Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?

Sponsored by Committee F04 on Medical and Surgical Material Devices

November 16, 2010
Grand Hyatt San Antonio
San Antonio, Texas

Symposium Co-chairs:
Jove Graham
U. S. Food and Drug Administration (FDA)
Danville, PA
USA

David B. Spenciner
DePuy Mitek
Raynham, MA
USA

Laura M. Jensen
Zimmer Spine
Minneapolis, MN
USA

Paul Anderson
University of Wisconsin-Madison
Madison, WI
USA

TUESDAY, NOVEMBER 16, 2010

8:00 AM
Welcome Remarks
Jove Graham and David B. Spenciner, Symposium Co-Chairs

8:10 AM
Student Paper Competition Winner:
Derivation of Clinically Relevant Boundary Conditions Suitable for Evaluation of Chronic Impingement of Lumbar Total Disk Replacement: Application to Standard Development
S. Rundell, Drexel University, Philadelphia, PA, USA
SESSION 1: INTERBODY FUSION DEVICES

8:25 AM  
**Kinematic Stability Evaluation of Spinal Fusion Device**  
T. Hansen, Biomechanics R&D LLC, Tempe, AZ, USA; B. Hildebrand, Spinal Elements, Carlsbad CA, USA

8:38 AM  
**A New Surrogate Model for Testing Interbody Fusion Cage Devices**  
A. Au, H-L Ploeg, A. Aiyangar, and P. Andersen, University of Wisconsin-Madison, Madison, WI, USA

8:51 AM  
**ASTM 2077-03 Static Compression-Shear Fixture Variations**  
C. W. Metheny, Medtronic Spinal and Biologics, Memphis, TN, USA

9:04 AM  
**Mechanical Comparison of an Interbody Device Tested in Compression-Shear to the ASTM F2077-03 Standard of 45 and at the Proposed 27 Shear Angle**  
S. Summy, J. Turner, D. Woods, and M. Schroeder, Medtronic Spinal and Biologics, Memphis, TN, USA

9:17 AM  
**The Effect of Foam Block Height & Density in Subsidence Testing**  
R. A. Konz, Zimmer Spine, Minneapolis, MN, USA

9:30 AM  
**Questions and Answers #1**

9:45 AM  
**BREAK**
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?

SESSION 2: DISC AND NUCLEUS DEVICES

Session Chair: D. B. Spenciner
DePuy Mitek
Raynham, MA USA

10:00 AM
**Continuous Daily Living Motion of the Neck Compared to ASTM F2423.05 Testing**
P. Anderson, University of Wisconsin-Madison, Madison, WI, USA

10:13 AM
**Motion of Lumbar Spine during Daily Living Compared to ASTM F2423.05 Testing**
P. Anderson, University of Wisconsin-Madison, Madison, WI, USA

10:26 AM
**TDR Wear Sensitivity to Device Design and Input Kinematics**
P. Hyde, R. Vicars, J. Fisher, and R. Hall, Institute of Medical and Biological Engineering, Leeds, UK

10:39 AM
**The Impact of Frequency on Dynamic Biomechanical Testing of a Viscoelastic Total Artificial Disc**
R. Blice and K. Zimmers, AxioMed Spine Corporation, Garfield Heights, OH, USA

10:52 AM
**Fatigue and Wear Evaluation of Nucleus Pulposus Replacements**
R. Siskey and M. Villarrga, Exponent, Philadelphia, PA, USA

11:05 AM
**Questions and Answers #2**

POSTER SESSION

11:20 AM    Posters will be displayed for viewing
(Poster titles and presenters names are listed at the end of the program)

12:00 PM    LUNCH (On Your Own)
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?

SESSION 3: IN VITRO TESTING METHODS

Session Chair: L. M. Jensen
Zimmer Spine
Minneapolis, MN USA

1:15 PM
Development of a More Physiological Loading Environment for Spine in Vitro Flexibility Testing
C. A. Niosi, R. E. Thompson, and M. Fröhlich, Zimmer GmbH, Winterthur, Switzerland

1:28 PM
Primary Stability of a Total Disc Replacement Device
T. Nydegger, R. E. Thompson, J. Seebeck, and M. Fröhlich, Zimmer GmbH, Winterthur, Switzerland; and O. Schwarzenbach, Das Rueckenzentrum, Thun, Switzerland

1:41 PM
Inter-Laboratory Variability in In Vitro Spinal Segment Flexibility Testing
A. Freeman, D. J. Wheeler, A. L. Ellingson, D. J. Nuckley, J. M. Buckley, and J. K. Sheer, Excelen Center for Bone and Joint Research, Minneapolis, MN, USA

1:54 PM
In Vitro Study to Evaluate the Center of Rotation (COR) Following Dynamic Stabilization Using Different Pedicle Screw Based Dynamic Posterior Stabilization Systems (PDS) - Recommendation for the Implementation of a Standardized COR In ASTM F2624
C. Wing and S. Krüger, Implant Systems, Center Valley, PA, USA; J. Beger and C. Schilling, Aesculap AG, Tuttlingen, Germany

2:07 PM
Questions and Answers # 3

2:20 PM  BREAK
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?

SESSION 4: LONGITUDINAL SYSTEMS 1

Session Chair: P. Anderson  
University of Wisconsin-Madison  
Madison, WI USA

2:30 PM
Shear Fatigue Testing Based on the Vertebrectomy Model  
L. M. Jensen and J. M. Dawson, Zimmer Spine, Minneapolis, MN, USA

2:43 PM
Fatigue Performance of Peek Spinal Fusion Rod Systems Using a Modified ASTM F1717 Approach  
R. Siskey, J. Day, and S. Kurtz, Exponent, Philadelphia, PA, USA

2:56 PM
The Use of a Single-Level Construct Model to Evaluate Non-Metallic Flexible Rods  
R. Loke, J. L. Turner and J. Prevost, Medtronic Spinal and Biologics, Memphis, TN, USA

3:09 PM
Vertebrectomy Model for the Assessment of Fusionless Scoliosis Growth Rods  
J. Shorez and J. L. Turner, Medtronic Spinal and Biologics, Memphis, TN, USA

3:22 PM
Static Evaluation of Pedicle Screw Spinal Constructs to the ASTM Standard: A Comparison of Multiple Test Laboratories  
D. B. Spenciner, DePuy Mitek, Raynham, MA, USA

3:35 PM
Questions and Answers # 4

3:50 PM  BREAK
SESSION 5: LONGITUDINAL SYSTEMS II

Session Chair:  P. Anderson
University of Wisconsin-Madison
Madison, WI USA

4:05 PM
Peek and Commercially Pure Titanium Rod ASTM F1717 Construct Testing with Strain-Gauged Multi-Axial Pedicle Screws and Interbody Devices
J. L. Turner and C. B. Murrell, Medtronic’s Spinal and Biologics Business, Memphis, TN, USA; and D. Paller, Warren Alpert Medical School of Brown University, Providence, RI, USA

4:18 PM
ASTM F2624 - Evaluating an Alternate Fixture for Testing Extra Discal Motion Preserving Implants

4:31 PM
Dynamic Testing of Pedicle Screw Based Dynamic Posterior Stabilization Systems (PDS) Using an Alternative Test Setup to ASTM F2624
C. Wing, Aesculap Implant Systems, Breinigsville, PA, USA; S. Krüger, and J. Berger, Aesculap AG, Tuttlingen, Germany; D. A. Lissy, C. J. Lissy, and M. C. Andersen, Empirical Testing Corporation, Colorado Springs, CO, USA

4:44 PM
Effect of Tightening Torque on ASTM F1798 Gripping Capacity
S. Vadapalli, Medtronic Spinal and Biologics, Memphis, TN, USA

5:10 PM
Questions and Answers # 5

5:25 PM
Group Work: Summary and Gap Analysis
Laura M. Jensen and Paul Anderson, Symposium Co-Chairs

5:45 PM
Closing Remarks
Jove Graham and David B. Spenciner, Symposium Co-Chairs

6:00 PM  SYMPOSIUM ADJOURNS
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?

POSTER PRESENTATIONS

1.) The Contribution of Muscle Forces to Spinal Loads
   A. Rasmussen and M. de Zee, Aalborg University, Aalborg, Denmark; and S. Dendorfer, AnyBody Technology, Aalborg, Denmark

2.) The Influences of Screw-Fixture Interface on the Torsion Fatigue Corpectomy Test of Posterior Cervical and Upper Thoracic Fixation System
   L. Wolocko, Zimmer Spine, Minneapolis, MN, USA

3.) Effect of Loading Environment on the Kinematics of Dynamically Stabilised Cadaveric Spines
   R. E. Thompson, Zimmer GmbH, Winterthur, Switzerland

4.) Additional Testing for Posterior Cervical Implant Characterization: Biomechanical Human Cadaveric Flexibility Protocols
   B. Cheng, W. C. Welch, and D. Whiting, Allegheny General Hospital - Drexel, Mars, PA, USA

5.) ASTM F1717 - Fixture Variations When Evaluating F1717 Constructs in Torsion Axial Load, Sagittal Plane Rotation Constraints, and Test Direction
   D. A. Lissy, C. J. Lissy, and M. C. Anderson, Empirical Testing Corp., Colorado Springs, CO, USA

6.) Developing Clinically Relevant Impingement Test Methodology for Fixed and Mobile Bearing Lumbar Total Disc Replacements
   R. L. Siskey, S. Rundell, and S. Kurtz, Exponent, Philadelphia, PA, USA; and G. Hill and J. Peck, U.S. Food and Drug Administration, Silver Spring, MD, USA

7.) Motion-Preserving Spine Implants Under Traumatic Loading Conditions
   P. A. Cripton, C. F. Jones, and C. Van Toen, University of British Columbia, Vancouver, Canada; E. Itshayek, Hadassah University Hospital, Jerusalem, Israel; and C. Demetropoulos, University of Toledo, Toledo, Ohio, USA

8.) ASTM F2624 - Evaluating Alternate Fixtures for Flexion/Extension, Lateral Bending, and Axial Rotation Testing of Extra Discal Motion Preserving Implants

9.) The ASTM F1717 Screw-Block Assembly: What Matters When?
   K. Warden, Chesterland, OH, USA

10.) Fixture Variations When Evaluating F1717 Construct Stiffness: Pin Diameter and Material
    V. Shah, Empirical Testing Corporation, Colorado Springs, CO, USA