Does powered stapler improve the mechanical integrity of gastrojejunal anastomosis compared to the current techniques? Experimental study in ex vivo porcine models

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Abstract

Background: Numerous techniques have been described for fashioning gastrojejunostomy (GJ) in a Roux-en-Y gastric bypass. These include hand-sewn anastomosis (HSA) and mechanical anastomosis; the latter includes circular stapled anastomosis (CSA) or manual linear stapled anastomosis (mLSA). More recently, this list also includes powered linear stapled anastomosis (pLSA). The aim of this study was to analyse if addition of power to stapling would improve the integrity of GJ anastomosis in ex vivo porcine models.

Subjects and Methods: The present study included five groups – mLSA1, mLSA2, HSA, CSA, and pLSA. Sequential infusions of methylene blue-coloured saline were performed into the GJ models. Pressure readings were recorded till the point of leak denoting burst pressure (BP). Total volume (TV) and site of leak were recorded. Compliance was calculated from the equation ΔTV/ΔBP.

Results: Differences in pouch and intestinal thickness were not statistically significant between the models. BPs were higher in the mechanical anastomosis groups, i.e., pLSA 21 ± 9.85 mmHg, CSA 20.33 ± 5.78 mmHg, mLSA1 18 ± 4.69 mmHg and mLSA2 11 ± 2.94 mmHg, when compared to HSA 9.67 ± 3.79 mm Hg, which was found to be statistically significant (Kruskal–Wallis test, P = 0.03). Overall, the highest BP was recorded for powered stapling followed by circular, and then, linear stapling; however, this difference was not statistically significant (P = 0.86). There was no statistically significant difference among groups with regard to compliance (Kruskal–Wallis test, P = 0.082).

Conclusion: Despite the limited number of samples, mechanical anastomosis showed a statistically higher BP when compared to HSA, suggesting better anastomotic integrity. The pLSA group showed promising results with the highest BP recorded among all groups; however, this did not reach statistical significance.

Keywords: Bariatric surgery, burst pressure, ex vivo, obesity, Roux-en-Y gastric bypass

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Submitted: 13-Sep-2020, Revised: 13-Dec-2020, Accepted: 04-Jan-2021, Published: 06-May-2021

Access this article online

Quick Response Code:
Website: www.journalofmas.com
DOI: 10.4103/jmas.JMAS_222_20

How to cite this article: Sahloul M, Kapoulas S, Giet L, Ludwig C, Mahawar K, Dennison AR, et al. Does powered stapler improve the mechanical integrity of gastrojejunal anastomosis compared to the current techniques? Experimental study in ex vivo porcine models. J Min Access Surg 2022;18:90-6.
INTRODUCTION

Obesity is now a global pandemic, with 1.9 billion adults classified as overweight, and 650 million suffering with obesity.\(^1\) Bariatric surgery is currently the only durable treatment that results in significant weight loss and more importantly improvement or resolution of obesity-associated co-morbidities.\(^2\)

Since their introduction in the early twentieth century, surgical staplers have constantly evolved and have now become one of the most commonly used surgical instruments being used for gastrointestinal surgery, thoracic surgery, and more recently bariatric surgery.\(^3,4\) Various designs of surgical staplers are available for the commercial use, but they all follow the same concept developed in 1920 by Aladár Petz. This concept was subsequently improved by the Russian and the American scientists to reach the current iteration of surgical staplers using the B configuration of surgical staples.\(^4\)

Laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass (RYGB) remain the two most commonly performed primary bariatric procedures worldwide, representing 46% and 38% of the global activity, respectively.\(^5\) RYGB is one of the most commonly performed revisional bariatric procedures.\(^6,7\) Gastrojejunostomy (GJ) is considered to be one of the key steps whilst performing RYGB.\(^8\) Various techniques have been described for fashioning the GJ in RYGB. These include linear-stapled anastomosis (LSA), hand-sewn anastomosis (HSA) and circular-stapled anastomosis (CSA).\(^8\) These three techniques together represent most of the commonly performed techniques for fashioning the GJ.\(^8\) There is limited comparative data on these techniques.\(^9,10\)

Leak following bariatric surgery can hugely impact patients’ quality of life and health services expenses.\(^11\) Leak rates following RYGB range between 0.1% and 5.8%,\(^10\) The pathogenesis of anastomotic leak following RYGB can be multifactorial.\(^10,12\) Mechanical factors play a major role in the pathogenesis of GJ leak.\(^12\) Most studies in literature on this topic have investigated leak rates in the clinical setting only. Only a few studies have previously investigated the pathogenesis of GJ leak in a controlled laboratory-based setting.\(^13,14\)

We present here the results of a series of experiments performed in a laboratory-based setting to study the mechanical factors which had been partially published previously, especially the addition of powered stapling that could affect the integrity of GJ anastomosis in ex vivo porcine models. Data from previous experiments, already published previously\(^13,14,15\), were used and compared to the newly introduced powered staplers. Our secondary aim was to continue evaluating the compliance (C) of the tissues in porcine GJ models.

SUBJECTS AND METHODS

Porcine GJ models were created using porcine stomachs and segments of small intestines acquired from freshly sacrificed swine. Each GJ model was created using one animal’s stomach and small bowel segment. Tissues from a total of 22 animals meant for the food industry were used for these experiments. The age of the swine used in these experiments was between 6 months and 1 year. They were of hybrid breed (Large White and Landrace breeds) and were freshly sacrificed for the industrial purposes. Stomachs and small intestinal segments were collected immediately following sacrifice and jet-washed through the lumen to discard intra-luminal contents. The specimens were kept refrigerated at 4°C till time of use for the experiment, which was within 24 h of sacrifice, with an average time of approximately 16 h.

The gastric pouch was fashioned replicating our current clinical practice. A linear surgical stapler was used for pouch creation-Endo GIA™ (Medtronic™, Fridley, MN, USA). Care was taken to use one stapler handle per specimen. The lesser curve of the stomach was dissected 5–6 cm distal to the gastroesophageal junction (GOJ). Care was taken to remove all fat from the gastric wall to avoid stapler malfunction due to increased thickness. The pouch was created with one horizontal and two vertical cartridges-Tri-staple™ Purple 60 mm cartridges (3, 3.5 and 4 mm inner to outer rows) (Medtronic™, Fridley, MN, USA) in all the models. In a few models, an extra vertical cartridge Tri-staple™ Purple 45 mm was used to completely divide the gastric pouch from the stomach remnant. During pouch creation, the pouch was calibrated loosely over a 34 Fr Bougie (Argyle™ Covidien™ Suction Tube) (Covidien™, Fridley, MN, USA). A 15-cm long small intestinal segment was prepared for the creation of GJ anastomosis, with both ends stapled off using Tri-staple™ Tan 60 mm cartridges (2, 2.5 and 3 mm inner to outer rows), except in the CSA group, where the proximal end was stapled off following the creation of GJ as per the standard clinical technique. The final prepared model appeared, as shown in Figure 1 before the creation of GJ anastomosis.

Gastric pouch and small intestinal thickness were recorded using a tissue thickness measuring device (Mitutoyo QEZ767 No. 2050S; Mitutoyo Corp., Kawasaki, Japan),
Sahloul, et al.: Burst pressure in GJ anastomosis using powered stapler

at the centre of the gastric pouch and small intestinal segment (both anterior and posterior walls) for each GJ model. The GJ anastomosis (the technique of anastomosis is described later) was calibrated over a 34Fr Bougie, and then, the oesophageal end of the gastric pouch was stapled off at approximately 10 cm from the GOJ using Tri-staple™ Purple 60 mm cartridge.

**Variables measured**

For all models, the following measurements were performed – burst pressure (BP) and total volume (TV). These measurements were obtained as per the protocol below. A 14G (Orange) intravenous (IV) catheter (BD Venflon™ Pro Safety Shielded IV Catheter) was inserted into the oesophageal end of the gastric pouch, via which sequential infusions of methylene blue-coloured saline (1:100 dilution) were made. The small intestinal end of the GJ model was connected to an arterial cannula (GRIP-LOK® BD Arterial Cannula with FLOSWITCH® Securement) attached to a manometer through an invasive arterial blood pressure monitoring set (Edwards® TruWave™ Single Disposable Pressure Transducer). The manometer was reset before recording the measurements for each specimen. A series of infusions were conducted, each of 20 mL over a period of 5 s, till a leak was noticed. Pressure readings were recorded for each infusion cycle, and at the point of leak, the latter represented the BP. The volume infused till point of leak was the TV. The site of leak was also recorded.

Experiments were conducted in batches. This was due to logistic purposes since it was only possible to process between 8 and 10 models in one experiment whilst allowing for 1–2 models being discarded for technical/other reasons (described in results).

**First experiment**

The first experiment was conducted to investigate the effect of the direction of stapler firing on the mechanical integrity of GJ anastomosis. Ten porcine GJ models were created, divided into two groups, manual LSA (mLSA) 1 and 2. The GJ anastomosis was performed using Purple 45 mm cartridges in all models. In the mLSA 1 group, the cartridge was fired from the stomach side, i.e., the cartridge (soft, thick jaw of the stapler) was introduced into the gastrotomy and the anvil (thin, metal jaw of the stapler) was introduced into the enterotomy, and vice versa in the mLSA2 group. The resultant gastro-enterotomies were then suture closed using 2/0 monofilament absorbable suture material (Monocryl®, Ethicon™, Somerville, New Jersey, USA) in two layers as per our standard clinical practice.

**Second experiment**

The second experiment was then performed to compare CSA versus HSA. Eight porcine GJ models were fashioned and divided into two groups. In the CSA group, following the preparation of the gastric pouch and small intestinal segment, the stapler's anvil was introduced through the oesophageal end and the circular stapler DST SERIES™ EEA™ (Medtronic™, Fridley, MN, USA) 31 mm (4.8 mm staples, green cartridge) was introduced via the proximal end of the intestinal segment. Then, the proximal end of the intestinal segment was stapled off using Tan 60 mm cartridge as per the protocol. In the HSA group, a two-layer GJ anastomosis was performed in each model using 2/0 monofilament absorbable suture material as per our current clinical technique.

**Third experiment**

The third experiment was conducted to evaluate the newly introduced powered linear surgical stapler (Signia™ Medtronic™, Fridley, MN, USA). Four porcine GJ models were fashioned using the Signia™ staple as described in the first experiment. With regard to the anastomosis, the cartridge, Purple 45 mm, was fired from the stomach side, i.e., the cartridge (soft, thick jaw of the stapler) was introduced into the gastrotomy and the anvil (thin, metal jaw of the stapler) was introduced into the enterotomy since we had previously published that anastomotic integrity was superior in the mLSA1 group as compared to mLSA2. The resultant gastro-enterotomies were suture closed using a 2/0 monofilament absorbable suture material in two layers.

All the models were inspected thoroughly before BP testing to detect any technical errors that could affect the testing process and the results. Figure 2 shows the resultant GJ model from each group before testing.
Data are presented as mean (standard deviation). Continuous variables were compared using the Mann–Whitney U-test or the Kruskal–Wallis test. Compliance (C) was calculated using the equation \( C = \Delta TV/\Delta BP \). Least squares fitting was performed using a software within the MatLab® programming environment. \( P < 0.05 \) was considered statistically significant.

**Ethical considerations**

All procedures involving animal tissues were processed in accordance with the University hospitals of Leicester and University Hospitals Birmingham NHS Foundation Trusts’ policies for the use of animal tissues for training and research purposes in accordance with the National Centre for the Replacement, Refinement and Reduction of Animals in the Research guidelines. All porcine tissues used in the study were collected and processed in accordance with the Animal By-products Regulations 2005 (Regulation EC no. 142/2011).

**RESULTS**

Five models were excluded, one from each group, at the stage of model preparation before BP testing due to technical errors, for example, defects in the wall of the stomach near the GOJ and the pylorus; hence, they had no effect on the results. Collective data from previously published experiments\[^{13,14}\] were collated, analysed and compared to the newly tested powered LSA (pLSA). Descriptive statistical data are demonstrated in Table 1.

The site of leak from the tested GJ models varied in each group. In the mLSA and pLSA group, it was from the anastomotic staple line (away from the sutured enterotomies). For the CSA group, it was from the CSA [Figure 3], and in the HSA group, it was at the suture line at the site of needle punctures.

The mean pouch and intestinal thickness for all five groups were 3.66 ± 3.37 mm (\( P = 0.18 \), Kruskal–Wallis test) and 0.47 ± 0.14 (\( P = 0.10 \), Kruskal–Wallis test), respectively.

The mean TV from all five groups was 78.88 ± 29.33 mL (\( P = 0.23 \), Kruskal–Wallis test). The mean BP from all five groups was 15.82 ± 6.84 mmHg, and this was found to have statistically significant difference among the groups; \( P = 0.03 \) (Kruskal–Wallis test). The mean value of C in all five groups was 5.78 ± 3.37 (\( P = 0.08 \), Kruskal–Wallis test).

Table 1: Descriptive statistical data for all groups

| Group   | Variable                  | Minimum | Maximum | Mean±SD      |
|---------|---------------------------|---------|---------|--------------|
| mLSA1   | Pouch thickness (mm)      | 3.6     | 4.9     | 4.2±0.61    |
|         | Bowel thickness (mm)      | 0.2     | 0.6     | 0.4±0.18    |
|         | TV (mL)                   | 55      | 65      | 60±4.08     |
|         | BP (mmHg)                 | 15      | 25      | 18±4.69     |
|         | C (mL/mmHg)               | 2.20    | 4.63    | 3.5±0.88    |
| mLSA2   | Pouch thickness (mm)      | 3.8     | 4.4     | 4.08±0.28   |
|         | Bowel thickness (mm)      | 0.28    | 0.42    | 0.37±0.06   |
|         | TV (mL)                   | 40      | 60      | 51.25±8.54  |
|         | BP (mmHg)                 | 8       | 15      | 11±2.94     |
|         | C (mL/mmHg)               | 3.64    | 6.25    | 4.98±1.43   |
| CSA     | Pouch thickness (mm)      | 2.07    | 3.66    | 2.73±0.83   |
|         | Bowel thickness (mm)      | 0.44    | 0.62    | 0.52±0.93   |
|         | TV (mL)                   | 96      | 130     | 113.67±17.04|
|         | BP (mmHg)                 | 17      | 27      | 20.33±5.78  |
|         | C (mL/mmHg)               | 3.56    | 7.65    | 5.89±2.15   |
| HSA     | Pouch thickness (mm)      | 2.68    | 4.93    | 3.44±1.28   |
|         | Bowel thickness (mm)      | 0.45    | 0.69    | 0.61±0.14   |
|         | TV (mL)                   | 90      | 115     | 105±13.23   |
|         | BP (mmHg)                 | 7       | 14      | 9.67±3.79   |
|         | C (mL/mmHg)               | 7.86    | 14.38   | 11.69±3.41  |
| pLSA    | Pouch thickness (mm)      | 3.2     | 4.1     | 3.51±0.51   |
|         | Bowel thickness (mm)      | 0.42    | 0.6     | 0.53±0.09   |
|         | TV (mL)                   | 60      | 120     | 80±3.64     |
|         | BP (mmHg)                 | 13      | 32      | 21±5.85     |
|         | C (mL/mmHg)               | 3.33    | 4.62    | 3.89±0.65   |

mLSA: Manual linear stapled anastomosis, CSA: Circular stapled anastomosis, HSA: Hand-sewn anastomosis, pLSA: Powered linear stapled anastomosis, TV: Total volume, BP: Burst pressure, C: Compliance, SD: Standard deviation

Figure 2: Final gastrojejunostomy models from all groups before testing. (mLSA: Manual linear stapler anastomosis, HSA: Hand-sewn anastomosis, CSA: Circular stapler anastomosis and pLSA: Powered linear stapler anastomosis)

Figure 3: The final gastrojejunostomy model after burst pressure testing (a) from the circular stapled anastomosis group showing site of leak (b)
groups, mLSA1, mLSA2, CSA and pLSA, 18, 11, 20.33 and 21 mmHg, respectively, was higher than that of the HSA group, 9.67 mmHg. This difference was found to be statistically significant (\( P = 0.03; \) Kruskal–Wallis test). Despite the higher BP recorded in the pLSA group, 21 mmHg, when compared to that of the mLSA1, 18 mmHg, the difference was found not to be statistically significant (\( P = 0.72, \) Mann–Whitney U-test). Figure 4 demonstrates BP differences among all five groups.

Calculated C values for all the five groups, mLSA1, mLSA2, CSA, HSA and pLSA were 3.5, 4.98, 5.89, 9.67 and 3.82, respectively. The difference in C between the groups was found to be not statistically significant (\( P = 0.08, \) Kruskal–Wallis test).

**DISCUSSION**

Gastric bypass (Roux-en-Y/one anastomosis) is one of the most commonly performed bariatric procedures worldwide. It is also the predominantly performed revisional bariatric procedure,[5,6] with the technique of the GJ anastomosis being one of the key steps of the procedure.[8] With the rapid evolution of bariatric surgery, comes the development and improvement of surgical instruments, including surgical staplers.[3] Surgical staplers have proven to be time efficient and yielding comparable results with regard to leak rates when compared to the best hand-sewn technique in intestinal anastomoses.[16,17] However, this cannot be generalised to all gastrointestinal anastomoses due to the differences in tissue characteristics.[3]

Anastomotic leaks following bariatric surgery are considered to be one of the most morbid complications with major impact on the patient’s health and the health system.\[18,19\] The incidence of leak following RYGB ranges between 0.1% and 5.6%,\[20\] with the underlying avoidable cause of an early leak is believed to be of mechanical origin.\[15,20\] There is limited evidence in surgical literature, especially bariatric literature, with regard to mechanical factors affecting anastomotic leaks.

We have conducted a series of laboratory-based experiments to investigate the mechanical aspects of the different techniques currently in use to fashion the GJ anastomosis, including the recently developed powered stapler. This is of relevance not only to bariatric surgery, but also to a range of minimally invasive procedures involving GJ anastomosis. Although the use of the powered stapler is increasing, scientific evidence regarding its efficacy is lacking.

The current study describes a standardised and reproducible way for the evaluation of surgical staplers in an *ex vivo* setting, not just in bariatric surgery, but a methodology that can be implemented across surgical subspecialties.

In the first experiment, we studied the effect of the direction of stapler firing, i.e., when the cartridge (thick plastic part of the stapler cartridge jaws) introduced into the gastroscopy and the anvil (thin metallic part of the staple cartridge jaws) into the enterotomy in Group mLSA1 and vice versa in Group mLSA2. To our knowledge, this has never been addressed in the bariatric literature. It also has the potential to change surgical practice, since majority of the surgeons introduce the cartridge into the small bowel rather than into the gastric pouch.\[21\] Kimura *et al.* described a similar experiment on porcine oesophagojejunostomy models using open surgical staplers.\[22\] The authors of this study had concluded that firing the surgical staple from the thinner side, i.e., the small bowel, is better as it yielded higher BP on testing. This was in contradiction to our experiment where we demonstrated that firing the staple from the gastric side, i.e., Group mLSA1, yielded higher BP when compared to Group mLSA2. However, the staple used in the study by Kimura *et al.* was different to our as were the tissues (oesophagus vs. stomach), which thus raises the possibility that tissue mechanics during the stapling process maybe important in the pathogenesis of an anastomotic leak.

In the second experiment, we reported on CSA and HSA.\[8,23\] These anastomotic techniques have not been previously compared in a laboratory setting. At the end of the first two experiments, we were thus able to conclude that mechanical stapling provided better anastomotic integrity as compared to HAS.\[14\] With regard to literature, no difference in anastomotic leak rates has been demonstrated between
these techniques. However, it is important to note that the current study was conducted in an experimental setting and thus clinical factors that may affect leak rates did not apply. During the final set of experiments, we evaluated the newly introduced powered linear stapler (Signia™) as per our standardised protocol for testing GJ anastomosis.

On collective analysis of the statistical data gathered from all experiments, tissue characteristics, i.e., gastric pouch and small bowel thickness, were proven to be not statistically significant across the models \((P = 0.18\) and 0.47, respectively). Mean TV and C in all groups were 78.88 ± 29.33 mL and 5.78 ± 3.37 mL/mmHg, respectively. There was no statistical difference among all groups on analysis of C. These findings confirm standardisation of our techniques across the experiments with similarity in tissue characteristics.

With regard to BP, there was a statistically significant difference between the models \((P = 0.03,\) Kruskal–Wallis test), with the highest BP being reported in the pLSA Group 21 mmHg ± 9.85 and the least in the HSA Group 9.67 mmHg ± 3.79. Arranged in a descending order of BP, pLSA, CSA, mLSA1, mLSA2 then HSA; thus, concluding that mechanical anastomosis yielded a better anastomotic integrity than hand-sewn technique. On further sub-analysis comparing BP values between the mechanical anastomosis groups (mLSA, CSA and pLSA), the difference failed to reach a statistical significance. Furthermore, on comparing mLSA1 and pLSA, i.e., comparing manual to powered with the same direction of stapler firing, i.e., cartridge in the gastric pouch, mean BP value recorded with the pLSA was higher; however, this too did not reach statistical significance.

Tissue compliance is another factor in the pathophysiology of anastomotic leak that merits further research, as it has been previously implicated in other gastro-intestinal anastomoses. Given the contradictions between the results of our experiments and those by Kimura et al., tissue characteristics probably play a major role in the pathogenesis of anastomotic leak. Compliance is a measurement that may enable us to understand and quantify tissue properties in the future. In the current study, there was no statistically significant difference in the compliance across the models thus confirming that the tissue stretch dynamics were uniform across all samples, which may in turn depend on the type of tissue and tissue processing variables.

**Study limitations**

Standardisation of the protocol was challenging mainly due to the fact that the porcine tissues used were acquired from swine sacrificed for the food industry. Reassuringly the statistical analysis of tissue characteristics, i.e., compliance, revealed no statistically significant difference among all groups. More importantly, pouch construction was uniform since there was no statistically significant difference in TVs of the pouch-small bowel complex.

The time interval between the sacrifice of the animal and the experiment was <24 h in all cases. The tissues had been uniformly refrigerated until the time of experiment and cold chain was maintained. However, we accept that refrigeration might have affected tissue characteristics, although uniformly across all the groups. Furthermore, comparison of tissue compliance between these experiments did not reveal any statistically significant differences in the tissue stretch characteristics.

The technique used for HSA (2 layer, continuous, 2/0 PDS) in these experiments is a true representation of our clinical technique. Although a leak was noted in HSA at much lower BPs, the clinical relevance of these findings needs to be examined in a separate study.

This was an investigator funded study accounting for the small number of porcine GJ models tested. However, this was also limited by the number of samples that could be processed in a day whilst maintaining standards across the models and experiments.

**CONCLUSION**

Mechanical GJ anastomoses, either mLSA, CSA or pLSA produced a higher BP as compared to HSA thus translating into a better anastomotic integrity.
The newly introduced powered linear stapler demonstrated the highest BP when compared to other anastomotic techniques. This may indicate superiority of the powered linear stapler. However, these differences did not reach statistical significance. Further studies are required to investigate the newly introduced powered linear stapler in the clinical setting.

Acknowledgement

MS and RS conceived the research idea. MS, SK and LG were responsible for conducting the experiments. MS and RS analysed the collected data and performed literature search. RS and CL performed all the statistical analysis for the study. KM, ARD and RS were responsible for results interpretation. All the authors were involved in writing the manuscript and approved the final version before submission for publication.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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