



Characterization of Biomaterials: Chapter 8. Characterization of Orthopaedic Devices

Imran Khan, Malcolm Naylor, Gautam Gupta

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Preclinical testing is a critical part of the orthopaedic device design process and is required to demonstrate efficacy, safety and adherence to the requirements of essential regulations. The following chapter provides an overview of the key regulatory and technical requirements associated with mechanical and tribological testing of orthopaedic devices and the characterization of metallic coatings applied to such devices for improved biological fixation. Mechanical testing is typically carried out according to regional or international standards that define the type of device to be tested, its laboratory-based performance requirements and reference criteria that a product must meet. The most widely used tests for orthopaedic devices are static or fatigue tests. These may be conducted under compression, bending, shear or torsion, depending on the in vivo loading conditions that they are trying to replicate. Bearing wear simulator test methods have evolved over several decades from simpler tests such as pin-on-plate to more realistic tests that replicate the forces and motions experienced during walking or other gait cycles and, importantly, allow the testing of actual components. Current wear simulator test standards for hip and knee joints are reviewed and methods of characterizing wear debris and measuring friction are discussed. Metallic coatings on orthopaedic devices can be employed to improve the fixation of the implant to the host bone. This chapter discusses methods to characterize critical properties of metallic coatings for orthopaedic devices and also identifies the acceptance standards set by regulatory bodies for these kinds of coatings.

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