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

JAI Guest Editors:

**Laura M. Jensen
David B. Spenciner
Jove Graham
Paul A. Anderson**

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Foreword

THIS COMPILATION OF THE JOURNAL OF ASTM INTERNATIONAL (JAI), STP1535 *Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?* contains papers that were presented at a symposium in San Antonio, TX, on November 16, 2010 and sponsored by ASTM Committees F04 on Medical and Surgical Materials and Devices and F04.25 on Spinal Devices.

The Symposium Chairs and JAI Guest Editors are Laura M. Jensen, MS, Zimmer Spine, Minneapolis, MN, David Spenciner, PE, ScM, MBA, DePuy Mitek (Johnson & Johnson), Raynham, MA, Jove Graham, PhD, Geisinger Center for Health Research, Danville, PA, and Paul Anderson, MD, University of Wisconsin-Madison, Madison, WI.

Contents

Overview	vii
Acknowledgments	xi

Interbody Fusion Devices

Kinematic Stability Evaluation of Spinal Fusion Devices by Synthetic FSU Model T. Hansen	3
Comparison of Two Bone Surrogates for Interbody Device Subsidence Testing A. K. Aiyangar, A. G. Au, P. A. Anderson, and H.-L. Ploeg	15
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately? C. W. Metheny	25
Errata—Title Correction, ASTM F2077-03 Static Compression–Shear Fixture Variations . . .	33

Disc and Nucleus Devices

Comparison of Daily Motion of the Cervical and Lumbar Spine to ASTM F2423-11 and ISO 18192-1:2011 Standard Testing D. Cobian, B. Heiderscheit, N. Daehn, and P. A. Anderson	37
Wear Simulation of Total Disc Arthroplasties: Sensitivity to Device Design and Test Parameters P. Hyde, R. Vicars, J. Fisher, and R. Hall	51
How Frequency Affects Fatigue Testing of an Artificial Disc With a Viscoelastic Polymer Core R. L. Blice, K. B. Zimmers, and R. Linovitz	66
Derivation of Clinically Relevant Boundary Conditions Suitable for Evaluation of Chronic Impingement of Lumbar Total Disk Replacement: Application to Standard Development S. A. Rundell, J. S. Day, J. Isaza, R. Siskey, D. MacDonald, and S. M. Kurtz	73

In vitro Testing Methods

Development of a More Physiological Loading Protocol for Spine In Vitro Flexibility Testing C. A. Niosi, R. E. Thompson, and M. Froehlich	97
Primary Stability of a Dynamic Artificial Disc Tested in a Human Cadaveric Model R. E. Thompson, O. Schwarzenbach, J. Seebeck, and M. Fröhlich	119
Rationale of a Test Setup with a Defined COR for Extra-Discal Motion-Preserving Implants with a Low Implant Stiffness C. Schilling, S. Krüger, J. Beger, and C. Wing	134
Biomechanical Cyclical Loading on Cadaveric Cervical Spines in a Corpectomy Model B. C. Cheng, D. J. Cook, M. Cuchanski, S. M. Pirris, and W. C. Welch	154

Longitudinal Systems

A Method to Test Anterior-Posterior Construct Shear Fatigue Based on the Vertebrectomy Model	
L. M. Jensen and J. M. Dawson	171
The Use of a Single-Level Construct Model to Evaluate Nonmetallic “Flexible” Rods	
I. Rubin de la Borbolla, J. Prevost, C. Scifert, and J. Turner	181
Vertebrectomy Model for the Mechanical Assessment of Fusionless Scoliosis Growth Rods	
J. P. Shorez	200
Static Evaluation of Pedicle Screw Spinal Constructs to the ASTM Standard: A Comparison of Multiple Test Laboratories	
D. Spenciner	210
ASTM F2624-07—Evaluating an Alternate Fixture for Testing Extra Discal Motion Preserving Implants	
M. C. Anderson and C. J. Lissy	222
ASTM F2624—Evaluating Alternate Fixtures for Flexion/Extension, Lateral Bending, and Axial Rotation Testing of Extra Discal Motion Preserving Implants	
M. C. Anderson and D. A. Lissy	234
Symposium on Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately? Effect of Tightening Torque on ASTM F1798 Axial Gripping Capacity	
S. Vadapalli and D. L. Woods	246
Errata—Title Correction, Effect of Tightening Torque on ASTM F1798 Axial Gripping Capacity	
.	254
Comparison of Self-Drilling and Self-Tapping Cervical Spine Screws Using ASTM F543-07	
R. J. Konz, L. M. Jensen, and B. L. Kincaid	255
Fixture Variations When Evaluating ASTM F1717 Construct Stiffness: Pin Diameter and Material	
V. G. Shah, M. C. Anderson, D. A. Lissy, and C. J. Lissy	273
Author Index	287
Subject Index	289

Overview

Background

“The field of spinal implants continues to be a dynamic one. New designs of modular constructs and components used in spinal fusions and the development of spinal implants intended to allow or maintain motion are major areas of change [I].”

These words described the state of affairs for ASTM Subcommittee F04.25 on Spinal Devices in 2001, when a symposium was held on the subject of “Spinal Implants: Are We Evaluating Them Appropriately?” This description still holds true ten years later, even after having revised nearly a dozen standards and created several more. Clinicians are able to implant a bewildering array of spinal devices, some meant to maintain certain physiological motions while others focus on achieving a solid fusion mass. At the same time that much of the growth in the spinal device market is being driven by the development of new, dynamic implants, the business environment in the spine world is quite a bit different now than it was a decade ago. The atmosphere is harsher, including such well-documented factors as increased price pressure, lowered prospects for industry growth, greater difficulty securing reimbursement for emerging technologies, device failures, and a more difficult fundraising environment. However, even with these challenges, we still see reasons for optimism. The members of ASTM F04.25, including manufacturers, clinicians, academics, and regulatory bodies, are working together to develop more sophisticated methods for the evaluation of spinal devices. Improved test methods help us better understand technologies and quantify improvements. With better measurements, we can design better spinal devices which benefit the ultimate customers—the patients.

On November 16, 2010, the ASTM International Committee F04 on Medical and Surgical Materials and Devices and F04.25 sponsored a symposium titled, “Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately?” The primary goal of the symposium was to invite discussion among the 113 attendees regarding how spinal devices are evaluated worldwide. There were 25 presentations and ten posters (of nearly 50 submitted) from researchers representing the USA and five other countries. All presenters were encouraged to submit manuscripts for inclusion in this publication. From these efforts, the 20 manuscripts which make up this STP emerged. The peer review process was stringent and we hope that you find this compilation to be a useful resource in the years ahead. The symposium papers published with the current STP can be loosely grouped into four subjects:

interbody fusion devices, disc and nucleus devices, *in vitro* testing methods, and longitudinal systems.

Interbody Fusion Devices

The goal of this session was to examine several test parameters used in the evaluation of interbody spacers and other fusion devices (ASTM F2077). This represents a maturation of the field in that at the first symposium, this session mainly dealt with the clinical relevance of the test methods. Papers covering variations in the fixture design, bone analog material, and mode of testing are presented.

Disc and Nucleus Devices

At the first symposium, testing of artificial discs was in its infancy, but the breadth of the current papers show an evolving sophistication to the test engineer's knowledge. Topics include the frequency dependence of polymeric core discs, sensitivity of wear and impingement tests to input parameters, and a ground-breaking comparison of human *in vivo* ranges of motion to the parameters outlined in ASTM F2423, "Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses. [2]"

In vitro Testing Methods

This session represented a departure from the previous symposium. Despite that fact that *in vitro* kinematic testing of spines has been performed for decades, no current effort exists within ASTM for an *in vitro* testing standard (ISO is currently developing N438, "Flexibility Testing of Spinal Segments"). Several papers are presented that either mechanically test spinal devices using human spinal segments as the test medium or develop a more physiological loading protocol.

Longitudinal Systems

This topic was expanded to two sessions in the symposium due to the greater number of submissions and higher level of interest. This likely indicates the overarching importance of ASTM F1717 "Standard Test Method for Spinal Constructs in a Vertebrectomy Model" and its related standards to this subcommittee in particular and the spinal industry as a whole. Several papers address various aspects of the standard including suggested improvements. Other papers describe innovative uses for the standard in evaluating new types of rods technologies.

Significance and Future Work

The 2010 symposium, with its Question & Answer sessions and subsequent discussion at the regularly scheduled subcommittee meeting, revealed many areas in which Subcommittee F04.2's standards could be improved. This process of cleaning up inconsistencies has already begun in earnest. As was noted following the 2001 symposium, none of these changes are major, but rather they appear to be a matter of improving clarity and consistency of interpretation.

One sure sign of a maturing testing technology is the community exerting effort to increase the accuracy and repeatability of the measurements. Interestingly, ASTM F04.25's recent interlaboratory study to establish the precision and bias of the methods described in F1717 [3] is currently being repeated with a different design of fusion devices. We look forward to the continued improvement of spinal device testing methods so that users of F04.25's standards can continue to effectively evaluate spinal implants. Relatively mature standards, such as F1717 and F2077 are actively being supplemented by additional standards concerning a wide variety of innovative spine solutions. Current standards activities within F04.25 include impingement of motion preserving technologies, subsidence of interbody fusion devices, evaluation of annular repair, and combination cagescrew devices.

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Laura, Dave, Jove, and Paul



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