

Evidence for the long-term safety and effectiveness of millions of knee replacement implants lacking

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Knee replacement is amongst the most common surgical procedures in developed countries, with over 650 000 total knee replacements (TKR) performed in the USA in 2008 alone, at a cost of more than \$10 billion. Yet there is very little or no evidence of the safety or cost-effectiveness for many of the numerous types of implants on the market. Furthermore, a lack of reliable information comparing patient-reported outcomes with different implants and surgical techniques is preventing surgeons from achieving the best outcomes for patients, according to a Seminar published Online First in *The Lancet*.

"The [regulatory framework](#) for new implants varies worldwide but has been generally much less rigorous than for [new drugs](#). Currently, proof of safety of implanted materials is all that is required prior to approval for clinical use, rather than evidence for [clinical effectiveness](#)"*, explains Andrew Carr from the University of Oxford, Oxford, UK, author of the Seminar. "Widespread surveillance of existing implants is urgently needed alongside the carefully monitored introduction of new implant designs as part of well conducted large-scale randomised trials."

National joint-replacement registries that collect data on patient characteristics, type of implant, surgical technique, and surgeon experience, are one of the few sources of comparative information for patients and surgeons.

But, according to Carr: "There is increasing evidence to suggest that published clinical-trial outcomes for individual knee replacements report better results than those available from registries." He adds: "Without high-quality, unbiased, and reliable information, surgeons cannot make informed decisions about how to achieve the best outcome in each clinical situation."

Because orthopaedic manufacturers are continually introducing new implant designs, registries (as the ultimate quality-assurance [surveillance system](#)) need to monitor outcomes of new implants and technologies.

However, Carr points out: "Patients should be reassured that knee replacement surgery has proved to be one of the outstanding success stories of modern medicine and has resulted in significant quality of life gains for people with end stage arthritis."

Since the first knee replacement was performed in 1968, the numbers of knee replacements have increased year on year in [developed countries](#). For instance, in the USA, rates have risen from 31.2 per 100 000 person-years in 1971^[1], to 220.9 in 2008. In the UK, rates for women increased from 43 per 100 000 person-years in 1991 to 137 in 2006.

There is considerable concern that an ageing population, rising rates of obesity, and replacements increasingly being fitted in younger patients will lead to a dramatic increase in demand for knee replacement surgery over the next two decades. This could have huge economic implications and lead to substantial increases in the likelihood of revisions (a replacement being redone) and complications.

Carr suggests improving patient selection for surgery and targeting resources to new treatment strategies that avoid the need for major surgery (including managing arthritis at earlier stages and reversing or slowing down the progression of disease) to reduce the demand for [knee-](#)

[replacement](#) surgery.

The Seminar concludes by calling for improved long-term monitoring of outcomes using national registries and electronic patient records (reporting rates of revision surgery, patient-reported outcomes, and patient satisfaction) with the aim of providing patients and surgeons with good quality evidence to assess different implants and techniques and enhance clinical decision making.

Provided by Lancet

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