

Development of a Novel Tool for Assessing Deformation and Hardness of Real Organs: Pressure Measuring Grasper (PMEG)

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Abstract In recent years, surgeries requiring high surgical skills – including laparoscopic surgery and function-preserving surgery – are being more commonly conducted, which has led to the growing importance of surgeons' training and preoperative simulations. Although various surgical simulators and 3D models of organs are now available, many surgeons still regard them as ineffective because they do not give a realistic sense of touch. In order to improve the quality of these simulations, it is necessary to collect data on how the shape of an organ is changed when pressed by laparoscopic forceps with various levels of force in actual operations. However, we have neither such data nor any equipment that can help us collect the data under operative environment. The main focus of this paper is to report on our development of the Pressure Measuring Grasper (hereinafter, PMEG) that can accurately measure the sizes of organs or tissues when they are grasped or pressed. PMEG is a modification of the digital vernier calipers, with the jaws modified to include our original parts (small load cells), making it possible to measure grasping pressure. The cross-sectional configuration of the PMEG jaws has the same structure as the tip of laparoscopic forceps, which allows the PMEG to simulate a situation in which tissue is grasped by laparoscopic forceps. We conducted two validation experiments to evaluate the measuring function of PMEG. One is verification of measuring pressure using weights, and the other is verification of measuring stiffness using a coil spring with known stiffness. These experiments showed that PMEG was able to measure the pressure and stiffness precisely. We also successfully used PMEG in a living pig's body, and expressed in numerical data the relationship between the surgeon's pressing force and organ deformation. The PMEG will contribute to the improvement of the surgical training system.

Keywords: hardness of organs, pressure measurement system, sense of touch, laparoscopic surgery, surgeon training, preoperative simulation.

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1. Introduction

In recent years, surgery has become markedly less invasive, and laparoscopic (including robotic) surgery is being performed in many fields. The content of surgery is also changing, with attention increasingly directed to function-preserving surgery [1, 2]. This trend of less invasive and more function-preserving surgery means that difficult surgical techniques are becoming mainstream, putting surgeons under an increasing technical burden. Therefore, greater importance is being placed on surgeon training and preoperative simulations, with the intent of improving the safety of surgery.

Computer graphic (CG) simulators and organ models fabri-

cated using three-dimensional (3D) printers are used for surgeon training and preoperative simulations [3–6]. Although many studies have reported that CG simulator haptic feedback (HFB) is useful in helping surgeons to memorize methods of operating forceps, other studies have found that the current simulator HFB function is inadequate [7–10]. In fact, many experienced surgeons have reported feeling somewhat uncomfortable with the current HFB.

During surgery, a surgeon primarily proceeds according to visual and tactile information, using this information to avoid danger at times. As tactile information is more difficult to obtain in laparoscopic surgery than in open surgery, the surgeon has to be sensitive to the available force feedback and reflect this in the procedure. For example, in the field of urology, it is important during procedures, such as laparoscopic partial nephrectomy, to create a good operative field with the left hand support forceps. However, inadequate force by the left hand will make it impossible to expose the operative field, whereas too much force may damage organs. Surgeons determine the appropriate amount of force based on the organ deformation volume and the amount of force that is transmitted to the forceps. This then allows surgeons to perform surgery safely and successfully.

Current simulators lack visual (CG movement) and tactile (HFB quality) reality. This may be why many surgeons report discomfort in using current simulators [11, 12]. Although modifications of the materials and colors used in 3D organ models are useful to confirm the position of tumors locating deep within organs [13], there is currently no model that accurately recreates

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organ stiffness. This means that currently available models cannot aid the learning of the appropriate level of force to be applied when dealing with organs.

To increase the effectiveness of surgeon training and preoperative simulations, and to improve safety during surgery, it is important that simulators realistically recreate actual surgery in terms of organ hardness and HFB quality [8]. To achieve this, sensory information of hardness obtained by surgeons during surgery on actual organs needs to be converted to numerical data and studied. This includes information on the relationship between the amount of organ deformation during surgery and the amount of force applied at that time.

Attempts were made in the past to measure organ elasticity in laparoscopic surgery. In particular, attempts using linear or stepper motors have been reported [14, 15]. However, as the shape of the tip in these devices differs from the actual surgical forceps and elasticity measurement assumes uniformity of organs, it is only possible to predict values based on the calculations of organ changes that occur when force is applied with laparoscopic forceps. Therefore, the actual intraoperative state may not be accurately reflected. To accurately recreate laparoscopic surgery on a simulator, it is necessary to take measurements directly and as simply as possible and then convert the measurements to data with detailed information on the organs as close as possible to surgeons' perceptions.

Therefore, we developed an equipment to accurately measure the relationship between *in vivo* organ deformation and external force under conditions similar to actual surgery. We called this device a pressure measuring grasper (PMEG). In the present report, we explain in detail the development of the PMEG and the evaluation of its measurement precision, and describe an experiment to measure organ hardness in living animals.

2. Materials and Methods

2.1 Device design

We identified three specifications necessary for the PMEG to convert the relationship between organ deformation and external force in intraoperative simulation. These are:

Requirement 1: Ability to take measurements under the same

conditions as actual surgery (*in vivo*).

Requirement 2: Ability to measure both the amount of force applied to an organ and the amount of deformation of an organ with arbitrary timing.

Requirement 3: Application to operations in the same contact area as when the organ is enclosed in the body during actual surgery.

The necessary conditions for each requirement are discussed below.

2.1.1 Requirement 1

The device has to be waterproof so that measurements can be taken when fluids such as blood are present. It also has to be small and shaped so as not to damage the organ, allowing it to be inserted into deep and narrow regions within an animal's body to take measurements.

2.1.2 Requirement 2

The device has to be able to accurately measure small tissues (1 cm or smaller) and large organs (10 cm or larger), and both hard organs and soft tissues. Therefore, an extensive measurement range for deformation volume measurements and high resolution are required to ensure a high level of precision in pressure measurement, regardless of the degree of such pressure.

2.1.3 Requirement 3

The modeled organ and contact area must recreate the same situation as that encountered during actual surgery. In actual surgery, the surgeon makes two typical movements with forceps when applying force on an organ. They are "grasping tissue or membrane with the forceps tip" and "pressing the organ or tissue with the side of forceps." Therefore, the PMEG should have a structure that makes it possible to recreate these two typical forceps movements.

We designed a device that meets all the above requirements while having high operability.

Figure 1 shows an overall design plan of the PMEG. We used a vernier caliper base to maintain the compactness demanded by requirement 1, while offering measurement range and precision demanded by requirement 2. Furthermore, to meet require-

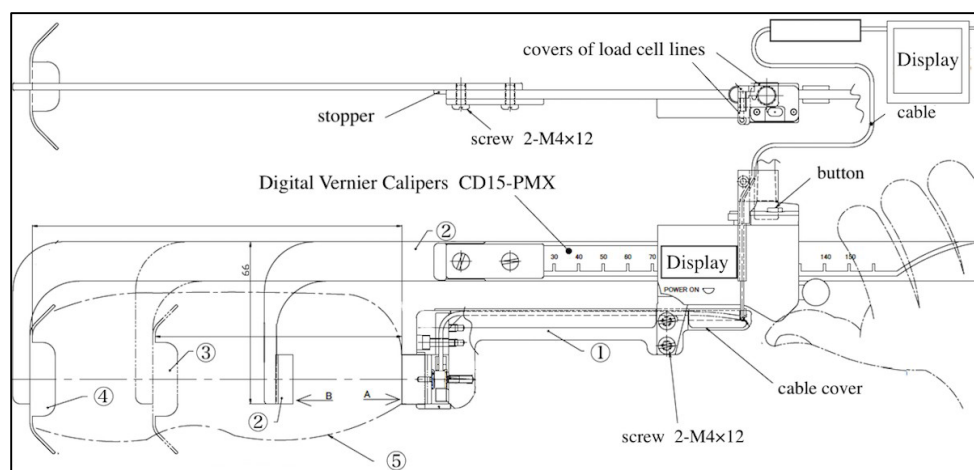


Fig. 1 Overall design plan of the PMEG.

① lower jaw, ② upper jaw (normal type), ③ dish type (short), ④ dish type (long), ⑤ measuring target.

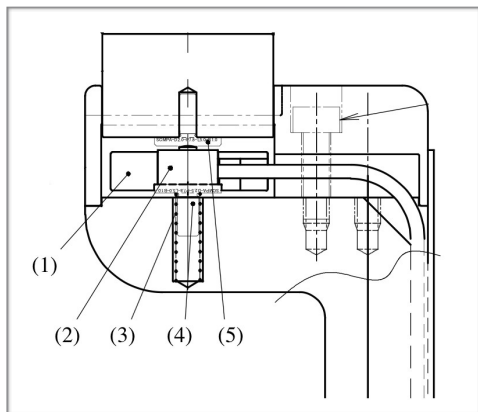


Fig. 2 Details of the interior of PMEG jaw.

- (1) Holder
- (2) Load cell: MCDW-5L
- (3) Spring (Sotec, Kanagawa, Japan) CS0.16-3.2-12 (4.2 gf)
- (4) Misumi CSMIPA-D2.5-P7.8-L5.0-B1.0
- (5) Misumi CSMIPA-D2.0-P7.8-L5.0-B1.0

ment 3, the vernier caliper jaw was changed to an originally designed part, in which a small load cell was inserted. The details are discussed below.

2.2 Design of the sensor

Figure 2 shows the details of the PMEG sensor. A preliminary survey indicated that the amount of pressure applied when normally handling an organ is approximately 5–10 N, with a maximum of 20 N or below. Therefore, we determined that measurement up to 50 N would be sufficient. We also determined that high resolution at minimum pressure is necessary to measure the hardness of soft organs with high precision. We selected a load cell that met these requirements. As a space between the load cell and depressor would make accurate pressure measurement impossible, we placed a weak spring (CS0.16-3.2-12, 4.2 gf; Sotec, Kanagawa Japan) on the back surface of the load cell, i.e., the load cell was fitted snugly against the depressor to ensure accurate measurement.

2.3 Jaw shape

To meet requirement 3, the cross-sectional shape of the PMEG jaw was the same as that of the general Maryland forceps. This allows recreation of the changes that occur when a tissue is grasped by forceps. Making two parallel jaws means that the movement was not exactly the same as that of forceps, but PMEG was designed to be able to measure subtle amounts of changes on the organ side in response to very slight external force.

As large organs are not grasped by the tip of the forceps, we used a dish shape for the upper jaw of the PMEG (**Fig. 1**). This makes it possible to recreate situations in which the organ is held stably between the lateral surface of the forceps and the body wall.

2.4 Validation experiments

We conducted two validation experiments to assess the performance of the PMEG. As a pressure of approximately 5–10 N is used when normally handling organs during surgery, an error

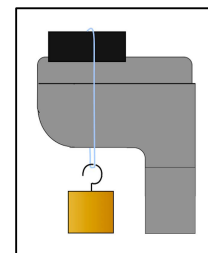


Figure 3

range of ≤ 0.1 N was considered acceptable for this experiment.

2.4.1 Validation experiment 1

This experiment aimed to confirm that the PMEG correctly displays pressure values. First, the PMEG was set so that the jaw was parallel to the ground. Next, a nylon thread was used to hang a weight from the center of the jaw (**Fig. 3**). The displayed pressure was recorded and measurement performance was evaluated by comparing the recorded weight with a 1 kg weight converted to 9.8 N. The weights used were 50, 100, 150, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1200, and 1400 g.

2.4.2 Validation experiment 2

Validation experiment 2 aimed to confirm whether the PMEG can accurately measure the relationship between pressure and object deformation volume. The spring constant was set for a conventional compression coil spring. This was inserted into the PMEG, and we verified whether the measured data are consistent with the true spring constant. To perform thorough verification, two types of stainless steel compression coil springs were used. One spring was 0.8-10-21 and the other was 1.2-10-41.

2.5 *In vivo* organ hardness measurement using the PMEG

The PMEG was used to measure organ hardness of a living pig, and data were recorded. The usual anesthesia time for a pig used in laparoscopic training was extended, and the PMEG was inserted into the pig's body during open surgery to measure the hardness of each organ. We measured the hardness of the liver, kidneys, spleen, small intestine, large intestine, stomach, gallbladder, bladder, renal artery, and renal vein, in that order. For the bladder, measurement was conducted with five urine volumes (0%, 25%, 50%, 75%, and 100%), with 100% indicating a bladder full of urine. Measurements were conducted at more than one point in each organ. During all measurements, care was taken not to cause the animal any suffering.

3. Results

3.1 Overall image of the PMEG

Figure 4 shows a photograph of the completed PMEG. The PMEG comprises a measurement part and a pressure display part. For the vernier caliper base, we selected a Mitutoyo digital vernier caliper CD-15PMX, and changed the jaw to an original part suitable for measurement. The jaw is thin (width of 11 mm) and has a compact size appropriate for measurement in deep, narrow sites within the body. Measurement data are transferred by Microsoft Excel through a USB cable by pressing a button (arrow shown in **Fig. 4**).

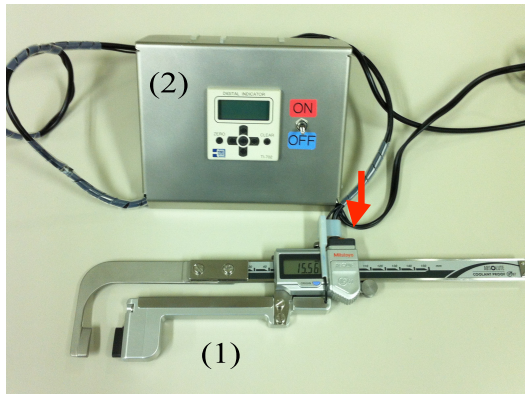


Fig. 4 Photograph of the completed PMEG.
(1) Measurement part, (2) pressure display part.



Fig. 5 Sensor.

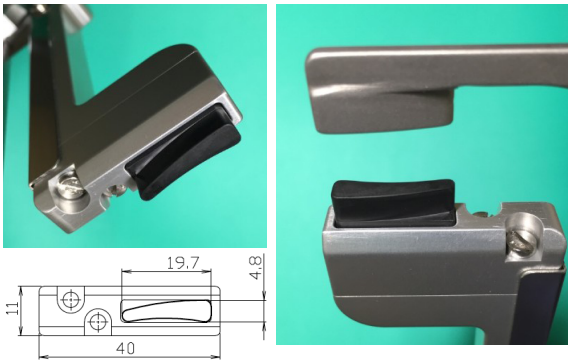


Fig. 6 The depressor shape is the same as that of the Maryland forceps.

3.2 PMEG Sensor

Figure 5 shows the PMEG sensor. We used a MCDW-5L load cell (Toyo Sokki, Kanagawa, Japan). This is an extremely small load cell that is fitted inside the PMEG jaw, with a rated capacity of 50 N and a resolution of 0.25 N, 25 gf. After installing the load cell, a plastic cover is fitted to the upper part of the PMEG lower jaw, making it possible to perform measurements even when the area is covered in blood. The signal line loading and unloading sites are also protected by the plastic cover, i.e., it is unlikely to be damaged during measurement.

3.3 Jaw shape

Figure 6 shows the jaw depressor area. We used a jaw depressor shape similar to the tip of the Maryland forceps, such as K33310 ML manufactured by Storz. This means that the same organ

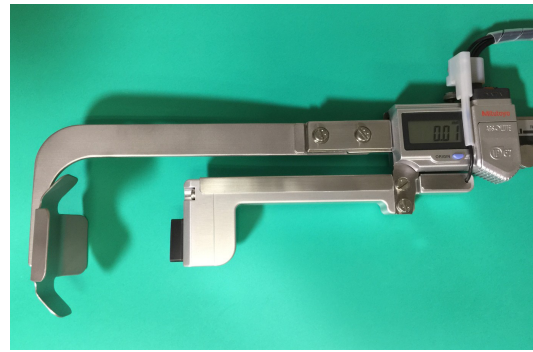


Fig. 7 The PMEG with the upper jaw switched to a dish-type shape.

changes that occur when grasping the tissue with forceps during surgery can be measured with the PMEG. Because the jaw position display can be arbitrarily set at 0, measurement of tissues of arbitrary width can be done easily.

Figure 7 shows the PMEG with the upper jaw switched to a dish-type shape. When used to measure large organs, the dish-shaped jaw can recreate the conditions when the organ is deformed while being held between the body wall and the lateral surface of the forceps. The dish-type shape is adjusted to allow the organ to be held stably while conducting measurement.

3.4 Measurement experiments

3.4.1 Validation experiment 1

Table 1 shows the results of validation experiment 1 using known weights. Converted values (1 kg weight = 9.8 N), PMEG display values, and errors are shown. Experimental conditions were approximately the same as in a normal operating theater (temperature: 26°C, humidity: 63%). The mean errors were 0.0543 N.

3.4.2 Validation experiment 2

Validation experiment 2 was a two-part experiment using two different compression coil springs.

Validation experiment 2-1 involved the use of a stainless steel compression coil spring (0.8-10-21). The coil spring constant (κ_{1a}) = $Gd^4/8NaD^3 = 0.9008$.

G : modulus of transverse elasticity. For a stainless steel spring, $G = 6.85 \times 10^4$.

d : diameter of the spring material. $d = 0.8$ (mm). Na : number of active coils. $Na = 5$.

D : mean coil diameter. $D = (\text{coil inner diameter} + \text{coil outer diameter})/2 = (8.4 + 19)/2 = 9.2$.

Figure 8a shows the results of the PMEG measurements. From this graph, the spring constant κ_{1b} was calculated to be 0.9091, and the error 0.0083 (0.92%).

Validation experiment 2-2 involved the use of a stainless steel compression coil spring (1.2-10-40). The coil spring constant (κ_{2a}) = $Gd^4/8NaD^3 = 2.004$.

G : modulus of transverse elasticity. For a stainless steel spring, $G = 6.85 \times 10^4$.

d : diameter of spring material. $d = 1.2$ (mm). Na : number of active coils. $Na = 13$.

D : mean coil diameter. $D = (\text{coil inner diameter} + \text{coil outer diameter}) / 2 = (7.6 + 10) / 2 = 8.8$.

Figure 8b shows the results of the PMEG measurements.

Table 1 Results of validation experiment 1.

Converted value: 1 kgf = 9.8 N

Weight(g)	50	100	150	200	300	400	500	600	700	800	900	1000	1200	1400
Converted value [N]	0.49	0.98	1.47	1.96	2.94	3.92	4.9	5.88	6.86	7.84	8.82	9.8	11.76	13.72
PMEG display [N]	0.4	0.9	1.4	2	3	3.9	5	5.9	6.9	7.8	8.8	9.8	11.7	13.6
error [N]	0.09	0.08	0.07	0.04	0.06	0.02	0.1	0.02	0.04	0.06	0.02	0	0.06	0.12

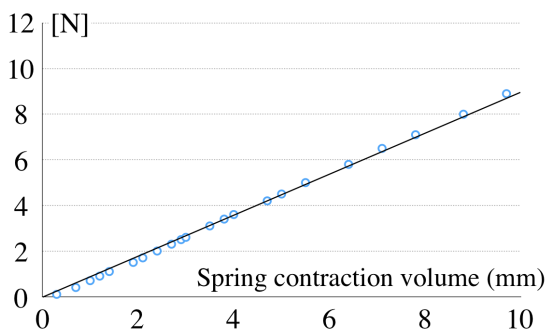


Fig. 8a Validation experiment 2-1. compression coil spring (0.8-10-21)

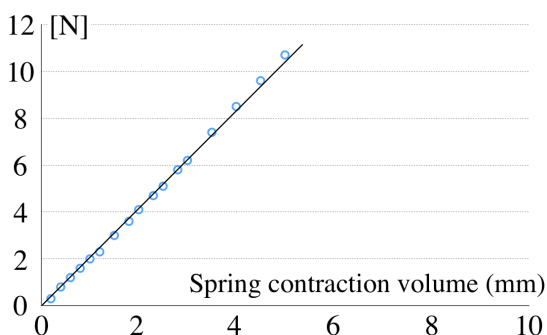


Fig. 8b Validation experiment 2-2. compression coil spring (1.2-10-41)

From this graph, the spring constant (k_{2b}) was calculated to be 2.067 and the error 0.0627 (3.13%).

3.5 In vivo organ hardness measurement experiment

We successfully used PMEG to measure organ hardness of a living pig (Fig. 9). Figure 10 shows the results of the hardness measurements for each organ. Measurement was performed at two to three points for each organ, but only at one point for the gallbladder. All these measurements were performed according to the regulations of the animal facility and relevant international and national guidelines.

It is apparent that even for the same organ, measurement results differ depending on the site within the organ. In luminal organs such as the large intestine and gallbladder, squeezing causes the contents to move, leading to dramatic deformation movements.

Next, Fig. 11 shows the results of bladder measurements. When the bladder was 100% full with urine, an external force of 6 N or less resulted in hardly any deformation. However, when the bladder was 50% or 75% full, various patterns of deformation

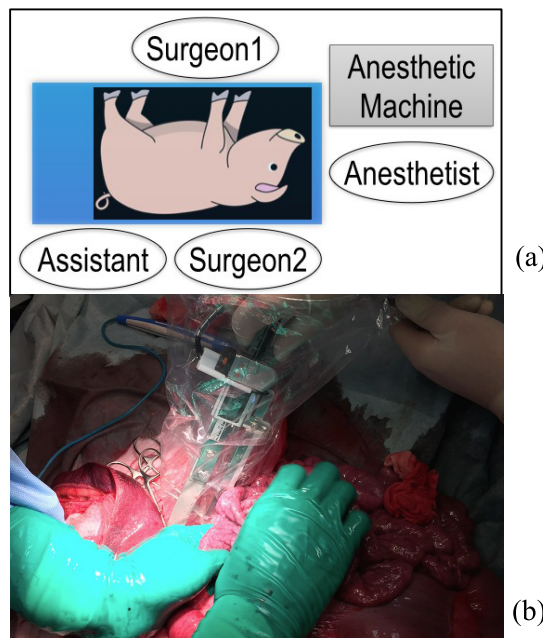


Fig. 9 In vivo organ measurement. (a) placement of the measurement, (b) measurement using PMEG in the pig's body.

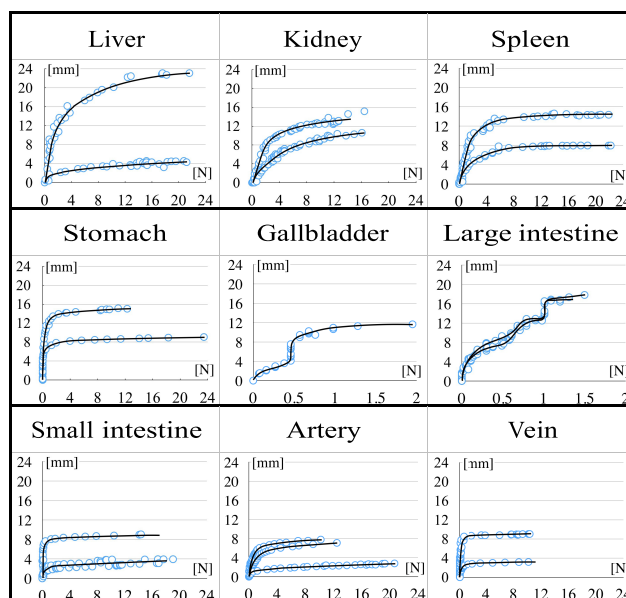


Fig. 10 Results of the hardness measurements in in vivo organs [x axis: (N) and y axis: (mm)].

were observed as urine moved accompanying grasping of the organ. We also confirmed the softness of the bladder when it was

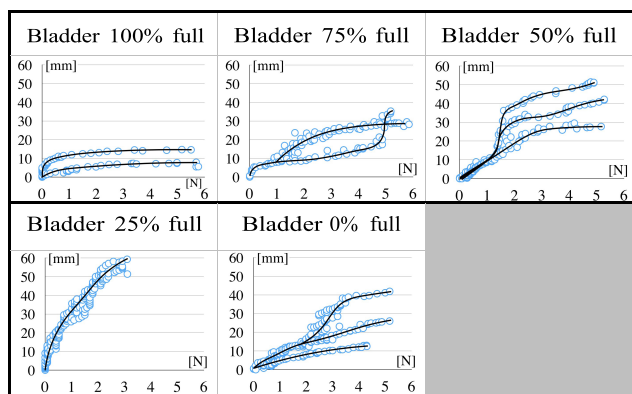


Fig. 11 Bladder hardness measurements [x axis: (N), y axis: (mm)].

25% full, when significant deformation was observed even with a slight amount of pressure.

4. Discussion

4.1 Development of the device

We successfully developed the PMEG, a pressure measurement device that fulfilled all of the three identified requirements. A vernier caliper was selected as the base of the device, and a small, high-performance load cell was used for precise measurement. This design also has the advantage of being able to measure even large organs when pressed with the side of forceps. However, because the parallel movement of the two PMEG jaws is not exactly the same as the grasping movement with forceps, questions remain, such as whether PMEG can really be used to measure changes during grasping with forceps. We, therefore, verified these questions.

Consider a situation where a target object with circular cross-section such as a blood vessel is pinched. Because the target object is not a rigid body, counterforce in accordance with pushing displacement of each site is equal to the load. We compare the grasping patterns between the actual forceps and the parallel clamp of the PMEG. When the same target object is grasped, we hypothesize that if the deformed area is equal, the sum total of perpendicular counter force to the grasped surface would be the same as that produced by the parallel clamp (**Fig. 12**). Accordingly, if a sensor is affixed to the forceps jaw, the load displayed by the sensor would be the same.

Thus, although there are slight differences in the target object deformation site and direction when pinched using parallel movement or grasping according to the angle α , the same amount of pressure would cause the same amount of deformation. Therefore, organ measurement using PMEG not only can be used to measure changes when the organ is pressed with the side of the forceps but is also advantageous for estimating changes produced when the organ is pinched with the forceps.

4.2 Validation experiments

Our experimental results indicate that the PMEG pressure display performs with high precision, and that there is a positive correlation between spring deformation volume and measured pressure. In addition, errors are of a minor level, i.e., they can be ignored. This suggests that the PMEG measurement function is highly precise. Furthermore, approximately the same level of error was ob-

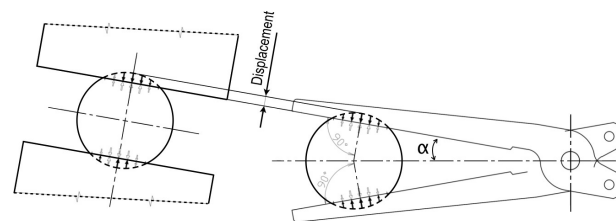


Fig. 12 Comparison between parallel pattern and grasping pattern. α is 1/2 of the degree of opening of the forceps. Differences between parallel and grasping patterns are deformation site and direction of the target object.

tained over multiple measurements, indicating that the PMEG measurement data is reliable. In the future, the measured value should be further evaluated by comparing between different grades of simulated stiffness, using a simulation model with precise organ element elasticity parameters measured by a tensile strength meter.

4.3 *In vivo* animal experiment

The PMEG has an attached output cable. Two experienced physicians were required to secure the surgical field and operate the PMEG, while one staff member was needed to manage the measurement data. Animal welfare considerations meant that the anesthesia time was limited, and we were able to conduct measurements only at two to three points for each organ (one point for the gallbladder). As much as possible, we selected measurement points with different shapes and thicknesses. Measurement points were also decided reflecting the typical pattern of surgical manipulations. Large amount of force feedback data, which is measured at a point close to a typical manipulation point, provides the reference force in a simulation.

The plots of measured values yield interesting data (**Fig. 10 and 11**). The area where the curve rises (small external force) approximates direct changes. This means that these measurements may be used as an approximate modulus of organ elasticity, suggesting the possibility of measuring data that could be significant in demonstrating organ hardness parameters.

Because of time restriction in measuring the plastic deformation of organs, we were unable to verify whether there are differences between the pressure when pressing on the organ and the pressure when the deformation was relieved from being pressed. This merits separate verification in future studies.

4.4 Clinical significance for each organ

It is interesting to note that in luminal organs such as the large intestine or bladder, we observed data showing the movement of contents that escaped from pressure. Our results demonstrate that even in the same organ, the hardness of the organ as perceived intraoperatively by the surgeon differs according to the site measured within the organ. These differences may be related to differences in organ thickness and in the internal structures (presence/absence of blood vessels). This suggests that conventional simulators that define organ hardness as a fixed parameter are not ideal.

The organ hardness data obtained in the present study conformed to one author's personal empirical understanding of organ

hardness as a surgeon, indicating that we successfully expressed sensory data as perceived by surgeons. Thus, the present device has a significant advantage that changes in the organ perceived by the surgeon can be directly measured in numerical terms. However, we only performed measurements once to obtain organ hardness data. However, organ hardness varies depending not only on the site, but also among individuals. Therefore, we need to collect more detailed data in the future to further investigate this issue.

5. Conclusion

To improve the safety of laparoscopic surgery, the quality of available surgery simulators and 3D organ models needs to be improved. The recreation of organ elasticity and rupture limits in the actual surgical field with simulator tools would lead to revolutionary advances in surgeon training.

Different from existing systems, the PMEG is potentially useful for examination, and has enough accuracy for surgical training. We expect that data obtained with the PMEG will contribute to future advances in surgeon training and continuing medical education.

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Conflict of interest

The authors have no conflicts of interest associated with this manuscript.

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