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Computational mechanics of Nitinol stent grafts

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Abstract

A finite element analysis of tubular, diamond-shaped stent grafts under representative cyclic loading conditions for abdominal aortic aneurysm (AAA) repair is presented. Commercial software was employed to study the mechanical behavior and fatigue performance of different materials found in commercially available stent–graft systems. Specifically, the effects of crimping, deployment, and cyclic pressure loading on stent–graft fatigue life, radial force, and wall compliances were simulated and analyzed for two types of realistic but different Nitinol materials (NITI-1 and NITI-2) and grafts (expanded polytetrafluoroethylene—ePTFE and polyethylene therephthalate—PET). The results show that NITI-1 stent has a better crimping performance than NITI-2. Under representative cyclic pressure loading, both NITI-1 and NITI-2 sealing stents are located in the safe zone of the fatigue-life diagram; however, the fatigue resistance of an NITI-1 stent is better than that of an NITI-2 stent. It was found that the two types of sealing stents do not damage a healthy neck artery. In the aneurysm section, the NITI-1&ePTFE, NITI-1&PET, and NITI-2&PET combinations were free of fatigue fracture when subjected to conditions of radial stress between 50 and 150 mmHg. In contrast, the safety factor for the NITI-2&ePFTE combination was only 0.67, which is not acceptable for proper AAA stent–graft design. In summary, a Nitinol stent with PET graft may greatly improve fatigue life, while its compliance is much lower than the NITI–ePTFE combination.

Keywords: Stent; Stent graft; Abdominal aortic aneurysm; Nitinol; Graft material; Finite element analysis; Computer simulations; Wall stress and strain; Crimp; Fatigue; Fracture

1. Introduction

Endovascular repair of abdominal aortic aneurysms (AAAs), i.e., the placement of a stent graft into the diseased artery segment, has stimulated considerable interest among vascular surgeons, stent–graft manufacturers, and researchers alike. Endovascular aneurysm repair (EVAR) 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 AAA rupture (see Kleinstreuer and Li, 2006), remains a major concern. Focusing on endovascular implants, they may experience metal fracture, fabric erosion, suture breakage, and ultimately device failure (Beebe et al., 2001; Jacobs et al., 2003; Zarins et al., 2004; Chakfe et al., 2004; among others).

Due to their high flexibility and deployment methodology, self-expanding Nitinol stent grafts are a common selection for EVAR. Available numerical studies regarding Nitinol stents are focused so far on idealized designs without considering stent–graft combinations (see Duerig and Wholey, 2002; Duerig et al., 1999, 2000; Gong et al., 2002, 2003; Rebelo and Perry, 2000; Pelton et al., 2003, among others).

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Contrary to conventional engineering materials, Nitinol stent fracture is not stress based but strain based, where it was found that the oscillating strain amplitude is the main contributor to fatigue behavior. Recently, several researchers investigated the effects of mean and alternating strain on the fatigue behavior of superelastic Nitinol and observed that the oscillating strain has a greater effect on fatigue life than the mean strain (Tolomeo et al., 2000; Kugler et al., 2000; Harrison and Lin, 2000). For example, based on 432 Nitinol diamond-shaped stent specimens that were exposed to a maximum life of 10^7 cycles, Gong et al. (2002) reported that low-cycle fatigue data from zero-mean strain conditions follow the Coffin–Manson behavior with an exponent of -0.41 and high-cycle data under these conditions indicate an endurance limit of 0.4% strain. Currently, maximum principal strain is generally used to investigate Nitinol stent fracture.

In this paper, following FDA guidelines (see Cavanaugh et al., 2006) a computational analysis of different stent–graft material combinations and their impact on mechanical characteristics while undergoing cyclic pressure loads was carried out, employing the finite element solver ABAQUS (Warwick, RI).

2. Materials and methods

2.1. Nitinol and graft material properties

Nitinol is becoming more and more popular in biomedical applications due to its remarkable superelasticity, shape memory, biocompatibility, corrosion resistance, as well as fatigue resistance and durability (Duerig et al., 1999; Petrini et al., 2005). A self-expandable Nitinol stent for AAA repair utilizes these characteristics rather well. Cooled to less than 5 °C, it fully transforms into martensite and hence becomes very deformable and easily compressed into a small catheter. When the stent is released from the catheter in the aneurysm section, it recovers to its predetermined, considerably larger diameter at the 37 °C body temperature. As a result, it shields the aneurysm from the circulation with a sealing contact at the aortic neck, thereby providing a new blood vessel (Li and Kleinstreuer, 2005a). For this study, we selected two types of Nitinol material and compared their mechanical performances under cyclic loadings in light of improved stent–graft design. Fig. 1 provides the stress–strain and stress–temperature curves, while Table A1 (see Appendix) lists the parameters of the two Nitinol materials. The Nitinol material properties were selected to represent those used in current stent designs (Farber, 2006; personal communication) and are based on tubing tests, which used Nitinol that had undergone the same heat treatment as laser-cut stents. The idea is to employ realistic but contrasting stent materials paired with different graft materials.

Currently, expanded polytetrafluoroethylene (ePTFE) and polyethylene therephthalate (PET, also known as Dacron) are the two most popular graft materials in AAA repair due to their remarkable biocompatibility and durability. We chose two typical ePTFE and PET grafts with material properties given in Table A2 (see Appendix) after Catanese et al. (1999) and Alicea et al. (2004).

2.2. Stent–graft modeling approach

Fig. 2 shows a Nitinol stent–graft model with a total of 20 diamond cells and 10 rows built into the tubular stent. Because stent and graft are sutured together, a tight, rigid contact is assumed to simulate the interaction between stent and graft.

In reality, a stent graft contains many more diamond cells, encounters significant changes in blood pressure, and experiences multiple regions of contact with the viscoelastic arterial wall. Rather than modeling all of these multi-physics phenomena simultaneously, the different mechanical environments considered were: (i) the crimping/compressing of the stent graft prior to delivery, (ii) the region of contact with the surrounding arterial wall (labeled the sealing section), and (iii) the section of the stent graft that is freely suspended after deployment (labeled the main-body section). In each environment the boundary conditions and model parameters were altered to adequately simulate each form of mechanical loading.

2.3. Numerical methods

The ABAQUS/Standard (v. 6.6) 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 governing equation for the structure(s) was the condition for static equilibrium, where zero body loads were applied:

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

In Eq. (1), div() is the divergence operator and σ_{ij} the resulting stress tensor of the applied loads. A single node was fixed in the direction perpendicular to the diamond surface to prevent out-of-plane rigid body translation. Mesh sensitivity and density independence studies were performed to ensure that all results are independent of further mesh refinements. The number of each element type used is listed in Table A3

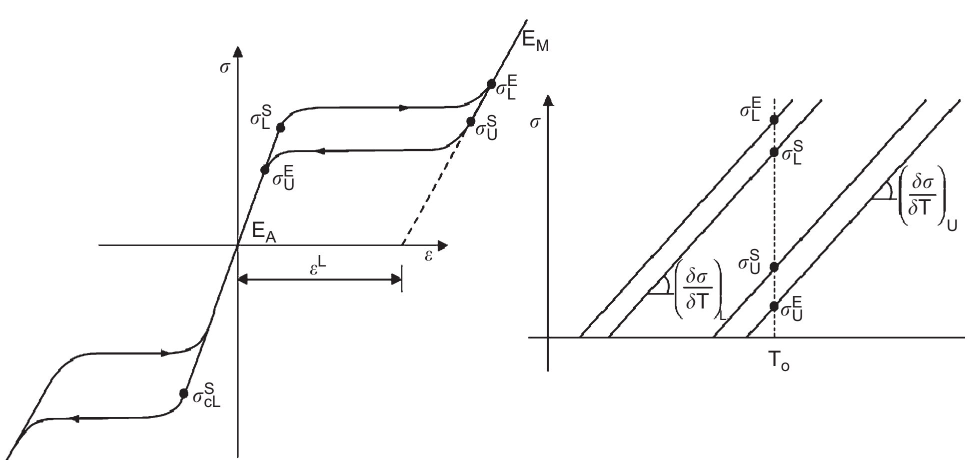

Fig. 1. Nitinol material properties (from ABAQUS Nitinol UMAT).