



Expanding the Frontiers of Physical Intervention: Case Study

Enabling a new era of innovative knee treatments

A wider range of therapies, a better chance of avoiding complete knee replacement, closer matching of treatments to individual needs: patients with one of the most common, most painful forms of osteoarthritis are set to benefit from a game-changing project.

Meeting the Grand Challenge:

Engineering and Physical Sciences Research Council

Led by the University of Leeds, the 'Optimising Knee Therapies'¹ project has targeted a significant advance in the field of physical healthcare interventions. By developing and demonstrating a novel testing regime for new treatments for osteoarthritis of the knee, it aims to encourage and accelerate the emergence of much-needed innovations which reduce the necessity of major surgery.

Vision and Value:

In England alone, over 4 million people suffer from osteoarthritis of the knee caused by injury or the degenerative effects of ageing. Therapeutic strategies often involve full joint replacement – an expensive option that is not suitable for all patients, especially challenge those who are younger and more active. Earlier-stage therapies involving more modest surgery are limited in number and effectiveness; pinpointing the one that best suits a specific patient is also a big.

The Leeds team recognised the huge value of developing cutting-edge methods of testing novel knee therapies that would make it easier to predict their real-world performance, to identify scope for improving them and to pinpoint which types of patient they would most benefit. The vision was to devise a comprehensive testing regime that academia and industry could readily adopt and adapt to test, tune and optimise new treatments at an early point in the design process.

Key Components:

Supported by a £4 million EPSRC Programme grant and due to end in 2021, this 5-year project integrates engineering, biology and clinical expertise. It has involved close collaboration with industrial partners who have provided implantable devices and other treatments for testing as well as software and hardware for the new testing regime. NHS Blood and Transplant, the NIHR (National Institute for Health Research) Leeds Biomedical Research Centre and academic partners in both the UK and the US have also played key roles.

The project has innovatively interwoven two elements. Firstly, physical labbased tests have been developed that use sample knee joints to assess how therapies perform. Secondly, for each knee sample, a computer model has been built and validated: the models enable simulation of the effect of varying the materials used, for example, or changing the precise part of the knee that the therapy targets. In addition, the team has developed ideas for new treatments, including implantable scaffolds made of bone, cartilage or synthetic material which the patient's tissue can grow back round; some of these have received EPSRC proofof-concept funding via an Innovation and Knowledge Centre based at the university.

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Outputs and Outcomes:

- The project has proved the effectiveness of the physical tests and computer models in terms of their capacity to enable accurate assessment of knee therapies.
- A 'library' of knee types and 'bank' of computer models have been established for use in evaluating novel therapies' suitability for different patient subgroups; both resources will be expanded further.
- Collaborative projects using the methods developed through the programme have evaluated the effectiveness of novel scaffold designs for potential knee therapies.
- The project has generated valuable new insight on how changes in the shape of the knee and in its tissue properties affect the outcome of clinical therapies.

Impacts and Benefits:

- Better, more targeted knee therapies. The new testing methods offer big potential to help improve less-invasive knee therapies and tune them to specific patients, minimising the likelihood that full replacement will be necessary.
- Lower costs, quicker time-to-market. By enabling therapies to be optimised
 - at an early stage of development, the new methods will reduce the risk of costly clinical trials being undertaken for treatments that are impractical or not ready for real-world use.
- Growth and jobs. There is a clear opportunity for the UK to build on its strength in the medical technology

('medtech') sector, with both large companies and SMEs incentivised to invest more in developing novel knee therapies.

Feeding the talent pipeline. The

project's success in attracting high-quality doctoral students and postdoctoral researchers and enabling them to develop specialist expertise in orthopaedic devices will help increase skills in this segment of the medtech sector.

Next Steps:

As well as assessing a wider range of knee therapies, the team will explore opportunities to inform their work using real-world patient data, while carefully complying with data privacy requirements. Medical scans of knees at the point of replacement and gait-related data are just two examples of data that could be harnessed to further strengthen the new testing methods.

Behind the Project:

Professor Ruth Wilcox is the project's Principal Investigator. Director of the Institute of Medical and Biological Engineering and Professor of Biomedical Engineering at the University of Leeds, she won an MRC Suffrage Science Award for Leading Women in Science and Engineering in 2015. Colleagues at Leeds who have made key contributions to this project include Professors Philip Conaghan, John Fisher and Eileen Ingham, Dr Louise Jennings and Dr Alison Jones. "Millions of people could benefit from the emergence of innovative, early-intervention knee therapies," Ruth says. "Our testing methods have potential to be a genuine game-changer, enabling such therapies to reach the real world more quickly and ensuring every patient receives the right treatment at the right time."

18%

of over-40s in the UK have osteoarthritis of the knee

Relevant EPSRC Research Areas:

- Assistive Technologies, Rehabilitation and Musculoskeletal Biomechanics
- Clinical Technologies
- Biomaterials and Tissue Engineering