Stapler for Uretero-Intestinal Anastomosis with Absorbable Staples

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Abstract
Bladder cancer is the 6th 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
• 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, Coviiden)
• Absorbable staples (Insorb, Coviiden)
• Previous design project stapler

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

Testing

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

References

Acknowledgements:
Professor Willis Tompkins, Dr. Tracy Downs, Professor John Pucinoiselli, Scott Johanean, UW Student Shop, Tom Mulholland, Purdue Biomaterials, Black Earth Meats