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The fundamentals of biotribology and its application to spine arthroplasty

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Abstract

The biological effect of wear of articulating surfaces is a continued concern with large joint replacements and, likewise, of interest for total disc replacements. There are a number of important biotribological testing parameters that can greatly affect the outcome of a wear study in addition to the implant design and material selection. The current ASTM and ISO wear testing standards/guides for spine arthroplasty leave many choices as testing parameters. These factors include but are not limited to the sequence of kinematics and load, phasing, type of lubricant, and specimen preparation (sterilization and artificial aging). The spinal community should critically assess wear studies and be cognizant of the influence of the selected parameters on the test results.

Keywords: Wear; Spine; Metal-on-metal; Metal-on-polymer; Arthroplasty; Total disc replacement

The bone and joint sequelae associated with wear of articulating surfaces are continuing concerns of total joint replacement, and are similarly highlighted for total disc replacements (TDR). For TDRs, this focus is primarily based on the expectations of even longer implantation lifetimes because of the implantation in younger patients than total joints, difficulties with anterior revision surgery, and the presence of periprosthetic neural elements. Although the literature helps to avoid past total joint errors and accelerate designs, research is still needed to adapt this technology to spinal motion preservation. Because there are gaps in our understanding of biomechanics and wear behavior of TDRs, variations in test methods have resulted. Standardized methods are being adopted, but the variety in spinal motion devices has prompted manufacturers to customize wear testing techniques. This can lead to concerns about the relevance of some test methods. A thorough discussion of total disc wear testing methodology may help compare wear test methods and, therefore, interpret results in terms of test validity. Although not within the scope of this paper, the biocompatibility of wear debris, which depends on particle size, shape, and composition, is a critical factor in interpreting wear test results. Wear rates of devices with different materials cannot be directly compared due to different biological response, particle portability, and biological byproducts.

The biotribological performance of devices depends on many factors, including implant inputs, such as bearing materials (metals, ceramics, polymers, and elastomers) and bearing design, and test conditions, such as, applied motions, loads, and fluid environment. In general, soft bearing wear, such as with polyethylene and other polymers (eg, poly[aryl-ether-ether-ketone] [PEEK]), tends to be dominated by adhesive wear while metal-on-metal (MOM) bearing wear, with cobalt alloy or stainless steel, is dominated by abrasive and surface fatigue wear. Wear mechanisms determine the type of damage, volume of wear, wear rate, particle size, and overall trends such as steady-state behavior and run-in, and can be sensitive to test conditions. For example, cyclic, unidirectional (reciprocating curvilinear) motions represent the greatest challenge for MOM bearings, because of roughening due to abrasive wear,[1,2] but the least challenge for polyethylene bearings due to polymer chain alignment.[3,4]

Wear test methods must also consider bearing kinematics. Ideally, devices are cycled so that they accurately replicate implanted motion patterns, which requires careful fixturing and test frame design. For conforming, fixed center

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of rotation (COR) devices such as the ProDisc-L Total Disc Replacement (Synthes, West Chester, PA) and Maverick Artificial Disc (Medtronic, Memphis, TN), the device's COR is usually aligned with the simulator's COR. Variable COR devices, like those of the Charite Artificial Disc (DePuy Spine, Raynham, MA) or the Prestige Cervical Disc (Medtronic, Memphis, TN), may be setup in multiple ways, which may produce significantly different motion patterns. For example, a Charite disc may be placed so that one or both of the core's bearing surfaces slide, and a Prestige disc may be fixtured to either slide or roll in its trough. Which setup is chosen should depend on the device's demonstrated in vivo behavior.

Although the fluid environment has been shown to affect total joint wear,[5–8] little is known about the fluid volume, content, or turnover in the disc space, post-discectomy. The fluid volume could vary in vivo with the formation of a pseudocapsule, as the device would be immersed; otherwise, the disc space would be merely wet. There is some evidence from disc retrievals that suggests the fluid environment contains protein content,[9] but the exact content is unknown. Additionally, little is known with regards to the fluid turnover. If the fluid is replenished, the particles may be removed from the bearing region to local tissues; or if the fluid is static, the particles could be recaptured by the bearing and accelerate wear as third bodies. As research into answering these questions continues, the currently accepted practice for wear testing is to immerse the implants in a bovine serum solution with a protein concentration up to 30 g/L.[10] The test fluid is replaced every 500,000 to 1,000,000 cycles to minimize the effect of serum degradation on wear and inspect the test specimens.

There is currently 1 wear test standard and 1 wear test standard guide for TDRs. Although both reflect a consensus of the organizations' members from industry, academia, medicine, and regulatory agencies, these standards developed independently and arrived at different procedures using different philosophies. While generally quite alike, they differ in their scope and kinematics. The American Society for Testing and Materials, International (ASTM), ASTM F2423-05 Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses[11] is a guide and, therefore, less specific in its protocol than a Standard Test Method. It encompasses both articulating bearings and elastomeric devices and allows for motions to be applied in either unidirectional or multidirectional (coupled) paths. (It should be noted that the ASTM Standard Guide, like other standards, continues to evolve.) It prescribes larger ranges of motion, close to the maximum ranges of healthy individuals. In contrast, the International Standards Organization (ISO) test method, ISO18192-1:2008[10] is specific for sliding bearings and prescribes multidirectional, relatively lower ranges of motion, reflecting the ISO committee's expectation of actual in vivo usage. It should be noted that although attempts have been made to make the test methods relevant to physiologic conditions, neither document is a performance standard and both documents caution the user that clinical performance may differ from the test results. The documents advise considering other testing methods to assess other potential failure mechanisms and even different wear conditions. Both standards assess just 1 of the 4 modes of wear defined by McKellop.[12] Wear can be produced by different surface interactions, and both standards investigate only the intended wear mode, as opposed to third-body wear, impingement wear, or extraneous wear due to micromotion against the vertebral endplate.

Influential wear parameters

There are a number of important biotribological testing parameters, such as load and kinematics, test fluid media, and specimen preparation, that can greatly affect the outcome of a wear study. For in vitro biotribological evaluations of TDR to be clinically relevant, these testing parameters must be carefully selected.

Load and kinematics

Load and kinematics can influence the wear, wear rate, and type of wear mechanism generated in a wear test. The load and motion profiles, which essentially describe the direction and extent to which one component slides over the other under a described compressive force, is typically controlled by the user's selection of the amplitude, waveform (typically a constant or cyclical load), phasing (ie, timing of the motion in one direction against that in another), and specimen orientation. Specimen orientation can introduce shear loads between the articulations, as recommended by the ISO standard[10]; but the effect may depend on the implant design. The test frequency combined with total device range of motion determines the sliding speed and distance, which can, in turn, affect surface temperatures, lubrication, and wear (volume and mechanisms). Proper selection of these parameters will allow the implant to be evaluated in a realistic, in-service state.

The bearing biomaterial and the type and magnitude of motion between the articular components are of great importance with respect to implant wear. For example, crossing-path motion, which occurs when a specific location on the implant is subjected to motion in different directions during a wear cycle, can influence wear. The analysis of wear tracks on explanted ball-in-socket lumbar TDRs suggests crossing-path motion.[9,13] This result is not surprising, based on the published literature characterizing lumbar spinal motions for various activities of daily living.[14–16] The analysis of wear tracks on cervical TDRs suggests curvilinear motion for a ball-in-trough design[17] and asymmetrical motion patterns for a ball-in-socket design.[18] It is important to consider the biomaterial, bearing design, and spine location when selecting the type of motion to apply in a wear test.

The proposed motions in the ISO 18192-1 wear standard[10] lead to crossing-path motion for both the lumbar and