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Fatigue and Fracture of Medical Metallic Materials and Devices

2nd Volume

JAI Guest Editors

Kenneth L. Jerina
Michael R. Mitchell
Terry O. Woods
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Foreword

THIS COMPILATION OF THE *JOURNAL OF ASTM INTERNATIONAL (JAI)*, STP1515, *Fatigue and Fracture of Medical Metallic Materials and Devices, 2nd Volume*, contains only the papers published in JAI that were presented at a symposium in Denver, CO, on May 7, 2008 and sponsored by ASTM Committees E08 on Fatigue and Fracture and F04 on Medical and Surgical Materials and Devices.

The JAI Guest Editors are Professor K. L. Jerina, Washington University, St. Louis, MO, Professor M. R. Mitchell, Northern Arizona University, Flagstaff, AZ, Dr. Terry O'Riska Woods, USDA, Rockville, MD, and Mr. Brian T. Berg, Boston Scientific, Maple Grove, MN.

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Overview

The Second Symposium on Fatigue and Fracture of Medical Metallic Materials and Devices was held in Denver, Colorado, May 7, 2008 to address the unique thermal and mechanical properties of shape memory alloys (SMA's) and metallic medical materials and devices. ASTM Committees E08 on Fatigue and Fracture and F04 on Medical and Surgical Materials and Devices, in addition to Shape Memory and Superelastic Technologies (SMST), shared co-sponsorship of the Second Symposium. Approximately 100 attendees listened to 14 informative and entertaining presentations. Although the conference focused much attention on nitinol-based technologies, 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 SMA's, 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, deformation behavior, fatigue lifetime response, and fracture behavior of metallic SMA's. 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 medical metallic SMA's. 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 special technical publication (STP) features the work of knowledgeable and distinguished researchers in the emerging field of metallic SMA's. 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 crystallographic basis of deformation and fracture in nitinol, the mechanics and fatigue of stents as influenced by arterial deformations, and a verification of the strain level for determination of the mechanical response and fracture initiation in nitinol. Finite element analysis of stents and bench test results are described to determine fatigue to fracture lifetime. Multiaxial characterization methods to explore yield and failure envelops are reviewed and discussed. Methods are described for arterial deformation assessment and stent deformation determination in

femoral and carotid arteries. Standard coronary arterial geometry and duty cycles for use in life prediction methodologies are presented. Other topics include standards development regarding fatigue to fracture and the state of reporting systems for safety alerts and recalls of implanted devices.

The considerable audience response at the Symposium to this topical matter and the interest of ASTM Committees E08 on Fatigue and Fracture, F04 on Medical and Surgical Materials and Devices, and Shape Memory and Superelastic Technologies (SMST) underscored the need to develop meaningful and much needed standards for proper testing, design and lifetime predictions for this important class of medical materials.

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