Fatigue Life Estimation of Nitinol Medical Devices

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Abstract: Stents have been used in the treatment of coronary artery disease for decades, and their use in the peripheral arterial vasculature is growing rapidly. Mechanical loads imposed on peripheral stents may include loads due to arterial pulsation, axial compression, bending and torsion. These stents are most often manufactured using nitinol, a nickel-titanium alloy that exhibits unique shape memory and superelastic characteristics. Finite element analysis can be a powerful tool in designing medical devices to withstand such a rigorous loading environment. This paper will focus on the use of Abaqus/Standard for fatigue life characterization of nitinol stents and comparison of performance predicted by FEA to experimental data. Abaqus is used to simulate stent expansion and fatigue loading under expected physiologically relevant loading conditions. A strain based fatigue criterion is used to determine the fatigue characteristics of the stents, and bench top fatigue testing is used to verify the numerical results. The study is extended to a competitive benchmarking of different stent designs. Results show a close correlation between analytical and experimental results, indicating that finite element analysis is a powerful tool in the design and fatigue life estimation of nitinol medical devices subjected to complex loading conditions.

Keywords: *Medical Devices, Stents, nitinol, Fatigue.*

1. Introduction

Stents are tubular metal structures used in the treatment of occlusive arterial disease, delivered to the site of placement using minimally-invasive surgical techniques. Stents fall into two broad categories: balloon-expandable devices, which are mounted on and expanded to their operational diameter using an inflatable balloon, and self-expanding stents which expand to their operational diameter upon withdrawal of a constraining sheath. Most self-expanding stents are cut from drawn, seamless nitinol tubing and exhibit unique shape memory and superelastic attributes. These attributes make a self-expanding stent generally more flexible and conformable than its balloon-expandable counterpart.

It is well known that certain peripheral arteries, especially the superficial femoral artery, are subjected to radial as well as non-radial deformations (Smouse, 2004). Stents placed in these locations must be designed to withstand a complex fatigue loading environment, including radial pulsation, compression, bending and torsion (United States Food and Drug Administration guidance, 2005). The purpose of this study was to use finite element analysis (FEA) as a tool in