Patient-reported outcome measures (PROMs) are used when traditional measures of surgical success (eg, mortality rate, procedural volume) are not sensitive enough to distinguish variations in patient outcome. Patient-reported outcome measures are useful to define and better understand patient expectations from surgery and to characterize how well surgery has met those expectations. Patient-reported outcome measures typically focus on patient-perceived outcomes such as pain, symptom relief, quality of life, disability, and restoration of functional ability. However, preoperative patient expectations were shown to be inconsistently correlated with postoperative PROMs in a recent meta-analysis. Patient-reported outcome measures are sometimes used as clinical trial endpoints, especially in orthopedics. Because of the documented inconsistency of PROMs as an evaluative tool, we believe that they should be used with an understanding of their limitations.

Surgical outcomes can potentially conflict with patient perceptions. For example, patients given opioids for fracture analgesia may be less troubled with pain but may be put at risk for poor clinical outcomes, including fracture nonunion or opioid addiction. Patient-reported outcome measures that measure patient satisfaction would therefore conflict with the desired clinical outcome.

Patient-reported outcome measures can be insensitive to clinical outcomes important to the clinician. In a clinical trial that randomized patients to pain relief with nonsteroidal anti-inflammatory drugs or placebo following hip replacement surgery, there was a lower risk of ectopic bone formation with nonsteroidal anti-inflammatory drugs, although PROMs related to hip pain did not differ. Given that ectopic bone formation affects more than one-third of patients undergoing elective hip replacement, this is an important clinical finding that was not captured by PROMs. Study authors—who argued in favor of the importance of PROMs in hip replacement patients—concluded that trial results did not support routine prophylaxis with nonsteroidal anti-inflammatory drugs. However, the odds of developing a severe grade of ectopic bone formation were significantly and substantially reduced with ibuprofen prophylaxis.

Other examples of the insensitivity of PROMs to surgical outcomes of importance are not difficult to find. For example, a randomized clinical trial tested 3 different types of graft for anterior cruciate ligament reconstruction. This trial randomized 330 patients to grafting with patellar tendon, hamstring tendon, or double-bundle hamstring tendon. Quality-of-life PROM scores for all graft materials were comparable at 2-year follow-up, showing that patients could not discern between these surgical approaches. However, traumatic reruptures and other surgical complications were significantly less likely to occur with a patellar tendon reconstruction.

Patient-reported outcome measures and clinical measures were also discordant in a clinical trial that evaluated pain outcome in patients with osteoporotic vertebral compression fracture. Patients were allocated to either balloon kyphoplasty or conservative treatment, with the latter including analgesics,
bed rest, a back brace, and walking aids. Patients reported better 1-month pain outcomes following kyphoplasty, although kyphoplasty and conservative treatment had equivalent clinical outcomes at the 1-year follow-up. If clinical outcomes are equivalent, conservative treatment should be preferred because it promotes natural healing, is substantially less expensive, and does not induce fracture in adjacent vertebrae. We note as well that pain during conservative treatment can usually be successfully medicated.

Self-reported pain, a common PROM, can be a misleading measure of clinical success. In a recent study, patients were randomized to either cognitive behavioral therapy or standard pre-surgical information prior to lumbar spinal fusion. Cognitive behavioral therapy was offered in an effort to improve mobility and reduce analgesic use in the first week following surgery. Participation in preoperative cognitive behavioral therapy did not significantly reduce self-reported back pain, but patient mobility was improved following the intervention. Furthermore, cognitive behavioral therapy significantly reduced analgesic consumption by the second postoperative day. In this trial, cognitive behavioral therapy may have encouraged beneficial pain-coping behavior by altering patients’ perception, thereby reducing the adverse effects of pain. That self-report of pain is so malleable to psychological intervention suggests that patient pain perception is a function of intangibles such as anxiety, ambivalence, worry, uncertainty, and insecurity. It is possible that a focus on pain alleviation through cognitive behavioral therapy encouraged patients to experience the same pain in a more positive way, confirming that the experience of pain is subjective and therefore prone to placebo effect.

Patient-reported outcome measures are unverifiable because they rely on patient report, and they can be influenced by preexisting depression or anxiety. Patients who have positive preoperative expectations report less postoperative pain and disability than patients who have negative preoperative expectations, confirming that PROMs are dependent on perception and can be independent of the surgical outcome achieved. In orthopedic studies, PROMs are generally associated with greater responsiveness to treatment than are clinician measures, suggesting that placebo effects can influence PROMs. We note as well that PROMs can be manipulated; patients may be motivated to report a poor surgical outcome if they seek a prescription for opioid analgetics.

Patient-reported outcome measures and clinical outcomes both have validity, but they have strikingly different purposes. Patients want PROMs that meet their information needs prior to surgery, and patients who receive appropriate information from PROMs may be more satisfied after surgery. This can be important, as it helps surgeons to market surgery appropriately to patients. Patient-reported outcome measures are ultimately most useful if the concern is with patient satisfaction. However, clinical and radiological outcomes are superior to PROMs if the concern is with documenting patient healing. Surgeons are generally good at assessing surgical results, especially when there is an objective measure of success, such as an imaging examination of a healed fracture. Whether to use PROMs or clinical measures in a study should be determined by study goals and not by ideology.

REFERENCES