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Reinforcement Material on the Intestinal Stump Staple Line-The Effect and Mechanism of Reinforcement

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Background: In gastrointestinal surgery, the quality of anastomosis is one of the most important factors influencing the postoperative course. The purpose of this study was to verify the effectiveness and the mechanism of one type of reinforcement material.
Methods: We analyzed the effect of Neoveil® on the rate of staple line failure. Fresh pig small bowel was used. Neoveil® sheets were placed on the anvil alone, cartridge alone or both sides of the stapler. Groups were: A, without Neoveil®; B, the cartridge and anvil; C, the cartridge alone; D, the anvil alone. The burst pressures were measured.
Results: In group A, a leak occurred at the intestinal stump in 5 of 10 cases (As). In the other 5 cases, the mesenteric side burst before failure of the staple line (Am). In groups B, C, and D, the mesenteric side burst before failure of the staple line. The median leak pressure was 100±46 mm Hg in group A (As; 57±6, Am; 143±12). In the other groups, the leak pressures were approximately

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140 mm Hg. In group As, the middle staple only exists on the edge of stump. In group Am, however, both sides of the 3-row staple line exist on the edge of stump.
Conclusion: The burst pressure of the stump became the result of the bipolarization. The strength of the stump staple line is affected by the arrangement of the staples. Neoveil® was effective in obtaining a stronger staple line.

Keywords: Neoveil®; reinforcement; stump; leak; staple.

1. INTRODUCTION

In gastrointestinal surgery, stapling devices have shortened operation time and reduced the postoperative complications. Moreover, they have reduced the inter-operator variability that exists in handsewn techniques. The devices themselves have also been improved upon and have evolved [1]. The most serious complications in gastrointestinal surgery after using a stapling device are bleeding and anastomotic leak. Staple line reinforcement materials for the stapler are likely to reduce these complications [2-4]. In thoracic surgery, reinforcement materials are widely used, for example in dividing the emphysematous lung. In digestive surgery, there are some experimental reports showing the utility of reinforcement material, but clinical reports are few. Bioabsorbable staple line reinforcement is often used in metabolic surgery for obesity, such as in laparoscopic sleeve gastrectomy, but the mechanism of the reinforcement is not clear [5,6]. The purpose of this study was to verify the effectiveness and the mechanism of reinforcement material on staple lines.

2. MATERIALS AND METHODS

In this experiment, we analyzed the effect of Neoveil® on the rate of staple line failure. Fresh pig small bowel was used for all experiments. The specimens were obtained from an animal that had been sacrificed for use in approved non-gastrointestinal research studies. The specimens were used within 24 hours after sacrifice. Each segment of intestinal tract was 40 cm in length. Small intestine segments were stapled and divided into two segments of approximately 20 cm using the linear surgical stapler. Each of the divided segments had a stapled end and an opened (non-stapled) end. Neoveil sheets were placed on the anvil alone versus the cartridge alone or on both sides. Non-buttressed staple lines were used as control. A plastic tube was inserted into the open lumen and secured using a braided silk tie. The sphygmomanometer and tubing for instillation of air was connected, and the anastomosis was submerged in water. Air was then blown into the intestine with a syringe (Fig. 1). The burst pressure of the anastomotic region was indicated by the presence of bubbles. All procedures were performed by the same surgeon. The experiments were divided into four groups based on the method used to reinforce the staple line (Fig. 2).

A: Without Neoveil®
B: The cartridge and anvil were covered with Neoveil®
C: The cartridge alone was covered with Neoveil®
D: The anvil alone was covered with Neoveil®.

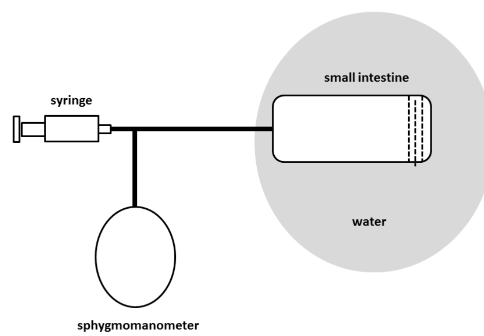


Fig. 1. Experimental setup for the measurement of leak pressures of porcine small intestine

Measurements with 10 separate intestines in group A and 5 intestines in other groups were completed.

The stapling device used was the Powered ECHELON FLEX™ ECR60W (ETHICON, Tokyo, Japan). Suture length was 6 cm and the number of staplers fired was 88. These staplers consist of two rows of 2.5 mm staples prior to firing. Post-fire heights were 1.0 mm.

2.1 Statistical Analysis

Discrete variables were analyzed by the Mann-Whitney test and significance was indicated at $p<0.05$.

3. RESULTS

In group A, without Neoveil, an air leak occurred from the end of the stump in 5 cases in 10 cases (As). In 5 cases, the mesenteric side of the intestine burst before failure of the staple line (Am). In groups B, C, and D, the mesenteric side of the intestine burst before failure of the staple line. The air leak from the staple line of the stump was very small. The air leak from the mesenteric side, however, was large due to rupture of the intestinal wall (Fig. 3). Comparison of the burst pressures is shown in Table 1. The median leak pressure was 100±46 mm Hg (range 49-158) in group A. When divided into two groups based on leak point, burst pressures were 57±6 mm Hg (range 49-64) in group As and 143±12 mm Hg (range 128-158) in group Am. This was significant (<0.001). In the other groups, the leak pressures were approximately 140 mm Hg. No significant differences were found in leak pressures between the groups with Neoveil®. In group A, we observed a difference in burst pressures dependent on staple line arrangement. In group As, as shown in Fig. 3, the middle staple exists only on the edge of the stump. Additionally, the fixation of the staple is weak and the staple is easily moved. On the other hand, in group Am, as shown in Fig. 4, the three rows of staples extend along the entire length of the stump. In group As, only one staple exists on the side of the stump. This staple is also loosely fixed and can be moved easily (Fig. 5). As shown in Fig. 3, in group Am, the three rows of staples extend along the entire length of the stump causing it to be fixed.

4. DISCUSSION

Among the various reconstruction methods after intestinal resection, side-to-side anastomosis has increased in popularity since the advent of the automatic stapling device, as it can be done without the need for handsewn sutures [7-9]. Staplers can also be used in gastrointestinal surgery in cases were reconstruction is not performed, such as the closure of the duodenum in a Bilroth II or the rectal stump in a Hartmann's procedure.

Anastomotic complications can lead to leak, bleeding, or ischemia, among other complications, with leak being one of the most serious. The etiology of staple line leaks is variable, but we categorize them into two main causes: mechanical/tissue causes and ischemic causes. In both instances, the intraluminal pressure exceeds the strength of the tissue and the staple line, resulting in a leak [10,11].

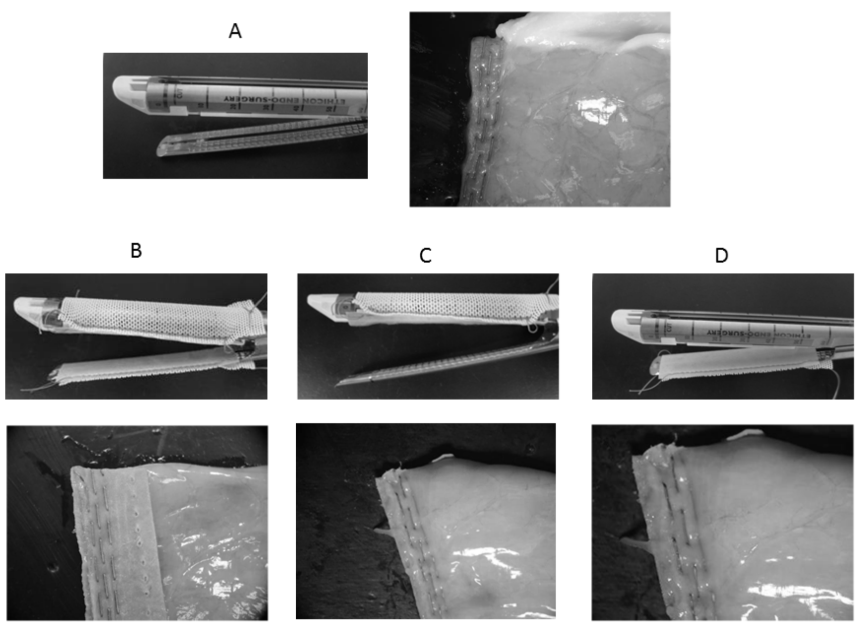


Fig. 2. Stapler with/without Neoveil® and the intestinal stump

A: Stapler only, B: Stapler with Neoveil® on both sides, C: Stapler with Neoveil® on the cartridge side D: Stapler with Neoveil® on the anvil side

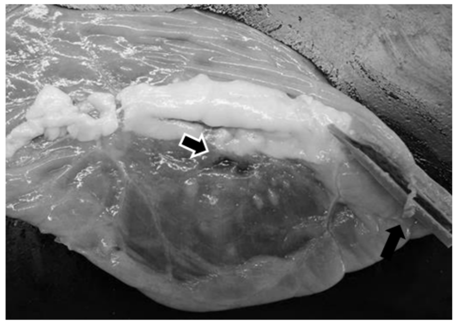
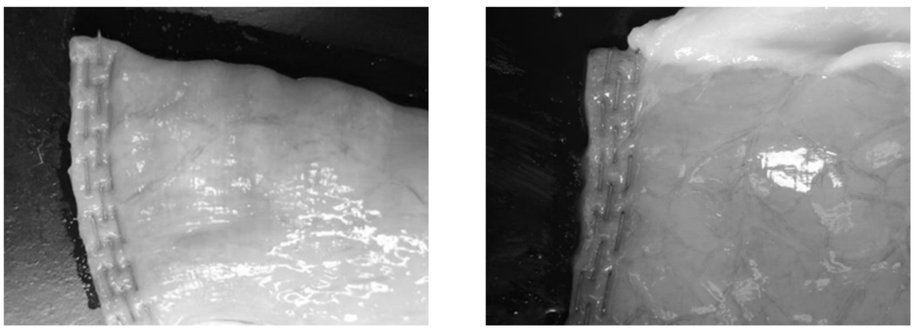
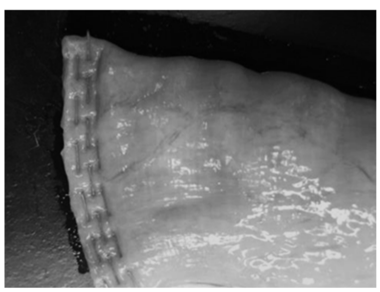


Fig. 3. Macroscopic findings of the burst intestine on the mesenteric side (arrow)

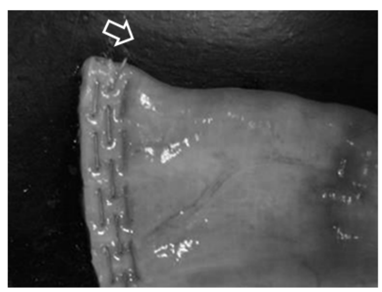


As **Am**

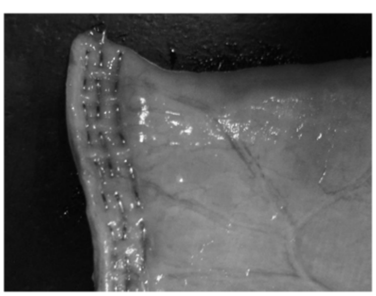
Fig. 4. Macroscopic findings of the staple line of group A



Linear portion



Moving staple



Hook portion

Fig. 5. Macroscopic findings of the staple line of group As

Linear and hook portion of the stump

Moving staple

Table 1. Comparison of the burst pressures

Neoveil	Point	Bursting pressure	P value
(-) A:(n=10)	**Mesenteric side (n=5):Am stump (n=5):As**	**100±46 (49-158) Am: 143±12 (128-158) As: 57±6 (49-64)**	**Am vs As <0.001**
Cartridge+Anvil B: (n=5)	Mesenteric side	148±14 (131-165)	B vs D 0.043
Cartridge C: (n=5)	Mesenteric side	143±11 (128-158)	
Anvil D: (n=5)	Mesenteric side	145±13 (128-158)	

Mean±s.d(Range)

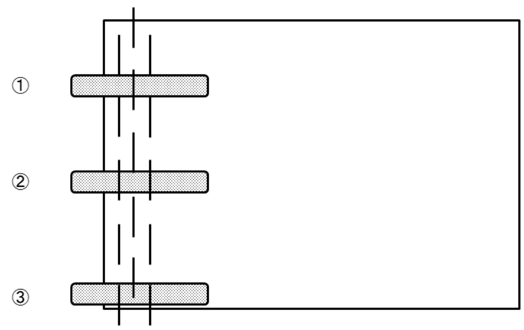


Fig. 6. Arrangement of staples

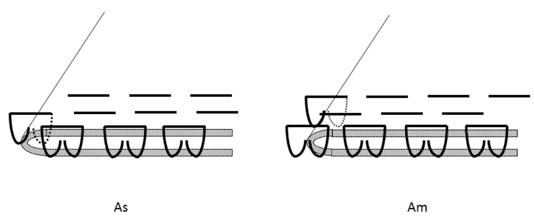


Fig. 7. Schema of the arrangement of staples in group A

The abnormally high pressures are the result of a variety of conditions, including obstruction, trauma, vomiting, or coughing. When a leak occurs in a stump, this can seriously affect recovery time of a patient after gastrointestinal surgery. For this reason, surgeons often reinforce the stump with Lembert sutures on the staple line. However, in laparoscopic surgery, such reinforcement is technically difficult. It would be optimal if both the staple line and reinforcement could be completed at the same time.

A variety of buttressing materials have been developed, most of which are absorbable. In the formation of intestinal anastomosis, examples of clinically available buttress reinforcement materials include bovine pericardium (Peri-strips), expanded-poly-tetrafluoroethylene carbonate (TMC), copolymer (Gore Seamguard), and small intestinal submucosa (Surgisis) [12-14]. These products have demonstrated some success in reducing leak rates and bleeding complications associated with staple lines.

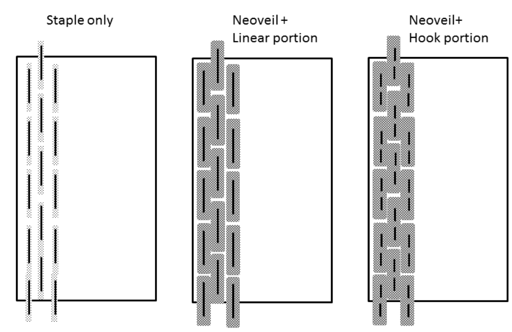


Fig. 8. Schema of the hypothesis of the reinforcement

In this study, we used the tube-type Neoveil®. We attach this to the stapling device before use. The buttressing material is PGA (Polyglycolic Acid) and has a thickness of 0.15 mm. It is a version of Neoveil felt developed by GUNZE Ltd, which has been validated clinically in the Japanese market for more than 20 years. In recent years, a stapler has been developed that has Neoveil® pre-applied to the device by the manufacturer. The felt is fixed with a thread in both ends of the stapler and the thread is designed to escape fixation after stapling. To define the precise reinforcement mechanism of tube-type Neoveil, we compared the aforementioned 4 groups.

Stapling devices are used for the closure of intestinal stumps in a variety of clinical scenarios [15]. Most staplers have three rows on one side.

In this study, we used a stapler with 88 staples. The crown of the staple is 3 mm and the interval between each staple is 1 mm. Since the staples in each line are alternately arranged, reinforcement by staples can be in the form of one, two, or three rows (Fig. 6). This arrangement becomes problematic on staple lines ending in a stump. All leaks were detected from the end of the stump in our experiments. In addition, the arrangement of the staples was the same as that in group As in all cases. In this arrangement, the outer portion of the intestine is not fully closed with the 1st and 3rd rows of staples. Only the 2nd staple line is complete. However, the 2nd staple line is so loosely fixed that the staples can be easily shifted. On the other hand, the 1st and 3rd staple lines that close the outer portion are firmly fixed, as in group Am (Fig. 7).

However, in all groups with Neoveil, no stump leaks were observed. The same reinforcement effects were observed with those staple lines to which only one side of Neoveil® was applied, which is not a normal use. We believe this phenomenon to be due to the following mechanism:

- Application of reinforcement material to the staple line is thought to moderate tension of the staple line because it acts as a neutralization plate.
- The buttressing materials seal off the staple holes and narrow the spaces in between each staple.
- The 2nd staple line in group Am loses mobility with the buttressing materials, and closes the outer portion of the intestine.

The schema of this hypothesis is shown in Figure 8. The compressed area with only staples and no Neoveil® is very narrow. With the use of Neoveil®, however, the compressed area becomes wide and the stump is compressed at the surface.

The purpose of this study was to clarify whether Neoveil® must be applied to both sides of the stapling device. Based on our results, we expect that reinforcement of the hook portion (anvil side) is more important than reinforcement of the linear portion (cartridge side). The reason for this is that, comparing the linear portion and the hook portion, the pressure on the staple line is higher on the hook portion. In the Neoveil® groups, the mesenteric side of the intestine burst in all cases. We were therefore unable to compare the strength of the staple line between the groups. As in humans, the mesenteric side of the porcine small intestine is vulnerable because of the absence of serosa. However, pressure resistance more than the pressure, normal mesenteric side becomes rupture, is not necessary. Thus, there is no need to compare the burst pressures between the three groups.

The Neoveil® is so thin that we ignored the thickness. However, we cannot deny the possibility that gave the effect of the thickness completely.

5. CONCLUSION

The burst pressure of the stump of the small intestine became the result of the bipolarization. The strength of the stump staple line is affected by the arrangement of the staples. Neoveil® was effective in obtaining a stronger staple line. The fact that burst pressures are elevated after application of Neoveil® to only one side of a stapling device is a novel finding.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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