WORKSHOP ON MEDICAL DEVICE STANDARDS UTILIZING COMPUTATIONAL MODELING

Sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices

November 5, 2019
Marriott Marquis Houston
Houston, TX

Workshop Chairmen:

Jeff Bischoff
Zimmer Biomet
Warsaw, IN, USA

Walter Schmidt
Stryker Orthopaedics
Mahwah, NJ, USA

Brian Choules
Embry-Riddle Aeronautical University
Prescott, AZ, USA

Jeff Sprague
Medtronic
Memphis, TN, USA

ABOUT THE WORKSHOP

The purpose of the workshop is to continue development of a path forward for Committee F04 standards that are principally based on computational methods (e.g. finite element analysis, computational fluid dynamics). A number of computational standards exist, and there are a number of active work items related to computational methods, that span multiple subcommittees within F04. With these standards, as well as the recently published ASME V&V40 standard on computational modeling of devices, it is expected that utilization of computational methods in support of medical device development will increase. There is value in ensuring a degree of harmonization of these efforts within ASTM F04 and ASME V&V40.

The intent of this workshop is to bring together thought leaders in the medical device modeling and standardization communities to review existing modeling-based standards including the motivation behind their development and current state of their usage, identify common challenges to creation, adoption and/or usage of modeling-based standards, and further develop a strategy for F04 standards in this space in the future.

TUESDAY, NOVEMBER 5, 2019

8:00 AM
Opening Remarks
Jeff Bischoff, Workshop Co-Chairman

SESSION 1:
ASTM MODELING STANDARDS – INITIATION, EVOLUTION AND CURRENT STATE

8:10 AM
Development and Critique of ASTM F2514 Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading
Brian Choules, BDC Laboratories, Wheat Ridge, CO, USA

8:25 AM
Development and Critique of ASTM Test Method Computational Corollaries - A Joint Reconstruction Historical Perspective
Walter Schmidt, Stryker Orthopaedics, Mahwah, NJ, USA

8:45 AM
Review of Current ASTM Orthopaedic Finite Element Analysis Standard Practices
Jeff Sprague, Medtronic, Memphis, TN, USA

SESSION 2:
ASME V&V40 – PHILOSOPHY AND PRACTICAL CONSIDERATIONS

9:00 AM
Introduction to ASME V&V40: Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices
Jeff Bischoff, Zimmer Biomet, Warsaw, IN, USA

9:20 AM
An End-to-End Example of the ASME V&V 40 Standard
Dana Coombs, Depuy Synthes, West Chester, PA, USA

9:40 AM
Using 3D Image-Based Methods for Assessing Mechanical Properties of an Additive-Manufactured Interbody Fixation Spinal Device: A Practical Experience with ASME V&V40
Ali Kiapour, 4WEB Medical, Frisco, TX, USA

10:00 AM BREAK

SESSION 3:
APPLICATIONS OF V&V40 TO ASTM MODELING STANDARDS – EXPERIENTIAL LEARNING

10:15 AM
Simulating F1800 to Evaluate Tibial Baseplate Strength
Mehul Dharia, Zimmer Biomet, Warsaw, IN, USA

10:35 AM
Comparison of Mechanical Testing to FEA of Titanium Straight Plate Under Four-Point Bending Load
Victoria Trafka, Engineering & Quality Solutions, Inc., Colorado Springs, CO, USA

10:55 AM
ASME V&V 40.4 Calculation Verification Working Group for Computational Modeling of Medical Devices
Ismail Guler, Boston Scientific, Maple Grove, MN, USA

11:15 PM
Incorporating the V&V40 Standard into a Revision of ASTM F2514
Brandon Lurie, W. L. Gore & Associates, Flagstaff, AZ, USA

11:35 AM
Discussion & Wrap-Up
Walter Schmidt, Workshop Co-Chairman

11:45 AM LUNCH (on your own)

SESSION 4:
FDA PERSPECTIVES ON MODELING STANDARDS

1:00 PM
Development of Best Practices for Finite Element Analysis of Spinal Fusion Cages
Andy Baumann, FDA, Silver Spring, MD, USA

SESSION 5:
CO-DEVELOPMENT OF TEST AND MODELING METHODS

1:40 PM
Co-Development of Tibiofemoral Contact Area and Contact Pressure Methods
Walter Schmidt, Stryker Orthopaedics, Mahwah, NJ, USA
Michael Lowry, B-one ORTHO, Cedar Knolls, NJ, USA

1:55 PM
FEA and Experimental Verification for Ceramic Knee Testing
Roman Preuss, CeramTec GmbH, Plochingen, Germany

2:10 PM
A Proposed Method to Determine the Opening-Mode Fatigue Strength of a Total Knee Femoral Component
Yanming Zheng, Smith & Nephew, Memphis, TN, USA

2:25 PM
Predicting and Measuring Strain in a Nitinol Cardiovascular Device Using Digital Image Correlation to Validate FEA
Kenny Aycock, FDA, Silver Spring, MD, USA

2:40 PM BREAK

SESSION 6:
APPLICATIONS OF V&V40 TO ASTM TEST STANDARDS – EXPERIENTIAL LEARNING

2:55 PM
Static and Dynamic Evaluation of Metallic Orthopaedic Bone Plates and Screws Using Finite Element Analysis Methods
Mike Bushelow, Depuy Synthes, West Chester, PA, USA

3:10 PM
Simulating ASTM F2028-17 to Evaluate Motion in Reverse Shoulder Arthroplasty
Mehul Dharia, Zimmer Biomet, Warsaw, IN, USA

3:25 PM
A Test Method Proposal for the Calibration and Uncertainty Quantification of Nitinol Material Properties in Finite Element Models
Harshad M. Paranjape, Confluent Medical Technologies, Fremont, CA, USA

3:40 PM
Application of V&V40 to Computational Modeling of Axial Fatigue of Vascular Stents
Brian Choules, BDC Laboratories, Wheat Ridge, CO, USA

3:55 PM
Standards and Guidance Documents Enabling Broad Acceptability of Computational Representation of ASTM F2182 Standard
Payman Afshari, Depuy Synthes, Raynham, MA, USA

4:10 PM
Assessing Computational Models of Centrifugal Blood Pump Performance
Marc Horner, ANSYS, Inc., Evanston, IL, USA

4:25 PM
Discussion and Wrap-up
Jeff Bischoff, Walter Schmidt, Brian Choules, Jeff Sprague
Workshop Co-Chairmen

5:00 PM WORKSHOP ADJOURNS