



Validation of the vulnerable crotch on a side-to-side anastomosis: Observation of the burst process

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Summary

Background The vulnerability of the crotch on a side-to-side anastomosis to leak has been widely recognized. However, countermeasures to prevent leaks from the crotch have not proven to be sufficient.

Methods A side-to-side anastomosis was performed between two intestinal specimens using a linear stapler. We analyzed the burst pressures of anastomoses. Comparison was made in five groups, with different staple heights, presence of Neoveil® (Gunze, Japan), with or without crotch buttressed with nylon. Using an endoscope inserted into the intestinal lumen, we observed the burst process.

Results We observed a significant difference in the resistance of the crotch to leak between the two types of reinforcement. In all experimental groups, the leak was observed not only on the serosal surface but also from within the lumen. Neoveil® significantly increased the burst pressure (41.4 ± 3.6 vs. 88.8 ± 14.6 mmHg; $p < 0.01$). When reinforced with nylon suture, resistance to leak was recognized only in anastomoses with suture reinforcement from within the lumen. Observing from within the intestinal lumen, as the pressure increased, the intestine split along the length of the stapled anastomosis. A leak occurred when the split reached the center of the staple line. In the group using Neoveil® there was no obvious change in the Neoveil® itself with increases in pressure. In the group reinforced with nylon su-

tures, the crotch of the anastomosis expanded, and the intestine split, leading to a dehiscence and leak.

Conclusions The efficacy of various crotch reinforcement methods both experimentally and clinically has thus far been in doubt. With our experiment, the mechanism by which leaks occur at the crotch has become clear, giving evidence for the optimal reinforcement method for stapled intestinal anastomoses.

Keywords Leak · Staple · Intestinal lumen · Burst process · Neoveil®

Introduction

Improvement of automatic stapling devices and the growth of laparoscopic surgery have both influenced methods of anastomoses. Hand-sewn anastomoses and anastomoses with a circular stapler are still performed, albeit much less commonly [1, 2]. The frequency of stapled side-to-side anastomoses has increased, including the esophagojejunal anastomosis after total gastrectomy and the anastomosis between small and large intestine segments. The advantage of the side-to-side anastomosis using a linear stapler, with subsequent closure of the insertion hole of the stapler, is that it is both simple and reproducible. The disadvantage of the side-to-side anastomosis is that the crotch is an inherent point of weakness compared with the longitudinal part of the anastomosis [3, 4]. Multiple experiments have described the vulnerability of the crotch, but the reason for this vulnerability is not clear. Subsequently, it is not clear which method of crotch reinforcement is most effective in preventing anastomotic leak. In this study, the location of and means by which leaks occur from the crotch was studied by observing the crotch from within the intestinal lumen. Based on these results, we compared crotch reinforcement methods.

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Materials and methods

In this experiment, we analyzed the burst pressures of anastomoses. Using an endoscope (IMAGE1S camera system, HOPKINS telescope) inserted into the intestinal lumen, we observed the burst process. Fresh small intestine from a pig weighing 100 kg was used. 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 h after sacrifice. Each segment of intestinal tract was 25 cm in length.

A side-to-side anastomosis was performed between two intestinal specimens using a linear stapler. The stapler was inserted from the edge of each segment of intestinal tract. Two trocars (ECEL TROCAR; Ethicon, Tokyo Japan) were then placed into the lumen through each intestinal wall. The side of the anastomosis was clamped with forceps (Fig. 1). A sphygmomanometer and tubing for insufflation was connected to one trocar. The burst pressure of the anastomosis was measured upon the initial presence of bubbles. All procedures were performed by the same surgeon. In all experimental groups, the origin of the air leak was observed not only from the serosal surface but also from within the lumen. Furthermore, the integrity of the intestine after burst was noted.

Experiment 1

Two staplers (Medtronic, Tokyo, Japan) with different staple heights were compared.

EGIA-AVM/AMT: Endo GIA Reload with Tri-Staple cartridges Camel/Purple.

The open and closed staple heights are shown in Table 1.

Experiment 2

We verified the effect on the crotch reinforced using Neoveil®. With the Medtronic stapler, we used the EGIA Reinforced Reload preloaded with Neoveil® (EGIA-AMT-R).

Experiment 3

In this experiment we sought to verify the reinforcement effect on the crotch. After creation of a side-to-side anastomosis with the EGIA-AMT, the crotch was buttressed with 3–0 nylon suture in one of two ways: the crotch was reinforced either from the serosal surface (Group-S) or from within the intestinal lumen (Group-L; Fig. 2).

Five staplings were performed in all groups.

This study was performed with no industry funding.

Statistical analysis

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

Results

Burst pressure

Experiment 1

In comparison between the EGIA-AVM and EGIA-AMT staplers, the EGIA-AMT stapler showed significantly higher burst pressures (Table 2).

Experiment 2

In comparison between the EGIA-AMT and EGIA-AMT-R staplers, the latter demonstrated burst pressures that were twice as high (41.4 ± 3.6 vs. 88.8 ± 14.6 mm Hg; $p < 0.01$; Table 3).

Experiment 3

The burst pressures after crotch reinforcement with nylon were 40.5 ± 5.9 (Group-S) and 68.9 ± 8.1 (Group-L). No reinforcement effect was observed in Group-S. On the other hand, burst pressures in Group-L (68.9 ± 8.1) were significantly higher than those in the control group (41.4 ± 3.6 ; $p < 0.01$; Table 4).



Fig. 1 System used to examine burst pressure and observe from the intestinal lumen. **a** Before insufflation. **b** Insertion of scope. **c** Observation from the intestinal lumen

Table 1 Specifications of staples

	Open staple height (mm)	Closed staple height (mm)
EGIA-AVM	2/2.5/3	0.75/1/1.25
EGIA-AMT	3/3.5/4	1.25/1.5/1.75

Table 2 Burst pressure for each stapler

	Burst pressure (mmHg)	Standard deviation	Range
EGIA-AVM	16.1	4.6	11.3–21.8
EGIA-AMT	41.4*	3.6	30–51

* $p < 0.01$

Table 3 Effect of Neoveil®

	Burst pressure (mmHg)	Standard deviation	Range
EGIA-AMT	41.4	3.6	30–51
EGI-AMT-R	88.8*	14.6	73.5–112.5

* $p < 0.01$

Table 4 Effect of reinforcement with nylon

	Burst pressure (mmHg)	Standard deviation	Range
EGIA-AMT	41.4	3.6	30–51
Group-S: Outside	40.5	5.9	31.5–46.5
Group-L: Inside	68.9*	8.1	58.5–81

* $p < 0.01$ vs EGIA-AMT

Observation from within the intestinal lumen and macroscopic findings of the damaged intestine after leak

In all specimens, the leak occurred at the crotch with-out exception. Upon inspection of the serosal surface, the exact origin of the presence of bubbles upon the presence of leak was not identified (Fig. 3).

Observing from within the intestinal lumen, the line of dehiscence reached the second staple on the innermost side of the staple line (Fig. 4a). As the pressure increased, the intestine was attenuated along the staple line (Fig. 4b, c). A leak occurred when the dehiscence reached the center of the staple tip (Fig. 4d). The same phenomenon was observed at both the linear and hook portions of the staples. This was observed when the intestine was opened as well (Fig. 5).

On the other hand, in the group using EGI-AMT-R preloaded with Neoveil®, there was no obvious change in the Neoveil® itself with increases in pressure (Fig. 6a–c). Even after leak occurred, the continuity of the Neoveil® was preserved (Fig. 6d). When the Neoveil® was disconnected, the intestine was split along the extension of the staple line (Fig. 6e).

In the experiment in which the crotch was reinforced with nylon suture, there was no clear difference between the normal group and that in which the crotch was reinforced from the serosal surface. On the

other hand, in the group reinforced from within the lumen, the crotch of the staple line expanded as the pressure increased (Fig. 7a, b, d, e) and the intestine split, leading to a leak (Fig. 7c, f). Additionally, the degree to which the intestinal segments split was clearly greater than that in the normal group.

Discussion

A typical method for anastomosis using an automatic linear stapler is the side-to-side anastomosis. There are numerous scenarios in which this technique can be used [5–10]:

- Overlap method between the esophagus and jejunum after total gastrectomy,
- Side-to-side small intestine anastomosis,
- Gastrojejunostomy after gastrectomy or bypass surgery,
- Functional end-to-end anastomosis after small or large intestine resection.

These methods are increasing in frequency with the widespread adoption of laparoscopic surgery. Concomitant with the increase in use of automatic staples, the vulnerability of the crotch has been reported on, with no reports elucidating the mechanism by which this occurs. We have reported clinical and experimental studies describing the process of anastomotic leaks, but have fallen short of describing the exact mechanism by which this happens [3, 11].

We analyzed the burst pressures and burst points of side-to-side anastomoses between pig esophagus and small bowel [3]. With two-row stapling devices, the side and the crotch of the staple line are equally prone to leak. Three-row staplers, on the other hand, have not only greater burst pressures compared with two-row staplers (34.5 vs. 74.3 mm Hg), but the crotch is weaker than the side of the staple line.

Next, we conducted side-to-side anastomoses with nine different staplers with different shapes and forms using pig small intestine [4]. The site of the leak in all cases was the crotch. Regarding the influence of the number of staple rows, the burst pressure in anastomoses using three-row staplers was significantly higher than that using two-row staplers. With regard to the relationship between staple height and burst pressure, staples with a height slightly shorter than the intestinal thickness showed the highest burst pressures. Comparing staplers with uniform staple heights to those with staples of three different heights, the latter had significantly lower burst pressures. Neoveil® significantly increased the burst pressure in the crotch and contributed to the highest burst pressure of all the staplers used in this experiment.

In the above experiments, we verified the vulnerability of the crotch in side-to-side anastomosis and clarified the importance of the selection of stapling devices. We conducted an experiment to clarify the effect of Neoveil® and the mechanism by which it

Fig. 2 **a** Crotch was reinforced either from the serosal surface (Group-S). **b** Crotch was reinforced within the intestinal lumen

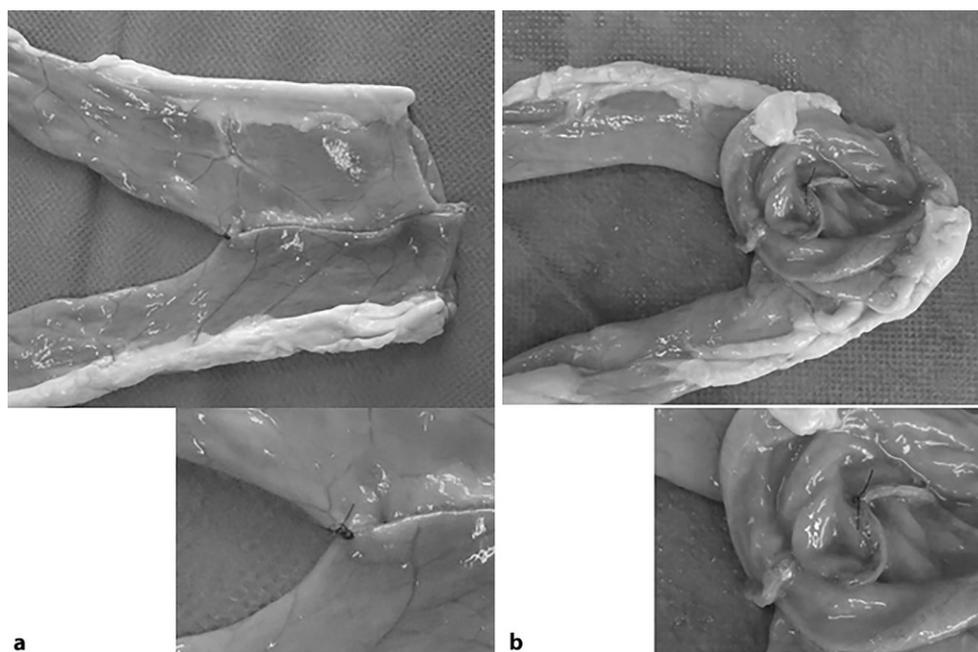
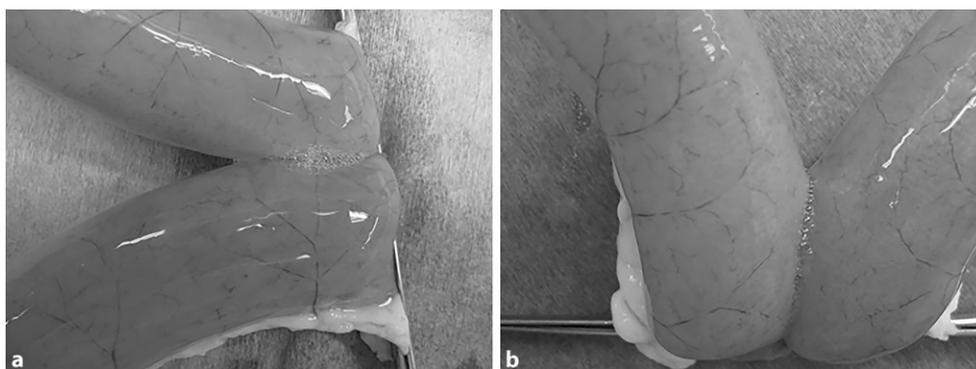


Fig. 3 Leakage from the crotch (observation from the serosal surface) (side; Fig. 3a/crotch; Fig 3b)



reinforces. Neoveil® is a polyglycolic acid and has a thickness of 0.15 mm. It is a version of the Neoveil® felt developed by GUNZE Ltd. [10, 12–14], which has been validated clinically in the Japanese market for over 20 years. In recent years, the Endo GIA Reinforced Reload with Tri-Staple technology has been developed with Neoveil® preapplied to the device by the manufacturer.

In the present experiment comparing suture line strength based on the direction of the stapling, burst pressures were significantly greater when the staplers were driven from the thin portion of the intestine to the thick portion of the intestine. One of the reasons for this is the shape of individual staples. Staples have a linear portion and a hooked portion, which are located on the cartridge side and the anvil side of the stapler, respectively. Comparing these two portions, the linear portion compresses the tissue linearly, whereas the hook compresses the tissue with two short lines or dots. Therefore, when a force is applied to separate the two tissues on either side of an anastomosis, it is possible that the compressing force

on the hook side is weaker than that on the linear side. On the other hand, Neoveil® is said to exert its power as a two-dimensional plate incorporated into the compressed tissue on a staple line, similar to how a washer distributes the force on screws. Therefore, we think that burst pressures of anastomoses may be increased by attaching Neoveil®.

In elucidating the mechanism by which Neoveil® increases burst pressures, it was interesting to note that the Neoveil® itself did not change. When the Neoveil® was removed after leak occurred, a split in the intestine was confirmed, and was not clearly different than the group that did not have such reinforcement. We thus deduced that Neoveil® alone does not reduce the tension applied to the crotch.

Reinforcement of the crotch is relatively quick and technically straightforward. Therefore, the concept of buttressing at the anastomotic crotch to strengthen the staple line is very attractive.

Clinically, the crotch can also be reinforced with sutures. Experimentally, Goto reported that burst pressures significantly increased (27.5 vs. 44 mm Hg) by

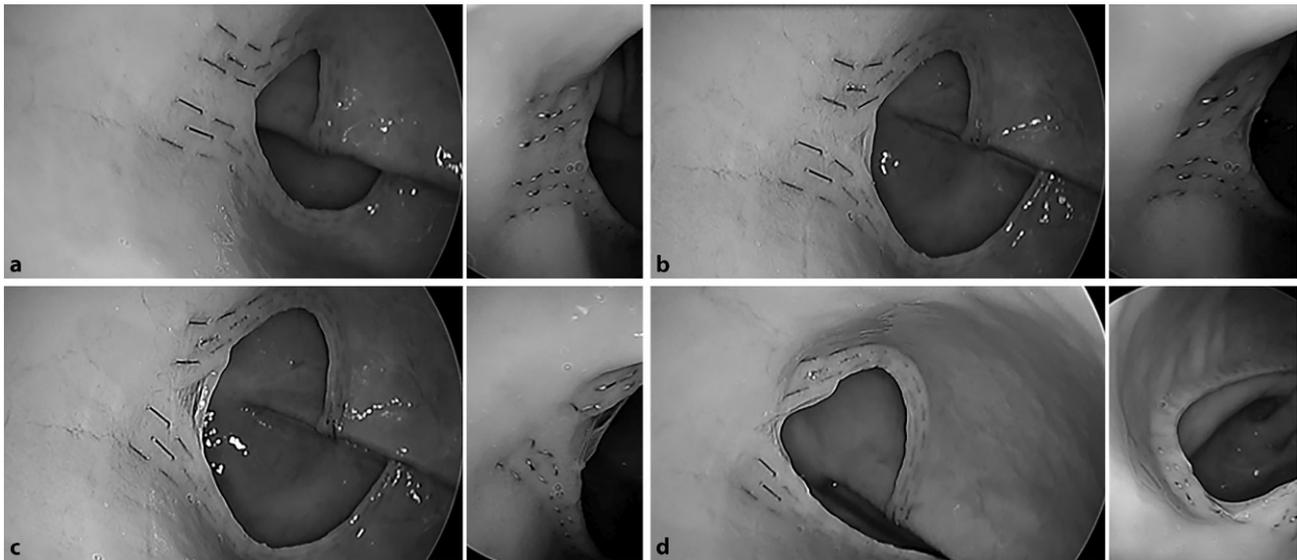
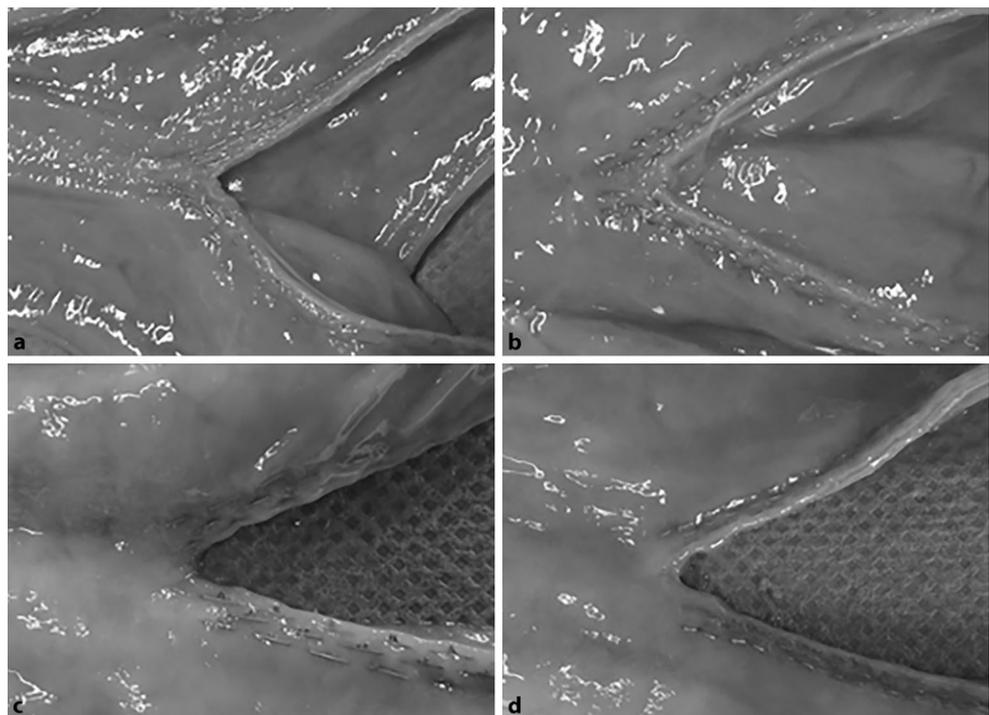


Fig. 4 Burst process observed from within the intestinal lumen. **a** Insufflated intestine. **b** Attenuated intestine on the crotch. **c** Just before leakage occurred. **d** After leakage

Fig. 5 Findings of the crotch. **a** Linear portion before insufflation. **b** Hook portion before insufflation. **c** Linear portion after leakage. **d** Hook portion after leakage



reinforcing the crotch with silk sutures [15]. We also examined suture reinforcement at the crotch. With reinforcement from the serosal surface, there was no change in burst pressures. With reinforcement from within the lumen, burst pressures were the same as those in the non-reinforced group. Therefore, as is clear from our observations from within the lumen, since the starting point of the leak was the cut end of the stapler, reinforcement from within the intestinal lumen was attempted. In this method, nylon sutures were applied after pulling the second staple from

the tip of the innermost staple. With this method, we thought that it was possible to prevent the cut line from splitting toward the tip. In this group, although the angle formed by the cut line widened as the pressure increased, dehiscence did not readily occur. However, when the pressure reached approximately 70 mmHg, dehiscence occurred in the intestinal tract and extended towards the distal side in the non-reinforced group. Even upon observation from the outside of the intestine, the crotch had completely dehisced.

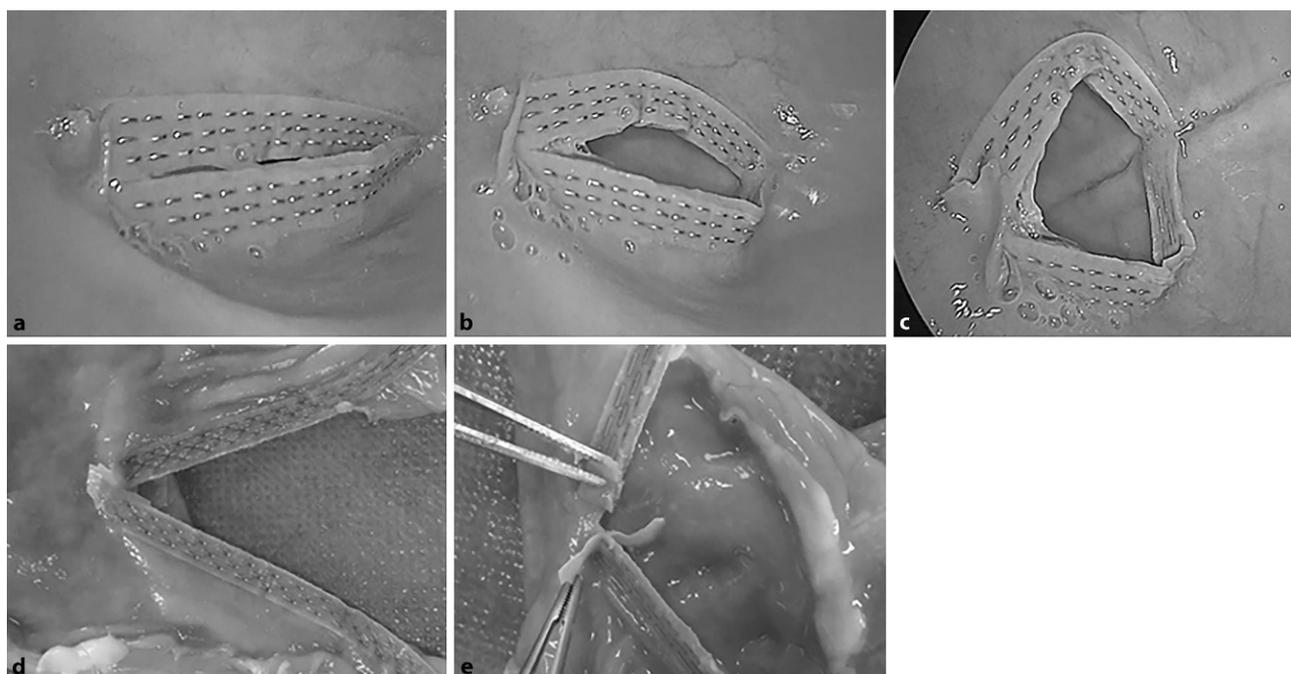


Fig. 6 Burst process in the group using Neoveil®. **a** Before insufflation. **b** Insufflated intestine. **c** Just before leakage occurred. **d** Finding of the crotch after leakage. **e** Removal of Neoveil®

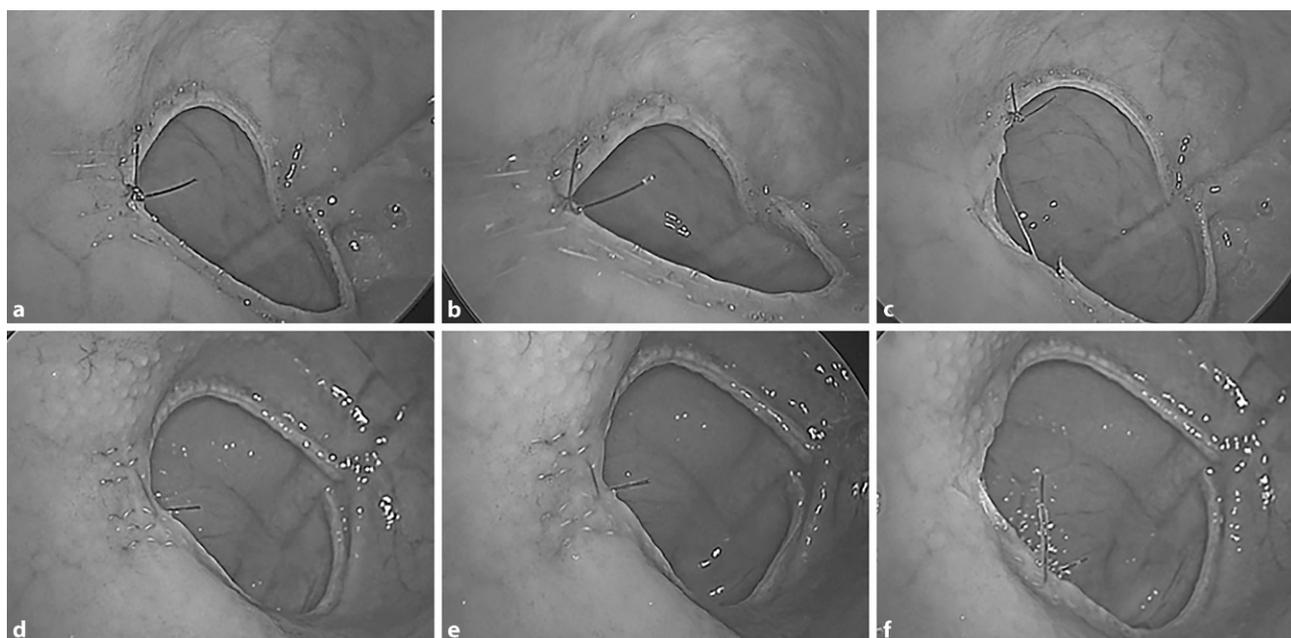


Fig. 7 Burst process in the group reinforced from within the lumen. **a, d** Insufflated intestine. **b, e** Just before leakage occurred. **c, f** Finding of the crotch after leakage. **a–c** Linear portion. **d–f** Hook portion

There are few reports in the literature describing the cause of crotch vulnerability and countermeasures to prevent leaks at this location. Based on past experiments, we conjecture that leaks occur at this location due to two different causes:

- Concurrent with the rise in intraluminal pressure, the outermost staple at the tip damages the intestinal wall.
- Automatic staplers have a cut function that is applied after stapling. Therefore, the mechanism of the device is such that a cutting blade runs in the center of the staple lines. For this reason, the distance between the arranged staples is wider at the center. The distance between the staplers is the longest at the site crossing the cut line and is approximately twice as large as the other staples. Therefore, the center of the crotch is inherently

weak due to the structural design of the stapling device.

Naito examined the integrity of anastomoses using a probe in a pig experiment. When the Endo GIATM Tri-staple™ Technology was used, a probe could be inserted into the crotch. When the Endo GIATM Reinforced Reload with Tri-Staple™ Technology was used, the PGA felt turned the staple lines into a plane.

However, all experiments, including the present one, were observations of the crotch from the outside of the intestinal wall. In our experiment, we observed leaks as they occurred from within the intestinal lumen for the first time. With the injection of air, the intestinal lumen expanded, and areas of dehiscence began to appear at the edge of the cut line. A leak was observed regardless of whether or not the areas of dehiscence exceeded the tip of the staple line. On the other hand, in the group reinforced using Neoveil®, leaks occurred without changes in the Neoveil®. Separating the Neoveil® at the crotch after a leak, there was a split in the edge of the intestine, similar to the groups without Neoveil® reinforcement. We think that this phenomenon is due not to the tensile strength of Neoveil® itself, but an increase in the tensile strength of the edge at which the staple and Neoveil® are apposed.

In any case, we have shown that the most fragile part of the crotch is the edge of the cut line, and it became clear in our experiments that the starting point of the dehiscence leading to the leak is on the side of the intestinal lumen. All prior experiments have included observation of leaks from the outside of the intestinal tract; the true cause of crotch vulnerability has thus been misunderstood. For that reason, reinforcement from the serosal surface is of questionable utility. However, intraluminal crotch reinforcement is not technically feasible with current surgical techniques.

Methods to reinforce the crotch formed in a side-to-side anastomosis may require the use of a reinforcing material such as Neoveil®. Alternatively, one could conceivably narrow the space between staples near the crotch.

With improvements in suturing devices, the stapled side-to-side anastomosis has become reliable and safe, with the caveat that the crotch is prone to leaks.

Conclusion

The frequency of side-to-side anastomoses is on the rise due to its simplicity, as well as due to the increase in laparoscopic surgery in general. The disadvantage of the side-to-side anastomosis is that the crotch is an inherent point of weakness compared with the longitudinal portion of the anastomosis. The mechanism by which this weakness occurs has not been previously elucidated. In our experiments, we examined

the cause of vulnerability of the crotch, and were able to compare the effect of various types of crotch reinforcement with different stapling devices.

The observation from the lumen was fresh and surprising. With our experiment, the mechanism by which leaks occur at the crotch has become clear, giving evidence for the optimal reinforcement method for stapled intestinal anastomoses.

Compliance with ethical guidelines

Conflict of interest M. Kimura, S. Taniwaki, Y. Shibata, N. Ochi, T. Nagasaki, S. Ueno, Y. Eguchi, and H. Asai declare that they have no competing interests.

Ethical standards This article does not contain any studies with human participants or animals performed by any of the authors.

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