Load-Deflection Behavior of Bare and Covered Stents
Jeffrey W. Simons, Alex Dalal, and Donald A. Shockey
SRI International
333 Ravenswood Ave
Menlo Park CA 94025
650-859-4495  650-859-2587
jeffrey.simons@sri.com, alexdalal@gmail.com, donald.shockey@sri.com

Abstract—The effect of artificial arteries on the in-vitro load-deflection behavior of endovascular stents was investigated. Previously reported test devices to characterize the mechanical response of Nitinol stents under simple loading conditions were applied to stents emplaced in mock arteries and the load-deflection behavior was compared with that of bare stents. The results will be helpful in validating and further developing finite element codes used in stent design.

1. INTRODUCTION

In order to design SFA stents with improved durability, the forces they experience in-vivo must be determined. These forces can be obtained from 3D X-ray images of deformed stents in stented patients, if the images can be correlated with known in-vitro load-displacement-image data. In previous work [1] we described mechanical devices designed and fabricated to test stents in a 3D CT X-ray scanner under axial tension, pure bending, and pure torsion at body temperature and performed tests on stents of several architectures.

The resulting test data are intended to help validate FE codes, which in turn can be used to calculate local stresses in the struts of the stents and improve stent designs. However, these tests did not account for the effect of radial compression by the artery. Therefore, similar in-vitro tests were performed on stents emplaced in mock arteries. This work is reported here.

2. EXPERIMENTAL PROCEDURE

As previously described [1], three mechanical testing devices fabricated to load 6x40 mm bare stents in axial tension, pure bending, and pure torsion. The test devices were designed to measure the low loads needed to deform very compliant Nitinol stents. We used a 50 g load cell (Model ALD-MINI-UTC from A. L. Designs, Buffalo, NY) that was specially prepared to be temperature compensated and water resistant. To reduce friction as much as possible, we used watch jewels for the bearing surfaces and, as much as possible, suspended the stents and fixtures without allowing them to contact each other. Because the response of Nitinol is very sensitive to temperature, the stents were tested inside a water-filled test chamber held at 37°C (at body temperature). The devices were designed to have boundary conditions that were simple, well-known and easy to model. Finally, to acquire CT X-ray images of the stents under load, the testing devices were metal-free within the sight line of the stent.

We tested a number of Nitinol stents from different manufacturers and characterized and compared their cyclic response under axial tension, pure bending, and pure torsion.
We then measured the response of a single brand of Nitinol stent (Cordis Smart stent) placed in a mock artery—a 5 mm OD latex tube (Dynatek Delta latex mock artery) with a radial compliance of 5-7% per 100 mm Hg @72 bpm. The objective was to investigate the mechanical interaction between the stent and artery. Our approach was to first measure the load-deflection response of the stent and mock artery alone, and then test the stent emplaced in the artery. The level of loading was chosen to cover the range of deformation experienced by the SFA during patient activity. In our devices, with no interaction, the stent and artery would act like springs in parallel and the stiffness of the stent in the mock artery would be equal to the sum of the individual rigidities of the stent and artery. Any differences between the sum of the individual responses and the combined response would be evidence of interaction.

3. RESULTS

In axial extension, the stiffness of the mock artery was about two-thirds that of the bare stent and the stiffness of the stent emplaced in the artery was greater than the sum of the rigidities of the stent and artery alone. Thus, interaction did occur. Possibly the stent restricted the artery from pulling in when stretched, thus resulting in a stiffer artery. Or possibly the confined stent was not free to deform in the same way as a bare stent because of radial compression and the friction between stent and artery.

In torsion, the stiffness of the mock artery alone was about one-third that of the bare stent and the amount of interaction was not clear. The stiffness of the stent/artery combination was within the scatter of the rigidities of the stent and the artery added together, but the hysteresis during cycling was considerably greater, that is, during unloading the load dropped much more rapidly in the combined stent and artery than in either the bare stent or artery alone. More analysis needs to be done to understand the torsional interaction. It is possible that some slipping occurred at the peak load, either between the stent and artery, or in the device.

The results generated so far provide insight on the loads required to deform stents in overall torsion and axial extension and will be useful in validating finite element models for stent design and analysis. Tests to characterize the interaction between the stent and artery under pure bending are underway.