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Research Paper

High compressive pre-strains reduce the bending fatigue life of nitinol wire

Shikha Gupta[a], *Alan R. Pelton*[b], *Jason D. Weaver*[a],
Xiao-Yan Gong[c], *Srinidhi Nagaraja*[a,*]

[a]*U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Applied Mechanics, Silver Spring, MD, USA*
[b]*G. RAU Inc., Fremont, CA, USA*
[c]*Medical Implant Mechanics, Irvine, CA, USA*

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ABSTRACT

Prior to implantation, Nitinol-based transcatheter endovascular devices are subject to a complex thermo-mechanical pre-strain associated with constraint onto a delivery catheter, device sterilization, and final deployment. Though such large thermo-mechanical excursions are known to impact the microstructural and mechanical properties of Nitinol, their effect on fatigue properties is still not well understood. The present study investigated the effects of large thermo-mechanical pre-strains on the fatigue of pseudoelastic Nitinol wire using fully reversed rotary bend fatigue (RBF) experiments. Electropolished Nitinol wires were subjected to a 0%, 8% or 10% bending pre-strain and RBF testing at 0.3–1.5% strain amplitudes for up to 10^8 cycles. The imposition of 8% or 10% bending pre-strain resulted in residual set in the wire. Large pre-strains also significantly reduced the fatigue life of Nitinol wires below 0.8% strain amplitude. While 0% and 8% pre-strain wires exhibited distinct low-cycle and high-cycle fatigue regions, reaching run out at 10^8 cycles at 0.6% and 0.4% strain amplitude, respectively, 10% pre-strain wires continued to fracture at less than 10^5 cycles, even at 0.3% strain amplitude. Furthermore, over 70% fatigue cracks were found to initiate on the compressive pre-strain surface in pre-strained wires. In light of the texture-dependent tension–compression asymmetry in Nitinol, this reduction in fatigue life and preferential crack initiation in pre-strained wires is thought to be attributed to compressive pre-strain-induced plasticity and tensile residual stresses as well as the formation of martensite variants.

Despite differences in fatigue life, SEM revealed that the size, shape and morphology of the fatigue fracture surfaces were comparable across the pre-strain levels. Further, the mechanisms underlying fatigue were found to be similar; despite large differences in cycles to failure across strain amplitudes and pre-strain levels, cracks initiated from surface inclusions in nearly all wires. Compressive pre-strain-induced damage may accelerate such crack initiation, thereby reducing fatigue life. The results of the present study indicate that large compressive pre-strains are detrimental to the fatigue properties

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[*] Correspondence to: U.S. Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, Building 62, Room 2210, Silver Spring, MD 20993-0002, USA. Tel.: +1 301 796 0396; fax: +301 796 9932.
E-mail address: srinidhi.nagaraja@fda.hhs.gov (S. Nagaraja).

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of Nitinol, and, taken together, the findings underscore the importance of accounting for thermo-mechanical history in the design and testing of wire-based percutaneous implants.

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1. Introduction

Over the last decade, Nitinol, the nearly equiatomic metal alloy of nickel and titanium, has become a ubiquitous medical device material due to its unique shape memory and pseudoelastic material properties. These properties are attributed to a reversible martensitic transformation between the austenite and martensite phases, which may be temperature-induced (shape-memory) or stress-induced (pseudoelasticity). The parent austenite phase is an ordered B2 cubic lattice which is stable at high temperature while the lower symmetry martensite daughter phase possesses a B19′ monoclinic crystal which is stable at lower temperatures. Conversion of the austenite phase to the martensite phase occurs via a diffusionless solid-to-solid phase transformation. This transition confers fully recoverable strains in excess of 6% to the material (Duerig et al., 1990; Shaw and Kyriakides, 1995), making Nitinol especially attractive as a material for percutaneous cardiovascular devices such as stent-grafts, vena cava filters and septal occluders (Duerig et al., 1999).

Endovascular implants are subjected to millions of cycles of multi-axial loading in vivo due to pulsatile blood flow and skeletal motions, making them susceptible to fatigue failure. Fatigue fracture of Nitinol endovascular devices remains a major concern, particularly in peripheral stents and septal occluders, where clinical fracture rates between 4% and 10% are still commonly reported (Fagan et al., 2009; Kay et al., 2004; Trabattoni et al., 2010). The fatigue properties of the Nitinol (NiTi) in intravascular devices is not just sensitive to material composition and processing (Launey et al., 2014; Matheus et al., 2011; Reinoehl et al., 2001; Schaffer and Plumley, 2009) but to the full thermo-mechanical history of the formed device. The thermo-mechanical history may include final shape-setting heat treatments/aging (Pelton et al., 2004; Pelton et al., 2003), and post-processing step such as loading onto a delivery system, sterilization, and final deployment (Duerig et al., 1999). Heat treatments have typically been used to optimize austenite finish temperature (A_f) and microstructural parameters (Pelton et al., 2000), and the effect of such treatments on the fatigue life of Nitinol devices has been studied over the past decade (Patel et al., 2006). In contrast, the effects of constraining the device onto a delivery system (crimping), sterilizing the device at high temperatures in this constrained state, and then releasing the constraint during deployment are still not well understood.

Crimp strains, or pre-strains, in endovascular devices may range from 4% to over 10%. For instance, Kleinstreur et al. reported maximum crimp strains of 8.86% and 10% for two different Nitinol materials in a diamond stent-graft model (Kleinstreuer et al., 2008). Similarly, pre-strains of 6–8% were calculated for different percutaneous heart valves (Kumar and Mathew, 2012). Though these pre-strains are largely recovered upon deployment, the material in the device has undergone a large forward and reverse mechanical strain excursion even before encountering any physiological deformation.

Similarly, sterilization imposes a thermal cycle on endovascular devices prior to deployment. Constraining onto the delivery system, such as a catheter, is often performed at low temperatures near or below the martensite finish temperature (M_f) The constrained device may then be sterilized at temperatures above A_f, stored at ambient temperature before implantation, and finally exposed to body temperatures just prior to deployment/release.

Irrespective of whether it results in a permanent set, this single large thermo-mechanical strain cycle can alter the material microstructure through the accumulation of dislocations, interface formation and the persistence of martensite nuclei within the austenite matrix (Brinson et al., 2004; Pelton, 2011; Pelton et al., 2012). Such changes may manifest as shifts in phase transition temperatures, plateau stresses and transformation strains (Gong et al., 2002; Henderson et al., 2011; Miyazaki et al., 1986; Urbina et al., 2009), and as a result, may alter the fatigue behavior of the material. Designing Nitinol devices against fatigue fracture not only demands an understanding of in-service loads, but of how the device's complex thermo-mechanical history affects its material level fatigue behavior. While numerous computational (Grujicic et al., 2012; Kumar et al., 2013; Rebelo et al., 2009) and some experimental studies (Pelton, 2011; Pelton et al., 2008) of device-level fatigue have incorporated crimping and deployment into the investigational protocol, few studies have clearly examined how this pre-strain cycle impacts overall fatigue properties. Schlun et al. subjected pseudoelastic NiTi to an 8% tensile pre-strain and examined the evolution of the cyclic strain–stress behavior at 0.2% and 1.2% strain amplitude and 2% mean strain for 100 cycles (Schlun et al., 2011). The authors observed hysteresis and permanent set in the stress–strain curve at 1.2% strain amplitude over 100 cycles but the curve remained constant at 0.2% strain amplitude. However, they did not elucidate the impact of the initial 8% pre-strain on these findings. More recently, Pelton et al. investigated the fatigue behavior of different compositions of Nitinol wire at large strain amplitudes (5–10%) and found the wires fractured in less than 10^3 cycles (Pelton et al., 2013). Though such strain amplitudes exceed physiologic loading conditions, the results suggest that even a single strain excursion at such high strains may consume a measurable portion of the fatigue life of the material.

Bending is one of the predominant loading modes in many wire-based endovascular devices (Berg, 1995; Wick et al., 2005). As the fatigue life of pseudoelastic Nitinol is strain-controlled, rotary bend testing, which provides a simple method for strain-controlled materials characterization of wires, has been employed extensively over the past decade to investigate the fatigue behavior of medical grade Nitinol.