Title: **Ex vivo coronary stent implantation evaluated with digital image correlation**

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Abstract:

Intracoronary stenting (PCI) has become standard revascularization technique to reopen blocked arteries. Although significant progress in stenting technology and implantation techniques has been made a number of problems remain. Specifically, stent sizing and inflation pressures are still a matter of scientific debates. Despite a large number of biomechanical computational simulations experimental data are rare, likely due to technical difficulties to measure dilatation pressures and coronary dimensions in the same settings. Our study shows that valuable data can be obtained by employing digital image correlation for 3D strain measurement during stent inflation ex-vivo that can provide further insight into the stent–artery wall interactions.

Keywords:

Artery wall–stent interaction; coronary stent; digital image correlation; experimental implantation; strain.

Abstract/Introduction

Intracoronary stenting (PCI) has become standard revascularization technique to reopen blocked arteries. Although significant progress in stenting technology and implantation techniques has been made a number of problems remain [1-6]. Specifically, stent sizing and inflation pressures are still a matter of scientific debates. Despite a large number of biomechanical computational simulations [3,7-10] experimental data are rare [3,4,6,11], likely due to technical difficulties to measure dilatation pressures and coronary dimensions in the same settings. Our study shows that valuable data can be obtained by employing digital image correlation for 3D strain measurement during stent inflation ex-vivo that can provide further insight into the stent–artery wall interactions.

Methods

Stent and PCI equipment

The balloon-expandable CoCr coronary stent Kaname^{TM} (Terumo Corporation, Tokyo, Japan) with nominal diameter 3.5 mm, and length 15 mm (at pressure 0.9 MPa; and diameter 3.73 mm at 1.6 MPa) was used in this study. The stent was premounted on PCI dilatation catheter RX-2 (Terumo Corporation).

Sample

The sample of the main branch of the left coronary artery was obtained from autopsy. The male donor was 40 years old and atherosclerotic lesions were presented inside the sample. The experiment was performed 70 hours post mortem.

Experiment

The sample was mounted into the experimental setup (Fig. 1) with both ends cannulated to allow catheterization. Displacement measurement was based on 3D digital image correlation (DIC) conducted with commercial system Dantec Q-450 (Dantec Dynamics, Ulm, Germany).

DIC is non-contact optical method based on the stereoscopic principle which is becoming more popular especially within the strain measurement of geometrically nonuniform objects. The algorithm identifies material points on the object surface and the correlation between consecutive images allows material point tracking. Detailed description can be found in the literature [12-15, 18]. A random pattern is required for successful automatic evaluation. It was created by careful spraying the surface of the sample with acrylic lacquer (two different colors were used, white color was used to create the first layer and subsequently black dots were created with another spray; Fig. 1).

The artery was recorded with two digital cameras (NanoSens Mk III, Dantec Dynamics; 1MPx CCD chip; lens Sigma EX, 105 mm, 1:2.8 D Macro) during the balloon expansion (sampling rate 25 Hz). In fully expanded state, the object ROI approx. 18*3 mm*mm was projected onto 600*300 px*px (in each camera). RX2 manometer was recorded with another camera to obtain time course of change of the balloon distending pressure (pressure transducer connected with PC was not available at the time of experiment). The stent was deployed within manual pressurization up to 1.6 MPa which spanned approximately 42 seconds.

Results

DIC revealed significant overloading of the artery by the expanded stent. The results are depicted in Figure 2. Principal strains' distribution (Green-Lagrange strain is considered within this study) shows artery response within maximally expanded stent. Principal vectors are predominantly aligned with the circumferential and longitudinal direction which is supposed to be the consequence of the cylindrical stent expansion.

Circumferential deformation attains 0.5 mm/mm at the peak value which is far beyond physiological situation. The circumferential strain concentration appears non-symmetrically with respect to the length of the sample which is supposed to be the result of irregular reference geometry (an asymmetrical partially occluded lumen of the artery). Fig. 2B shows areas of compressive longitudinal strain. This is in accordance with the simplified idea of dilated tubular structure inside a vessel (see Fig. 4).

Six points (P1-6) were chosen to illustrate specific strain values (Fig. 2). We also computed stresses at these points by direct substitution into the constitutive equation adopted from [16]. However, unrealistically high values were obtained and their presentation is omitted. It is probably due to unsuitable constitutive equation resulting from different loading conditions and atherosclerotic specimen in our experiment.

Figure 3 illustrates displacements observed on lines and points on the surface. Interestingly balloon pressure–displacement relationships (panel C) indicate that non-uniform and abrupt initial stent expansion (at approx. 0.18÷0.3 MPa), reported in [3], might be detectable also on the object surface.

Discussion

This is a preliminary report concerning a stent implantation in ex-vivo settings employing a human coronary artery harvested from autopsy. The results suggest that 3D DIC is promising tool suitable for the evaluation of ex-vivo stent implantation potentially useful for validation of computational models and clinical considerations.

Presented results suggest that overexpansion of a stent during deployment may overstretch the target site potentially resulting in implantation injury associated with restenosis and/or intimal tears associated with dissections.

To obtain exact intraluminal dimensions during stent deployment optical coherence tomography or intra-vascular ultrasound (IVUS) would be required, currently not available in our laboratory. Nevertheless we plan to combine IVUS with 3D DIC in future experiments.

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Figure legends

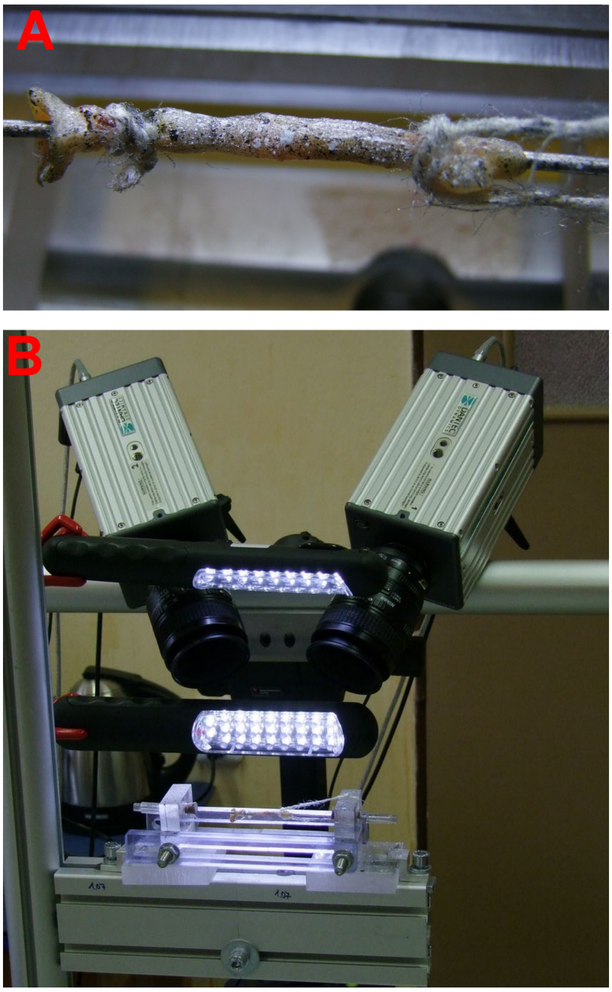

Figure 1 A – the sample with random pattern on the surface. B – experimental setup.

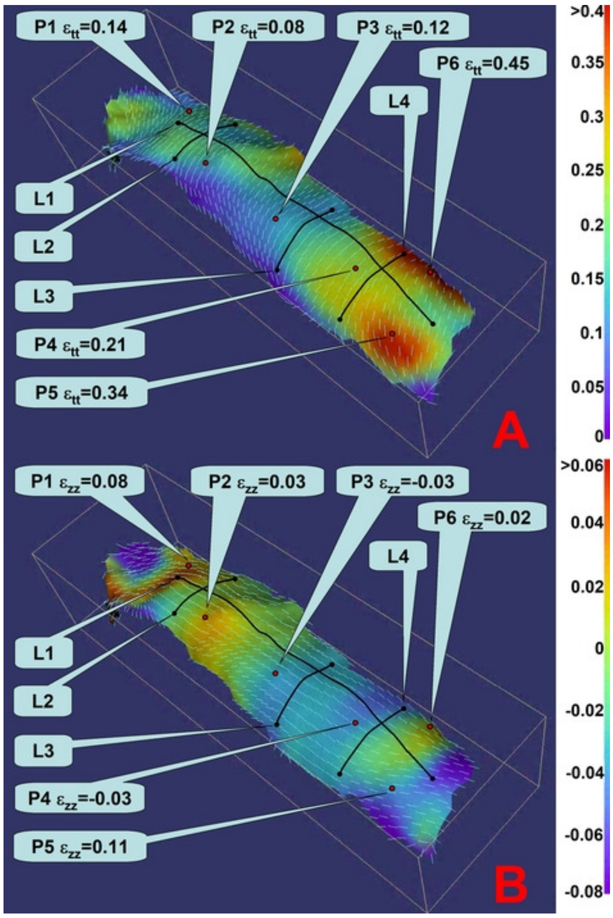

Figure 2 Evaluated part of the artery surface after total stent expansion. A – color map of the first principal strain; B – second principal strain. The position of evaluated points (P1-6) and lines (L1-4) is depicted. Strains evaluated at P1-6 are denoted with indices "tt" and "zz" since they are considered to be parallel with circumferential and longitudinal strains in a pressurized vessel. It should be noted, however, that in case of "zz" tangential plane of the surface (where the strains are evaluated) may be deflected from longitudinal direction. Scale of the bars – Green-Lagrange strain [mm/mm]. The object is bounded by assistant lines oriented according to global Cartesian coordinate system (not scaled).

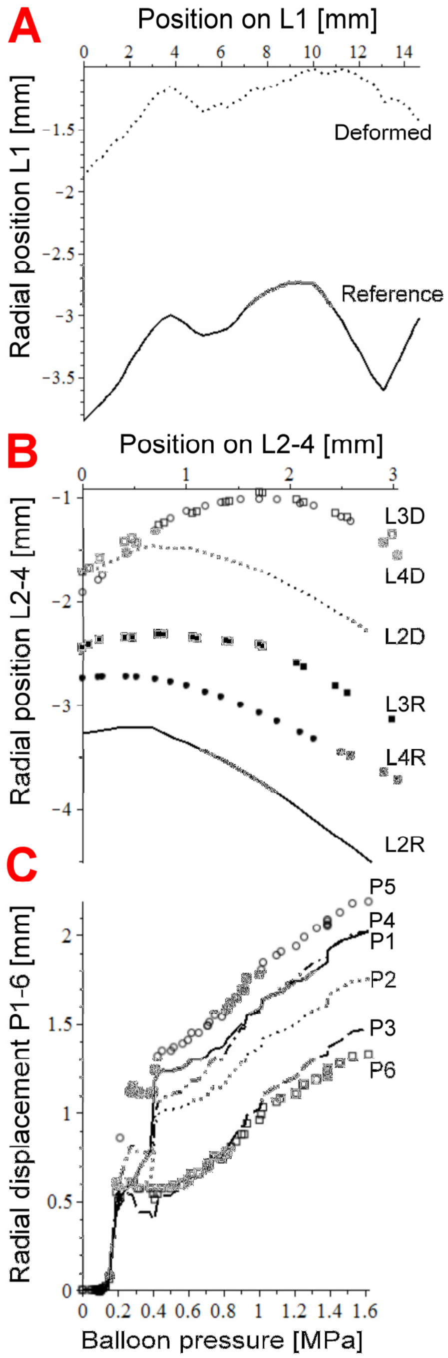

Figure 3 Displacements and coordinates of entities on the object surface. A – reference and deformed coordinates of L1. B – coordinates of L2-4 (R = reference = non-expanded stent; D = deformed = totally expanded). C – displacements of P1-6 with respect to the pressure in the expansion balloon.

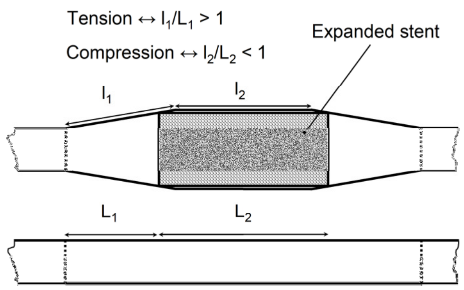

Figure 4 Simplified model kinematics explaining compression of the object surface during stent expansion.