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Monitoring the Wall Mechanics During Stent Deployment in a Vessel

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Abstract

Clinical trials have reported different restenosis rates for various stent designs[1]. It is speculated that stent-induced strain concentrations on the arterial wall lead to tissue injury, which initiates restenosis[2-7]. This hypothesis needs further investigations including better quantifications of non-uniform strain distribution on the artery following stent implantation. A non-contact surface strain measurement method for the stented artery is presented in this work. ARAMIS stereo optical surface strain measurement system uses two optical high speed cameras to capture the motion of each reference point, and resolve three dimensional strains over the deforming surface[8,9]. As a mesh stent is deployed into a latex vessel with a random contrasting pattern sprayed or drawn on its outer surface, the surface strain is recorded at every instant of the deformation. The calculated strain distributions can then be used to understand the local lesion response, validate the computational models, and formulate hypotheses for further *in vivo* study.

Keywords: Biomedical Engineering, Issue 63, Stent, vessel, interaction, strain distribution, stereo optical surface strain measurement system, bioengineering

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Protocol

1. Preparation of the Latex Vessel

1. Fix both ends of the latex vessel to barbed hose connections, which are fastened on a sturdy workbench.
2. Measure the area of interest on latex vessel to determine the field of view. The area of interest for a stent test should be centered between the barbed hose connectors and include approximately one inch on each side of the stent in order to observe the strains outside the stented area.
3. Record the distance from the outside edge of one barbed hose connector to the center location between the connectors, which is also the approximate center of the latex vessel. Translate the distance onto the catheter by measuring from the center of the stent up the catheter. Then mark the catheter with a marker.
4. Remove the latex vessel from the barbed hose connectors.
5. Prepare the latex vessel by spraying the area of interest with a stochastic pattern of white and black spray paint or marking the area of interest with random dots using permanent marker. For smaller samples and finer stochastic pattern is required.

2. *In vitro* Test System and Calibration of ARAMIS System

1. Select the calibration panel that is slightly larger than the area of interest measured in step 1.
2. Place the calibration panel between the barbed hose connectors at the area of interest and ensure that the area of interest is well lit.
3. Adjust the distance between two cameras, the distance from the sample, and the camera height based on the calibration panel selected. Each calibration panel is different; therefore the ARAMIS user manual will have to be consulted to determine these distances.
4. Open a new project in ARAMIS by selecting "File", then "New Project". Next click on the "Sensor" tab and select "Calibration", then "Full Calibration".
5. The ARAMIS software will now walk the user through the steps to calibrate the cameras.
6. With the lens aperture fully open, focus the camera on the calibration panel by loosening the set screw on the camera and rotating the lens. Once focused, retighten the set screw and close the aperture.
7. Take the first image of the calibration process. Displace or rotate the calibration panel according to the demonstration on the computer, until the image is focused on the computer screen. Take the second image. Repeat this process for the remainder of the calibration images.
8. Once all of the calibration images are taken, the ARAMIS imaging analysis software will calculate the calibration settings. The calibration process should be repeated if the calibration deviation is greater than 0.04. Any adjustments made to the focus of the camera or the distance between cameras will render the calibration process void.
9. Remove the calibration panel and place the painted latex vessel back onto the barbed hose connectors.

3. Pretest to Avoid Excessive Background Noise

1. Determine the number of frames per second that is desired for the test. Increased frames per second will produce more uniform strain results.
2. Adjust the shutter speed to less than 1 frame per second and so that no red is displayed on the image.
3. Take 5 images.
4. Add start points on the image series and compute the test.

5. While holding "ctrl", click on the center of sample to observe the background noise. If the pretest noise is above 75 microstrain the calibration process must be redone.

4. Stent Deployment

1. Select the amount of images desired to take during the test. 200 images will suffice for the stent expansion.
2. Gradually insert the catheter into the latex vessel, and using the marker indicator on the catheter to guide the stent insertion until it reaches the central location.
3. Begin taking images with ARAMIS.
4. For the balloon-expandable stent, gradually increase the balloon pressure to expand stent until the balloon is fully expanded; then gradually decrease the pressure of balloon to zero and the balloon is deflated and withdrawn along with the catheter.
5. For the self -expanding stent, gradually remove the sheath until the stent is fully expanded; then gradually retract the catheter.

5. Images Analysis

1. *Strain history of a specific point on the vessel*
   1. Create a stage point by holding the "ctrl" key and clicking on the area of interest.
   2. Select the type of strain that is desired, i.e. strain in the X, Y, XY, major strain, minor strain, or Mises strain.
   3. The plot in the lower right corner will display the strain at the point selected over the duration of the test.
2. *Spatial strain along a specific path of the vessel*
   1. Create a multistage point line by clicking on the "sections" tab, then "create section". Select a line on the image parallel to the X axis at Y equals zero. This will create a number of stage points in a line.
   2. After the multistage line is created the plot in the lower corner will display a series of lines on one plot. Each line represents the strain at one instance in time along the length of the section.
3. *Creating a best fit cylinder to analyze expansion rate and radius of the vessel*
   1. In the upper tool bar select "primitives", then "best fit cylinder".
   2. Select a small section of the image using the "select through surface" tool on the right tool bar.
   3. The ARAMIS software will generate a three dimensional best fit cylinder.
   4. The images can then be cycled through to observe how the diameter of the latex vessel is varying.
4. *Evaluating the distance between two points*
   1. Under the "analysis" tab click on "point to point distance".
   2. Select a length on the image that is desired for analysis by selecting two points.
   3. The images can then be cycled through to observe the change in distance between the two points over time.

6. Representative Results

The stent struts expand the vessel wall outwards, strains will generally be higher around stent location. **Figure 1** is an example of strain mapping during the recoil process of balloon-expandable stent, as well as major strain history at one specific point. The black dots in **Figure 1** are reference points, which were used by the high-speed cameras to capture and track the displacements of these reference points on the conduit. Based on the recorded movement of reference points, the software will then be used to calculate the strains of the conduit or any other targeted object. Major strain, also referred to as the maximum principal strain, is

calculated as follows:

$$\varepsilon_1 = \frac{\varepsilon_x + \varepsilon_y}{2} + \sqrt{\left(\frac{\varepsilon_x + \varepsilon_y}{2}\right)^2 - \left(\varepsilon_x \varepsilon_y - \varepsilon_{xy}{}^2\right)}$$

It is clear that the implanted stent led to non-uniform strain distribution on the vessel surface. This could be explained by the recoil loading from ends-constrained latex conduit and the mesh structure of stent. This strain field corresponds to the initial stage of stent recoil, as identified by the red cross marker in the bottom image of **Figure 1**. The major strain-history curve of a specific point 10 demonstrated distinguishable stages of stent implantation. The balloon expansion occurs from approximately 10 to 12 seconds and stent recoil following the deflation of the balloon occurs between 12 and 14 seconds.
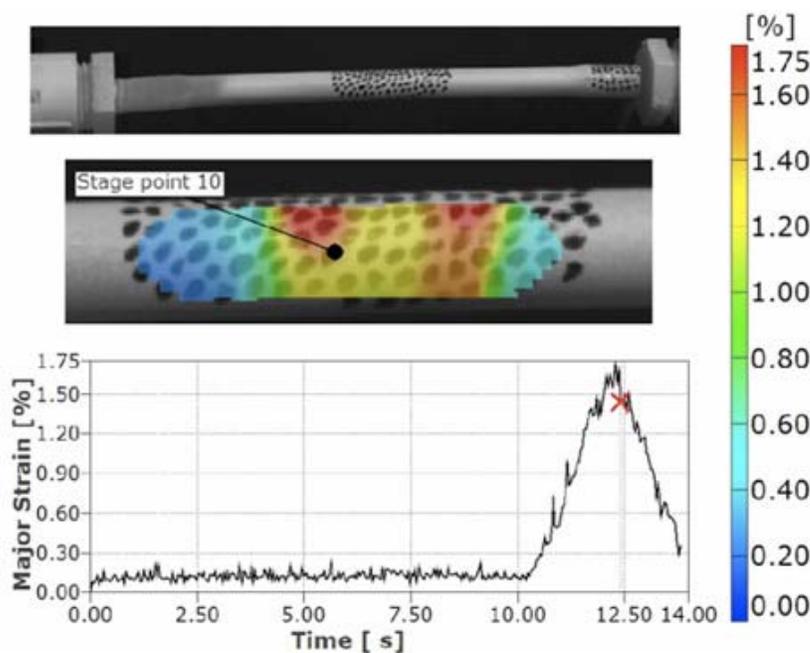
Figure 1. Experimental setup (top); non-uniform strain distribution on the stented conduit surface (middle); the major strain history at the point 10 (bottom).

Discussion

The stereo optical surface strain measurement system is used to measure the local strains over the deforming surface for both the in- and out-of-plane motions without contacting the specimen. This system uses two high-speed optical cameras to take pictures of a random contrasting pattern putting on the surface to construct accurate measurements of motions of each point, with a high accuracy of resolving surface strains.

It should be noted that the required contrasting pattern need adheres to the surface sufficiently enough to provide accurate measurements. In addition, the targeted sample area need be well lit, without glare, for the cameras to distinguish the movements of the contrasting pattern. Otherwise, the captured glare images will create void data regions. Two light sources, at opposite ends of the latex vessel, angled at approximately at 45 degree angles relative to the tubing is recommended. A flat spray paint rather than a gloss paint for the stochastic pattern will also help to reduce the amount of glare.

Here we present a protocol of surface strain measurements using a mocked vessel, which could be used to test the nonuniform strain mapping on the heterogeneous native vessel. *Ex vivo* native vessels study will be

incubated in physiological solution to maintain the cellular activity. The common black inkjet stylus could be used to stain a real vasculature, which has been used on the femoral artery of rabbit by Squire *et al*[10]. This optical surface strain measurement system could then capture the movement of reference points through transparent window. Surface strain measurements using *ex vivo* native vessels with histological assessments of the vessels will provide more insight on the injury mechanism of stented artery. The three dimensional surface strains demonstrated in this work may also be extended to obtain the strain map anywhere in the heterogeneous test sample including its inner surface as well as across the thickness of the vessel through further numerical analysis.

The presented stereo optical surface strain measurement system is one of the very unique methods that can capture and measure the local strains observed over all the deforming surface without actually contact the specimen and with high accuracy for both the in- and out-of-plane motions of the surface. It was compared with other strain measurement systems such as intravascular ultrasound (IVUS) imaging as well as inflation test[11,12]. The traditional inflation test is useful for obtaining the averaged strain along the test conduit[11]; however it cannot provide the three dimensional local strain captured by the optical surface strain measurement system in this work. The IVUS elastography[12] could obtain the two dimensional strain map throughout the cross section of the vessel, and hold great potential for clinical application. The optical system demonstrated in this work has its unique advantage by providing three dimensional surface strains and displacements on irregular surfaces, particularly those resulting from irregular shapes or inhomogeneous bodies.

Disclosures

No conflicts of interest declared.

Acknowledgments

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