

Fatigue and Fracture of Medical Metallic Materials and Devices



M. R. Mitchell and K. L. Jerina
Editors

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Foreword

This particular ASTM International publication contains research manuscripts from the First Symposium — Fatigue and Fracture of Medical Metallic Materials and Devices that was sponsored by ASTM Committees E08 on Fatigue and Fracture and F04 on Medical Devices held in Dallas, TX, November, 2005. It was the intent of this conference to bring together technical experts in both disciplines, in order to initiate a dialogue between the two groups that would further our knowledge and understanding of the cyclic deformation, of most specifically, nitinol-based medical devices and the physical environment in which they are expected to survive for considerable periods of time. The ultimate goal of this interaction is intended to (1) define the environments (i.e. duty cycle deformation-time histories) in body-specific locations such as the superficial femoral artery, carotid, abdominal and thoracic arteries (2) develop constitutive expressions for the deformation response of nitinol via specific test methodologies and data analyses (3) develop the appropriate mechanics analyses for cumulative damage calculations and to ultimately (4) ascertain the fatigue lifetime of medical devices in the human body. To this end, standards must be developed to define the subject matter listed above.

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Overview

A conference held in Dallas, TX in November of 2005 addressed the unique thermal and mechanical properties of shape memory alloys (SMA's) and metallic medical materials and devices. Although the conference focused much attention on nitinol-based technologies, several other metallic medical materials and devices are included in the conference publications. The principle focus was on nitinol since these unique alloys offer the designer new dimensions in controlling the shape of devices used in medical and many structural applications. Shape memory devices such as valves, actuators, clutches and gaskets are proposed for monitoring units, drive systems and repair schemes. Biocompatible implanted medical devices rely on the hyperelastic response of these unique materials. Relative to conventional materials, little is known about the fatigue, fracture and deformation behavior of shape memory alloys particularly in a contemporary sense for fatigue lifetime predictions.

The primary intent of the conference was to provide a firm basis of fundamental mechanical response for development of ASTM standard procedures for determination of the constitutive relationships, the deformation behavior, the fatigue lifetime response and fracture behavior of metallic shape memory alloys. Also, the conference provided a forum for dissemination of knowledge and research on methodologies in the developments of constitutive models for fatigue and fracture behavior of metallic shape memory alloys. Such understanding and standards development are essential for determination of the *in situ* lifetime assessment of self-expanding medical devices that employ these unusual metallic materials. This ASTM STP features the work of knowledgeable and distinguished researchers in the emerging field of metallic shape memory alloys.

The contents of this STP elucidate on such topics as the metallurgical basics of martensitic transformations and fatigue behavior of nitinol as well as the influence of phase transformations on the mechanical properties and the thermoelastic transformational behavior of these alloys. Additional insight is provided on the mechanics and fatigue of stents as influenced by arterial deformations and a verification of the strain level determination for compressive-compressive response of nitinol. To improve recovery stress and recovery strain capabilities of nitinol it is necessary to facilitate deformation by martensitic transformational mechanisms while avoiding a risk of plastic deformation. Included herein is a manuscript illustrating that such goals can be effectively reached by judicious thermal-mechanical processing of this alloy. Also included herein is a description of a rotating-bending test technique for rapid determination of the completely reversed fatigue response of thin nitinol wires.

Additional information is provided on low plasticity burnishing to improve the fatigue performance of Ti-6Al-4V femoral hip stems, lessons learned from an existing heart valve design with failure rates that have been followed for over 20 years and a comparison of the corrosion-fatigue characteristics of Mn-Cr-Mo and Cr-Ni-Mn stainless steels.

Because of the considerable audience response to this topical matter and the interest of both ASTM Committees E08 on Fatigue and Fracture and F04 on Medical Devices, a Second Symposium on the Fatigue and Fracture of Metallic Medical Materials and Devices is being held in Denver, CO in May 2008 with co-sponsorship of SMST (Shape Memory and Superelastic Technologies). It is anticipated that with such co-sponsorship within ASTM as well as with SMST, the

premier professional societal group involved in nitinol research and dissemination of technical information, we will be able to develop meaningful and much needed standards for proper testing, design and lifetime predictions for these important medical materials.

Dr. M. R. Mitchell,
Northern Arizona University,
Flagstaff, Arizona

Prof. Kenneth L. Jerina,
Washington University at St. Louis,
St. Louis, Missouri

**SECTION I: PROCESSING, PROPERTIES
AND
ENVIRONMENT**



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