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Azarnoush, Hamed; Bourezak, Rafik; Vergnole, Sébastien; Lamouche, Guy; Boulet, Benoît

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OPTICAL COHERENCE TOMOGRAPHY CHARACTERIZATION OF BALLOON DIAMETER AND WALL THICKNESS

Hamed Azarnoush[1,2], **Rafik Bourezak, Sébastien Vergnole, Guy Lamouche**
[1]Industrial Materials Institute, National Research Council of Canada
Boucherville, QC, Canada
Contact: Guy.Lamouche@imi.cnrc-nrc.gc.ca

Benoit Boulet
[2]Centre for intelligent Machines, McGill University
Montreal, QC, Canada

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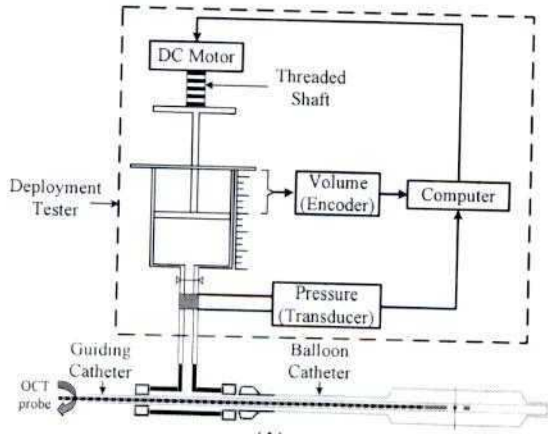
ABSTRACT
An intravascular optical coherence tomography probe is integrated in a computerized angioplasty balloon deployment system. The resulting setup can be useful in many applications. In this paper, based on the acquired intraluminal images, we achieve a detailed assessment of the diameter and wall thickness of the inflated balloon at different pressures. Such analysis is helpful in testing the balloon quality, in assessing deformation model, or in validating new balloon designs.

INTRODUCTION
Optical coherence tomography (OCT) is an imaging modality that has become popular in clinical applications [1], including cardiovascular research [2]. The availability of high-speed swept-source OCT systems and of catheterized probes has recently led to a more active development of intravascular OCT applications [2]. OCT is an ultrahigh-resolution imaging technique and further applications in cardiovascular research have yet to be explored. In this paper, we present a structure to integrate an OCT catheter into a computerized balloon deployment system to monitor the controlled balloon inflation process. This provides an excellent setup to experimentally analyze deformation of balloons through combining cross-sectional images with precisely measured deployment pressures. We present an analysis of balloon diameter and thickness at different pressures. Traditionally, a laser scan micrometer is used externally to assess the outer diameter of balloons. Such assessment is limited to a side view and a particular angle. Using the proposed setup, characterization of diameter and thickness can be performed with high flexibility and precision. Imaging of different cross-sections is also achievable by a motorized pullback of the probe. A thorough analysis of different balloon properties may lead to improvements in balloon production. For example, in a balloon with a uniform wall thickness, a better molecular orientation is achieved, resulting in a higher rated burst pressure. Therefore, assessment of the wall thickness may help modify balloon forming parameters, e.g. stretch and forming pressure.

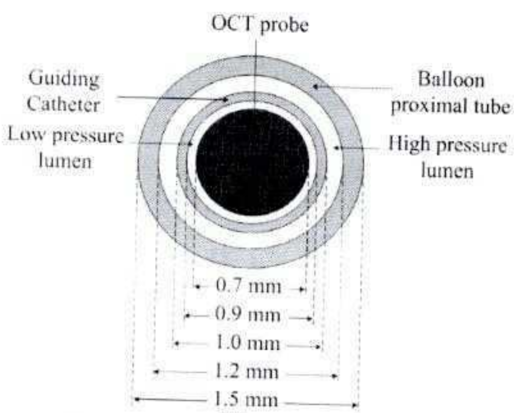
In the following, we first provide information about the integration of OCT in the balloon deployment setup. Imaging results are provided for the deployment of the balloon in the air, followed by an analysis of the balloon diameter and thickness.

INTEGRATION OF OCT PROBE IN THE BALLOON DEPLOYMENT SYSTEM
An in-house swept-source OCT system is used with a measured resolution of 12 μm. The intravascular probe has a diameter of 0.7 mm. For the experiments to be presented, we produced a semi-compliant balloon with a nominal diameter of 4 mm. Figure 1 demonstrates our experimental setup. The deployment testing system is based on a hydraulic pressure tester (Interface Catheter Solutions, model PT-3070). Using this system we can target a desired deployment volume and pressure. A DC motor drives the plunger of a syringe pump. Water is used as the medium for pressurization. The position of the plunger, which is measured by an encoder, corresponds to the delivered volume. The pressure is made available by a transducer. A computer controls the motor according to the real-time pressure and volume measurements. Both the deployment testing system and OCT probe are connected to the balloon through a T-connector. The lumen of the balloon tubing is divided into two isolated concentric lumens by a guiding catheter (Figure 1B). The probe is introduced through a low-

pressure liquid in the inner lumen. The outer lumen is allocated for high pressure liquid, used for balloon deployment.



(A)



(B)

FIGURE 1- INTEGRATION OF OCT INTO THE BALLOON DEPLOYMENT SETUP (A) AND THE CROSS-SECTION OF THE BALLOON PROXIMAL SIDE (B)

RESULTS

In this section, we present some results, obtained from the balloon deployment in the air. Figure 2 presents cross-sectional images of the balloon at pressures of 2 and 4 atm. Each OCT image (Figure 2A and 2B) is coupled with a deformation profile (Figure 2C and 2D), which provides a detailed analysis of balloon diameter and thickness at different angles. In order to obtain the deformation profiles, the first step is to perform image segmentation to obtain the coordinates of the points, which delimit the two layers of the balloon. The next step is to carry out adjustments to achieve scales that represent real distance values. The ticks in the OCT images in Figures 2A and 2B represent 1 mm in optical path. The imaging is performed in water. Results in Figures 2C and 2D 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 under-deployed and over-deployed segments of the balloon. The under-deployed segments are closer to the center of the balloon and generally have a larger wall-thickness. These segments are depicted in blue. The over-deployed segments, on the other hand, are farther from the center and generally possess a smaller wall thickness. These segments are depicted in red. Non-uniform balloon deployment is evident in Figure 2D; it is possible to observe the significant reduction in wall thickness in the red areas of the balloon. An overall assessment of the balloon diameter and thickness at different pressures is presented in Figure 3. The average diameter increases from 4.2 mm at a pressure of 0 atm to 5.3 mm at a pressure of 4 atm (Figure 3A). The standard deviation of the diameter increases as pressure increases from 1 atm to 4 atm. This is consistent with the fact that the balloon has a more asymmetric shape at larger pressures (Figure 2D). The standard deviation of the diameter decreases as pressure increases from 0 atm to 1 atm. The reason is that at a pressure of 0 atm, the balloon is not fully deployed. Therefore, at this pressure, the diameter variation at different angles is larger than the diameter variation at a pressure of 1 atm. The average thickness of the wall decreases from 91.5 μm to 71.7 μm as pressure increases from 0 atm to 4 atm (Figure 3B). The standard deviation of the wall thickness does not change significantly with pressure. Although the wall thickness variation at different angles is larger at higher pressures (Figure 2D), the overall thickness is smaller, which can describe why the standard deviation of thickness remains almost constant.

CONCLUSIONS

In this paper, we characterized a balloon's diameter and wall thickness, by integrating OCT and a balloon deployment system. This integrated setup, however, can benefit many other applications as well. Future work may address characterization of balloon deployment inside mock or excised arteries. OCT is an excellent technique for such applications. In this paper, we presented the micrometer precision, achievable by OCT. In fact, it provides a resolution that is almost 10 times better than the competing technology, intravascular ultrasound. More research should be conducted to extend the application of OCT in development of percutaneous coronary intervention devices.

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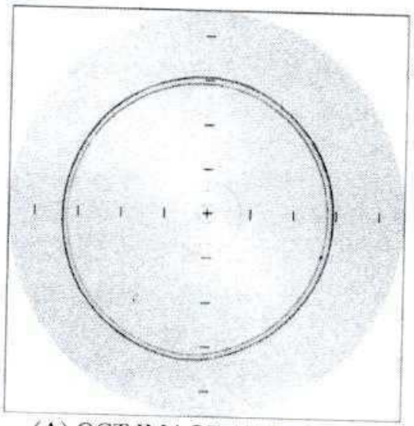
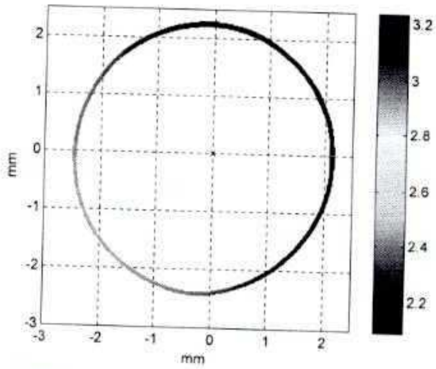
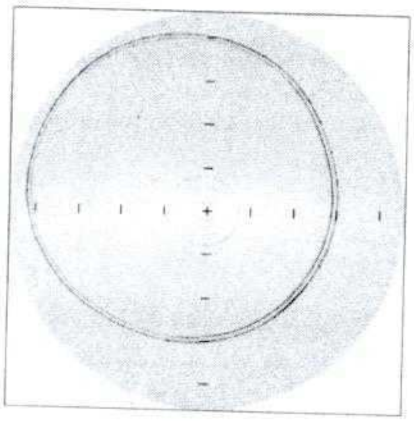


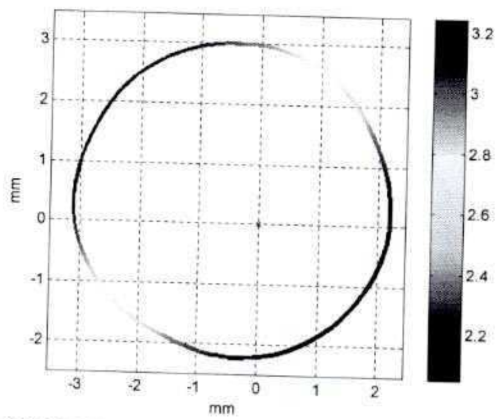
(A) OCT IMAGE AT P=2 ATM



(C) DEFORMATION PROFILE FOR P=2 ATM

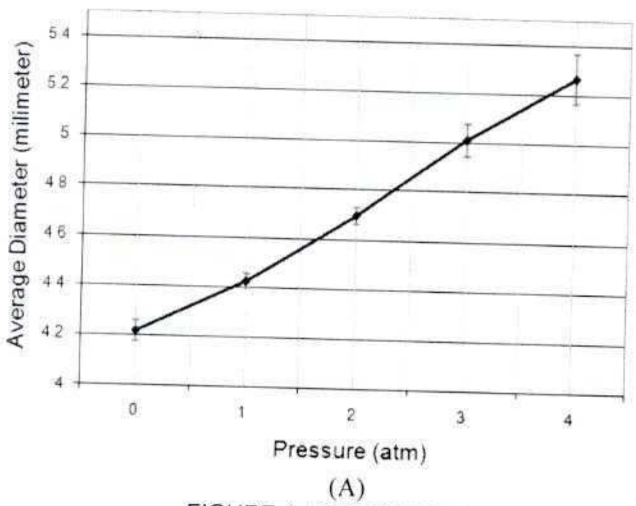


(B) OCT IMAGE AT P=4 ATM

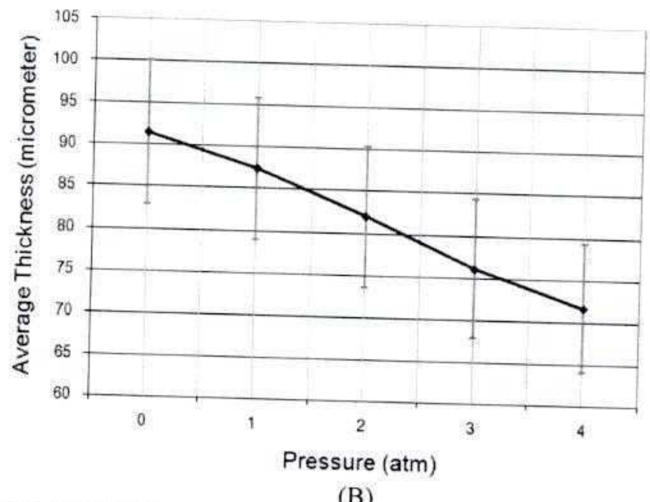


(D) DEFORMATION PROFILE FOR P=4 ATM

FIGURE 2- OCT IMAGES OF THE BALLOON (A,B) AND BALLOON DEFORMATION PROFILES (C,D)



(A)



(B)

FIGURE 3- OCT CHARACTERIZATION OF BALLOON DIAMETER (A) AND THICKNESS (B)