Performance Evaluation of a Novel Gastric Stapler: Blowing up the Competition

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Introduction

The industry standard for stapling in gastric resection is use of a powered 60mm endocutter. Mechanical integrity of the staple line is essential to prevention of postoperative leaks and can be assessed by examining staple formation and measuring burst pressure. A newly developed gastric stapler may introduce improved technology and performance.

Technology

- **A novel 230 mm-stapler (Figure 1)**
- **Engineered using a distal fulcrum**
- **Varying staple heights along its length**
- **Recently FDA-approved for use specifically in gastric resection such as sleeve**

Purpose

To measure and compare performance characteristics of the Echelon Flex™ GST (Ethicon), an industry standard stapler, against a novel 230 mm gastric stapler, the Titan SGS.



Figures 1. Titan SGS (Standard Bariatrics, Cincinnati OH)

Materials and Methods

Study design was a prospective, randomized controlled trial.

Following IRB approval, 36 participants were enrolled and randomized to either the Ethicon (control) or Titan (intervention) group.

- **Excised sleeve gastrectomy specimens were tested immediately and tissue thickness measured**
- **Experimental staple line was created with either Ethicon (using a series of 60 mm reloads according to measured tissue thickness) or Titan (single cartridge with varying staple heights).**
- **Two specimens resulted from creation of the experimental staple line and were sent for**
    1) **industrial CT to assess staple formation and height (Figure 2) or**
    2) **pneumatic burst pressure which was performed immediately.**

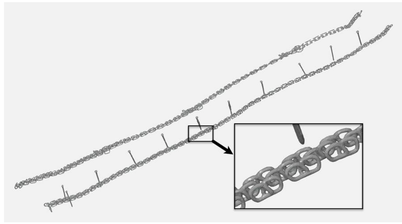


Figure 2. CT of staples within specimen (two pins at the antrum). Clinical staple line on left, experimental on right

Results

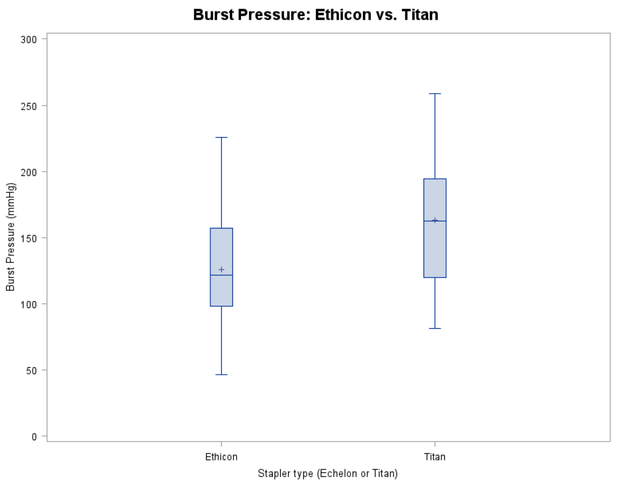
There were no differences in demographics or specimen tissue thickness between groups.

- **Titan produced significantly fewer malformed staples compared to control (% malformed = 0.2% vs 1.1%, p <0.01)**
- **After accounting for location, staple height in the Titan group was more closely correlated with tissue thickness than in the control group (R2 0.87 vs 0.61)**
- **Staple lines created with the Titan burst at significantly higher pressures than the control (163 +/- 55mmHg vs 125.8 +/- 45mmHg, p =0.046) (Figure 3), with minimum Titan burst pressure exceeding maximum tolerable gastric pressure in humans by a factor of 3**
- **Burst location was similar in both groups, with most bursts occurring in the fundus and body. There were more bursts remote to the staple line in the Titan group which may underestimate the true staple line strength**

Discussion

Titan produced a robust staple line with very low theoretical potential for leak, potentially due to improved staple formation and elimination of crossing staple lines. The mechanical integrity of staple lines produced with the Titan in human gastric tissue are shown in this study to be at least equal if not superior to the current standard, despite use of a TMD to guide choice of staple cartridge in the control group.

Figure 3. Burst pressure of Ethicon vs. Titan



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