



Investigation of Deformities in Staples Used for Gastrectomy -Comparison of Two Different Staplers in Clinical Practice

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Authors' contributions

This work was carried out in collaboration between all authors. Author MK designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors YS, HI and TA managed the literature searches, analyses of the study and experimental process. All authors read and approved the final manuscript.

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ABSTRACT

Background: Few studies have investigated or verified the deformation of staples surgically administered in the human stomach. The shape of the formed staple must represent the characteristics of the stapler used.

Methods: In cases of gastrectomy, the shape of staples administered to resected segments of stomach was observed. Deformation of staples was scored according to the degree of folding of the legs and the degree of leg twisting. Two kinds of staplers, A and B, were used.

Results: 640 staples in group A and 1704 staples in group B were evaluated. In group A, proportions of deformation and twisting were 54.2% and 81.7% respectively. In group B, these were 0.7% and 47.4% respectively. The proportions of deformation and twisting were significantly

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higher in group A ($p < 0.01$) The proportion of penetration was significant higher in group B.
Conclusions: Degrees of deformation, twisting, and penetration were significantly different between the two groups. These results cannot be said to reflect superiority or inferiority of the staples themselves; they more likely represent a difference between the stapling functions of the two staplers examined. We believe that investigation of staples from excised organ components such as occurred in this study is very important and useful. In addition, these findings must be the basic data of selection and future improvement of staplers.

Keywords: Gastrectomy; deformities in staples; twist; penetration: stapler.

1. INTRODUCTION

Surgical instruments contribute greatly to the speed and safety of operations. Improvement of staplers used in all organs has been remarkable. Not only improvement of the staples themselves, but the arrangement of the staples, powered manually has been the most significant improvement [1]. Nevertheless, the effectiveness of this improved stapler has not been fully verified. The reason for this is that the staple itself is almost like a completed shape and the complications associated with stapler use are almost zero. However, it is necessary to verify the shape of the staples formed. Experiments using animal intestinal tracts and lungs are common, but there has been no clinical validation [2]. In this study, we verified two kinds of staplers used for gastrectomy in actual operations. And based on this result, the existence of superiority was verified.

2. MATERIALS AND METHODS

2.1 Experiment 1

We examined whether there is a difference in staple deformation between the right and left side of the cut line. Fresh small bowel from same porcine was used for all experiments. Specimens were obtained from animals that had been sacrificed for use in approved non-gastrointestinal research studies. These specimens were used within 24 hours of sacrifice. Each segment of the intestinal tract was 20 cm in length. The front and rear walls of the small intestine segments were stapled in the longitudinal direction using a linear surgical stapler. To match the thickness of the human small intestine, the two pieces of intestine were overlapped in the experiments. ECHELON FLEX™ with Ethicon Echelon Stapler Reloads White (St E: ECR60W, Ethicon, Japan) and the Endo GIA™ tri-staple™ with the Endo GIA60AVM (St M: Medtronic, Tokyo, Japan) were the two staplers used in our experiments. Five staplings were completed in each stapler.

First, we wrapped a plastic bag on the cartridge side of the stapler, and then we stapled the intestine. After stapling, the segment of intestine with the plastic bag was put in sodium hydroxide to dissolve the tissue. The degree of staple deformation was evaluated. The number of malformed staples, strongly malformed staples, staples malformed to the knife side, and the absolute value of the degree of deformation were compared.

2.2 Experiment 2

The study was conducted in the Nagoya City University Graduate School of Medical Sciences and related hospital from Nov 2015 to May 2016. Staplers from 20 cases were evaluated. In the gastrectomy cases, the shape of the staples as they existed in the resected stomach was observed. Two kinds of staplers, ECHELON FLEX™ with Ethicon Echelon Stapler Reloads Gold; Group A and Endo GIA™ tri-staple™ with the Endo GIA60AVM; Group B, were used. The staples were removed so as not to result in damage from the stomach. Stomach tissue and staples were immersed in sodium hydroxide solution to completely dissolve the tissue. When multiple staples were used for gastrectomy, there were overlaps. Since staples at such locations may be damaged, these were excluded.

As clinical background, age, sex, diagnosis, operative procedure, and post-operative complications were examined. The deformation of staples was scored as described below according to the degree of folding of staple legs and the degree of leg twisting (Fig. 1).

Deformation score

- a; The height of the stapler
- b; The length from the backspan to the closest staple tip
- 0: $b/a < 1/2$
- 1: $1/2 \leq b/a < 2/3$
- 2: $2/3 \leq b/a < 1$
- 3: $1 \leq b/a$

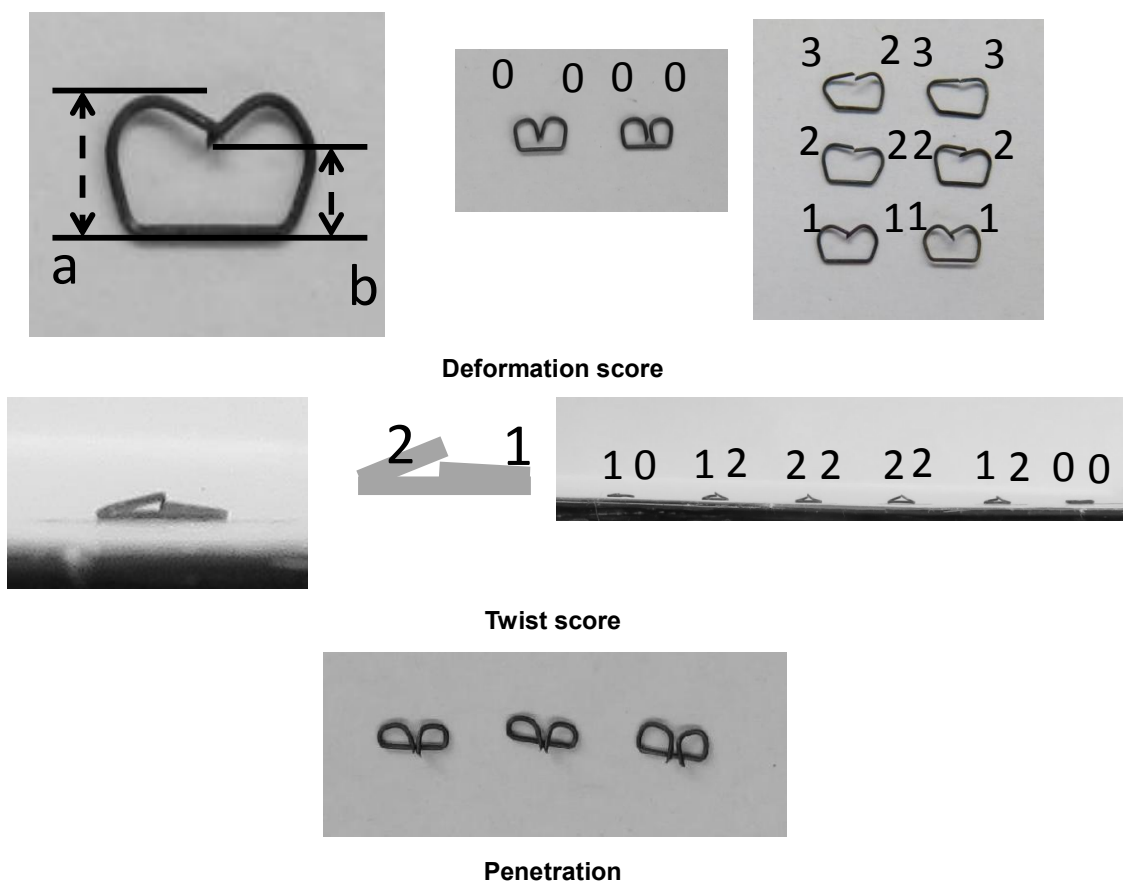


Fig. 1. Deformation of staplers and example of the score

Twist score

- 0: No twist
- 1: The leg is overlapped with the backspan
- 2: The leg does not overlap with the backspan

2.3 Statistical Analysis

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

3. RESULTS

3.1 Experiment 1

For both staplers, there was no significant difference in staple deformation between the right and left side of the cut line (Table 1).

3.2 Experiment 2

There were 7 cases in group A and 13 cases in group B. There were no differences between sex

and age. All diagnoses were gastric cancer, and all operative procedures were distal gastrectomy. No complications were observed (Table 2). The proportion of deformation and twisting in each group was compared. 640 staples in group A and 1704 staples in group B were evaluated. In group A, the proportion of deformation and twisting were 54.2% (347/640) and 81.7% (523/640) respectively. In group B, these were 0.7% (13/1704) and 47.4% (807/1704) respectively (Table 3). There was no correlation between the degree of deformation and twisting. The proportion of deformation and twisting was significantly higher in group A. Seven staples with deformation score 3 were recognized in group A. The degree and proportion of deformation, twisting, and penetration were compared between groups A and B. The proportions of deformation and twisting were significantly higher in group A regardless of degree. The proportion of penetration was significantly higher in group B (Table 4).

4. DISCUSSION

Development and improvement of staplers have shortened operation times and reduced postoperative complications including leakage and bleeding. In particular, staplers are indispensable for endoscopic surgery. Without staplers, there would have been no development of endoscopic surgery. As for the shape of the staple, there is only one report on the "D" shape staple [3]. A "B" shaped staple is considered the gold standard for staple formation [2,4,5,6,7]. This "B" shape allows blood flow through the tissue, which is a very important factor for healing. In addition, it is important to adhere tissue with moderate force. In order to make these elements more reliable, the following improvements of stapler and staple technologies have been made.

Improvement of staples themselves

- Staple materials
- Staple diameter
- Attachment of reinforcing materials

Array of staples

- From 2 to 3 rows
- Different length of staple legs in one stapler

How to grip tissue

- Gripping surface technology
- Intelligent compression technology

Stapling method

- Manual to powered

Use of reinforcing materials

Companies will often tout their respective improvements, but there have not been a great number of studies that have verified the differences [8,9,10]. Of these, a relatively large number of studies on reinforcing materials have been published. We previously reported the usefulness of bioabsorbable staple reinforcement materials in side-to-side anastomosis [11,12]. In that study, we evaluated the effectiveness of Neoveil for strengthening the weak point of the anastomosis in pig small intestine. Using Neoveil, the burst pressure of the crotch of side-to-side anastomoses increased more than two-fold. In an investigation of the number of staple rows, we found that 3 rows was advantageous. As for gripping style at the time of stapling, we previously compared two different types of staplers. One used "Gripping Surface Technology", and the other used "Intelligent Compression Technology". The former is characterized by firmly grasping the tissue between the anvil and cartridge, and the latter is

designed to release the tissue laterally. The deformation of the inner staples was larger with the former stapler, and the outer staples became larger with the latter stapler. We also conducted experiments comparing differences in staple formation based on stapling methods which showed usefulness of powered staplers. However, most of these results are from experiments on animals. Therefore, we conducted clinical research to verify the characteristics of different stapling devices [13].

In the case of gastrectomy for gastric cancer, the shape of the staples on the resected stomach was evaluated. Prior to this study, we analyzed previous data regarding staple deformation on whether or not there is a difference in the staples arranged to the left and right of the knife blade. This study evaluated deformation of staples after stapling of porcine small intestine. The degree and direction of the staple twisting were analyzed. As shown in the table, there was no difference between the staples arranged to the left and right of the knife.

In this study, staples at each intersection were excluded from evaluation. There are two reasons for this: one is the deformation of staples due to staple overlap; the other is staple disconnection by the stapler knife [13,14].

Regarding the staple shape, a "B" shape is considered to be the best. But no relationship has been demonstrated between staple shape and suture strength. However, there is no objection as to the fact that the inverted staple on the cartridge side generates force to grasp the tissue. In the comparison of deformation, there were 0 instances of a score of 3 in group B, and 7 instances in group A. Four out of 7 cases had staples of a score of 3, and the maximum number in one case was 2. However, it is not clear whether these two staples were in close proximity. Including staples up to score 2, it was 119 in group A and 3 in group A. Post-operative bleeding and leakage related to stapling were observed in neither group, but this is believed to be the result of the influence of compression width and characteristics of the staplers.

There are a few studies investigating staple twisting, which occurs due to tissue slippage during stapling. The staple pushed out from the cartridge strikes the anvil and reverses in the cartridge direction. If the tissue slips a considerable amount, the tip of the staple will not reach the groove of the anvil and it will not invert.

After reaching the groove of the anvil, if the tissue shifts to the knife side, the tip of the staple also twists to the knife side. Conversely, if the tissue slides in the direction away from the stapler, the tip of the staple also twists outward. There was a significant difference observed between the two groups regarding staple twist. It was an unexpected result that the twist score was significantly larger in group A, which was designed to grasp the tissue strongly. This result was the same as the results of the study comparing deformation of staples in porcine small intestine. These results are considered to be related to the fact that the “Gripping Surface Technology” in group A is designed to provide less tissue slippage for more consistent staple formation, but the tissue is compressed by the knife running in the center, and the twist of the inner staples accordingly becomes larger.

Penetration was significant in group B. One of the causes of penetration is that the leg length of the staples is longer than the thickness of the tissue. The height of the staple mounted on each stapler was 4.1 millimeters in group A and 4/4.5/5 millimeters in group B. Thus there are three types of staples with different leg lengths in group B. After stapling, the staple heights are 2 millimeters in group A, and 1.75/2/2.25 millimeters in group B. Detailed observation revealed that 48 out of the 54 staples with penetration were the lowest staples arranged at the inner side of the stapler. We believe that the cause of this phenomenon may be that, since the

tissue is strongly compressed at the center of the stapler, the height of the lowest staple is relatively high in comparison to the tissue.

There are some studies comparing the strength of anastomosis and the shape of staples formed with different staplers [8,9,10]. However, most of these are animal experiments. In clinical research, there is a study on the effect of reinforcing material on staplers. But this is not a study that examined staples used for actual operations. This is the first study verifying the shape of staples used in actual clinical practice.

Due to improvements made in stapler and staple technologies, complications such as leakage and bleeding have been drastically reduced. Also in this study, there were no complications related to the stapler in either group. However, in the comparison of formed staples, the degree of deformation, twisting, and penetration was significantly different between the two groups. These results cannot be said to reflect superiority or inferiority of the staples themselves; they more likely represent a difference between the stapling functions of the two staplers.

Because staples are extremely small, it is difficult to judge the shape of the staples during operation. Therefore, investigation of staples from excised organ components such as occurred in this study is very important and useful.

Table 1. Staple deformation between the right and left side of the cut line

		Left	Right	P value
Deformed staples (%)	StE	41.6±4.1	42.5±11	ns
	StM	31.1±7.8	32.7±3.5	ns
Deformation degree 2 ≤ (%)	StE	26.8±7	35.6±14.9	ns
	StM	23.1±13.5	23.1±6	ns
Deformation degree <0 (%)	StE	3±3	1.9±2.3	ns
	StM	3.5±13.5	6.5±7.7	ns
Absolute value of Deformation degree	StE	0.9±0.3	1±0.4	ns
	StM	0.8±0.4	0.7±0.1	ns

Table 2. Clinical background

	Group A	Group B	P value
m/f	5/2	9/4	ns
age	52-83 (69)	58-84 (69.2)	ns
Disease	Gastric cancer (7)	Gastric cancer (13)	ns
Post operative complication	0	0	ns

Table 3. The proportion of deformation and twisting in each group

		Group A		
Deformation/Twist	0	1	2	
0	31	112	204	
1	39	45	90	
2	45	43	24	
3	2	0	5	

		Group B		
Deformation/Twist	0	1	2	
0	884	700	107	
1	10	0	0	
2	3	0	0	
3	0	0	0	

Table 4. The degree and proportion of deformation, twisting, and penetration

		Group A	Group B	P value
Deformation score	Severe (2,3)	119/640 (18.6%)	3/1764 (0.2%)	P=0.02
	Severe+Mils (1,2,3)	293/640 (45.8%)	13/1767 (0.7%)	<0.01
Twist score	Severe (2,3)	323/640 (50.5%)	107/1764 (6.1%)	<0.01
	Severe+Mils (1,2,3)	523/640 (81.7%)	807/1764 (45.7%)	<0.01
Penetration (+)		3/320 (0.9%)	54/882 (6.1%)	<0.01
		3/320 (0.9%)	54/882 (6.1%)	<0.01

5. CONCLUSION

Improvement of staplers used in all organs has been remarkable. Not only improvement of the staples themselves, but the arrangement of the staples, powered manually has been the most significant improvement. In this study, we verified two kinds of staplers used for gastrectomy in actual operations. In the comparison of formed staples, the degree of deformation, twisting, and penetration was significantly different between the two groups. These findings from this study are very important and useful for selection and future improvement of staplers.

CONSENT

Institutional Review Board approval had taken. Patient's written consent has been collected and preserved by the author.

ETHICAL APPROVAL

This study is approved by the ethics committee of Nagoya City East Medical Center (No. 15-03-432) and Nagoya City University (No. 1236).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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