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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

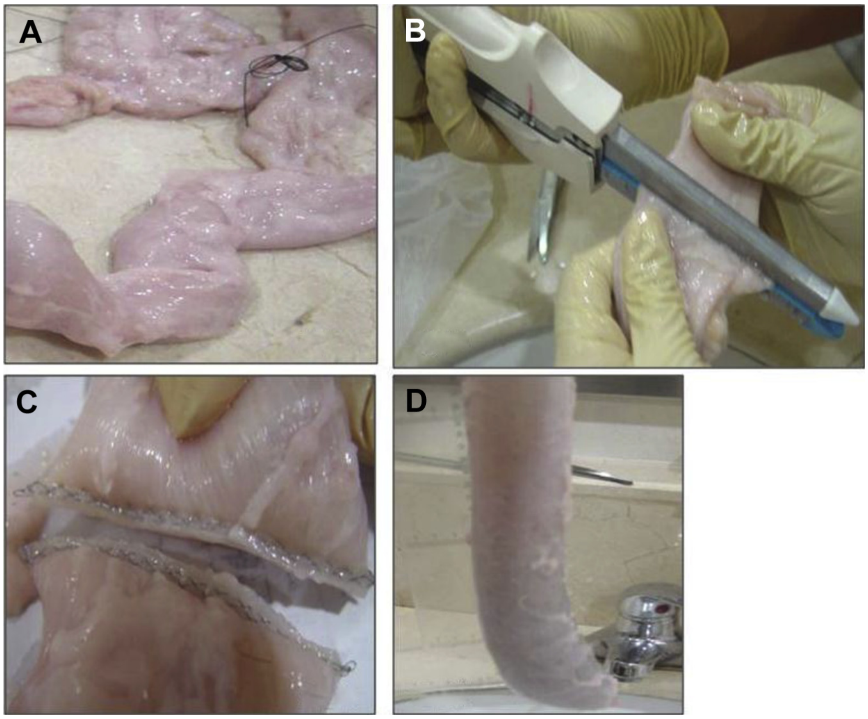

Fig. 1 – (A—D) Pressure resistance test. Fresh porcine intestines from healthy pigs were used for all testing (A). They all measured > 50 cm and were washed and prepared to remove internal feces and external fat (A). All porcine intestines were divided in two identical parts by the linear staplers (B and C). A tube was inserted for injection of saline solution at a pressure ≥3.6 KPa (D). The pressure that provoked a saline leakage from the intestinal closure was recorded. (Color version of the figure is available online.)

differences between the instruments about anastomotic pressure resistance (P values ranging from 0.072–0.926) as shown in Table 2.

3.2. *Tensile strength*

For tensile strength testing, we performed 50 anastomoses with each stapler and cartridge, with a resulting of 350 total anastomoses. Mean strength values necessary to separate the Tyvek paper anastomosis for the staplers were 1175.5 N for LC8038, 175.65 for LC8042, 175.56 for LC8045, 175.24 N for DLC B-80B, 175.05 N for DLC B-80G, 175.78 N for GIA8038s, and 175.60 N for GIA8048s. A complete list of mean strength values is reported in Table 3, together with each SD.

Graphics representing strength values of all 50 intestine sutures performed with each stapler are reported in Figure 4. According to the graphic of pressure (Fig. 3), values are similar among the different staplers.

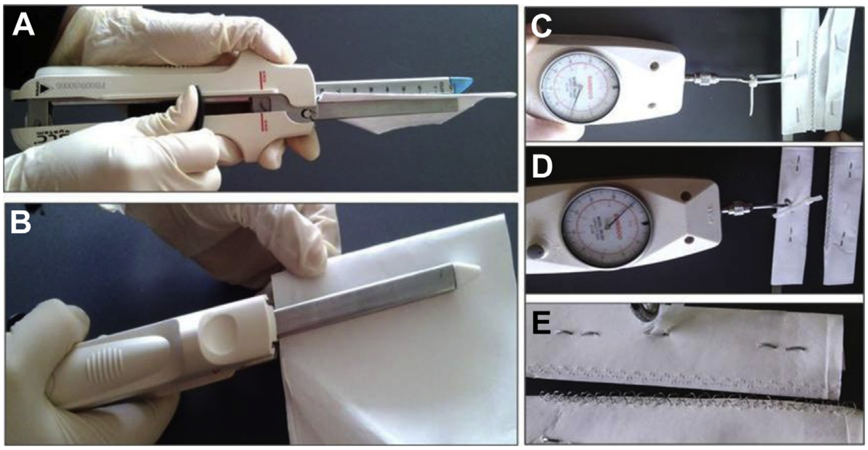

Fig. 2 – (A–E). Tensile strength test. The Tyvek paper is divided with the linear staplers (A and B). The two ends of the stapled paper were pulled by a testing machine, and the tensile force that could open the anastomosis was registered (C–E). (Color version of the figure is available online.)

Table 2 – Pressure resistance test.

Linear staplers	Mean pressure, KPa	Standard deviation	Staplers comparison	P value
LC8038	29.36a	0.81	*versus* DLC B-80B	0.072
LC8042	29.11	0.89	*versus* DLC B-80B	0.543
LC8045	29.16	1.28	*versus* DLC B-80G	0.351
DLC B-80B	29.01	1.02	*versus* GIA8038s	0.636
DLC B-80G	28.91	1.09	*versus* GIA8048s	0.223
GIA8038s	29.10	1.05	*versus* LC8038	0.210
			versus LC8042	0.926
GIA8048s	29.18	0.95	*versus* LC8045	0.922

Mean pressure necessary to provoke saline solution leak from the porcine intestine divided with the different linear staplers and comparison between the pressure resistance of the different surgical staplers. P is always >0.05: there are no statistically significant differences between the staplers regarding pressure resistance. Pressure is expressed in kilopascal: KPa.

Then we statistically evaluated and compared mean strength values obtained with each instrument, as shown in Table 3. In any of the comparisons, there were no statistically significant differences between the instruments about anastomotic tensile strength with *P* values ranging from 0.072–0.917 (Table 3).

4. Discussion

AL is one of the most dreaded complications after GI surgery. It leads to prolonged hospital stay, increased morbidity, mortality, and medical costs [4]. Anastomotic failure depends on various parameters, ranging from patient to surgical technique and instruments and surgeon's experience [9]. Well-recognized patient risk factors for AL are localization (increased incidence on the distal tract, highest on the lower rectum), previous radiotherapy (locally advanced rectal cancer), emergency operation, male sex, advanced age, diabetes mellitus, vasculopathy, obesity, chronic obstructive pulmonary disease, denutrition, chronic corticosteroidal use, and unknown vascular abnormalities [9]. Multiple numbers of stapler firings during rectal division and double-stapled colorectal anastomosis significantly increases the incidence of anastomosis leak and strictures, as shown in the study of Ito *et al.* [10]. Surgeon's experience and, in particular, low-case volume per center (<20 per year) are also involved in AL etiology [9].

Mechanical staplers are nowadays widely used in GI surgery [5,6]; notwithstanding the important diffusion of these instruments, there are very few published articles about their mechanical characteristics. 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.

Recently, a study on porcine and canine lungs using variable-height staplers testing air leak has been published with promising results [11].

The importance of correct tissue compression generated by the staples has been addressed by Myers *et al.*, performing, like in our study, anastomosis on porcine fresh tissues. They used stomachs and small intestines and tested the strength of the anastomosis infusing colored water in the samples and registering the maximum intraluminal pressure that induced the leak. They showed that the more the tissue was

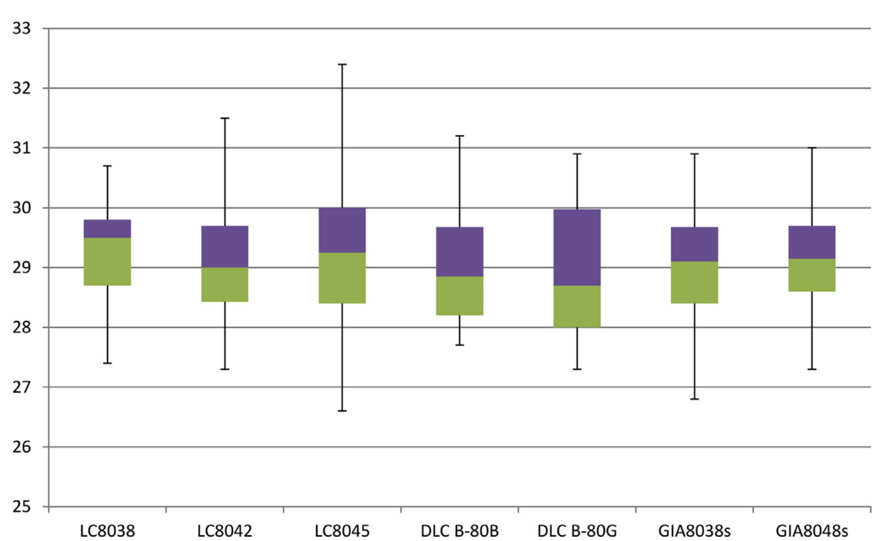

Fig. 3 – Pressure resistance test. Graphics representing leak pressure values of all 50 sutures performed with each stapler. Pressure, represented on x-axis, is expressed in kilopascal: KPa. (Color version of the figure is available online.)

Table 3 – Tensile strength tests.

Linear staplers	Mean strength, N	Standard deviation	Staplers comparison	P value
LC8038	175.55	1.45	*versus* DLC B-80B	0.385
LC8042	175.65	1.21	*versus* DLC B-80B	0.156
LC8045	175.56	1.24	*versus* DLC B-80G	0.085
DLC B-80B	175.24	1.55	*versus* GIA8038s	0.094
DLC B-80G	175.05	1.49	*versus* GIA8048s	0.072
GIA8038s	175.78	1.24	*versus* LC8038	0.437
			versus LC8042	0.759
GIA8048s	175.60	1.26	*versus* LC8045	0.917

Mean strength necessary to separate the Tyvek paper anastomosis in the different linear staplers and comparison between the strength necessary to take apart the anastomosis in the different surgical staplers. There are no statistically significant differences between the staplers regarding tensile strength test (P is always >0.05). Strength is expressed in Newton: N.

compressed, the stronger the anastomosis was. Moreover, the authors underlined the importance of adequate mechanical strength of the anastomosis [12]. Kawasaki K *et al.* published an experimental study on small porcine intestine for studying mechanical strength of different stapling techniques. They compared Endo GIA blue with Endo GIA green and GIA blue and demonstrated that the strangest anastomosis was performed with Endo GIA blue, most probably because of three staple lines compared with the two of GIA. Then they showed that buttressing the anastomosis performed with Endo GIA blue does not significantly increase anastomotic strength. Finally, they evaluated single stapling and double stapling techniques, finding no significant differences in anastomotic strength but concluding that single stapling, having no crossing points, might be safer [13].

Also Yang *et al.* performed anastomosis on porcine small bowel with a 21-mm circular stapler, focusing their attention on circumferential and longitudinal strains. They found out that longitudinal compression between staples in the longitudinal direction may have a beneficial effect, therefore helping to prevent AL [14]. In addition, another randomized study compared two different brand 6-rows linear staplers (Covidien *versus* Ethicon, Cincinnati, OH). They operated on, for laparoscopic gastric bypass, 100 patients. In the Ethicon group, they registered more misfires, more hemoclips applied, more intraoperative blood loss, and longer operating room time; all differences were statistically significant [15].

Moreover, a randomized trial has been conducted on 40 patients about the comparison between 4-rows and 6-rows linear cutter stapler of the same brand (Ethicon Endo-Surgery). In each group, there were 20 patients, undergoing GI anastomosis during open surgery procedures. Results were comparable in terms of AL, but not for anastomotic bleeding that was statistically significant lower in the 6-rows stapler group [16].

Another interesting study has been made from Gentilli *et al.*, where they compared staplers from five different companies (two American and three Chinese), performing ultrastructural analysis of the staples. About morphology, they found out that all staples were round, except one that had a squared section. All except one were made of titanium; the one composed of an alloy of titanium and aluminum had a bigger metal release. The staples were comparable in terms of roughness [17].

Our study demonstrates that there are no statistically significant differences between the different staplers regarding anastomotic pressure resistance and tensile strength. This

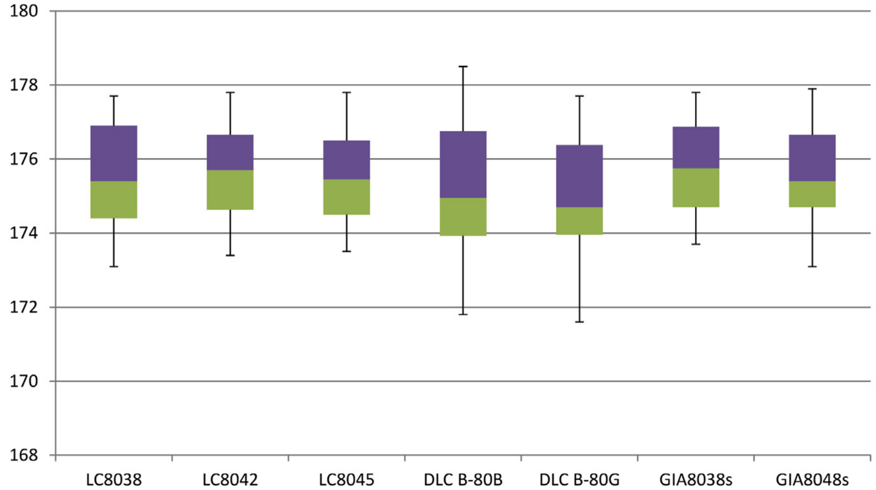

Fig. 4 – Tensile strength test. Graphic representing strength values necessary to separate all 50 anastomosis performed with each stapler. Strength, represented on x-axis, is expressed in Newton: N. (Color version of the figure is available online.)

might suggest that small dissimilarities between different devices (e.g. 1- or 2-mm differences in staple height) are not involved in AL etiology, at least as major parameters. On the contrary, other factors such as patient characteristics, tumor location, and tissue thickness may play a more significant role.

The strength of our study was the important number of the anastomosis performed (a total of 700), giving an additional value to the statistical analysis. The main drawback of our study was the use of porcine model that is similar but cannot be completely compared with the human model in terms of tissues thickness.

5. Conclusions

Technical characteristics of the surgical staplers are crucial to build up anastomosis with a good strength, to avoid the devastating complication of AL.

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.

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Authors' contributions: V.G. contributed to the conception and design. V.G. and M.S.A. did the acquisition of data. V.G., M.S.A., P.C.A., and G.C. did the analysis and interpretation and drafting of the article. V.G., M.C., and G.G. did the critical revision.

Disclosure

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