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Vascular Load Reduction Control based on Operator's Skill for Catheter Insertion*

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Abstract— **This paper proposes a method for vascular load reduction control that operates in regard to the load on contact points of catheter and blood vessels in catheter insertion. We make an extracorporeal estimation of the load on the contact points, and perform control with a robot arm to reduce the estimated load. We aim to reduce the vascular load through extracting and vibrating action as actually applied by operators. In order to confirm the effectiveness of the proposed method, we conduct an evaluation experiment where a wire is inserted in a tube that simulates a blood vessel. As a result of the experiment we were able to estimate the force on the contact points with an accuracy of an estimation error of 9.1%. Moreover, through vibration control we were able to reduce the load to below 0.1[N] for places where there was an overload of more than 0.5[N]. For vibration control, the experiment also enabled us to derive an effective parameter adjustment method to remove obstructions.**

I. Introduction

In recent years, catheter treatment has spread in the medical field as a minimally invasive treatment to reduce the physical burden on the patient[1]. In catheter treatment, a thin guidewire is inserted further into the body from a catheter. An operator inserts this while looking at the blood vessel and the guidewire displayed on a screen using X-ray imaging equipment. He inserts the catheter using visual confirmation and, simultaneously, kinesthetic feedback from the resistance generated by contact with the vessel. With regard to the size of the vascular load and the guidewire insertion - i.e., insert, stop - operators greatly depend on their sensing of minute forces in their fingers. Systems have therefore been developed for quantitative measurements of vascular load and stable guidewire insertion in order to prevent vascular overload and achieve stable manipulation[2],[3].

To obtain quantitative information on vascular load, studies have been performed where a force sensor is attached to the tip of the catheter and minute reaction forces on the tip are obtained[2],[4]. The vascular load can be measured by measuring the reaction force generated when the catheter comes into contact with the vessel. However, the problem of attaching sensors to fine guidewires, or the increased costs of attaching force sensors to individual guidewires present an issue.

On the other hand, studies have been carried out in catheter insertion using a robot to achieve stable manipulation and avoid overload. A method[5] has been developed where position and force are controlled with a remote operation method called master-slave, and where a wire is inserted in a branched tube. Similarly, studies have been performed where the kinetics at the time of catheter insertion are modeled, with the purpose of stabilizing catheter insertion[3],[6]. However, stable manipulation with these robots requires the acquisition of the size of the load at the point of contact between the catheter as it is inserted and the vessel. The size of the load at the point of contact and accurate contact point detection therefore present an issue.

This paper detects the point of contact between the guidewire and vessel in catheter insertion, and estimates the load on the vessel for each detected contact point. The guidewire is inserted by a robot arm, and using the force displacement measured in inserting it, the force applied on the vessel at the contact point is estimated. Furthermore, in order to reduce the vascular load, when the force on the vessel exceeds a given value the vascular load is reduced by temporary extraction or by vibration of the guidewire through the robot arm. We performed an experiment where a wire of similar rigidity to a guidewire was inserted with a robot arm into a tube forming a mock-up vessel, in order to confirm the effectiveness of this technique.

II. Guidewire Insertion System and Vascular Load Control

This paper will outline a technique to estimate the load on the vessel from the guidewire insertion force, and a method for operator guidewire control when the load on the vessel is high.

A. Guidewire Insertion Assistance Equipment

The force on the catheter-vessel contact point when a guidewire is inserted with the catheter manipulation assist equipment proposed in this paper, is shown in Fig. 1. When a guidewire is inserted with force F_0 at point P_0, the force on guidewire-vessel contact points as indicated in P_1, P_2, P_3, P_4 in Fig. 1 is F_1, F_2, F_3, and F_4. When the frictional force of the guidewire and the vessel outside of these contact points is f, the relation between the insertion force and each contact point's force is:

$$F_0 = F_1 + F_2 + F_3 + F_4 + f. \tag{1}$$

Here, f is sufficiently small compared to the force at the contact points. It is difficult to obtain the force at each vessel contact point P by only measuring guidewire insertion force F_0. In this way we don't discriminate between stiction and dynamic friction. So we can use this method when a catheter move and stop.

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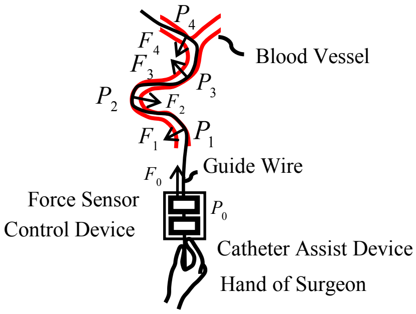

Fig. 1. Catheter assist device and force at the point of contact

The operator estimates the load on the vessel wall by feeling the reaction force in his hand when making contact with the vessel wall as he is inserting the guidewire. Following the operator's method, we therefore estimate the force at each contact point using the data for the insertion force in the guidewire insertion process. This paper also uses the changes in insertion power when inserting the guidewire to estimate the contact points with the vessel and the force at those contact points.

If the inserted length of the guidewire is h, the insertion force at P_0 is $F(h)$. Then, if there are K guidewire-vessel contact points and the force at contact point k is $F(h_k)$ (k=1,2,…,K), this can be expressed as

$$F(h) = \Sigma_k F(h_k). \qquad (2)$$

Moreover, when the guidewire is inserted into the vessel at a constant speed, and the guidewire does not make contact with the vessel wall, the guidewire is inserted with a constant insertion force $F(h)$. However, when the guidewire makes contact with the vessel wall the insertion force changes greatly in order to insert the guidewire at a constant speed. We estimate the guidewire-vessel contact point position at guidewire inserted length h for the point at which the insertion force greatly changes, and, using the change in force between before and after vessel wall contact, we estimate the size of the force at that contact point. Moreover, when the guidewire is inserted and a new contact point (k+1) with the vessel is detected, it is possible to estimate the force $F(h_{k+1})$ at that contact point by using force $F(h_k)$ at vessel wall contact point P_k with number k.

$$F(h_{k+1}) = F(h) - \Sigma_k F(h_k). \qquad (3)$$

As a result, guidewire insertion force F_0 increases as the length of inserted wire increases. This method assumes, however, that there is no change in the level of force at contact points up to point (k-1) when estimating the force at guidewire-vessel contact point k.

The relationship between the inserted guidewire length and the insertion force at a given insertion speed is given in Fig. 2. The illustration beneath the graph indicates how the guidewires have been inserted into the vessel. When the difference $F(h+\Delta h)$-$F(h)$ with the force of a given length (Δh) exceeds threshold (F_θ), the contact with the vessel at guidewire inserted length h is deemed to have started. In Fig. 2, contact points P_1, P_2, P_3 are detected in this way. Moreover,

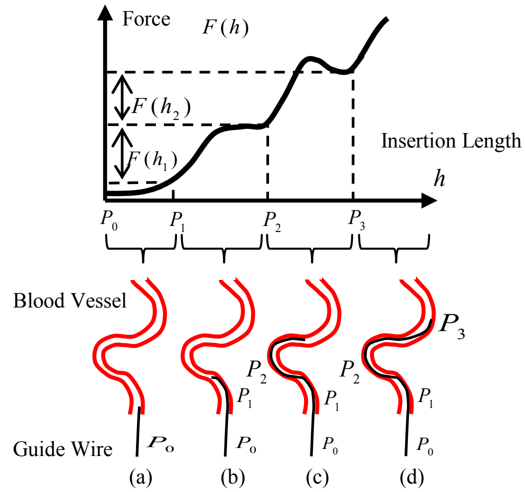

Fig. 2. Guide wire insertion amount and insertion Force

force $F(h_k)$ at the contact points is derived based on equation (3). Where in Fig. 2 contact is deemed to have been started at P_1, and the next start of contact has been detected at P_1, the level of force $F(h_1)$ at P_1 is calculated using the difference between the insertion force at P_1 and the insertion force at P_2. In the same way, when P_3 has been detected, the level of force $F(h_2)$ at P_2, can be calculated by using the difference between the insertion force at P_2 and the insertion force at P_3.

The flowchart in Fig. 3 shows the contact point detection and estimation method for the force at the contact point. Here, the force at contact point P_0 when the insertion start position is k=0 is $F(h_0)$. For each given inserted length, a comparison is made to ascertain whether inserted length ($h+\Delta h$) is shorter than vessel length L. If vessel length L is exceeded, the guidewire is deemed to have reached the endpoint, and $F(h_{k+1})$ is calculated with equation (3). If it is shorter than vessel length L, a comparison is made to ascertain whether the difference $F(h+\Delta h)$-$F(h)$ with the force at the immediately preceding contact point exceeds a given threshold (F_θ). If it does not exceed the threshold, another given length Δh is inserted and the same processing is repeated. If it does exceed the threshold value, contact is estimated to have started at P_{k+1}, and comparisons are performed with vessel length L on inserting another given length Δh with given force (F_θ). If it is still higher than the threshold (F_θ), it is deemed to still be in contact, and another given length Δh is inserted and the same processing is repeated. If the threshold (F_θ) is not exceeded, it is estimated that contact at P_{k+1} has ceased. Thereafter, a comparison is performed with vessel length L on inserting another given length Δh, and a comparison is performed with given force (F_θ). If it still does not exceed threshold (F_θ), another given length Δh is inserted and the same processing is repeated. If the threshold (F_θ) has been exceeded, it is estimated that contact has started at P_{k+2}, $F(h_{k+1})$ is calculated with equation (3), and the same processing is repeated as k=k+1.

In realistic conditions it is possible to estimate the actual length of the vessel length L by a prior examination.

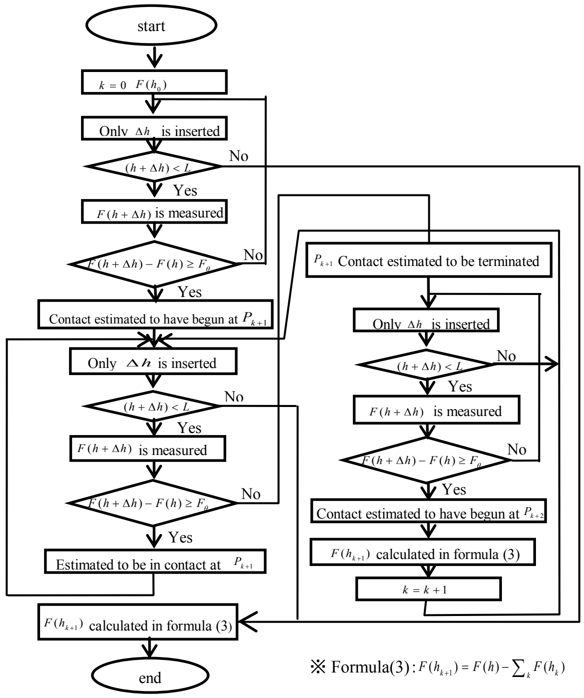

Fig. 3. Flowchart of estimation of the load on blood vessels

B. Guidewire Manipulation for Vascular Load Reduction

If, in inserting a catheter, the guidewire and the vessel touch and the operator feels resistance and cannot insert it any further, he returns it in the opposite direction, and when the feeling of resistance weakens begins to re-insert it in a direction to least resistance. Moreover, when it cannot be inserted any further because of an obstruction in the vessel, the operator removes the obstruction by vibrating the guidewire. Reducing the load through returning or vibrating the guidewire when overload is detected in these ways is effective and frequently applied during procedures[7]. In this section we call the control to reduce the load onto the vessel wall by, for example, returning or vibrating the guidewire, load reduction control, and explain its control method. Reversible control is applied when the force on the vessel wall is great, and vibration control is applied when there is an obstruction and there is no change in the inserted length of the guidewire tip.

First, we will outline reversible control. With the method described in the previous section, the force applied on the guidewire-vessel contact point could be estimated. Any estimated force in excess of a given threshold (e.g. 0.5[N]) for each contact point is detected as overload. Then, the guidewire is manipulated so as to reduce the load in the overloaded area. The manipulation method known to be effective is the control method where the guidewire is moved in the opposite direction of how it was inserted (return direction). This is repeated until the value falls below a given threshold (e.g. 0.1[N]). However, in fact safety force range is different by the area of the vessel or each person. So it is necessary to decide the threshold on a case-by-case basis. Similarly, we should change the values of some parameters in Fig. 3.

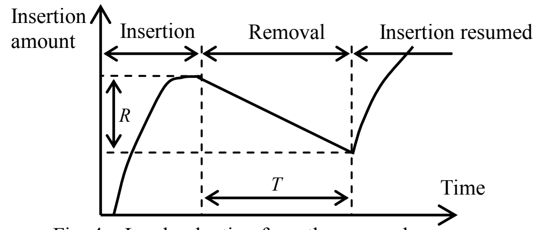

Fig. 4. Load reduction from the removal process

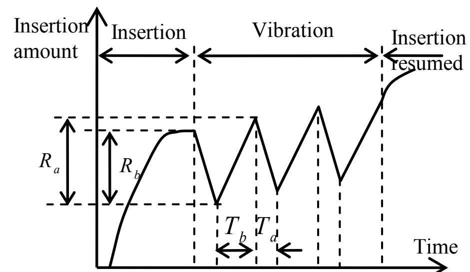

Fig. 5. Load reduction from the vibration process

We will outline the method to reduce the load on the vessel wall using Fig. 4. Fig. 4 shows the relationship between guidewire insertion time and insertion length, with the horizontal axis representing time and the vertical axis representing insertion length. When the force at the contact point exceeds 0.5[N] extraction is started, and is stopped when it drops below 0.1[N]. The time in between is expressed as T, and the distance over which the wire has been extracted during that time is expressed as R. Extraction is performed at constant speed, while the speed can be adjusted.

Next, we outline vibration control when the guidewire meets with an obstruction. Here, the guidewire is continuously vibrated back and forth, and amplitude and cycle parameters are set as shown in Fig. 5. The degree (distance) of vibration is expressed with the forwards amplitude being R_a and the backwards amplitude R_b. The progress length in one cycle is R_a-R_b. The amplitude expresses the time of one vibration cycle, with the forwards time being T_a and the backwards time T_b. The progress ratio is expressed through amplitude ratio and time ratio, with the progress ratio being expressed as ratio R_a/R_b of the forwards distance and the backwards distance, and the time ratio expressed as ratio T_a/T_b of the forwards time and backwards time. By changing the aforementioned parameters, the effectiveness of removing the obstruction changes.

III. Evaluation of Force Estimation Accuracy in Wire Insertion

A. Hardware Configuration of Experimental System

This paper uses a robot arm as control equipment, shown in Fig. 1. The robot arm used in this paper is the PHANTOM Desktop from Sensable, which is a 3D tactile/force feedback interface. With its inertia of 45[g], it is very light and enables manipulations as performed in manual human procedures. The robot arm comes with a force sensor attached at the tip, and a hand to hold a wire at the sensor tip. The reaction force when the wire makes contact with another object is measured with a force sensor. We used the TFS12-10 force sensor from the NITTA Corporation, which can measure minute forces of to a level of 1[gF].

B. Guidewire Insertion

In this paper we insert a wire into a silicon tube, mimicking the insertion of a guidewire into a blood vessel. The experimental equipment for wire insertion into a silicon tube is shown in Fig. 6. As illustrated, a hand attached to the tip of a force sensor is made to hold a wire, which through human manipulation of the robot arm is inserted into the silicon tube. The force sensor is attached to the robot arm via jigs. Owing to the jigs, the gimbal center of the robot arm is kept freely. The wire held by the hand is moved along by a person moving the robot arm in the insertion direction (along the x axis) indicated by the arrow in Fig. 6. This results in the wire moving forwards into the tube. Here, the wire is inserted through human manipulation because of restrictions of the robot arm, but automatic insertion is also possible by using, for example, roller-type equipment[3]. Moreover, as shown in Fig. 6, the silicon tube is set up to mimic the serpentine shape of blood vessels. An endpoint force sensor is placed at the end of the silicon tube. This is to verify the accuracy of the force estimated at the endpoint when estimating the force at the contact point from the force measured by the sensor attached to the robot arm. In other words, by measuring to what extent the force estimated at the endpoint after the wire has passed through the meandering tube, and the force measured by the endpoint force sensor, agree, the estimation accuracy of the forces at the contact points is verified.

The wire used in this experiment was a stainless wire with a diameter of 0.81[mm] and a length of about 10[cm]. Although guidewires are usually close to 1[m], we shortened the wire to simplify the experimental equipment since our main focus is on force measurements and wire control. To perform an experiment with the normal length, a wire can be inserted using roller-type insertion equipment[3], etc. Because we did not get a lot of actual guidwires, we selected the similar wire. Bending stress and torsional stress were measured for the wire and a wire of a length close to the actual wire was used. More specifically, for the guidewire, the bending stress is 1.23[mN] and the torsional stress 0.306[mN/m]. For the wire, the bending stress is 1.63[mN] and the torsional stress is 0.355[mN/m]. The tube is a flexible silicon tube with an outer diameter of 5.0[mm] and an inner diameter of 3.0[mm]. We selected a flexible silicon tube to imitate actual vessels. The endpoint sensor is a NITTA Corporation TSF12-10, identical to the sensor attached to the robot arm. This sensor is used to measure the actual force.

During wire insertion, data were sampled in a cycle of 2[ms] for the distance the inserted length had moved into the robot insertion direction and the force sensor value. Moreover, following reference[8], the wire insertion direction and the force measuring direction are only performed for the insertion direction (x axial direction).

C. Estimation Accuracy for the Force at the Contact Points

We ran the experiment 15 times. For each run we assumed that when the wire came out of the tube it touched the vessel wall, and we performed an evaluation using the error between the force estimated for that point and the force measured with the sensor. Specifically, in this experiment we performed an evaluation using the force in the x direction, which is the insertion direction. The results are shown in Table I, which gives the inserted length and the estimated force at the point where contact with the vessel is detected. The estimation accuracy is evaluated by comparing the estimated force $F_x(h_3')$ at the endpoint and the catheter-tip force sensor value $G_x(h_3')$.

D. Experimental Results

The measured value was 0.471[N], whereas the estimated value was 0.514[N], resulting in an estimation error of 9.1%. When considering that the resolution of the force sensor was about 1[gf], it could be said that the estimation was precise.

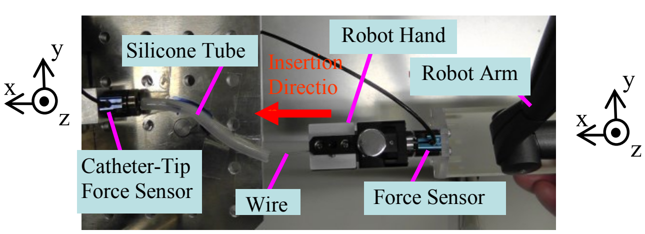

Fig. 6. Experimental apparatus for the guidewire insertion process

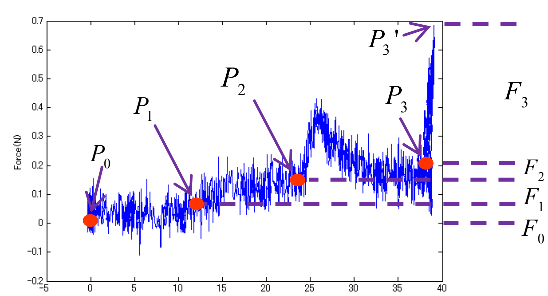

Fig. 7. Estimated results at the points of contact

TABLE I. ESTIMATED AND MEASURED VALUES OF FORCE

	P_1		P_2		P_3		P_3'		Sensor value
	h_1(mm	$F_x(h_1)$(N)	h_2(mm	$F_x(h_2)$(N)	h_3(mm	$F_x(h_3)$(N)	h_3'(mm)	$F_x(h_3')$(N)	$G_x(h_3')$(N)
1	13.08	0.0229	27.24	0.0149	40.96	0.0748	41.83	0.506	0.479
2	14.81	0.0241	27.61	0.0332	42.49	0.0901	43.73	0.501	0.494
…	…	…	…	…	…	…	…	…	…
15	13.43	0.0466	25.47	0.0682	40.44	0.0933	41.86	0.510	0.498
Ave.	13.74	0.0384	26.11	0.0470	40.22	0.1400	41.48	0.514	0.471

Next, detected points of contact will be examined based on the test results. The horizontal axis of the graph in Fig.7 is the insertion amount (mm) and the vertical axis is the amount of force (N). The solid line represents the measured valued from the force sensor mounted on the robot arm. In addition, red circles represent the detected points of contact P_0, P_1, P_2, and P_3. The points of contact were detected where the change in force was significant. The estimated value at the contact point P_3 only exceeded 0.5[N].

IV. Effect of Processes that Reduce the Load on Blood Vessels

A. The Load Reduction Effect on Blood Vessels from the Operation of Removing Guide Wires

Under the experimental conditions mentioned in chapter III, both the location of the guidewire's point of contact with the tube when inserted and the amount of force at each point were estimated. When the value of the force was higher than the predetermined values, the insertion of the wires were stopped and removed to determine whether the force at the point of contact was reduced.

The experiment was conducted 15 times. Each time, when the estimated force reached overload (above 0.5[N]), the removal process was conducted until the load was reduced (0.1[N] or less), and we evaluated whether the load was reduced. When the load was reduced, the insertion process was concluded.

The results are shown in Table II. Table II shows the insertion amount and estimated force at the point of contact at the catheter tip before and after the removal process. Results from all 15 experiments show that the load where an overload (above 0.5[N]) existed was reduced below the threshold (load of under 0.5[N]). It can be seen that load reduction is possible by performing a removal of about 1.0[mm].

B. The Load Reduction Effect on Blood Vessels from the Operation of Vibration of the guide wire

Experiments were conducted to verify whether vibrating the guide wire will free it when the wire gets stuck inside the tube after the wire is inserted under the experimental conditions mentioned later in this section. The effect of removing the stuck guide wire by the parameters of the vibration process mentioned in II.C was verified through experiment.

Experimental conditions are as follows. A robot arm (PHANToM DeskTop), similar to the one mentioned in the earlier section, was used as the control device. The tube setup is in a U-shaped form as shown in Fig. 8, instead of a meandering shape as shown in Fig. 6. In this way, the stuck condition of the wire can be reproduced. The wire is inserted in the direction of the arrow (x-axis direction) as shown in Fig. 8, and is vibrated by moving it back and forth.

TABLE II. Load Changes from the Removal Process

	P_3'(Before Removal)		P_3'(After Removal)	
	h_3'(mm)	$F_x(h_3')$(N)	h_3'(mm)	$F_x(h_3')$(N)
1	41.83	0.506	40.95	0.0849
2	43.73	0.501	42.83	0.0297
…	…	…	…	…
15	41.86	0.510	40.75	-0.0139
Ave.	41.48	0.514	40.49	0.0301

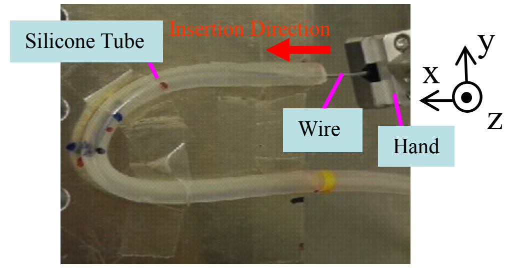

Fig. 8. Experimental apparatus for the vibration

The following are the steps of the experiment. First, the robot arm is controlled (by a person) and moved in the direction of the insertion, and the wire is inserted into the tube. Next, when the wire is stuck, the vibration process is started (by a robot arm). The stuck condition is detected by observing whether the wire tip moves when inserted. The wire is vibrated and then inserted until the wire becomes stuck again. The length of the wire that was inserted is recorded. The longer the length indicates it can be inserted further into the tube, and the more effectively the blockage was resolved. However, the experimental conditions were set up and insertion method adjusted so that the wire was stuck at the same length each time.

Here, the experimental results will be explained. Parameters including amplitude, period, and advance ratio were varied, and the results are summarized in Table III.

When only the amplitudes were adjusted to (R_a,R_b)=(0.6,0.3) and (R_a,R_b)=(3.6,1.8), the inserted length of the wire was 115.38[mm] and 125.37[mm], respectively. This result shows that when the amplitude is increased, the insertion length increases. However, when the insertion is stopped, because any further insertion of the wire causes a load to the blood vessel, the amplitude could not be increased as much.

When only the periods were adjusted to (T_a,T_b)=(15,15) and (T_a,T_b)=(60,60), the inserted length of the wire was 125.60 [mm] and 119.10[mm], respectively. This result shows that when the period is shortened, the insertion length increases. The operator vibrated the wire manually; however, mechanically induced vibrations can shorten it even further.

When only the advance ratio was adjusted so that the amplitude was R_a/R_b=6, and the time ratio T_a/T_b=3, or the amplitude was R_a/R_b=12, and the time ratio T_a/T_b=6, the insertion length of the wire was 125.78[mm] when the amplitude was R_a/R_b=6 and the time ratio was T_a/T_b=3, and it was 132.62[mm] when the amplitude was R_a/R_b=12 and the time ratio was T_a/T_b=6. This result shows that when the advance ratio is increased, the insertion length increases. However, there is a load on the blood vessel when the advance ratio is increased, so it cannot be increased too much.

TABLE III. AMOUNT OF INSERTION FROM THE VIBRATION PROCESS

		R_a(mm)	R_b(mm)	R_a/R_b	T_a(ms)	T_b(ms)	T_a/T_b	Insertion amount(mm)
Amplitude	Small	0.6	0.3	2	30	30	1	115.4
	Large	3.6	1.8	2	30	30	1	125.4
Period	Short	1.8	0.9	2	15	15	1	125.6
	Long	1.8	0.9	2	60	60	1	119.1
Advance ratio	Min.	1.8	0.3	6	30	10	3	125.8
	Max.	3.6	0.3	12	60	10	6	132.6

The above test results show that, for the vibration parameters, increasing the amplitude, shortening the period, and increasing the advance ratio effectively removes the wire blockage.

C. Observations

In this section, the effect of reducing the load on blood vessels by the guide wire removal and vibration process is examined. First, the removal process will be examined. It is preferred that the amount removed does not pass the nearest point of contact. If the wire passes the nearest point of contact, when the insertion is restarted, the same amount previously inserted needs to be reinserted. Furthermore, it is considered that the faster the speed of retraction, the quicker the load on the blood vessel will be decreased.

Next, the vibration process will be examined. The experiment was also conducted by changing the location where the vibration originates and used as another parameter. The results of the experiment show that the insertion length became longer by locating the origin of the vibration in an earlier location, and by vibrating the wire before it begins to become stuck. In addition, an experiment was conducted where the degree of intervention by the operator was changed. The experimental results show that the insertion length became longer more quickly when having the operator intervene while the wire was pushed in the direction of insertion. Although, in this study, the insertion direction was set as back and forth, because of the shape of blood vessels and the condition of the wire blockage, it may be more effective to vibrate the wire in a rotational or horizontal direction. Furthermore, when the wire is vibrated by using a control device, it can be vibrated more quickly than by doing it manually. Thus, using a control device can more effectively remove the wire blockage, rather than by doing it manually. When the length of the wire insertion doesn't change even when vibrated, it is thought that there is a load being added to the blood vessel. Therefore, if the wire cannot be inserted further even after the designated time of vibration has passed, the vibration process will be terminated or the removal process will need to be conducted.

V. CONCLUSION

In this study, the load from outside the body at the point of contact in the blood vessel during the catheter insertion process was estimated and the load reduced based on operator's skill. The load was estimated by estimating the force from outside the body at points of contact. Using this method, an estimation error of 0.0531[N] was achieved. Moreover, the load, at places where over 0.5[N] of overload on the blood vessel existed, was reduced to below 0.1[N] by conducting the removal process. As for the vibration process, the arrangement of parameters that was effective in removing the wire blockage was derived.

Furthermore, in this paper, experiments were conducted under the condition where blood vessels that only curve in plane were simulated. In the future, experiments under the condition where complex blood vessels that simulate multiple locations of curvature and that curve three-dimensionally need to be conducted to test its validity, in order to generically confirm the method of blood vessel load estimation and blood vessel load reduction.

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