Absorbable Staples for Uretero-Intestinal Anastomosis

Matthew Bollom, Vanessa Grosskopf, Samantha Paulsen, Jeff Theisen

Overview

- Project Background
- Motivation and Problem Statement
- Current Devices
- Design Specifications
- Material Choice
- Staple Designs
- Future Work

Bladder Cancer

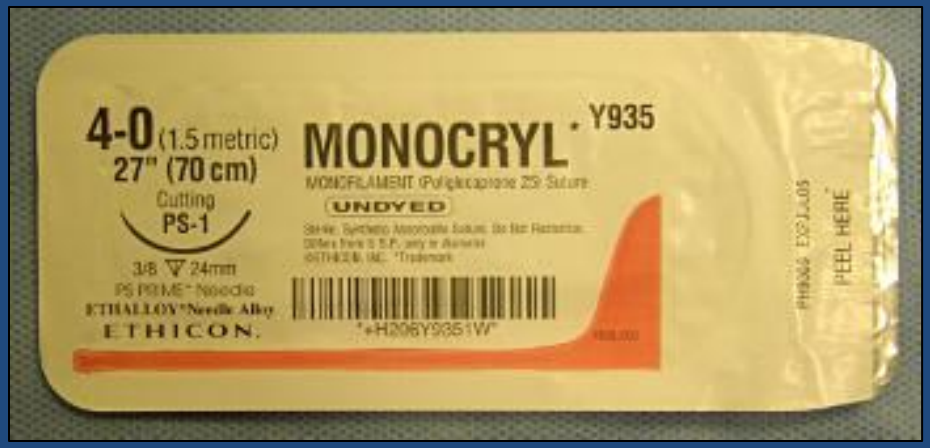
- 5th most common cancer in United States [1]
- Most expensive over time
- Treatment when cancer invades muscle: radical cystectomy [2]
  - Urostomy bag
  - Neobladder

Motivation & Problem Statement

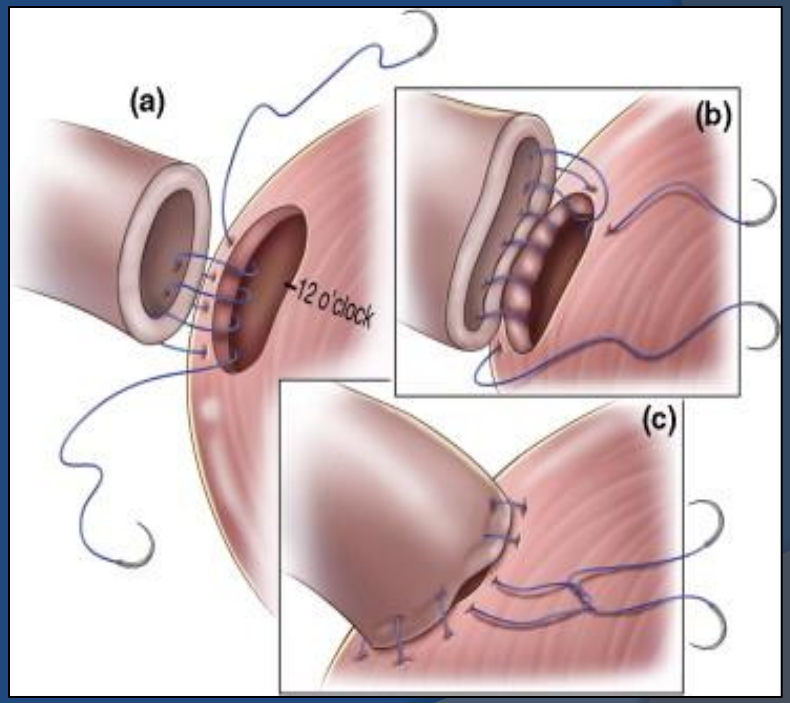
- Ureters attached to new bladder via absorbable sutures
- Lengthy procedure
- Inconsistency between surgeons
- Metal staples cause stones
- Minimize subsequent interventions

Current Devices

- Sutures



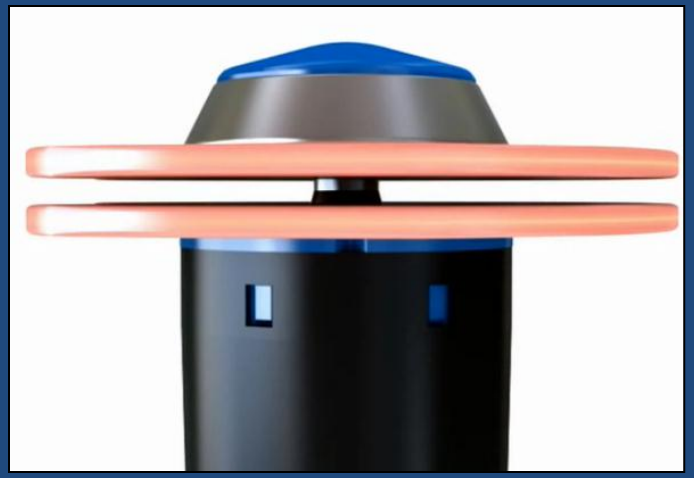
http://www.bernsteinmedical.com/resources/publications/a-new-suture-for-hair-transplantation-poliglecaprone-25/



http://www.europeanurology.com/article/S0302-2838(08)01513-3/fulltext

Current Devices

- Anastomosis Circular Staplers (Ethicon, Covidien)
  - Circular placement
  - Titanium staples
  - Too large for ureters



http://www.ees.com/Clinician/Product/stapling/circular-intraluminal#videos-media

Current Devices

- Absorbable Staples (Insorb, Covidien)
  - Linear placement
  - PLGA

http://insorb.com/documents/IFU_English_20xx.pdf

Design Specifications

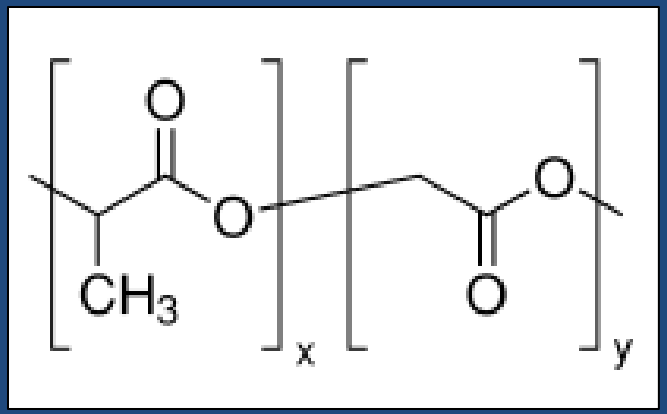
- Biocompatible
- Secures ureter to neobladder for a minimum of 30 days
- Able to create water-tight seal
- Withstands bladder environment
- Does not damage surrounding tissue
- Sterile

Material Selection

- Common Absorbable Polyesters
  - Poly(lactic acid), poly(glycolic acid) and copolymers
  - Polycaprolactone (PCL)
  - Polydioxanone (PDS)
- Previous applications include:
  - Staples
  - Sutures
  - Stents

Material Selection

- Poly(lactide-co-glycolide) – PLGA

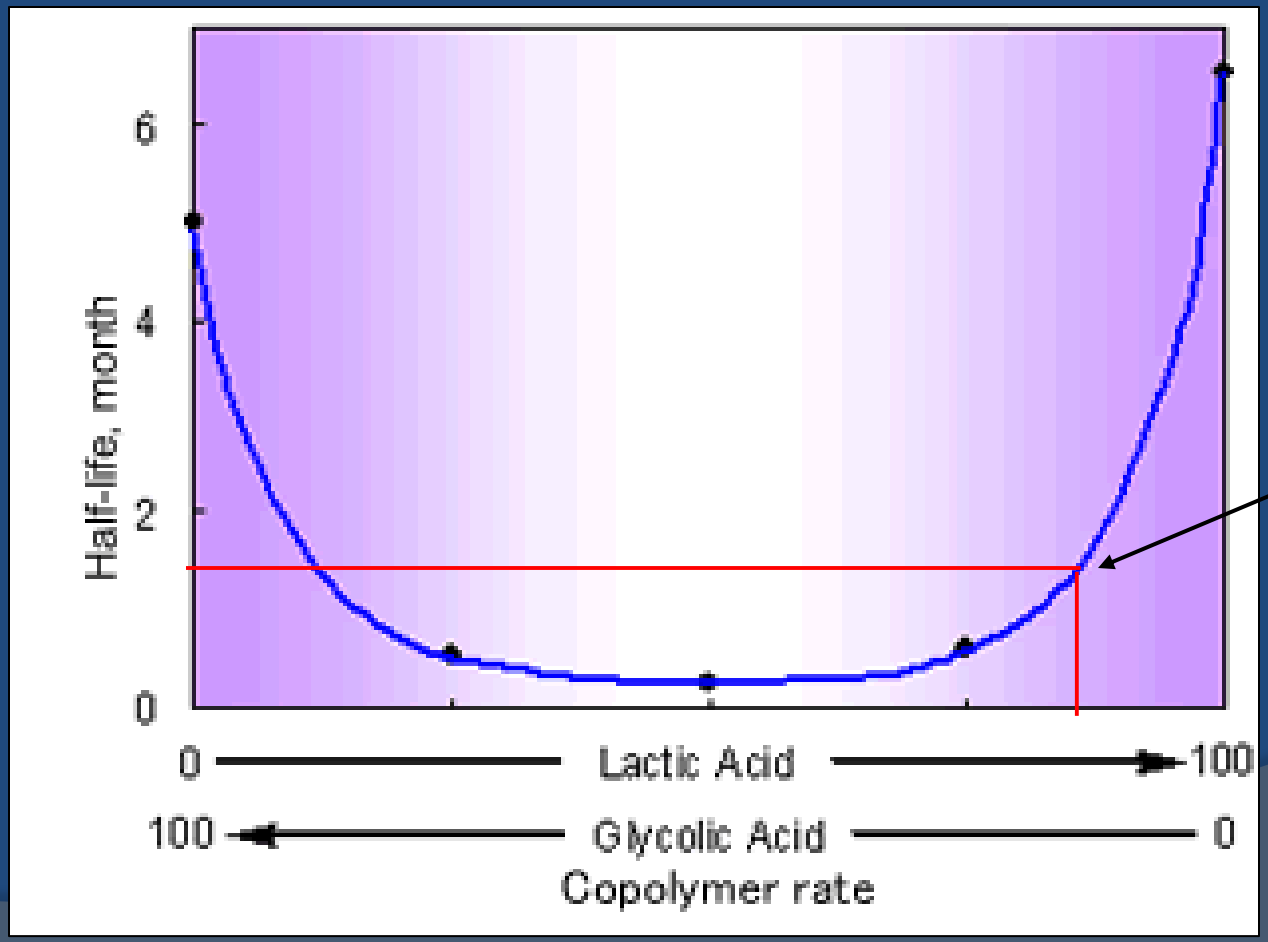


  - Used in INSORB and POLYSORB staples
  - Degradation rate and mechanical strength variable based on molar ratio
  - Copolymer more consistent than PLA/PGA blend

http://www.sigmaaldrich.com/materials-science/material-science-products.html

Material Selection

- PLGA degradation rate vs. molar ratio

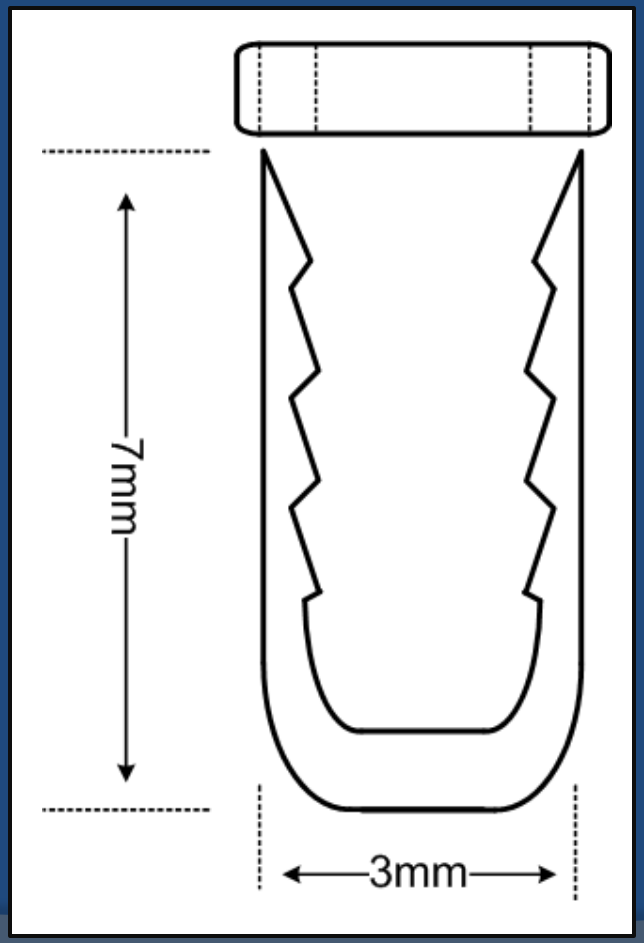


85:15
half-life = 1.5 month

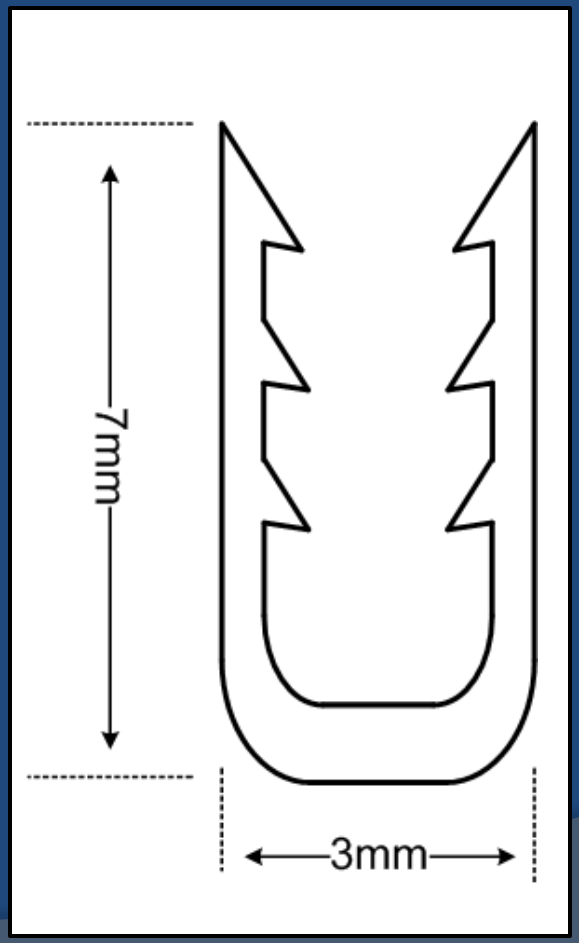
http://www.wako-chem.co.jp/specialty/plga/index.htm

Staple Designs

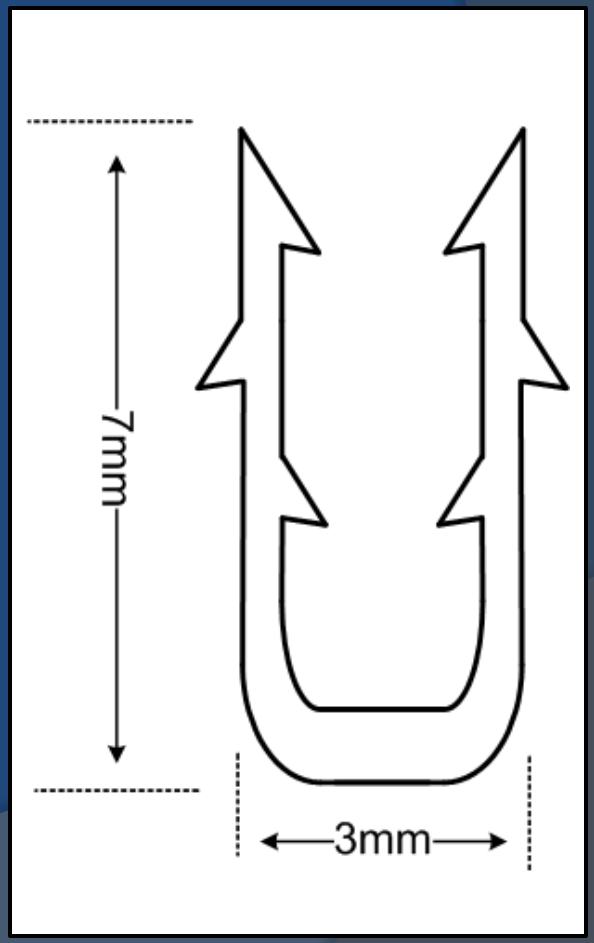
Zip Tie Design



Simple Barbs



Alternating Barbs



Future Work - Testing

- Tensile Strength Testing
- Degradation Testing
  - Mimic tissue environment using gelatin with buffer
  - Various pH (Urine range 4.5 - 8)
- Functional Testing
  - Create anastomosis similar to actual surgery
  - Measure burst strength
- All testing of staples will be compared against sutures currently in use

http://www.instron.us/wa/product/5980-floor-model-systems.aspx

Future Work - Fabrication

- Compression molded plate of PLGA
  - Desired staple thickness
  - Necessary to have a “2D” design
- Cut out staple design with laser cutter
- Fabrication method testing
  - Verify with PLGA using material samples
  - Verify parameters such as frequency, power, and speed
  - Verify staple design

http://www.woodlaserengraver.com/2010/10/26/laser-cutter-2/

Future Work - Stapler

Stapler head designed by previous team.

Acknowledgments

- Dr. Tracy Downs
- Professor Tompkins
- Professor Murphy
- Professor Turng
- Professor Puccinelli
- Purac Biomaterials

References

[1] Bladder Cancer. *National Cancer Institute*. Retrieved October 17, 2011, from http://www.cancer.gov/cancertopics/types/bladder

[2] Bladder Cancer. *U.S. National Library of Medicine*. Retrieved October 17, 2011, from http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001517/

Questions?