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## Softness Measurement System for Biological Object by Using Balloon Catheter

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**Abstract.** Elucidating causes of infertility is important to conduct proper treatment for infertility. Mechanical characteristics of the endometrium may be mentioned as a cause of infertility. In this paper, we focus on softness of the endometrium. As a fundamental research for the softness measurement of the endometrium, we developed a system for measuring softness of cylindrical objects by using a balloon catheter. The measurement system is composed of a balloon catheter, a syringe and a pressure sensor. Young's modulus of cylindrical objects is calculated from balloon radius and internal pressure when the balloon is expanded in the object. In the experiment, we prepared four kinds of cylindrical samples with different softness. By using the measurement system, Young's modulus of each cylindrical sample is estimated. And the estimated values are compared with Young's modulus measured by compression test. From the results, it was found that the developed system is effective for measuring softness of cylindrical objects.

Keywords: Balloon catheter, Young's modulus, Measurement, Softness

#### 1. Introduction

In Japan, it is estimated that approximately 500,000 people receive infertility treatment currently [1]. There are various factors of infertility and approximately 20% of causes of infertility cannot be elucidated [2]. Because it is difficult to identify the factor, appropriate treatment may not be provided. The factors of infertility include the mechanical characteristics and the shape of the endometrium. Kasius et al. [3] reported that the thickness of the endometrium is related to a fertility index. In addition, it is generally known that it is difficult to become pregnant when the endometrium is hard. The thickness of the endometrium can be evaluated by tomogram. However, it is difficult to evaluate the softness of the endometrium quantitatively. Therefore, the method for measuring and evaluating the softness of the endometrium objectively is required.

Some methods for evaluating the softness of biological tissue have been researched [4-6]. For example, Okuyama et al. [4] have developed a hardness measurement sensor that has a structure placing a column made of soft silicone rubber inside a metal cylinder. By using the sensor, Young's modulus of the measured object is calculated from the ratio of the reaction force applying to the column and the cylinder when the sensor contacts a measuring object. Omata et al. [5] and Motoo et al. [6] have developed a method to calculate Young's modulus of the measured object from change of natural frequency when the vibrator contacts with the object.

However, in these sensor systems, measurement for cylindrical organ is not considered. And there is a risk to damage objects due to contact of these sensors because sensor part is harder than general biological tissue. Uterus is cylindrical and thin tissue, so it is difficult to use the

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methods in uterus.

Higashimori et al. [7] have measured the hardness of tubular left ventricular of rat by using the balloon probe. Although tubular left ventricular is harder than endometrium, the method is possible to measure the softness of cylindrical biological tissue. However, the measured objects are assumed as single layered objects in the work. Because the uterus is double layered tissue; endometrium layer and muscular layer, we need to modify the mechanical model to estimate softness. In addition, for practical use, the balloon part needs to be replaced with the balloon catheter for uterus.

In this paper, a softness measurement sensor system by using a balloon catheter, which is generally used as a test for tubal patency at obstetrics and gynecology, is developed. By substituting the balloon radius and internal pressure into the theoretical formula from the proposal mechanical model, Young's modulus of endometrium layer is calculated. We conduct experiment of calculating softness for cylindrical bilayer samples simulating the size and the structure of the real uterus. And comparing calculated Young's modulus of endometrium layer and Young's modulus of sample, the availability of the developed system is investigated.

#### 2. Softness measurement system

Figure 1 shows a schematic drawing of the softness measurement system and experimental setups. The measurement system consists of a balloon catheter, a syringe, and a pressure sensor. The balloon catheter is generally used as a test for tubal patency at obstetrics and gynecology as shown in Fig.2. The balloon part is inserted in a measured object, and air is injected into the balloon catheter with the syringe to blow up the balloon. When the balloon inside the measured object is inflated, the expansion of the balloon is prevented by the measured object, and internal pressure of the balloon rises. In other words, the radius and internal pressure of the balloon are related to Young's modulus of the measured object.

In this system, the internal pressure is measured by the pressure sensor connected between the balloon and the syringe. Concerning the radius of balloon, it is obtained by camera image. In practical use, the radius may be obtained by ultrasonic image.





#### 3. Samples

Cylindrical bilayer samples simulate the muscularis and the endometrium of uterus. And it is based on the size and the structure of the real uterus [8, 9]. Figure 3 shows dimension of samples. Length of sample is 30mm, inside diameter is 6mm, the thickness of endometrium layer is 4mm and the thickness of muscular layer is 10mm. The endometrium layer and the muscular layer are made of silicone material. In addition, softness of silicone materials is changed by amount of diluents. Young's modulus of each layer is shown in Table 1. Young's modulus of each layer is obtained by compression test for silicone materials. We prepare four kinds of samples with two kinds of the muscular layer and two kinds of the endometrium layer.

#### 4. Mechanical model for calculating Young's modulus of endometrium

Figure 4 shows a mechanical model composed of a muscular layer, an endometrium layer, and a balloon. Concerning the measured objects, we assume that the endometrium layer and the muscular layer are thickness walled cylinders with the open-ended condition. Regarding endometrium layer, internal pressure and external pressure are loaded. And regarding muscular layer, only internal pressure is loaded. In addition, we assume that the endometrium layer contact to the muscular layer without gap.

From these assumptions, displacement of internal radius of the endometrium layer is expressed by

$$r_{Ei1} - r_{Ei0} = \frac{r_{Ei0}}{E_E(r_{Ee0}^2 - r_{Ei0}^2)} \left\{ (1 - v_E) \left( r_{Ei0}^2 p_{Ei1} - r_{Ee0}^2 p_{Ee1} \right) + (1 - v_E) r_{Ee0}^2 \left( p_{Ei1} - p_{Ee1} \right) \right\}.$$
(1)

And displacement of external radius of the endometrium layer is expressed by

$$r_{Ee1} - r_{Ee0} = \frac{r_{Ee0}}{E_E(r_{Ee0}^2 - r_{Ei0}^2)} \left\{ (1 - v_E) \left( r_{Ei0}^2 p_{Ei1} - r_{Ee0}^2 p_{Ee1} \right) + (1 - v_E) r_{Ei0}^2 \left( p_{Ei1} - p_{Ee1} \right) \right\}.$$
(2)

External radius of the endometrium layer equals internal radius of the muscular layer and external pressure of the endometrium layer equals internal pressure of the muscular layer. Therefore, displacement of internal radius of the muscular layer is expressed by

$$r_{Ee1} - r_{Ee0} = \frac{r_{Ee0}}{E_M (r_{Me0}^2 - r_{Ee0}^2)} \{ (1 - v_M) r_{Ee0}^2 + (1 + v_M) r_{Me0}^2 \} p_{Ee1}.$$
 (3)

 $r_{Ei0}$ ,  $r_{Ee0}$  and  $r_{Me0}$  denote the internal radius of the endometrium layer, the external radius of the endometrium layer and the external radius of the muscular layer before the balloon blows up, respectively. In addition,  $r_{Ee1}$ ,  $p_{Ei1}$  and  $p_{Ee1}$  denote the external radius of the endometrium layer, the internal pressure of the endometrium layer and the external pressure of the endometrium after the balloon blows up, respectively.  $E_E$ ,  $v_E$ ,  $E_M$  and  $v_M$  denote Young's modulus and Poisson's ratio of the endometrium layer and Young's modulus and Poisson's ratio of the endometrium layer, respectively.

Concerning the balloon part, we assume that the balloon is thinness walled cylinder with the close-ended condition that internal pressure and external pressure are loaded. From the assumption, change of the balloon radius is expressed by

$$r_{B1} - r_{B0} = \frac{2 - v_B}{2E_B t_B} r_{B1}^2 (p_{Bi1} - p_{Ei1}).$$
(4)

 $E_B$ ,  $t_B$  and  $v_B$  denote Young's modulus, the thickness and Poisson's ratio of the balloon, respectively.  $r_{B1}$  and  $p_{Bi1}$  denote the radius of the balloon and the internal pressure of the balloon after the balloon blows up, respectively. In addition, external pressure of the balloon equals internal pressure of the endometrium layer.

By substituting above four formulas to each other,  $r_{Ee1}$ ,  $p_{Ei1}$  and  $p_{Ee1}$ , which cannot be measured, are cancelled. As the result, the theoretical formula to calculate Young's modulus of the endometrium layer  $E_E$  is expressed by

$$E_E = \frac{(A \cdot B - D) + \sqrt{(A \cdot B - D)^2 + 4A \cdot C \cdot F}}{2A \cdot C},$$
(5)

where

$$A = \frac{(1 - v_M)r_{Ee0}^2 + (1 + v_M)r_{Me0}^2}{E_M(r_{Me0}^2 - r_{Ee0}^2)}$$
(6)

$$B = \left\{ (1 - v_E) r_{Ei0}^2 + (1 + v_E) r_{Ee0}^2 \right\} \left( p_{Bi1} - \frac{r_{B1} - r_{B0}}{r_{B0}^2} \frac{2 - v_B}{2E_B t_B} \right)$$
(7)

$$C = \frac{\left(r_{Ee0}^2 - r_{Ei0}^2\right)(r_{B1} - r_{Ei0})}{r_{Ei0}} \tag{8}$$

$$D = \frac{r_{B1} - r_{Ei0}}{r_{Ei0}} \{ (1 - v_E) r_{Ee0}^2 + (1 + v_E) r_{Ei0}^2 \}$$
(9)

$$F = (1 - v_E^2) \left( r_{Ee0}^2 - r_{Ei0}^2 \right) \left( p_{Bi1} - \frac{r_{B1} - r_{B0}}{r_{B0}^2} \frac{2 - v_B}{2E_B t_B} \right)$$
(10)

The internal radius of the endometrium layer,  $r_{Ei0}$ , the external radius of the endometrium layer,  $r_{Ee0}$  and the external radius of the muscular layer,  $r_{Me0}$  are obtained as the initial condition by tomogram or camera image in advance. In addition, in this work,  $E_M$  is known by compression test. However,  $E_B$  and  $t_B$  in equations (4), (7), and (10) cannot be measured.

Here,  $\frac{2-v_B}{2E_B t_B}$  in these equations is replaced with  $E'_B$ . It is a parameter corresponding to mechanical properties of the balloon. To determine  $E'_B$ , we consider the expansion of only balloon part. It means that only internal pressure is applied to the balloon. In the case, the change of the balloon radius is rewritten as follows.

$$r'_{B1} - r'_{B0} = E'_B r'^2_{B1} p'_{B1} \tag{11}$$

 $r'_{B0}$ ,  $r'_{B1}$  and  $p'_{B1}$  denote the balloon radius before balloon blows up without measured objects, the balloon radius and internal pressure of the balloon after balloon blows up without measured objects.

By performing the expansion experiment of only balloon beforehand,  $r'_{B0}$ ,  $r'_{B1}$  and  $p'_{B1}$  were measured. From the results, it was found that  $E'_B$  depends on the balloon radius. And the Poisson's ratios  $v_E$  and  $v_M$  are set to be 0.5. Therefore, approximate curve between  $E'_B$  and  $r_{B1}$  was obtained by using least square for the experimental results.

$$E'_B = 1.19r_{B1}^2 - 18.6r_{B1} + 87.6 \tag{12}$$

Equation (12) is relationship between  $E'_B$  and  $r_{B1}$  for the balloon catheter using this experiment.

In this work, the radius of balloon after the expansion  $r_{B1}$  is acquired from a camera image, the internal pressure of balloon after the expansion  $p_{Bi1}$  is acquired from a pressure sensor. As the consequence, by substituting measured  $r_{B1}$  and  $p_{Bi1}$  into the theoretical formula and equation (12), Young's modulus of endometrium layer  $E_E$  is calculated.

#### 5. Experiments

#### 5-1 Experimental condition

To investigate the availability of the developed system, we measure softness of the fabricated samples by using the measurement system as shown in Fig.1. In the experiment, air is injected into the balloon with the syringe to blow up the balloon in the sample, and then the radius of the balloon and the internal pressure of the pressure sensor are measured. We conduct experiments for three kinds of air injection volume 1.8cm<sup>3</sup>, 2.2cm<sup>3</sup>, and 2.6cm<sup>3</sup>.

#### 5-2 Results and discussions

Figure 5 shows relationship between sample's index and the radius of the balloon after extension,  $r_{B1}$  for each injection volume. Figure 6 shows relationship between sample's index and the internal pressure of the balloon after extension,  $p_{Bi1}$  for each injection volume. It was confirmed that the balloon radius and the pressure increases with increase of air injection volume. Comparing S<sub>1</sub> and S<sub>2</sub>, the difference of the balloon radius and pressure are slight although the hardness of the muscular layer is different. The tendency is the same as that between S<sub>3</sub> and S<sub>4</sub>. In the future, we need to analyze the influence of the muscular layer on calculated Young's modulus of endometrium layer  $E_{\rm E}$ .

Figure 7 shows the calculated Young's modulus of the endometrium layer from the results of the radius as shown in Fig.5 and the pressure as shown in Fig.6. From the results, the calculated Young's modulus of the endometrium is almost agreement with Young's modulus measured by compression test, although Fig.7 shows slight variation of calculated Young's modulus of the endometrium layer in response to air injection volume. It is confirmed that Young's modulus of the endometrium can be calculated by using the proposed mechanical model and the developed measurement system.



Fig.7 Relationship between sample's index and Young's modulus

#### 6. Conclusions

In this work, the measurement system composed of the balloon catheter, the syringe and the pressure sensor was developed. As fundamental research for the softness measurement of the endometrium, softness of cylindrical bilayer soft samples was measured. In the experiment, Young's modulus was calculated from the balloon radius and internal pressure by using the proposed mechanical model. It was found that the calculated Young's modulus of the endometrium layer is almost agreement with Young's modulus by compression test. As the results, the availability of the developed system was verified.

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