

EDITORIALS



Parachutes and Preferences — A Trial of Knee Replacement

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The term parachute trial entered the medical lexicon to depict studies of treatments everyone already assumes to be effective. (In other words, do we need a trial to show that parachutes save the lives of persons who jump from airplanes?¹) The parachute trial has been invoked to decry randomized trials of total joint replacement as senseless. After all, joint replacements are among the most significant advances of the 20th century; don't we already know they are successful?

Nearly 1 million elective total knee and hip replacements are performed annually in the United States; rates of total knee replacement tripled in the past 20 years and are projected to increase further.^{2,3} More than 90% of total knee replacements are performed for knee osteoarthritis, which affects approximately 14% of adults in the United States in their lifetimes.⁴ Prior to the introduction of total knee replacement in the 1970s, patients with advanced knee osteoarthritis frequently became housebound; now such patients can remain mobile. By all accounts, total knee replacement is a game changer. So why subject it to a randomized, controlled trial?

First, total knee replacement poses risks. About 0.5 to 1% of patients die during the 90-day postoperative period. The risks of deep venous thrombosis, pulmonary embolus, deep prosthetic infection, and periprosthetic fracture range from 0.1 to 1.0%,^{5,7} with higher risks among older persons and those with a higher number of coexisting conditions.^{5,7} Second, the procedure is not universally successful; approximately 20% of patients who undergo total knee replacement have residual pain 6 or more months after the

procedure.⁸ Third, there are alternatives. Clinical trials have shown that physical therapy (including exercises and manual therapies) can diminish pain and improve functional status in patients with advanced knee osteoarthritis.⁹⁻¹¹ Until now, we have lacked rigorously controlled comparisons between total knee replacement and its alternatives.

Finally, an ideal treatment for one patient may not be right for the next. Patients with knee osteoarthritis differ in the importance they attach to pain relief, functional improvement, and risk of complications. Therefore, treatment decisions should be shared between patients and their clinicians and anchored by the probabilities of pain relief and complications and the importance patients attach to these outcomes.

These considerations set the stage for the carefully designed and executed trial by Skou et al., whose results are reported in this issue of the *Journal*.¹² In this randomized, controlled trial, involving 100 patients with symptomatic knee osteoarthritis, patients were assigned to undergo total knee replacement followed by a rigorous 12-week nonsurgical-treatment regimen (total-knee-replacement group) or to receive only the nonsurgical treatment (nonsurgical-treatment group), which consisted of supervised exercise, education, dietary advice, use of insoles, and pain medication. Total knee replacement proved markedly superior to nonsurgical treatment alone in terms of pain relief and functional improvement. The percentage of patients who had an improvement of at least 15% (a clinically important difference) in the score for pain after 1 year was 85% in the total-knee-replacement group and 68% in the nonsurgical-treatment group. In

fact, 26% of patients in the nonsurgical-treatment group elected to undergo total knee replacement before the 12-month follow-up, and more patients are likely to cross over as follow-up extends further.

However, it is noteworthy that more than two thirds of the patients in the nonsurgical-treatment group had clinically meaningful improvements in the pain score and that this group had a lower risk of complications. In the total-knee-replacement group, several severe adverse events occurred, including three episodes of deep venous thrombosis, one deep infection, one supracondylar fracture, and three episodes of stiffness requiring manipulation of the knee while the patient was anesthetized. The nonsurgical-treatment group had one episode of stiffness requiring manipulation of the knee while the patient was anesthetized and none of the other complications. In short, although total knee replacement was clearly superior in terms of pain relief, these findings suggest that the decision for treatment with total knee replacement is no parachute at all. Patients face choices that are associated with different levels of symptomatic improvement and risk: as compared with nonsurgical treatment, total knee replacement is associated with a higher level of improvement and a higher risk of adverse events. Each patient must weigh these considerations and make the decision that best suits his or her values.

As with all good studies, this randomized, controlled trial answers some questions and raises others. Sham-controlled trials have suggested that both surgical therapy and physical therapy can have a potent placebo effect.^{13,14} In the absence of an untreated control group, some of the improvement that was seen in both groups may be attributable to placebo effects. Also, we do not know whether the benefit of nonsurgical treatment will be sustained over time. Finally, the study by Skou et al. was too small to examine the efficacy of total knee replacement in relevant subgroups, such as patients with mild baseline pain and dysfunction.

The trial by Skou et al. provides the first rigorously controlled data to inform discussions between patients and their physicians about whether to undergo total knee replacement or rigorous nonsurgical therapy. For most patients, the dramatic pain relief associated with total knee re-

placement provides a compelling rationale to choose surgery. Other patients, particularly those who are more risk-averse, may prefer nonsurgical care. Since patients vary considerably in their preferences, physicians should present the relevant data to their patients and then listen carefully.

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