

Comprehensive Pre-Clinical Evaluation of Spinal Implants: Corrosion and Wear under Physiological and Inflammatory Simulations

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Spinal implants, especially modular systems like bilateral instrumentation constructs, are susceptible to fretting corrosion due to micro-motion at interfaces. This study presents a novel combined biomechanical and electrochemical testing setup for pre-clinical assessment, enabling evaluation under sequential and physiological load conditions. The investigation included bilateral spinal constructs comprising Ti6Al4V pedicle screws and CoCrMo rods, tested in phosphate-buffered saline (PBS) and PBS supplemented with 30 mM hydrogen peroxide (H₂O₂) to simulate inflammatory conditions.

The experimental protocol involved uniaxial loading, flexion/extension, lateral bending, and axial rotation, applying over 250,000 cycles. Electrochemical data, such as open circuit potential (OCP) and corrosion currents, were recorded, alongside material degradation analysis through gravimetry, microscopy, and inductively coupled plasma mass spectrometry (ICP-MS). Physiological testing incorporated combined motion profiles, offering a closer simulation of clinical conditions.

Results showed pronounced corrosion and wear under H₂O₂ conditions, with a fourfold increase in ion release and higher fretting currents. Combined motion testing revealed significantly higher material loss compared to sequential testing, with Ti6Al4V pedicle screws exhibiting up to a 14-fold mass loss increase. Surface analysis confirmed oxide layer damage, third-body accumulation, and material transfer between components. ICP-MS revealed elevated Co, Cr, and Ti ion concentrations, highlighting the aggressive nature of the inflammatory environment.

This study underscores the importance of incorporating inflammatory simulations and complex motion profiles in pre-clinical testing to enhance implant design and ensure patient safety. The novel methodology establishes a benchmark for evaluating wear and corrosion mechanisms in spinal instrumentation systems.

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