On Modeling Assumptions in FEA of Stents

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Finite element analysis (FEA) of Nitinol medical devices has become prevalent in the industry. The analysis methods have evolved in time with the knowledge about the material, the manufacturing processes, the testing or in vivo loading conditions, and the FEA technologies and computing power themselves. As a result, some common practices have developed. This paper presents a study in which some commonly made assumptions in FEA of Nitinol devices were challenged and their effect was ascertained. The base model pertains to the simulation of the fabrication of a diamond shape stent specimen, followed by cyclic loading. This specimen is being used by a consortium of several stent manufacturers dedicated to the development of fatigue laws suitable for life prediction of Nitinol devices. The FEA models represent the geometry of the specimens built, for which geometrical tolerances were measured. These models use converged meshes, and all simulations were run in the FEA code ABAQUS making use of its Nitinol material models. Uniaxial material properties were measured in dogbone specimens subjected to the same fabrication process as the diamond specimens. By convention, the study looked at computed geometry versus measured geometry and at the maximum principal strain amplitudes during cyclic loading. The first aspect studied was the effect of simulating a single expansion to the final diameter compared with a sequence of three partial expansions each followed by shape setting. The second aspect was to ascertain whether it was feasible to conduct the full analysis with a model based on the electropolished dimensions or should an electropolish layer be removed only at the end of fabrication, similar to the manufacturing process. Finally, the effect of dimensional tolerances was studied. For this particular geometry and loading, modeling of a single expansion made no discernable difference. The fabrication tolerances were so tight that their effect on the computed fatigue drivers was also very small. The timing of the removal of the electropolished layer showed an effect on the results. This may have been so because the specimen studied is not completely periodic in the circumferential direction.

Cerebrospinal Fluid Volume Monitoring for Hydrocephalus Therapy

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Hydrocephalus is a disease in which cerebrospinal fluid (CSF) accumulates in the ventricular system of the brain. Clinical therapy involves surgically implanting a catheter system to drain this fluid. These systems typically use a pressure-regulated valve system that diverts CSF into a cavity within the body for patients with chronic hydrocephalus. While the treatment is implanted into patients worldwide, its success is unsatisfactory, often requiring numerous revisions due to shunt malfunction. We have recently suggested that a continuous volume sensor may be an alternative approach for use in hydrocephalus treatment. This article highlights advancement of our novel device, which consists of parylene coated sensors with openings for electrode contacts. The instrumentation is miniaturized with the use of surface mount technology. In order to demonstrate the working principle of the technology, the feasibility of acute volume measurements was assessed in an animal model. 250 μl of CSF was removed from a hydrocephalic rat, and measurements are shown. Our vision of an improved therapy consists of incorporating this impedance based volume sensor with a controller and micropump for feedback control of CSF volume.