Foreword

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As the treatment of spinal disorders evolves to include therapies that preserve motion, there is a heightened need to better understand these new technologies. Currently, the majority of motion-preserving implants incorporate components that articulate against each other; total disc arthroplasty is the most common example. From a design perspective, the requirements for an implanted medical device include host biocompatibility, mechanical properties consistent with the specific application in the body, and long-term stability under physiological conditions. Devices for motion preservation involve an additional level of complexity in that they must also be engineered with the appropriate wear resistance.

Techniques to evaluate the biotribological (wear) performance of articulating implants have evolved over the past half-century in the general orthopaedic literature, but have only gained visibility in the spine community during the last decade. It is thus important to assimilate the historical knowledge from the area of hip and knee arthroplasty in the context of the spine, considering that the spine is a more complex set of joints with unique sets of physiological and biomechanical boundary conditions. An additional level of complexity is introduced by the vastly different loading and kinematic conditions associated with the cervical, thoracic, and lumbar regions of the spine. A review of the current state-of-the-art in biotribological testing is provided in this issue, because the understanding of biotribological principles is essential in the design of motion preservation devices for the spine.

From the perspective of implant performance in vivo, devices that incorporate articulating parts will generate wear, the etiology of which is complex and a function of factors such as implant material, implant design, implant positioning in situ, and patient-specific factors and activities that affect biomechanical loading and kinematics. To understand the long-term clinical value proposition for motion preservation in the spine compared with the historical gold standard of fusion, it is important to understand how the body responds to these devices over time. Central to device biocompatibility are 2 key areas of science related to wear particle characterization and the host response to wear particles. First, the ability to identify and characterize wear particles is essential in understanding the specific wear mechanisms at play in a specific implant design. Furthermore, an understanding of the nature of wear particle characteristics is also important as a prerequisite to animal studies that are often required as part of the preclinical tests in regulatory submissions for motion preservation devices. Second, understanding the specific response of the host to these wear particles and their by-products provides not only information important to the implant designer, but also informs clinical decision-making from the standpoint of appropriate implant design and implant material selection for a specific patient. These 2 areas of science are complex, and reviews of leading-edge thought for wear particle analysis and host response to wear particles are provided in this issue.

Just as clinical outcomes provide the practical validation for the performance of a specific implant, the analysis of retrieved devices and periprosthetic tissues provides valuable feedback on the reasons for the in vivo success or failure of a specific device in situ. A well-designed program for implant retrieval and analysis is thus critical in the life cycle management of an implant, as it inevitably drives the research and development process towards medical devices that ultimately result in better patient care. This issue of the *SAS Journal* includes a comprehensive discussion of the elements of a rigorous explant program.

Finally, as the spinal community is witnessing the development of novel technologies to provide patients with alternatives to fusion, the level of sophistication in techniques to evaluate the mechanical performance of these devices is also being elevated necessarily. In many cases, the traditional in vitro testing methods are not themselves sufficient for the full and comprehensive preclinical evaluation of new implants. An understanding of what testing standards are, how they are developed, and what they mean has implications from an implant design perspective. Standards also provide the spine surgeon with insight on the level of rigor with which these technologies are evaluated. The current testing standards and the process by which testing standards are developed in one organization are described in this issue.

This issue thus comprises a collection of review papers authored by some of the world's leading authorities and reflects the state of current scientific knowledge related to motion-preserving spinal implants. The topics of these reviews are highly dynamic areas of science, evolving as quickly as the technologies, devices, and therapies to which they apply. For the spine researcher, engineer, and allied health professional, this issue provides an overview of the foundational scientific activity in which you are all engaged on a daily basis. For the spine surgeon, it hopefully provides a relevant review of some of the nuances in the design,

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testing, analysis, and performance of motion-preservation devices, and forms a basis for the critical assessment of implant technologies currently available for the treatment of degenerative spine disease.

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