Experimental Validation of a Single Z-Stent Spring for Stent-Graft Fatigue Analysis Models

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Introduction:

An abdominal aortic aneurysm is the ballooning of the wall of the largest blood vessel in the body where continued pressure applied by blood flow causes the aorta to balloon. This expansion will continue until the aorta ruptures unless treated. To manage this condition, a stent-graft which is a tube of fabric held open by stents which is inserted into the weakened area to prevent further pressure on the aortic wall and allow it to return to its original diameter. The wire is most commonly manufactured from a superelastic shape memory alloy called Nitinol.

Finite Element Analysis (FEA) is used in the development of stent-grafts to assess the strains experienced by the stents during their life-cycle. ASME V&V 40 require rigorous validation of stent-graft models for use in medical device manufacture [1]. For this, a three-tier experimental method is proposed to fully characterise the Nitinol material model with a tensile experiment, a load-deflection experiment and a dynamic compliance experiment. These experiments increase in complexity from a simple wire section to a single apex of a z-stent to a full z-stent spring deployed into a mock artery. The objective of this three-tier method is to validate the Nitinol material model in stages of increasing complexity to reduce the influence of external factors such as the complex geometry of the stents.

Methodology:

To use Nitinol in the engineering program Abaqus, the Nitinol material parameters defining the stress-strain loading and unloading path need to be defined. Once these have been defined, more complex simulations can then be undertaken. These complex simulations can be used in parallel to physical testing for worst-case condition investigations and to determine quantities that cannot be readily measured.

The Nitinol material model is defined by 15 inputs into a user defined material model or UMAT in Abaqus. An additional 16th input defines the number of stress-strain points required to describe the plasticity curve. To obtain these key parameters, a tensile experiment was conducted, then a load-deflection experiment was conducted to increase the complexity of geometry, then to validate the stent model a dynamic compliance experiment was conducted.

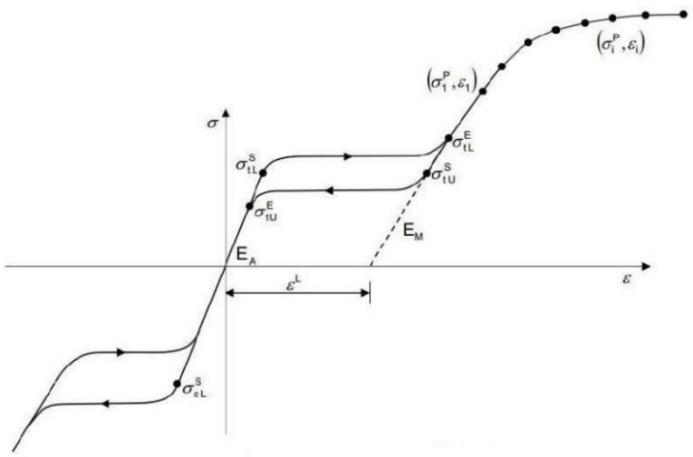

Figure 1: True stress-strain graph displaying key Nitinol material model input parameters. [2]

Tensile experiments of the Nitinol wire was performed following the recommendations of ASTM F2516-22 [3]. Samples of Nitinol wire were loaded into an Instron 5965 machine, an Instron 3229-600 environmental chamber and an Instron AVE2 non-contact video extensometer. A 2kN load cell was used to record the load applied to the wire samples. The load carried by the wire is recorded by the load cell and used to find the stress and the extensometer is used to measure the strain undergone by the wire. The environmental chamber was heated to 37°C. Eight standard samples from the same batch at a diameter of 0.475mm were tested. The wire samples are loaded up to 6% strain, released to rest and then pulled to failure. The cord and yarn grips allow for a smooth transition from the stress free region of the samples to the clamped region to prevent the wires snapping near the jaws and also prevent the wires from slipping out of the grips. Round, white labels are glued to the wire sample at approximately 30mm apart so that the extensometer can track the increase in length of the wire sample and thus the strain in the samples.

The load-deflection experiments involve taking a single apex of a z-stent, referred to as a coupon, and compressing it to a high strain state. The apex was then released and cycled at a relative strain that the apex would experience during the cyclic load of the blood pressure. To do this, the coupon is loaded into the Instron 5965 machine with side action-grips with a 2kN load cell and then the grips are moved closer together to compress the coupon. The coupon is then released up to a mean strain representative of a deployed stent within an artery and cycled within a representative small strain amplitude. The load and displacement experienced by the stent coupon are recorded by the load cell and crosshead respectively and then compared against the results of the FEA models.

The dynamic compliance experiment is the final validation conducted as part of this study. A single z-stent spring is deployed into a mock silicone artery and then pressurised with distilled water. A BDC Laboratory Control Flow Model System PD-1100 pulse duplicator/pulsatile pump was used to regulate the pressure as well as the temperature in the system. A Millar SPR-524 3.5F Mikro-Tip Catheter Transducer was used instead of the built-in pressure probe. A Keyence optical micrometer was used to measure the diameter of the mock artery during the experiments.

The silicone artery is mounted into the test setup and secured. The optical micrometer is moved into position and the control flow system is then switched on and the pressure and temperature allowed to stabilise. From here the initial systolic and diastolic pressures can be selected. The flow rate of the system was kept at a steady 5.0 ±0.25L/min. Five pressure conditions were chosen to test the stented artery. At each of these pressure conditions the diameter of the silicone artery was measured, both unstented and stented. The unstented changes in diameters were used to characterise the material model of the mock artery and then the stented changes in diameter were used to compare against the complimentary FEA model.

Conclusions:

From these experiments, the Nitinol material model was created using the test data and then implemented into Abaqus. The results from the experiments and the FEA models were then compared to check agreement. The single z-stent spring model was validated so that this can then be used in more complex stent-graft deployment scenarios

The single z-stent spring model can then be used in a series of comparison studies between the z-stent and different designs of stent-grafts. This includes an initial simple comparison between a single z-stent and a single ring-stent in ideal artery geometries to more complex artery geometries such as spinal intrusions and oval arteries. This comparison will improve the understanding of the durability limits of the stents which will in turn help improve the design of the stent-grafts overall.

References:

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[3] *ASTM F2516-18. Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials* www.astm.org., *(2022)*