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Title page

Title

Serosal laceration during firing of powered linear stapler is a predictor of staple malformation

Short title

Laceration predicts staple malformation

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Key words

serosal laceration; staple malformation; powered linear stapler; optimal formation rate; pre-compression; slow stapling

Author contributions

Konishi and Homma made a plan of this research and contributed the collection of the data. Matsuzawa, Yoshida and Shibasaki analyzed the collected data. Kawamura, Takahashi and Taketomi conceived of the study, and participated in its design and coordination and helped to draft the manuscript. Iijima gave advice about statistical analysis. All authors read and approved the final manuscript.

Abstract (242 words)

Background: Although several types of staplers have been developed, staple-line leaks have been a great problem in gastrointestinal surgery. Powered linear staplers were recently developed to further reduce the risk of tissue trauma during laparoscopic surgery. The aim of this study was to identify the factors that predict staple malformation and determine the effect of pre-compression and slow firing on the staple formation of this novel powered stapling method.

Methods: Porcine stomachs were divided using an endoscopic powered linear stapler with gold reloads. We divided the specimens into nine groups according to the pre-compression time (0/60/180 s) and firing time (0/60/180 s). The occurrence and length of laceration and the shape of the staples were evaluated. We examined the factors influencing successful stapling and investigated the key factors for staple malformation.

Results: Pre-compression significantly decreased the occurrence and length of serosal laceration. Pre-compression and slow firing significantly improved the optimal stapling formation rate. Univariate analysis showed that the pre-compression time (0 s), firing time (0 s), and presence of serosal laceration were significantly associated with a low optimal formation rate. Multivariate analysis showed that these three factors were associated independently with low optimal formation rate and that the presence of serosal laceration was the only factor that could be detected during the stapling procedure

Conclusions: We have shown that serosal laceration is a predictor of staple malformation and demonstrated the importance of pre-compression and slow stapling when using the powered stapling method.

Introduction

Mechanical stapling is now widely used in various types of gastrointestinal surgery. Several models of stapling devices have been widely used in gastrointestinal and respiratory surgery, especially for endoscopic surgical procedures. However, since the development of modern staplers, surgeons have been confronted with the dilemma of decreasing staple-line bleeding while avoiding leakage. Staple-line leaks have long been a great problem in gastrointestinal surgery.

Surgeons must be sufficiently knowledgeable to select and use appropriate surgical stapling devices that achieve safe mechanical anastomosis because appropriate formation of B-shaped staples is essential for proper tissue accommodation in healing process [1]. According to the manufacturers' instructions, stapling instruments are designed to improve staple security across a wide range of tissue thicknesses while preserving the blood supply to the intestinal stump. However, education and data regarding the correct use of stapling instruments remain insufficient [2]. Although the protocols for the safe use of these devices are standardized, device efficacy is not always ensured [3]. Such instruments are now widely used in various clinical settings, but no data are available on the efficacy of this technology in relation to secure staple formation. Several investigators described that the proper staple formation after firing could be one of the important factors for secure suturing [4,5]. Hasegawa et al. reported that the optimal staple formation rate (number of optimally shaped staples divided by total number of staples in each area) is thought to predict the likelihood of stapling failure [4]. However, stapling failure is difficult to predict intraoperatively. Thus, an intraoperative predictor of stapling failure would be helpful in the clinical setting.

To further reduce the risk of tissue trauma during laparoscopic surgery, Ethicon Endo-Surgery Inc. announced the launch of the ECHELON FLEX™ Powered ENDOPATH® Stapler. Stability is thought to be critical to the safe and effective use of endoscopic stapling devices during laparoscopic surgical procedures. The above-mentioned linear stapler is the first powered end cutter with system-wide compression and stability. It is expected that the electronic powered firing will reduce the shaking of divice's tip, and will result in the stable firing.

The aim of this study was to identify the factors that predict and reduce staple malformation, thus improving operative outcomes, and to determine the effect of pre-compression and slow firing on the staple formation of this novel powered stapling method.

Materials and Methods

Materials

Stomachs from 6-month-old pigs (Fig.1a) were used in this study because the tissue thickness of the porcine stomach is almost identical to that of the human colorectal wall. The organs were provided by Tokyo Shibaura Organ Co., Ltd. The thickness of the cardiac, body, and fundus portion of each stomach was measured using a digital caliper (Shinwa Rules Co., Ltd., Niigata, Japan).

Methods

Stapler application

A powered stapler (ECHELON FLEX™ Powered ENDOPATH® Stapler; Ethicon Endo-Surgery Inc., Cincinnati, OH, USA) with a gold cartridge (3.8-mm staple leg length, 1.8-mm closed staple height) was used in this study (Fig. 1b). We fired the stomach from greater curvature to lesser curvature direction. We stapled tissues in the non-articulated position, which means that the cartridge is not angled, to exclude the effect of articulation. The staple line was divided to three portions (top, middle and base) (Fig. 1c). We utilized three different methods for pre-compression (waiting time of 0, 60, and 180 s) and three different methods for firing (stapling time of 0, 60, and 180 s); thus, nine different methods were used in total. Pre-compression time means the duration from closing and locking the cartridge till starting fire. Firing time means the duration from starting fire till finishing the firing. We showed the representative image of successfully stapled (Fig. 1d) and of serosal laceration (Fig. 1e).

Outcome evaluated

The occurrence and length of serosal lacerations and the staple formation were evaluated macroscopically. These data were examined by two independent investigators (Y.K., S.H.). The staple formation was evaluated blindly as reported by Nakayama et al. [5]. Briefly, the tissue was

dissolved using CLEAN K-200 (CLEAN Chemical Co., Osaka, Japan), and the staples were extracted. The staple shape was evaluated macroscopically, and the staple formation was categorized as “optimal” (B, R, and D) and “suboptimal” (C, X, and U) according to the final shape. The “optimal” category indicated a closed final staple position, and “suboptimal” indicated an open position (Fig. 1f). The optimal formation rate was defined as the number of optimally shaped staples divided by the total number of staples in each area.

Primary endpoint: Investigation of the relationship between the portion of the stomach (antrum / body / fundus) / tissue thickness / the portion of the stapler line (base / middle / top) and optimal formation rate / serosal laceration, and decision of the optimal tissue thickness for subsequent experiment.

Secondary endpoint: Evaluation of the relationship between pre-compression time / firing time and optimal formation rate / serosal laceration, and analysis of the factors influencing the occurrence of serosal laceration and the optimal formation rate, including the pre-compression time, tissue thickness, location of the cartridge, and others.

Statistical analysis

Statistical analysis was performed using the software package JMP Pro 12.0 (SAS Institute, Cary, NC, USA). In descriptive statistics, continuous data were shown as mean ±SD. Two-sided p values of < 0.05 were considered for the statistical significance. The data in each group were compared using the chi-square test, unpaired t-test, and Dunnett’s test. Dunnett’s test is a multiple comparison procedure to compare each of a group with a single control[6]. Chi-square test and unpaired t-test were performed for comparison between optimal formation rate (divided into two groups according to several number of optimal formation rate) and pre-compression time (0s or ≥60) / firing time (0s or ≥60) / serosal laceration (absence or occurrence), respectively. As for Dunnett’s test, we examined the relationship between the frequency of laceration and pre-compression time and performed statistical test amongst pre-compression times by setting zero pre-compression time as the reference value. For the identification of the staple malformation predictors, multivariate logistic regression analysis was carried. The statistical power in this study was calculated, because this study was not

designed to achieve more than 80% of power before starting this experiment.

Results

In this study, we evaluated 4422 staples (54 cartridges) to determine the relationship between the tissue thickness and serosal laceration/optimal formation rate. We also evaluated 9322 staples (108 cartridges) to identify predictors of staple malformation and determine the efficacy of pre-compression and slow firing with no episodes of broken devices or firing failures. We used one linear cutter for nine times of fire and then the device was changed. We confirmed that the statistical power was more than 80%.

Tissue thickness

The mean thickness of the antrum, body, and fundus of the stomach was 5.26 ± 0.84, 8.83 ± 1.63, and 3.78 ± 0.91 mm, respectively (Table 1).

Influence of stapling portion and tissue thickness on occurrence of serosal laceration and optimal staple formation rate

The tissue thickness positively influenced the frequency of laceration. Serosal laceration occurred in all cases involving tissue of >8 mm in diameter (Fig. 2a). The optimal formation rate was significantly lower in the body than in the antrum and/or fundus of the stomach (Fig. 2b). There was no significant difference in the optimal formation rate among the base, middle, or top of the staple line (Fig. 2c).

Effect of pre-compression on occurrence and length of serosal laceration

Next, we investigated the effect of pre-compression and slow firing on serosal laceration and staple formation. According to the above-mentioned results (also shown in Fig. 2a), we used the antrum and fundus of the stomach and adjusted their thicknesses to 4 to 6 mm in diameter to exclude the influence of tissue thickness. Longer pre-compression times significantly decreased the occurrence of serosal laceration; however, the firing time did not. These data are shown in Figure 3a and b. The length of the serosal laceration at a pre-compression time of 180 s was significantly shorter than that at a pre-compression time of 0 s (Fig. 3c). No serosal laceration occurred at a pre-compression time

of 180 s. A longer firing time also tended to gradually improve the length of the laceration, but without statistical significance (Fig. 3d).

Effect of pre-compression and slow firing on optimal stapling formation rate

As shown in Figure 4a, the optimal formation rate at a pre-compression time of 0 s was significantly lower than that at 60 and 180 s. The optimal formation rate at a pre-compression time of 60 s was not different from that at 180 s. Figure 4b shows the association between the firing time and optimal formation rate. The optimal formation rate gradually improved as the firing time increased.

Serosal laceration as a predictor of a low optimal formation rate

We evaluated the factors correlated with a low optimal formation rate. The pre-compression time (0 s), firing time (0 s), and presence of serosal laceration were significantly associated with a low optimal formation rate (<50%) (Table 2). Multivariate analysis showed that all of these three factors were associated independently with low optimal formation rate. In these factors, the presence of serosal laceration was the only one that could be detected during the stapling procedure (Table 3).

Discussion

This is the first study performed to evaluate the efficacy of a powered linear stapler. Our findings demonstrate two major points regarding the use of powered linear staplers. First, slow stapling and pre-compression are important for safe stapling, even when using an powered stapler. Second, macroscopic observation of serosal lacerations during firing occasionally predict a low optimal formation rate. The proper staple formation after firing could be one of the important factors for secure suturing [4,5], therefore these findings suggest that serosal laceration is a risk factor for stapling failure and thus could be a risk factor for leakage in the clinical setting.

Laparoscopic surgery is being performed more frequently worldwide, and we have reported the usefulness of reduced-port surgery [7-12]. Mechanical stapling devices are widely used in all fields of surgery, especially laparoscopic reduced-port surgery, allowing tissue to be divided and closed in a quick and easy manner. In colorectal surgery, particularly for lower rectal cancer, the anastomosis is

difficult to complete without proper devices [13,14]. However, anastomotic leakage of the staple line is a serious postoperative complication. Although proper surgical techniques are essential to ensure a satisfactory blood supply and no tension at the anastomotic site, correct use of the proper devices is also important to prevent anastomotic failure [15-19]. Nevertheless, only a few studies have evaluated the proper use of linear suturing devices. Staple-line leakage often leads to peritonitis, septic shock, multisystem organ failure, and even death. Even “minor” leaks, which are associated with few or no physiologic signs or symptoms of sepsis, can lead to a protracted recovery course. Differentiation of leaks is essential when attempting to compare data and decrease the incidence of leakage. Baker et al. [1] reported that most leaks are due to mechanical/tissue issues and that true ischemic leaks are rare. Although there are several known risk factors for leakage, none can be obtained intraoperatively. In the present study, the occurrence of serosal laceration had a strong negative impact on the optimal formation rate, especially those were under 50%. Our results showed that the occurrence of serosal laceration during firing predicts a low optimal formation rate, suggesting that serosal laceration is a predictor of stapling failure and thus could be a risk factor for leakage in the clinical setting.

Kawada et al. [20] recently found that employing a pre-compression time was one of the factors associated with reduced anastomotic leakage after laparoscopic low anterior resection. Nakayama et al. [5] reported that their study provided the first evidence that the pre-compression time played an important role in optimizing the staple formation, showing that an increased pre-compression time achieved a higher optimal staple formation rate. They stated that although the reason for this association is unclear, one assumption is that the tissue is gradually compressed and becomes thinner during compression [5]. Hasegawa et al. [4] recently showed the significance of slow firing using tri-staple technology. Although these data were collected using the conventional hand-firing stapling method, the results were consistent with our data in our previous study using an automated stapling method. In the present study, pre-compression both improved the optimal formation rate and reduced the incidence of serosal laceration. In contrast, although slow firing improved the optimal formation rate, it hardly contributed to the reduction of serosal laceration. We also showed that the absence of laceration was significantly related to optimal formation rate > 50%. Based on these results, we

expect that the absence of serosal laceration could be one of the important factors for good staple formation; however, it could not be enough by itself. Nakayama et al. [5] showed that when the tissue thickness is excessive, even with a sufficient pre-compression time, the outcome is not satisfactory. Therefore, the proper cartridge must be selected according to the thickness of the intestinal wall. In the clinical setting, however, accurate measurement of the wall thickness is not always easy. Nakayama et al. [5] concluded that even when intraoperative selection of the proper cartridge is difficult, a longer pre-compression time will enhance secure staple formation. Based on our results, we agree with these authors' opinion on the importance of pre-compression.

In the present study, we used the ECHELON FLEX™ Powered ENDOPATH® Stapler, a novel powered linear stapler. In the above-mentioned previous study, the optimal formation rate at the top of the stapler was lower than that at the base using the conventional hand-firing stapling method [5]. In contrast, we found no difference in the optimal formation rate between the top and base of the stapler using the powered stapling method in the present study. The manufacturer's instruction manual stated that increased distal tip stability provides improved control of the target and surrounding tissue during the firing sequence over manually fired end cutters, resulting in potentially less trauma to vital structures. We consider that the stability of the powered stapler led to the good results in the present study.

This study had certain limitations. First, the stomachs were removed from the pigs; therefore, neither blood flow nor bleeding could be evaluated. Second, we could not determine whether our findings were truly related to the occurrence of leakage in the clinical setting because the optimal formation rate and laceration are indirect data. In addition, there has been no reports those demonstrated that the optimal formation rate under 50% were really related to the occurrence of clinical problems including leakage. Therefore, further research connecting these *ex vivo* results to clinical setting is required.

Conclusions

We have shown that serosal laceration is a predictor of staple malformation and demonstrated the

importance of pre-compression and slow stapling when using the powered stapling method. In the future, we plan to use *in vivo* specimens to evaluate the clinical application of the present results.

Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

Figure Legends

Figure 1. Representative images of the porcine stomachs which were used in this study. a) The overview of the porcine stomach. b) Application of a powered stapler with a gold cartridge. c) Staple line was divided to three portions (top, middle and base). d) Representative image of successful stapled case. e) Representative image in which serosal laceration (white arrow head) occurred. f) Representative images of the optimal formation / suboptimal formation staple.

Figure 2. Relationship between thickness/aspects and serosal laceration/optimal formation rate. a) The frequency of serosal laceration was positively correlated with the tissue thickness. All cases involving tissue of >8 mm in diameter had serosal laceration. b) The optimal formation rate in the body of the stomach was significantly lower than that in the antrum and fundus. c) There was no difference in the optimal formation rate among the base, middle, and top aspects of the stapler.

Figure 3. Comparison of serosal laceration in the different pre-compression/slow stapling groups. a) A longer pre-compression time significantly decreased the frequency of laceration. b) A longer firing time had a tendency to decrease the frequency of laceration, but not significantly. c) The laceration length at a pre-compression time of 0 s was significantly lower than that at a pre-compression time of 180 s. d) Slow firing had a tendency to shorten the laceration length in all groups, but not significantly.

Figure 4. Comparison of optimal formation rates in different pre-compression/slow stapling groups. a) The optimal formation rate at a pre-compression time of 0 s was significantly lower than that at a pre-compression time of 60 and 180 s. b) Slow firing improved the optimal formation rate in

all groups.

Tables

Table 1. Wall thickness of each portion of the porcine stomach

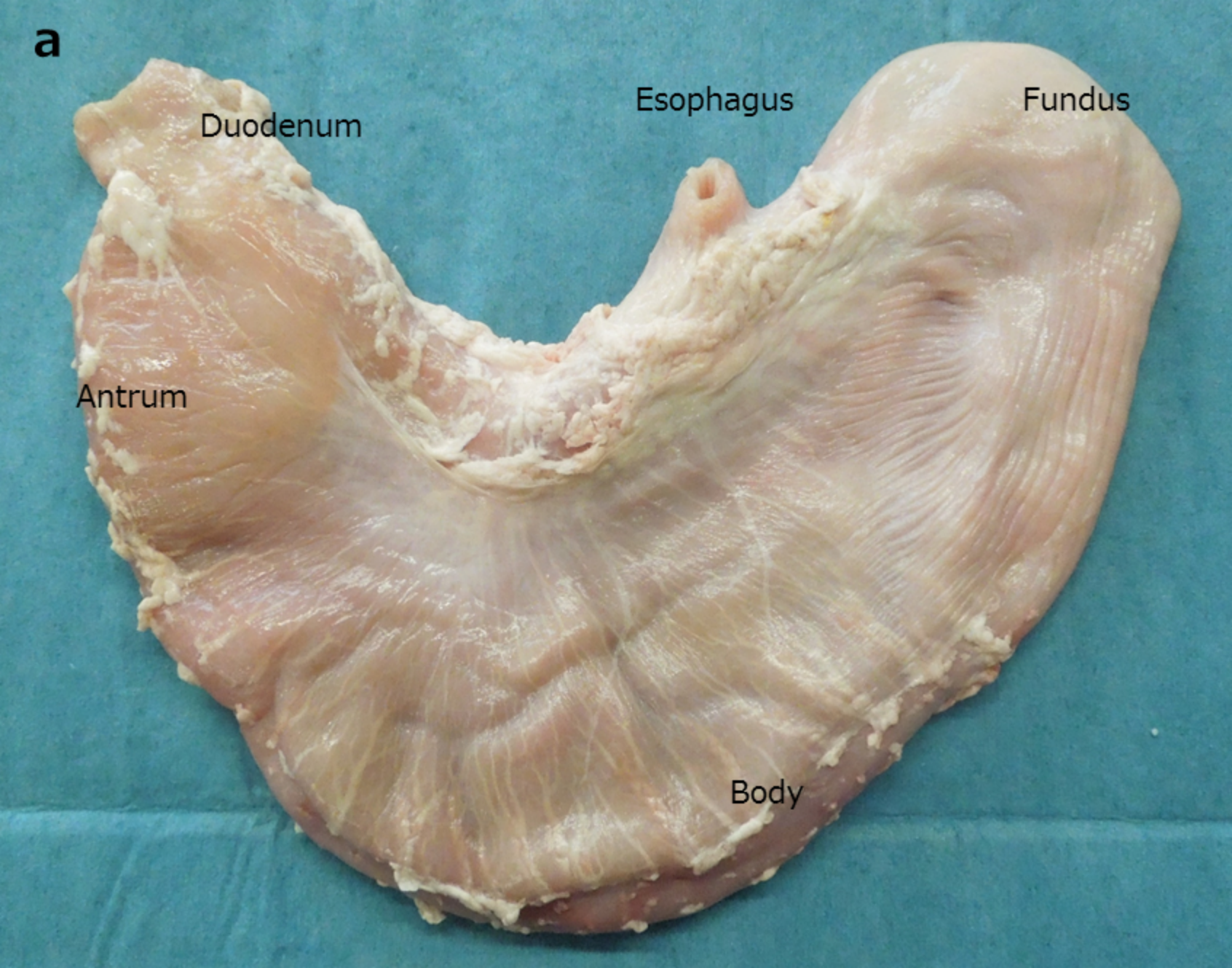
Table 2.Relationship between optimal formation rate and material/technical factors

Table 3. Multivariate analysis of factors associated with low optimal formation rate

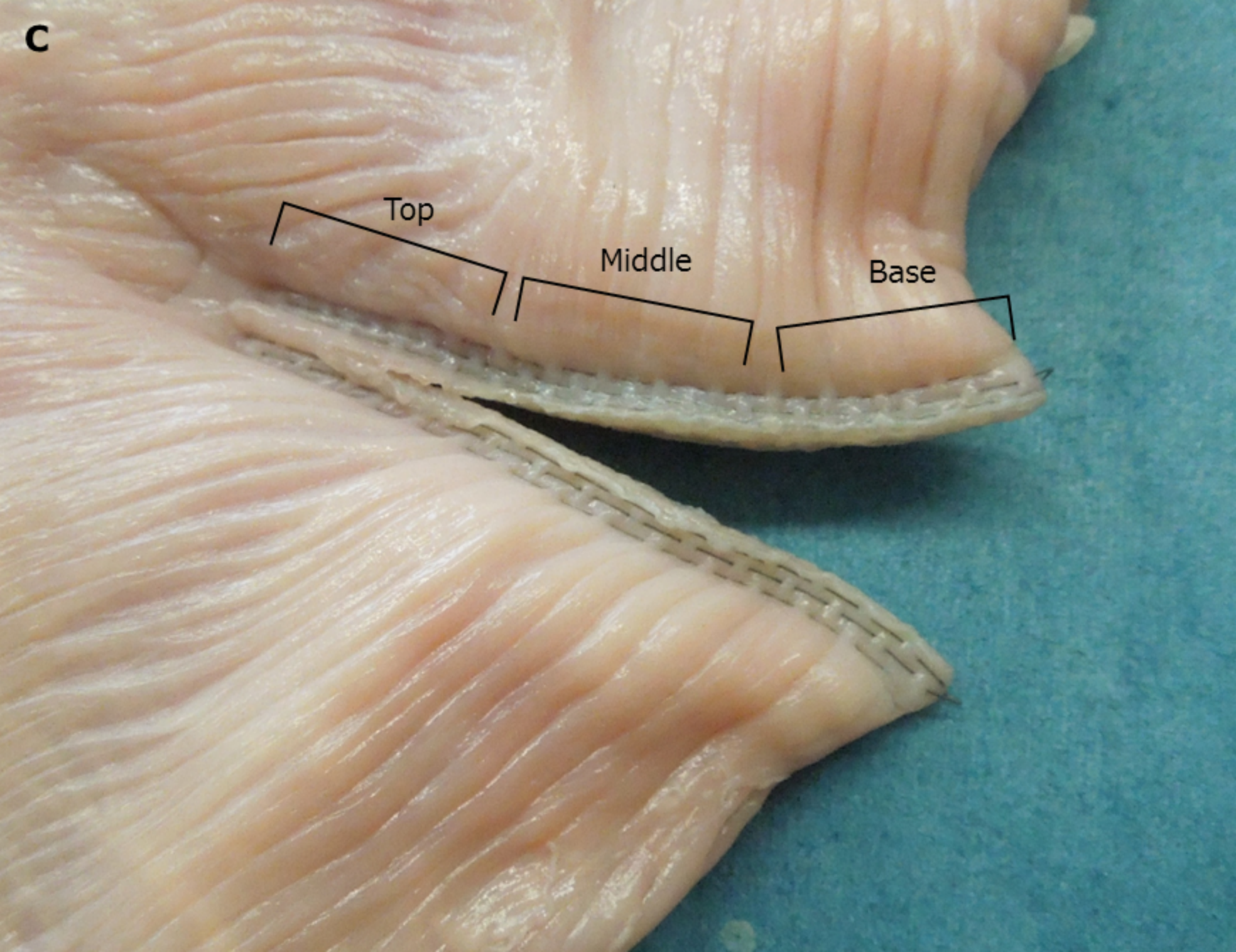
References

1. Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The science of stapling and leaks. *Obesity surgery.* 2004;14(10):1290-1298.
2. Offodile AC, 2nd, Feingold DL, Nasar A, Whelan RL, Arnell TD. High incidence of technical errors involving the EEA circular stapler: a single institution experience. *Journal of the American College of Surgeons.* 2010;210(3):331-335.
3. Wind J, Safiruddin F, van Berge Henegouwen MI, Slors JF, Bemelman WA. Staple line failure using the Proximate 100 mm linear cutter. *Dis Colon Rectum.* 2008;51(8):1275-1278.
4. Hasegawa S, Nakayama S, Hida K, Kawada K, Sakai Y. Effect of Tri-Staple Technology and Slow Firing on Secure Stapling Using an Endoscopic Linear Stapler. *Dig Surg.* 2015;32(5):353-360.
5. Nakayama S, Hasegawa S, Nagayama S, et al. The importance of precompression time for secure stapling with a linear stapler. *Surgical endoscopy.* 2011;25(7):2382-2386.
6. Dunnett CW. New Tables for Multiple Comparisons with a Control. *Biometrics.* 1964;20(3):482-491.
7. Kawamata F, Homma S, Minagawa N, Kawamura H, Takahashi N, Taketomi A. Comparison of single-incision plus one additional port laparoscopy-assisted anterior resection with conventional laparoscopy-assisted anterior resection for rectal cancer. *World J Surg.* 2014;38(10):2716-2723.
8. Homma S, Kawamata F, Shibasaki S, Kawamura H, Takahashi N, Taketomi A. Does reduced-port laparoscopic surgery for medically uncontrolled ulcerative colitis do more harm than good? *Asian J Endosc Surg.* 2015.
9. Ishikawa T, Homma S, Shibasaki S, et al. Dual-port laparoscopic abdominoperineal resection using the intended stoma site as the multichannel port. *Surg Today.* 2015.

10. Matsuzawa F, Homma S, Yoshida T, et al. Successful treatment of rectovaginal fistula and rectal stenosis due to perianal Crohn's disease by dual-port laparoscopic abdominoperineal resection: a report of two cases. *Surgical case reports.* 2016;2(1):83.
11. Shibasaki S, Homma S, Yoshida T, Kawamura H, Takahashi N, Taketomi A. Epidermal Sutureless Closure of the Umbilical Base Following Laparoscopic Colectomy for Colon Cancer. *The Indian journal of surgery.* 2016;78(3):203-208.
12. Yoshida T, Homma S, Shibasaki S, et al. Postoperative analgesia using fentanyl plus celecoxib versus epidural anesthesia after laparoscopic colon resection. *Surg Today.* 2016.
13. Memon AA, Marks CG. Stapled anastomoses in colorectal surgery: a prospective study. *The European journal of surgery = Acta chirurgica.* 1996;162(10):805-810.
14. Wheeler JM, Mc CMNJ. Reconstructive rectal surgery. *Surgical oncology.* 1998;7(1-2):13-23.
15. Morita K, Maeda N, Kawaoka T, et al. Effects of the time interval between clamping and linear stapling for resection of porcine small intestine. *Surgical endoscopy.* 2008;22(3):750-756.
16. Kawasaki K, Fujino Y, Kanemitsu K, et al. Experimental evaluation of the mechanical strength of stapling techniques. *Surgical endoscopy.* 2007;21(10):1796-1799.
17. Goto T, Kawasaki K, Fujino Y, et al. Evaluation of the mechanical strength and patency of functional end-to-end anastomoses. *Surgical endoscopy.* 2007;21(9):1508-1511.
18. Yo LS, Consten EC, Quarles van Ufford HM, Gooszen HG, Gagner M. Buttressing of the staple line in gastrointestinal anastomoses: overview of new technology designed to reduce perioperative complications. *Dig Surg.* 2006;23(5-6):283-291.
19. Ahmed S, Hanna GB, Cuschieri A. Optimal angle between instrument shaft and handle for laparoscopic bowel suturing. *Archives of surgery (Chicago, Ill. : 1960).* 2004;139(1):89-92.
20. Kawada K, Hasegawa S, Hida K, et al. Risk factors for anastomotic leakage after laparoscopic low anterior resection with DST anastomosis. *Surgical endoscopy.* 2014;28(10):2988-2995.

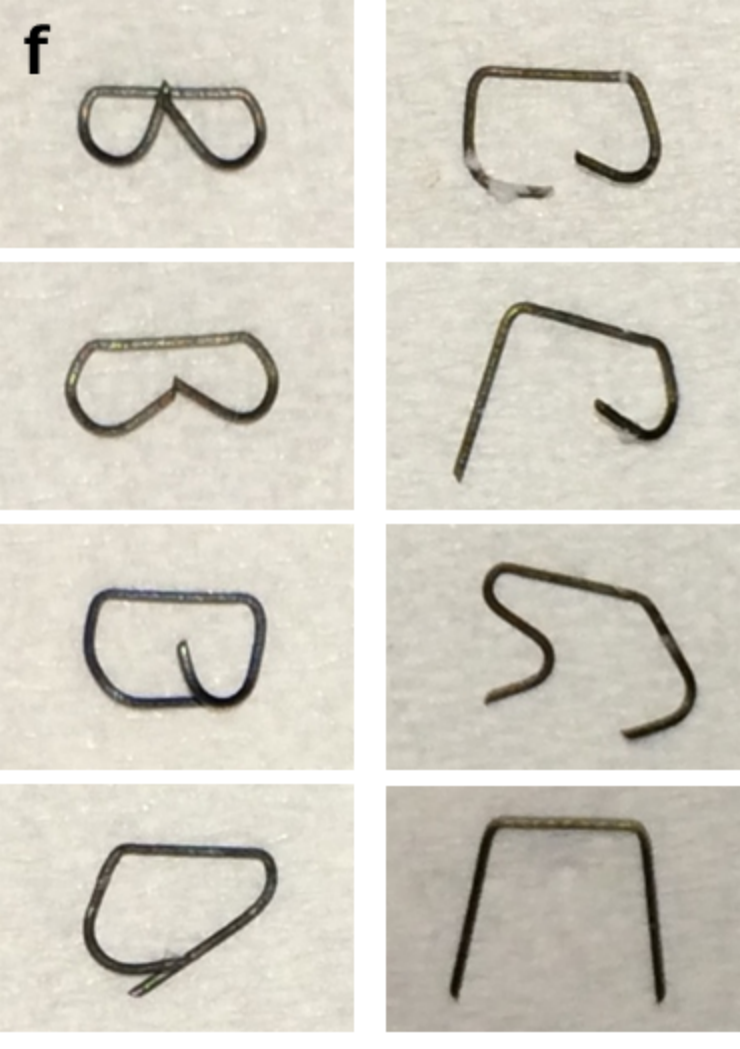

a
Duodenum
Esophagus
Fundus
Antrum
Body

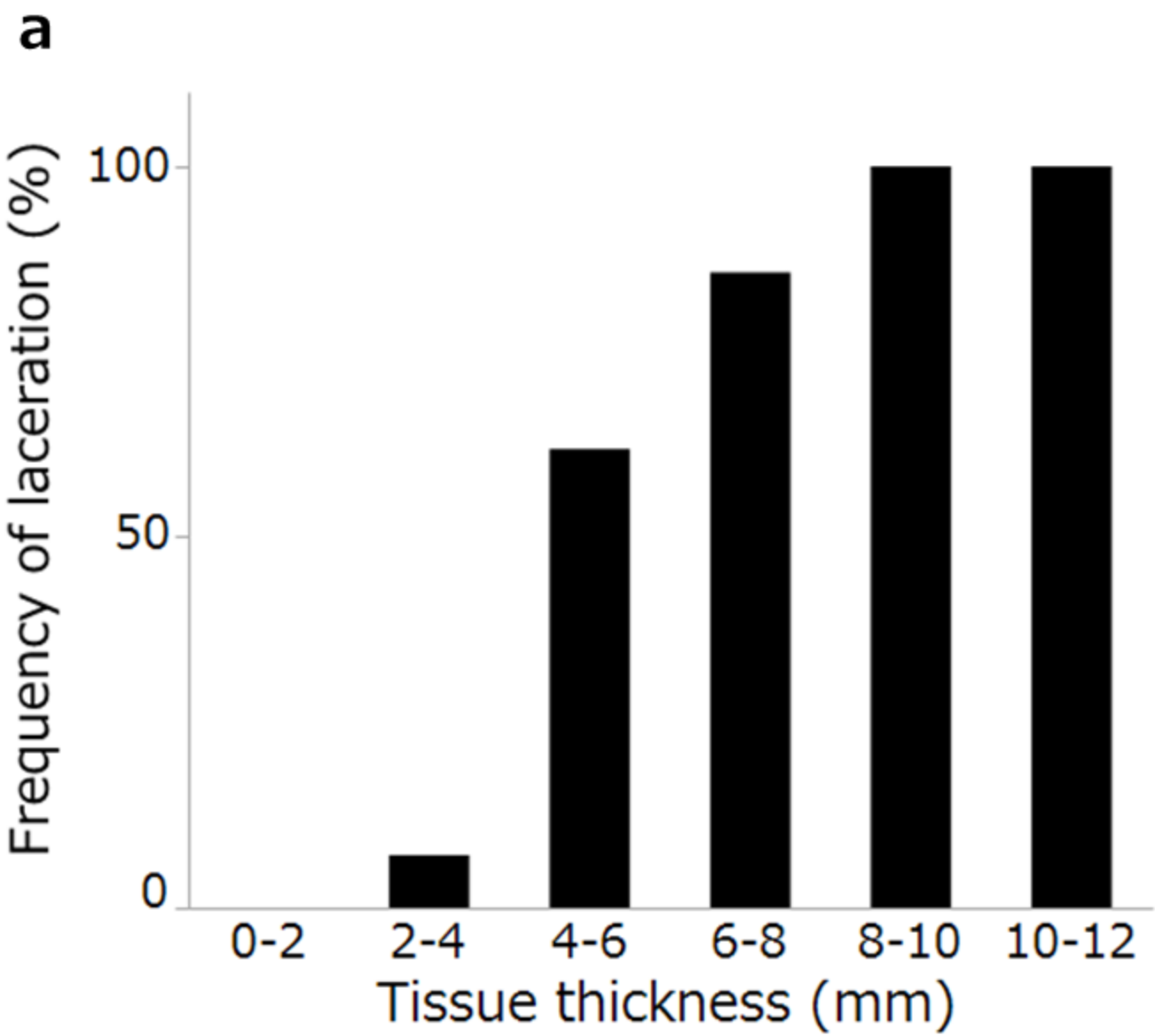

b
ETHICON ENDO-SURGERY
CUT
0
30
40
50
60

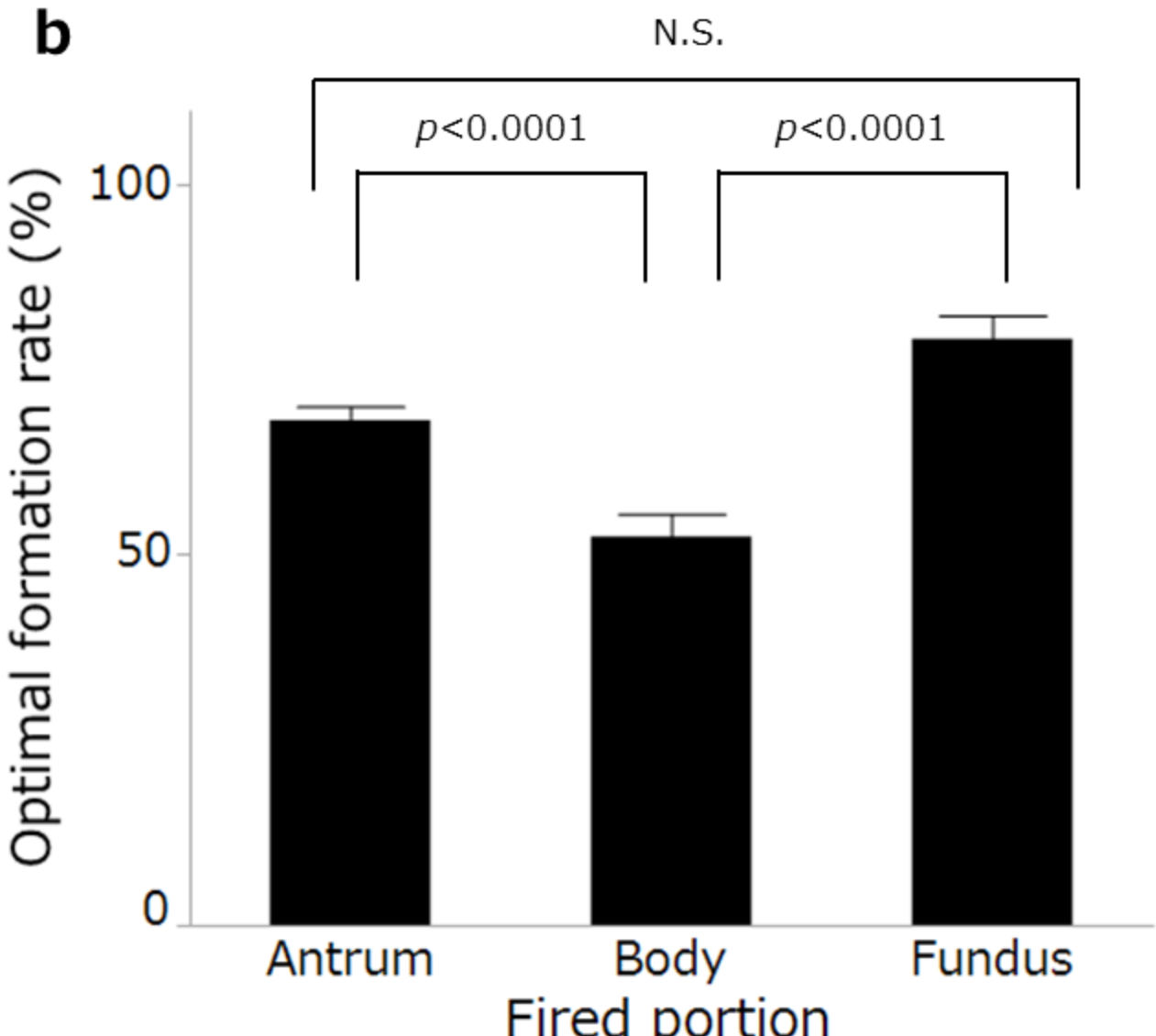

c
Top
Middle
Base

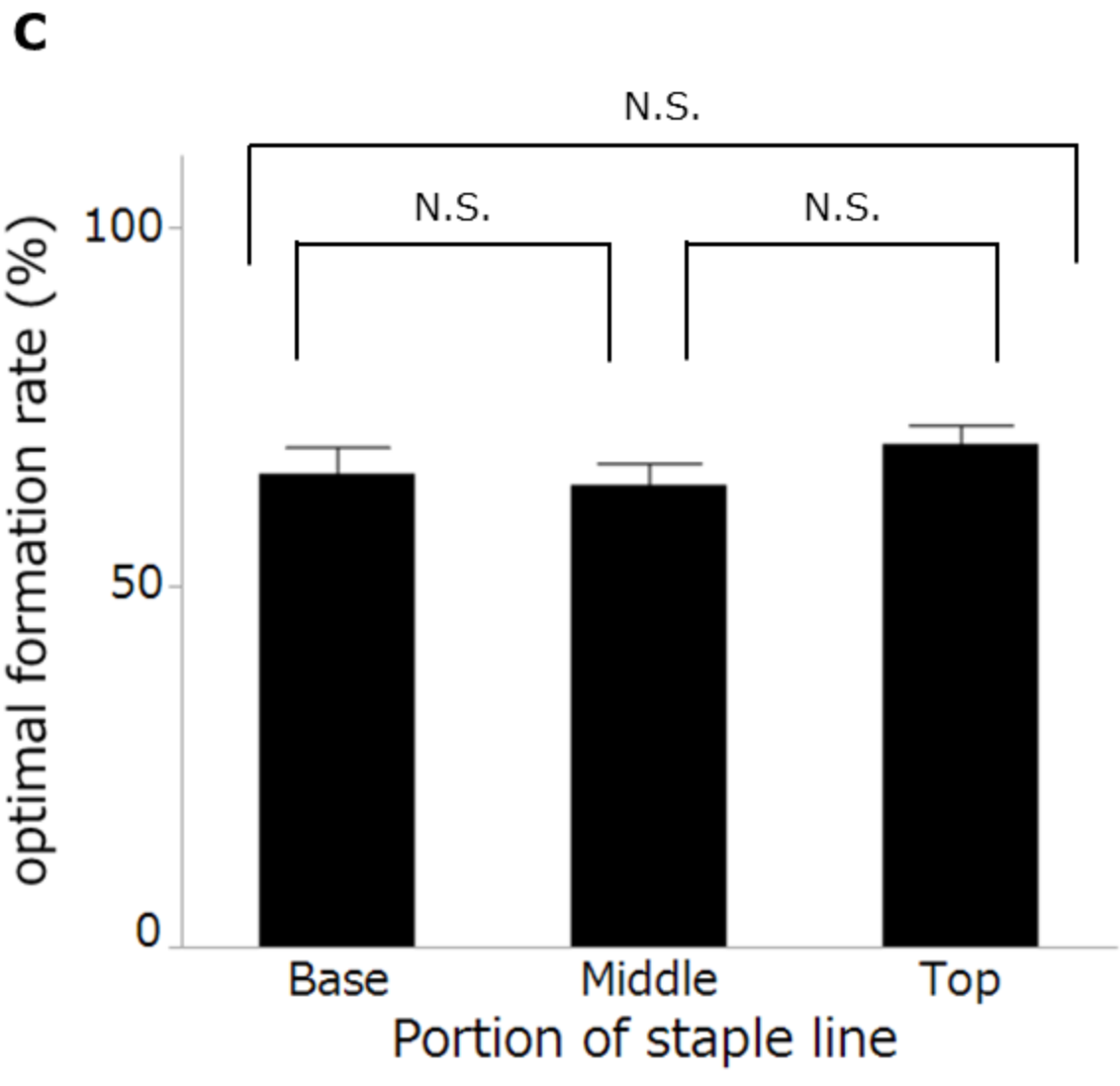

d

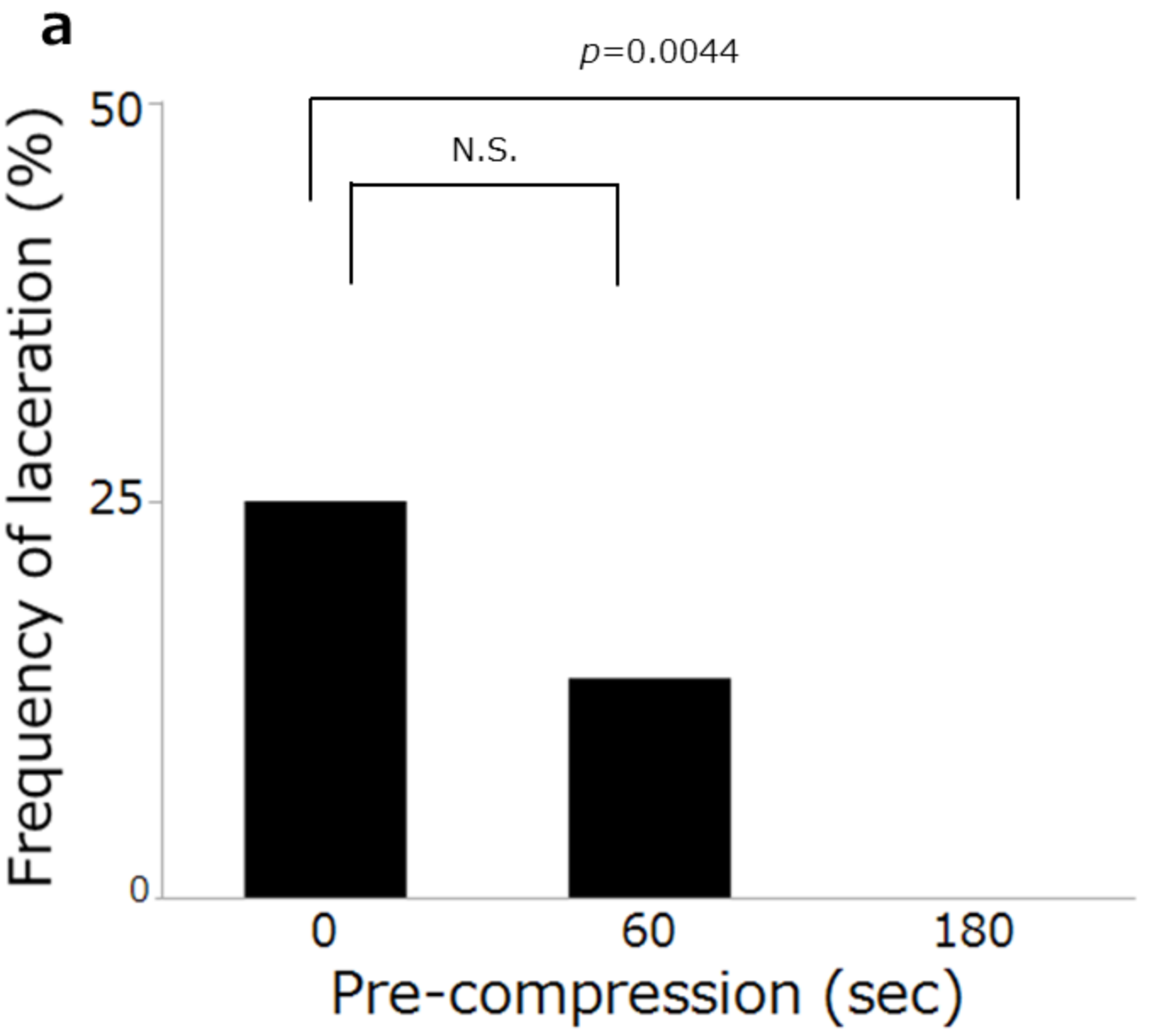

e

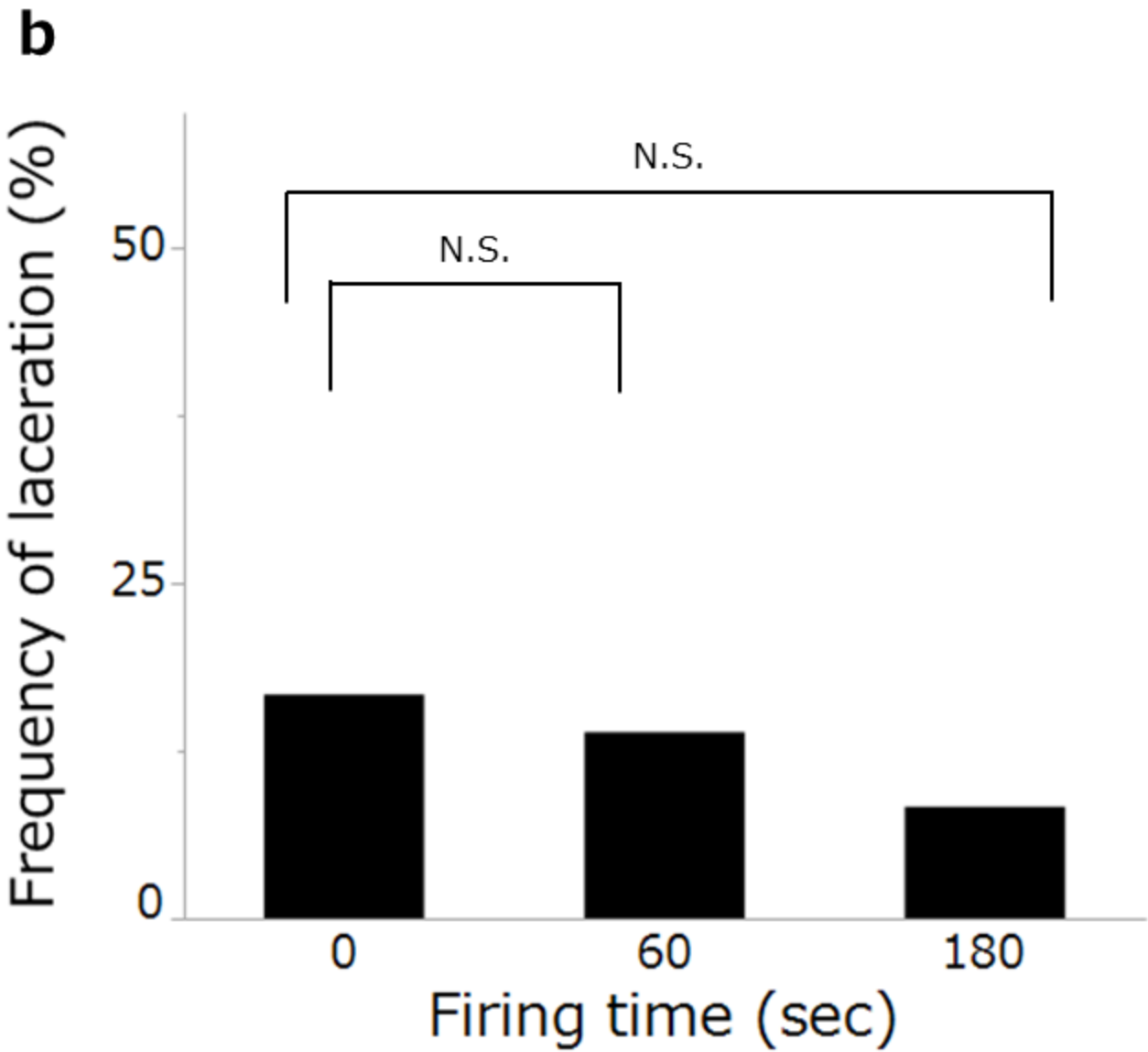

f
Optimal
Suboptimal

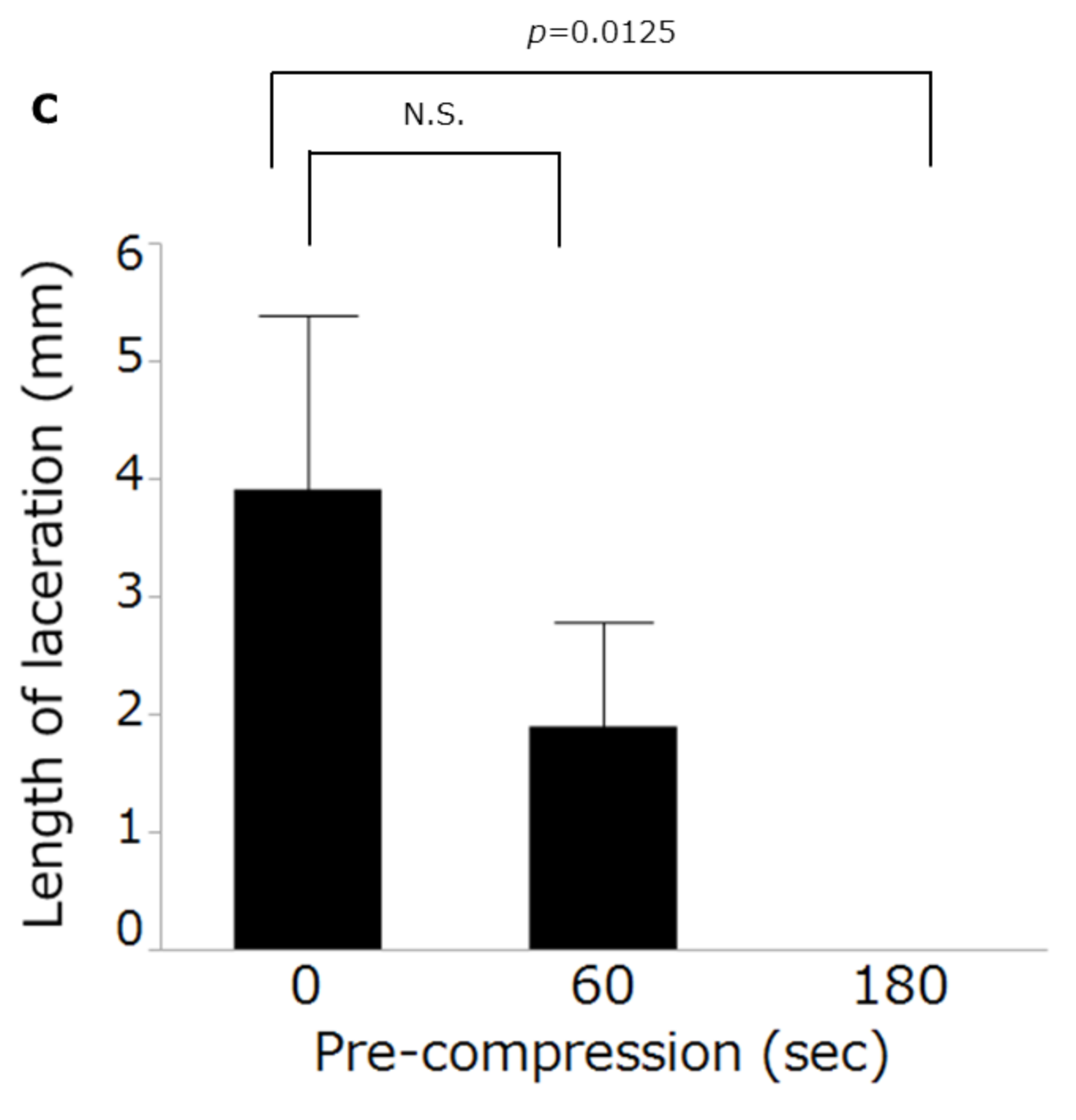

a
Frequency of laceration (%)
100
50
0
0-2
2-4
4-6
6-8
8-10
10-12
Tissue thickness (mm)


b
N.S.
p<0.0001
p<0.0001
100
50
0
Optimal formation rate (%)
Antrum
Body
Fundus
Fired portion

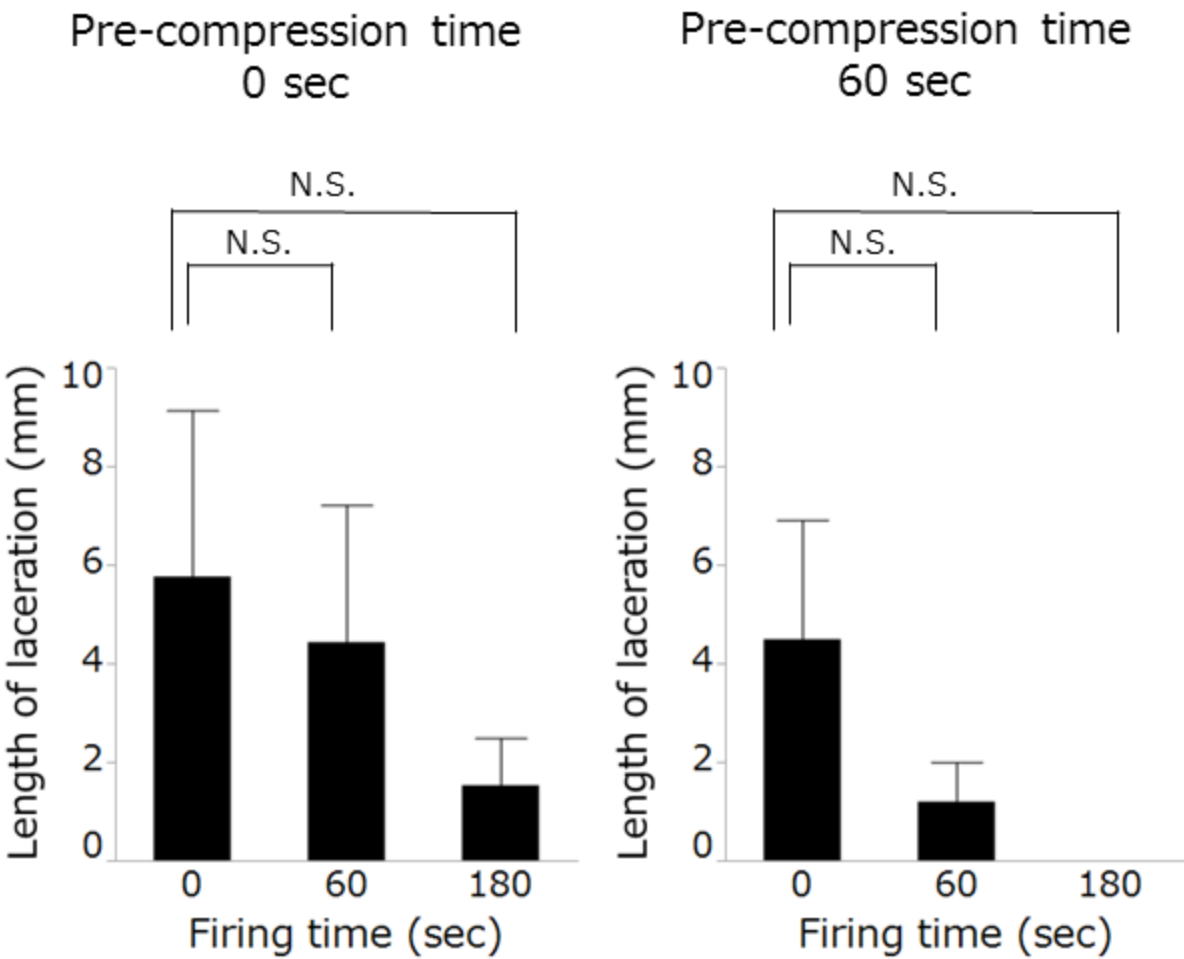

C
N.S.
N.S.
N.S.
100
50
0
optimal formation rate (%)
Base
Middle
Top
Portion of staple line

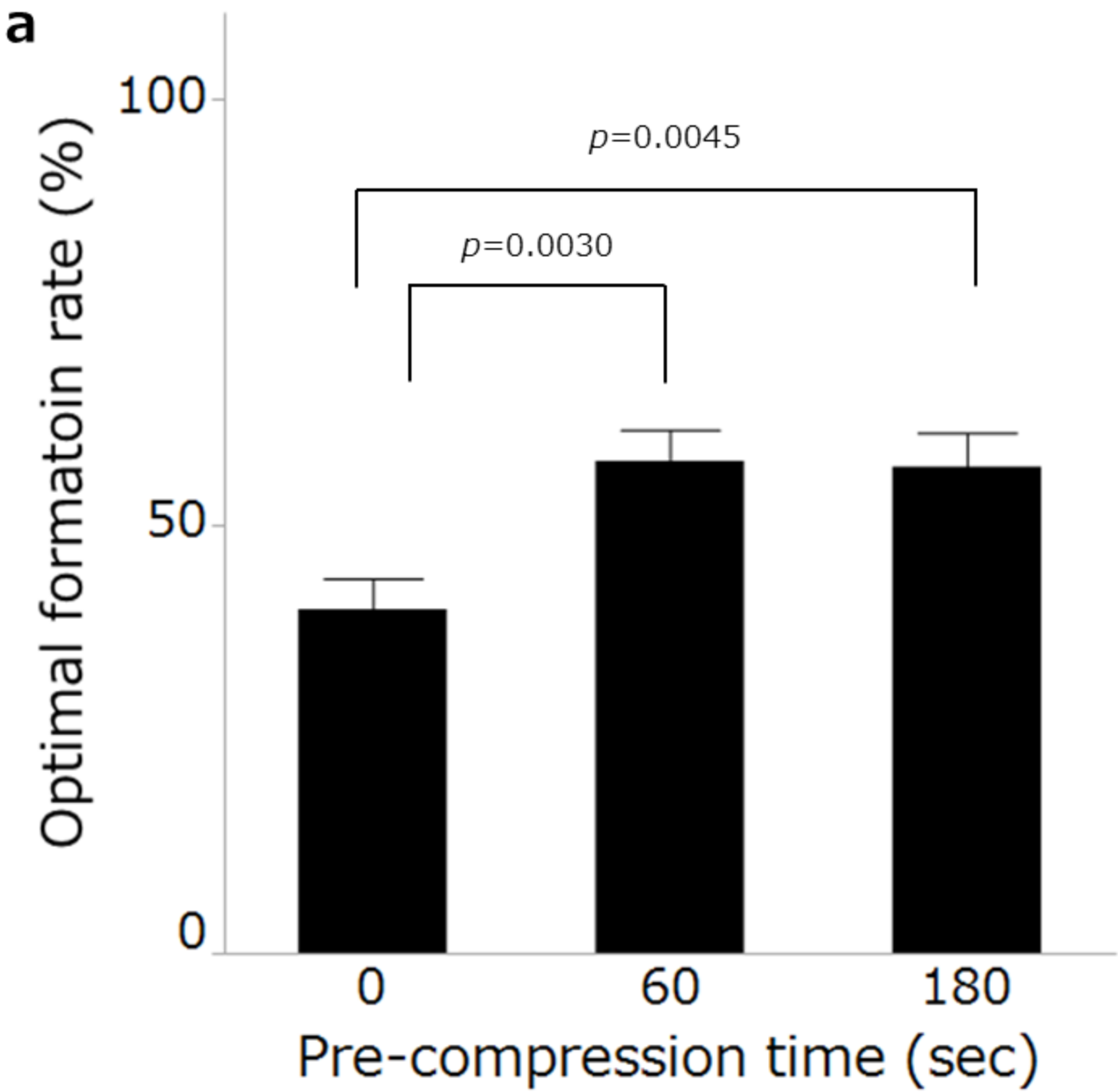

a
p=0.0044
N.S.
50
25
0
Frequency of laceration (%)
0
60
180
Pre-compression (sec)


b
N.S.
N.S.
50
25
0
Frequency of laceration (%)
0
60
180
Firing time (sec)


c
p=0.0125
N.S.
Length of laceration (mm)
6
5
4
3
2
1
0
0
60
180
Pre-compression (sec)

d


Pre-compression time
0 sec
N.S.
N.S.
Length of laceration (mm)
10
8
6
4
2
0
0
60
180
Firing time (sec)
Pre-compression time
60 sec
N.S.
N.S.
Length of laceration (mm)
10
8
6
4
2
0
0
60
180
Firing time (sec)


a
100
50
0
Optimal formatoin rate (%)
p=0.0045
p=0.0030
0
60
180
Pre-compression time (sec)

b

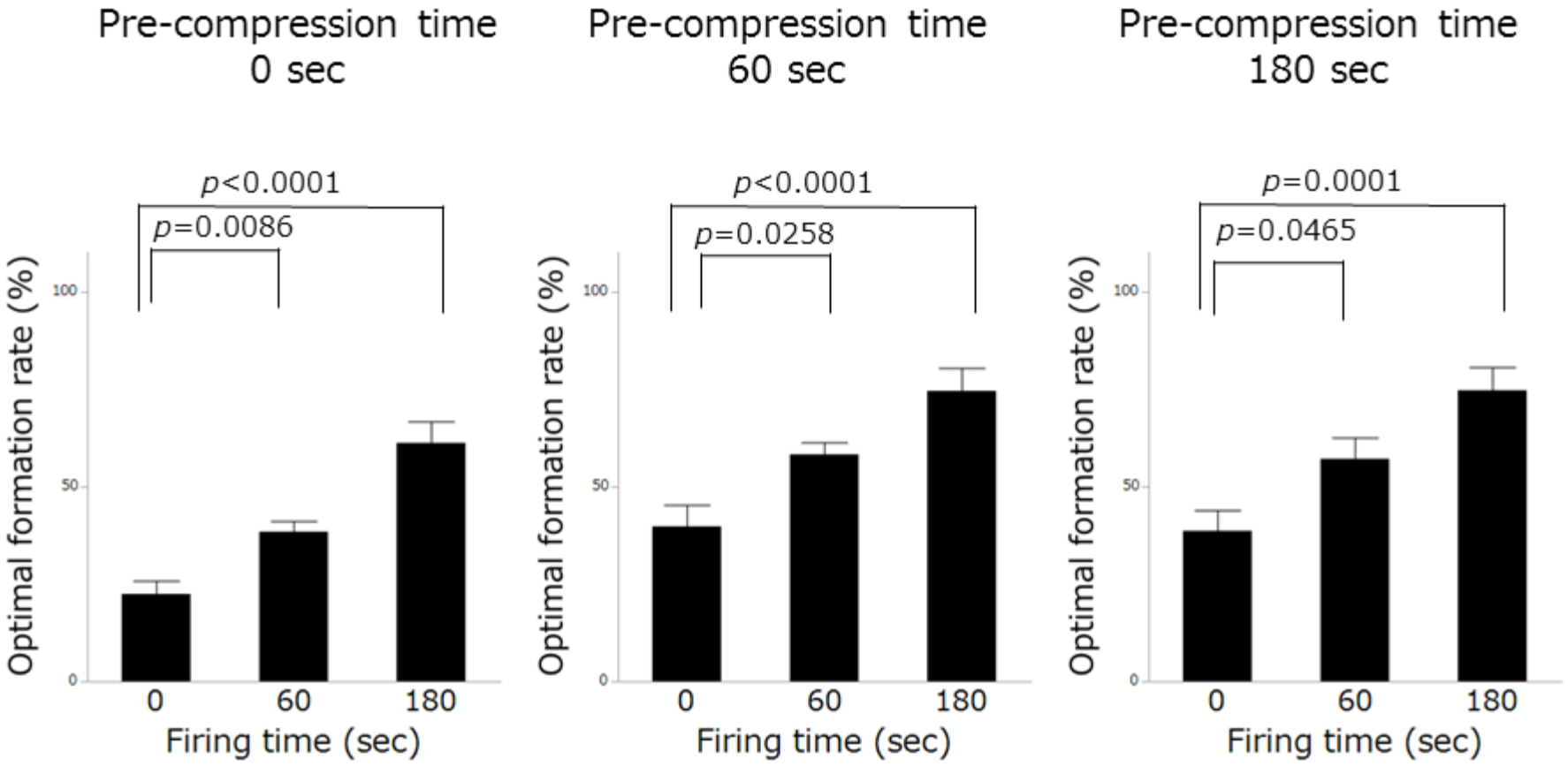

Pre-compression time
0 sec
Pre-compression time
60 sec
Pre-compression time
180 sec
p<0.0001
p=0.0086
p<0.0001
p=0.0258
p=0.0001
p=0.0465
Optimal formation rate (%)
100
50
0
0
60
180
Firing time (sec)

Table 1. Wall thickness of each portion of the porcine stomach

Suturing portion	Mean ± SD (mm)	Range (mm)
Antrum	5.26 ± 0.84	4.0-7.9
Body	8.83 ± 1.63	4.8-11.7
Fundus	3.78 ± 0.91	1.9-5.8
Total	5.95 ± 2.43	1.9-11.7

SD, standard deviation

Table 2. Relationship between optimal formation rate and material/technical factors

			Optimal formation rate			Optimal formation rate			Optimal formation rate			Optimal formation rate		
		Total	< 45%	≥ 45%	p value	< 50%	≥ 50%	p value	< 55%	≥ 55%	p value	< 60%	≥ 60%	p value
Pre-compression time	0 s	36	23	13	***0.0002***	26	10	***0.0007***	30	6	***0.0019***	30	6	***0.0135***
	60 s / 180 s	72	19	51		27	45		38	34		43	29	
Firing time	0 s	36	27	9	***<0.0001***	30	6	***<0.0001***	31	5	***<0.0004***	32	4	***<0.0008***
	60 s / 180 s	72	15	55		23	49		37	35		41	31	
Serosal laceration	(+)	14	11	3	***0.0014***	12	2	***0.0033***	12	2	*0.0588*	12	2	*0.1205*
	(−)	94	31	61		41	53		56	38		61	33	

Table 3. Multivariate analysis of factors associated with lov

Parameters	Optimal formation rate < 45%			Optimal formation rate < 50%		
	p-value	Odds ratio	95% Confidence interval	p-value	Odds ratio	95% Confidence interval
Pre-compression time: <60 s	0.0001	9.10	2.809-36.332	0.0009	5.65	2.003-17.277
Firing time: <60 s	<0.0001	23.04	7.303-95.541	<0.0001	15.42	5.325-52.184
Serosal laceration: presence	0.0203	6.04	1.306-36.442	0.0324	5.64	1.146-42.897

w optimal formation rate

Optimal formation rate < 55%			Optimal formation rate < 60%		
p-value	Odds ratio	95% Confidence interval	p-value	Odds ratio	95% Confidence interval
0.0024	**4.71**	**1.698-14.801**	**0.0172**	**3.43**	**1.236-10.771**
0.0002	**6.65**	**2.372-22.131**	**0.0004**	**6.46**	**2.200-23.968**
0.3114	2.29	0.485-16.657	0.4288	1.92	0.409-13.821