

In-vitro Imaging of Femoral Artery Nitinol Stents for Deformation Analysis

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ABSTRACT

Purpose: Femoral artery stents are prone to fracture, and studying their deformations could lead to a better understanding of the cause of breakage. The present study sought to develop a method of imaging and analyzing stent deformation in vitro with use of a calibrated test device.

Materials and Methods: High-resolution (approximately 200 μm) volumetric data were obtained with a flat-panel detector–based C-arm computed tomography system. A nitinol stent placed in a testing device was imaged with various loads that caused bending, axial tension, and torsion. Semiautomatic software was developed to calculate the bending, extension, and torsion from the stent images by measuring the changes in the radius of curvature, eccentricity, and angular distortions.

Results: For the axial tension case, there was generally good agreement between the physical measurements and the image-based measurements. The bending measurements had better agreement at bend angles lower than 30°. For stent torsion, the hysteresis between the loading and unloading curves were larger for the image-based results compared with physical measurements.

Conclusions: An imaging and analysis framework has been set up for the analysis of stent deformations that shows fairly good agreement between physical and image-based measurements.

ABBREVIATION

SFA = superficial femoral artery

The superficial femoral artery (SFA) is prone to the development of atherosclerosis causing vessel stenosis and occlusions. This is typically treated with percutaneous transluminal angioplasty followed by stent deployment (1). However, it has been found that, in a fairly high number of cases (19% to 71% as reported), stenosis and occlusion

recur within 1 year of treatment. It is believed that recurrent stenosis may be correlated with the rate of fracture of SFA stents, which is reported to be as high as 35% (2–4). It has become a high priority among stent manufacturers and the United States Food and Drug Administration to analyze the in vivo mechanical response of SFA stents in an effort to understand the underlying cause of damage. The exact mechanism for fracture is not well understood. It is hypothesized that knee and hip flexions cause the untethered SFA to undergo dramatic deformations. These large deformations in turn cause the stents to bend, torque, stretch, and compress in the axial and radial directions. Repetition of such deformations could lead to fatigue fracture (4,5).

To better understand the mechanical environment experienced by stents in the femoral arteries, noninvasive imaging techniques, such as computed tomography (CT) and magnetic resonance (MR) imaging can be used. Although CT imaging produces high-contrast images of the stents, the closed-bore setup does not allow flexibility in positioning of the leg, which is essential for observing deformations of the stent in vivo. Also, the CT imaging resolution of approximately 0.5–1 mm is insufficient for visualization of the stent wires that are typically on the

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order of 100 μm in diameter. Higher-resolution imaging is needed to identify and locate broken stent wires and to allow better image segmentation. Use of MR imaging is not feasible when a stent is present as a result of the large signal voids that occur around metallic objects in the image. However MR imaging can be used to study the changes in shape that occur in vessels without stents when the leg is in different positions (6).

An ideal system for imaging the stents is the C-arm CT system. A well calibrated rotation of the C-arm about the axis parallel to the patient table allows for CT-like imaging. Such a system has the advantages of CT imaging, primarily the generation of three-dimensional (3D) image data with excellent contrast resolution for high-density objects such as stent wires and atherosclerotic plaque. The large area detectors used in current C-arm CT systems have high spatial resolution (ie, a few hundred micrometers). In terms of patient accessibility, the main advantage of such a system is its open gantry structure that allows relative ease in positioning the subject to produce different types of deformation on the stent.

With the use of images obtained from a C-arm CT system in a calibrated stent phantom, a method has been developed for the analysis of stent deformations. This could lead to better understanding of the causes of SFA stent fracture.

MATERIALS AND METHODS

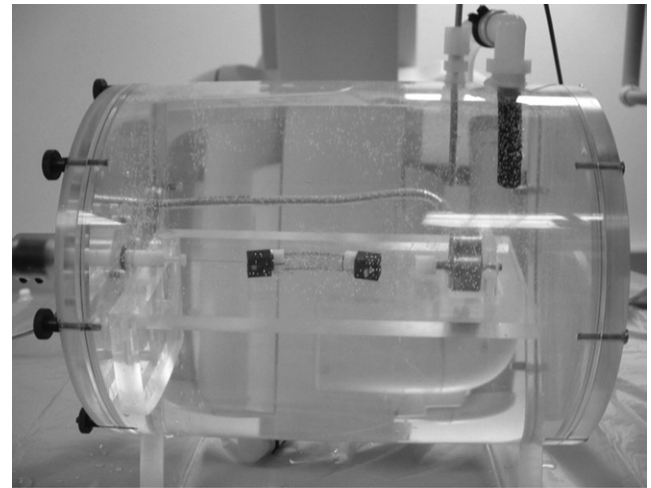
The imaging and analysis method involved imaging a stent placed in specially constructed testing devices that deform the stent under known loading conditions. The stent deformations were calculated from the acquired C-arm CT images and compared with the physical measurements from the testing device.

Mechanical Testing Devices

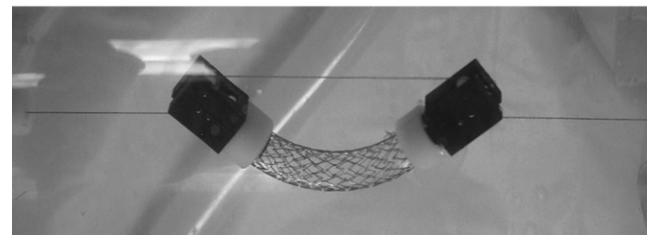
Mechanical testing devices were developed to measure force-deformation response of a stent under bending, axial, and torsional loading. Because the mechanical properties of nitinol are sensitive to temperature, the stent and testing device are immersed in water that is maintained at a body temperature of 37°C.

Bending Device

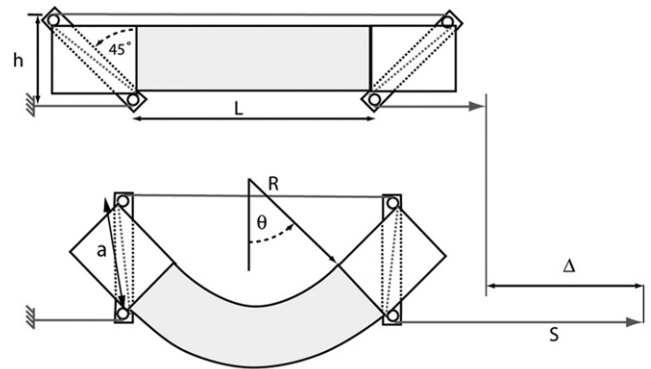
The design of the device to test the response of the stent in pure bending is shown in **Figure 1**. The stent is fitted onto Delrin endcaps, each of which has a pair of bearings at 45° to the axis of the stent. A high-strength silk string with one end fixed is passed over the bearing surfaces. The other end of the string is attached to a micrometer head. Pulling the string produces only a constant moment along the stent length equal to the string tension S , times the moment arm (which is a function of the endcap diameter, h , and the rotation of the endcaps, θ). This fixture produces no axial force in the stent. Assuming no



a.



b.



c.

Figure 1. (a) Apparatus for measuring the bending moment. (b) Magnified view of the stent shows the endcaps. (c) Schematic illustration of the stent bending device.

stretching of the string, the relationship between the extension, Δ , and θ is $2h(1 - \cos\theta + \sin\theta)$ (Equation [1]). The bending moment, M , is $Sh(\cos\theta + \sin\theta)$ (Equation [2]). The curvature, c , of the stent, is equal to the reciprocal of the radius of curvature R , as a function of θ , is given by the following:

$$c = \frac{1}{R} = \frac{2\theta}{L} \quad (\text{Equation 3})$$

where L is the length of the stent between the two endcaps.

For the theoretical calculations of the bending force, the following parameters obtained from previous measurements were used: a , 7.54 mm; L , 34.0 mm.

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