

Mechanics of Laser Cu Stent Grafts

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Abstract. This article is dedicated a finite element analysis of tubular, laser cut stent grafts with peak-to peak bridge geometry under representative cyclic loading conditions for abdominal aortic aneurysm repair. Cardiovascular diseases are the principal cause of death in the developed world. For computational analysis. ANSYS software was employed to study the mechanical behavior of stents. Contrary to conventional engineering materials, Nitinol stent fracture is not stress based but strain based. The effects of crimping and cyclic pressure loading on stent–graft fatigue life were simulated and analyzed.

Introduction

Stent-grafts are tubes made out of wire or by cutting laser meshes that are inserted into arteries to help keep them open so blood can flow properly. The stent is mounted on a balloon catheter and delivered to the site of blockage. Endovascular aneurysm repair has clear benefits when compared with conventional open surgery in terms of less trauma, earlier return to daily activities, reduced mortality, and lower morbidity. However, stent–graft failure, i.e., implant migration, device fatigue, and endoleaks resulting potentially in abdominal aortic aneurysms rupture, remains a major concern [1,2,3].

Stent-graft geometry

Virtually all previously published analyzes, however, dedicated stents with a diamond shape geometry [1,3]. This study is dedicated to stents with peak-to peak bridge geometry. Fig. 1a shows a stent–graft with a total of 54 bridges or cells and 9 rows built into the tubular stent. Fig. 1b show detailed view on the peak-to peak bridge geometry. Stent-grafts are composed from two different parts: stent and graft. Stent represents tubular structure which keeps the vein expanded, while the graft is covering the pipe. Stents are produced either by bonding wire or by laser cutting from tubes of small diameter. This diameter matches to diameter of crimped or compressed stent-graft.

Materials of Stent-graft

Nickel-titanium alloys (known as Nitinol), are alloys where this two elements are present in roughly equal atomic percentages. This alloys are characterised by two closely related and unique properties: shape memory and superelasticity. Shape memory is the ability of nitinol to undergo deformation at one temperature, then recover its original, undeformed shape upon heating above its "transformation temperature". Superelasticity occurs at a narrow temperature range just above its transformation temperature; in this case, no heating is necessary to cause the undeformed shape to

recover, and the material exhibits enormous elasticity, some 10-30 times that of ordinary metal. This behavior can be explained by changes in crystal structure. At high temperatures, nitinol assumes austenitic structure, which is an interpenetrating simple cubic structure. At low temperatures, nitinol spontaneously transforms to a more complicated body-centered tetragonal crystal referred to as martensite. A self-expandable Nitinol stent-grafts repair utilizes these characteristics rather well. Cooled to less than 5 °C (so-called austenite finish temperature), it fully transforms into martensite and hence becomes very deformable and easily compressed into a small catheter. The stents studied in this work were made from two different Nitinol alloys Nitinol-55 and Nitinol-49 (Marked by titanium content) characterised by these mechanical properties: Young modulus $E_{austenite} = 83$ GPa, $E_{martensite} = 32$ GPa for Nitinol-55 and $E_{austenite} = 81$ GPa, $E_{martensite} = 41$ GPa for Nitinol-49 and a Poisson ratio for both alloys was 0.333. Contrary to conventional engineering materials, Nitinol fracture is not stress based but strain based. Outer packaging referred to as Graft was made from polyethylene terephthalate (PET, also known as Dacron). This material is characterised by Young's modulus is 1.2 MPa and a Poisson ratio of 0.495.

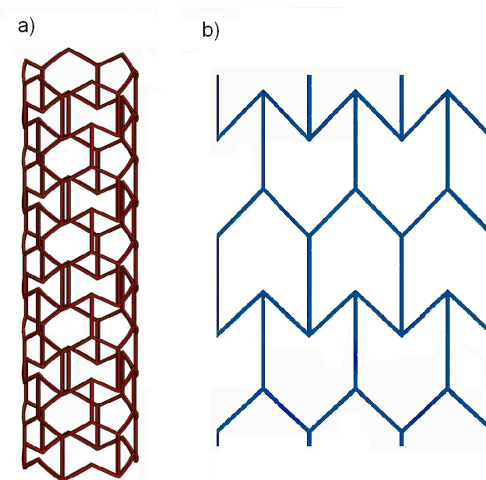


Fig. 1. a) stent-graft with a total of 54 bridges and 9 rows ;b) Peak-to-peak bridge geometry of stent-graft.

Stent-graft function and loading

The stent-graft is loaded in different ways depending on its function and its state. First, before placing into the vein, the cooled stent-graft is crimped into small catheter and strung onto the delivery device. In this compressed state, the stent-graft using a device placed on the planned site in artery. After placement the stent-graft placed in the body, the stent is released from delivery device by an balloon. Then, the stent-graft is heated to body temperature, then expands to its original size to create a passage between two hollow spaces. In this stage, the stent can not expand to its original diameter (as if it was in a free space), because the walls of the artery prevents further growth of the diameter. This creates a certain pressure between the wall of the artery and a stent. This contact loading causes a firm grip of the stent in place. We will call this phase of stent-graft placement, sealing phase. Expanded stent-graft in the artery is after placement loaded not-only by pressure caused by contact of the stent and artery walls, but also by the pressure caused by pulsating blood flow. This pulsating loading corresponds to the lower and upper pressure value of flowing blood, e.g. to the diastolic pressure 50 mmHg (6.3 kPa) and systolic pressure 150 mmHg (20 kPa).

Modeling

Geometry modeling. 3D-model of stent with a total of 54 bridges or cells and 9 rings (or rows) built into the tubular stent mesh was prepared in the SolidWorks, see Fig. 1b. The model of graft is

was formed by a thin wall tube. Because stent and graft are sutured together, a tight, rigid contact is assumed to simulate the interaction between stent and graft interaction. Fully expanded stents has a length L of 100 mm, an expanded outer diameter D_{ED} of 30 mm, a thickness s of 0.38 mm. Although the actual stent-graft comprises nine rows, it can show that you can use model containing only four rows (24 bridges). To verify this assumption, another model was created, which contains only four rows. Other models have been created to describe the unit cell, respectively a bridge. All models were prepared in SolidWorks software and exported in ANSYS software, where they are meshed and solved. First model of stent-graft with 9 rings is composed of 684.024 tetrahedral elements and second with only 4 rings contains 312.888 elements. Model of sole cell, respectively of bridge is composed of 360.088 and 300.128 elements. The ANSYS Finite Element Analysis package, in combination with user-defined material subroutines for the Nitinol material properties, was employed to calculate the stress and strain fields. The calculation of stent-graft state under diferent loadings was based on equation for static equilibrium of the structure(s):

$$\text{div}(\sigma_{ij}) = 0 \tag{1}$$

where $\text{div}(\)$ is divergence of stress tensor.

Material modeling. The two materials of the artery wall, arterial tissue and stenotic plaque, were modelled using a 5-parameter third-order Mooney–Rivlin hyperelastic constitutive equation. This has been found to adequately describe the non-linear stress-strain relationship of elastic arterial tissue. The general polynomial form of the strain energy density function in terms of the strain invariants, given by [1,3] for an isotropic hyperelastic material is

$$W(I_1, I_2, I_3) = \sum_{i,j,k=0}^{\infty} a_{ijk} (I_1 - 3)^m (I_2 - 3)^n (I_3 - 3)^o \tag{2}$$

$a_{000} = 0$

where W is the strain-energy density function of the hyperelastic material, I_1, I_2 and I_3 are the strain invariants and a_{ijk} are the hyperelastic constants.

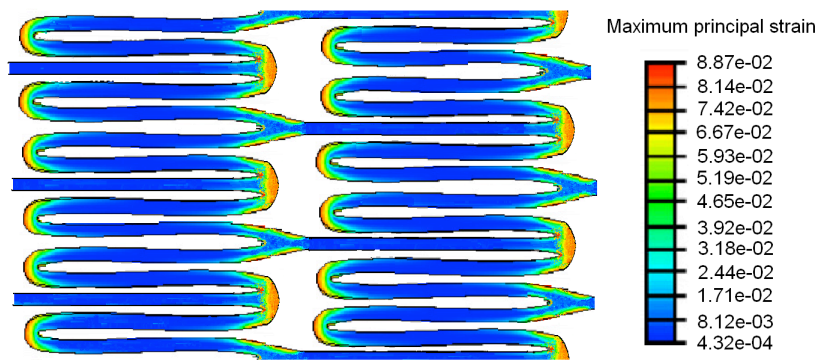
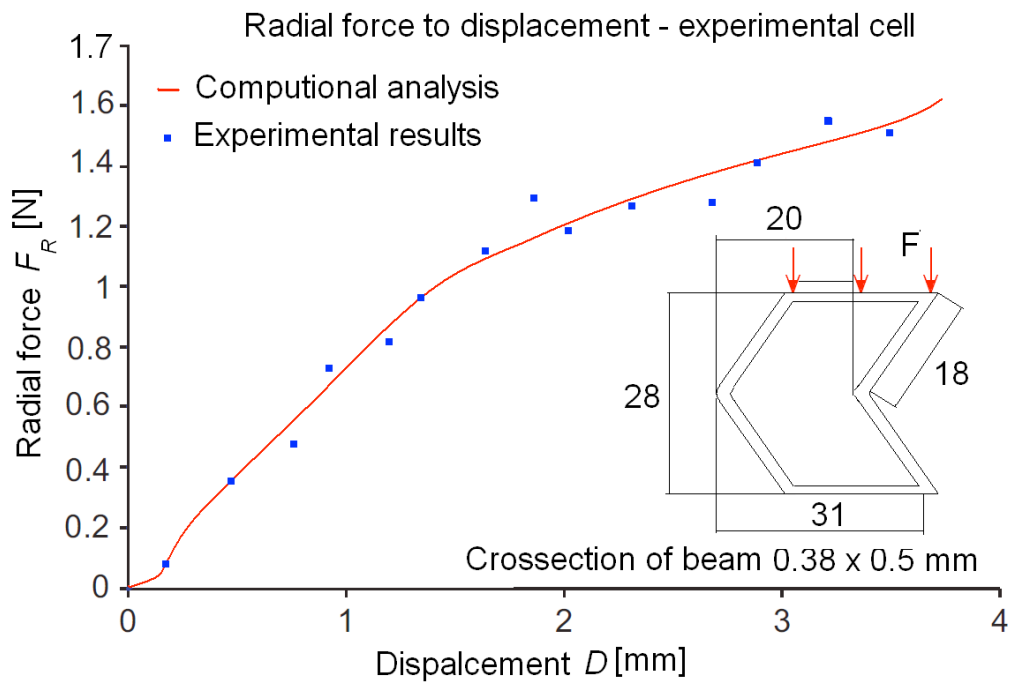


Fig.2 Maximum principal strain fields ind crimled stent (The stant made from alloy Nitinol-55). The maximum crimping strain (7.8%) is lower under its critical threshold in safe zone.

Crimpling and radial force

By crimping loading, the expanded stent is compressed to a diameter corresponding to about 1/5 of its diameter. The compressed stent-graft is strung into a delivery system. In this case, the stent-graft was compressed from the expanded diameter of 30 mm to compressed diameter of 5 mm. It can be

assumed, that reaction forces induced in stent against external loading are much larger than the reaction forces in graft. The model is simplified, so that it uses symmetry. The model assumes, that the stent was fixed in axial direction at the end nodes. In the radial direction, of the stent can freely



deform due to external loading caused by crimping tool.

Fig.3. The radial force as the function of the displacement

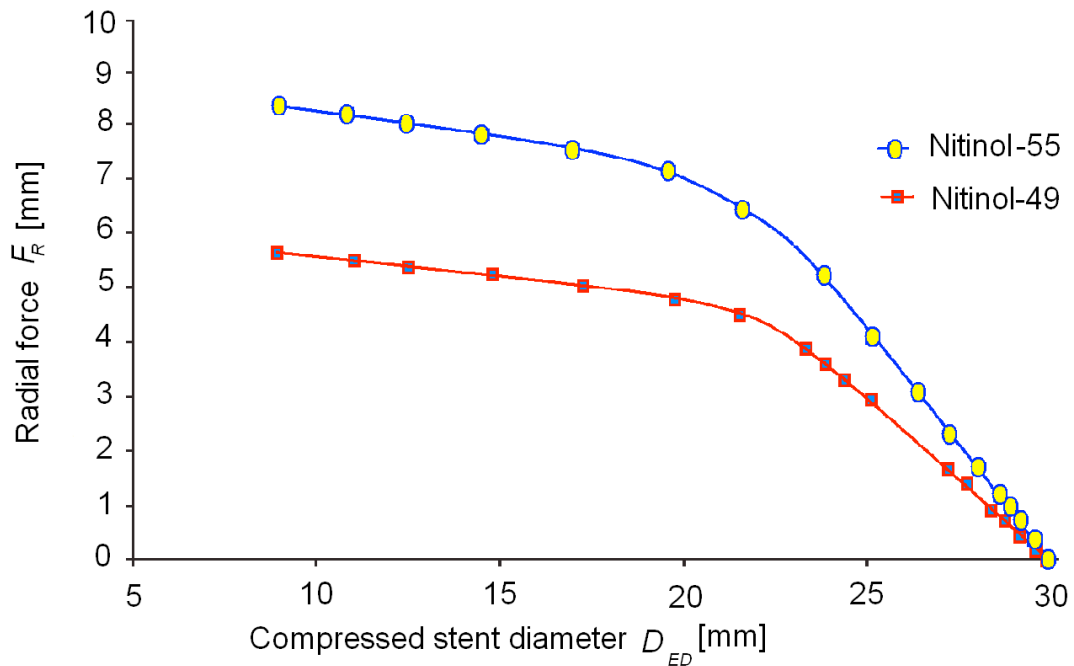


Fig.4 The radial force as the function of the compressed stent diameter.

The maximum crimping strain and radial force have not only effect on fatigue life, but too high radial force can cause rupture of device. Therefore, major emphasis is placed on assessment maximum crimping strain and radial force. The maximum principal strain fields in an stent after crimping are shown in Fig.2. The maximum crimping strain is 7.8% and 10.1% for Nitinol-55 and Nitinola-49. The radial force as the function of the displacement is shown in Fig.2. For validation of FEM-model, the experimental cell was prepared. This experimental model is 2x larger then real cell in the stent. Larger dimensions of experimental cell were chosen, because on the smaller cell was no facility for installation of measuring equipment. Fig.3 shows a good accordance between experiment and calculations.

Sealing

The outer diameter of stent-grafts is about 15–30% over the diameter of artery. When the stent-graft is placed in the artery, the arterial wall prevents the stent-graft from completely expanding and contact pressure between arterial wall and stent-graft caused reaction – radial force. This prevents movement of the stent-graft in the artery. The stent-graft is firmly rooted on the spot. It is assumed, that the graft material is considered to have a negligible effect on the mechanical response of the stent and is not included in this analysis. Same displacement boundary conditions were applied to the stent and artery as in the case of crimping loading. Furthermore, the uniform pressure was applied to the inner diameter of the arterial wall. The applied pressure corresponds to the 100 mmHg (13kPa). The radial force as the function of the compressed stent diameter is shown in Fig.4. This graph shows the relationship between the radil force and the diameter for both alloys. The radial force is higher for stents made from alloy Nitinol-55.

It is widely known, that the oscillating strain has a greater influence on fatigue life than the mean strain and stress. Therefore, oscillating values of stress/strain were calculated. This changes in stress/strain were caused by oscillating pressure in the vessel/artery. The pressure in the artery oscillates from 50 mmHg to 150mmHg (6.3-20kPa). The strein changes for one cell are shown in Fig. 5. Alternating strain represents 0.2% of mean strain and safety factor is 2.1 for stents made from Nitinol-55. Alternating strain is 0.24% of mean strain and safety factor is 1.7 for stents made from Nitinol-49.

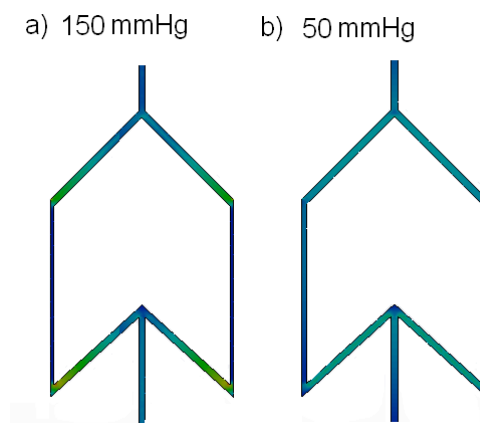


Fig. 5 Strain field in ine cell of stent under oscillates from 50 mmHg to 150mmHg (6.3-20kPa) for Nitinol-55. Maximum of strain is clearly vidibe at sharp angle.

Stent-graft as presure vessel – main-body loadyng

After deployment of stent-graft in the artery, the main part of the stent-graft forms a new vessel, which excludes blood flow from the abdominal aortic aneurysms cavity. Model used for

simulations of this state used same displacement boundary conditions as in the case of crimping and sealing loadings. In addition to crimping and sealing a cyclic arterial pressure from 50mmHg (diastolic-6.3kPa) to 150mmHg (systolic-20kPa) was applied to the inner surface of the graft sheath, together with representative mean pressure of 100mmHg (12.7kPa). FEM shows that the Maximal wall stresses 3.4MPa in graft is much lower than its yield stress of 59.6MPa. In Fig.6 experimental fatigue life curves for stent-grafts under cyclic loading are shown.

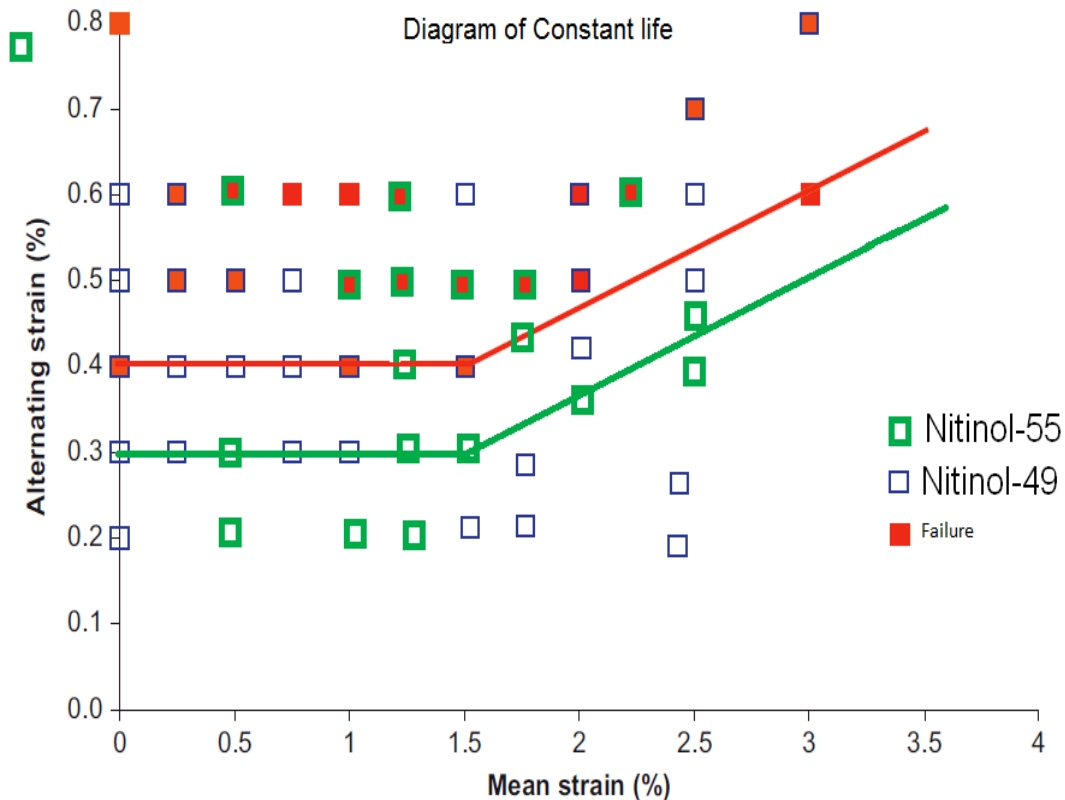


Fig.8 Experimental Fatigue life of stent-grafts

Results

It was found that the maximum strain is located at the strut's internal side, bridge connection. The maximum crimping strain for Nitinol-55 is 7.8% and 10.1% for Nitinol-49. Radial force is higher than in the case of diamond shape geometry [1]. Thus, in terms of crimping performance, the peak-to-peak bridge geometry of stents is preferable to diamond shape geometry. Under representative cyclic pressure loading, sealing stents are located in the safe zone of the fatigue life zone.

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