Proceedings of the 2023 Design of Medical Devices Conference
DMD2023
April 17-19, 2023, Minneapolis, MN, USA

DMD2023-8985

A COMPARISON OF THE PRESSURE FAILURE OF TWO COLORECTAL ANASTAMOSES STAPLING TECHNIQUES

Youssef Fahmy
Howard R. Hughes College of Engineering, University of Nevada, Las Vegas
Las Vegas, NV, USA

Mohamed Trabia, PhD
Howard R. Hughes College of Engineering, University of Nevada, Las Vegas
Las Vegas, NV, USA

Brian Ward, MD, PhD
Kirk Kerkorian School of Medicine, University of Nevada, Las Vegas
Las Vegas, NV, USA

Lucas Gallup
Howard R. Hughes College of Engineering, University of Nevada, Las Vegas
Las Vegas, NV, USA

Whitney Elks, MD
Kirk Kerkorian School of Medicine, University of Nevada, Las Vegas
Las Vegas, NV, USA

ABSTRACT

Anastomotic leakage (AL) is a serious complication that effects thousands of patients undergoing colorectal surgery annually. Stapling is generally used to perform anastomoses. Two common anastomosis techniques are the End to End (EE), and End to Side (ES). Currently there is no experimental approach to compare the effectiveness of these two techniques against AL. This work proposes an ex-vivo experimental setup of burst testing of anastomoses using porcine tissues. Twelve pigs were used with three specimens harvested from the colon of each of them: EE, ES, and a control specimen. Failure of the anastomoses were monitored, and the corresponding leakage pressures were recorded. Preliminary results indicated that ES led to higher strength than EE.

Keywords: Colorectal Anastomosis, Anastomotic Leakage, Burst Pressure, Stapled Anastomosis.

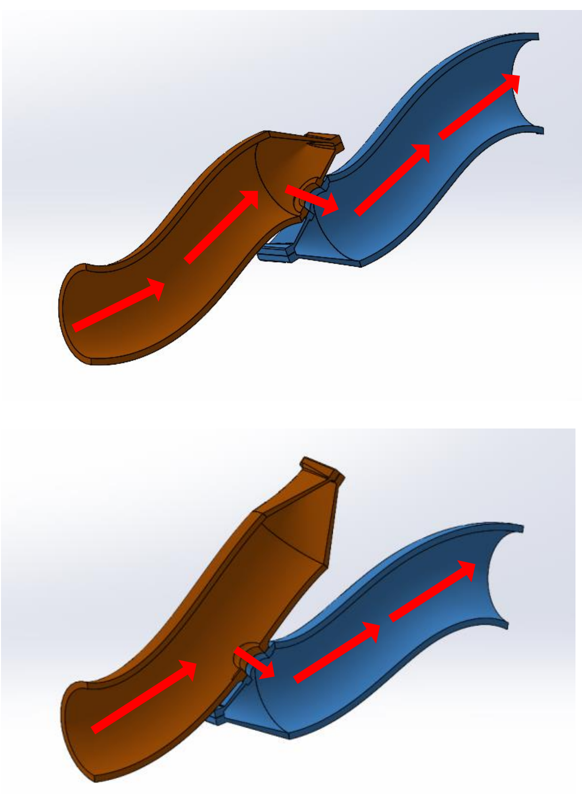
1. INTRODUCTION

Over 320,000 patients undergo colorectal surgery in the United States every year [1], and require reconstruction of the colon by reconnecting the proximal and distal ends of the intestine. Unfortunately, it has been reported that up to 29% of those who go through colorectal anastomosis suffer from anastomotic leakage (AL) [2]. AL leads to increased patient morbidity and mortality rates. Additionally, AL has a tremendous economic impact; it is estimated that for every 1000 patients suffering from AL, $28.6 million additional costs are incurred in addition to 9,500 days of additional hospitalization [1].

Several techniques are used for colorectal anastomosis including sutures and staples. However, stapled anastomosis is currently more commonly used, due to repeatability and reduction in operation time in comparison to sutures [3]. While multiple stapled anastomosis methods were developed [4]–[6], surgeons typically use either End to End (EE) or End to Side (ES) stapled anastomoses for colorectal anastomoses. The main difference between these two techniques is in the distance to the attachment of the distal and proximal ends of the reconstructed colon. Both techniques start with sealing the openings of the tract using linear staples followed by circular staples to form the anastomosis. In EE anastomosis, circular staple line occurs close to the linear staple line while in ES anastomosis the circular staples are placed farther away from the linear staple line, creating a pocket on the proximal end of the circular staples. FIGURE 1 shows schematics of these two approaches. Surgeons typically test the integrity of an anastomosis by pumping pressurized air through the colon and monitor evidence of leakage by looking for bubbles.

A recent review indicated that there were fewer cases of AL in ES compared to EE [7]. Unfortunately, there is a limited understanding of the reasons behind this observation. Due to the difficulties associated with harvesting and testing human colorectal tissues, researchers conducted relevant testing using porcine tissues because of their relative structural and general physiological functionality. The following is a review of relevant studies that were conducted using porcine colons. For instance, in-vivo experiments were conducted on eighteen live pigs to compare EE to compression anastomosis [8]. These pigs were monitored over the course of two weeks. The results showed that EE stapled anastomoses were able to withstand higher burst pressures than compression anastomoses. Another research team investigated buttressed staple lines in ex-vivo models on three pigs [9]. Results showed almost double the strength in buttressed staple lines in comparison to non-buttressed staple lines. An ex-vivo experimental model to compare different techniques of anastomosis was presented, [10], including stapled anastomosis in single-stapled double purse string, double stapled, EE linear staple, EE circular staple, and EE circular staple with sutured reinforcement. Using fifteen pigs, each of these techniques was tested using six specimens. The results showed that EE reinforced with sutures held highest pressure. EE anastomosis leakage pressure was evaluated using six specimens, each taken from a separate pig in an ex-vivo model [11]. A Finite Element Model (FEM) was developed to simulate the interaction of the tissues and the staples of this experiment. The results showed that further investigation is needed to understand the interaction of the tissue and the anastomosis.

(a)



(b)

FIGURE 1: *Two possible approaches for stapled colorectal anastomosis: (a) End to End (EE) Connection, (b) End to Side (ES) Connection*

This research proposes to examine the following hypothesis: circular staple line is where anastomotic leakage most likely occurs. Additionally, this research is attempting to understand two common anastomosis techniques: End to End (EE), and End to Side (ES) differ in terms of leakage pressure. To address these issues, a leakage experiment was developed using colorectal pig tissues while closely mimicking the process used in surgeries.

2. MATERIALS AND METHODS

2.1 Tissue Preparation

The experiments were conducted on porcine colon specimens harvested from a local farm. Harvested pigs (n = 12) were 3–8-month-old; all of them were of the F1 cross-species (a Yorkshire and Landrace mix). The entire gastrointestinal tract was collected immediately post-mortem and taken to the lab to prepare for experimentation, FIGURE 2. The freshly harvested colon tract was drained of all the luminal content and flushed. Three adjacent segments were collected from each colon and three testing specimens were made: EE, ES, and a control. A tubular section was used for the control specimen, which provided baseline pressure comparison for each tested colon.

FIGURE 2: *HARVESTED PORCINE COLORECTAL TRACT*

2.2 Preparation of Anastomotic Staples

Preparation of anastomoses started by recording the specimens' tissue thickness and average tract diameter. PROXIMATE® Regular Tissue Linear Cutter, 75mm (Ethicon, Inc. NJ, USA) [12] were used to prepare the EE and ES specimens. The specimens were centered on the cutter, and a linear staple line is applied sealing these two ends. Once stapled, a linear cutter split the specimen into two halves. Following this step, Ethicon® Circular Stapler Curved (ILS), 21 mm diameter staples[13] (Ethicon, Inc. NJ, USA) were used to perform the circular anastomosis on the specimens. In EE, the circular anastomosis would occur 2 cm away from the linear staple line while in ES the circular anastomosis would occur 2 cm away from the linear staple line at the distal end and 8 cm away from the linear staple line at the proximal end creating a pocket. FIGURE 3 shows anastomosed colorectal tissues.

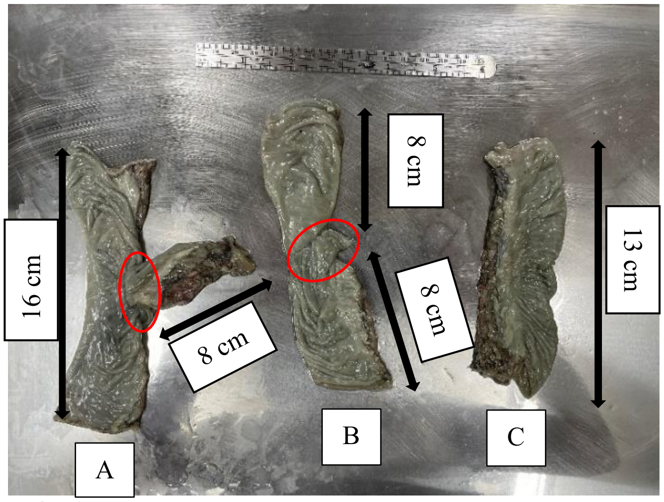


FIGURE 3: *ANASTAMOSED TISSUES, (A) ES, (B) EE, (C) CONTROL SPECIMEN. CIRCULAR STAPLED ANASTOMOSES ARE SHOWN USING RED ELIPSE*

2.3 Burst Experiment

To identify the burst pressure for each of the anastomosis method, an ex-vivo model was designed to inflate specimens at a constant rate while monitoring any indications of failures, FIGURE 4. To simulate the surgical procedure as closely as possible the experiment was fully submerged in a temperature-controlled water tank (set to 38 °C to simulate internal body temperature). To simulate inner body pressure, specimens were placed under approximately 100 mm of water corresponding to the pressure of 0.93 kPa [14]. The two unstapled distal and proximal ends of the colon section were connected to inlet and outlet adapters. Using a snap-grip hose clamps, an air-tight seal was created without damaging the tissues. To inflate the specimens, a peristaltic pump was used to pump air within the system at a given rate of 50mL/min. A pressure transducer was used at the outlet to measure the pressure in the system. To ensure that the tissue was not stretched before the start of inflation, a load cell (Interface Inc. AZ, USA) was placed behind the inlet adapter, and the linear stage was manually adjusted until the tissue experienced approximately 3 N in tension**.** Additionally, two cameras were placed on both sides of the tank to monitor the specific instant of failure and its location.

Failure of the EE and ES specimens was defined as the instant at which the anastomosis leaked, and air-bubbles were observed.

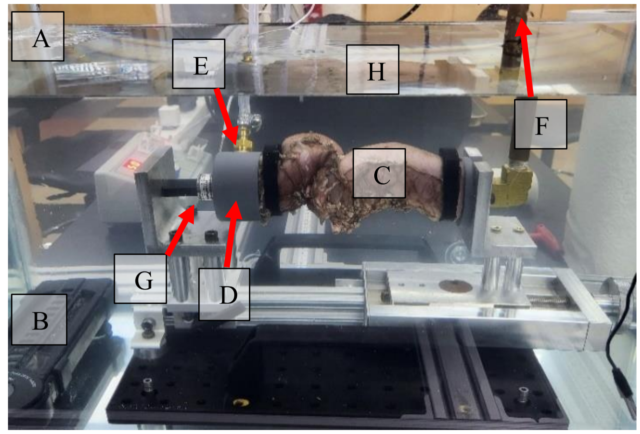


FIGURE 4: *EXPERIMENTAL SETUP FOR BURST TESTING, (A) WATER TANK, (B) TEMPERATURE CONTROLLER, (C) SPECIMEN, (D) ADAPTER AND CLAMP, (E) AIR INPUT FROM PUMP, (F) PRESSURE TRANSDUCER, (G) LOAD CELL, (H) CAMERA*

3. RESULTS AND DISCUSSION

The tested colorectal tissues were reasonably consistent, with a diameter and thickness of 46.6 ± 4.9mm and 0.9 ± 0.1mm, respectively. The observed mode of failure of each anastomosis method in each pig was recorded, as seen in TABLE 1.

TABLE 1: *DIFFERENTIAL PRESSURE AT LEAKAGE & MODES OF FAILURE IN EE & ES ANASTIMOSIS, & CONTROL GROUP PRESSURE*

Pig #	EE (kPa)	ES (kPa)	Control Specimen (kPa)
1	Clamp (0.13)	Circular (0.55)	(2.61)
2	Linear (0.82)	Circular (0.62)	(0.87)
3	Circular (0.11)	Circular (0.33)	(0.56)
4	Circular (0.50)	Circular (0.58)	(2.18)
5	Circular (0.19)	Circular (0.68)	(1.19)
6	Circular (1.32)	Circular (1.50)	(1.98)
7	Circular (0.60)	Circular (0.53)	(2.13)
8	Circular (0.26)	Linear (0.29)	(3.29)
9	Circular (0.71)	Circular (0.23)	(0.73)
10	Circular (0.92)	Linear (0.80)	(4.50)
11	Tissue Failure (0.35)	Circular (1.30)	(1.92)
12	Circular (0.61)	Circular (0.74)	(6.25)

It was observed that the control specimens were consistently able to withstand higher pressures than both anastomosis methods. The results also show that out of twenty-four anastomosed specimen, nineteen failed at the circular staple line, three at the linear staple line, and one failed due to improper clamping. The three cases in which the linear staple connection failed before the circular ones were not biased toward either method of anastomoses. In one case, the tissues failed before leakage was observed. For the seven pigs where failure took place at the circular staple lined, leakage pressures were compared across both methods of anastomosis, showing a large pressure variation: 0.58 ± 0.40 kPa and 0.66 ± 0.40 kPa for EE and ES respectively, FIGURE 5. The results showed that five pigs exhibited higher failure pressures for ES compared to EE, which indicates that there could be a validated trend that ES can withstand higher pressure in comparison to EE. Overall, the results show that the experimental setup was successful in achieving the goal of this research.

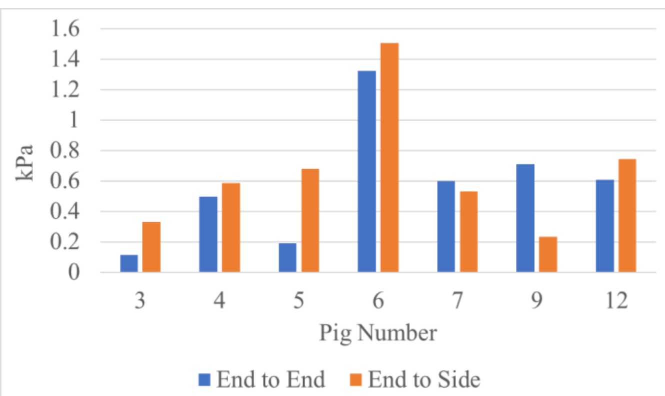


FIGURE 5: *COMPARISON OF EE AND ES PRESSURE FAILURES*

Statistical analysis was conducted using a Two-Tailed unpaired T-test. The results showed that the two-tailed P value is equal to 0.7148. The mean of EE minus ES equals to -0.080 and the 95% confidence interval of this difference is from -0.5458 to 0.3858. These results indicate that the data has no statistical significance in the burst pressures of EE versus ES, which can be attributed to the small sample size and the high standard deviation of the measurements.

4. CONCLUSION

It was hypothesized that the circular staple line may be the point at which the anastomosis is the weakest and therefore anastomotic leakage occurs. This hypothesis was clearly proven based on the current results obtained from an air pressure leakage experiment that was developed as a part of this research using colorectal pig tissues and mimicking actual testing done in surgeries. Additionally, this study aimed to compare the effectiveness of two common anastomosis techniques: End to End (EE), and End to Side (ES). Preliminary results show a general trend of higher leakage pressures in the case of ES in comparison to EE. Further testing using a larger number of specimens as well as the development of an accurate Finite Element Analysis will be needed to further identify the mechanisms of anastomotic leakage.

ACKNOWLEDGEMENTS

The authors would like to recognize MW CTR-IN Program and associated award from the National Institute of General Medical Sciences, National Institutes of Health under grant number U54 GM104944 for the financial support provided for this research. We would also like to acknowledge the Ethicon Endo-Surgery, Inc. Research Support MIP-2021-07, for donating the anastomosis stapler and staples used in the experiments. University of Nevada, Las Vegas, Troesh Center for Entrepreneurship, and Innovation, NSF I-Corps for financial support. Las Vegas Livestock generous donation of colorectal tissues is much appreciated. Dr. Mary Froehlich provided essential help with sample preparation at the early stages of this research. Mr. Lucas Abreu-Romero assisted in the CAD modeling of the experimental setup.

REFERENCES

[1] J. Hammond, S. Lim, Y. Wan, X. Gao, and A. Patkar, “The Burden of Gastrointestinal Anastomotic Leaks: An Evaluation of Clinical and Economic Outcomes,” *Journal of Gastrointestinal Surgery*, vol. 18, no. 6, pp. 1176–1185, 2014, doi: 10.1007/s11605-014-2506-4.

[2] G. Brisinda *et al.*, “End-to-end versus end-to-side stapled anastomoses after anterior resection for rectal cancer,” *J Surg Oncol*, vol. 99, no. 1, pp. 75–79, Jan. 2009, doi: 10.1002/jso.21182.

[3] C. B. Neutzling, S. A. Lustosa, I. M. Proenca, E. M. da Silva, and D. Matos, “Stapled versus handsewn methods for colorectal anastomosis surgery,” *Cochrane Database of Systematic Reviews*, Feb. 2012, doi: 10.1002/14651858.cd003144.pub2.

[4] M. Machado, J. Nygren, S. Goldman, and O. Ljungqvist, “Similar Outcome after Colonic Pouch and Side-to-End Anastomosis in Low Anterior Resection for Rectal Cancer: A Prospective Randomized Trial,” *Ann Surg*, vol. 238, no. 2, pp. 214–220, 2003, doi: 10.1097/01.sla.0000080824.10891.e1.

[5] C. A. Maurer, K. Baselland, B. Kern, and C. Basel, “A new surgical concept for rectal replacement after low anterior resection: the transverse coloplasty pouch,” 2001. [Online]. Available: https://www.researchgate.net/publication/11627288

[6] R. Parc, E. Tiret, P. Frileux, E. Moszkowski, and J. Loygue, “Resection and colo-anal anastomosis with colonic reservoir for rectal carcinoma,” *British Journal of Surgery*, vol. 73, no. 2, pp. 139–141, 1986, doi: 10.1002/bjs.1800730223.

[7] T. McKechnie, S. Sharma, R. Daniel, and C. Eskicioglu, “End-to-end versus end-to-side anastomosis for low anterior resection: A systematic review and meta-analysis of randomized controlled trials,” *Surgery*

(United States), vol. 170, no. 2. Mosby Inc., pp. 397–404, Aug. 01, 2021. doi: 10.1016/j.surg.2020.12.030.

[8] D. Stewart *et al.*, “Validation of the NITI endoluminal compression anastomosis ring (EndoCAR) device and comparison to the traditional circular stapled colorectal anastomosis in a porcine model,” *Surg Innov*, vol. 14, no. 4, pp. 252–260, 2007, doi: 10.1177/1553350607312241.

[9] K. C. Norbury, D. v. Kilpadi, B. A. Collins, and M. R. Cunningham, “Burst strength testing of porcine intestinal anastomoses following negative pressure therapy,” *Surg Innov*, vol. 19, no. 2, pp. 181–186, 2012, doi: 10.1177/1553350611418254.

[10] T. Ikeda *et al.*, “Evaluation of techniques to prevent colorectal anastomotic leakage,” *Journal of Surgical Research*, vol. 194, no. 2, pp. 450–457, 2015, doi: 10.1016/j.jss.2014.11.045.

[11] L. Y. Ai, S. C. Ge, J. J. Xu, M. Y. Li, L. Mao, and C. L. Song, “Finite element analysis and experiment on large intestine end-to-end anastomosis,” *Frontiers in Biomedical Devices, BIOMED - 2018 Design of Medical Devices Conference, DMD 2018*, vol. 3, pp. 7–9, 2018, doi: 10.1115/DMD2018-6832.

[12] Ethicon, “TLC75.” https://www.ethicon.com/na/epc/code/tlc75?lang=en-default (accessed Nov. 14, 2022).

[13] Ethicon, “ECS21A.” https://www.ethicon.com/na/epc/code/ecs21a?lang=en-default (accessed Nov. 14, 2022).

[14] B. L. de Keulenaer, J. J. de Waele, B. Powell, and M. L. N. G. Malbrain, “What is normal intra-abdominal pressure and how is it affected by positioning, body mass and positive end-expiratory pressure?,” *Intensive Care Medicine*, vol. 35, no. 6. pp. 969–976, Jun. 2009. doi: 10.1007/s00134-009-1445-0.

[15] F. Beer, R. Johnston, J. DeWolf, and D. Mazurek, *Mechanics of Materials*.