iMBE Capabilities

Within the iMBE facility, we have the world's largest academic facility for the pre-clinical testing of artificial joint replacements and have developed standard methods for the pre-clinical functional assessment of medical devices, including artificial and biological heart valves and early interventions for cartilage repair. Our facilities and expertise include:

- Tribology of artificial and natural joints
- Characterisation of biomaterial properties
- Biomechanical function of artificial and natural heart valves
- Metrology
- Imaging

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Pre-clinical Wear Simulation

iMBE has extensive pre-clinical wear simulation facilities with in excess of 80 stations for studying tribology of hip, knee and spine arthroplasty bearing materials and cartilage repair interventions.

Material Screening

Pin on plate wear testing can be used to rank wear performance of different material combinations in simple geometric configurations. The test combines linear reciprocating motion of the plate with rotation of the pin to deliver a multi axial test.

iMBE has four six-station pin on plate simulators used for wear testing of polymers, metals, ceramics and biological specimens and characterisation of the resulting wear debris. Wear is determined gravimetrically.

Tests are typically run for 1 Million Cycles over a duration of 3 weeks and can be used to assess:

- Materials
- Lubricants
- Kinematics
- Contact pressures

A single station rig is available for testing samples under aseptic conditions to produce physiologically relevant, sterile wear debris to investigate its effect on cells in culture.

Hip

Leeds II Physiological Anatomical Hip Joint Simulator

The Leeds II Physiological Hip Joint Simulator has six articulating stations with two independently controlled motions: flexion/extension and internal/external rotation of the acetabular cup. A cyclic compressive load is applied in the vertical axis. Machine is capable of running at 1Hz or lower.

Number of simulators: **2**.

Prosim Physiological Anatomical Electro-Mechanical Hip Joint Simulator

The Prosim hip joint simulator has one load-only station and six articulating stations with three independently controlled motions: flexion/extension, internal/external rotation and abduction/adduction of the acetabular cup. A cyclic compressive load is applied in the vertical axis. Machine is capable of running at 2Hz or lower.

Number of simulators: **4**.

Testing capabilities:

Capable of simulating a standard gait cycle using iMBE profiles or ISO14242 profiles.

Capable of simulating a well positioned prosthesis as described in the ISO14242 standard.

Capable of simulating different daily activities such as rising from a chair, stair climbing, and stop-start conditions

Capable of simulating surgical mal-positioning and edge loading conditions, including the following variables:

- A wide range of acetabular cup inclination angles
- A wide range of acetabular cup version/ante-version angles
- Acetabular cup and femoral head surgical offset deficiencies (translational mal-positioning)
- Joint laxity with varied swing phase loads
- Dynamic micro-separation conditions (translational mal-positioning)

A typical test:

A typical wear test of five million cycles takes six months to complete with measurements carried out every one million cycles. However, this varies depending on the research question and customers' need.

Lubricant: 25% new-born calf serum supplemented with sodium azide to retard bacterial growth. The lubricant is changed every one third of a million cycles.

Measurements Capabilities

Wear can be assessed on metallic, ceramic or any polymeric materials, gravimetrically using a microbalance or geometrically using a coordinate measuring machine.

Deformation, penetration and damage of the bearing surface can be assessed using coordinate measuring machines, profilometry, stereo-microscope, or scanning electron microscope.

Surface roughness can be determined using a contacting or a non-contacting profilometry techniques

Knee Simulators

iMBE has six Leeds/ProSim Force/Displacement controlled Knee Simulators with six articulating stations per simulator. Each simulator has 6 degrees of freedom and 4 or 5 controlled axes of motion:

- Axial force
- Femoral flexion
- Tibial (interior/exterior) rotation
- Tibial (anterior/posterior) displacement
- Abduction/adduction

A typical test involves 3 test and 3 control samples and is run for 5 Million cycles (MC) with gravimetric analysis of the tibial inserts to determine wear carried out after 1, 3 and 5MC. The test conditions used are:

- Load: ISO 14243-3 (2004)
- Frequency: 1Hz
- Motion: ISO 14243-3 (2004) and physiological
- Orientation: Normal, upright
- Lubricant: 25% bovine serum with sodium azide to retard bacterial growth which is changed every 0.3MC.

Testing Capabilities

- All simulators are capable of testing to and beyond the ISO standard.
- The simulators can be run under force or displacement control depending on the research question.
- Simulators are capable of testing under different kinematic conditions by changing input profiles; for example, the anterior-posterior displacement can be increased to deliver a test under high kinematics.
- Four simulators are capable of running studies under a high flexion gait cycle (up to 125°).
- Capabilities have been developed to study malalignment such as femoral condylar lift off
- Tests have also investigated the effect of setup of the components.

Measurement capabilities

Wear of the tibial components is determined gravimetrically by their loss in mass using a 0.1mg digital microbalance. The surface topography of the articulating surfaces is measured both pre- and post-test using a contacting Form Talysurf. Further surface characterisation can be carried out using 3D optical profilometry to investigate how surface topography affects tribological properties.

Determination of Friction

To complement our pre-clinical wear simulation facilities we have capability to measure the friction of artificial and natural joints through a variety of methods, from simple geometrical configuration using a pin-on-plate, to a pendulum friction simulator predominantly used for hip replacements, through to single station physiological anatomical hip and knee simulators.

Single station pin on plate friction simulator

The pin on plate friction simulator can be used to compare the coefficient of friction of different combinations of bearing couples in simple geometric configurations under reciprocating test conditions. 2 rigs are available for the measurement of friction between metals, polymers, ceramics and biological specimens.

Test variables include:

- Load (10-200N)
- Kinematics
- Lubricant

Hip

Pendulum friction simulator

iMBE has two ProSim single station pendulum friction simulators. The simulators apply motion in a single axis and a cyclic compressive load is applied in the vertical axis. This machine has hydrostatic bearings to ensure the accurate determination of the friction factor of hip replacement bearings. Machine is capable of running at 1Hz or lower.

The simulators are capable of determining the frictional torque and friction factor under standard (well positioned) and surgical mal-positioning and edge loading conditions and can be used with both natural tissues and artificial bearing materials.

Single station hip simulator

The Prosim hip joint simulator has one articulating station with three independently controlled motions: flexion/extension, internal/external rotation and abduction/adduction of the acetabular cup. This machine has a six axis load cell capable of measuring load and torques about the hip bearings being tested. A cyclic compressive load is applied in the vertical axis. Machine is capable of running at 2Hz or lower.

The simulator can be used with both natural tissues and artificial bearing materials.

Single station knee simulator

iMBE has three single station knee simulators used for the measurement of wear and friction/anterior-posterior shear force acting on the tibio-femoral articulation. The application of constraints to the tibia allow simulation of the rolling and sliding motion seen in the tibio-femoral joint during a physiologically relevant gait cycle.

Methodology has been developed to assess early inventions to cartilage repair, as well as artificial materials used for total knee arthroplasty. Tests are typically short-term (10 minutes to 4 hours) and are carried out in 25% bovine serum.

These simulators can also be used to investigate biomechanics and biotribology of ankle and patella-femoral joints.

Characterisation of Biomaterial Properties

We have developed a range of testing methodologies in order to characterise the material properties of natural tissues. This includes tensile/compressive testing to failure, creep/stress relaxation testing, and suture pull-out testing, for a range of biological tissues such as heart valves, ligaments, tendons, bone-patellar-tendon-bone constructs, arteries, meniscus etc

iMBE has a range of materials testing capabilities including three Instron Mechanical Testing systems:

- 1 x Instron 3365 compatible with 5N, 50N, 500N & 5kN load cells and dedicated digital video extensometer.
- 1 x Instron 3365 compatible with 500N & 5kN load.
- 1 x Instron 3366 compatible with 1kN and 10kN load cells and dedicated digital video extensometer.

A selection of purchased and custom made grips, platens and fixtures are available for all Instron devices suitable for a variety of applications. Bio-baths are also available to complete testing of specimens in a fluidic environment at a desired temperature.

Typical applications include but are not limited to the tensile/compressive failure testing and creep/stress relaxation testing of biological tissues.

There are also two indentation rigs with a selection of custom made indenters of different shapes (flat, spherical), diameters (above 1mm), and different materials (metal pours, metal solid, PE).

Typical applications include; indentation, confined and unconfined creep tests which can be carried out in a fluidic environment.

Hydrodynamic and Biomechanical Testing Of Artificial and Natural Heart Valve Prostheses

A series of tests have been designed to test the hydrodynamic and mechanical properties of heart valve prostheses.

Hydrodynamic Testing

Pulsatile Flow Testing Rig

The Pulsatile Flow testing rig is computer controlled cardiovascular simulator designed for heart valve studies which can assess the performance of prosthetic heart valves under simulated cardiac conditions.

It is equipped with instrumentation for pressure and flow measurements and is capable of testing a range of prosthetic heart valves including stented tissue valves, stentless valves and mechanical valves. The equipment meets ISO 5840 (2005) requirements.

The rig has two test chambers for testing valves in the aortic/pulmonary or mitral/tricuspid valve positions under simulated physiological complex cardiac waveforms. The chambers are optically clear which allows

the function of mitral and aortic valves to be imaged and filmed during testing using an external high speed video camera.

Heart Valve Pulsatile flow testing Rig Specification:
Heart rate: 30bpm to 120bpm
Stroke volume: 100 ml
Afterload: 120/80 mmHg
Compliance: Adjustable compliance
Sine waveforms and other cardiac modified waveforms
Test Fluid: 0.9 % Sodium Chloride at 20°C

Measured parameters

- RMS flow and Peak flow measured directly at aortic or mitral sites
- Valve pressure gradient
- Effective Orifice Area (EOA)
- Closing, Leakage and total energy loss
- Valve Regurgitation

Static Leakage Testing Rig

Static Leakage Rig is used to quantify closed regurgitant volume of stented, stentless, mechanical prosthetic heart valves and biological roots. The rig has the capacity to control static head pressure up to 120 mmHg with 0.9 % Sodium Chloride at 20°C used as a test fluid.

Mechanical Testing

A portfolio of methods has been developed to study the mechanical properties of artificial and natural heart valve prostheses and heart valve tissue.

Uniaxial tensile testing of heart valve constructs

A methodology has been developed to assess the uni-directional stiffness and strength of biological and prosthetic heart valve constructs. The test uses an Instron® Mechanical Test Rig with load cells appropriate to the sample to apply a tensile force. The sample is clamped with custom-made soft tissue grips and studies are carried out in a BioPuls™ bath to maintain an aqueous environment and a consistent temperature up to 37°C.

Suture Pull–Out testing

A suture pull-out test method has been developed to investigate the effect of suturing on the strength of heart valve tissue. The Instron® Mechanical Test Rig with custom-made soft tissue grips to clamp the heart valve tissue has enabled the ability of the heart valve tissue to withstand the forces associated with suturing to be measured.

Dilation Testing Rig

The Dilation Test Rig allows tubular stiffness to be assessed and therefore the compliance of arterial and vascular grafts to be measured. Pressure is applied to the graft in increments up to 120mmHg, images of the graft are taken at each pressure and image analysis software is used to estimate the graft diameter. This is extrapolated to give a measurement of graft compliance.

Metrology

Our Metrology capability is critical to our pre-clinical biotribological experimental simulation. We are able to determine the wear of joint replacements through 2 methods, gravimetrically using high precision balances and comparators, and geometrically through the use of co-ordinate measuring machines. The surface topographies of the wear couples can be determined through contacting profilometry or non-contacting interferometry.

Within the iMBE facility there is a dedicated laboratory for gravimetric, geometric and surface topography measurements. The environment is temperature and humidity controlled to create a stable atmosphere to improve consistency of measurements.

- Gravimetric measurements can be carried out on a range of balances with an accuracy of up to 1µg. Gravimetric analysis is used to assess the wear performance of bearing couples following tribological testing.
- Surface topography can be analysed by either 2D contacting profilometry or by 3D optical profilometry. A typical applicaton for measurement of surface topography is following wear testing where changes in surface roughness are measured and surface parameters which may affect the tribology of components are investigated.
- Geometric analysis can be carried out on one of the coordinate measurement machines with programmes tailored for specific components and post-processing of data to enable measurement of wear volumes.

Imaging

Within iMBE, there are specimen and clinical CT imaging facilities for high resolution imaging.

Clinical CT – Scanco XtremeCT

XtremeCT is designed to perform high-resolution pQCT studies at distal tibia and radius of humans for clinical *in vivo* assessment of Bone Quality. Although live patient scanning is not conducted, samples such as knee and hip joints, spinal segments, bone implants etc are scanned for morphological, density and structural characterisation.

Structural parameters – Cortical Thickness, Trabecular separation, Trabecular Number, Volume Fractions

Density Parameters – Cortical Density, Trabecular Density

Specifications	**XtremeCT**
Type	High-resolution peripheral quantitative CT No external shielding required
X-ray source	Sealed Air-cooled Maintenance-free 80 µm spot size 60 kVp / 40 keV (900 µA)
Detector	3072 x 255 elements Fiber-optic taper 41 µm pitch
Resolution	‹ 105 µm (10% MTF) 41 - 246 µm nominal isotropic (pixel size)
Image matrix	512 x 512 to 3072 x 3072 pix
Max. scan size	126 x 150 mm (ØxL)
Scan time	2.8 min. with standard protocol (9 mm/110 slices)
Effective Dose	‹ 5 µSv per measurement (ICRP91)
Electrical	100 - 230 V / 50 - 60 Hz / 10A 370W
Approvals	CE

Specimen microCT – Scanco µCT100

Designed to handle wide range of sample sizes for non-destructive 3D imaging and characterisation of specimens *in vitro*, µCT 100 offers a very wide field of view while maintaining high imaging resolution. The automatic sample changer accommodates up to 12 sample holders to help automate large studies, and a filter changer of 4 different materials in combination with X-ray power settings enhances the range of materials that can be scanned.

Specifications	**µCT 100**
Type	Cabinet cone-beam microCT Fully shielded No additional shielding required
X-ray source	Sealed Air-cooled Maintenance-free 5 - 30 µm spot size (4 - 18 W) 30 - 90 kVp / 20 - 50 keV (160 µA)
Detector	3072 x 400 elements, 48 µm pitch
Resolution	‹ 4 µm 10% MTF 1.25 - 200 µm nominal isotropic (pixel size)
Image matrix	512 x 512 to 8192 x 8192 pixels
Max. scan size	100 x 140 mm (ØxL)
Max. specimen size	100 x 160 mm (ØxL)
Electrical	100 - 230 V / 50 - 60 Hz max. 400 W
Dimensions	130 x 135 x 80 cm (HxWxD)
Weight	390 kg