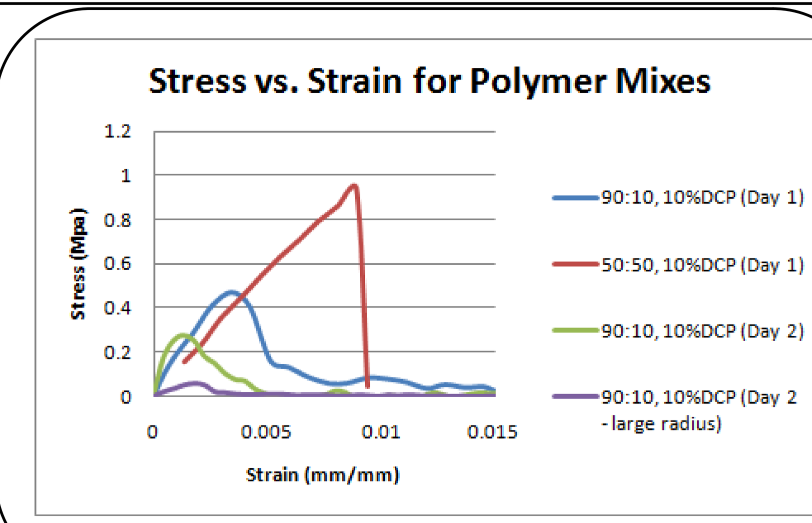


Fig 7. Tensile testing of polymer mixes

Testing procedures/results:
- Polymers heated at 180ºC and blended in different ratios (Fig 6), then formed using PDMS molds.
- Tensile testing on polymer blends performed to determine material properties
- Samples which survived testing are displayed
- Comparative testing done w/sutures

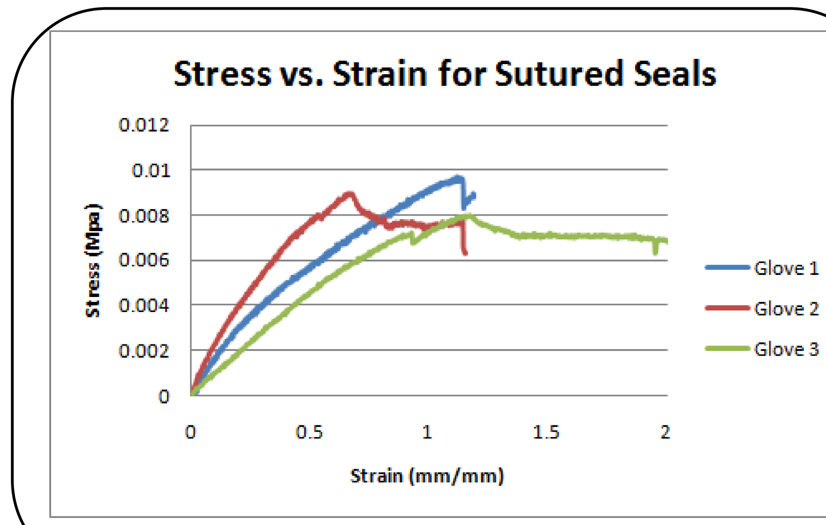


Fig 8. Tensile testing of sutured tubes

Future Work

- Incorporate all metal parts
- Test stapler with metal staples
- Test stapler with absorbable staples
- Compare water-tightness of stapled vs. sutured tissues
- Test burst pressure of seal
- Determine PLA-PCL ratio for degradation profile of ~30 days
- Test stapler & staples on animal cadaver

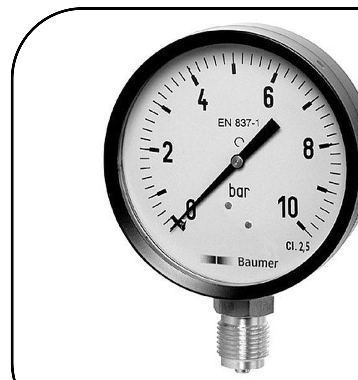


Fig 9. Pressure gauge

Acknowledgements/References

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Ethicon®

[1] National Cancer Institute. "Bladder Cancer." National Cancer Institute: U.S. National Institutes of Health, 2010. 19 November 2010. <www.cancer.gov/cancertopics/types/bladder>