MeDe Innovation

EPSRC Centre for Innovative Manufacturing in Medical Devices

CASE STUDY

Functionally stratified design and manufacture of hip and knee joints

Our aim

Our aim is to develop and deliver new simulation methods for the design and manufacture of hip and knee prostheses, to be evaluated through two design and manufacture case studies. The resulting robust design solutions will accommodate patient and surgeon variability, delivering greater reliability in a cost-effective manner.

The **academic partner** leading this project is the University of Leeds (Fisher, Wilcox, Jennings and Ingham). **Collaborators** are simulation specialists, Simulations Solutions Ltd; device manufacturers, DePuy Synthes; Jaiotong University in China; distribution partners in China, Gaitech, Shanghai.

Clinical collaborators from the NIHR Leeds Musculoskeletal Biomedical Research Unit (LTHT LMBRU) are Venkatesh and Stone (surgery), Redmond (gait analysis) and Conaghan (imaging).

This project has **three research challenges**: (1) To develop models characterising variations in geometry, properties, surgical delivery and activities of the patient population. (2) To develop simulation models predicting biomechanical and biotribological function. (3) To apply these new approaches to hip and knee prostheses.

Our approach

We will **define**:

> Models of hip and knee anatomy, geometry and properties, compatible with engineering design systems which characterise both the eastern and western patient population;
> The variation in surgical positioning of artificial hip and knee joint components in these patients;
> A set of biomechanical and kinematic inputs for of hip and knee joint replacements for a variety of different activities - control, standard walking, stair-climbing and descent, and rising from a chair – through collaborations with Leeds, North America and China.

Using these inputs, we will **develop** finite element models to predict the biomechanical and biotribological function of the joint replacements for a range of activities and surgical positions.

We will experimentally **validate** functional predictions, with evidence from patients and tissue specimens.

This work will result in a **validated** tool-kit of stratified pre-clinical simulation methods which will functionally differentiate the design and manufacture of new prostheses, the application of which will be demonstrated through case studies.

What we want to achieve

1. Parameterised models for natural hips and knees which characterise variations in anatomy, geometry, material properties, surgical delivery and patient activities.
2. New simulation methods which predict biomechanical and biotribological function for the parameterised models.
3. Functionally stratified design solutions using the hip and knee simulation systems.
4. A systematic design methodology, consisting of parameterised models, data and simulation systems, to predict function which can be adopted as an international standard by manufacturers and their supply chain.

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CASE STUDY

Stratified bioprocesses for the manufacture of acellular scaffolds

Our aim

Our aim is to develop bioprocesses for the manufacture and production of acellular biological scaffolds for bone and cartilage repair. These scaffolds will have a range of different properties and will, through our stratified design and simulation processes, be better matched to patient and surgical needs.

The **academic partner** leading this project is the University of Leeds (Ingham, Fisher, Wilcox). **Collaborators** will be NHS Blood & Transplant and Tissue Regenix PLC.

This project has two **research challenges**: (1) To determine and control the variation in the manufacturing bioprocess for acellular bone and cartilage scaffolds, producing a product range which can be matched to surgical and patient needs. (2) Applying stratified design and simulation methods to match the properties of the acellular scaffold to the patient, based on functional performance.

Our approach

This project will **focus** on the manufacturing challenges of the next generation of products for bone and cartilage repair.

We will **determine**:
> The effect of different source materials (animal or human tissue and different body sites) on the properties of the scaffold;
> The effect of variation in process conditions on the scaffold's properties;
> The effect of different terminal sterilisation methods on the scaffold.

We will **define**:
> A portfolio of manufacturing processes that produce a stratified product range for bone and cartilage scaffolds;
> The repeatability of the defined processes for each product.

We will **apply** stratified design and simulation methods to provide guidance on the matching of scaffold properties to the surgical procedure and the patient, to ensure enhanced performance and reliability.

What we want to achieve

1. Quantification of the effect of variation in source materials on scaffold properties.
2. Quantification of the effect of changes in process conditions on the scaffold's properties.
3. A suite of different bio-manufacturing processes to produce a product range.
4. Quantification of the process's reliability and variation in product properties.
5. A stratified approach for enhanced reliability, matching patient needs.

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CASE STUDY

Stratified design and manufacture of nonwoven collagen scaffolds

Our aim

Our aim is to develop processes for the rapid manufacture of collagenous nonwoven scaffolds for bone repair which are stratified by structure and physical properties in response to surgical and patient needs.

The **academic partner** leading this project is the University of Leeds (Russell, Wood, Tronci, Kirkham, Ingham, Yang). **Collaborators** include NIRI Ltd (scaffold product manufacturing). The **clinical collaborator** is Leeds Teaching Hospitals NHS Trust (LTHT).

This project has two **research challenges**: (1) To control the physical properties and reproducibility of collagen-based synthetic scaffolds, based upon a new, multi-route manufacturing platform. (2) To implement a functionally stratified approach to the design and manufacture of scaffolds so that the structure and properties meet specific patient needs.

Our approach

Conventional approaches to manufacturing three-dimensional regenerated collagen scaffolds will be transformed with triple helix integrity preserved and suitable for application as bone repair products such as small defects. The new generic approach will enable precision-manufacture of porous, mechanically stable, collagen-based scaffold components as templates in various forms depending on patient needs. This new photoactive collagen biomaterial will form the basis of the stratified design of soft as well as hard tissues in the future.

We will **determine**:

> The effect of manufacturing process conditions on the mechanical properties, internal structure and biocompatibility of the collagen matrices produced in various macroscopic forms as well as the influence on structure and property variation;
> Methods of minimising variations in the uniformity of scaffold architecture and physical properties, implementing control procedures;
> Additional methods for tailoring mechanical properties by process parameter selection during scaffold manufacture. We will evaluate and implement effective modifications to process equipment design to enable rapid manipulation of scaffold dimensions, shape and internal geometry on demand. We will also optimise processing parameters to ensure effective, uniform and reproducible distribution of appropriate fillers to augment physical and biological properties;
> The in-vitro performance of newly-designed scaffold architectures, post-manufacture.

We will **define**:

> Compatibility and effective manufacturing procedures using new forming techniques, e.g. wet spinning and forcespinning;
> A manufacturing quality control system for the scaffold production process, including effective inspection and instrumental test procedures;
> Stratified patient groups and the scaffold forms; implement design methods linking scaffold properties to the requirements of the surgical procedure.

What we want to achieve

1. Scalable manufacturing routes delivering three-dimensional collagen scaffold products with robust properties, shapes, sizes and internal geometries.
2. A stratified range of scaffold products with robust manufacturing specifications.
3. A new stratified method for the design and manufacture of synthetic collagen scaffolds.
4. Quantitative scaffold performance and specification data linked to well-defined processing conditions and manufacturing parameters.

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CASE STUDY

Manufacture of fully bioresorbable multiphase fixation devices to order

Our aim

Our aim is to deliver design and manufacture for next generation multiphase bioresorbable spinal fixation devices, focusing on cost efficiency and validation of process chains.

The **academic partners** in this project are the University of Nottingham (Grant, Ahmed, Warrior, Lester); the University of Bradford (Coates) and the University of Leeds (Wilcox).

Clinical collaborators are Jaspan and Ellis (imaging) and Scammel and Boszczyk (orthopaedics) Nottingham University Hospitals.

This project has one key **research challenge**: The development and application of stratified design and manufacture processes for a new resorbable fracture fixation device. This achieved by combining modelling for stratified patient groups with specific new manufacturing processing routes to enhance capability in delivering devices to order to customers.

Our approach

We will **develop**:
> A manufacturing route for fully resorbable calcium phosphate based glass fibres (PGF) that can be integrated effectively to reinforce degradable polymers;
> Coating technologies to enhance tooling and moulds;
> Models to validate performance and safety.

We will **tailor**:
The degradation rates for PGFs by altering their chemical composition.

We will **evaluate**:
The manufacturing methodologies, for example, incorporation of these PGF fibres with micro-moulding and extrusion technologies to manufacture fixation components and related scale-up issues.

We will **investigate**:
New manufacturing methods to enhance composite mechanical and bioactive performance suitable for micro-processing methods.

We will **assess**:
In vitro performance of these novel structures, post processing and sterilisation.

We will **identify**:
Stratified patient groups and suitable fixation devices.

We will **enable**:
The rapid conversion of medical images into usable digital patient-customised device designs.

We will **create**:
High-fidelity 3D models of patient anatomy (both hard and soft tissue) in real time.

What we want to achieve

1. Manufacturing methodologies for delivering resorbable fibre-reinforced composites through micro-moulding and extrusion.
2. Manufacturing processes for polymer encapsulation of calcium phosphate nanoparticles
3. Demonstration of proof of concept of the stratified approach to the design and manufacture of a resorbable fracture fixation device.

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CASE STUDY

Minimally invasive implantation of bioactive materials

Our aim

Our aim is to develop the materials and surgical techniques for the production of novel complex implants in vitro.

The **academic partners** in this project are Newcastle University (Dalgarno, German, Bretcanu, Fulton) in collaboration with University of Bradford (Coates), University of Nottingham (Grant, Ahmed) and University of Sheffield (Hatton). **Collaborators** are JRI Orthopaedics Ltd, Surgical Innovations Ltd, Glass Technology Services Ltd, Ceramisys Ltd and Materialise NV.

This project has two **research challenges**: (1) Development of micro-scale extrusion and droplet deposition equipment which can be operated through an arthroscope. (2) Creation of mechanically robust and biologically enhanced structures in vivo.

Our approach

We will **characterise** the potential processing windows for material deposition within the context of having an available maximum diameter of 5mm within the arthroscope to deliver the material, and of needing to deliver the implant within clinically useful timescales. This WP will measure, model and extend the useful combinations of viscosity, surface tension and deposition rate which are achievable.

We will **develop** bioactive cements and composites which can be processed in situ to provide robust mechanical support to the musculoskeletal system, together with biopolymer membranes which may be used in kyphoplasty-type approaches.

We will **integrate** the instrumentation, processing and property knowledge to create a functionally gradient osteochondral plug in a simulated in-vivo environment.

What we want to achieve

1. Definition of achievable combinations of viscosity, surface tension and deposition rate;
2. Characterisation of the mechanical and biological properties which can achieved;
3. Demonstrated surgical technique for the production of novel complex implants in vivo.

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CASE STUDY

Processes for in-clinic manufacture

Our aim

Our aim is to develop new material printing, moulding and deposition techniques in order to support the in-clinic manufacture and configuration of bioactive devices for large defects which are load bearing, functionally gradient and biologically enhanced.

The **academic partners** in this project are Newcastle University (Dalgarno, German, Bretcanu, Fulton), the University of Bradford (Coates) and University of Nottingham (Grant, Ahmed). **Collaborators** are JRI Orthopaedics Ltd, Surgical Innovations Ltd, Glass Technology Services Ltd and Materialise NV.

This project has **two research challenges**: (1) Co-processing of cells and structural biomaterials whilst maintaining mechanical and biological function. (2) Development of micro-factories for in-clinic use.

Our approach

We will **assess**:

> Printing and deposition techniques for their ability to deliver functionally gradient mechanical properties whilst simultaneously encapsulating a functionally gradient cell population through the structures.

> Low temperature moulding techniques for their ability to quickly create porous hard/soft material combinations which could be infiltrated with cells, proteins and other agents.

We will initially **define** material combinations and processing windows in order to finalise basic device designs and methods of fixation, which could then be adapted to individual patient needs.

We will **produce** and **evaluate** these basic designs for their mechanical and biological function.

What we want to achieve

1. New micro-factories for manufacturing robust, functionally gradient tissue engineering scaffolds for use with minimally manipulated cells that have been harvested during surgery.
2. Characterisation of the combinations of mechanical and biological properties created.
3. Creation of implantable devices with functional and coherent bone-cartilage and bone-tendon/ligament interfaces.

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Join our community

The MeDe Innovation Network exists to provide support to the medical device sector, including academic, industry and clinical members. As a member of the Network, you will benefit from:

> access to information about manufacturing research, from our Centre's research outputs, international partnerships, and clinical centres in medical device innovation throughout the UK

> access to Technology Roadmapping techniques to help shape and inform future research needs

> updates on sector news and events, through e-newsletters, network events and an annual conference

> access to commercial opportunities arising from our work with the Medical Technologies Innovation and Knowledge Centre

> being part of an influential contributor to the UK medical device landscape

> marketing opportunities to highlight your organisation's news and events on the MeDe Innovation website

Dissemination of research and moving it along to adoption and commercialisation is central to our mission and we value input from those working across the medical device sector in the UK. The network aims to not only inform, but also to connect, enabling businesses, policy makers, academics and clinicians to share information, knowledge and ideas and debate the challenges and issues facing the community.

Membership is free and it's easy to join – contact us now.

Contact us

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