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Technical characteristics can make the difference in a surgical linear stapler. Or not?

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ABSTRACT

Background: Anastomotic leak (AL) after gastrointestinal surgery is a severe complication associated with relevant short- and long-term sequelae. Most of the anastomosis are currently performed with a surgical stapler that is required to have appropriate characteristics to guarantee good performances. The aim of our study was to evaluate, in the laboratory, pressure resistance and tensile strength of anastomosis performed with different surgical linear staplers, available in the market.

Materials and methods: We have been studying three linear staplers, with diverse cartridges and staple heights, of three different companies, used for gastrointestinal anastomosis and gastric or intestinal closure. We performed 50 anastomosis for each device, with the pertinent different cartridges, on fresh pig intestine, for a total of 350 anastomosis, then injected saline solution and recorded the pressure that provokes a leak on the staple line. There were no statistically significant differences between the mean pressure necessary to induce an AL in the various instruments ($P > 0.05$). For studying the tensile strength, we performed a total of 350 anastomosis with the different linear staplers on a special strong paper (Tyvek), then recorded the maximal tensile force that could open the anastomosis.

Results: There were no statistically significant differences between the different staplers about the strength necessary to open the staple line ($P > 0.05$).

Conclusions: we demonstrated that different linear staplers of three companies available in the market give comparable anastomotic pressure resistance and tensile strength. This might suggest that small dissimilarities between different devices are not involved, at least as major parameters, in AL etiology.

1. Introduction

Anastomotic leakage (AL) is the most dreaded surgical complication in patients undergoing gastrointestinal (GI) surgery. AL has been described as having great variability, ranging between 2% and 30%, with a higher incidence after colorectal and gastrojejunal anastomosis and lower frequency after small bowel resections [1–3]. AL after GI surgery has a

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remarkable impact on patient's outcome, involving higher morbidity and mortality, longer hospital stay and, overall, worse oncological and functional outcomes [4].

Nowadays, most of the GI anastomosis are performed with mechanical staplers because they help shortening operating room time, standardizing surgical technique, and they are an essential tool for minimally invasive approaches (laparoscopic and robotic intracorporeal anastomosis) [5,6].

On the other hand, stapled anastomosis is obviously more expensive than hand-sewn technique [7]. Technical features leading to optimal stapler-tissue interaction, correct stapler and cartridges choice, and proper handling are crucial issues [8]. Surprisingly, to date, there are very few published articles regarding these topics.

Therefore, we performed a study to evaluate pressure resistance and tensile strength of anastomosis performed with different linear staplers available in the market.

2. Methods

2.1. Staplers

For our study, we compared similar linear staplers for GI surgery of three different companies as follows: staplers A, B, and C. All staplers are currently available in American, European, and Asian markets. Stapler A is the Touchstone linear cutter (Touchstone International Medical Science Co, Ltd, Suzhou, China), with the 38, 42, and 45 mm cartridges (respectively: LC8038, LC8042, and LC8045). Stapler B is the Sinolinks product (Sinolinks Medical Innovation Co, Ltd, Jiangsu, China), with the 3.8 and 4.8 cartridges (DLC B-80B and DLC B-80G). Stapler C is the Covidien linear stapler (Covidien, New Haven, CT), with the 3.8 and 4.8 cartridges (GIA8038s and GIA8048s).

They all have four rows of staples and 84 total staples. Open staple height varies from 3.8–4.5 mm for stapler A and from 3.8–4.8 mm for staplers B and C. Closed staple height varies from 1.5–2.0 mm for all staplers. All stapler characteristics are summarized in Table 1.

Table 1 – Characteristics of linear staplers.

Linear stapler	Different cartridges	Rows of staples	Number of staples	Open staple height, mm	Closed staple height, mm
A	LC8038	4	84	3.8	1.5
	LC8042	4	84	4.2	1.7
	LC8045	4	84	4.5	2.0
B	DLC B-80B	4	84	3.8	1.5
	DLC B-80G	4	84	4.8	2.0
C	GIA8038s	4	84	3.8	1.5
	GIA8048s	4	84	4.8	2.0

Stapler A is the Touchstone linear cutter, with the 38, 42, and 45 mm cartridges (respectively: LC8038, LC8042, and LC8045). Stapler B is the Sinolinks product, with the 3.8 and 4.8 cartridges (DLC B-80B and DLC B-80G). Stapler C is the Covidien linear stapler, with the 3.8 and 4.8 cartridges (GIA8038s and GIA8048s).

2.2. Pressure resistance

Fresh large bowel from healthy pigs was used for all testing regarding pressure resistance. Three-hundred fifty segments of porcine intestines were prepared. They all measured at least 50 cm and were washed and prepared to remove internal faeces and external fat (Fig. 1A). Subsequently, all intestines were divided in two identical parts by the linear staplers (Fig. 1B and C). Then a tube was inserted for injection of saline solution at a pressure $\geq$3.6 KPa (Fig. 1D). The pressure that provoked a saline leakage from the intestinal closure was recorded. Pressure values were expressed in kilopascal (KPa). All experiments were performed at the Touchstone Technical Laboratory, The Science Plaza, Suzhou International Science Park, Suzhou, China.

2.3. Tensile strength

Tyvek paper was used for tensile strength experiments; this is the paper used for stapler package and has big tenacity (DuPont China Holding Co Ltd, Beijing, China). Seven hundred pieces of this paper have been prepared with scissors, to anastomize them with the linear staplers (Fig. 2A and B). Then the two ends of the stapled paper were pulled by a testing automated machine, and the tensile force that could open the anastomosis was registered (Fig. 2C–E). Force was applied to the paper, by the machine, in a continuous fashion and normalized along the whole staple line of the anastomosis. The machine was used both to apply the force and record the data. Tensile strength values were expressed in Newton (N). All experiments were performed at the Touchstone Technical Laboratory, The Science Plaza, Suzhou International Science Park.

2.4. Statistical analysis

All data were collected and entered in a computerized database. Values were expressed as numbers, means, and standard deviations (SD). All statistical tests were two tailed and a two sided; P value of 0.05 was considered for significance. The statistical analyses were performed using Microsoft Office Excel 2010 XLSTAT 2014.5.01.

3. Results

3.1. Pressure resistance

A series of 350 intestinal divisions have been performed, 50 with each stapler and cartridges. Mean pressure values necessary to produce saline solution leak were 29.36 KPa for LC8038, 29.11 KPa for LC8042, 29.16 KPa for LC8045, 29.01 KPa for DLC B-80B, 28.91 KPa for DLC B-80G, 29.10 KPa for GIA8038s, and 29.18 KPa for GIA8048s. A complete list of mean pressure values is reported in Table 2, together with each SD.

Graphics representing leak pressure values of all 50 anastomosis performed with each stapler are reported in Figure 3. It emerges that all values are very similar, one to the other.

Then we statistically evaluated and compared mean pressure values obtained with each instrument. In any of the comparisons, there were no statistically significant