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...
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, $\theta$). This fixture produces no axial force in the stent. Assuming no stretching of the string, the relationship between the extension, $\Delta$, and $\theta$ 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 $\theta$, is given by the following:

$$c = \frac{1}{R} = \frac{2\theta}{L}$$

(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.
Axial Tension Device
A device similar to the bending device is used to determine the response of the stent in axial tension. One endcap is fixed and the other endcap is connected with a string to a micrometer head and aligned to pull the stent in pure tension. The change in the stent length, $\Delta L$, as a function of the string tension $S$, is measured to give the axial load-deformation response of the stent.

Torsion Device
The torsion device is shown in Figure 2a, with the design details shown in Figure 2b. The top endcap is held fixed to a rod extending up through the center of the stent. On the lower endcap, a string is attached to two anchors and through pulleys to a micrometer head. A load cell is placed in line between the pulley and micrometer head. Turning the micrometer pulls the string and twists the stent. In this design, the stent is free to extend or contract under torsion. The torque, $T$, applied to the stent is the string force, $S$, times the endcap diameter, $d$. The string force is related to the measured force, $F$, through the loading angle, $\beta$, as $2S \cos \beta$ (Equation [4]), where $\beta$ is determined by the location of the pulleys relative to the stent center, $t$, and to the micrometer head, $l$, as follows:

$$\beta = \tan^{-1}\left(\frac{l}{t}\right)$$

(Equation 5)

The rotation, $\theta$, is related to the difference between the current length of the string, $L$, and the length at the beginning of the test, $L_0$, as follows:

$$\theta = \frac{L - L_0}{d}$$

(Equation 6)

The current length, $L$, is given by the following:

$$L = 2\left(\sqrt{t^2 + d^2} + \sqrt{t^2 + (l_0 + \Delta L)^2}\right)$$

(Equation 7)

where $l_0$ is the distance between the pulley and micrometer head at the beginning of the test. For the torsion calculations, the following values were used: $X$, 80.72 mm; $L_0$, 85.51 mm; $d$, 7.92 mm; and $a$, 28.21 mm.

Adjustment for String Compliance
In all three devices, the compliance of the string must be taken into account when determining the stent deformation from the measured displacements. To calculate the contribution of the string extension in the test data, the compliance of the string for loading and unloading was fit to a power function of the string tension, $S$, as follows:

$$\frac{d\varepsilon_s}{dS} = aS^n$$

(Equation 8)

where $\varepsilon_s$ is the axial strain in the string and $a$ and $n$ are constants. For each test, the extension of the string was calculated by using power-law fits with the string extension scaled by the relative length of the string in each device.

Imaging
The C-arm CT system (Axiom Artis dTA; Siemens, Forchheim, Germany) uses a $30 \times 40 \text{ cm}^2$ amorphous silicon-
based flat-panel detector with 154-μm pixels. A standard algorithm that uses 3D convolution back-projection for cone-beam geometry (7), combined with “short scan” weighting for acquisition of only π and fan-angle rotation (8), is used for 3D volume reconstruction. To achieve improved 3D image quality, a sequence of algorithms is applied to correct for scatter, beam hardening, truncation, and ring artifact (9). Reconstruction in the region of interest around the stent with smaller voxels is then obtained.

### Image Processing

The complete set of projection images obtained during each scan was used to provide a 256 × 256 × 256 voxel reconstructed volume of the entire field of view. A smaller region surrounding the stent was then reconstructed with 512 × 512 × 512 voxels. The reconstruction voxel size was dependent on the dimension of the region to be included that was selected manually. A “vessel-sharp” kernel, which is a system standard and is a modified Shepp–Logan filter, was used during the reconstruction for highlighting the stents in the reconstructed images.

Semiautomatic software was developed in-house to analyze the imaged volumes. The basic framework for this software uses the National Library of Medicine Insight Segmentation and Registration Toolkit. A series of filtering and segmentation steps are used to calculate the centerline and fit ellipses in a plane perpendicular to the centerline along the length of the stent. The axial and radial dimensions of the stent are calculated under different loading conditions and the radius of curvature along the stent centerline is calculated to determine the amount of bending experienced by the stent. Finally, the 3D stent is “unwrapped” onto a two-dimensional surface. The calculated quantities allow estimation of the tension, bending, and torque experienced by the stent. To start the analysis, the user is required to provide a bounding box for the stent, a starting guess of the direction vector for the centerline, and a rough estimate of the inner diameter of the stent. The radius of the disk is obtained from the initial estimated value input by the user. (iv) Finally, the search stops if any sharp changes are found in the forward derivative of the centerline trace.

### Threshold filtering

First, a coarse threshold is set and all voxels greater than this value are selected for processing. This value is based on an estimate of the CT numbers (in HU) for the stent wires determined a priori by sampling some of the stent data.

### Discrete Gaussian filtering

Second, by using a discrete Gaussian kernel, image noise is filtered and the data are smoothed.

### Region segmentation

Third, the filtered image is then passed through a binary threshold filter. It is used to segment voxels that represent the actual stent. This coarse mask is subsequently refined as described in the subsequent steps.

### Mask dilation

Next, after binary thresholding, a fast dilation operation is applied. This allows filling of the contours of the stent. As this step is followed by calculation of a signed distance map, a true closing operation (ie, dilation followed by erosion) is not required. This step is therefore less computationally expensive.

### Signed distance map

Next, the shortest Euclidean distance between each image voxel and the cylindrical shell of the stent (generated with use of the mask in the previous step) is calculated. The voxels that are within the cylinder are assigned a negative value and those outside have positive values. The centerline is generated by selecting the voxels with the minimum signed distance value.

### Recursive Gaussian filtering

Further refinement of the centerline is then achieved by applying a Gaussian filter to the volume of interest that results in a tubelike structure that fits around the stent. This blurred volume is used for additional refinement of the stent centerline.

### Refinement of stent centerline

Next, the centerline search starts at one end of the volume of interest and proceeds along a direction for which the initial vector is specified. At each step, the nearest 26-voxel “neighborhood” is searched for the lowest value in the signed distance map. When a preliminary centerline trace has been established, it is refined by penalizing the points that are too close to the stent wall. Noise and artifacts typically resulting from the gold markers at the ends of stents cause inaccuracies in the identification of the correct start and end points of the stent, requiring changes in the criteria for selection of a voxel for the centerline. All centerline points are further refined by using the following four criteria: (i) if the selected centerline point has a nonnegative value in the signed distance map, then the search stops. (ii) The angle between successive centerline vectors should not exceed 45°. (iii) The point must have a value with a difference from the mean value on a circular disk through the point perpendicular to the centerline that falls within a certain threshold. The radius of the disk is obtained from the initial estimated value input by the user. (iv) Finally, the search stops if any sharp changes are found in the forward derivative of the centerline trace.

Slices normal to the centerline are then calculated and best-fit ellipses to the stent profile are found in these slices with use of a Matlab implementation of a direct least-squares ellipse-fitting function. The new center of each ellipse is calculated and the centerline points are adjusted to

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**Figure 3.** Flowchart of the steps involved in calculating the stent centerline and unwrapping of the stent.
Figure 4. Visualization of the steps for calculating the stent centerline: (a) 3D stent image, (b) Gaussian filtering, (c) binary thresholding, (d) stent dilation, (e) signed distance map, (f) 3D stent overlaid on signed distance map, (g) recursive Gaussian filtering, (h) calculated centerline overlaid on 3D stent image, and (i) unwrapped stent image.
coincide with these centers. The final centerline points are resampled into equidistant steps and a polynomial fit is applied to permit calculation of the derivatives shown in Equation (9).

The centerline is used to calculate the actual length and length changes of the stent for different loads. Calculation of expansion and contraction provides the strain on the stent. The radius of curvature and hence the curvature is recorded at each point along the length. The curvature value is computed at each vertex according to the following formula:

\[
\kappa = \frac{\| \hat{r} \times \hat{\tau} \|}{\| \hat{r} \|} \quad \text{(Equation 9)}
\]

where \( r \) is the radius vector of each centerline point.

**Stent unwrapping.** Another functionality of the software is the ability to “unwrap” the 3D stent images. This is equivalent to cutting open the stent along its length parallel to its centerline and is achieved by using the slices calculated that are normal to the centerline used in torsion calculations. To isolate the torsion, first the curvature vectors of points along the centerline are calculated. The curvature gives a measure of the amount by which each centerline location must be moved to straighten the stent along its length without altering the effect of torsion. When the stent has been straightened, the angular location of every pixel in the slice is calculated with respect to the center of the slice. The pixel value is then placed on a line with its position index, \( p \), calculated as follows:

\[
p = \text{int} \left( \frac{\theta + \pi}{2\pi} \right) \delta \quad \text{(Equation 10)}
\]

where \( \theta \) is the angular location of the point from \( -\pi \) to \( \pi \) and \( \delta \) is the width of the unwrapped image in number of pixels. The values of each pixel along a given angle are summed and normalized by the number of pixels contributing to the value in the final unwrapped image.

**In-vitro Imaging**

In the bending device, the micrometer was incremented from 0 to 12.7 mm (or 0 to 500 mil) in steps of 2.54 mm (100 mil). The tension in the string was recorded at each state just before the stent was imaged. The testing device was placed on the patient table and the deformed stent was imaged with the C-arm CT system. The data were reconstructed using an isotropic voxel size of 1,503 μm. For all in-vitro tests, a nitinol stent was used that was 44 mm long and 4 mm in diameter.

During imaging, a small piece of wire was attached to a strut at one end of the stent for use as a reference marker to overcome the issues arising from the circular symmetry of the stent. This was particularly useful when analyzing the images using the “unwrapping” technique described in the previous section.

During development, repeatability of the testing devices was established by repeat cycling, typically three to five cycles per test. The measured loads were within 1–2 g of peak loads of 30–100 g.

Accuracy of the measurements was established by placing a scale into the test setup and using high-resolution photographs to compare stent deformations with the testing device output.

**RESULTS**

The images of the stents under various loading conditions were obtained and the images were processed according to the algorithm described. The resultant data at each step of the processing for one case is shown in Figure 4.

**Figure 5.** Compliance of wet silk string during loading and unloading.

### Constants for Power-law Fit for Silk Thread Compliance in Equation (8)

<table>
<thead>
<tr>
<th>Constant</th>
<th>Loading</th>
<th>Unloading</th>
</tr>
</thead>
<tbody>
<tr>
<td>( a )</td>
<td>0.00161</td>
<td>0.00281</td>
</tr>
<tr>
<td>( n )</td>
<td>-0.316</td>
<td>-0.599</td>
</tr>
</tbody>
</table>

In Figure 5, the fit to the displacement of the silk string during loading and unloading. The fit parameters are listed in the Table.

The results comparing the calculated and measured values for the response of the stent to bending, stretching, and torsional forces are shown in Figure 6. For bending, the results from the physical and image-based measurements had good agreement at smaller bend angles. The differences at larger bend angles may be attributed to the accumulation of errors in calculation of the bend angle, which is calculated from the sum of angles between successive centerline points. For the tension case, the results from the two measurements were generally in good agreement except for a few outliers. The torsion curves agreed well during load increase. However, for decreasing loads, the image-based data were not well correlated with the physical measurements.
The measurement errors for bend angle in Figure 6a were obtained by using the relation between the bend angle, stent length, and curvature in Equation (3). In case of tension (Fig 6b), the errors were directly related to the error in measurement of the stent length. For the torsion measurement (Fig 6c), the error bars represent the SD in the angular displacement between six pairs of gold markers at the two opposite ends of the stents on the unwrapped images.

DISCUSSION

The in-vitro study provides an effective method for testing the accuracy of the image acquisition, reconstruction, segmentation, and analysis framework. However, the stent used for imaging in this case was a single nitinol stent from a specific manufacturer. These tests need to be performed for stents from different manufacturers to provide a broad range of data for greater clinical relevance. The in-vitro data need to be extended to study at what point stent fracture happens and whether this fracturing load changes with a history of loading and unloading. Changes in results with multiple overlapping stents also need to be studied. Such data would provide greater insight into the causes of stent failure and help in developing improved stents. A more complete work that analyzes all these parameters for every make of stent is outside the scope of this study.

There are various reports in the literature that describe experimental and theoretical methods for measuring forces on stents. These include some in-vitro (10–17) and ex vivo studies (18) as well as computational modeling methods (19). Among the imaging studies, high accuracy in measuring the diameter (error < 0.1 mm) and length (error < 0.3 mm) was achieved with micro-CT (13). In the present study, the average error in measuring the length of the stent was 0.7 mm ± 0.5.

The present in-vitro study was used to create an imaging and analysis technique to study the deformations of femoral artery stents. Increasing the range of load in-vitro and including different stent designs from multiple manufacturers will provide a more complete reference dataset. Even though the current study lacks some degree of completeness, it lays the basic foundation and provides some important initial results. In an accompanying publication (20), we report on the use of the technique developed to measure in vivo stent deformations.

REFERENCES


