In vitro coronary stent implantation: vessel wall-stent interaction

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Abstract: *This study was designed to assess the biomechanical interactions between the coronary artery wall and intracoronary stents following implantation in vitro. Balloon expandable stent was deployed in vitro into the sample of the left anterior descending coronary artery of a 67 years old female with multiple atherosclerotic lesions. The stent was selected to match approximately the internal diameter of the healthy segment of the target artery. The stent implantation procedure was recorded with CCD camera. Digital images were subsequently processed with the edge detector based on Canny algorithm. Obtained coordinates of the surface contours were used in the deformation analysis. For the sake of simplicity the deformation was considered as the ratio between the distances of deformed and reference contour points at the same longitudinal position. We found that the stent expansion induced significant over-stretching of the external coronary artery. We have concluded that optical tracking of the external surface of the artery during the stent deployment provides sufficiently accurate deformation analysis potentially useful in the assessment of biomechanical interactions during intracoronary stenting.*

Keywords: *edge detection, coronary stent, over-stretching, PCI, stent-artery interaction.*

1. Introduction

Intracoronary stenting has become standard revascularization interventional technique worldwide. Alone in the USA and in Europe more than 2 Millions stenting interventions are performed annually [1].

There are two basic stent designs; so-called *balloon-expandable*, which expand at the target location due to the pressurized balloon inducing plastic deformation in stent's material, and so-called *self-expandable* (manufactured from shape memory alloys like Nitinol). The latter are metalurgically treated in order to ensure final shape before using [2-4]. Due to Nitinol superelasticity they can be deformed into small dimensions necessary within a catheterization. At the target place they expand theirselves without the need for external loading. Such an approach also avoids possible slippage of the stent at the balloon. Recent results of the experimental in vitro comparison between self-expanded and balloon-expanded stents suggest, how-

ever, that the advantage of the self-expanding is lowered with the decreased radial expansion force and lower degree of precision in case of self-expanding stents in contrast to balloon-expanding stents [5].

High restenosis rate in bare-metal stents has resulted in the development of the so-called *drug-eluting stents*. Here stent's struts are coated with a thin layer of polymer containing anti-proliferative drugs in order to prevent in-stent-restenosis (in 2006, 76% of stents implanted within PCI were drug-eluting compared with 24% that were bare-metal stents [1]).

Significant effort has been made in experimental simulations to optimize stent implantation procedure [5-12]. However a number of issues remains unresolved. Besides general questions such as the extent of implantation-induced injury, minimizing the compliance mismatch between a stent and an artery, optimal stent diameter, and a strut design, also curved shapes of arteries, bifurcations and specific geometries and material properties of lesions have to be of concern. The complexity of experimental simulations give rise to increasing amount of computational analyses which can better be designed with respect to large number of variables involved in the problem [6,13-17]. Recently Schmidt et al. [18] and Lanzer et al. [19] showed that the mechanical properties of stents and stent deliverability are critical for the outcome.

This study aims at the possibility of the evaluation of the biomechanical interactions between the coronary artery wall and stents during the in vitro stent deployment by the tracking external surface of the coronary artery. The main question we addressed was whether the tracking of the surface of the coronary artery during stent expansion is technically feasible; and if so, whether the information derived can be used to calculate parameters of biomechanical interactions such as axial and circumferential stresses and strains. Positive results could be useful to develop and to standardize techniques allowing broader application in biomechanics of coronary interventions.

2. Methods

2.1 Stent and PCI equipment

The balloon-expandable CoCr coronary stent Kaname^{TM} (Terumo Corporation, Tokyo, Japan) with nominal diameter 3.5mm, and length 15mm was obtained from Gesundheitszentrum Bitterfeld/Wolfen gGmbH (Bitterfeld/Wolfen, Germany). It was mounted on PCI dilatation catheter RX-2 (Terumo Corporation, Tokyo, Japan). The documentation provided by the stent producer gave these further information: stent nominal pressure NP=9atm (912kPa); rated burst pressure RBP=14atm (1419kPa); and dilated stent diameters after the balloon pressurization: 14atm≈3.67mm; 15atm (1520kPa)≈3.70mm; and 16atm (1621kPa)≈3.73mm.

2.2 Sample of artery

The sample of the main branch of the left coronary artery was obtained from the Department of Forensic Medicine of the Third Faculty of Medicine of the Charles University and the Faculty Hospital Na Kralovskych Vinohradech in Prague (Prague, Czech Republic). The female donor was 67 years old and the calcified lesions were presented inside the sample. The experiment was performed approximately 60 hours post mortem. The usage of the human tissue within this study was approved by the Ethic committee of the University Hospital Na Kralovskych Vinohradech in Prague.

2.3 Experimental setup

The experimental stent deployment was performed in the Laboratory of Biomechanics of the Faculty of Mechanical Engineering of the Czech Technical University in Prague (Prague, Czech Republic). The setup, usually employed in the inflation-extension experiments with large arteries, was scaled-down with respect to smaller dimensions of the coronary artery. The sample was cannulated and fixed at both ends. The setup with mounted specimen was placed in the field of view of the digital camera NanoSense MkIII (Dantec Dynamics GmbH, Ulm, Germany) with the lens Sigma 105mm 1:2.8D (Sigma Corporation, Japan); see Fig. 1.

The delivery catheter with mounted stent was inserted into the artery. Since the radiological tracking of the stent's position was not available within the deployment, it was estimated by the length of the pushed guide wire. Subsequently the balloon was inflated by standard pressurization accessory (manual hydraulic pump) delivered with the stent and catheter (PCI catheter RX-2).

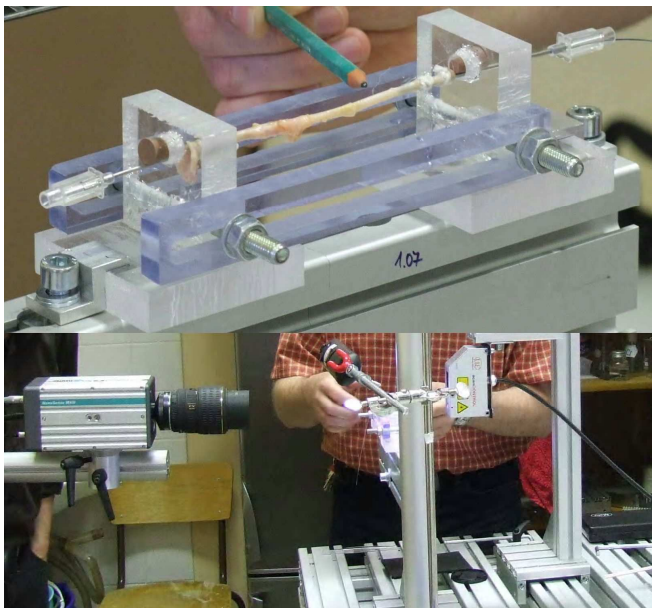

Figure 1. Top – mounted specimen; bottom – digital camera focused on the sample.

2.4 Stent deployment

The artery was recorded with the digital camera within the balloon expansion (at the sample rate 40Hz). The manometer of the dilatational setup was recorded with another camera in order to obtain time course of change of the distending pressure. Consecutive manual pressurization from 0 up to 16atm (1621kPa) spanned approximately 45 seconds.

2.5 Data processing

The photographs of the artery were evaluated with Matlab (MathWork Inc., USA) utility Imconture 7 which employs Canny algorithm for the edge detection in a digital image [20,21]. Known scale of the photographs of the sample and the detection of the artery contours gave coordinates of contour points. Preliminary computations revealed insufficient brightness of the recorded images. Thus selected images (number=45) were segmented manually in Adobe Photoshop CS5 (Adobe Systems Inc, San Jose, USA) with one of the authors. In order to

eliminate human subject effect, other three authors were involved in the interface segmentation. They additionally segmented the reference (before deployment) and the final (fully-inflated stent) image with three different PC (each person carried out three segmentations). One of them also employed different software, Corel Photo-Paint 12 (Corel Corp., Ottawa, Canda).

3. Results

The post-processing resulted in ten evaluations of coordinates of the sample contour points which were intended for the determination of the stretched external surface of the artery. For the sake of simplicity the deformation was considered to be given with (1). Here *D* and *d* denote the external diameter of the artery before and after the stent deployment, respectively. *D* and *d* were assumed to be equal to the distance between the upper and lower contour point with the same longitudinal coordinates.

$$\varepsilon = \frac{d}{D} - 1 \qquad (1)$$

The results of the deformation analysis are depicted in Fig. 3. Besides average coordinates of the contours and resulting distribution of the deformation, also the variability of the results is presented.

4. Discussion

This study presents the simple image processing-based method intended for the evaluation of the state of deformation in the stented artery. We found (Fig. 3A, B) that the interaction between the stent and the lesion can result in curved final expanded stent geometry. In such a case significant deformations can be observed at the external surface of the artery (Fig. 3C shows that the deformation reached up to 0.2). Significant standard deviations (Fig. 3D) presented under longitudinal coordinate higher than approx. 30mm shows that the light conditions were not optimal (insufficient brightness). Used method, nevertheless, determined strains at the points with longitudinal coordinate from 0 to 25mm with sufficient accuracy; here the standard deviation of ε is two orders of magnitude smaller than the deformation itself.

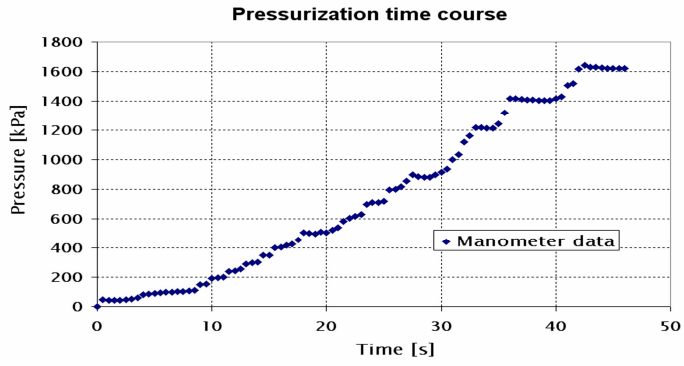

Figure 2. The time course of the balloon pressurization determined from the video record of the manometer.

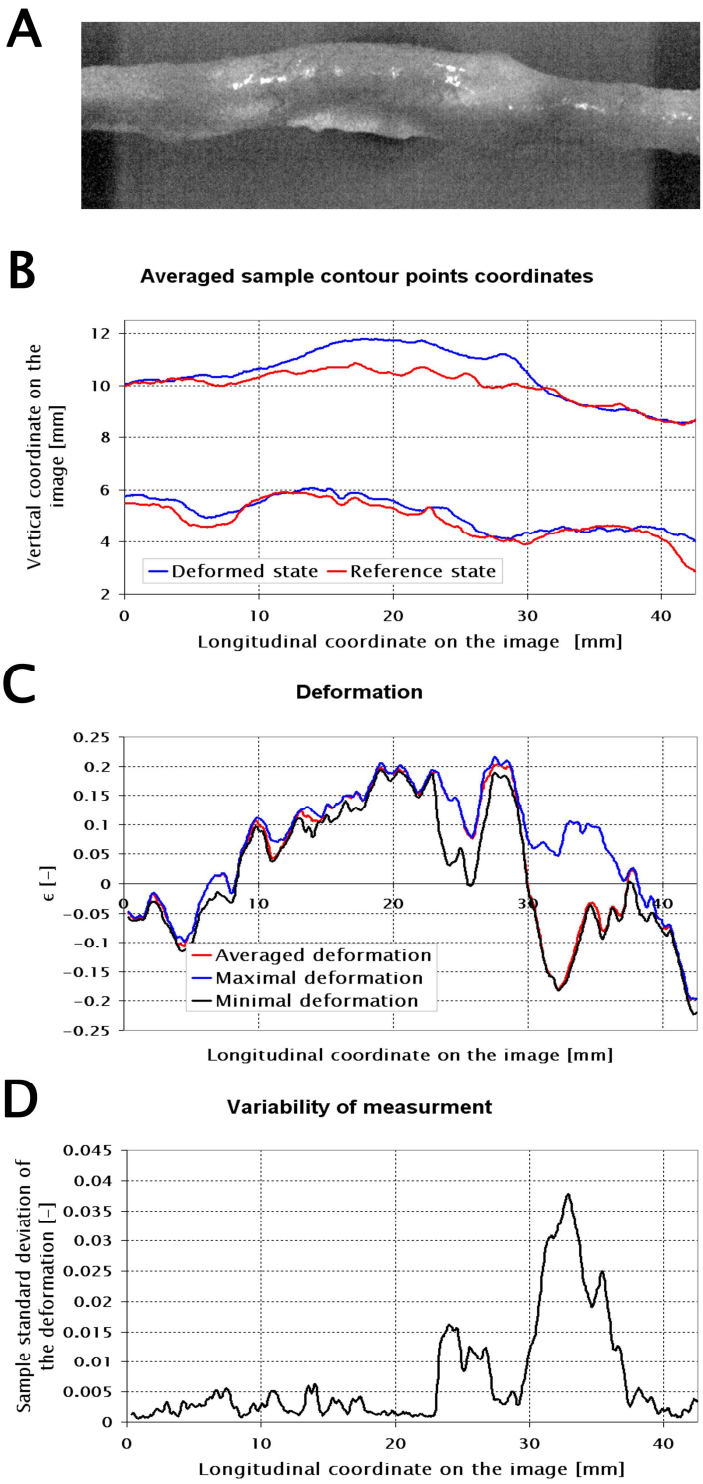

Figure 3. A – the example of the true recorded image (with fully expanded stent); B – coordinates of the contour points obtained by averaging ten individual segmentations and subsequent edge detections; C – the distribution of the deformation according to (1) along the longitudinal coordinate; D – the distribution of standard deviation of the deformation.

The main reservation, however, should be aimed to the method. One must be careful to avoid the misinterpretation of the observations. The edge detection reduces 3D object to contours only. Thus employed method can not provide full 3D field of the deformation. However, it strongly suggests that averaged deformations within the stent expansion attained magnitudes which significantly change the stress state of the artery. In accordance with it, it can be said that diseased arteries can manifest the stent-induced over-stretching observable on the external surface.

5. Conclusion

This is pilot study showing the feasibility of the presented experimental set-up to monitor surface morphology of coronary arteries during stent implantations. We expect that measurements of biomechanical forces during stenting shall also become feasible and will provide further information useful in stent designing.

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