Stapler for Uretero-Intestinal Anastomosis with Absorbable Staples

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Abstract

Bladder cancer is the 5th most common cancer in the United States. When cancer cells invade the bladder muscle, surgical removal of the bladder, called radical cystectomy, is the desired treatment. A neobladder is formed out of a portion of intestine, and the ureters are currently attached via absorbable sutures. We have designed rigid absorbable staples comprised of 85:15 poly(lactide-co-glycolide) (PLGA) and a surgical anastomosis stapler to fire concentric rings of staples. Degradation testing shows that the staples will retain strength for at least 20 days, long enough to promote healing of the tissue. Functional testing shows that the average grip strength of a single staple is 5.34 ± 1.5 N and 11.58 ± 2.28 N for a single suture stitch. Future testing will analyze the anastomosis strength of 12 staples fired using the circular stapler.

Background

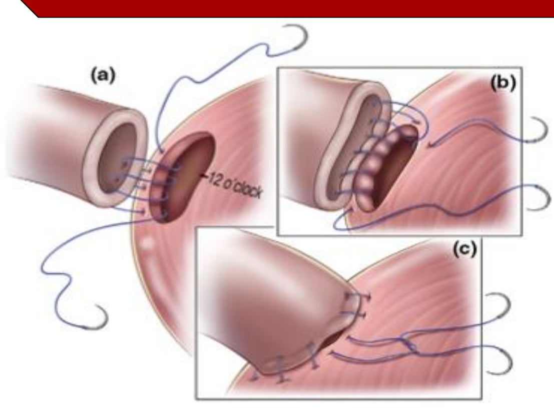

Figure 1: Ureter attachment to neobladder via suture [1]

- Radical cystectomy – surgical removal of bladder when cancer invades muscle
- Ureters attached to neobladder via absorbable sutures
- Procedure lengthy and inconsistent between surgeons
- Desire to automate process

Current Devices

- Absorbable sutures (Ethicon Monocryl and Vicryl)
- Anastomosis circular staplers (Ethicon, Covidien)
- Absorbable staples (Insorb, Coviden)
- Previous design project stapler

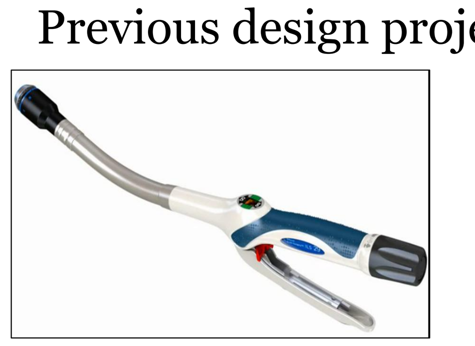

Figure 2: The Ethicon Endo-Surgery Intraluminal Stapler [2]

Figure 3: Insorb staple [3]

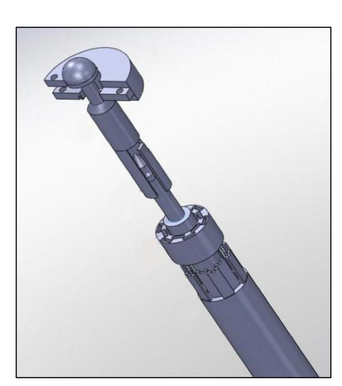

Figure 4: Stapler head designed by previous team

Device Requirements

- Biocompatible and sterile
- Secures ureter to neobladder for a minimum of 30 days
- Creates a water-tight seal
- Withstands bladder environment
- Does not damage surrounding tissue
- Increases efficiency and consistency of the procedure

Staple Design

- 85:15 Poly(lactide-co-glycolide)
- Widely used for absorbable, medical applications, thus easily approved by FDA
- Reported to degrade in ~60-70 days *in vivo*
- Multiple barbs to secure staples and account for variable tissue thickness

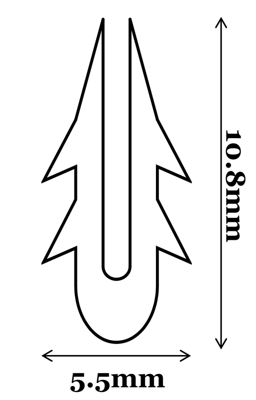

Figure 5: Line drawing used with the laser cutter

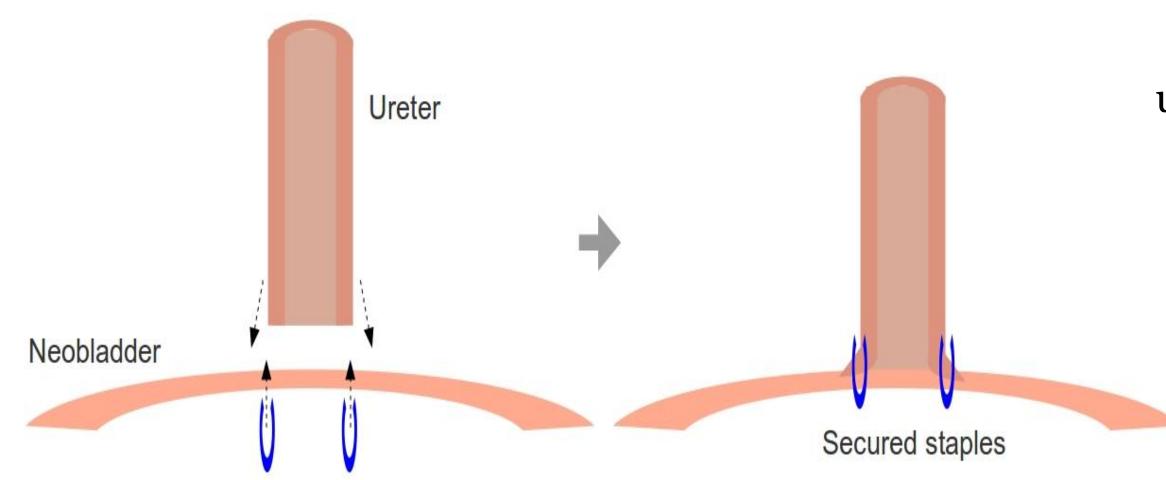

Figure 6: Proposed staple mechanism for uretero-intestinal anastomosis

Figure 7: Staple after being cut with laser cutter

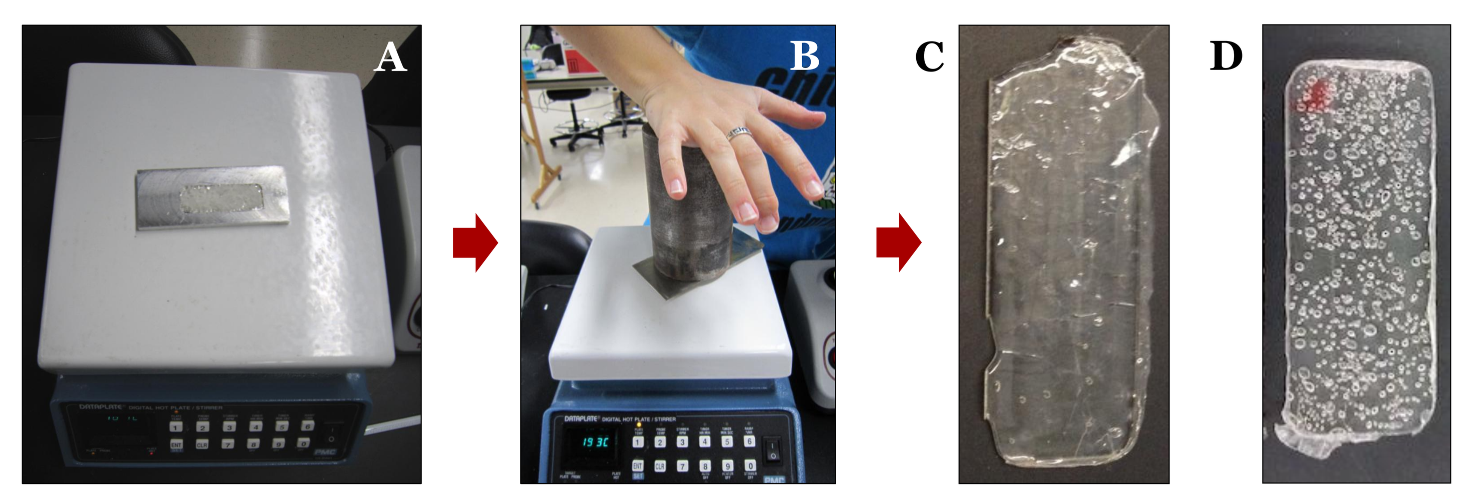

Figure 8: (A-B) Plate fabrication method was changed to eliminate bubbles. Staples are cut out of the PLGA plate using an Epilog CO2 laser cutter. PLGA plate from current semester (C) and last semester (D).

Stapler Design

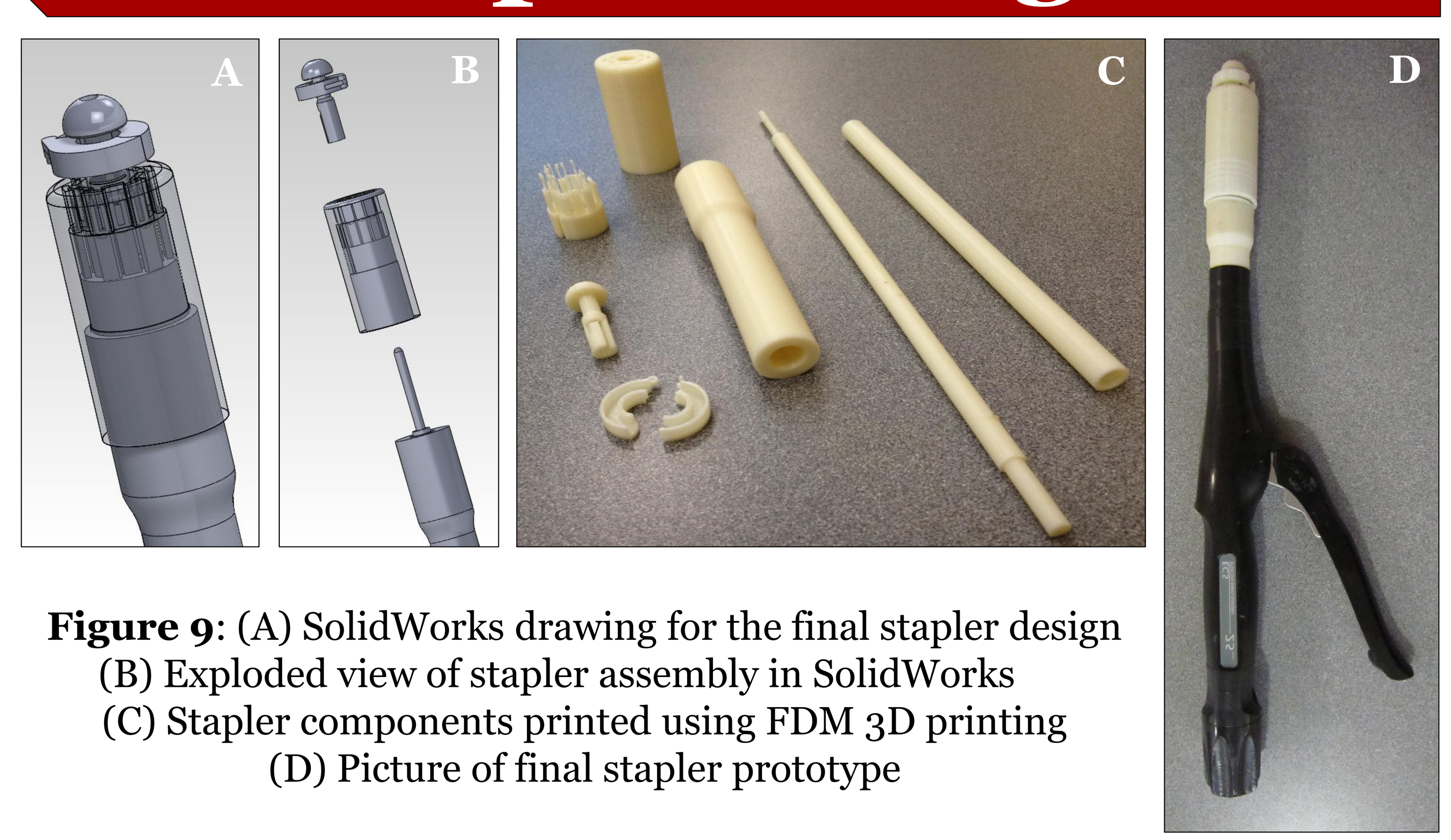

Figure 9: (A) SolidWorks drawing for the final stapler design
(B) Exploded view of stapler assembly in SolidWorks
(C) Stapler components printed using FDM 3D printing
(D) Picture of final stapler prototype

Testing

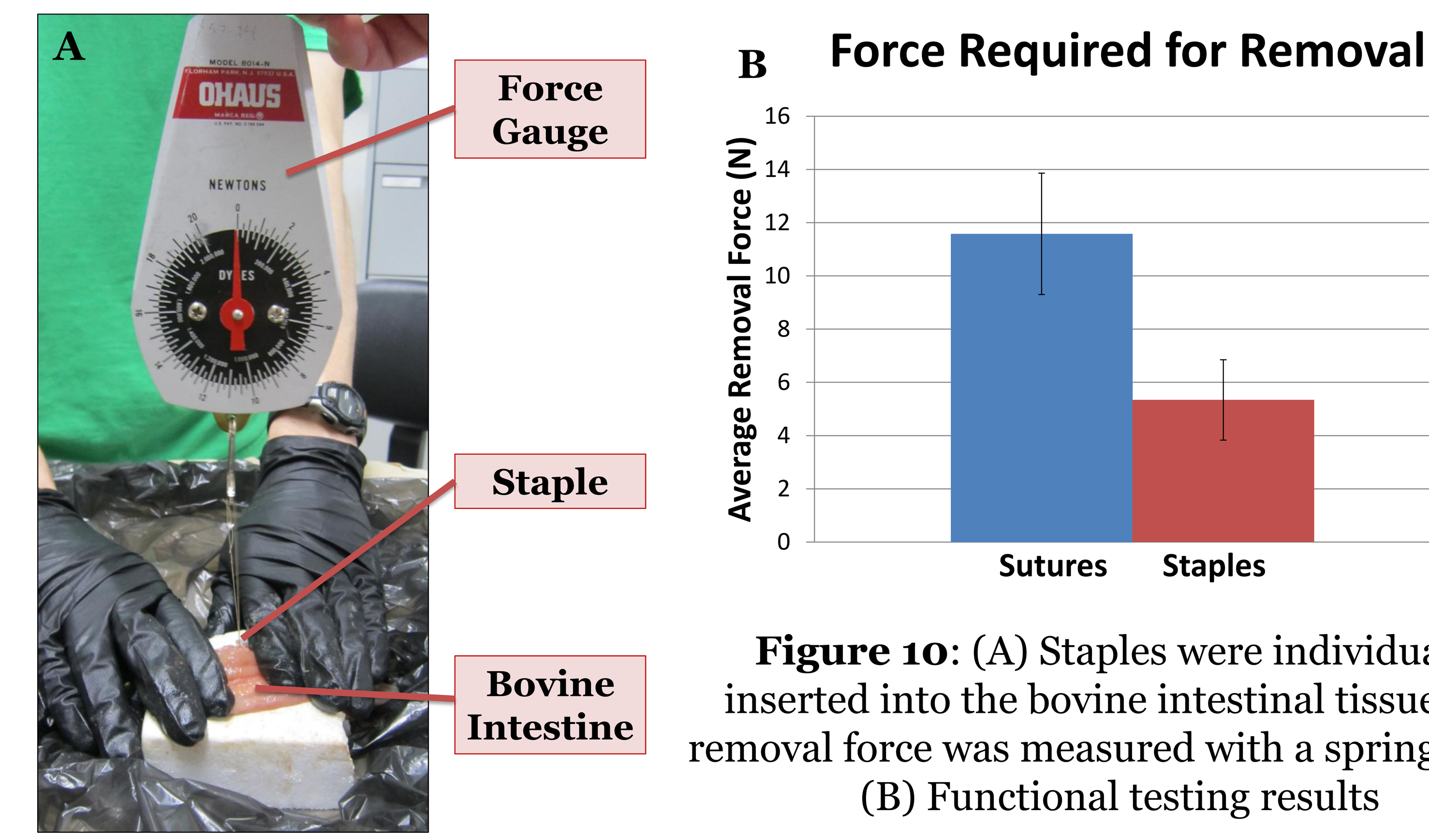

Figure 10: (A) Staples were individually inserted into the bovine intestinal tissue and removal force was measured with a spring gauge (B) Functional testing results

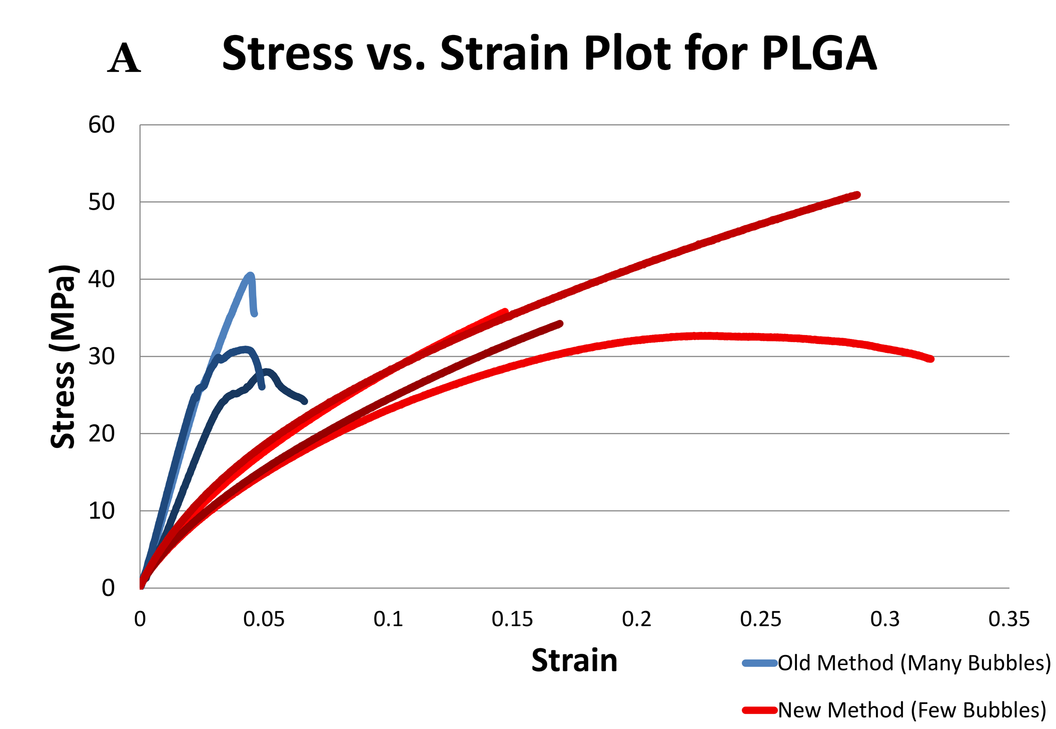

Figure 11: (A) Tensile testing results (B) MTS Criterion Model 43 used for tensile testing (C) Tensile test specimen with dimensions specified by ASTMD638-10

Conclusions:

- Sharp staples or a puncturing mechanism is necessary to pierce the intestinal tissue
- Staple barbs effectively gripped the intestinal tissue
- New plate fabrication method improves material

Future Work

- Scale down stapler dimensions
- Integrate staples with metal stapler prototype
- Test anastomosis strength with full set of staples
- Additional degradation testing for staples
- Force analysis for stapler use

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References
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[2] Circular Staplers + Intraluminal Staplers. *Ethicon Endo-Surgery*. (2010). Retrieved September 15, 2011, from http://www.ees.com/Clinician/Product/stapling/circular-intraluminal.
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