Tighter formed staples lead to fewer malformed staples in thick tissue

Studies conducted by: Dwight Henninger, Jason Jones, Jeffrey W Clymer, Ethicon, Inc., Cincinnati OH
Results from this study have not been subject to scientific peer review.

Background
The PROXIMATE® Linear Cutter (TLC55 & TLC75) with its unique cam mechanism with tissue retention pin is designed to deliver controlled tissue compression from thin to thick tissue. The cam, located at the base of the device, forces the distal tip downward when firing begins, allowing for uniform pressure throughout the anvil and controlled tissue compression, ensuring a consistent staple line. The tissue retention pin, located at the distal tip of the device, is designed to deliver controlled compression from thin to thick tissue.

An ex vivo study was conducted to compare the PROXIMATE TLC (Ethicon Inc.) and the DST Series™ GIA™ (Medtronic) to examine how uniform compression produced by the PROXIMATE TLC cam mechanism enables tighter, well-formed staples. In Tighter formed staples produce stronger sealing against luminal leakage, Henninger et al. concluded that tighter formed staples were associated with fewer leaks.

Methods
Devices were fired following the manufacturer’s Instruction for Use on bowel segments with tissue thicknesses of 2.0mm, 3.0mm, 4.0mm and 5.0mm. A precompression period of 15 seconds was used prior to firing the devices.

A statistical analysis of harvested staple lines was conducted and the average staple height and the maximum staple height of each formed staple was measured for TLC75* and GIA80†. Staple height and staple form quality were examined to determine if staple height is a factor in the occurrence of malformed staples. The quality of each formed staple was categorized into one of five descriptive groups. (Figure 1)

Results
The mean height of formed staples over all tissue thicknesses was 8.4% lower for TLC75 than for GIA80 (p<0.001).

No malformed staples were observed for either device at 2.0mm tissue thickness. The TLC75 had 58.3% fewer malformed staples than the GIA80 at 4mm tissue thickness (p<0.001), and the TLC75 had 51.3% fewer malformed staples than GIA80 over all tissue thicknesses. (p<0.001).

Conclusion
The TLC75 produced 8.4% tighter formed staples than the GIA80 in thick tissue (p<0.001).

While no malformed staples were observed for either device at 2.0mm tissue thickness, the proportion of malformed staples increased as staple height and tissue thickness increased. Over all tissue thicknesses, TLC75 had the tightest formed staple heights and the lowest proportion of malformed staples.

The PROXIMATE TLC with its unique cam mechanism and tissue retention pin delivers the most consistent staple form over the widest range of tissue conditions compared to any leading competitive brand of open linear cutter.

*PROXIMATE® Linear Cutter (TLC75), †DST Series™ GIA™ (GIA8038S)

1. DD Henninger, J Jones , JW Clymer. Tighter formed staples produce stronger sealing against luminal leakage. Medical Devices & Diagnostic Engineering. 2017: 2(1); 48-51
2. Benchtop testing in porcine tissue vs DST Series GIA (GIA8038S), Frankenman LC80B, Reach RLC8038S and Touchstone LC8038 at 2mm-5mm thickness range (p<0.001).

For complete product information, including full steps for use, indications, contraindications, warnings and precautions, please see the Instructions for Use.

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