Spinal Implants:

ARE WE EVALUATING THEM APPROPRIATELY?

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Foreword

The Symposium on *Spinal Implants: Are We Evaluating Them Appropriately?* was held in Dallas, Texas on 6–7 November 2001. ASTM International Committee F04 on Medical and Surgical Materials and Devices was its sponsor. Symposium chairmen and co-editors of this publication were Mark N. Melkerson, M.S.; John S. Kirkpatrick, M.D.; and Steven L. Griffith, Ph.D.

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To make technical information available as quickly as possible, the peer-reviewed papers in this publication were prepared "camera-ready" as submitted by the authors.

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Overview*

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. Current implants allow the surgeon to tailor the spinal device used to impact the patho-anatomy confronted on the operating table. The multiple implant options also present some interesting problems to the designing engineers, surgeons, researchers, and regulatory entities in testing and evaluating the appropriateness of the devices' designs and/or materials in a given patient or population of patients. In May 1989, ASTM Committee F04, Medical and Surgical Devices and Materials, conducted a workshop on the subject of Spinal Implant testing and initiated standards development for spinal implants with the establishment of Subcommittee F04.25.

Members of this subcommittee (F04.25 of the ASTM Committee F04), that include industry, academic, and private concerns, have continued to collaborate on the development of standardized test methods evaluating numerous mechanical characteristics of components, subassemblies, and constructs of spinal systems. Existing ASTM standards published at the time of the symposium included: F1717-96, "Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy Model"; F1798-97 "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants"; F1582-98 "Standard Terminology Relating to Spinal Implants"; and F2077-00 "Static and Dynamic Test Methods for Intervertebral Body Fusion Devices." Standards under development included Static and Dynamic Test Methods for Spinal Disc Replacement Devices.

These published and draft standards are intended to be applied to constructs, assemblies, and subassemblies of posterior hook, wire, and pedicle screw spinal systems, anterior spinal systems, intervertebral body cages, total and partial spinal disc replacements, and vertebral body replacements for the cervical, thoracic, and lumbar levels. After several years of clinical experience and standards utilization, the subcommittee deemed it prudent to compare clinical results from these various devices with the results from standardized mechanical testing, failure analyses, and device retrieval analyses. This would help to determine whether current standards and drafts are relevant. Correlation of bench and clinical results would determine whether standards are adequately addressing each of the real or perceived potential failure modes seen clinically. Results from these analyses could then be used to improve existing standards or suggest new ones. Other goals included determining the critical clinical loading parameters and determining the most relevant mechanical testing performance characteristics.

In November 2001, ASTM Committee F04 on Medical and Surgical Materials and Devices and the AAOS (American Academy of Orthopaedic Surgeons) Committee on Biomedical Engineering sponsored a symposium on the subject of "Spinal Implants: Are We Evaluating Them Appropriately?" The objectives of the symposium were to assess our knowledge base at that time for testing of spinal implants, improve the published standards and draft standards under development,

* This overview represents the professional opinion of the authors and is not an official document, guidance or policy of the U.S. Government, the Department of Health and Human Services, or the Food and Drug Administration, nor should any official endorsement be inferred.

identify, and encourage new standards activities, and determine whether the standards were adequately predicting clinical experience. The symposium also continued the global harmonization efforts of the F04.25 Spinal Implant Subcommittee by seeking out participation of international presenters, researchers, and manufacturers. The symposium papers published here evaluate the experience available at that time for testing spinal constructs, spinal device components, subassemblies and interconnections; cages and interbody fusion devices; and functional spinal devices and/or artificial discs. Also considered in this symposium were suggestions for future directions for test methods, models, fixtures, or needed improvements. All presenters were encouraged to submit their work for inclusion in this publication. The editors applied strict peer review criteria utilizing independent qualified reviewers, but in order to facilitate prompt dissemination of the material, the editorial requirements were very liberal. This publication presents those topics whose authors met the peer review and editorial requirements of the editors.

Spinal Constructs

The intent of this section was to present developments and results associated the application of ASTM F1717-96 test methods. Papers described the clinical results from spinal constructs having marketing clearance or approval using these test methods, addressed device failure modes, and examined corrosion seen with explanted devices. Other papers evaluated impact on results due to gauge length used in tests, mobility or constraint of the test blocks, and use of transverse rod connection. These issues continue to be of particular interest in the improving of the existing spinal construct test methods.

Spinal Device Components, Subassemblies, and Interconnections

The developments of a new component or modifications to existing components of a construct do not necessarily require retesting of the entire construct. Instead, only the component or sub-assembly needs to be tested. ASTM F1798-97, the test methods and draft test methods for components, provided the background for this section. Papers describing the impact from application of different transverse connector designs on clinical outcomes are included. Other papers evaluated impact on bench testing results due to protection of the longitudinal member, to the anchoring materials, gauge length used in tests, mobility or constraint of the test blocks, and use of transverse rod connection. The issues identified during this session of the symposium related to the spinal components, subassemblies, and interconnections standards and are likely to be considered in future review and revision of these test methods.

Interbody Spacers and Intervertebral Body Fusion Devices

Standards efforts have not only focused on spinal fusion constructs attaching to the anterior and posterior spine, but have also included interbody spacers and other devices. The intent of this section was to present developments and results associated the application of ASTM F2077-00 test methods for intervertebral body fusion devices (spacers and fusion cages). One paper described the clinical results from lumbar interbody fusion devices and examined the causes of some of these devices that extruded. The remaining papers compared strength testing methodologies and evaluated the usefulness of pull-out or push-out testing for spinal cages. The issues discussed in this session of the symposium have led to the proposed revision of F2077-00 to exclude push-out testing and continue to be of particular interest in the improvement of the existing intervertebral body fusion device test methods.

Functional Spinal Devices and/or Artificial Discs

Recent standards development efforts have also been initiated for those devices that are not necessarily intended to fuse the spine. The intent of this section was to present developments associated with the application of draft ASTM test methods for disc replacement prostheses. The remaining presentations in this session of the symposium examined comparative cadaveric testing, durability testing, and alternative test methods for spinal constructs intended for posterior stabilization without fusion. The issues identified in this session of the symposium provide the basis of further development and refinement of draft standards for functional and motion preserving spinal devices.

Suggested Test Methods, Models, Fixtures, or Needed Improvements

Addressing today's limitations and tomorrow's concerns in spinal implants standards was the intent of this section. Papers describing the results from alternative models for fusion, non-fusion, or functional spinal implants are discussed in this section. The remaining presentations in this session of the symposium examined the impact on testing due to preload, block design, and material properties. The issues identified in this session of the symposium provide the basis of future development and refinement of existing, draft, and yet to be developed standards for spinal implants. The subcommittee plans to further investigate these issues.

Significance and Future Work

The symposium presentations and publications demonstrated the appropriateness and limitations of the existing and draft standards for spinal implants and identified many potential improvements. While the magnitude of some of these issues raised, like corrosion, remains unquantified, they may, at a later date, present a reason to alter the scientific wisdom expressed here. While changes to improve existing and draft standards have been initiated or are justified, none of the changes appear to be extreme. Future areas to be considered by Subcommittee F 04.25 should include determining the critical clinical loading parameters thus determining the most relevant mechanical testing performance characteristics, and examining the mechanistic interaction of these implants with anatomy and physiology.

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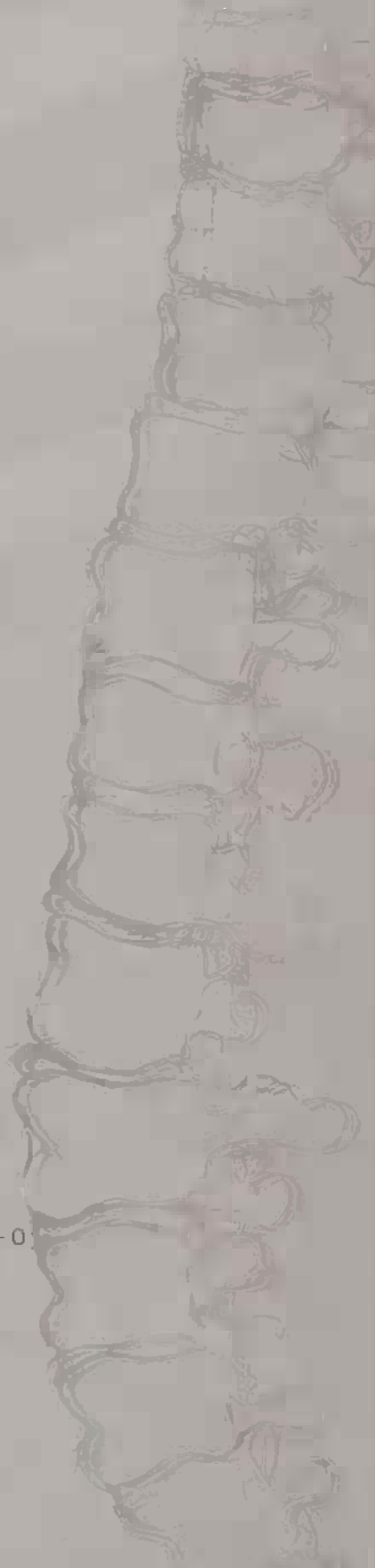

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