Effect of the thickness and nonlinear elasticity of tissue on the success of surgical stapling for laparoscopic liver resection

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Abstract—**Recently, the range of applications of surgical staplers has been extended to include laparoscopic liver resection because manipulation of a surgical stapler is very simple. Revealing the causes of stapling failure and suggesting a method to solve stapling failure are important for safe laparoscopic liver resection. Surgeons say that tissues make stapling more likely to fail if they are thick and brittle. However, the combinatorial effect of the thickness and stiffness of tissues on the success of surgical stapling for laparoscopic liver resection has not been investigated. Therefore, the objective of the present study was to investigate the effect of tissue thickness and tissue stiffness on the success rate (SR) of surgical stapling. From *ex vivo* stapling experimental results using pig livers, it is suggested that the effect of tissue thickness is greater than the effect of tissue stiffness on the SR of stapling. If tissue thickness is 5 mm, the SR of stapling is high regardless of the magnitude of the tissue-stiffness parameter. However, if tissue thickness is >10 mm, the SR of stapling has a relationship with nonlinear viscoelastic parameters. Therefore, the SR of stapling could be predicted from tissue thickness and nonlinear elastic parameters.**

I. INTRODUCTION

Recently, the range of applications of surgical staplers has been extended to include laparoscopic liver resection because manipulation of a surgical stapler is very simple [1–4]. However, problems with surgical staplers have been reported such as bleeding caused by cuts made by the surgical stapler; bleeding during liver resection increases mortality owing to liver failure or acute blood loss [5]. Therefore, revealing the causes of stapling failure and suggesting a method to solve stapling failure are important for safe laparoscopic liver resection.

Some researchers have reported causes of stapling failure owing to the stapler. Carlos et al. investigated the effect of staple height, buttressing, and overlapping of staple lines on stapling failure, and concluded that staple height was an important determinant of stapling failure [6]. Yo summarized that buttressing of the staple line seems to be effective in minimizing the risk of leakage and bleeding [7]. Nakayama et al. reported that a sufficient amount of pre-compression time was effective for stapling success [8].

Causes of stapling failure owing to surgical staplers have been investigated but the causes of stapling failure owing to tissues have not. Surgeons say that tissues make stapling more likely to fail if they are thick and brittle. Nakayama et al. also reported that stapling failure increased with increasing thickness of the intestinal wall [8]. However, the combinatorial effect of the thickness and stiffness of tissues on the success of surgical stapling for laparoscopic liver resection has not been investigated. Investigating the combinatorial effect of the thickness and stiffness of tissues is important because compressional deformation and breaking behaviors of elastic material have an intimate relationship with the thickness and stiffness of tissue.

Breaking of soft tissue in the body depends on the stress of tissue [9]. In general, the stiffness of soft tissue in the body shows not only linear elasticity, it shows viscoelasticity and nonlinear elasticity. Nonlinear elasticity of soft tissue in the body is an increase in stiffness under large strain. Nonlinear elasticity is an important property for breaking of soft tissue because the increasing rate of stress of tissue during stapling varies with the increase in stiffness. In addition, when the height of the staple needle is identical then the stress caused by a large strain during stapling increases with increasing tissue thickness. Therefore, we consider that investigating the combinatorial effect of the thickness and nonlinear elasticity of tissue is important.

The aim of this study is to investigate the effect of the thickness and nonlinear elasticity of liver tissue on the success of surgical stapling for laparoscopic liver resection. We undertook *ex vivo* stapling experiments using pig livers sliced into several thicknesses. We measured the nonlinear elasticity of each pig liver to discuss the effect of thickness and nonlinear elasticity on the success of surgical stapling.

II. METHOD

In this section, we describe an *ex vivo* experiment to investigate the relationship between tissue thickness and tissue stiffness and its effect upon stapling. Nine pig livers were cut into slices of four thicknesses. A surgeon sutured these slices using a surgical stapler. The success or failure of stapling for each slice was then evaluated. The tissue stiffness of each pig liver was measured using a rheometer.

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A. Experimental material

We used pig livers because they are of similar size and have a metabolism similar to that of human livers. After killing, livers were removed from healthy pigs and frozen until transportation to our laboratory. Upon arrival in our laboratory, livers were defrosted to 23°C.

Pig livers were cut into four thicknesses: 5, 10, 15, and 20 mm. We removed two slices of each thickness from each pig liver. The direction of tissue thickness was perpendicular to the cross-section of the liver. The length of each tissue slice was ≥60 mm and the width ≥11.5 mm (Figure 1). Nine pig livers were cut into slices. Slices of liver tissue were cut while avoiding large vessels. Parenchyma without capsules was selected for stapling because we wanted to exclude the effect of capsules and vessels on the success of stapling.

B. Surgical stapler

We used an Echelon Flex 60™ Endopath® stapler (Johnson & Johnson Inc., NJ, USA). The cartridge type of the staple needle was blue (designed for normal-thickness tissue and thin tissue). This cartridge had six staple lines. Staples were located 25 mm from a hinge of the forceps part. The height of the staple needle was 1.5 mm and the length of the suture was 60 mm (Figure 2). The opening width of the position 25-mm away from the hinge was ≈7 mm.

C. Setting and procedure of stapling experiments

A tissue slice was laid on a table sheeted by a surgical non-woven material without fixing because minimizing initial stress to the tissue slice was desirable for basic research. First, a surgeon held the tissue slice between the forceps part of the surgical stapler shown in Fig. 3. Next, the forceps part of the surgical stapler was closed for 15 s. The forceps part of the surgical stapler was closed completely, and the surgeon maintained this state for 15 s. Finally, the surgeon fired the staple needle. During this procedure, the surgeon kept movement of the position of the surgical stapler to a minimum. After stapling, the surgeon evaluated the success of stapling by visual judgment (described in detail in section II E).

D. Measurement of tissue stiffness

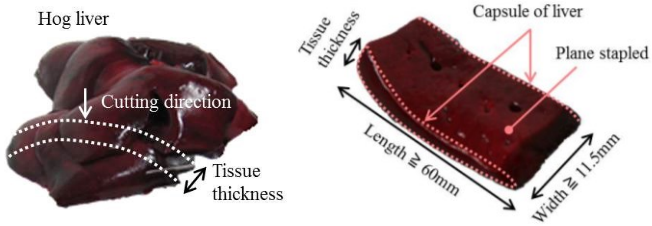
We used a nonlinear viscoelastic model that agreed well with the deformation behavior of pig livers described in our previous work [10]. The nonlinear viscoelastic model is expressed by (1) and (2).

$$G\frac{d^k\gamma}{dt^k} = \tau \quad , \tag{1}$$

$$G(\gamma) = \begin{cases} G_o & (\gamma < \gamma_0) \\ G_0\left(1 + a_\gamma(\gamma - \gamma_0)^2\right) & (\gamma > \gamma_0) \end{cases} , \tag{2}$$

where G is the viscoelasticity depending on shear strain, t is time, γ is shear strain, k is the order of the derivative, τ is shear stress, G_0 is the viscoelastic modulus of the linear part, a_γ is the coefficient determining the change in the viscoelastic modulus, and γ_0 is the point at which nonlinearity is observed.

We focused our attention on the three nonlinear parameters G_0, a_γ and γ_0. We did not focus on the viscoelastic parameter k because the manipulation time and speed of the surgical stapler were constant. Three nonlinear parameters were measured by the creep test using Rheometer AR-G2 (TA Instruments Waters LLC, DW, USA). The conditions and procedure of measurement were identical to those detailed in our previous work [11].



(a) Whole pig liver (schematic) (b) Slice of liver tissue (schematic)

Figure 1. Experimental material.

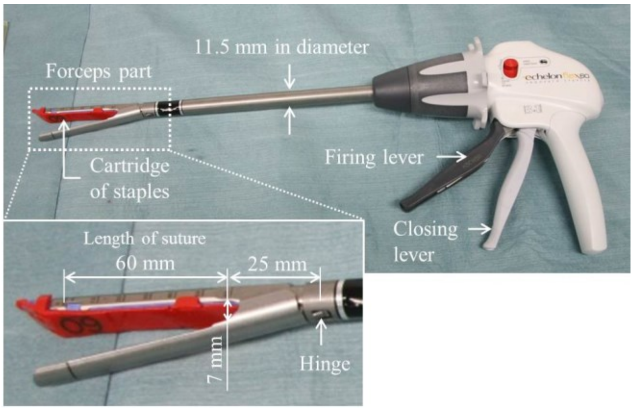


Figure 2. Echelon Flex 60™ Endopath® Surgical Stapler

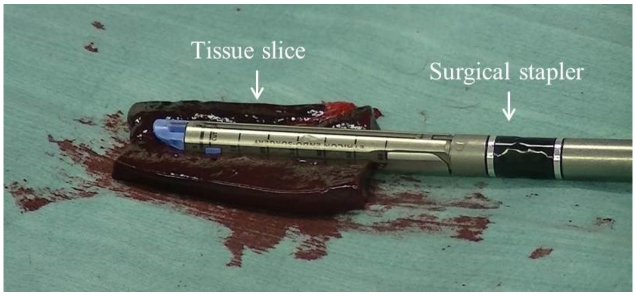
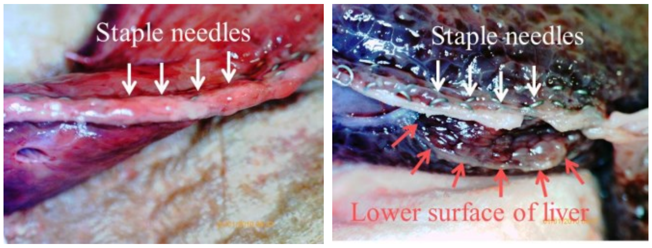


Figure 3. Experimental setup



(a) "Success" state (b) "Failure" state

Figure 4. Stapling state.

E. *Evaluation index*

We defined the success rate of stapling SR as an index to evaluate the degree of success of stapling by following (3).

$$SR\ (\%) = \frac{L_s}{L_t}, \tag{3}$$

where L_t is the total length of stapling, and L_s is the length of stapling in the "success" state. When stapling is in the success state, staple needles steady the upper and lower surfaces of the tissue slice (Figure 4(a)). When stapling is in the "failure" state, the staple needles tear the surface of tissue slice (Figure 4(b)). The SR of stapling was evaluated upon visual judgment by the surgeon after each stapling.

III. RESULTS

In this section, we describe the distribution of the SR of stapling for each tissue thickness. We also detail the relationship between tissue thickness and the parameters of tissue stiffness, and the SR of stapling.

A. *Distribution of the SR of stapling for each tissue thickness*

Figure 5 shows boxplots of the SR of stapling for each tissue thickness. The results are for 18 slices of tissue per tissue thickness. The SR of stapling decreases with increasing tissue thickness. If tissue thickness is 15 mm, the variability in the SR of stapling is greatest. If tissue thickness is 20 mm, the SR of stapling is <50% with a probability of 75%.

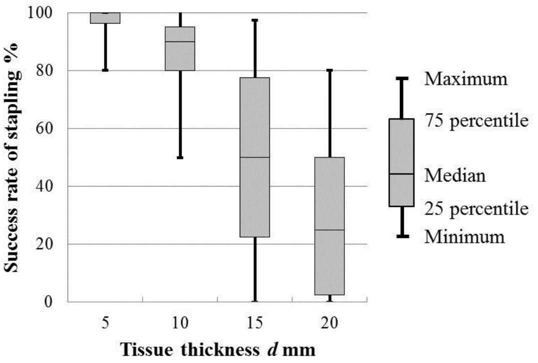


Figure 5. Boxplots of the success rate of stapling for each tissue thickness

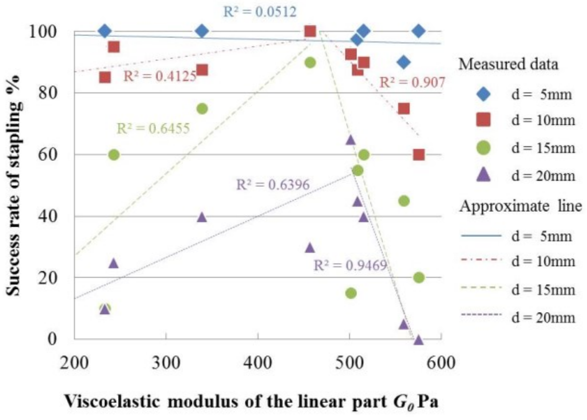


Figure 6. Relationship between the success rate of stapling and viscoelastic modulus of the linear part for each tissue thickness

B. *Relationship between tissue thickness and the parameters of tissue stiffness, and the SR of stapling*

Figures 6–8 are plots of the SR of stapling for each tissue thickness and each parameter of tissue stiffness. Data in Figs 6–8 were calculated as mean SR values of two slices for each liver and each tissue thickness.

If tissue thickness is 5 mm, there is no direct relationship between the SR of stapling and all parameters of tissue stiffness. If tissue thickness is >10 mm, a different relationship between the SR of stapling and each parameter of tissue stiffness is observed. The lines in Figs 6–8 are merely aids to show the different relationships of the SR of stapling to each tissue thickness and each parameter of tissue stiffness.

With respect to the viscoelastic modulus of the linear part G_0, the SR of stapling appears to be maximal at 450–500 Pa. With increasing tissue thickness, the peak position of the SR shifts in the direction of increasing G_0, and changing the SR to G_0 makes it larger. Additionally, changing the SR to G_0 in the peak aft-position is larger than changing the SR to G_0 in the peak fore-position.

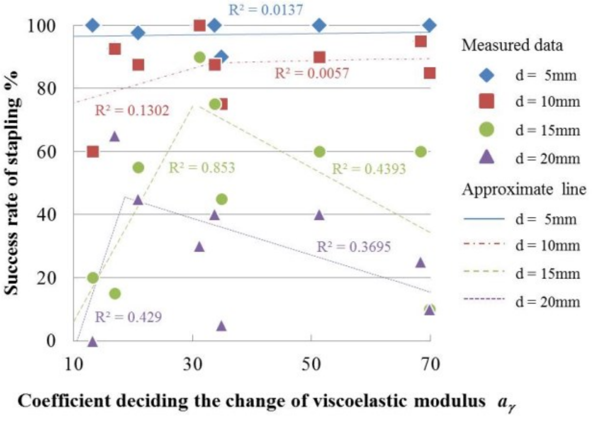


Figure 7. Relationship between the success rate of stapling and the coefficient that decides the change in viscoelastic modulus for each tissue thickness

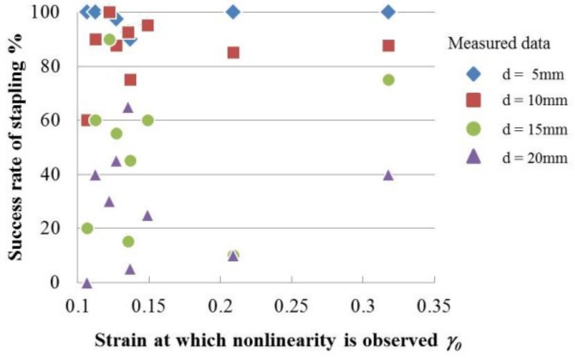


Figure 8. Relationship between the success rate of stapling and strain at which nonlinearity is observed for each tissue thickness

With regard to the coefficient that decides the change in the viscoelastic modulus a_γ, it seems that the SR of stapling is maximal at 15–35%. With increasing tissue thickness, the peak position of the SR shifts in the direction of decreasing a_γ, and changing the SR to a_γ makes it larger. Additionally, changing the SR to a_γ in the peak aft-position is smaller than changing the SR to a_γ in the peak fore-position. With respect to the strain at which nonlinearity is observed γ_0, it seems that the SR of stapling shows greatly variability.

IV. DISCUSSION

In this section, we discuss the effects of tissue thickness and tissue stiffness on the SR of stapling from experimental results.

A. *Effects of tissue thickness and tissue stiffness upon the SR of stapling*

The results suggest that the effect of tissue thickness is greater than the effect of tissue stiffness on the SR of stapling. If tissue thickness is 5 mm (i.e., more than three-times the height of the staple needle) the SR of stapling is high regardless of the magnitude of the tissue-stiffness parameter. However, if tissue thickness is >10 mm (i.e., more than seven-times the height of staple needle) the SR of stapling has a relationship with the viscoelastic modulus of the linear part G_0 and the coefficient that decides the change in the viscoelastic modulus a_γ. In future works, we will build a quantitative mathematical and statistical model of the relationship between the SR of stapling and theses nonlinear elastic parameters by a computational mechanic method and statistical boundary method (e.g., finite elemental method and support vector machine).

In conclusion, these results suggest that the SR of stapling could be predicted from tissue thickness and the nonlinear elastic parameters G_0 and a_γ. Additionally, the results suggest that the safety of stapling for laparoscopic liver resection could be improved if a device that can measure the tissue thickness and two nonlinear elastic parameters before stapling can be invented. In addition, the results suggest that the relationship among the SR of stapling, tissue thickness and tissue stiffness could serve as a new design guide for safer surgical staplers.

B. *Limitations of this investigation*

We undertook these experiments *in vitro* to minimize initial stress to tissue slices. However, livers in the real-world surgical situation will have some initial stress, and it is suggested that initial stress influences the SR of stapling. Therefore, we need to investigate in the real-world surgical situation.

We did not consider the effect of the heterogeneity of tissue stiffness (e.g., capsules and vessels in livers) or the effect of the viscosity of tissue on the SR of stapling. Also, we investigated the livers of healthy pigs, not the normal, fatty, or cirrhotic livers of humans. We need to investigate more tissue samples using more surgeons to better understand the statistical inferences of our data. These limitations will be overcome in future work.

V. CONCLUSION

The object of the present study was to investigate the effect of tissue thickness and tissue stiffness on the success of surgical stapling for laparoscopic liver resection. Our *ex vivo* stapling results suggested that the effect of tissue thickness was greater than the effect of tissue stiffness on the SR of stapling. If tissue thickness is 5 mm, the SR of stapling is high regardless of the magnitude of the tissue-stiffness parameter. However, if tissue thickness is >10 mm, the SR of stapling has a relationship with nonlinear viscoelastic parameters. Therefore, the SR of stapling could be predicted from tissue thickness and nonlinear elastic parameters.

In future works, we will carry out more experiments and undertake finite elemental analyses and statistical boundary decision analyses using experimental results. We will build a mathematical and statistical model of the probability of success of stapling taking into consideration the heterogeneity of stiffness and viscosity of tissue. Additionally, we will investigate human livers in more real-world surgical situations. After those studies, we will develop a device that can measure tissue thickness and two nonlinear elastic parameters before stapling, and develop a system to plan manipulation of surgical staplers and a new, safer design of surgical stapler.

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