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Toward better treatment of clogged arteries

Lamouche, Guy; Vergnole, Sébastien; Azarnoush, Hamed

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Monitoring angioplasty balloon inflation with optical coherence tomography

Guy Lamouche, Sébastien Vergnole, and Hamed Azarnoush

Monitoring balloon inflation with optical coherence tomography allows real-time detailed characterization of balloon deformation with pressure. It is an innovative tool to validate balloon design.

Figure 1. Optical coherence tomography probe monitoring balloon inflation.

Intravascular optical coherence tomography (IVOCT) is a catheter-based technique that provides detailed cross-sectional imaging of the artery wall with a resolution of the order of ten micrometers. This minimally invasive technology has evolved tremendously over the last few years with the development of swept-source optical coherence tomography (SS-OCT), also referred to as Optical Fourier Domain Imaging¹. The SS-OCT technology allows fast pullbacks (rotation and translation) over tens of millimeters during a few seconds. IVOCT not only provides a detailed imaging of the atherosclerotic structures over a large segment of an artery, but also allows stunning 3D reconstructions. The clinical relevance of IVOCT has been demonstrated in many studies for the diagnosis and treatment monitoring of atherosclerosis². The technology is mature enough to be distributed commercially³.

Our research group investigates further applications of the IVOCT technology. One field of interest is the development of percutaneous coronary intervention (PCI) devices. For example, IVOCT can be used to monitor the inflation of an angioplasty balloon in a deployment tester⁴. 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. These measurements are only obtained from a side view and from a particular orientation. IVOCT allows a full characterization of

Figure 1 illustrates our custom-built catheter-based OCT probe inserted in an inflated semi-compliant balloon. The IVOCT probe is composed of single mode fiber, a gradient index lens, and a small prism to redirect light in a direction perpendicular to the probe axis. The whole assembly rotates and translates in a liquid within a polymer sheath. The semi-compliant balloon is connected at both ends to a tube. The OCT probe is introduced in the balloon tube through a T-connector (not shown) that also connects the balloon tube to the high pressure line of the deployment tester. A typical IVOCT cross-section obtained at a given pressure is presented in Fig. 2a). Since IVOCT measures distances in optical length (refractive index times geometrical length), a conversion to geometrical length is provided in Fig. 2b) where the thickness is color encoded to ease viewing. This type of measurement is an invaluable tool to validate the design of an angioplasty balloon. Since the mechanical properties of the balloon material are modified by the balloon forming process, the data can be processed to extract mechanical properties of the final product. Monitoring the

Figure 2. OCT cross section of the balloon (a) and balloon deformation profile (b) at an inflation pressure of 3 atm. In (a) markers are spaced by 1 mm in optical thickness. In (b) gridlines are spaced by 1 mm in geometric thickness.

Figure 3. OCT cross sections of balloon inside an artery phantom before inflation (a) and during inflation (b). Markers are spaced by 1 mm in optical thickness.

erage diameter of the balloon as a function of the pressure can provide important parameters like the compliance and the elastic modulus. The complete data can also be compared to a 3D simulation of the balloon deformation to infer mechanical properties at all locations in the balloon.

Monitoring of balloon inflation under more realistic condition can be performed by inserting the balloon inside an excised artery or an artery phantom using the same setup. Figure 3 shows different steps during the balloon deployment in an artery phantom. The phantom is a silicon based structure composed of three layers that provide the same optical signatures as the three artery layers: the intima, the media, and the adventitia⁵. Figure 3a) shows the IVOCT measurement right after balloon insertion. Flaps can be observed since the semi-compliant balloon was manually folded to ease insertion. The flaps distort the IVOCT image due to refraction of light

video that is available online⁶. Data can again be extracted from the IVOCT cross-sections to fully assess the balloon performance but under more realistic conditions.

The IVOCT technology represents an innovative powerful development tool for angioplasty balloon manufacturers. The applicability of the technology is even larger: a similar setup can be used to ease the development of numerous devices for percutaneous coronary intervention procedures. Examples include the assessment of the deployment of new stent designs or of the efficiency of new atherectomy devices.

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Author Information

Guy Lamouche, Sébastien Vergnole, Hamed Azarnoush
Industrial Materials Institute, National Research Council
Boucherville, QC, Canada

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