Online August 31, 2021
Journal of Neuroendovascular Therapy 2022; 16: 192–197
DOI: 10.5797/jnet.oa.2021-0068

Original Article

In Vitro Measurement of Contact Pressure Applied to a Model Vessel Wall during Balloon Dilation by Using a Film-Type Sensor

Takeshi Moriwaki,[1#] Yoshihiro Okamoto,[2#] Hiroo Yamaga,[3] Kazuhiro Fujisaki,[1] Miyuki Uematsu,[2] Hideyuki Sakoda,[2] and Yuji Haishima[2]

Objective: As an important evaluation index of vascular damage, the study aims to clarify the value of contact pressure applied to blood vessels and how it changes with respect to balloon pressure during balloon dilation.
Methods: The contact pressure was evaluated through an in vitro measurement system using a model tube with almost the same elastic modulus as the blood vessel wall and our film-type pressure sensor. A poly (vinyl alcohol) hydrogel tube with almost the same elastic modulus was fabricated as the model vessel. The film-type sensor was inserted between the balloon catheter and the model vessel, and the balloon was dilated.
Results: The contact pressure applied to the blood vessel was less than 10% of the balloon pressure, and the increase in contact pressure was less than 1% of the increase in balloon pressure (8 to 14 atm). Moreover, the contact pressure and its increase were larger in the model with a high elastic modulus.
Conclusion: The contact pressure to expand the soft vessel model was not high, and the balloon pressure almost appeared to act on the expansion of the balloon itself. Our experiment using variable stiffness vessel models containing film-type sensors showed that the contact pressure acting on the vessel wall tended to increase as the wall became harder, even when the nominal diameter of the balloon was almost identical to the vessel. Our results can be clinically interpreted: when a vessel is stiff, the high-pressure inflation may rupture it even if its nominal diameter is identical to the diameter of the vessel.

Keywords ▶ balloon, catheter, percutaneous transluminal angioplasty, pressure, in vitro

Introduction

Percutaneous transluminal angioplasty (PTA) is one of the main treatments for dilation of stenosis or occluded blood vessels. In PTA treatment, a semi-compliant (SC) or non-compliant (NC) balloon catheter, a balloon made of strong film and used at a relatively high pressure, is often used. Naturally, a balloon with a higher internal pressure has a higher dilation performance of blood vessels, but excessive dilatation may lead to vascular damage. Therefore, excessive dilation may cause intimal thickening and thrombus formation. Generally, an SC or NC balloon inflator is equipped with a pressure gauge, and PTA treatment is often performed using balloon internal pressure as a guide. Here, the balloon pressure and the contact pressure applied to the blood vessel wall existing outside the balloon are different, but it is still not sufficiently clear how the contact pressure on the vessel changes depending on the balloon device and/or balloon pressure. Contact pressure is a load that acts directly on the vessel wall, and it can serve as a useful indicator for understanding the relationships between device dilation conditions and actual expansion results or postoperative negative events.

[1]*Faculty of Science and Technology, Hirosaki University, Hirosaki, Aomori, Japan*
[2]*Division of Medical Devices, National Institute of Health Sciences, Kawasaki, Kanagawa, Japan*
[3]*Showa University Northern Yokohama Hospital, Yokohama, Kanagawa, Japan*

Received: April 13, 2021; Accepted: July 5, 2021
Correspondence author: Takeshi Moriwaki. Faculty of Science and Technology, Hirosaki University, 3, Bunkyocho, Hirosaki, Aomori 036-8561, Japan
Email: moriwaki@hirosaki-u.ac.jp
[#]These two authors equally contributed to this work.

As described earlier, the physical properties of catheter devices directly affect treatment performance and vascular injury, and various evaluations have been reported. To evaluate the force applied on the vessel wall, there are reports on the development of force-detectable catheters[1] or guidewires.[2] Studies have also evaluated the force during balloon dilation within a blood vessel model made of rigid material.[3,4] These studies were evaluated using a single or a small number of measurement points, and no in vivo or in vitro measurement methods have been established that can evaluate the distribution of the force applied on the blood vessel wall. Therefore, the distribution of force or deformation caused when applying force to a vessel wall was evaluated by numerical simulations.[5,6]

A film-type sensor was developed to understand the force distribution between contact interfaces.[7] The sensor has sub-millimeter-level spatial resolution and can accurately observe contact pressure distribution. In addition, because the sensor is thin and flexible, it can be used on a curved surface and can follow the deformation of the measurement object. We have already applied this sensor to measurements between a balloon catheter and a model vessel made of a relatively hard material, and evaluated the relationship between balloon pressure and contact pressure applied on the vessel wall and pressure distribution around the pseudo-plaque.[8]

It is necessary to adjust the deformation characteristics of the model vessel wall to simulate the value of the contact pressure applied between the balloon and the vessel. In this study, to clarify the value of the contact pressure applied to the blood vessel and how it changes with respect to the balloon pressure by using SC or NC balloons, the contact pressure was measured using a model tube with almost the same elastic modulus as the blood vessel wall and our film-type pressure sensor. The contact pressure was also measured with a rigid model of the same shape. Through a comparison of these experimental results, we considered the parameters that can closely influence the contact pressure on the blood vessels. By measuring the contact pressure as one of evaluation indices of vascular damage and using the obtained knowledge as a reference for the selection of procedures and devices, improvements to effectiveness and safety can be made.

Materials and Methods

Blood vessel model

Straight tubes simulating the elastic modulus of blood vessel wall were fabricated by a poly (vinyl alcohol) hydrogel (PVA-H). To prepare the PVA-H model, we referred to previous reports.[9,10] Briefly, PVA powder (degree of polymerization [DP] 1500–1800; FUJIFILM Wako Pure Chemical, Osaka, Japan) was dissolved in a solvent mixture of distilled water and dimethyl sulfoxide (20/80 w/w; FUJIFILM Wako Pure Chemical). Concentrations of 8 wt% and 12 wt% PVA in the solvent were used. The PVA solution was stirred for 90 min at 100°C before it was cooled to approximately 40°C and poured into a mold, which was then stored at –30°C for 24 h to promote gelation. The mold was designed to fabricate a straight tube with an inner diameter of 7 mm, an outer diameter of 10 mm, and a length of 90 mm. The gelled PVA-H tubes were removed from the mold and immersed in water for several days so that the dimethyl sulfoxide in the solvent mixture would be replaced by water.

To measure the elastic modulus of the PVA-H material, cylindrical blocks with a diameter of 60 mm and a height of 30 mm were fabricated in the same manner as described earlier. The elastic modulus was measured via an indentation test[11] using a universal testing machine (Instron 4464; Illinois Tool Works, Buffalo Grove, IL, USA). A load cell (Unipulse, Tokyo, Japan) and a data logger (PCD-430A; Kyowa Electronic Instruments, Tokyo, Japan) were used to accurately detect minute forces. A cylindrical indenter with a diameter of 5 mm was fixed to the load cell. The indentation depth and speed were 1 mm and 0.01 mm/s, respectively.

Film-type pressure sensor

A single-point pressure sensor was fabricated. The procedure for sensor fabrication was the same as that described in our previous report.[8] Briefly, the upper and lower electrodes were fabricated from a flexible photosensitive film (NZ-M3K. base layer: polyimide, metal layer: copper; Sunhayato, Tokyo, Japan) through photolithography and wet-etching processes (**Fig. 1A**). Conductive rubber (INABA RUBBER, Osaka, Japan) with a diameter of 2.5 mm and a thickness of 0.3 mm was inserted between both electrodes and sealed with polyurethane adhesive films (**Fig. 1B** and **1C**). The sensing area, which is the overlapping area of the upper or lower electrode and conductive rubber, was a 1 mm diameter circle. The overall thickness of the film-type sensor was 0.5 mm.

The electrical resistance of the conductive rubber of the film-type sensor changed when the contact pressure was applied. The change in electrical resistance was converted into a voltage signal using a driven circuit with the

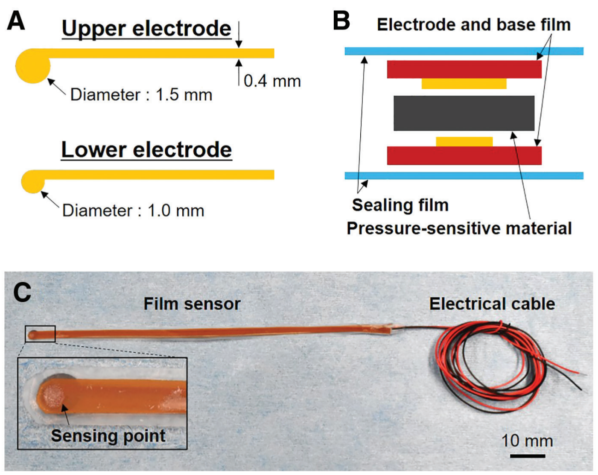

Fig. 1 Film-type pressure sensor. (**A**) Upper and lower electrode structures, (**B**) schematic cross-sectional view of measurement points, and (**C**) sensor film after assembly.

function of inverting amplification. The output voltage V_{out} is obtained as follows:

$$V_{out} = -\frac{R_f}{R_s} V_{in} \tag{1}$$

In this study, the input voltage V_{in} was 5 V, and the feedback resistance R_f was 1000 Ω for the PVA-H soft model measurement and 330 Ω for the rigid model measurement. The output voltage V_{out} according to the change in the sensor resistance R_s was obtained through the circuit. The calibration curves between the applied contact pressure and sensor signal V_{out} were obtained in the range 0–0.40 atm for soft model measurement and 0–5.5 atm for rigid model measurement.

Contact pressure measurement during balloon dilation

The contact pressure applied between the balloon catheter and the model vessel was measured by inserting a film-type pressure sensor. The construction of the measurement system is illustrated in **Fig. 2A**. In this measurement, a PTA balloon catheter (NSE PTA. 7.0 mm diameter at 8 atm, SC; GOODMAN, Aichi, Japan) was used. The non-slip elements of the balloon were removed before the experiment. This is because the PTA balloon was expanded several times prior to the experiment, and the compliance chart might have changed; the relationship between the balloon diameter and internal pressure was measured (n = 3). The balloon diameter was monitored using an optical micrometer (LS-7030; Keyence, Osaka, Japan). The balloon pressure was monitored using a digital pressure gauge (PSE576-02; SMC, Tokyo, Japan). The film-type sensor was inserted between the balloon catheter and the model vessel, and the balloon was dilated (**Fig. 2B** and **2C**). The balloon pressure signal and the contact pressure signal were monitored using a data logger (PCD-430A; Kyowa Electronic Instruments) and a laptop. The contact pressure measurements were performed three times for three specimens at each concentration (n = 9). The same matter measurement was also conducted on an acrylic pipe with an inner diameter of 7 mm and an outer diameter of 10 mm as a rigid model.

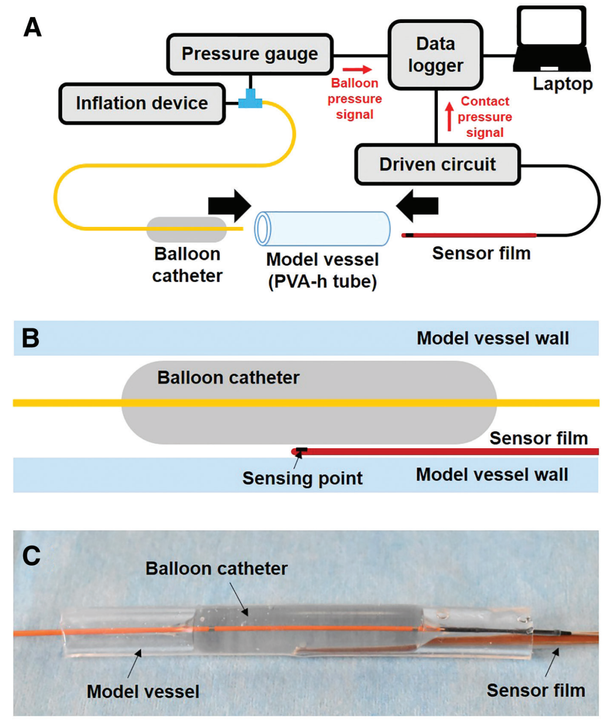

Fig. 2 Contact pressure measurement during balloon dilation. (**A**) Schematic of measurement system, (**B**) schematic longitudinal section view of the inside of the model vessel, and (**C**) photograph of the model vessel setup during balloon dilation.

Results

Elastic modulus of PVA-H material

The elastic modulus of PVA-H material was measured via an indentation test. During 1 mm indentation, almost linear relationship between the indentation distance and reaction force was obtained for all samples. The obtained elastic modulus was 31.6 ± 0.6 kPa at 8 wt% PVA-H and 69.7 ± 0.5 kPa at 12 wt%.

Calibration curve of film-type sensor

The calibration curves of the film-type sensors are shown in **Fig. 3**. Because the contact pressure was considered to

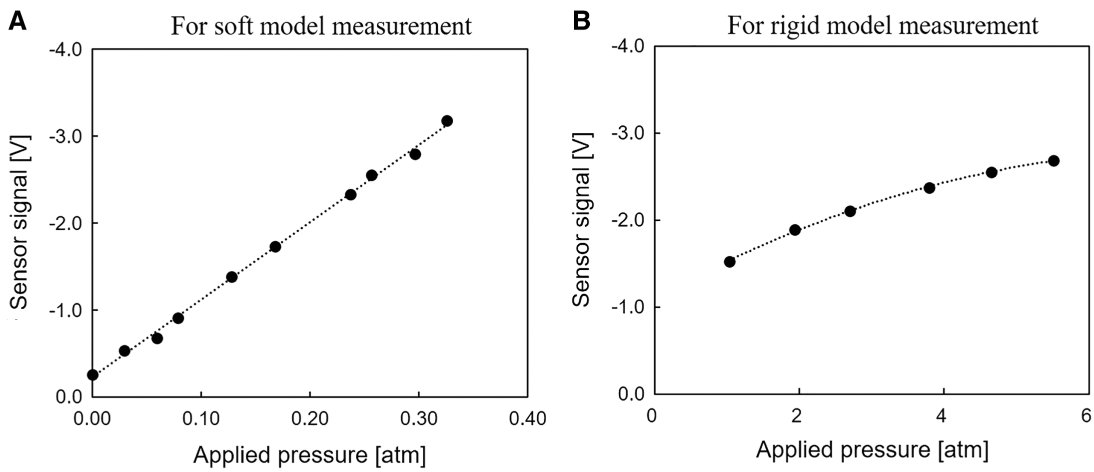

Fig. 3 Calibration curves' contact pressure and output voltage for the film-type sensor. (**A**) Relationship in the low pressure range for soft model measurement and (**B**) relationship in the high pressure range for rigid model measurement.

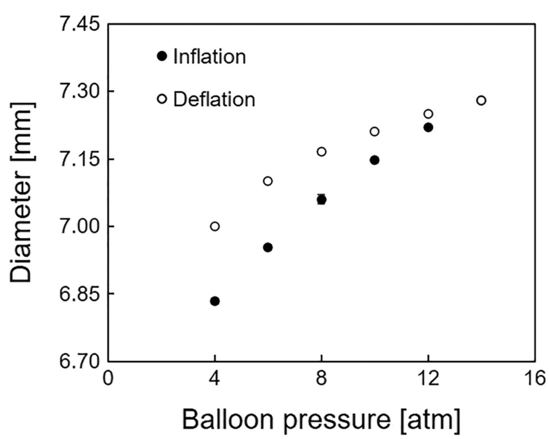

Fig. 4 Compliance chart of the PTA balloon used in this study. The data (n = 3) are shown as mean (plot) and standard deviation (bar). PTA: percutaneous transluminal angioplasty

be significantly different between the acrylic rigid model and the PVA-H soft model, two calibration curves with different pressure ranges and feedback resistances were obtained. In the calibration curve of the soft model measurement, the square of the autocorrelation coefficient was 0.998 for linear approximation. In the calibration curve of the rigid model measurement, the square of the autocorrelation coefficient was 0.999 for quadratic approximation. Both curves showed a clear change and high correlation in the sensor signal with respect to the applied pressure.

Compliance chart of balloon catheter

Figure 4 shows the compliance chart of the balloon used in this experiment. The measurements were performed up to the rated burst pressure of 14 atm. The standard deviation of each measurement point was 0.01 mm or less. The relationship between the balloon pressure and diameter was different between the inflation and deflation processes. Contact pressure measurements during balloon dilation were performed during inflation.

Contact pressure applying to model vessel wall

Figure 5 shows the relationship between contact pressure and balloon pressure. The contact pressure acting on the vessel wall differs from the balloon internal pressure in all the models. For example, when the balloon internal pressure was 14 atm, the contact pressure was 6.5 atm for the rigid model, 0.20 atm (150 mmHg) for the 8% PVA-H model, and 0.23 atm (174 mmHg) for the 12% PVA-H model. The contact pressure in the rigid model was significantly higher than that in the soft model. With regard to the soft models, the contact pressure for the 12% PVA-H model was higher than that for the 8% PVA-H model. As the balloon pressure increased from 8 to 14 atm, the contact pressure increased by 3.5 atm for the rigid model, 0.032 atm (24 mmHg) for the 8% PVA-H model, and 0.035 atm (27 mmHg) for the 12% PVA-H model.

Discussion

In a previous study,[8] we investigated the feasibility of measuring the contact pressure distribution on the blood vessel wall with a film-type sensor and the change in the pressure distribution due to the balloon pressure and vessel shape by using a relatively hard silicone gel model vessel. In this study, to determine the actual pressure applied on the blood vessel during balloon dilation, the contact pressure was measured using a model tube with an elastic modulus similar to that of the blood vessel wall. PVA-H can be adjusted to the

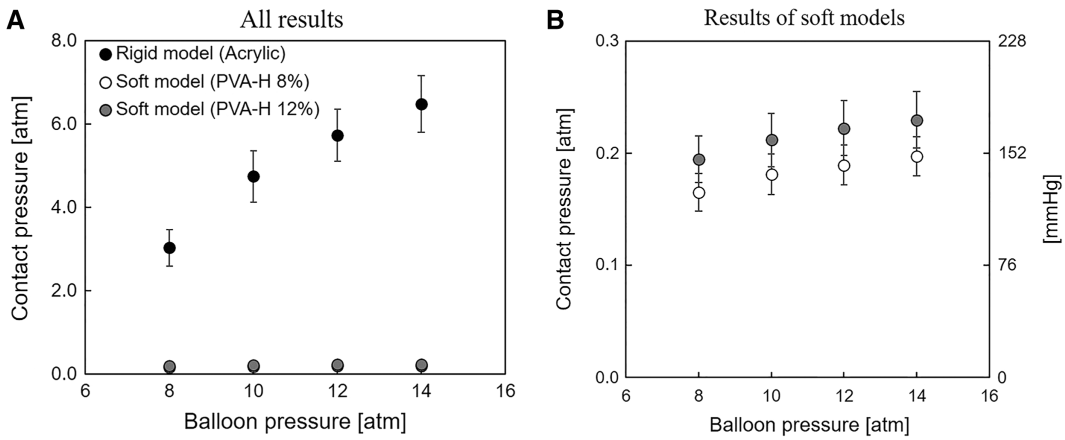

Fig. 5 Relationships between the balloon pressure and contact pressure applied to the model vessel. The data (n = 9) are shown as mean (plot) and standard deviation (bar). (**A**) and (**B**) depict the same data with different contact pressure ranges.

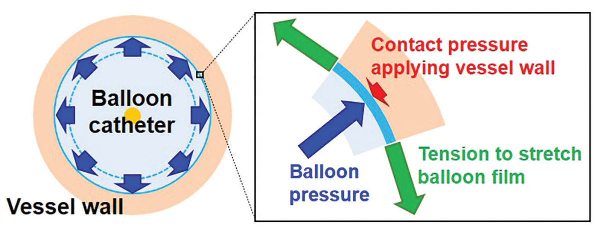

Fig. 6 Schematic of the force relationship of circumferential cross-section during balloon dilation. Balloon pressure is not applied directly on the blood vessel wall because it first acts as a tensile force to stretch the balloon film.

same elastic modulus as biological soft tissues and can also be used as a blood vessel model. Shimizu et al. used 10–15 wt% PVA-H to realistically simulate the mechanical properties of blood vessels.[10] In this study, we used 8 or 12 wt% PVA-H, which exhibits a slightly lower elastic modulus because the thickness of the model tube exceeds that of an actual blood vessel wall. To ensure generality and reproducibility, the contact pressure measurements were conducted under the simplest scenario, i.e., at a single point in a straight model vessel with a circular cross section.

In the PVA-H model, the contact pressure applied to the blood vessel was less than 10% of the balloon pressure, and the increase in contact pressure was less than 1% of the increase in the balloon pressure (i.e., 8–14 atm). These results show that the balloon pressure and the contact pressure do not have a one-to-one relationship. During balloon dilation, the internal pressure of the balloon acts not only as the contact pressure applied to the vessel wall but also as a tensile force expanding the balloon itself (**Fig. 6**). If the balloon is not in contact with the blood vessel, the contact pressure acting on the vessel is zero, regardless of the balloon pressure. The contact pressure expands the inner diameter of the blood vessel up to the balloon diameter. In such cases, healthy blood vessels dilate by several tens of percent of blood pressure (100 mmHg).[12,13] Therefore, even in the balloon dilation conducted in this study, the force required for expanding the soft vessel model was not high, and it is considered that the balloon pressure almost acted on the expansion of the balloon itself.

With regard to the PVA-H model, the contact pressure and its increase were greater in the model with a high elastic modulus. As described earlier, the contact pressure expands the inner diameter of the blood vessel up to the balloon diameter, and the contact pressure is greater in the harder blood vessel. Furthermore, in significantly hard blood vessels, such as calcified blood vessels, the contact pressure can be considerably high because the balloon does not expand sufficiently to the diameter of the compliance chart[14] and the tension of the balloon film is decreased. Indeed, a high contact pressure was observed in the experiments with high balloon pressure and the rigid model, which could not be expanded to the diameter of the compliance chart. While the physical characteristics of calcified vessels are diverse and cannot be rigorously discussed here, there are clinical situations in which they cannot be extended to the diameter of the balloon compliance chart. In such cases, it is assumed that a large contact pressure is applied to the blood vessel.

In this study, we conducted experiments on straight blood vessel models with circular cross sections and uniform elastic modulus. However, balloon dilation in a curved vessel can generate a large contact pressure with deformation; in calcified blood vessels, this causes stress concentration due to the non-uniformity in shape and properties.[8] As this sensor is thin and flexible, it is expected to be applicable for measurements with the blood vessel model, as described earlier. Excessive force or deformation of the vessel wall during balloon dilation may increase the risk of negative postoperative events such as intimal thickening and thrombus formation. It is important to obtain quantitative data through in vitro experiments and investigate the correlation of the results in clinical practice. This would help reduce complications during surgery, establish guidelines for procedures and device selection, and determine mechanical guidelines for developing new medical devices.

Limitations

The elastic modulus of the blood vessel models can only be adjusted to approximately the same level, and the change in the elastic modulus according to deformation was not simulated. The inner and outer diameters of the PVA-H tube described correspond to the dimensions on the mold side, and the actual dimensions have a submillimeter-level error. Furthermore, measurement errors occur depending on the thickness of the sensor film. Lastly, these results may not be applicable to compliant balloons, because they are only suitable for cases wherein the balloon is sufficiently stiffer than the blood vessels.

Conclusion

A PTA balloon catheter was expanded with a model vessel simulating deformation characteristics, and the contact pressure applied on the blood vessel wall was measured using a film-type sensor. The contact pressure was found to be significantly lower than the internal pressure of the balloon. Our experiment using variable stiffness vessel models containing film-type sensors showed that the contact pressure acting on the vessel wall tended to increase as the wall became harder even when the nominal diameter of the balloon was almost identical to the vessel. Our results can be clinically interpreted: when a vessel is stiff, the high-pressure inflation may rupture it even if its nominal diameter is identical to the diameter of the vessel.

Acknowledgment

This study was partly supported by a Grant-in-Aid (18K18352 and 17K01444) from the Japan Society for the Promotion of Science.

Disclosure Statement

The authors have no conflicts of interest directly relevant to the content of this article.

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