Understanding the Deformation and Fracture of Nitinol Endovascular Stents Using *In Situ* Synchrotron X-ray Microdiffraction

Endovascular stents manufactured from superelastic Nitinol represent a major component in the fight against heart disease. However, accurate characterization of the stress/strain distributions in such stents, which govern their deformation and fracture behavior, is essential for their prolonged safe use in human arteries. Here we report the first direct *in situ* x-ray micro-diffraction measurements inside the synchrotron of the local strain field (at 10-µm resolution) of a stent-like Nitinol component subjected to realistic multiaxial loading. Our micro-diffraction measurements indicate that state-of-the-art commercial finite-element models are sufficient for predicting local strain fields up to 3%. However, there are significant discrepancies between measured and calculated strains at larger displacements, which result from the continuum-mechanics-based model predictions. Consequently, it is imperative that future development of finite-element models must incorporate effects of transformational strain, phase redistribution, and plastic strain to provide higher fidelity predictions of Nitinol stent performance *in vivo*.

Nitinol, a nearly equiatomic alloy of nickel-titanium, can "remember" a previous shape and can recover strains as high as 10% by deformation (*superelasticity*) or temperature change (*shape memory*)[1]. These properties result from a reversible first-order phase transition between austenite (cubic, B2) and martensite (monoclinic, B19'). As such, deformation mechanisms of Nitinol are more complex than the conventional modes of plastic deformation in traditional alloys. Consequently, the mechanical behavior of Nitinol under multiaxial conditions remains poorly understood.

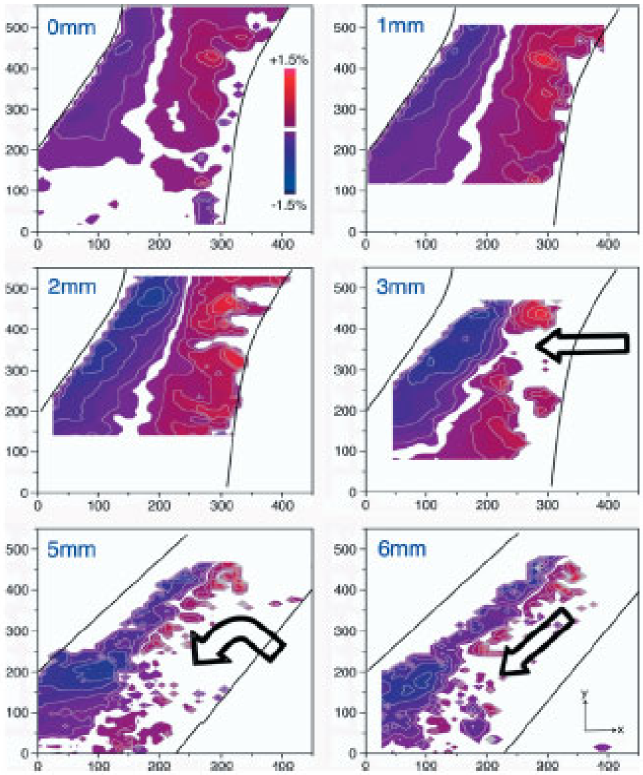

Fig. 1: Maps of the deviatoric strain of the B2 austenite along the vertical y axis (ε_{yy}) from x-ray diffraction analysis. The global displacements for these maps are shown in the upper left corner of each image. The dark lines illustrate the approximate location of the edges of the diamond strut. The red color indicates tensile strain whereas blue indicates compressive strain; note also the presence of a white neutral axis. The maximum local strain in austenite was measured to be ±1.5%. Above this strain, austenite transforms to martensite, which for this analysis is not analyzed, but can be inferred from where the austenite disappears. Martensite generally initiates at the surfaces with the highest applied deformation and begins to move toward the center of the diamond strut, as indicated by the arrows in 3mm, 5mm, and 6mm maps. However, it is observed that, even at 6mm deformation, there is a region of strain-stabilized retained austenite along the center of the strut that resists transformation. Consequently, the martensite transformation front moves down along

Nevertheless, because of these unique mechanical characteristics, in combination with excellent biocompatibility, Nitinol is used as self-expanding endovascular stents to scaffold diseased peripheral arteries. First-generation Nitinol stents were designed to provide sufficient scaffolding forces to hold open vessels, yet provide enough elasticity to "breathe" with pulsatile pressure differentials from the cardiac cycle. A variety of clinical studies indicate that these stents perform this primary function quite well. More recent in-depth studies, however, reveal that superficial femoral arteries (SFAs) are subjected to complex *in vivo* multiaxial deformation with up to 60% rotation and ~20% contraction in the SFA as the leg is bent from an extended position. Correspondingly, during a walking cycle, a stent deployed in the SFA undergoes severe multiaxial displacements from pulsatile motion (~$4x10^7$ cycles annually) plus bending, torsion, and axial motions (at a rate of ~$1x10^6$ cycles annually). Although there are ~40 times more cardiac displacement cycles, the combined non-pulsatile motions result in far greater cyclic strain magnitudes, and therefore, have the possibility of inducing greater fatigue damage, and sometimes fracture.

We investigated deformation of a stent-like component under moderate to high deformation conditions in an *in situ* apparatus at ALS BL 7.3.3, using a 1x1 micron white x-ray beam. The sample (the whole loading apparatus) was rastered to cover a 400x600 microns region on a 7x7 micron grid. A white beam Laue diffraction pattern was collected at each point on the grid. We were able to index the Laue pattern to obtain the all the 6 elements of the 2^{nd} rank deviatoric strain tensor (Fig. 1). Local strain maps thus obtained at several deformation levels were compared with a strain map obtained from the state-of-art finite element (FE) model used for Nitinol stent design.

Besides local granularities the strain maps from microdiffraction agreed well with FE model at low deformations, but difference between them increased dramatically at high deformation values. For example, contrary to the model predictions, there remains a spine of retained austenite in the middle of the strut even at the highest deformation studied here. Accordingly, it is observed that the transformation front moves *down* the length of the strut rather than moving towards the middle (3 – 5 mm).

The experimental observation of redirection of the transformation front has very important implications for strut fractures in Nitinol stents. At relatively low displacements, if the local strain field encounters a sufficiently large flaw, the defect will induce the strain field to grow such that the material may fracture at the location predicted by the FE model. Therefore, in this regime fracture of Nitinol stents is very well predicted by the current models. However, in the absence of flaws near the initial high-strain region predicted by FE model, the transformation front, *which has now changed direction*, will begin to propagate down the length of the strut. As the propagating strain front runs down the length of the strut, fracture may occur at locations significantly different from those suggested by the finite-element model, making fracture of SFA stents under non-pulsatile overload conditions unpredictable.

These results show that a much better understanding of crack propagation and modes by which superelastic Nitinol accommodated high deformation is needed. We are in process of publishing a series of investigations which sheds some light on these fundamental deformation and fracture processes in superelastic materials.

Primary Citation

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