Medical Device Innovation — Is "Better" Good Enough?

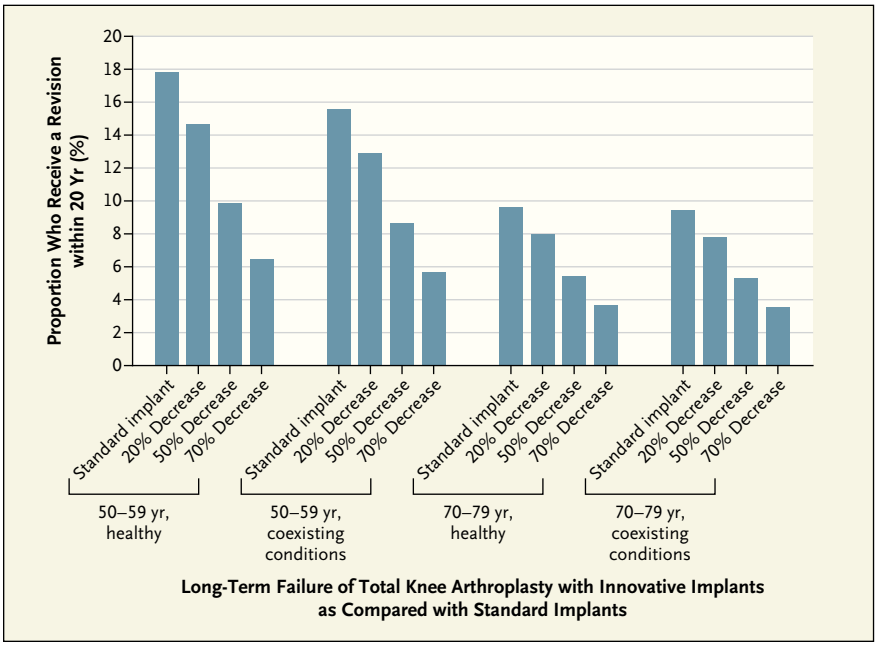
Lisa G. Suter, M.D., A. David Paltiel, Ph.D., Benjamin N. Rome, B.A., Daniel H. Solomon, M.D., M.P.H., Ilya Golovaty, B.S., Hanna Gerlovin, B.A., Jeffrey N. Katz, M.D., and Elena Losina, Ph.D.

Last year, the United States spent $95 billion on medical devices, nearly half of the $200 billion spent on devices worldwide.[1] Our investment in devices has yielded impressive gains in length and quality of life from products such as implantable cardioverter–defibrillators, pacemakers, and artificial joints (cardiovascular and orthopedic devices account for more than 35% of the market[1]). Roughly 10 million Americans have symptomatic knee osteoarthritis,[2] a leading cause of disability and the most common indication for total knee arthroplasty. More than 600,000 total knee arthroplasty procedures are performed annually in the United States; 85% of recipients report functional improvement, and the annual failure rate is 0.5 to 1.6%.[3] Inspired by these successes, medical device innovation continues. Each year for the past decade, the Food and Drug Administration (FDA) has approved more than 35 new systems or components for total knee arthroplasty. Most are designed to improve durability, and their manufacturers cite laboratory studies showing reductions in wear. Advertising campaigns promote innovative implants for younger, more physically active patients, expanding the market for knee arthroplasty.

But oversight of device innovation is currently under scrutiny. Safety concerns have been raised over total joint components and other devices approved through the FDA's 510(k) clearance process, whereby devices perceived as posing a low risk of complications are approved for marketing without clinical trials. These concerns led the Institute of Medicine to recommend eliminating the 510(k) process, calling it ineffective and unsalvageable.[4] The current oversight system has been simultaneously faulted for inadequate assurance of safety and efficacy and for suppressing innovation. Since regulatory approval hinges on claims of similarity to previously approved devices, the process may encourage the development of devices that provide only small improvements at higher cost than their predecessors. The trade-offs between incremental improvement and the additional costs and technical complexity of the required procedure are poorly understood and seldom investigated rigorously.

When adequately powered randomized trials are not feasible, a model-based approach can offer insight into the interplay among device efficacy and durability, patient characteristics, costs, and long-term outcomes. We used a validated "state-transition" computer-simulation model of the natural history and management of knee osteoarthritis[5] to forecast clinical outcomes associated with hypothetical "innovative" total knee implants as compared with existing implants. We considered cohorts of persons with end-stage, symptomatic knee osteoarthritis, stratified by age and presence of coexisting conditions at the time of arthroplasty. We used a range of values for the potential reduction in the likelihood of long-term implant failure with hypothetical innovative implants and estimated the proportion of each patient cohort that would remain alive with their original (standard or innovative) implant intact 20 years after surgery. We examined the effects of increasing the risk of short-term failure while simultaneously decreasing the rate of long-term failure, as might be expected from a device offering improved survival at the expense of greater technical complexity. (Details are presented in the Supplementary Appendix, available with the full text of this article at NEJM.org.)

According to our model, by 20 years after a standard total knee arthroplasty, 19% of people who were healthy and 50 to 59 years of age at the time of the surgery and 86% of those who were 70 to 79 years of age and had coexisting conditions would have died; 65% and 11% of these groups, respectively, would be alive with their original implant intact. In part because of the much higher risk of death among older patients, the cumulative risk of requiring revision surgery within 20 years after a primary total knee arthroplasty would be twice as high among younger, healthier patients than among older patients with coexisting conditions (18% vs. 9%; see graph). Innovative implants with long-term failure rates 70% lower than those of current implants (an improvement similar to those that some manufacturers have demonstrated in the laboratory) would reduce the cumulative risk of revision by 11% among healthy 50-to-59-year-olds and 6% among 70-to-79-year-olds with coexisting conditions.



Cumulative Risk of Revision Surgery 20 Years after Total Knee Arthroplasty with a Standard Implant and with an Innovative Implant, According to Computer-Simulation Modeling.

If short-term failure rates quintupled (as recent data on innovative orthopedic devices suggest they could), the reductions in cumulative risk of revision would be lessened by 35% among healthy 50-to-59-year-olds and 59% among 70-to-79-year-olds with coexisting conditions, potentially offsetting the benefits of decreases in long-term failure.

Our findings suggest that there can be no one-size-fits-all approach to the use of innovative devices. In the case of total knee arthroplasty, a patient's life expectancy has a marked effect on his or her anticipated benefit from improvements in durability over existing implants, whose survival rates are already excellent. Given the low annual failure rate of existing implants, even significant reductions in long-term failure rates would have little effect on overall implant survival in older, sicker patients. This finding is even more significant when innovative implants have greater short-term failure rates (possibly attributable to the learning curve associated with new technology). There are also additional trade-offs that should be considered in evaluating and pricing innovative devices. For example, innovations are typically accompanied by cost increases, and devices providing small, incremental clinical benefits may be less likely to offer good value for any additional investment.

We believe that our approach and the insights it can offer extend well beyond knee implants. Total knee implants are similar to many medical devices — such as hip and spinal implants, other orthopedic hardware, and ophthalmologic implants — in that they improve quality of life rather than survival. Thus, our work has implications for the development and adoption of any medical device offering improved long-term clinical benefit at increased initial cost. These analyses demonstrate that even small decreases in long-term device failure can provide clinical value, but these innovations are unlikely to provide equal benefit to all patients. Innovative technologies may also increase the risk of short-term complications, owing to increased complexity of the procedure or the greater technical skill required to optimally implement such advances — a phenomenon that is rarely captured in laboratory-based testing. Furthermore, these technologies typically cost more than their predecessors. These considerations may further restrict the populations in which an innovative device offers good value.

Our goal is not to set limits on who receives which implants, but to illustrate a model-based approach to improving new-device evaluation. Decisions about the marketing, use, and pricing of medical devices are often made in the absence of robust outcomes data. As the current controversy over the 510(k) process attests, traditional approaches to clinical investigation and evaluation are poorly suited to exploring and balancing the competing considerations at play — for instance, estimating likely improvements in long-term efficacy and device durability, factoring in the competing risks when devices are used in older or higher-risk patients, and determining our willingness to pay for incremental improvements. A model-based assessment can help to define the circumstances under which the diffusion of medical device innovations to ever-expanding patient populations is clinically and economically justified.

Model-based evaluations could help define the thresholds for complication and efficacy rates and costs that would be required

to improve on existing device performance while maintaining acceptable economic value. This information could then inform postmarketing surveillance efforts, triggering reviews at prespecified efficacy or complication thresholds and facilitating rapid application of new data as they become available. Manufacturers could use such data to improve device development; researchers could identify target populations for evaluating novel technologies; insurers could identify opportunities for value-based reimbursement; and consumers could be educated about what clinical benefits they are getting for their money. The complex trade-offs between short- and long-term health and economic consequences of technological innovation may not be captured by even the most sophisticated randomized trials. Model-based approaches may provide invaluable insights for evaluating medical device innovation and merit consideration as a standard component of the evaluation process.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From Yale School of Medicine (L.G.S.) and Yale School of Public Health (A.D.P.) — both in New Haven, CT; the Veterans Affairs Connecticut Healthcare System, West Haven, CT (L.G.S.); and Brigham and Women's Hospital (B.N.R., D.H.S., I.G., H.G., J.N.K., E.L.), Harvard Medical School (D.H.S., E.L.), Harvard School of Public Health (J.N.K.), and Boston University School of Public Health (E.L.) — all in Boston.

1. O'Keeffe K. The rise of Medtech. Medical Device and Diagnostic Industry, June 10, 2011. (http://www.mddionline.com/article/rise-medtech.)
2. Lawrence RC, Felson DT, Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: part II. Arthritis Rheum 2008; 58:26-35.
3. Paxton EW, Namba RS, Maletis GB, et al. A prospective study of 80,000 total joint and 5000 anterior cruciate ligament reconstruction procedures in a community-based registry in the United States. J Bone Joint Surg Am 2010;92:Suppl 2:117-32.
4. Institute of Medicine. Medical devices and the public's health: the FDA 510(k) clearance process at 35 years. Washington, DC: National Academies Press, 2011. (http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx.)
5. Losina E, Walensky RP, Reichmann WM, et al. Impact of obesity and knee osteoarthritis on morbidity and mortality in older Americans. Ann Intern Med 2011;154:217-26.

The Supply-Side Economics of Abortion

Theodore Joyce, Ph.D.

Under legislation recently signed by Kansas's governor, the Kansas Department of Health and Environment has issued new licensing standards for abortion clinics. The regulations stipulate, among other requirements, that facilities must have procedure rooms of at least 150 ft²; each procedure room must have janitorial space of at least 50 ft²; facilities must have designated dressing rooms for patients and separate ones for staff; and each dressing room must have a toilet, a washing station, and storage for clothing.[1] Two physicians who provide abortions in their office-based practice filed suit, stating that the requirements were unnecessary to ensure patient safety and would force them to stop providing abortion services. On July 1, 2011, a federal judge issued a temporary injunction allowing all three providers in Kansas to continue operating for the time being.

Such licensing requirements reflect an aggressive new thrust on the part of abortion opponents. Early approaches to restricting abortion access were directed largely at patients — the demand side of the market. For instance, laws requiring parental involvement in a minor's decision to abort, limiting Medicaid funding of abortion, mandating the provision of information including unfounded claims about risks, and requiring a 24-hour waiting period between receipt of mandated information and an abortion are all efforts to discourage women from terminating their pregnancies. Although these demand-side policies have had relatively little impact on national abortion rates, they have prevented some women from terminating an unwanted pregnancy. Not surprisingly, the women most affected are those without the support and resources to circumvent or comply with these requirements.[2]

Perhaps frustrated by many women's determination to overcome demand-side hurdles, abortion opponents have turned to supply-side restrictions, focusing on providers of abortion services. This strategy is likely to be more effective. In 2004, 12 states had fewer than five non-hospital-based abortion providers and 7 states had one or no provider that performed at least 400 abortions per year. Larger clinics are the mainstay of the service: 94% of all U.S. abortions are performed in