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Publisher's version / Version de l'éditeur:

<https://doi.org/10.1063/1.3465556>

Review of Scientific Instruments, 81, 8, pp. 083101-1-083101-8, 2010-07-15

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Optical coherence tomography monitoring of angioplasty balloon inflation in a deployment tester

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(Received 18 March 2010; accepted 28 June 2010; published online 2 August 2010)

We present an innovative integration of an intravascular optical coherence tomography probe into a computerized balloon deployment system to monitor the balloon inflation process. The high-resolution intraluminal imaging of the balloon provides a detailed assessment of the balloon quality and, consequently, a technique to improve the balloon manufacturing process. A custom-built swept-source optical coherence tomography system is used for real-time imaging. A semicompliant balloon with a nominal diameter of 4 mm is fabricated for the experiments. Imaging results correspond to balloon deployment in air and inside an artery phantom. A characterization of the balloon diameter, wall thickness, compliance, and elastic modulus is provided, based on image segmentation. Using the images obtained from the probe pullback, a three-dimensional visualization of the inflated balloon is presented. [doi:10.1063/1.3465556]

I. INTRODUCTION

Intravascular optical coherence tomography (IVOCT) is a minimally invasive technique that provides detailed cross-sectional imaging of the artery wall. This technology has evolved rapidly in the past few years thanks to the development of swept-source optical coherence tomography (SS-OCT).¹ Many studies^{2–5} have clearly demonstrated the clinical relevance of IVOCT for the diagnosis of atherosclerosis and for monitoring the results of percutaneous coronary interventions.

In the current paper, we propose a novel application of the IVOCT technology, i.e., the monitoring of balloon inflation in a balloon deployment tester. A deployment tester is used to test the quality of balloons through inflation under predetermined conditions. Traditionally, it can be equipped with a laser scanner that is used externally to provide measurements of the balloon's outer diameter at a given location. Such assessment, unfortunately, is limited to a side view and a particular angle. Combining IVOCT with a deployment tester allows a full characterization of balloon diameter and wall thickness during the inflation process. Measurements are not limited to a single location but with a quick pullback, the whole balloon can be imaged at a given pressure. Combining the computerized balloon inflation provided by the deployment tester with the accurate measurements of IVOCT results in a tool that can benefit many applications. For balloon development alone, one can validate balloon performance, explore new designs, validate balloon deformation models, or extract mechanical properties. The system can be used with a phantom or an excised artery to provide further applications. Not only can one follow balloon inflation with more realistic conditions, one can also obtain a very good

setup to simulate angioplasty procedures with IVOCT monitoring. This not only benefits balloon manufacturers but also the developers of percutaneous coronary intervention devices and clinical users.

In the following, we present the structure of our optical coherence tomography imaging balloon (OCTIB) catheter and its integration in the deployment tester. Imaging results are provided for balloon deployment in air and inside a phantom. We then present a characterization of balloon diameter, wall thickness, and mechanical properties, all obtained from segmentation of OCT images.

II. MATERIALS AND METHODS

In this section, the components and the structure of the optical coherence tomography imaging balloon catheter are described.

A. OCT

OCT is an imaging modality that is now being used in many clinical applications,⁶ including cardiovascular research.⁵ It is a nondestructive imaging technique, divided into two categories: the time-domain OCT (Ref. 7) and the Fourier-domain OCT (FD-OCT) which itself is further divided into spectral domain OCT^{8,9} and SS-OCT,^{10–12} also known as optical Fourier domain imaging.¹³ Measurements in this paper are performed with SS-OCT. We thus briefly review SS-OCT principles and describe our SS-OCT setup.

1. SS-OCT principles

A basic configuration of the SS-OCT setup is presented in Fig. 1. The light coming from the wavelength-swept source is split by an optical coupler into two parts, one of which goes into the reference arm and the other into the sample arm. The light reflected from the reference arm with

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FIG. 1. (Color online) Basic configuration of a fibered SS-OCT setup (Cp: coupler, D: detector).

intensity I_r and the backscattered light from the sample with intensity I_s are then combined in the coupler to create interference fringes. Assuming that the sample arm only contains a single reflector, the intensity received by the photodetector is given by

$$I = I_r + I_s + 2\sqrt{I_r I_s} \cos\left[\frac{2\pi}{c}\nu(t)2\Delta z\right], \quad (1)$$

where c is the speed of light, $\nu(t)$ is the optical frequency as a function of the time t , and Δz is the optical path delay between the two arms of the interferometer. In the presence of many reflectors, Eq. (1) takes a more complicated form to include a term describing the mutual interference between the reflectors.

For a source providing an ideal linear sweep in frequency, we have $\nu(t) = \nu_0 + (\Delta\nu/\Delta t)t$, where ν_0 is the start sweep optical frequency and $\Delta\nu$ is the swept bandwidth during the time interval Δt . Most commercial sources for SS-OCT do not provide such an ideal linear sweep, but the non-linearity can be corrected with one of the many techniques found in the literature.^{14–16}

Assuming an ideal linear sweep, the modulation term of the interference fringes is given by

$$I_{\text{mod}} \propto \cos\left(\frac{2\pi}{c}\nu_0 \cdot 2\Delta z + \frac{2\pi}{c}\frac{\Delta\nu}{\Delta t}t \cdot 2\Delta z\right). \quad (2)$$

The amplitude of the inverse Fourier transform of I_{mod} is then computed

$$|\mathcal{F}^{-1}[I_{\text{mod}}]| \propto [\delta(f - f_1) + \delta(f + f_1)], \quad (3)$$

where $f_1 = (2\Delta z/c)(\Delta\nu/\Delta t)$. The depth information Δz is thus recovered by computing $\Delta z = (1/2)c(\Delta t/\Delta\nu)f_1$.

This simple model illustrates one of the shortcomings of SS-OCT and FD-OCT in general; one cannot distinguish the positive depths from the negative depths. This is referred to as the mirror artifact, which is avoided in our system by placing the sample on one side of the zero-delay position in the sample arm.

2. Experimental SS-OCT setup

We use a custom-built SS-OCT system that operates with a commercial swept source. For this work, we use a wavelength-swept laser source (HSL2000, Santec, Komaki, Japan), operating with a sweep rate of 30 kHz and a sweep range of over 110 nm around 1.31 μm wavelength to provide a measured axial OCT resolution of about 12 μm in air.

FIG. 2. (Color online) SS-OCT setup (Cp1 and Cp2: couplers, PC: polarization controller, Cir1 and Cir2: circulators, D: balanced detection, ATU: artery testing unit).

The SS-OCT system is configured as a Mach–Zehnder interferometer with balanced detection and is packaged as a mobile unit. The setup is presented in Fig. 2.

B. Balloon production

A balloon was fabricated to perform this first investigation of the combination of OCT with a balloon deployment apparatus. The balloon fabrication process¹⁷ is generally composed of three main phases, i.e., extrusion, double-end stretching, and balloon forming. In the first phase, the aim is to extrude tubing with high concentricity and uniform wall thickness. An extruded polyurethane tube (Pellethane, 55D, Dunn Industries, Inc., Manchester, NH) was used for balloon production. In the usual second phase, i.e., the double-end stretching, both ends of the tube are stretched under high temperature, leaving in the middle an unstretched segment called parison. The polyurethane used in this work is more elastic than other balloon production materials, e.g., Pebax. A large stretch would cause the material to shrink back to its original length. Therefore, this second-phase was skipped and no double-end stretching was performed. In the third phase, the balloon forming is executed through a blow molding process by a balloon-forming machine (9810H, Interface Catheter Solutions, Laguna Niguel, CA), illustrated in Fig. 3. In blow molding, the operator places the proximal end of the tube into the chuck on the left side, which is connected to a

FIG. 3. (Color online) The balloon forming machine (9810-H, Interface Catheter Solutions).

FIG. 4. (Color online) Balloon forming stages.

supply of compressed nitrogen. The distal end goes through the center mold and the distal-end plugs. Compressed nitrogen is blown through the proximal end at a low pressure, while the heater jaws warm up the piece. Different stages of the balloon forming process are demonstrated in Fig. 4. During the primary heating stage, the pressure and temperature are raised, followed by axial prestretching of both ends. The process then enters the primary stretch phase, where both ends are further stretched at a predetermined speed to a specified length. This causes the tube to be extended inside the mold and expanded due to pressure, which leads to formation of the balloon. A secondary stretch is applied to form the cones of the balloon on both sides. At the end of the process the mold is cooled down, the pressure is released, and the balloon is ready to be removed from the mold.

Table I presents the values of parameters that we used for different stages of the balloon forming process. The machine advances from each stage to the next, once a user-defined condition on temperature, pressure, etc., is satisfied. The choice of these conditions and the applied stretch, pressure, and temperature affect the balloon quality, e.g., wall thickness, mechanical properties, and burst pressure.

The balloon forming process produced a semicompliant balloon with dimensions of (4 × 15 mm²), with an inner diameter of 1.2 mm and an outer diameter of 1.50 mm in the balloon tubing.

FIG. 5. (Color online) OCTIB catheter (B: Balloon, F: ferrule, PS: polymer sheath, GRIN: gradient-index lens, LB: light beam, OF: optical fiber, PT: polymer tube, RAP: right-angle prism).

C. Structure of the OCTIB catheter

Figure 5 illustrates the composition of the OCTIB catheter. The IVOCT probe is composed of a single-mode fiber enclosed within a spiral metallic tube in the proximal region and within a polymer tube in the distal region. At the tip of the probe, light is focused by a gradient index (GRIN) lens and redirected at 90° by a right-angle prism. The optical components are enclosed in a metallic ferrule. Rotation and translation are ensured by a custom pullback unit. The ferrule is 700 μm in diameter but the maximum probe diameter is 800 μm at the spiral metallic tube. It rotates in water within a polymer sheath (PS). The polymer sheath is used to protect the OCT probe and to prevent it from drifting away from the center of the balloon while rotating. The diameter of the polymer sheath should be close to the diameter of the probe in order to facilitate inclusion of the OCT assembly inside the balloon. On the other hand, it should provide sufficient space to allow the probe to be easily rotated with minimal friction. A heat-shrinkable Teflon tube [fluorinated ethylene propylene (FEP), Zeus, Inc., Orangeburg, SC] was chosen to achieve the desired characteristics. Teflon is a suitable material for this application, since it is translucent and causes small friction. After shrinking, approximate inner and outer diameters of 0.9 and 1.0 mm were, respectively, obtained for the Teflon tube. The probe and its polymer sheath are inserted into the balloon. Figure 6 provides a cross-sectional view for the proximal tube of the OCTIB catheter. As shown in this figure, the polymer sheath divides the lumen of the balloon catheter into two isolated lumens. The lumen between the polymer sheath and the balloon is allocated to a high-pressure liquid, used for deployment of the balloon. Within the polymer sheath, a low-pressure lumen contains the rotating OCT probe. It was essential to isolate the two lumens; if the high pressure water was allowed inside the

TABLE I. Balloon forming parameters.

	Primary heating	Primary stretch and balloon formation	Secondary stretch
Mold temperature target (°C)	90	170	175
Pressure (atm)	5	30	20
Stretch (mm)	30	35	38
Terminating condition	Temperature >80 °C	After 4 s	Temperature >150 °C

FIG. 6. Cross-section of the OCTIB catheter (proximal side).

polymer sheath, it would be necessary to entrap it with a tight sealing at the proximal end. This could restrict or hamper the probe motion. The two-lumen approach revealed to be an efficient solution. In Sec. II D, we describe how both lumens are connected to their respective low-pressure and high-pressure lines.

D. OCTIB catheter in the computerized balloon deployment setup

Percutaneous coronary intervention is usually performed using a manual inflation device monitored by a pressure gauge. However, in order to quantify, record, and analyze the measurements, we use a computerized deployment setup which is based on a hydraulic pressure tester (Interface Catheter Solutions, model PT-3070, Laguna Niguel, CA). Figure 7 illustrates the experimental setup, used to deploy the balloon. This setup allows for programming customized inflation and deflation cycles. In our experiments, water was used as the pressurization medium. A dc motor drives a syringe plunger, which delivers the deployment volume. The position of the plunger, measured by an encoder, corresponds to the amount of the delivered volume. A transducer measures the pressure. Based on these real-time measurements, a computer commands the motor to achieve a desired pressure. The OCT probe and the polymer sheath are introduced into the

FIG. 7. (Color online) The balloon deployment setup.

FIG. 8. (Color online) Photo of the inflated balloon.

balloon tube using a T-connector as shown in Fig. 7. This connector also provides a connection between the deployment tester and the high-pressure lumen, delimited by the polymer sheath and the balloon.

III. RESULTS

In this section, we first present images and movie clips obtained from real-time monitoring of balloon inflation under various conditions. This provides a qualitative demonstration of the new opportunities provided by the combination of IVOCT with a balloon deployment tester. We then present a more quantitative assessment of balloon inflation by extracting balloon diameters and thicknesses at various pressures. These data are of high interest for balloon design. An example of the use of such data is provided by extracting mechanical properties of the balloon material.

A. Real-time imaging results

Imaging results correspond to balloon deployment both in air and inside an artery phantom. A frame rate of 20 frames per second (fps) was selected for image acquisition. The pressure values represent the pressures relative to the atmospheric pressure.

1. Balloon deployment in air

Figure 8 illustrates a photograph of the of the OCT probe within an inflated balloon in air. Although imaging is performed with infrared light, we include red light in the system to locate the measurement region visually. Red light departing the OCT probe is clearly visible in Fig. 8. Figure 9 presents a movie clip made from an OCT monitoring of the

FIG. 9. Balloon inflation in the air from a negative pressure to a positive pressure of 2 atm. Frame rate is 20 fps. Markers represent 1 mm in optical thickness (enhanced online). [URL: <http://dx.doi.org/10.1063/1.3465556.1>]

FIG. 10. Motorized pullback inside the balloon at an inflation pressure of 4 atm. Frame rate is 20 fps. Markers represent 1 mm in optical thickness (enhanced online). [URL: <http://dx.doi.org/10.1063/1.3465556.2>]

balloon inflation at a single location from a negative pressure to a positive pressure of 2 atm. Some artifacts, such as the one at nine o'clock position, appear in the images. They are due to deflection and reflection of light at the air-balloon interfaces. To perform cross-sectional imaging at different locations along the axis of the balloon, a pullback of the OCT probe can be performed. Figure 10 presents a movie clip obtained from a motorized pullback at a speed of 2.5 mm/s at an inflation pressure of 4 atm, giving a 125 μm step between two successive cross-sectional images. The pullback was performed from the tube distal to the balloon to the tube proximal to the balloon. A pullback makes it possible to carry out a volumetric assessment of the balloon at different pressures and check the homogeneity of the balloon deformation along the longitudinal axis. Combination of the obtained tomographic images can provide a three-dimensional view of the balloon which is presented as a movie clip in Fig. 11. This figure depicts the balloon, inflated at a pressure of 4 atm. The three-dimensional (3D) view is composed of 200 cross-sectional frames.

2. Balloon deployment inside an artery phantom

This subsection presents imaging of the balloon inside a custom-built optical phantom.¹⁸ The phantom is composed of three layers with different optical scattering and optical attenuation properties. These layers simulate the layers of the coronary artery, namely, intima, media, and adventitia. The

FIG. 11. (Color online) 3D rendering of the balloon, obtained from a pullback at a pressure of 4 atm (enhanced online). [URL: <http://dx.doi.org/10.1063/1.3465556.3>]

FIG. 12. Real-time imaging of balloon deployment inside an artery phantom. Frame rate is 20 fps. Markers represent 1 mm in optical thickness. (a) OCT image of the folded balloon inside the phantom at a negative pressure. (b) OCT image of the inflating balloon inside the phantom at a pressure of 0 atm. (c) OCT image of the inflated balloon inside the phantom at a pressure of 4 atm.

phantom also has relevant mechanical properties in the low deformation regime. Figure 12 illustrates OCT images of the balloon inside the phantom at different pressures, i.e., a negative pressure, 0 and 4 atm. The nominal diameter of the balloon is higher than the inner diameter of the phantom. Therefore, prior to insertion, the balloon is manually folded. The balloon folding in the form of flaps in Fig. 12(a) and the balloon folding during inflation in Fig. 12(b) are visible. In Figs. 12(a) and 12(b), some segments of the phantom image

FIG. 13. Balloon inflation inside the phantom from a negative pressure to a pressure of 3 atm. Frame rate is 20 fps. Markers represent 1 mm in optical thickness (enhanced online). [URL: <http://dx.doi.org/10.1063/1.3465556.4>]

are distorted due to the deflection of light in some folded parts of the balloon. When the balloon is dilated at a pressure of 4 atm [Fig. 12(c)], the phantom can be viewed without such distortions. Figure 13 presents a movie clip of the balloon inflation inside the phantom from a negative pressure to a pressure of 3 atm.

B. Characterization of the balloon diameter, wall thickness, and mechanical properties

In this section, we present an application of our setup in a quantitative assessment of the balloon quality. Figure 14 presents cross-sectional images of the balloon at pressures (P) of 2, 3, and 4 atm. Each OCT image [Figs. 14(a)–14(c)] is coupled with a deformation profile [Figs. 14(d)–14(f)], which provides a detailed analysis of balloon diameter and thickness at different angles. In order to obtain these deformation profiles, the first step is to perform image segmentation to obtain the coordinates of the points, which delimit the two surfaces of the balloon. The algorithm is based on the fact that these surfaces in a typical A-scan correspond to two adjacent single-lobe distributions. The segmentation algorithm detects the peaks of these two distributions to localize the inner and outer balloon surfaces. Cubic B-splines¹⁹ are then used to connect the detected positions for both surfaces, which result in two smooth curves representing the inner and outer surfaces. Raw OCT images provide measurements with a length scale in optical thickness, i.e., the product of geometrical distance and refractive index. The next step is thus to carry out adjustments to achieve scales that represent real distance values. The markers in the OCT images in Figs. 14(a)–14(c) represent 1 mm in optical thickness. The imaging is performed in water. Results in Figs. 14(d)–14(f) are given in true geometric dimension after correcting for refraction and converting optical length to geometrical length with the various refractive indices. The final step is to obtain a color map to differentiate visually between segments with varying thickness. The underdeployed segments are closer to the center of the balloon and generally have a larger wall thickness. These segments are depicted in blue. The overdeployed segments, on the other hand, are farther from the

FIG. 14. (Color online) (a)–(c) OCT images of the balloon at different pressures and (d)–(f) the balloon deformation profiles with the thickness color map in microns. For (a)–(c), frame rate is 20 fps and markers represent 1 mm in optical thickness. For (d)–(f), scales are in millimeters and represent geometric thickness.

center and generally possess a smaller wall thickness. These segments are depicted in red. The thickness values represented next to the color map in Figs. 14(d)–14(f) are calculated in micrometers.

An overall assessment of the balloon diameter and thickness at different pressures is presented in Fig. 15. As shown in Fig. 15(a), the average value of diameter over different angles increases from 4.2 mm at a pressure of 0 atm to 5.3 mm at a pressure of 4 atm. Figure 15(a) also depicts the ratio of standard deviation of the diameter (σ_D) to its average ($\bar{D}$), which can be helpful in characterizing deployment symmetry. This ratio increases as pressure increases from 1 to 4 atm. This is consistent with the fact that the balloon is deployed more asymmetrically at larger pressures [Fig. 14(f)]. The ratio decreases as the pressure increases from 0 to 1 atm. The reason is that at a pressure of 0 atm, the balloon is not fully deployed to a round shape. Therefore, at a pressure of 0 atm, the diameter variation at different angles is larger than the diameter variation at a pressure of 1 atm.

As demonstrated in Fig. 15(b), the average thickness of the wall decreases from 91.5 to 71.7 μm as pressure increases from 0 to 4 atm. The ratio of the standard deviation

FIG. 15. (Color online) OCT characterization of (a) balloon diameter and (b) wall thickness.

of the wall thickness (σ_T) to its average ($\bar{T}$) determines the extent to which uniform wall thickness is preserved at different pressures [Fig. 15(b)]. The higher the slope of this ratio with respect to pressure, the faster the balloon approaches its burst pressure. Figure 15(b) reveals that the wall thickness becomes less uniform when pressure is increased from 0 to 3 atm, a trend that stops when the pressure is further increased from 3 to 4 atm.

In order to characterize the mechanical properties of the balloon, we estimate its compliance and modulus of elasticity. We define the compliance of the balloon as the variation of its volume with respect to its internal pressure. We assume that the cross-sectional area does not vary significantly in the axial direction. By measuring variation of cross-sectional area with respect to pressure, a normalized-over-the-length value will be obtained for compliance. Figure 16(a) demonstrates the cross-sectional area A at different pressures. The area is obtained by summation of surface area of all triangles, formed by the center and each two adjacent nodes on the inner surface of the balloon. Since the balloon is not under pressure at 0 atm, the corresponding point is eliminated in estimation of the compliance. A normalized compliance of 2.35 mm²/atm is calculated using linear regression.

One of the goals of the balloon forming process is to increase the elastic modulus of the material, which is achieved by heating and stretching of the material resulting in a better molecular orientation. The conducted experiments in this paper can be used to obtain an estimation of the elas-

FIG. 16. (Color online) OCT characterization of (a) balloon compliance and (b) elastic modulus.

tic modulus for the produced balloon. The hoop stress is calculated using the equation for thin-walled vessels

$$\sigma = \frac{P \cdot r}{T}, \quad (4)$$

where σ is the hoop stress, P is the internal pressure, r is the radius, and T is the wall thickness. Equation (4) is valid for $2r/T > 20$. In our experiments, we have $2r/T > 40$. In order to estimate the hoop stress, we replace in Eq. (4)

$$\begin{aligned} r &= \bar{D}/2, \\ T &= \bar{T}. \end{aligned} \quad (5)$$

The strain at each pressure is defined as

$$\epsilon = \frac{l - l_0}{l_0}, \quad (6)$$

where l_0 is the cross-sectional perimeter of the balloon at the pressure of 0 atm and l is the cross-sectional perimeter at the corresponding pressure. Figure 16(b) depicts calculations of strain versus hoop stress for the balloon cross-section. An elastic modulus of 0.05 GPa is obtained from linear regression. The elastic modulus for the polyurethane tube that was

used to fabricate the balloon is approximately 0.02 GPa. This indicates that after the balloon forming process the elastic modulus has been increased by 150%.

IV. CONCLUSION

We have presented an innovative integration of IVOCT imaging with a balloon deployment setup. The resulting setup allows accurate real-time monitoring of balloon inflation under predetermined conditions and is a valuable tool to validate and optimize balloon designs. In this paper, based on segmentation of the obtained images, we assessed the balloon diameter and wall thickness at different pressures. Such assessment is important in controlling the balloon quality.

Although the focus of this paper was on characterization of the balloon quality, the proposed setup has many more applications. We have demonstrated that it can be used to extract mechanical properties. It can also be used in the development of future generation of minimally invasive devices for percutaneous coronary interventions. One can monitor balloon inflation within an artery phantom or an excised artery to assess the efficiency of innovative balloon angioplasty or stent deployment procedures.

ACKNOWLEDGMENTS

The authors would like to thank Christian de Grandpré for invaluable technical support and Charles-Etienne Bisailon for producing the phantom. We also acknowledge the financial support of the Genomics and Health Initiative of the National Research Council and the financial support of the Natural Sciences and Engineering Research Council of Canada.

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