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100 Mio-Cycle Bending Durability of Generation III Nitinol for Medical Implants

During the past decade, manufacturers have accelerated the pace to provide "ultra-clean" Nitinol products to the medical device industry. High-purity Nitinol is required to survive the demanding requirements of high-performance medical devices, including - but not limited to - neurovascular and structural heart implants. Extensive research has shown that the size and volume fraction of $Ti_4Ni_2O_x$ and TiC inclusions are the limiting factor for long-term durability of these critical medical devices. For example, Robertson, et al. (2015) demonstrated that Generation I Nitinol (VAR and VIM/VAR) has statistically significant lower fatigue strain limits than Generation II Nitinol (HP VAR, VIM, and VIM/VAR). Under the test conditions in that study, the HP VAR had the greatest fatigue strain limit that was attributed to its lower average device inclusion size (40µm) compared with Generation I materials with > 100µm. These published results afford great insight into the potential of even higher purity microstructures, such as those found in Generation III Nitinol, the so-called HCF material, with <10µm inclusion size (Pelton, et al. 2019). The present study provides a statistical comparison of the bending fatigue performance of Generation III Nitinol with custom-designed "diamond-shaped" test articles manufactured from 7mm x 0.5mm Nitinol tubing. Test conditions of 8.6% crimp strain, with mean strains between -0.5 and 7% and alternating strains from 0.5 to 2.75% are used to characterize the effects of inclusion size and distribution on the fatigue behavior to 100,000,000 cycles. Results from tensile properties as well as microstructure (LOM, SEM) and grain orientation (EBSD) will be discussed as contributing factors for the fatigue behavior. These current results, in conjunction with those from recent publications (Pelton 2022, Launey 2023) on the effects of pre-strain, mean strain, and processing, indicate that inclusion size and distribution have a significant impact on the fatigue life for Nitinol medical devices.

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