Connected Innovation in Orthopedics to Drive Clinical Benefits

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Spotting innovation in orthopedics can be tricky for those not working in this field. Even within the medical community *innovation* is often seen only as the introduction or adoption of new technologies or techniques. Yet, this viewpoint fundamentally misses how new thinking and novel approaches, at many other levels, can tackle the challenges and contribute towards improving patient outcomes.

Along the entire product development pathway, from the research and testing stages to manufacturing, evaluation and finally market and service introduction, all milestones are opportunities for innovative thinking to make a difference. It is a process that requires stakeholders at all levels – researchers, clinicians, manufacturers, administrators, managers of health services, regulators and policy makers to be involved from the beginning.

Looking at the evidence in orthopedics, the average implant survival rates in patients receiving total hip and total knee joint replacements are typically above 90% at ten years across the population.[1] In younger patients, however, and for those who live more active lifestyles, revision rates can be higher.[2] As we see patients living longer with their implants, for up to 20-30 years, we can also expect to see revision rates increasing.[3]

More Durable Orthopedic Devices Needed

It is clear that orthopedic devices will need to perform for a longer period of time and be better suited for the patients who receive them. As a result, new outcome measures will be needed, as we currently know a significant proportion of patients are not satisfied with their joint function after a joint replacement procedure. As such, better measurement of function and performance, in addition to an increased ability to simulate and predict performance in different types of patients, are important areas that will require future innovation.

However, developing new orthopedic devices can be difficult partly because of the fragmented path between the stakeholders, beginning with research and development all the way through to the clinic. Researchers at universities, healthcare companies (including medical device manufacturers), regulators, healthcare providers (HCPs) and hospital systems are all links connected in this chain, yet all have different goals and targets. Innovation and research translation gaps often occur at the interface between these different stakeholders and organizations.

Innovation in the Development of the All-Polymer Knee

An example of this fragmented path is the all-polymer PEEK knee implant that the EPSRC (Engineering and Physical Sciences Research Council) Centre for Innovative Manufacturing in Medical Devices (MeDe) has been evaluating. Free from metal components, it will allow surgeons to use high resolution MRI scans to obtain a better image of the joint once it has been implanted – something that was impossible in the past with metal joint replacements (Figure 1).

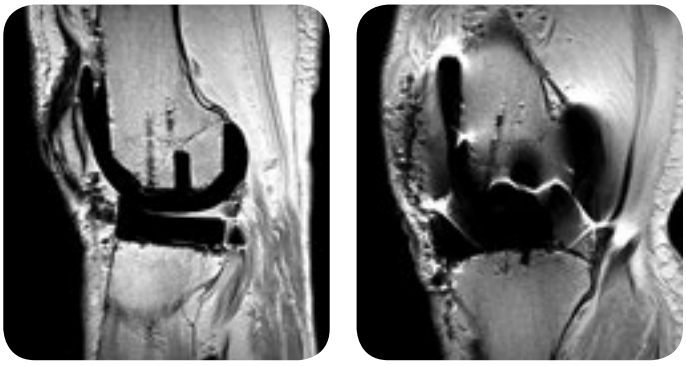

Figure 1: Sagittal MRI of a PEEK femoral component, Proton density (PD), turbo spin-echo (TSE) image (left). Sagittal MRI of a CoCr femoral component. Proton density (PD), turbo spin-echo (TSE) image (right).

For instance, this creates a problem for hospitals, as MRI may not be widely available, and HCPs will not understand how to interpret images of this new implant, as comparable images will not be available. Therefore, without a comparison, it will be difficult to evaluate the benefits of this innovation. As with many innovative technologies, changes in standards of care and clinical practice are typically needed to fully evaluate and adopt them. Therefore, in parallel, innovation in companion or enabling technologies will also be needed in order to derive benefits.

Strategic Partnerships for Innovation

The solution to these problems is greater strategic alignment. For several years, MeDe has been building networks to help the varied organizations and individuals involved in developing new orthopedic devices to work better, together, towards a single goal. There are currently 90 projects progressing through different stages of the development pathway with support from grant funding, private sector investment and industry. Some of the devices developed in these projects are now being tested in patients, thanks to vital investment in the critical late stages of research and innovation (i.e. clinical trials for safety and efficacy testing). Creating strategic partnerships between different stakeholders can create an innovative environment that helps overcome barriers to translating research.

Alignment of Different Stakeholders

The key to this coherent way of thinking between different stakeholders has been geography. MeDe has been able to bring together researchers, industry representatives and HCPs from within and around the City of Leeds, in the UK, enabling them to coordinate working towards the same goals in ways that are not possible at a national level.

It is an approach that was highlighted in the Science and Innovation Audit (SIA) for the Leeds City Region that MeDe conducted for the UK Government last year.[4] The audit found that this sort of connectivity is particularly important towards the late phases of the innovation process, when investment is needed to generate evidence required by regulators. While it may take another 10-20 years before these projects achieve large-scale patient benefits, the approach taken by MeDe and our sister program in the Engineering and Physical Sciences Research Council's (EPSRC) Medical Technology Innovation and Knowledge Centre can help drive medical technology innovation forward.

This does not mean, however, that national governments do not have a role to play. A challenge-led approach to funding scientific research – where new knowledge is created in an attempt to address a societal or market need – is the best way to create value and impact. There are some who will argue, however, that this is an inappropriate constraint on the scientific process. Policy judgements need to be made about the balance between discovery-led blue sky research and challenge-led research. In the UK, the Government's Industrial Strategy is attempting to address this by putting additional resources into challenge-led research.[5] It is an approach that may generate greater economic and social value from the science base, for what may only require a small shift in allocation of funding. The potential future for the UK is a strong economy supported by a science and engineering base that is world leading in innovation, as well as world leading in underpinning research.

National governments can also encourage innovation in medical devices by appropriately framing the legislation that governs them. Regulators mandated to enforce the legislation have a key role to play, too. While they can be seen as a barrier to innovation – primarily because regulations are based on historical precedent rather than future products – regulators can help drive innovation forward if they too, innovate. As new technologies are approved by regulatory bodies, further innovation in regulation will be needed as combination devices, digital health, robotics and artificial intelligence (AI) become available and are utilized in daily routines.

Innovation also requires new thinking from finance and investment communities. In the highly regulated medical environment, the return on investment can be much longer and carry a higher risk compared to other business sectors. Therefore, it will be important to have a clear understanding of projected timelines, while understanding that the return on those investments can be high, with some patience. As a result, new models will be needed to address risk and benefit over these longer timelines.

Despite the difficulties in getting all these disparate stakeholders to work together, the orthopedic industry is learning that it can work in new and exciting ways to innovate.

Innovation - Different Thinking and Better Application

With the growth in enabling digital technologies in the healthcare system, large, established orthopedic companies will find themselves increasingly working with young, dynamic organizations that they have not interacted with previously, in order to grow. Wearable technologies like smart watches and fitness trackers, for example, have the potential to provide round-the-clock monitoring of patients from pre-surgery to post-surgery and through rehabilitation. Monitoring in this way could be a new source of demonstrable evidence that an intervention is working, while also providing an early warning that something is going wrong.

New technologies are also driving advances in areas such as precision surgery with the use of robotics, and AI in diagnostics. There is also a push towards stratifying patient populations, creating patient subgroups based on key relevant factors, for treatment (i.e., personalized medicine), rather than treating all patients with a universal approach.

There can be little doubt that these developments and new combinations of technologies are going to fundamentally change the way healthcare is provided and delivered. Not to mention how the stakeholders will work together. These are big challenges, but they can be met if everyone continues to apply new thinking and new approaches. We need to keep innovating. ▲

ABOUT THE AUTHOR

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John Fisher, Professor of Mechanical Engineering at the University of Leeds, has over 40 years of experience in medical engineering research and development in academia, industry and the UK health service. He is the founding Director of the Institute of Medical and Biological Engineering, one of the world's leading medical engineering research units, which was awarded the Queen's Anniversary Prize in 2012.

Professor Fisher was honored as Commander of the Most Excellent Order of the British Empire (CBE) for services to Biomedical Engineering in 2013. He is a Fellow of the Royal Academy of Engineering, Fellow of the Academy of Medical Sciences, Fellow of the Institution of Mechanical Engineers, Fellow of the Institute of Physics & Engineering in Medicine, and a Chartered Engineer and Scientist. He was Pro-Vice-Chancellor / Deputy-Vice-Chancellor of the University of Leeds from 2001-2016.

Professor Fisher is currently Director of the EPSRC (Engineering and Physical Sciences Research Council) Centre for Innovative Manufacturing in Medical Devices (MeDe Innovation), Director of EPSRC Medical Technologies Innovation and Knowledge Centre, Director of the EPSRC Centre for Doctoral Training in Tissue Engineering & Regenerative Medicine.

He has published over 500 journal papers, has a publication h factor of >50 and has supervised over 100 PhDs. He has founded four medical device companies including Tissue Regenix plc, which is listed on AIM, a sub-market of the London Stock Exchange. His research to improve the longevity of artificial joints – and develop novel regenerative scaffolds and devices – is aimed at delivering *50 active years after 50*® and addressing the needs of an aging population.

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