

Pre-clinical Simulation and Testing of Total Joint Replacements

University of Leeds expertise in testing joint replacements can help companies validate the performance of artificial joint replacements - using a SAFER approach to meet the demands of more active patients.

World-class, accredited laboratories The Institute of Medical and Biological Engineering (iMBE) is the world's largest independent academic facility for the pre-clinical wear simulation testing of artificial joint replacements. With our ISO 9001 accredited and internationally recognised facilities, labs and equipment, we have a range of dedicated experimental and computational facilities to support and progress product development with industry partners ahead of clinical trials.

Supporting through pre-clinical testing Companies can directly access our expertise during product R&D, to verify and validate evidence, support regulatory approval (FDA and CE marking) and fulfil the requirements of industry-recognised ISO methods and standards.

Enhancing joint replacement implant safety and reliability

Our unique joint simulation facilities are world-leading. We can simulate the everyday wear of prostheses and their wear under adverse conditions. We use an approach called SAFER (stratified approach for enhanced reliability). SAFER ensures that adverse conditions (such as surgical misalignment or a patient's active lifestyle) that could accelerate wear and cause failure can be seen and potentially mitigated in the product development cycle. Recent industry collaborators using these facilities include:

Mathys, Corin, DePuy and JRI - and all our collaborations support new product development as well as investigations of existing products and devices. We can also help in the provision of pre-clinical evidence for regulatory approval.

Setting new medical standards through testing

Our expertise in testing joint replacements has helped global orthopaedics company DePuy validate the performance of a new knee joint able to accommodate the needs of today's younger, more active and high demanding knee patients.

With support from the Medical Technologies IKC, our researchers provided DePuy with independent expertise and product verification testing on the company's new Sigma® CR150 total knee femoral component. Working with innovative products like the Sigma® CR150 requires testing beyond industry standards - making us the ideal partner. Working with the IKC enabled DePuy to access this expertise and gain independently verified data on their new design, which they were able to publish in peer-reviewed journals and present at conferences.

iMBE's extensive track record meant DePuy could also benchmark their product against a wealth of existing data.

EXAMPLES OF PRE CLINICAL TESTS AND CONDITIONS

Screening analysis	<p>Six station pin-on-plate, biaxial reciprocating motion wear testing, typically involving 3 experimental and 3 control material samples. Wear measured gravimetrically.</p> <p>Cycle rate: 1 Hz Motion: Multi-directional Stroke: up to 30 mm, rotation +/- 60° Lubricant: 25% bovine serum, 0.03% sodium azide</p>
Test Duration	<p>Measurement interval: Every week, 17km, 330,000 cycles Total number of cycles: 1 million cycles, 50 km Test duration: 3 weeks</p>
Joint simulation	<p>Six station hip and knee simulators, typically involving 3 experimental and 3 control prosthesis samples. Wear measured gravimetrically or geometrically</p> <p>Load: Hip: Paul cycle (ISO14242-1) Knee: ISO14243-1 Cycle rate: 1 Hz Motion: Physiological Orientation: Normal, upright Lubricant: 25% bovine serum, 0.03% sodium azide Test condition options: Hip: Rotational mal-positioning Translational mal-positioning (microseparation) Knee: High kinematics (anterior-posterior translation 10mm) Intermediate kinematics (anterior-posterior translation 5mm)</p>
Test Duration	<p>Lubricant change: Every 330,000 cycles Measurements interval: Every 1 million cycles Total number of cycles: 5 million cycles Test duration: 6 months</p>
Particle analysis	<p>To isolate and quantify wear debris from Screening, and Joint Simulation testing, comprising serum digestion, filtering, and electron microscopy (FEGSEM) to provide: Distribution of particle size Number of particles as a function of size Number of particles per unit volume of wear</p>
Test Duration	<p>3 months to conduct full experimental protocol</p>
Biological reactivity	<p>Pin-on-plate biaxial reciprocating motion wear testing with foetal calf serum and tissue culture medium to create wear debris for experimental, positive (metal-on-metal) and negative (metal-on UHMWPE) controls. Subsequent cell culture to determine biological reactivity of the wear debris.</p> <p>Two tests are available to quantify biological reactivity of wear debris in terms of: (1) Biocompatibility assessment by viability of fibroblasts (2) Cytokine release assessment from macrophages</p>
Test Duration	<p>3 months to conduct each full experimental protocol</p>



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