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# The importance of precompression time for secure stapling with a linear stapler

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**Abstract**
*Background* One prerequisite for the safe stapling of anastomoses is the formation of perfectly aligned B-shaped staples. Using an animal model, this study investigated whether precompression enhances secure staple formation.
*Methods* A 45-mm linear stapler with a blue cartridge (staple leg length, 3.5 mm) was used on three portions each of six porcine stomachs (cardia, center, and pylorus). Staple shape and height were examined according to the precompression time (0, 1, or 5 min) before firing. The shape was classified as optimal or suboptimal, and the heights of the staples were measured individually. The completeness of the proximal staple lines also was compared with the distal lines.
*Results* The optimal staple rate in the 5-min group (52.7%) was significantly higher than in the 1-min group (28.7%; $p < 0.001$) or the 0-min group (17.1%; $p = 0.002$). The optimal staple rate in the 5-min group for the cardiac portion (mean wall thickness, 2.7 mm) reached 98.9%. However, this rate was less than 50% in the center (5.3 mm) and pylorus (4.2 mm) portions regardless of the precompression time. Compared with the root side, the top side of the cartridge had a lower optimal rate (45.3 vs. 18.7%; $p < 0.001$). A high correlation of completeness was observed between the distal and proximal sides of the stump.
*Conclusions* When a linear stapling device is used, proper staple formation is correlated with intestinal wall thickness, and a sufficient amount of precompression time is effective for gaining the secure staple formation.

**Keywords** Instruments · Complications · Anastomosis

Mechanical suturing and anastomotic devices have advanced in design significantly since their advent [1, 2]. Several models of devices have been used widely in gastrointestinal and respiratory surgery, especially for endoscopic procedures. Three types of linear staplers are available: precompression, parallel-compression, and dual-compression types.

With a precompression device, the tissue is compressed before firing. With a parallel-compression device, the tissue compression is simultaneous with firing. A dual-compression device combines both of the aforementioned.

Although the protocols for the safe use of these devices are standardized [3], this does not always ensure device efficacy [4, 5]. Several reports have described how to improve outcomes after mechanical anastomosis [6–10]. However, to our knowledge, no report describing the cause of staple malformation (staples not forming the "B" shape) exists.

Because it is easy to imagine that staple malformation can cause anastomotic leakage, it is important to understand device characteristics and proper use techniques. Therefore, we conducted this study to evaluate the effectiveness of the length of precompression time on final staple formation and the completeness of staples applied to different tissue thicknesses.

Furthermore, in performing human anastomoses, as the sutured intestine is left in the body, we cannot fully examine whether staple formation is optimal, thoroughly closed in the proper position or not. Therefore, we also investigated the possibility of predicting the completeness of used staples by evaluating staple formation in resected portions.

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## Materials and methods

All our animal experiments were approved by the Animal Research Committee of Kyoto University according to the Japanese Guideline for Animal Experimentation. Six porcine (Clawn miniature swine: age 20–25 weeks; weight, ~30 kg) stomachs were used in this study because they have a tissue thickness almost identical to that of the human colorectal wall.

The precompression type of stapler used in this study was the Endopath ETS-Flex 45 Endoscopic Linear Cutter Standard 6 Rows with a blue cartridge (3.5-mm staple leg length, 1.5-mm closed staple height) (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA).

### Experimental protocols

A 45-mm linear stapler with a blue cartridge was applied to divide the stomach of greater curvature at the cardiac, central, and pylorus portions (Fig. 1A). The wall thickness at each cutting portion was measured by a digital caliper (Mitutoyo Co., Kanagawa, Japan). Before firing, the jaws were closed and held for 0, 1, or 5 min (precompression). The angle of the jaw was kept straight during firing.

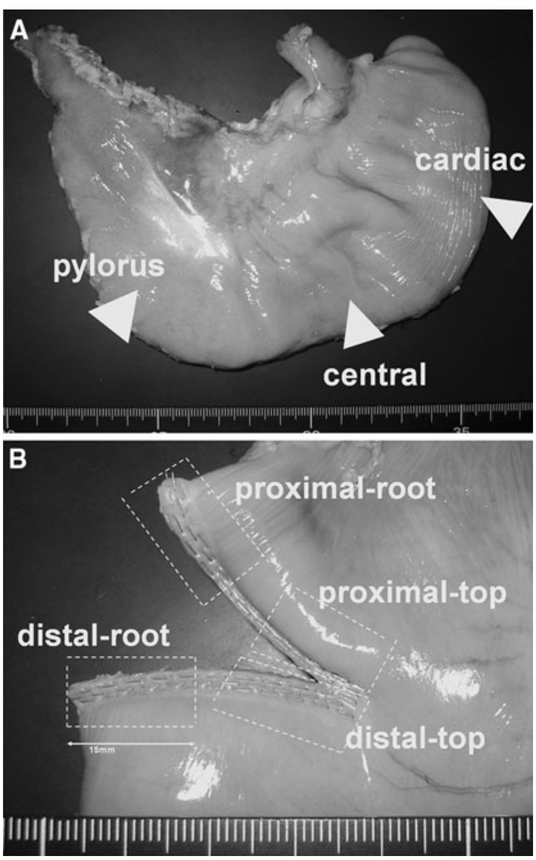


**Fig. 1** **A** Suturing portions of the porcine stomach. **B** The shape of the staple evaluated in four areas of the staple line: proximal root, distal root, proximal top, and distal top

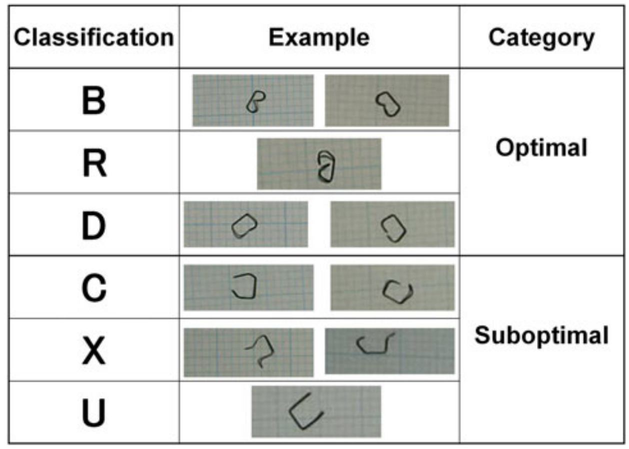


**Fig. 2** Classification of the staple shape. The shape of the staples was evaluated macroscopically and categorized into "optimal" (B, R, and D) and "suboptimal" (C, X, and U) formation according to their final shape. "Optimal" shape was defined as a closed staple tip and "suboptimal" as an open staple tip

Each staple line was divided into four areas (proximal root, distal root, proximal top, and distal top), as shown in Fig. 1B. Tissue was dissolved using CLEAN K-200 (CLEAN Chemical Co., Osaka, Japan), and staples were extracted. Each area of the staple line was 15 mm long and included about 10 staples.

Staple shape and height were evaluated macroscopically, and formation was categorized into "optimal" (B, R, and D) and "suboptimal" (C, X, and U) according to the final shape (Fig. 2). The "optimal" category indicated a closed final staple position, and "suboptimal" indicated an open position. Staple height was examined by two independent investigators (S.N., K.H.). According to the manufacturer's instructions, the ideal B-shape staple height is 1.5 mm, and the ideal D-shape staple height is 2 mm.

"Optimal formation rate" was defined as the number of optimally shaped staples divided by the total number of staples in each area. We investigated several factors influencing the optimal formation rate including precompression time, tissue thickness, and location (top or root) of the cartridge. To determine the possibility of predicting staple formation status, we also investigated the relationship of the optimal formation rate between the proximal and distal sides of the stump.

### Statistical analysis

The staple shape and height in each group were compared using the chi-square test and the unpaired $t$ test, respectively, with JMP 8.0 software (SAS Inc., Cary, NC, USA). A $p$ value less than 0.05 was considered statistically significant.

## Results

This study evaluated 768 staples, with no episodes of broken devices or firing failures. The mean wall thickness of all the cutting portions was 4.03 ± 1.18 mm (2.5–6.0 mm): 2.67 ± 0.41 mm for the cardiac portion, 5.25 ± 0.52 mm for the central portion, and 4.17 ± 0.52 mm for the pylorus portion (Table 1). This thickness is almost identical to that of the human colorectal wall.

The optimal formation rates were 52.7% for the 5-min, 28.7% for the 1-min, and 17.1% for the 0-min groups (Fig. 3A). Similarly, the rate was correlated with the thickness of the tissue (i.e., 72.3% in the cardia, 21% in the pyrolus, and 5.5% in the center). Regardless of tissue thickness, an increased optimal formation rate was achieved in the 5-min precompression group compared with the 1- and 0-min precompression groups (5 vs. 1 min, $p < 0.001$; 1 vs. 0 min, $p = 0.001$) (Fig. 3A). The optimal formation rate in the 5-min group for the cardiac portion reached 98.9% (Fig. 3B). However, this rate was found to be less than 50% in the central and pylorus groups even with precompression times as long as 5 min. Similarly, the mean height of the staples in 5-min precompression was significantly lower than in 0- or 1-min precompression (Table 2).

The optimal formation rate in the top aspect of the cartridge was lower than in the root aspect (Fig. 4). In both the top and root aspects of the cartridge, longer precompression times achieved increased the optimal formation rate (Fig. 4). Regarding the relationship of completeness between proximal and distal aspects of the stump, the optimal formation rate of the proximal side was highly correlated with that of the distal side (correlation coefficient, 0.83) (Fig. 5).

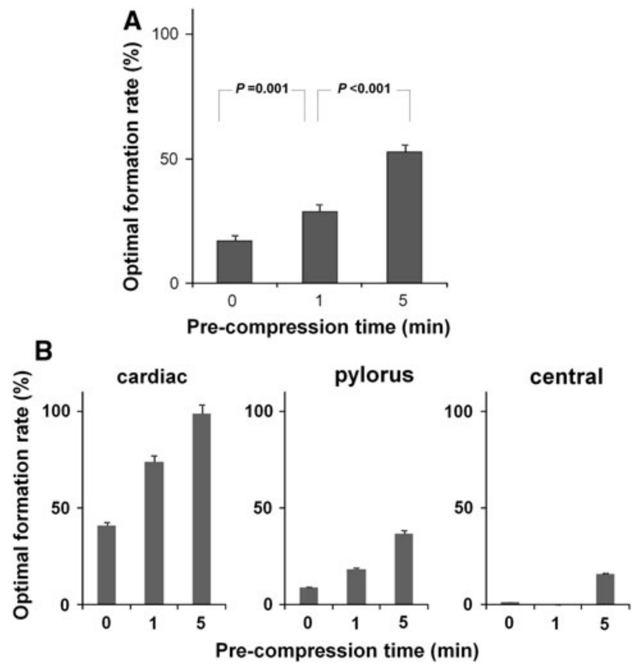


**Fig. 3** **A** Optimal formation rate of precompression times for each group. A precompression time-dependent increase in optimal formation rate was observed. **B** Time dependency was demonstrated regardless of the portion of the stomach

**Table 2** The height of the staples according to the precompression time

| Precompression time (min) | Mean (mm) | 95% CI |
|---|---|---|
| 0 | 2.98 | 2.91–3.04 |
| 1 | 2.84 | 2.77–2.90 |
| 5 | 2.54 | 2.47–2.61 |

*CI* confidence interval

## Discussion

Mechanical stapling devices are widely used in all fields of surgery, allowing tissues to be divided and closed in a quick and easy manner. In colorectal surgery, particularly for lower rectal cancers, the anastomosis is hardly

**Table 1** Wall thickness of each firing portion of porcine stomach ($n = 6$)

| Suturing portion | Mean ± SD (mm) | Range (mm) |
|---|---|---|
| Cardiac portion | 2.67 ± 0.41 | 2.5–3.5 |
| Pylorus portion | 4.17 ± 0.52 | 3.5–5.0 |
| Central portion | 5.25 ± 0.52 | 4.5–6.0 |
| Total | 4.03 ± 1.18 | 2.5–6.0 |

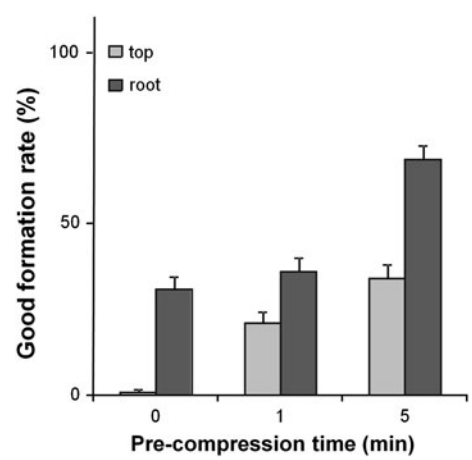


**Fig. 4** Comparison of good formation rates between the top and root aspects of the stapler in each precompression time group. The optimal formation rate in the top aspect was lower than that in the root

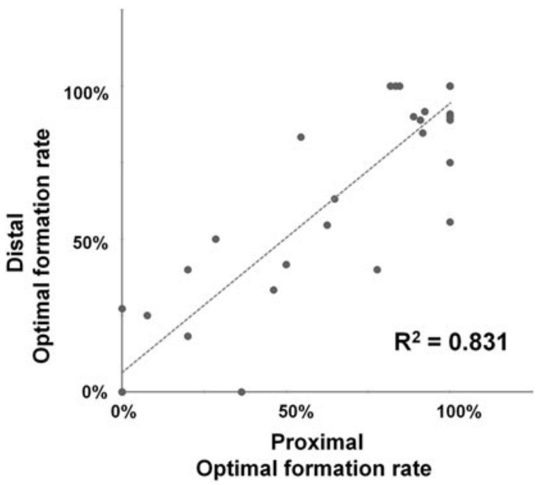


**Fig. 5** Relationship of optimal formation rate between the proximal and distal sides of the stump. The optimal formation rate of the proximal side was highly correlated with that of the distal side (correlation coefficient, 0.83)

completed without proper devices [11, 12]. Although the surgical techniques to ensure a satisfactory blood supply and no tension to the anastomotic site are essential, correct usage of the proper devices also is important to prevent anastomotic failure [6–10]. However, only a few studies have described the proper use of linear suturing devices.

We conducted this study to investigate the factors influencing proper staple formation, which is essential to safe anastomosis. Because proper staple formation after firing can be one of the important factors for secure suturing, we categorized staple formation as "optimal" or "suboptimal" according to whether the tip of the staple was closed or opened. It is easily imagined that proper adaptation of tissue is not achieved if the tips of the staple are open.

Three types of linear suturing devices are currently available. In using precompression type devices, 15 s of compression time are recommended in the manufacturer's instructions [3]. However, no experimental studies have evaluated the relationship between precompression time and staple shape in the use of precompression type devices.

This study provided the first evidence that precompression time plays an important role in optimizing staple formation, showing that increased precompression time achieved a higher optimal formation rate for the staples. Although the reason is not clear, one assumption is that the tissue is compressed gradually to be thinner during the compression time.

Although the staple height of the blue cartridge (3.5 mm) may seem to be insufficient in this experiment, we used it intentionally to test results clearly under such strict conditions. Our result showed that when the tissue thickness is excessive, even with sufficient precompression time, the outcome is not satisfactory. Therefore, first of all, it is desirable to select the proper cartridge according to the wall thickness of the intestine. However, in the clinical setting, it is not always easy to measure the wall thickness correctly. We believe that even when we sense difficulty selecting the proper cartridge intraoperatively, precompression time will enhance secure staple formation.

The findings showed a high correlation in the optimal formation rates between the proximal and distal staple lines. Therefore, we can easily assume the completeness of the staples on a remaining stump by examining those on the proximal line of the resected specimens. We believe this is useful in the clinical setting when the condition of staple lines in the divided intestine remaining in the abdomen cannot be evaluated directly.

This study had some potential drawbacks. First, although staple malformation can be a cause of anastomotic failure, we still do not know whether optimal staple formation always corresponds with improved clinical outcomes. Another drawback is that the other effects of precompression on the intestinal stump (e.g., vascular supply, bleeding, and tissue damage) were not examined in this study. We consider these topics very important, and further research is necessary.

In conclusion, the findings showed that proper staple formation is correlated with intestinal wall thickness and that a sufficient amount of precompression time is effective for gaining secure staple formation. The configuration of staples on resected specimens reflects the degree of patency to be found in the staple line of the opposite side and may be an important predictor for anastomotic failures.

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