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ORIGINAL ARTICLE

The use of the LigaSure device and the Stapler in closure of the small bowel: a comparative ex vivo study

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Abstract

Purpose To evaluate the feasibility and effectiveness of the LigaSure device in closing divisions of the small bowel in an ex vivo porcine model.

Methods Two types of closure were performed: stumps created by "muco-mucosa" fusion and stumps created by "sero-serosa" fusion. For each type of closure, different power levels of the LigaSure system were tested in combination with different numbers of applications and then compared with the Stapler group.

Results With both types of intestinal closure, the highest value of burst pressure was obtained with the application of a power level of three bars and one frequency application. The high burst pressure of the muco-mucosa stump group was significantly lower than that of the Stapler group (41.8 ± 5.9 vs. 75.8 ± 5.9, respectively, $p < 0.01$). No differences were found between the high burst pressure of the sero-serosa stump group and the Stapler group (74.1 ± 5.5 vs. 75.8 ± 5.9, respectively, $p = 0.2$).

Conclusions Our preliminary results showed that the LigaSure is an efficient tool for closing the intestines when sero-serosa stumps are created. The second step of our work will be to evaluate the feasibility of this tool in creating intestinal anastomoses.

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Keywords LigaSure · Small bowel · Bipolar vessel sealing system

Introduction

The creation of intestinal anastomoses is of central importance in the practice of surgery, considering the potentially disastrous consequences that can arise from leakage [1]. Stapling and hand suturing are common methods used to construct anastomoses to restore the continuity of the gastrointestinal tract. However, handmade sutures may increase operation times in inexperienced hands. In contrast, linear staples have the handicap of raising operative costs, and their use may be limited due to technical problems such as complex handling and applicability to all regions of the intestinal tract [2]. Therefore, developing new strategies in this setting is desirable.

Recently, a feedback-controlled bipolar sealing system called the LigaSure™ (Valleylab, Boulder, CO, USA) has been added to the armamentarium of surgery. This device applies a precise amount of mechanical pressure and radiofrequency energy to tissue, causing fusion of opposing layers by creating a seal of denatured collagen and elastin fibers. The seal can then be transected, permitting the safe division of a multitude of tissues, including blood vessels with a diameter of up to 7 mm [3]. Since its introduction, the LigaSure device has been applied with success in a variety of abdominal procedures, with the main purpose of dividing tissue [4]. Recently, we reported the use of this device in thoracic surgery for controlling hemostasis during dissection with good results and demonstrated that the device is safe for use in non-anatomical lung resection [5, 6]. On the basis of this experience, the aim of the present paper was to evaluate the feasibility and effectiveness of the LigaSure device in closing the small intestine in an ex vivo porcine model.

Materials and methods

Study design

In this study, the feasibility of performing intestinal closure using the LigaSure device was investigated in an experimental ex vivo porcine model. We performed two types of closure: stumps created by "muco-mucosa" fusion and stumps created by "sero-serosa" fusion. Each studied group was divided into nine subgroups on the basis of the power level of the LigaSure system and the number of radiofrequency applications. The intestinal closures were tested for early burst pressure (measured in mmHg). The highest value of burst pressure registered in each subgroup was then compared with that of the Stapler group in which intestinal closures were created using a stapler device. Finally, the specimens were sent for histological examination. The present study was approved by the Animal Ethics Committee of The Second University of Naples.

LigaSure device

In this study, we used the Ligasure-ForceTriad™, an energy platform that combines second generation tissue fusion technology with a sophisticated closed-loop cut and coagulation electrosurgery generator. The LigaSure Triad Force has three bars or power levels (Level 1, Level 2 and Level 3). The LigaSure Impact™ is used as a handpiece; it is a disposable, hand-activated, open instrument that occludes vessels using LigaSure-Forced Triad tissue fusion technology, and then employs a mechanical blade to divide the fused tissue [3].

Preparation of intestinal samples

Measurements were obtained in intestinal porcine samples freshly bought from the slaughterhouse. The intestines were harvested immediately after slaughtering and transported to the laboratory within 60 min. Then, the intestines were flushed with physiological buffered saline and stored in an incubator at 36 °C and 85 % humidity to avoid tissue desiccation. All pig samples were prepared. Three different levels of power were tested in association with three different numbers of radiofrequency applications (one application, two applications and three applications). For comparison, intestinal samples identical to those used for the fusion experiments were closed using a mechanical stapler.

Operative procedure

The intestinal samples, measuring 15 cm in length, were closed using the LigaSure device or a mechanical stapler (Multifire GIA 60, Tyco Heathcare UK Ltd).

In the first session of the experimental study, the LigaSure device was applied to the distal end of the intestinal wall and mechanical pressure was achieved by closing the jaws. After perfect positioning of the forceps was assured, radiofrequency energy was applied using the level of power and number of applications selected for evaluation. Once the intestines were completely sealed, as indicated by a sound from the device, they were transected using scissors and the handpiece. Therefore, the stump was created using "muco-mucosa" fusion (Fig. 1a).

In the second session, we reversed the colon samples. In this way, the wall structure of the colon was formed by serosa, muscularis externa, muscularis interna, submucosa

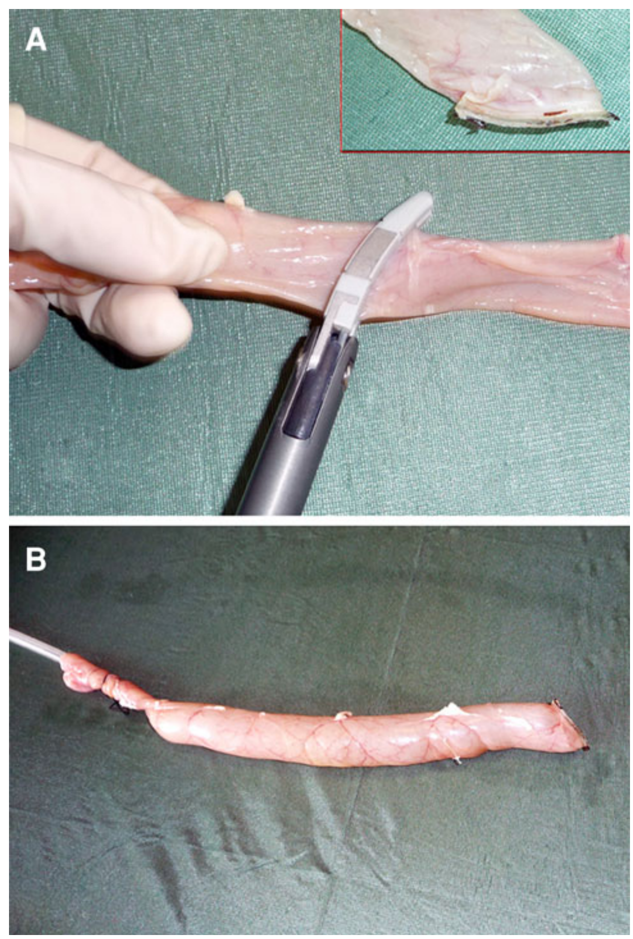

Fig. 1 The LigaSure device was applied to the intestinal wall and mechanical pressure was achieved by closing the jaws (**a**). Once the intestines were completely sealed, they were transected in order to create a stump (*insert*). Then, a catheter was introduced into the lumen proximal to the suture line and tied securely in place with a 2-0 Vycril (**b**)

and mucosa (from inside to outside). Using the same procedure reported above, we closed the distal end of each colon sample using the LigaSure device. In this way, the stumps were created using "sero-serosa" fusion.

For comparison, the distal ends of intestinal samples identical to those used for the LigaSure groups were closed with a mechanical stapler using single-use reloadable stapling units (Multifire 3–8 mm GIA 60, Tyco Heathcare UK Ltd), as reported elsewhere.

Then, through the proximal end of each sample, a cannula was inserted into the intestinal lumen and the intestines were tied over the cannula with a 2/0 polyglactin 910 (Vycril, Ethicon, Edinburgh, UK) (Fig. 1b). Proximally, the cannula was fixed to a three-way stopcock connected to an infusion pump (62-HF-0267-00, Abbott, Chicago, IL, USA) infusing air at a constant rate of 1 mL/min and a manometer to simultaneously measure the burst pressure (Fig. 2). The pressure gradually increased until an air leak was detected through the sealing line. The pressure at which leakage or rupture of the intestines occurred was recorded as the burst pressure.

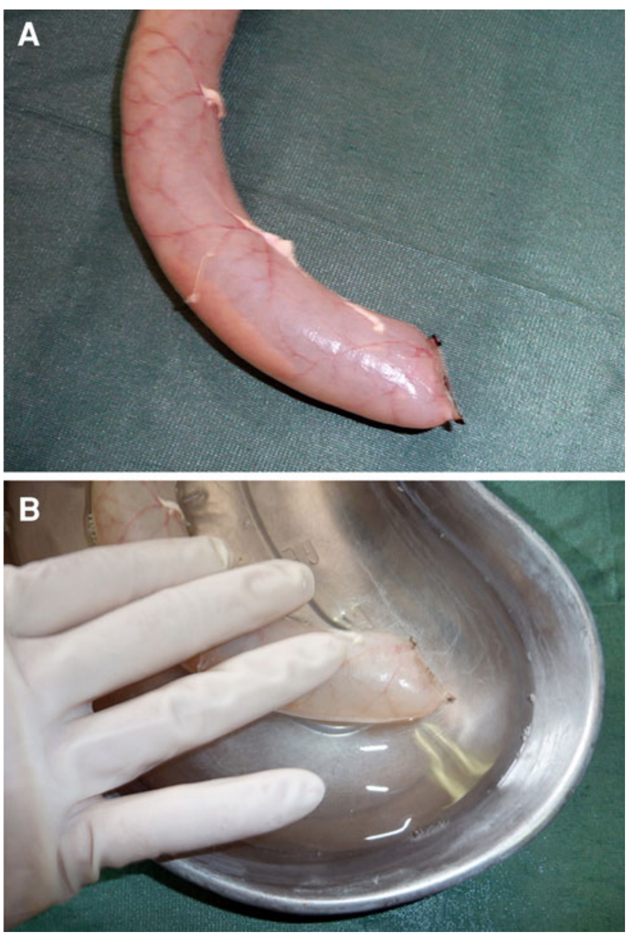

Fig. 2 The catheter was connected to an air flow meter and inflated with air (**a**). The colon sample was placed in a basin filled with saline. The airway pressure gradually increased until an air leak was detected through the sealing line (**b**)

Histological analysis

The specimens were fixed in formalin and subsequently processed to create paraffin-embedded slides. Finally, they were stained with hematoxylin and eosin, as well as Van Gieson's stain.

Statistical analysis

The data are expressed as the mean and standard deviation. Intragroup differences in burst pressure were assessed using ANOVA. The Mann–Whitney test was used to compare the highest burst pressures in the LigaSure groups with that of the Stapler group. Statistical significance was set at $p < 0.05$. The statistical analyses were performed using the MedCalc^{TM} software system.

Results

The measurements were obtained in a total of 190 porcine intestinal samples freshly bought from the slaughterhouse. In the LigaSure group, each studied group (the "muco-mucosa" and "sero-serosa" fusion groups) was divided into nine subgroups of 10 samples each according to the different power levels and number of applications tested. The Stapler group included the remaining 10 samples.

"Muco-mucosa" fusion

The data are summarized in Table 1. The burst pressures of the nine subgroups of LigaSure segments were as follows: 31.8 ± 4.4 (1 bar/1 application); 32.9 ± 6.2 (1 bar/2 applications); 32 ± 3.6 (1 bar/3 applications); 33.7 ± 4.8 (2 bars/1 application); 33 ± 4.4 (2 bars/2 applications); 32.6 ± 3.3 (2 bars/3 applications); 41.8 ± 5.9 (3 bars/1 application); 33 ± 5.2 (3 bars/2 applications); 29.3 ± 3.4 (3 bars/3 applications). An analysis of variance showed that the highest burst pressure was obtained with a power level of three bars and one frequency application (Subgroup 7) ($p < 0.01$; Fig. 3a). Failure always occurred in the middle of the seal, regardless of the level of power or the number of applications. However, the burst pressure in Subgroup 7 was significantly lower than that in the Stapler group (41.8 ± 5.9 vs. 75.8 ± 5.9, respectively; $p < 0.01$; Fig. 3b).

"Sero-serosa" fusion

The burst pressures of the nine subgroups were as follows: 63.8 ± 10 (1 bar/1 application); 62.2 ± 8.4 (1 bar/

Table 1 Burst pressure (mmHg) in the LigaSure groups

Variables	Muco-mucosa fusion			Sero-serosa fusion		
	1-application	2-applications	3-applications	1-application	2-applications	3-applications
Bar-1	31.8 ± 4.4	32.9 ± 6.2	32 ± 3.6	63.8 ± 10	62.2 ± 8.4	65.7 ± 9.2
Bars-2	33.7 ± 4.8	33 ± 4.4	32.6 ± 3.3	63.2 ± 8.3	60.9 ± 8.5	57.8 ± 7
Bars-3	41.8 ± 5.9	33 ± 5.2	29.3 ± 3.4	74.1 ± 5.5	63.7 ± 8	58.5 ± 8.1

The data are expressed as the mean ± standard deviation (SD)

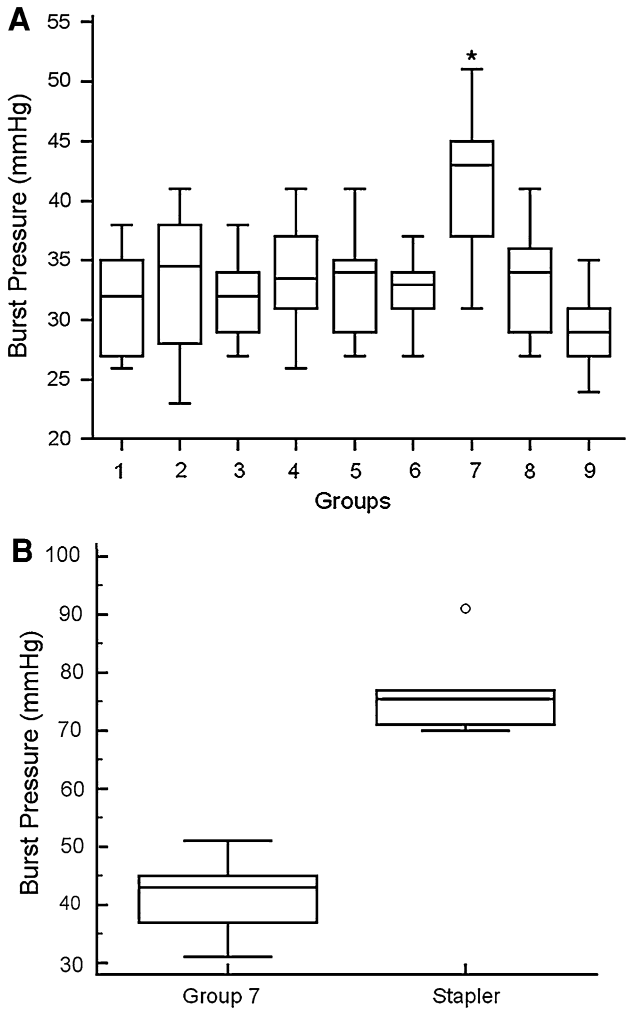

Fig. 3 An analysis of variance showed that the highest burst pressure was obtained in Subroup 7 (*$p < 0.01$, **a**). However, the burst pressure of Subgroup 7 was significantly lower than that of the Stapler group ($p < 0.01$, **b**)

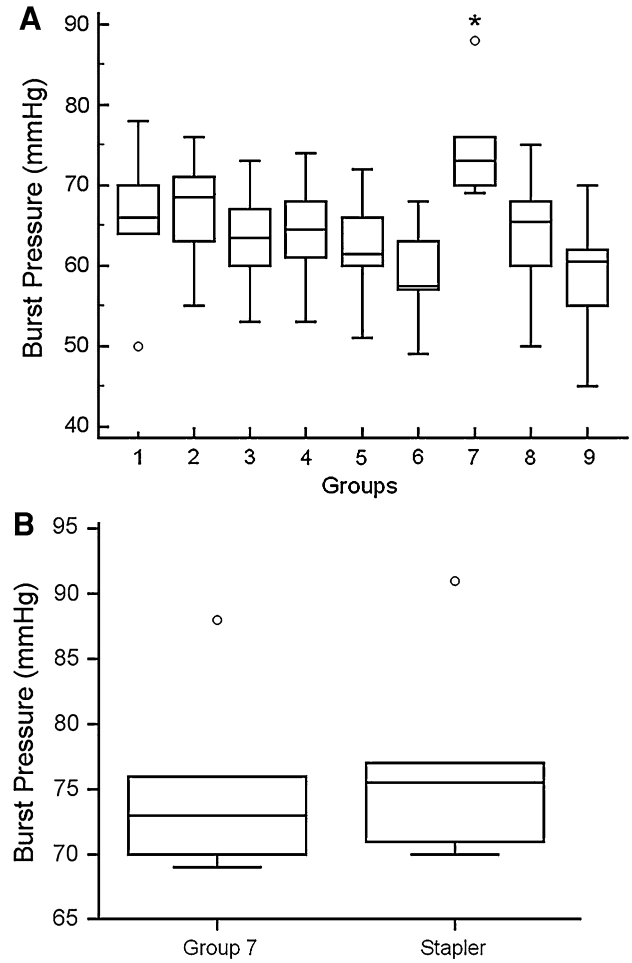

Fig. 4 An analysis of variance showed that the highest burst pressure was obtained in Subgroup 7 (*$p < 0.01$, **a**). No significant differences were found in burst pressure between Subgroup 7 and the Stapler group ($p = 0.2$, **b**)

2 applications); 65.7 ± 9.2 (1 bar/3 applications); 63.2 ± 8.3 (2 bars/1 application); 60.9 ± 8.5 (2 bars/2 applications); 57.8 ± 7 (2 bars/3 applications); 74.1 ± 5.5 (3 bars/1 application); 63.7 ± 8 (3 bars/2 applications); 58.5 ± 8.1 (3 bars/3 applications). An analysis of variance showed that the highest burst pressure was obtained in Subgroup 7 (3 bars/1 application), in comparison with that observed in the other subgroups ($p < 0.01$; Fig. 4a). However, in all groups, failure always occurred in the middle of the seal. No significant differences were found in the burst pressure between Subgroup 7 and the Stapler group (74.1 ± 5.5 vs. 75.8 ± 5.9, respectively; $p = 0.2$; Fig. 4a).

Histological analysis

The specimens in the "muco-mucosa" fusion group stained with hematoxylin and eosin showed that the fusion lines

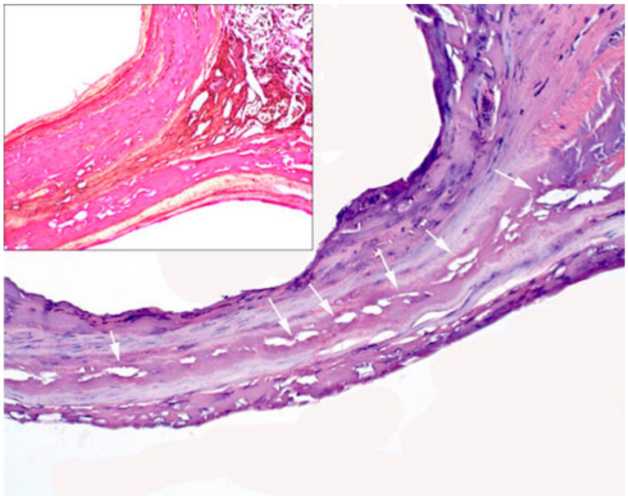

Fig. 5 The specimens of the “muco-mucosa” fusion group stained with hematoxylin and eosin (×40) showed that the fusion lines were punctuated by the presence of large and frequent gaps (*white arrow*). In addition, collagen was poorly stained with Van Gieson’s stain (*insert*) (×40)

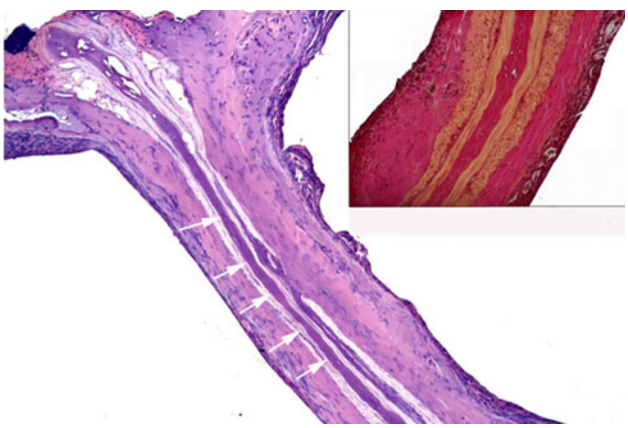

Fig. 6 The “sero-serosa” fusion samples did not present any gaps (*white arrow*) on hematoxylin and eosin staining (×40), and collagen was positively stained with Van Gieson’s stain (*insert*) (×40)

were punctuated by the presence of large and frequent gaps most likely created by the lack of reforming collagen, as confirmed with Van Gieson’s stain (Fig. 5). Conversely, the lines obtained with “sero-serosa” fusion did not present any gaps on hematoxylin and eosin staining, and the collagen in these samples was positively stained with Van Gieson’s stain (Fig. 6).

Discussion

Performing intestinal anastomosis remains a surgical challenge because dehiscence causes mortality and morbidity in patients who undergo gastrointestinal surgery. Current surgical strategies can increase operative times in inexperienced hands (hand sutures) or cost (stapler sutures). Therefore, there is great interest in developing alternative techniques and/or devices that offer the possibility to overcome these problems.

The LigaSure vessel sealing system is a feedback-controlled electrothermal bipolar vessel sealer. The device has been used successfully in a number of gastrointestinal [7, 8], hepatopancreatic [9, 10], gynecologic [11] and urologic surgical procedures [12], both open and laparoscopic, to seal and divide vessels. In previous studies [5, 6], we demonstrated the possibility of performing non-anatomical lung resection using the LigaSure device with burst pressures similar to that obtained with staplers. In light of such experience, in this preliminary study, we investigated the feasibility of using the Force Triad LigaSure device, a second generation LigaSure system, to close colon samples.

First, we performed “muco-mucosa” fusion. The highest value of burst pressure (41.8 ± 5.9) was obtained when intestinal closure was performed using the LigaSure device at a power level of three bars with one application. However, this value was lower than the burst pressure obtained with staplers (75.8 ± 5.9). Our data are in line with those of Salameh et al. [13] who found that the burst pressures of colonic anastomoses created using the LigaSure device were significantly lower than those observed in a Stapler group. Therefore, the authors concluded that the LigaSure device did not allow for safe and effective sealing and division of the small bowel.

In the second phase of this study, we valuated the burst pressure of “sero-serosa” fusion. As reported above, the highest level of burst pressure was obtained using the LigaSure device at a power level of three bars with only one application (74.1 ± 5.5 mmHg); however, in this case, the burst pressure was similar to that observed in the Stapler group (75.8 ± 5.9).

The quality of an intestinal closure is assessed according to the burst pressure. Burkitt et al. [14] monitored 15 patients undergoing colon resection to preserve continuity. A maximum value of 90 mmHg was measured during the first 89 h after surgery with 98 % of the measured values being below 50 mmHg. Therefore, the highest burst pressure obtained in the LigaSure group corresponds to physiological values and is significantly above known postoperative values, considering that, in cadaveric specimens, burst pressures are significantly decreased compared to those in living tissue [15].

In theory, the biochemical mechanisms responsible for colon closure are similar to those of vessel sealing. This explains the ability of the LigaSure device to seal the intestines. Type I collagen and other cytoplasmic substances are the primary ingredients affecting reliable tissue connections.

To create a permanent seal, the LigaSure device reforms collagen and connective tissue. The fact that, in the intestinal wall, the connective tissue is present in the serosa rather than the mucosa [16] may explain the superior results observed using "sero-serosa" fusion. This hypothesis was confirmed by the immunohistochemical studies. The "muco-mucosa" fusion samples were punctuated by the presence of large and frequent gaps with a poor presence of collagen. Conversely, the "sero-serosa" fusion samples did not present any gaps, and the collagen in these samples was positively stained.

This observation may have important consequences in future surgical practice using the LigaSure device for the construction of enteroanastomoses.

In theory, during the construction of an enteroanastomosis, the device is applied to the two colonic segments approximated side-to-side. The device is then activated, involving the entire wall of the bowel segments, which are fused and connected. This results in a "sero-serosa" connection; however, it actually involves other layers of the colonic wall because, the integrity of an anastomosis is greater if the mucosa and submucosa are included [17, 18]. This technique may have the potential to reduce the foreign body reactions that are observed with both stapling devices and hand-sewn sutures, hypothetically allowing for the occurrence of more physiological tissue healing.

Our impressions have been confirmed by the results of two experimental in vivo studies by Holmer et al. [19] and Smulders et al. [2]. Both groups of authors [2, 19] successfully used the LigaSure system to perform colon anastomosis in experimental in vivo studies. Adequate functioning of the anastomoses was deduced from the observation that the animals displayed normal behavior, food-intake bowel sounds and passage of stools in the postoperative period. In addition, histological examinations showed that the anastomoses were patent with normal structures.

The potential advantage of using the LigaSure device in general and thoracic surgery is that the device combines dissecting as well as reconstructive capacities within a single instrument without the need to reload after each application. Therefore, use of this device may reduce costs and operative times, because numerous instrument changes, as generally occurs, are not required. In addition, using the device is technically easy and may help trainee surgeons.

Our study presents several limitations. First, it is an ex vivo study; therefore, conclusions cannot be drawn regarding wound healing of thermofused anastomotic tissue. Second, the study design was unable to demonstrate the efficacy of the LigaSure device in creating entero-anastomoses, which is of crucial importance in the clinical setting. Therefore, we hope to investigate this issue in further experimental works.

Conclusion

Our preliminary results showed that the LigaSure device is an efficient tool for performing intestinal closure with burst pressures similar to those obtained with staplers using "sero-serosa" fusion. On histological examination, the closures appeared to have a normal structure. Whether the LigaSure device may have a role in creating enteroanastomoses is not an endpoint of the present paper and should be determined in further experimental studies.

Conflict of interest Mario Santini (author of the present paper), Alfonso Fiorelli, Gaetana Messina, Paolo Laperuta, Antonio Mazzella and Marina Accardo (coauthors) have no conflicts of interest to report.

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