Automated Uretero-Intestinal Anastamosis with Absorbable Staples – Staple specific PDS

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Leader: Samantha Paulsen
BSAC: Vanessa Grosskopf
BWIG: Matt Bollom
Communicator: Jeff Theisen

Problem Statement:

In patients with bladder cancer, the bladder can be either partially or completely removed. A procedure called a radical cystectomy is required to completely remove the bladder when cancer has invaded the muscle layer of the bladder. Afterwards, a section of the small intestine can be used to form a new bladder (neobladder). If the neobladder is not constructed, a ureostomy bag is implemented instead. However, in both procedures the ureters must be connected to the new bladder tissue; this is currently done using absorbable sutures. There are several complications associated with this approach due to the invasiveness and length of the procedure. Our goal is to design absorbable staples to be used in an automated uretero-intestinal anastomosis, to be used with a specialized stapler. The staples should be strong enough to secure the ureters to the neobladder or ureostomy bag and should degrade to avoid the need for a second intervention.

Client requirements:

- Must be completely absorbable to allow for full tissue healing and regeneration
- Must form a water tight seal on the intestine-ureter linkage
- Must be biocompatible – no immune reaction
- Must be able to withstand the caustic environment of the ureter when it is filled with urea.
- Must hold their shape
- Must be strong/sturdy but flexible enough to be bent
- Must work in conjunction with the stapler

Design requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: Will be used with a single use stapler to perform an automated anastomosis to secure two ureters to a neobladder.
    b. *Safety*: Must not damage surrounding tissue in the abdominal cavity, bladder, or ureters. Must create a secure water-tight seal with both ureters to allow for normal use of the kidneys post-surgery. Must not cause infection or immune response.

c. *Accuracy and Reliability*: The seal created must be water-tight.

d. *Life in Service*: Will be single use and should degrade in a period of 30-90 days in vivo.

e. *Shelf Life*: Should last at least 1 month in storage.

f. *Operating Environment*: The device will be inserted into the abdominal cavity for a surgical procedure. More specifically, the staples will be inserted into the ureters and will be exposed to temperatures around 37 ^{o}C and urine, which has a high salt content. The staples must be sterile to avoid cross-contamination.

g. *Ergonomics*: The user will not handle the staples, so ergonomic considerations will be focused on the stapler.

h. *Size*: The staples should be large enough to secure the ureter to the neobladder, but small enough to fit two concentric rings of staples into the tissue. The diameter of the ureter ranges from 7-10mm in diameter.

i. *Weight*: Negligible

j. *Materials*: The final material will be a bioabsorbable polymer FDA approved for use in the human body.

k. *Aesthetics*, *Appearance, and Finish*: Not applicable

2. Production Characteristics

a. *Quantity*: To be determined based on final staple design.

b. *Target Product Cost*: Undetermined, under $1 per staple.

3. Miscellaneous

a. *Standards and Specifications*: Must be approved for safety and function by the surgeons utilizing the device. Must have IRB approval once used in humans.

b. *Customer/Patient related concerns*: Must create a water tight seal after anastomosis is performed. Must not do damage to any other tissues in the body. The staples should degrade eventually to promote tissue healing and regeneration. Since the staples will be contacting high salt concentrations, the material should not promote the formation of kidney stones.

c. *Competition*: There is currently no product made specifically for sealing the ureter to the neo-bladder during anastomosis.