JOURNAL OF THE MECHANICAL BEHAVIOR OF BIOMEDICAL MATERIALS 53 (2016) 295–300

Available online at www.sciencedirect.com

ScienceDirect

www.elsevier.com/locate/jmbbm

Research Paper

Different characteristics of circular staplers make the difference in anastomotic tensile strength

V. Giaccaglia[a,*], M.S. Antonelli[a], L. Franceschilli[b], P.F. Salvi[a], A.L. Gaspari[b], P. Sileri[b]

[a]Department of Surgical and Medical Sciences and Translational Medicine, General Surgery and Emergency Surgery Units, Sant'Andrea Hospital, 'Sapienza' University of Rome, Italy
[b]Department of General Surgery, Tor Vergata University Hospital, 'Tor Vergata' University of Rome, Italy

ARTICLE INFO

Article history:
Received 8 June 2015
Received in revised form
13 August 2015
Accepted 21 August 2015
Available online 29 August 2015

Keywords:
Circular stapler
Anastomotic leak
Tensile strength
Pressure resistance

ABSTRACT

Anastomotic leak after gastrointestinal surgery is a severe complication associated with relevant short and long-term sequelae. Most of the anastomoses are currently performed with a surgical stapler that is required to have appropriate characteristics in order to guarantee good performances.

The aim of our study was to evaluate, ex vivo, pressure resistance and tensile strength of anastomosis performed with different circular staplers available in the market.

We studied 7 circular staplers of 3 different companies, 3 of them used for gastrointestinal anastomosis and 4 staplers for hemorrhoidal prolapse excision.

A total of 350 anastomoses, 50 for each of the 7 staplers, were performed using healthy pig fresh intestine, then injected saline solution and recorded the leaking pressure. There were no statistically significant differences between the mean pressure necessary to induce an anastomotic leak in the various instruments ($p>0.05$).

For studying tensile strength, we performed a total of 350 anastomoses with 7 different circular staplers on a special strong paper (Tyvek), and then recorded the maximal tensile force that could open the anastomosis. There were statistically significant differences between one brand stapler vs other 2 companies staplers about the strength necessary to open the staple line ($p<0.05$).

In conclusion, we demonstrated that different circular staplers of three companies available in the market give comparable anastomotic pressure resistance but different tensile strengths. This is probably due to different technical characteristics.

1. Introduction

Anastomotic leakage (AL) is a severe complication after gastrointestinal (GI) surgery. AL has a reported prevalence ranging from 1% up to 30%, with a higher incidence after colorectal and gastrojejunal anastomosis and lower following small bowel resections (Pickleman et al., 1999; Telem et al., 2010; Platell et al., 2006). Anastomotic leak after GI surgery has a remarkable

*Correspondence to: Department of Surgical and Medical Sciences and Translational Medicine, General Surgery 1 Unit, Sant'Andrea University Hospital, 'Sapienza' University of Rome, Via di Grottarossa 1085, 00189 Rome, Italy. Tel.: +39 06 3377 5693.
E-mail address: v.giaccaglia@gmail.com (V. Giaccaglia).

http://dx.doi.org/10.1016/j.jmbbm.2015.08.029
1751-6161/

impact on patient's outcome, involving higher morbidity and mortality, longer hospital stay and, over all, worse oncological and functional outcomes (Mirnezami et al., 2011). More than two decades have passed since surgeons have begun to use staplers in GI surgery; they help shortening operating room time, standardizing surgical technique, and are an essential tool for minimally invasive approaches (laparoscopic and robotic intracorporeal anastomosis) but they are more expensive than hand sewn technique and might have misfiring and malfunctioning during surgery (Picardi, 2002; Guivarc'h, 2004; Korolija, 2008).

Technical features leading to optimal stapler–tissue interaction, correct stapler and cartridges choice and proper handling are crucial issues (Chekan and Whelan, 2014).

Surprisingly, to date, there are a very few published papers regarding these topics. In particular, there is a lack of papers that compare a large number of different staplers' characteristics and their efficacy, especially regarding pressure resistance and tensile strength. Hence, we performed this study in order to evaluate pressure resistance and tensile strength of anastomosis performed with different circular staplers available in the market.

2. Methods

2.1. Staplers

We compared similar circular staplers for GI surgery (Group A) and hemorrhoidal surgery (Group B) of 3 different companies. All staplers are currently available in American, European and Asian markets. First of all we examined circular staplers (Group A), all 3 with a head diameter of 33 mm: CSC Series Intraluminal Stapler for Single Use (CSC33-KOL, Touchstone), Disposable Circular Stapler (DCS E-33, Sinolinks), and Proximate ILS Curved Intraluminal Stapler (CDH33A, Ethicon). They all have 2 rows of staples and their characteristics are summarized in Table 1.

Then we studied and compared 4 different hemorrhoidal staplers of 3 companies (Group B): Tissue Selecting Therapy (TST-WS and TST-36-S180, Touchstone), Disposable Hemorrhoidal Stapler (DHS B-34, Sinolinks) and Hemorrhoidal Circular Stapler (PPH03, Ethicon). They all have 33 mm head, except DHS (34 mm) and TST-36 (36 mm), and 2 rows of staples, Group B staplers characteristics are exposed in Table 2.

2.2. Pressure resistance

Forty male healthy pigs large bowel (Sus scrofa domesticus), with a height ranging from 100 kg to 180 kg, were used to test pressure resistance. All pigs have been regularly slaughtered.

Three-hundred and fifty segments of porcine large bowel, measuring 60 cm, were washed and prepared in order to remove external fat and internal feces, using room temperature water and paying attention not to damage the tissue, as shown in Fig. 1. Subsequently all intestines were divided into two identical parts with a scalpel (of 30 cm each) and end-to-end anastomosis was performed (Fig. 2), between same tracts of porcine intestine considering dimensions and physiological characteristics. It is to note that specimens have been randomly assigned between the two groups (A and B). A pre-compression time of 15 s has been used in all cases before stapling, as suggested in the Manufacturer's instruction. Then a plastic tube was perpendicularly inserted for injection of saline solution and the two ends were sealed. Saline solution was injected at 15 ml/min and the pressure causing saline leakage from anastomosis was recorded using a tonometer (Fig. 3). Pressure values were expressed in kilopascal (kPa), according to the international system of units (SI). The time passing between animals' death and experiments was 48 h, all porcine intestines were stored in a cold room and then unfrozen not using heat generator. All experiments were performed at the Touchstone Technical Laboratory, The Science Plaza, Suzhou International Science Park, Suzhou (China) by the same surgeon, expert in using stapler devices.

2.3. Tensile strength

Tyvek paper was used for tensile strength experiments; this is a nonwoven product consisting of spunbond olefin fiber also used for stapler package. The material is very strong; it is difficult to tear but can easily be cut with scissors or a knife. The fibers are 0.5–10 μm (compared to 75 μm for a human hair), they are first spun and then bonded together by heat and pressure, without binders. We decided to use this material instead of pig intestine because, due to its strength, it does not easily tear and allows focusing on staples properties. For this experiment we decided to measure strength as an absolute variable.

Seven-hundred pieces of this paper have been prepared with scissors, in order to perform 350 anastomoses. Anastomosis was made stapling two Tyvek papers together (Fig. 4). Then the two ends of the stapled paper were pulled by a testing machine and, as shown in Fig. 5, tensile force that could open the anastomosis was registered. Tensile strength values were expressed in Newton (N), according to the international system of units (SI). All experiments were performed at the Touchstone Technical Laboratory, The Science Plaza, Suzhou International Science Park, Suzhou (China).

2.4. Statistical analysis

A computerized database was used to collect all data. Numbers, means and standard deviations (SD) were used to express

Table 1 – Characteristics of circular staplers (Group A). CSC33-KOL: CSC Series Intraluminal Stapler for Single Use (Touchstone); DCS E-33: Disposable Circular Stapler (Sinolinks); CDH33A: Proximate ILS Curved Intraluminal Stapler (Ethicon).

Circular stapler	Head diameter (mm)	Rows of staples	Number of staples	Open staple height (mm)	Closed staple height (mm)
CSC33-KOL	33	2	32	5.0	1–2.5
DCS E-33	33	2	30	5.2	2.5
CDH33A	33	2	28	5.5	1–2.5

Table 2 – Characteristics of hemorrhoidal staplers (Group B). TST-WS and TST-36-S180: Tissue Selecting Therapy (Touchstone); DHS B-34: Disposable Hemorrhoidal Stapler (Sinolinks); PPH03: Hemorrhoidal Circular Stapler (Ethicon).

Hemorrhoidal stapler	Head diameter (mm)	Rows of staples	Number of staples	Open staple height (mm)	Closed staple height (mm)
TST-WS	33	2	32	4	0.75–1.5
TST-36-S180	36	2	34	4.2	0.75–1.8
DHS B-34	34	2	34	3.8	1.5
PPH03	33	2	28	4	0.75–1.5

Fig. 1 – Pressure resistance test. Three-hundred and fifty segments of porcine large bowel measuring 60 cm were washed and prepared in order to remove external fat and internal feces.

Fig. 2 – Pressure resistance test. All porcine intestines were divided into two identical parts (of 30 cm each) and finally end-to-end anastomosis was performed.

different values. In order to show differences between the values Kruskall–Wallis representation was used. Chi-square test was used to compare different means and a p value of 0.05 was considered for statistical significance. All statistical tests were 2 tailed and a 2-sided. Statistical analyses were performed using Microsoft Excel 2010.

Fig. 3 – Pressure resistance test. Saline solution was injected at 15 ml/min and the pressure that provoked a saline leakage from the anastomosis was recorded.

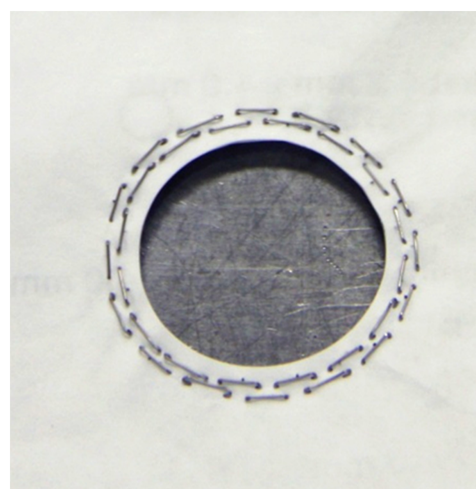

Fig. 4 – Tensile strength test. The anastomosis is made stapling two Tyvek papers together.

3. Results

3.1. *Pressure resistance*

A series of 350 anastomoses have been performed, 50 with each stapler. Mean pressure values necessary to produce an anastomotic leak of saline solution for the staplers of Group A were:

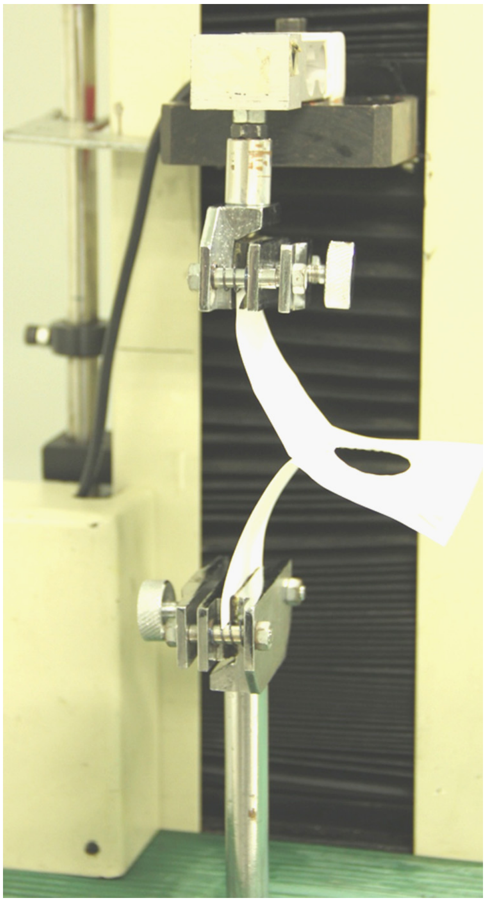

Fig. 5 – Tensile strength test. The two ends of the stapled paper were pulled by a testing machine and the tensile force that could open the anastomosis was registered.

Table 3 – Pressure resistance test. Mean pressure necessary to provoke anastomotic leak in the different circular staplers. Pressure is expressed in kilopascal (kPa). Group A: circular staplers; Group B: hemorrhoidal staplers.

Circular staplers	Mean pressure (kPa)	Standard deviation
Group A		
CSC33-KOL	23.58	0.89
DCS E-33	23.67	1.36
CDH33A	23.59	1.30
Group B		
TST-WS	23.88	1.38
TST-36-S180	23.95	1.11
DHS B-34	23.18	1.54
PPH03	23.66	1.55

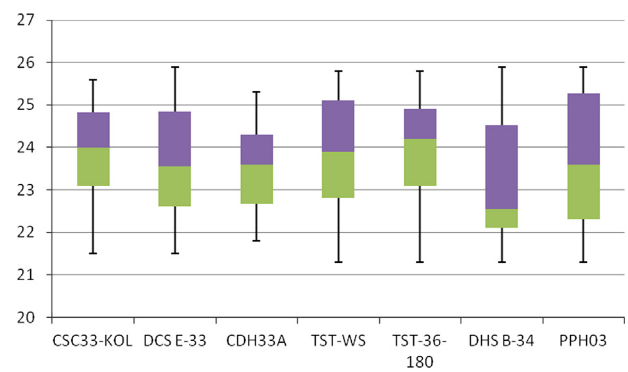

Fig. 6 – Pressure resistance test. Graphic representing leak pressure values of all 50 anastomoses performed with each stapler. Different staplers are represented on the *x*-axis. Pressure values are expressed in kPa on the *y*-axis.

23.58 kPa for CSC-33 KOL, 23.67 kPa for DCS E-33 and 23.59 kPa for CDH33A. Regarding staplers for excision of hemorrhoidal prolapse (Group B), mean pressures were: 23.88 kPa for TST-WS, 23.95 kPa for TST-36, 23.18 kPa for DHS B-34 and 23.66 kPa for PPH03.

Complete list of mean pressure values is reported in Table 3, together with each standard deviation. Graphic representing leak pressure values of all 50 anastomoses performed with each stapler is reported in Fig. 6. 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 of Groups A and B. In any of the comparison there are no statistically significant differences between the instruments about anastomotic pressure resistance (p ranging from 0.119 to 0.957) as shown in Table 4.

3.2. *Tensile strength*

For tensile strength testing, we performed 50 anastomoses with each of the 7 staplers, with a result of 350 total anastomoses. Mean strength values necessary to separate the Tyvek paper anastomosis for the staplers of Group A were: 106.98 N for CSC-33 KOL, 88.37 for DCS E-33 and 88.43 N for CDH33A. Regarding staplers of Group B, mean strengths were: 88.60 N for TST-WS, 106.81 N for TST-36, 87.92 N for DHS B-34 and 88.21 N for PPH03.

Complete list of mean strength values is reported in Table 5, together with each standard deviation. Graphic representing strength values of all 50 anastomoses performed with each stapler are reported in Fig. 7. In contrast to the graphic of pressure (Fig. 6), values are not similar between the different staplers; in fact, more strength is necessary to divide the staple line (respectively: 106.98 and 106.81 N) with CSC-33 (Group A) and TST-36 (Group B). On the contrary, for the other staplers, less strength is required to take apart the two anastomized Tyvek papers (mean: 88.30 N).

Then we statistically evaluated and compared mean strength values obtained with each instrument, as shown in Table 6. Regarding staplers of Group A, there are statistically significant differences between CSC33 and DCS E-33 and CSC33 and CDH33 ($p<0.05$); conversely there is no difference between DCS E-33 and CDH33 ($p=0.854$). Concerning staplers of Group B, there are statistically significant differences between TST-WS vs TST36, and TST36 vs DHS B-34 and vs PPH03 ($p<0.05$); on the other hand there are no differences between TST-WS vs DHS B-34 ($p=0.109$) and vs PPH03 ($p=0.218$) and between DHS B-34 vs PPH03 ($p=0.60$), as shown in Table 6.

Table 4 – Pressure resistance test. Comparison between the pressure resistance of the different surgical staplers. Group A: circular staplers; Group B: hemorrhoidal staplers. *p* is always >0.05: there are no statistically significant differences between the staplers regarding pressure resistance.

Staplers comparison pressure	*p*
Group A	
CSC33-KOL vs DCS E-33	0.677
CSC33-KOL vs CDH33A	0.957
DCS E-33 vs CDH33A	0.753
Group B	
TST-WS vs TST-36-S180	0.774
TST-WS vs DHS B-34	0.123
TST-WS vs PPH03	0.472
TST-36-S180 vs DHS B-34	0.053
TST-36-S180 vs PPH03	0.294
DHS B-34 vs PPH03	0.119

Table 5 – Tensile strength tests. Mean strength necessary to separate the Tyvek paper anastomosis in the different circular staplers. Group A: circular staplers; Group B: hemorrhoidal staplers. Strength is expressed in Newton (N).

Circular staplers	Mean strength (N)	Standard deviation
Group A		
CSC33-KOL	106.98	1.75
DCS E-33	88.37	1.90
CDH33A	88.43	1.29
Group B		
TST-WS	88.60	1.29
TST-36-S180	106.81	1.74
DHS B-34	87.92	2.27
PPH03	88.21	1.76

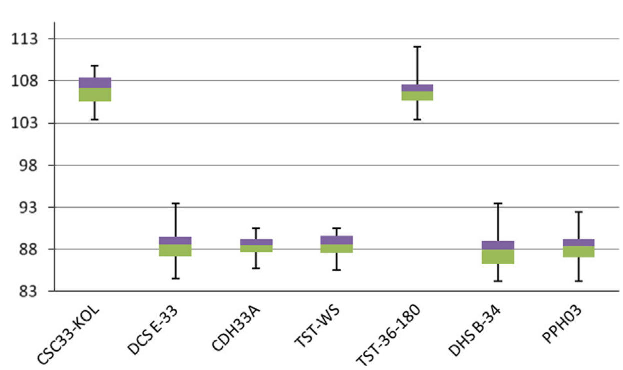

Fig. 7 – Tensile strength test. Graphic representing strength values necessary to separate all 50 anastomoses performed with each stapler. Different staplers are represented on the *x*-axis. Strength values are expressed in N on the *y*-axis.

4. Discussion

Mechanical staplers are nowadays commonly used in gastrointestinal surgery and for hemorroidal prolapse surgery (Longo

Table 6 – Tensile strength tests. Comparison between the strength necessary to take apart the anastomosis in the different surgical staplers. Group A: circular staplers; Group B: hemorrhoidal staplers. There are statistically significant differences between some staplers regarding tensile strength test.

Staplers comparison strength	*p*
Group A	
CSC33-KOL vs DCS E-33*	<0.05
CSC33-KOL vs CDH33A*	<0.05
DCS E-33 vs CDH33A	0.854
Group B	
TST-WS vs TST-36-S180*	<0.05
TST-WS vs DHS B-34	0.109
TST-WS vs PPH03	0.218
TST-36-S180 vs DHS B-34*	<0.05
TST-36-S180 vs PPH03*	<0.05
DHS B-34 vs PPH03	0.60

hemorrhoidopexy an variants) (Picardi, 2002; Guivarc'h, 2004). Surgical complications, as anastomotic leak, can be very important leading to prolonged hospital stay, increased morbidity, mortality and medical costs (Mirnezami et al., 2011; Longo, 1998; Boccasanta et al., 2004; Ribaric et al., 2014; Naldini et al., 2014; Naldini, 2011). Although those surgical devices are widespread in different surgical fields, there are a few published papers about their technical features.

Contini et al. (2013) published, with promising results, a study on porcine and canine lungs using variable-height staplers testing air leak.

Performing anastomosis on porcine stomachs and small intestines, Myers et al. (2011) showed the importance of correct tissue compression generated by the staples. They demonstrated that the more the tissue was compressed, the stronger the anastomosis was (Myers et al., 2011).

According to Manufacturer's instruction, we have been pre-compressing the tissue 15 s before firing, but new evidence suggests that a longer compression time might lead to securer staplers formation (Nakayama et al., 2011).

The compression between staples in the longitudinal direction helps to prevent anastomotic leak, as found by Yang et al. (2012) performing anastomosis on porcine small bowel with a 21-mm circular stapler. Gentili et al. performed a study in which they compared different companies' staplers performing ultrastructural analysis of the staples. They found that the majority of them were made of titanium and had a round section and all were comparable in terms of roughness (Gentili et al., 2012). Starting from these works, we found the need to investigate pressure resistance and tensile strength in GI and hemorroidal circular staplers, keeping in mind their different role in surgery.

Although the following results should not directly relate to “in vivo” values, we think that they could be a precious tool to surgeons to evaluate different staplers' efficacy.

Our study demonstrates that there are no statistically significant differences between the different staplers regarding pressure resistance but there are concerning tensile strength. This might be due to different staplers' characteristics, such as number of staples or staple height (Tables 1 and 2). For circular staplers used in GI surgery (group A) this may be due to a higher numbers of staples and a lower open stapler height.

Even if five staplers, involved in the tensile strength study, showed a significant lower strength value than other 2 staplers, we cannot assess whether those values might be insufficient in the clinical use or not.

The strength of our study was the important number of the anastomoses performed (a total of 700), giving an additional value to the statistical analysis. We consider that anastomotic healing in vivo is due to different factors as anastomotic tension, blood tissue supply, tissue approximation and patient clinical conditions and not simply a matter of anastomotic tightness. The main drawback of our study is the use of porcine model, which is similar, but cannot be completely compared to the human model in terms of tissues thickness and the use of saline solution to test anastomotic integrity without considering air tightness.

5. Conclusion

Technical characteristic of the surgical staplers is crucial to build up anastomosis with a good strength, in order to avoid the devastating complication of anastomotic leak.

We demonstrated that different circular staplers of three companies available in the market, give comparable anastomotic pressure resistance but different tensile strengths. This might be due to their differences in terms of technical characteristics.

Financial disclosure

None reported. All the experiments have been carried out in a laboratory owned by the Company that produces one of the tested staplers, even though none of the authors have any conflict of interest with this Company.

References

Boccasanta, P., Venturi, M., Salamina, G., et al., 2004. New trends in the surgical treatment of outlet obstruction: clinical and functional results of two novel transanal stapled techniques from a randomized controlled trial. Int. J. Colorectal Dis. 19, 359–369.

Chekan, E., Whelan, R.L., 2014. Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes. Med. Dev.: Evid. Res. 7, 305–318.

Contini, E., Godek, M.L., Whiffen, J.M., et al., 2013. Ex vivo pneumostasis evaluation of variable-height staple design. Innovations (Philadelphia) 8, 284–288.

Gentili, S., Portigliotti, L., Aronici, M., et al., 2012. Ultrastructural analysis of different-made staplers' staples. Minerva Chir. 67, 439–444.

Guivarc'h, M., 2004. The history of intestinal suturing: it's decisive influence on digestive surgery. J. Chir. (Paris) 141, 67–70.

Korolija, D., 2008. The current evidence on stapled versus hand-sewn anastomosis in the digestive tract. Minim. Invasive Ther. Allied Technol. 17, 151–154.

Longo, A., 1998. Treatment of hemorrhoids disease by reduction of mucosa and hemorrhoidal prolapse with a circular stapler device: a new procedure. In: Proceedings of the 6th World Congress of Endoscopic Surgery, Rome, Italy, June 3–6, 1998. Monduzzi Editore, Bologna, pp. 777–784.

Manufacturer's instruction for use by Ethicon Endo-Surgery Inc., Cincinnati, OH, USA, 1998.

Mirnezami, A., Mirnezami, R., Chandrakumaran, K., et al., 2011. Increased local recurrence and reduced survival from colorectal cancer following anastomotic leak: systematic review and meta-analysis. Ann. Surg. 253, 890–899.

Myers, S.R., Rothermel, W.S., Shaffer, L., 2011. The effect of tissue compression on circular stapler line failure. Surg. Endosc. 25, 3043–3049.

Nakayama, S., Hasegawa, S., Nagayama, S., et al., 2011. The importance of precompression time for secure stapling with a linear stapler. Surg. Endosc. 25, 2382–2386.

Naldini, G., 2011. Serious unconventional complications of surgery with stapler for haemorrhoidal prolapse and obstructed defaecation because of rectocoele and rectal intussusception. Colorectal Dis. 13, 323–327.

Naldini, G., Martellucci, J., Rea, R., et al., 2014. Tailored prolapse surgery for the treatment of haemorrhoids and obstructed defecation syndrome with a new dedicated device: TST STARR Plus. Int. J. Colorectal Dis. 29, 623–629.

Picardi, N., 2002. History of mechanical sutures in digestive system surgery. Ann. Ital. Chir. 73, 1–10.

Pickleman, J, Watson, W, Cunningham, J, et al., 1999. The failed gastrointestinal anastomosis: an inevitable catastrophe?. J. Am. Coll. Surg. 188, 473–482.

Platell, C., Barwood, N., Dorfmann, G., et al., 2006. The incidence of anastomotic leaks in patients undergoing colorectal surgery. Colorectal Dis. 9, 71–79.

Ribaric, G., D'Hoore, A., Schiffhorst, G., et al., 2014. STARR with CONTOUR TRANSTAR device for obstructed defecation syndrome: one-year real-world outcomes of the European TRANSTAR registry. Int. J. Colorectal Dis. 29, 611–622.

Telem, D.A., Sur, M., Tabrizian, P., et al., 2010. Diagnosis of gastrointestinal anastomotic dehiscence after hospital discharge: impact on patient management and outcome. Surgery 147, 127–133.

Yang, J., Soltz, M., Russell, H., et al., 2012. Surface deformation analysis of end-to-end stapled intestinal anastomosis. Surg. Innov. 19, 281–287.