Tighter formed staples and stronger sealing to reduce leaks

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Background

Although the overall rate of anastomotic leakage in gastrointestinal surgery is low, there is still room for improvement via advances in medical or procedural care. The PROXIMATE® Linear Cutter (Ethicon, Inc.) offers design advantages intended to produce more secure tissue apposition and reduce the occurrence of staple line leakage.

The PROXIMATE Linear Cutter is designed with a unique cam mechanism and tissue retention pin to help reduce staple line leakage. 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 (Figure 1). The tissue retention pin, located at the distal tip of the device, is designed to deliver controlled compression from thin to thick tissue.

Figure 1

In Risk factors for anastomotic leakage after laparoscopic low anterior resection with DST anastomosis, Kawada et al. found that precompression prior to firing the instrument reduced the risk of anastomotic leakage after low anterior resection by a factor of four.

This ex vivo study was performed to evaluate leak pressure for PROXIMATE TLC and compare to Covidien DST Series™ GIA™ (Medtronic). Both devices use B-staples in 4 rows with an interposed knife blade to transect the tissue, and both devices were used to deliver staples of a similar height intended for use in similar tissue ranges.

Methods

Devices were fired on bowel segments ranging from 1.0 to 3.0mm in tissue thickness, following the manufacturer’s Instruction for Use. A precompression period of 15 seconds was used prior to firing the devices.

The stapled bowel segments were evaluated for staple line leaks (pressure at first leak) as intraluminal pressure was increased in 10mmHg increments from 20-200mmHg.

Results

Mean luminal leak pressures were 51.8% higher for TLC75* than GIA80† (p<0.0001), and the proportion of luminal leakage occurring at or below a pressure of 50mmHg was 81.8% lower for TLC75 than GIA80 (p=0.013). The cumulative proportion of luminal leakage indicates a higher rate of leakage at or below 50mmHg for GIA80, and higher mean leak pressures for TLC75.

The mean height of formed staples was significantly lower for TLC75 (1.37 ± 0.04 mm) than for GIA80 (1.51 ± 0.05 mm, p<0.001).

No malformed staples were observed for either device, and there was no significant difference in the mean tissue thicknesses of samples between TLC75 and GIA80.

Cumulative proportion of luminal leakage showing a higher rate of staple line leakage at or below 50mmHg for GIA80 (Medtronic)*, and higher mean leak pressures for TLC75 (Ethicon)†.

Conclusion

TLC75 had fewer leaks at clinically relevant pressures than GIA80. The TLC75 linear cutter produced 9% tighter formed staples than the GIA80 linear cutter, and this may be a factor in the observed higher luminal leakage pressures and lower leak rates for TLC75.

*PROXIMATE® Linear Cutter (TLC7575), †Covidien DST Series™ GIA80™ (GIA808038S).
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

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