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# Obtaining secure stapling of a double stapling anastomosis



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## ABSTRACT

**Background:** Anastomotic leakage is a serious complication after rectal surgery. The aim of this study was to assess the effect of waiting time during firing of stapling devices on optimal staple formation.

**Methods:** An endoscopic linear stapler (Echelon Flex 60 Endopath) with either a 60 mm blue or gold cartridge was applied to the cardiac and pyloric portions of 27 fresh porcine stomachs. Three different waiting times were used for the precompression and interstroke periods (0/0, 2/0, and 2/2 min). The staple line was divided into four portions (oral, anal and top, base), and the shape of each staple was evaluated. Optimal staple formation was also assessed using the circular stapler (CDH 29).

**Results:** Mean thickness of the cardiac and pyloric portions was  $2.4 \pm 0.35$  mm and  $4.0 \pm 0.4$  mm, respectively. The waiting time improved optimal staple formation for the blue cartridge, especially when it was used for the pyloric portion. Staple malformation was observed more commonly in the top portion than in the base portion; however, the former was improved by an interstroke waiting time. Staple formation using the circular stapler was satisfactory and not influenced by the prefring waiting time or tissue thickness.

**Conclusions:** Employment of a waiting time improves optimal staple formation when the endoscopic linear stapler is used for challenging tissue.

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## 1. Introduction

Double stapling technique (DST) anastomosis is a standard reconstructive procedure in low anterior resection of rectal cancer. Despite advances in operative devices and techniques, anastomotic leakage remains a serious post-operative complication after DST, with a reported incidence of 1%–21% [1]. The cause is multifactorial, but ischemia and mechanical and/or tissue-related causes are two major concerns.

Appropriate selection and usage of the stapling device is necessary to obtain a strong staple line and secure intestinal closure. We previously reported that an adequate pre-compression time improved staple formation when a pre-compression type linear stapler (Endopath ETS-Flex 45) was applied to thick, challenging tissue [2]. Furthermore, we recently clarified that precompression time before firing was associated with anastomotic leakage after laparoscopic low anterior resection [3]. The ETS-Flex stapler has been since replaced by the Echelon Flex stapler in clinical practice.

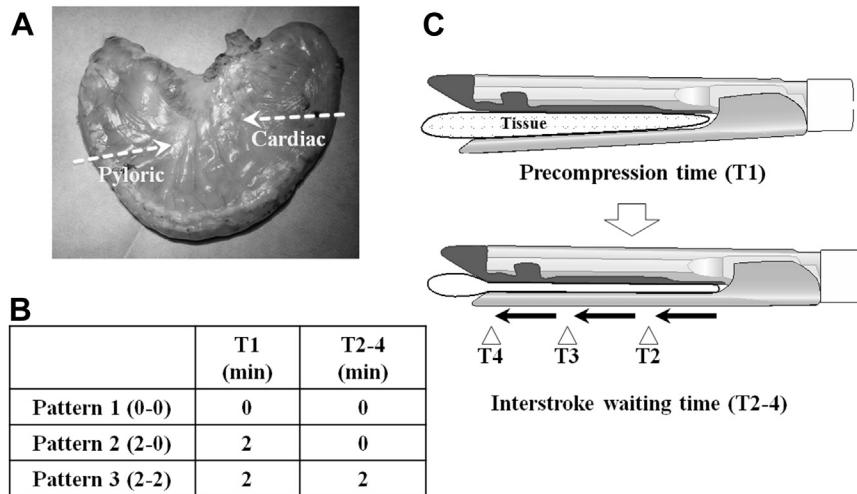
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**Fig. 1 – The endoscopic linear stapler was applied (A) to the cardiac and pyloric portions of the stomach, (B) using three patterns of firing, and (C) according to the precompression (T1) and interstroke waiting times (T2–4).**

Because the Echelon Flex stapler has a different stapling mechanism from that of the Endopath ETS-Flex stapler, the aim of the present study was to examine the effect of a waiting time on optimal staple formation in DST when using commonly used linear and circular endoscopic staplers.

## 2. Methods

### 2.1. Tissue

A total of 27 porcine stomachs excised from Clawm miniature swines (aged 20–25 wk, weight approximately 30 kg) were used in this study. The thickness of the stomach wall was measured at the cardiac and pyloric portions using a digital caliper (Mitutoyo Co, Kanagawa, Japan) as described previously [2].

### 2.2. Endoscopic linear stapler

We first evaluated the staple formation of the Echelon Flex 60 Endopath stapler with blue (3.5 mm staple leg length, 1.5 mm closed staple height) and gold (3.8 mm staple leg length, 1.8 mm closed staple height) cartridges (Ethicon Endo Surgery Inc, Cincinnati, OH). The stapler was applied to the cardiac and pyloric portions of the stomach in either a straight or full-articulated position (Fig. 1). We used three patterns of firing according to the precompression and interstroke waiting times (Fig. 1). Precompression time was defined as the time from closing the jaws until starting the firing, and interstroke waiting time was defined as the waiting time after each stroke (three strokes in total). The staple line was divided at its center to separate the top and base portions, and the shape of the staple in each area was assessed individually.

### 2.3. Circular stapler

Next, we evaluated the factors associated with optimal staple formation when using a circular stapler (CDH 29 Proximate ILS Curved Intraluminal Stapler; Ethicon Endo Surgery).

Both simple anastomosis and DST anastomosis were performed (Fig. 2). The cardiac or pyloric portion was opened, and the trocar of the circular stapler was brought out from the mucosal to serosal side. In the DST model, the stomach was divided using the Echelon stapler with a gold reload as in the previous experiment, the stapled part of the stomach was opened, and the trocar of the circular stapler was brought out from the mucosal side through the staple line (Fig. 2). The anvil was passed through the stomach wall and connected to the trocar. Before firing, the stapler was closed in half or full position (1.8 or 1.0 mm closed staple height, respectively), and held for 0 or 2 min.

The shape of the staple was assessed as previously described. A nylon sheet was placed on the anvil side to maintain the same staple alignment that was produced at the time of anastomosis.

### 2.4. Evaluation of staple formation

Staples were extracted after the stapled tissue was dissolved using CLEAN K-200 (CLEAN Chemical Co, Osaka, Japan). The shape of each staple was classified as either optimal or suboptimal as described previously [2]. Essentially, optimal staples were in a closed staple position, whereas the suboptimal staples were in an open position. The optimal staple formation rate was defined as the number of optimally shaped staples divided by the total number of staples in each area. We also investigated factors that might influence the optimal staple formation rate, namely, precompression and interstroke waiting times, tissue thickness, and location (top or base) of the cartridge.

### 2.5. Statistical analysis

Results are presented as the mean and standard deviation, unless otherwise stated. The continuous variable (optimal staple formation ratio) was compared between groups using an unpaired t-test, Mann–Whitney test, or Kruskal–Wallis test (followed by the multiple comparison test). All statistical

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