Study on Invitro Evaluation Method of Vascular Coagulation Performance Using Opposite Phase Vibration Ultrasonic Scalpel

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Abstract: The ultrasonic scalpel used in the operation can perform coagulation hemostasis and tissue incision in the affected area. For coagulation, thermal denaturation must be completed before incision. Improvement of coagulation performance is required to shorten the operation time. In this research, we developed an opposite phase vibration ultrasonic scalpel that can excite a combined vibration of longitudinal vibration and bending vibration in a commercially available ultrasonic scalpel. In previous studies, it was found that the heat generation performance was higher than that of the conventional ultrasonic scalpel, so the purpose of this tissue was development of experimental method to evaluate the vascular coagulation performance using an opposite phase vibration ultrasonic scalpel.

Key-Words: *Ultrasonic scalpel, Coagulation, Heat generation, Medical Device, Tensile Stress*

1. Introduction

The ultrasonic scalpel can perform coagulation, hemostasis and incision of the affected tissue. According to the reports [1,2], the essential hemostatic mechanism is that the coagulated proteins caused by the friction heat seal the bleeding vessels. For coagulation, thermal denaturation must be completed before incision [3]. Therefore, the improvement of coagulation performance is required [4]. In this research, we developed an opposite phase vibration ultrasonic scalpel that can excite a combined vibration of longitudinal vibration and bending vibration in a commercially available ultrasonic scalpel [5-11]. The purpose of this tissue was development of experimental method to evaluate the vascular coagulation performance using an opposite phase vibration ultrasonic scalpel.

2. The principle of opposite phase vibration

Fig.1 shows the principle of opposite phase vibration. The main parts are a rod and a branched tip. The rod part propagates the longitudinal vibration from the actuator. The generation of elastic waves in the cross-section of a rod part can be produced by applying a sinusoidal voltage at the required frequency to the transducers. The waves then propagate through the rod part to the branched tips. The tip of the branches has a slope for converting the vibration direction, which causes mode conversion. The resulting tip vibration is branched in the opposite direction of branch I and II, thereby exciting an opposite phase vibration.

3. Coagulation-incision experiment

In the experiments, developed opposite phase vibration model scalpel (Fig.2) was used to evaluate the vascular coagulation performance. In order to make the heat generation condition constant, an experimental system that controls the pressing force and the scalpel driving condition etc. was constructed. Fig.3 shows a schematic of the experimental system. In the experiment, the output power of the ultrasonic scalpel was controlled by the feedback control of the input current value. By feeding back control the input frequency so that the input voltage and current phase difference reaches 0, the resonance point tracking was realized. The frequency control result was around 47kHz. This system feedback frequency was about 80 Hz.

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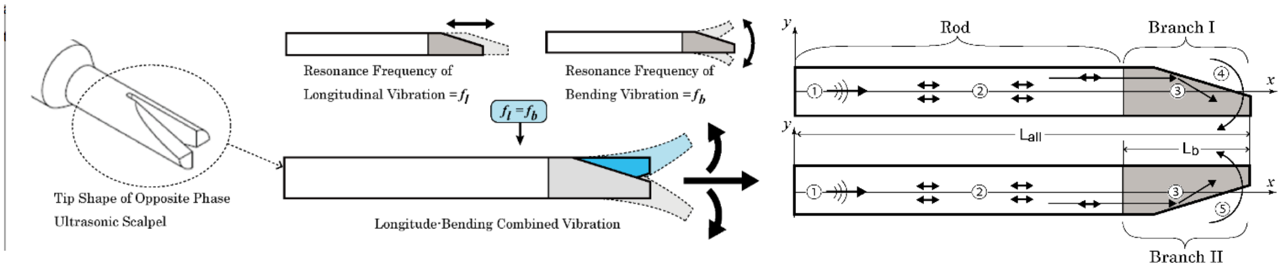


Fig.1 Operation of opposite phase vibration ultrasonic actuator. Cutaway of two inverse symmetry beam (Right). ①:input signal, ②: longitudinal wave propagating to tip ③: mode conversion to bending direction, ④: swing branch I, ⑤: branch II swing the opposite direction from branch I.

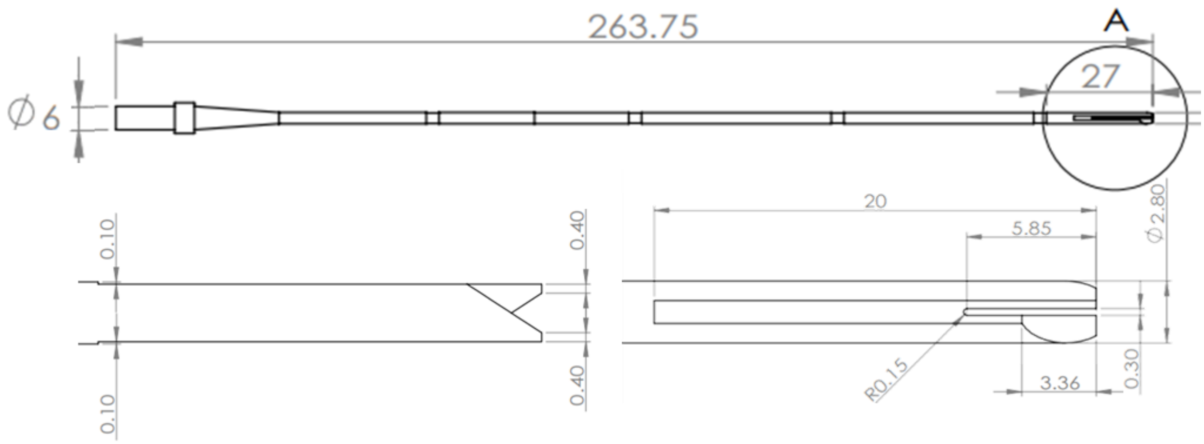


Fig.2 Design diagram of opposite phase vibration ultrasonic scalpel blade.

3.1 Experimental procedures

Fig.4 shows target blood vessel and schematic image of coagulation experiment. (a) is the photograph of internal side of bovine aorta, (b) is the cut-out intravascular membranes from it (the thickness is around 1 mm), (c, d, e) is the assembly image of the fixing plate and intravascular membranes, and (f) is the overview of experimental setup. The material of the ultrasonic scalpel was titanium. After wiping off the moisture, the two intravascular membranes were overlapped and attached to the load cell. A thermal camera was used to measure heat generation temperature during coagulation-incision experiment. After experiment, the coagulated intravascular membranes were stored in containers to prevent deterioration due to drying.

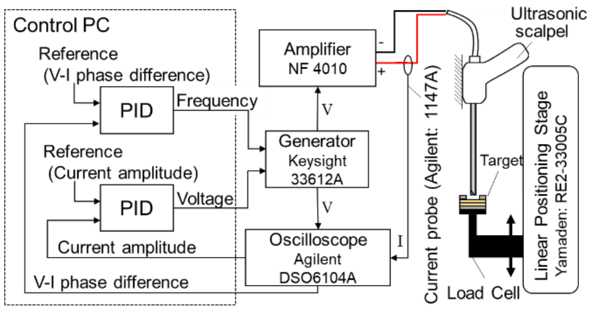


Fig 3 Schematic image of coagulation experimental system.

3.2 Experimental conditions

Target current value of controlled input was set to 0.4[A], pressing force of the ultrasonic scalpel tip was set to 4[N], speed was set to 0.5 [mm/s], pressing time was 25[sec], and the 3 drops of water on the membranes surface to promote cavitation. The fixing plate was made by ABS resin, and the upper part has a large square hole to easily measure the heat generation temperature by ultrasonic scalpel. The bottom part has a hole to penetrates two plates of intravascular membranes. The opposite phase model tip vibration amplitude driven without contacting the membranes with the input current 0.4 [A], it was observed 8.88 [μm] of longitudinal direction and the 7.37 [μm] of bending direction.

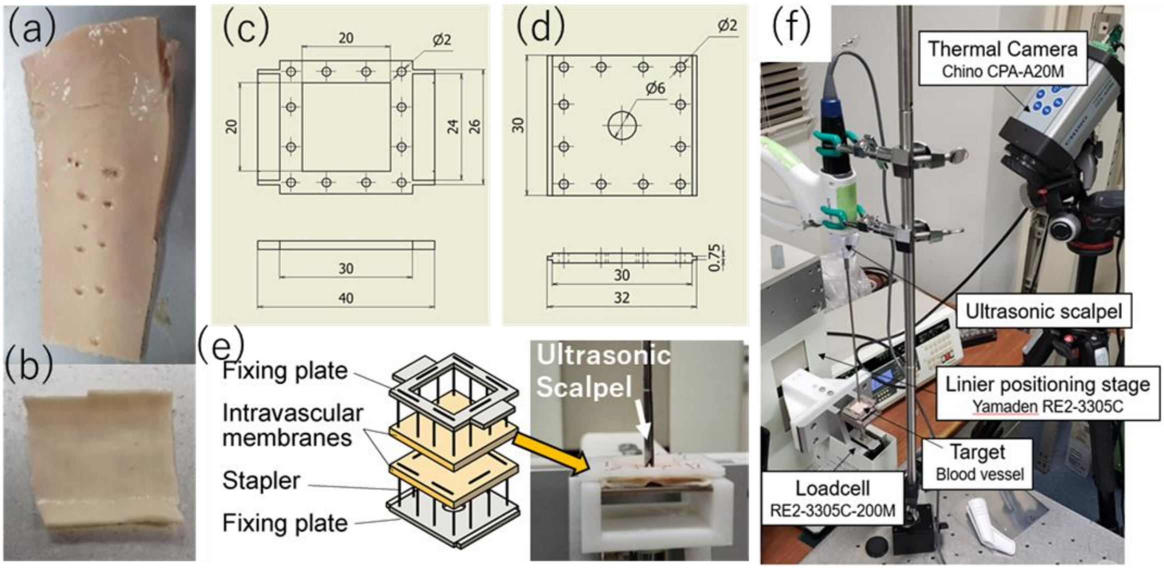


Fig. 4 Target blood vessel and schematic image of coagulation experiment. (a) inside photo of Bovine aorta, (b) cut- off intravascular membranes, (c) upper parts of fixing plate, (d) bottom parts of fixing plate, (e) assembly drawing of fixing plate and intravascular membranes and photograph during coagulation experiment, (f) overview of experimental setting

Table.1 Thickness of intravascular membranes, maximum temperature at coagulation experiment, maximum tensile load and strain at tensile test of each penetration. No. column is experiment number of incision experiment.

	NO.	Thickness [mm]	Max Temp. [˚C]	Max Tensil Load [N]	Max Strain [%]
(NC) Non Penetration	100	2.89	90.6	0.1	109
	114	1.47	89.4	0.08	152
(PP) Partial Penetration	93	1.73	90.4	0.35	264
	94	2.58	90.1	0.18	162
	96	1.05	90.5	No Coagulation	
	97	1.34	89	No Coagulation	
	98	1	90.6	No Coagulation	
	99	2.3	90	0.09	132
	101	1.66	95.9	No Coagulation	
	104	2.37	87.7	0.14	193
	106	2.5	87.7	0.06	45
	107	1.17	84.4	0.12	143
	111	1.7	89.8	0.14	153
	112	2.27	90.5	0.21	184
	126	1.54	85.3	0.09	84
	127	1.94	76	0.1	97
	128	2.17	87.1	0.04	76
	129	1.52	86.2	0.08	144
(CP) Complete Penetration	95	1.2	74.8	0.03	112
	103	1.36	75	0.14	163
	105	0.85	71.2	No Coagulation	
	108	1.45	74.5	0.13	141
	110	1.39	70	No Coagulation	

3.3 Result and discussion

In the results of coagulation experiment, there was a difference in coagulation performance and heating temperature depending on how much the tip of the ultrasonic scalpel penetrated the two vascular during cutting. Three criteria for the degree of penetration are shown in Fig.5. In addition, the exothermic temperatures during coagulation experiments are shown in Table 1. Number of successful coagulations was 17 of 23 experiments (74% successed).

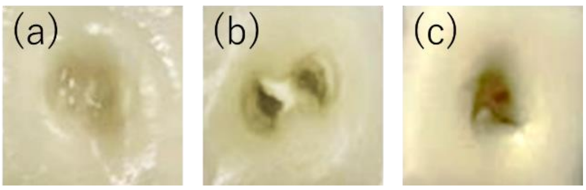


Fig.5 State of each penetration. (a)Non Penetration(NP), (b)Partial Penetration(PP), (c) Complete Penetration(CP)

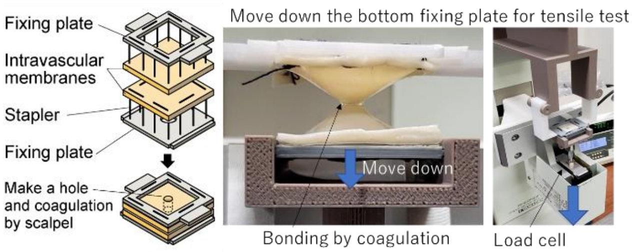


Fig.6 Overall photographs of coagulation performance evaluation tensile test.

Coagulation success rate was 100% in case non penetration (NP), 75% in case partial penetration (PP) and 60% in case complete penetration (CP). It became difficult to coagulate as the incision progressed. In the clinical site, coagulation and incision of ultrasonic scalpel are known to have a trade-off relationship, and our coagulation experimental result is considered to be valid result.

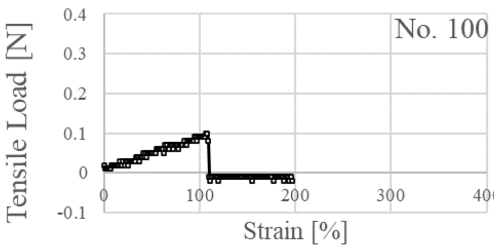
4. Tensile test

4.1 Experimental procedures and condition

Tensile test is often used in the performance evaluation of biological tissue [12-17]. After coagulation experiment, tensile test was done to evaluate coagulation performance. In the experiment, coagulation adheres two intimal in the cut surface of the ultrasonic scalpel. The coagulation performance was evaluated by estimating the tensile load of the adheres part by a tensile test. In order not to applied force to the coagulated intravascular membranes, the tensile test was performed by pulling the two fixing plates used in the coagulation experiment. Fig.6 shows the overall photographs of the evaluation experiment of the coagulation performance. In the test, a load cell of minimal inspection load 0.01 [N] was used.

4.2 Result and discussion

The experimental tensile load - strain curve is shown in Fig.7-9. Fig.7 is plotted result of case NP. Even if not penetrating, the two intravascular membranes were adhered, and its maximum tensile load was about 0.1[N]. The strain was 109[%] in No.100, 152 [%] in No.114. From Table 1, the thickness of the intravascular membranes of No.114 was about half of No.100, suggesting the relationship with strain. However, looking at the results in case PP of Fig.8, there is no correlation with the thickness of the intravascular membranes as seen in the non-penetration result. From this result, we suggest that only thickness is not a dominant factor. The result of tensile load was 0.04 to 0.35 [N] and the strain was 76 to 264 [%]. These results have a large variation, and the adhesion is considered to be unstable. Fig.9 shows the result of CP, and the intravascular membrane was possible to coagulated with a tensile strength of about 0.1 N. In addition, adhesion was confirmed in with a maximum temperature at coagulation experiment of 74.5 [℃] or higher. On the other hand, in the case PP, it was found that there is an individual which has not been coagulated even if over 90 °C, and it is considered not to be dependent on the heat generation temperature only. Table 2 is the result of averaging the thickness of the target blood vessel, the maximum exothermic temperature, the maximum tensile load, and the maximum strain in each penetration condition. The degree of penetration and the thickness of the intravascular membrane or the maximum heat generation temperature were correlated. When the membrane was thin, it was easy to penetrate, and the heat generation temperature was low. This fact indicates that a coagulation experiment considering the thickness of the target membrane is necessary. On the other hand, in the results of the tensile test, there was no difference in the average value under each condition. In this experiment, the pressing force, the ultrasonic power (amplitude, frequency), and the amount of water content affecting the coagulation performance of the ultrasonic scalpel are uniform, so it is no wonder that the coagulation performance was the same. This means that there was no difference in coagulation performance due to the thickness of the intravascular membrane, and the influence of the individual difference of the vascular in the tensile test was not seen. However, the variation of the individual results is large, and the influence of vascular individual differences cannot be ignored. By doing many time the experiment proposed in this paper, we hope to make clear the coagulation performance of ultrasonic scalpel.



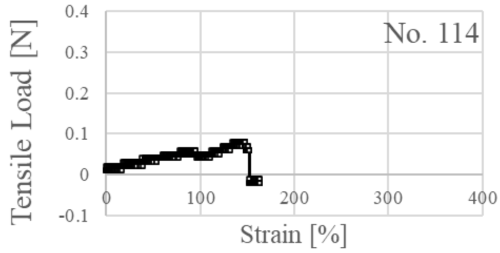
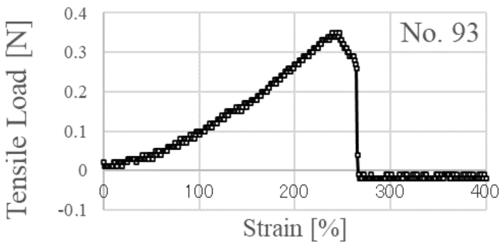
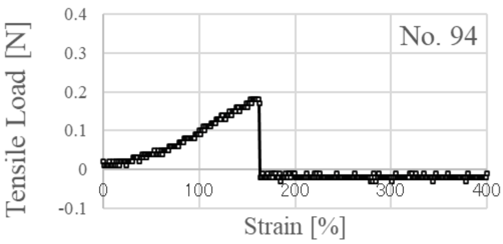
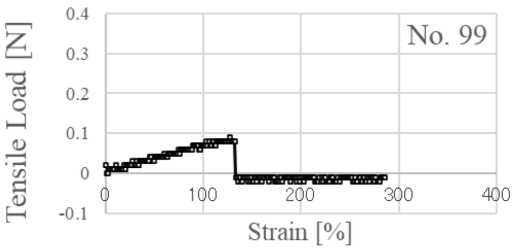
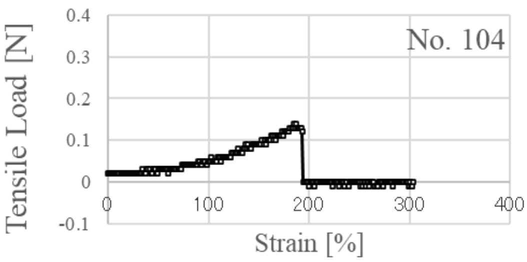


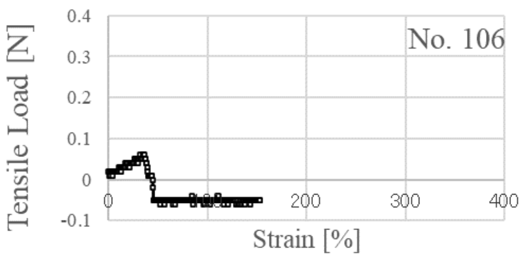
Fig.7 Tensile lode-strain curve of coagulation performance experiment with case Non Penetration.

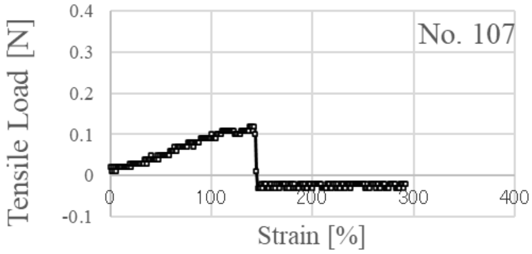


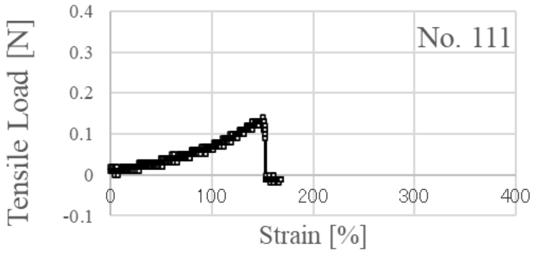


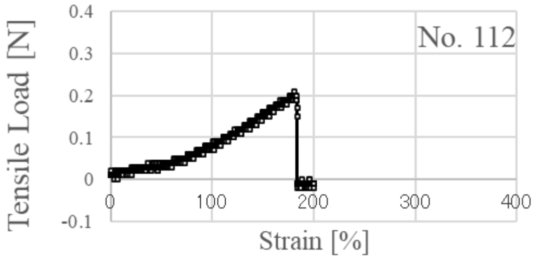


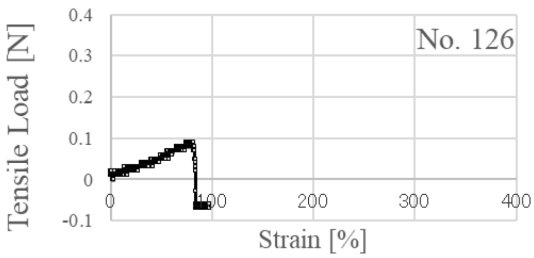


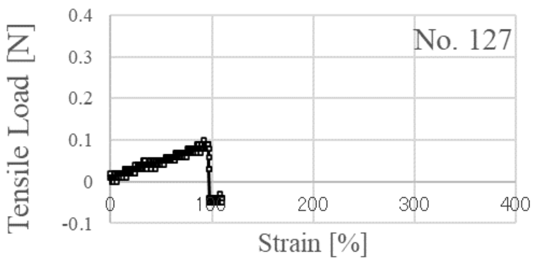












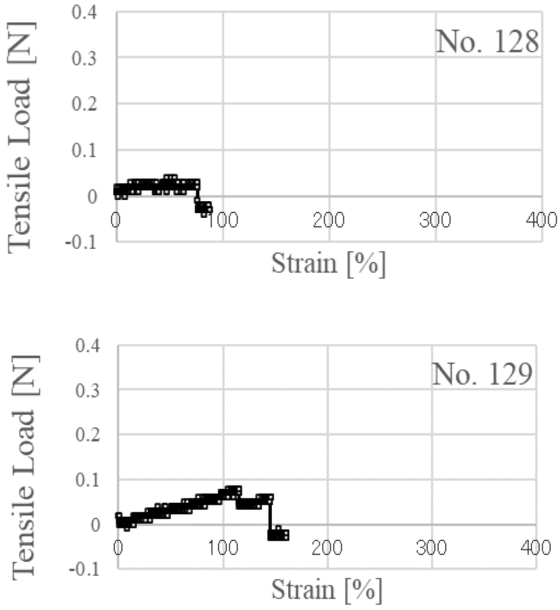


Fig.8 Tensile lode-strain curve of coagulation performance experiment with case Partial Penetration.

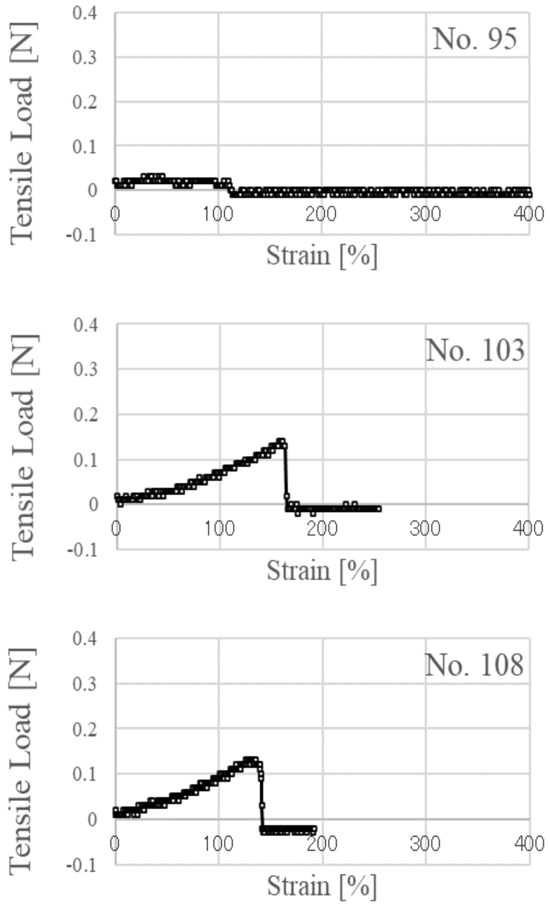


Fig.9 Tensile lode-strain curve of coagulation performance experiment with case Complete Penetration.

Table.2 Average of intravascular membranes thickness, maximum temperature at coagulation experiment, maximum tensile load and strain at tensile test of each penetration

	Thickness [mm]	Max Temp. [˚C]	Max Tensil Load [N]	Max Strain [%]
(NC) Non Penetration	2.18	90.0	0.09	130.5
(PP) Partial Penetration	1.80	88.2	0.13	139.8
(CP) Complete Penetration	1.25	73.1	0.10	138.7

5. Conclusion

In order to evaluate the vascular coagulation performance of the opposite phase vibration ultrasonic scalpel, we proposed an evaluation method of vascular coagulation performance by intravascular membranes coagulation-incision experiment and tensile test. In the coagulation-incision experiment, by driving the ultrasonic scalpel while pressing with a force of 4[N] to an overlapped two intravascular membranes, adhesion and incision due to coagulation were simultaneously realized. In addition, the tensile test of intravascular membranes was performed to evaluate the coagulation performance. In coagulation-incision experiment, the thin intravascular membrane was more likely to be incised and the smaller the heat generation results. On the other hand, the result in the tensile test was the same under all penetration conditions. This means that there was no difference in coagulation performance due to the thickness of the intravascular membrane, and the influence of the individual difference of the vascular in the tensile test was not seen. However, the variation in individual results is large and the number of times of experiment is small. In the future, we will change the conditions and perform many experiments to improve the evaluation method. And we would like to evaluate the relationship between the coagulation performance and ultrasonic scalpel power, then the usefulness of opposite phase vibration ultrasonic scalpel. In addition, since it is difficult to evaluate the blood vessel coagulation area, the tensile load to the coagulation part was used for evaluation. It is necessary to consider an evaluation method using stress.

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