

One size does not fit all for knee replacements and other medical devices

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Undergoing a knee replacement involves sophisticated medical equipment, but innovative prosthetic design may not offer the same benefits for all knee replacement recipients, Yale School of Medicine researchers report in a perspective article in the 20 October issue of New England Journal of Medicine.



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Devices like pacemakers, artificial joints, and defibrillators have extended lives and improved the quality of life for countless people. Medical device manufacturing has turned into a multi-billion dollar industry, with the United States spending an estimated \$95 billion on these devices last year alone, according to the article, which also noted that oversight of device innovation is under scrutiny for safety issues.

The current expedited approval process for low-risk medical devices is based on claims of similarity to previously approved devices, and as such may encourage development of devices that provide only small improvements at higher cost than their predecessors, note the researchers.

To assess whether the addition of a new medical devices to market would yield a greater benefit than using an older version, first author Dr. Lisa G. Suter, assistant professor of internal medicine at Yale School of Medicine, and colleagues used a mathematical model to simulate the consequences of undergoing total knee replacement for end-stage knee osteoarthritis with both standard and innovative implants. Knee osteoarthritis is a frequent and costly cause of disability in the United States.

The researchers used the Osteoarthritis Policy Model, a validated computer simulation model of knee osteoarthritis natural history and management, to project life expectancy and implant survival associated with using standard and innovative implants for both young and older total knee replacement recipients with and without illness.

Suter and her team found that older patients or those with multiple co-existing conditions may not live long enough to benefit

from small, incremental gains in the durability of the implant.

"Patients, physicians, device manufacturers, and policymakers should be aware that innovative medical devices may not offer equal value in all patients," said Suter, who added that mathematical models may improve medical device development, evaluation and monitoring.

Other authors on the perspective article include A. David Paltiel, Benjamin N. Rome, Daniel H. Solomon, M.D., Ilya Golovaty, Hanna Gerlovin, Jeffrey N. Katz, M.D., and Elena Losina, from Brigham and Women's Hospital and Harvard Medical School.

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