

EPSRC Centre for Innovative Manufacturing in Medical Devices

## **CASE STUDY**

## Stratified design and manufacture of nonwoven collagen scaffolds

Our aim	<b>Our aim</b> 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 <b>academic partner</b> leading this project is the University of Leeds (Russell, Wood, Tronci, Kirkham, Ingham, Yang). <b>Collaborators</b> include NIRI Ltd (scaffold product manufacturing). The <b>clinical collaborator</b> is Leeds Teaching Hospitals NHS Trust (LTHT).
	This project has two <b>research challenges</b> : (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.
	<ul> <li>We will determine:</li> <li>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;</li> <li>Methods of minimising variations in the uniformity of scaffold architecture and physical properties, implementing control procedures;</li> <li>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;</li> <li>The in-vitro performance of newly-designed scaffold architectures, postmanufacture.</li> </ul>
	<ul> <li>We will define:</li> <li>Compatibility and effective manufacturing procedures using new forming techniques, e.g. wet spinning and forcespinning;</li> <li>A manufacturing quality control system for the scaffold production process, including effective inspection and instrumental test procedures;</li> <li>Stratified patient groups and the scaffold forms; implement design methods linking scaffold properties to the requirements of the surgical procedure.</li> </ul>
What we want to achieve	<ol> <li>Scalable manufacturing routes delivering three-dimensional collagen scaffold products with robust properties, shapes, sizes and internal geometries.</li> </ol>
	2. A stratified range of scaffold products with robust manufacturing specifications.
	<ol> <li>A new stratified method for the design and manufacture of synthetic collagen scaffolds.</li> </ol>
	4. Quantitative scaffold performance and specification data linked to well-defined processing conditions and manufacturing parameters.



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