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# A New Approach to the Laparoscopic Double Stapling Technique: Exploration and Reinforcement of Weak Points

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#### Authors' contributions

This work was carried out in collaboration among all authors. Authos MK, YK, AM helped in conception and design the study. Authors MK, TN, SN performed experimental and operative work. Author MK did sample analysis and interpreted the data. Author MK wrote original draft of the manuscript. Authors MK, YK did critically revised the manuscript. All authors read and approved the final manuscript.

#### Article Information

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### ABSTRACT

**Background:** Anastomotic leakage is a serious complication in colorectal surgery, often associated with higher morbidity and mortality. Even with advances in medical technology and devices, the rates of anastomotic leakage is not on downward trend. We describe our experimental and clinical validation of our method to overcome the weakness of the double stapling technique, especially the intersecting staple lines.

**Methods:** Experimentally, we conducted double stapled anastomosis with pig small intestines. In order to verify pressure resistance, the anastomosis was tested and compared with that formed by a conventional stapler and a reinforced cartridge preattached to a Neoveil sheet. Additionally, during the anastomosis performed by the circular stapler, both ends of the Neoveil sheet were grasped by forceps, and the Neoveil sheet was pulled tight to fit the anastomotic surface. The burst pressure of the anastomosis was recorded. Clinically, we used a reinforced cartridge for rectal surgery performing a low anterior resection and verified its efficacy and safety.

**Results:** Unlike a conventional stapler, our methods with the use of a reinforced cartridge showed no leakage from the intersecting staple lines. Clinically, our method has been used for 20 patients without complications, including leakage and bleeding.

**Conclusion:** The addition of reinforcing material to the linear stapler should lead to increased strength of the anastomosis. We believe that a double stapling anastomosis that uses our method for the intersection lines provides increased safety and security and thereby should lead to a reduced rate of suture failure after rectal resection.

Keywords: Double stapling technique; anastomotic leakage; bioabsorbable material; intersection; pressure resistance.

#### **1. INTRODUCTION**

Among the complications of rectal resection, suture failure is the most common, and can lead to serious problems. In addition, complications have been reported to affect outcomes. The reported incidence of clinical leakage after rectal resection for rectal cancer varies from 6.3%% to 13.7% [1.2]. Several risk factors for anastomotic leakage have been reported, including advanced age, male gender, smoking, diabetes, obesity, preoperative chemotherapy, and tumor location [3,4]. In addition to these patient factors that contribute to anastomotic leakage, problems associated with the surgical technique and surgical equipment may be involved. For example, there are many reports that a large number of staples or a large-diameter circular stapler used for rectal transection increase the rate of anastomotic leakage.

Laparoscopic rectal resection has become widely accepted, and the double stapling technique (DST), which uses both linear and circular staplers, has become common for reconstruction. This simple method can minimize stool contamination and allows complete anastomosis with the use of staplers only. However, some weaknesses have been reported. Anastomosis by the DST uses a linear stapler to transect the rectum. The resulting ends of the bowel are anastomosed with a circular stapler, which leads to removal of the central staples placed by the linear stapler, and the formation of most of the anastomosis by the staples from the circular stapler.

We herein describe our experimental and clinical validation of our method to overcome the weakness of the DST, especially the intersecting staple lines.

#### 2. EXPERIMENTAL VERTIFICATION

When a linear and circular stapler are used for DST, the following 3 points are considered

#### vulnerable:

- 1) Both ends of the linear staple line ("dog ears").
- A circular part that is sparsely stapled in 2 rows with staples larger than the linear staples.
- 3) Intersection of the lines produced by the linear and circular staplers.

In order to identify the causes of these vulnerabilities and devise a reinforcement method, it was necessary to verify each vulnerability individually. The vulnerability of the both ends of the linear stapler and the staple line of the circular stapler has evaluated with our previous studies. In this study, we focused on the vulnerability of intersection of the line produced by the linear and circular staplers.

Fresh porcine small intestines were used for all experiments. The specimens were obtained from animals that had been sacrificed for use in approved nongastrointestinal research studies, and were used within 24 h after the animals were sacrificed. Each specimen consisted of a segment of the intestinal tract that was 15 cm in length.

A DST anastomosis was performed between 2 segments of small intestines with the use of the linear stapler (EndGIA Radial Reload with Tri-Staple technology) and a circular stapler (DST Series EEA 21-3.5 Stapler; Covidien, Tokyo, Japan).

In order to verify pressure resistance of the dog ears formed by the linear stapler and the intersecting staple lines from the linear and circular stapler, the anastomosis was tested and compared with that formed by a conventional stapler and a reinforced cartridge preattached to a Neoveil sheet (Group A vs Group B, respectively). Tubing for instillation of air was connected to the segment of small intestine, and the anastomosis was submerged in water. All procedures were performed by the same surgeon. Air was then blown into the intestine with a syringe. A leak was indicated by the presence of bubbles.

For the Group B experiment, the Neoveil sheet was brought into close contact with the anastomotic surface when the anastomosis was performed by a circular stapler, in order to create the intersecting staple lines.

After completion of the test for resistance to pressure, the anastomotic side was radiographed to assess the shape and arrangement of the staple lines. Five experiments were performed in each groups.

#### 3. RESULTS

Amona experimental group A, 2 of 5 anastomoses showed air leakage from the intersecting staple lines. Among experimental group B, all experimental anastomoses showed air leakage from the anastomosis formed by a circular stapler. In radiographs taken after completion of the experiment, the staple line formed by the linear stapler was shortened in group A. The 3 rows of staples were neatly arranged. In group A, the staples were intricately intertwined at the intersection. Some staples were deformed and did not form a "B". On the other hand, the staples placed by the circular stapler were not found to interrupt the staples placed by the linear stapler (Fig. 1).

#### 4. TECHNIQUE

Based on our experimental results, we used a reinforced cartridge for rectal surgery performing a low anterior resection and verified its efficacy and safety.

Procedures performed in this operative technique were conducted in accordance with the Helsinki Declaration of 1964 and its later versions.

Method Ac: DST was performed with the use of a linear stapler with conventional stapler.

The staple line performed with a linear stapler was shortened in both the major and minor axes of the staple line (Fig. 2a). At the time of performing the anastomosis with a circular stapler, holding or controlling the staple line with a forceps was impossible (Fig. 2b).

Method Bc: DST was performed with the use of a linear stapler equipped with a reinforced cartridge.

The staples applied to the Neoveil sheet and rectum were confirmed to be neatly arranged, and the staple line was not shortened (Fig. 2c,d).

During the anastomosis performed by the circular stapler, both ends of the Neoveil sheet were grasped by forceps, and the Neoveil sheet was pulled tight to fit the anastomotic surface (Fig. 2e,f). After confirmation that the Neoveil sheet on both sides of the intersecting staple line was pressed down, the anastomosis was completed by the circular stapler (Fig. 2g).

Fig. 3 shows the radiograph of the staples of a DST anastomosis. As in the experiments on porcine intestines, the staple line produced by the linear stapler was shortened, the staples overlapped, and identification of individual staples was difficult (Fig. 3a). Even at the intersections, discriminating between each staple from the linear and circular staplers was difficult, and many staples overlapped. On the other hand, in Group Bc, the 3 rows of staples were neatly arranged, and the arrangement was maintained up to the intersection (Fig. 3b). At the intersections, discriminating between the staples delivered by each type of stapler was possible.

To date, our method (Bc) has been used for 45 patients without complications, including leakage and bleeding.

#### 5. DISCUSSION

Because of advances in medical technology and devices, the rates of postoperative complications are on a downward trend. The rate of complications after gastrointestinal surgery is no exception. However, the rate of suture failure after resection of rectal cancer is higher than the rate of suture failure after resection of cancer in other locations of the gastrointestinal tract, and is reported to vary from 6.3% to 13.7%, depending on the institution. Suture failure contributes not only to postoperative morbidity and mortality, but also to local recurrence and poor outcome. As the rectal anastomosis is performed at a lower level of rectum and the use of laparoscopic surgery becomes widespread, the method of anastomosis has also changed. The types of anastomoses performed by automatic devices include end-to-end anastomosis. side-to-end anastomosis, and DST anastomosis. The DST

anastomosis was first reported by Knight in 1980 [5]. Even if the anastomosis is performed at a very low level, the DST is a relatively easy and safe procedure that is now used worldwide.

Complications such as leakage have been recently reported after DST anastomosis, and experimental verification and clinical research have been repeated [6-8]. Intrinsic weakness of the mechanical anastomosis in addition to patient characteristics have been reported to be causative factors. When a linear and circular stapler are used for DST, the 3 points are considered vulnerable:

In a previous study, we verified the bursting pressure of the cut margin of porcine small intestine that was performed by a linear stapler [9]. Air leakage was observed from both ends of the stump in 5 out of 10 experiments, and in the other 5 experiments, air leakage was observed from the mesentery. The bursting pressure was

57 mm Hg for the former and 143 mm Hg for the latter experiments. We observed a difference in bursting pressures based on the type of stapling pattern. In group of air leakage from the stump, only the middle row of staples out of the 3 rows of staples was seen the edge of the stump. Additionally, the fixations of the staples were weak and the staples were easily moved. On the other hand, in group of air leakage from the mesentery, the 3 rows of staples extended along the entire length of the stump. This was a result of the stapling method, and controlling the pattern of staples was impossible. Therefore, the same experiment was performed by attaching an absorbable reinforcement material to the stapler. The result of this procedure led to a mean bursting pressure of 148 mm Hg, and air leakage was observed from the mesentery in all experiments. These results indicated that the Neoveil sheet was useful for reinforcing the staple line produced by the linear stapler, especially at each end of the line.

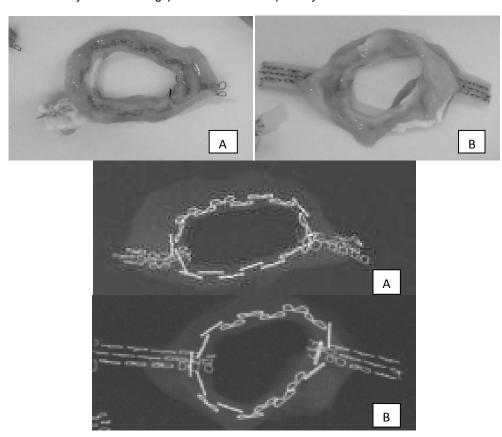


Fig. 1. Resected specimen and radiographs of the anastomotic sides a: Without Neoveil sheet b: With Neoveil sheet

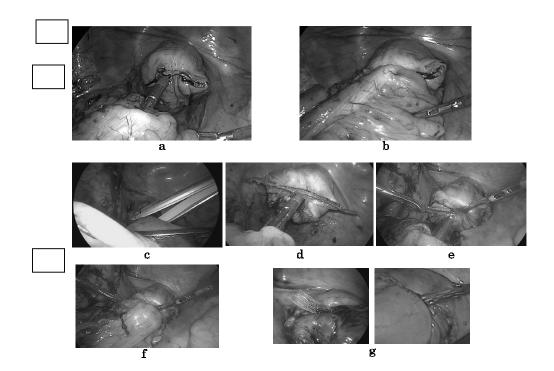
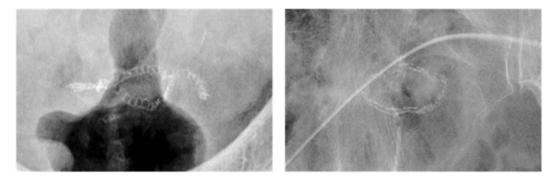


Fig. 2. Operative findings a, b: DST with a circular stapler without Neoveil sheet c, d: Rectum transected with linear stapler with reinforced cartridge e, f: Both ends of Neoveil sheet are grasped with forceps, and Neoveil sheet is pulled tight g: Intersection on both sides



а

b

#### Fig. 3. Radiograph of the staples placed by the DST a: With normal cartridge b: With reinforced cartridge

In the next study, we verified that an anastomosis performed by a circular stapler is weaker than an anastomosis performed by a linear stapler. The current widely used array of a circular stapler is the 2-row array; the staple is thicker and larger than the staple mounted on a linear stapler. Therefore, the staples placed by a circular stapler are more widely spaced and fewer than those placed by a linear stapler. In a pressure resistance test of an end-to-end anastomosis of Kimura et al.; JAMMR, 33(5): 1-7, 2021; Article no.JAMMR.65918

porcine small intestine performed by a circular stapler, the bursting pressure was about 25 mm Hg, which was incomparable to that of a linear stapler. In the same model, the use of a Neoveil sheet on the anastomotic surface increased the bursting pressure to 75 mm Hg. However, that pressure remains less than that for an anastomosis provided by the linear stapler. Further refinement is needed.

In this study, we examined the intersection of the staple lines produced by the 2 staplers. Since 2 staplers are used, the intersections are vulnerable [10-12]. The staples overlap in complicated patterns at the intersection lines, and the staples placed by the first stapler can become deformed by the staples placed by the second stapler. Conversely, staples placed by the first stapler can trigger the formation of irregularities. As in the porcine experiment, when the staple line created by the linear stapler is tilted to the anastomotic surface, the staples at the intersections remain neatly arranged and overlap of tissue at the intersections can be minimized. Since the pressure resistance of the region of anastomosis produced by the circular stapler was low, the effectiveness of this method could not be regarded as an increase in the resistance pressure. But considering that there was no air leakage from the intersection and the arrangement produced by the staplers, our method is considered to be an expected method.

Our method requires the addition of material to the linear stapler that can maintain a certain shape. Additionally, this material should be absorbable and of minimal thickness to reduce the difference between thicknesses between the points other than the intersection. For the past 5 years we have used reinforced cartridges only for reinforcing the staple line. However, we did not apply the reinforcing material and staple line to the anastomotic surface. Some have reported that reinforcing material might contribute to reduced leakage. However, as with our previous method, overlapping of the staples at the intersection line is similar to the overlapping produced by the conventional DST. In this case, the usefulness of the reinforced cartridge has not been fully demonstrated. The reinforcement material is folded together intricately by multiple staples, causing a large difference. Due to this step, anastomotic leakage may occur.

The material used in the reinforced cartridge is a very thin (0.15 mm) 100% polyglycolic acid sheet that has measurable strength during the critical

wound healing period and is essentially absorbed at 15 weeks [13-15]. An additional positive attribute is that it can be gripped when it is wet.

Regarding the circular stapler, 3-row staplers will soon be available for clinical use. The addition of reinforcing material to the circular stapler should lead to increased strength of the anastomosis. We believe that a DST anastomosis that uses our method for the intersection lines provides increased safety and security and thereby should lead to a reduced rate of suture failure after rectal resection.

#### **5. CONCLUSION**

A double stapling anastomosis that uses our method for the intersection lines provides increased safety and security and thereby should lead to a reduced rate of suture failure after rectal resection.

### CONSENT

The authors declared that informed consent was obtained from the participants of the study for publication of this paper.

#### ETHICAL APPROVAL

Authors confirmed that all necessary ethical approval from institutions were obtained.

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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