Letters to the Editor

Valid and Relevant Outcome Measures Are Critical for Objective Hypothesis-Testing

To the Editor:

Regarding Hofmann-Kiefer et al.’s article,1 we question the appropriateness of using the Constant-Murley Assessment score as the investigation’s primary endpoint. To test the study hypothesis, the Constant score was assessed the day before surgery and then 96 h postoperatively.1 However, the Constant score was originally designed “to assess function after injury”—not surgery2; and it has not been validated for patients in the immediate postoperative period.3 Among articles using the Constant score, none involved patients within 4 wk of surgery: five, including the initial report, included healthy volunteers and/or nonsurgical clinic patients3–7; another included postrotator cuff repair patients at least 1 mo postoperatively;8 and the last studied preoperative patients.9 The authors of the current study indirectly acknowledge this lack of validation in the immediate postoperative period when they explain, “because most of our (postoperative) patients were not completely pain-free, even at rest, one item of the Constant score had to be adopted for our purposes [emphasis added].” Moreover, it is doubtful that the Constant score is even relevant to the hospitalized population studied by Hofmann-Kiefer and colleagues.

Among the 100 possible points comprising the Constant score, maximum active shoulder abduction (10%), flexion (10%), external rotation (10%), strength (25%), and limb positioning (10%) comprise 65% of the total.2 Although there are no universally accepted post-open acromioplasty and rotator cuff repair rehabilitation guidelines, most patients receive passive range-of-motion within safe and pain-free ranges to prevent a loss of shoulder mobility, and progression to active exercises occurs only after “1–3 wk, but much more gradually after an open procedure.”10–12 This is to avoid injuring the supraspinatus and/or deltoid repairs. And, predictably, the authors found that only 5.9% of the patients in the PCA group and 13.5% in the PCISB group were able to perform the strength test.1” The majority of active range-of-motion and strength tests are simply inapplicable and irrelevant for this patient population in the immediate postoperative period. Eight additional Constant score points are determined by “activity level” during “work” and “recreation/sport,” which is, again, irrelevant in these hospitalized patients.3

Given that at least 73% of the Constant score is inapplicable or irrelevant to this hospitalized patient population, it is apparent why this measure has never been validated in the immediate postoperative period. We thus conclude that the Constant score was an inappropriate primary endpoint and that the study’s hypothesis was therefore inadequately tested. Drawing conclusions from the study results is a subjective exercise, and not an objective analysis. It would be unfortunate and counterproductive if the medical community assumed the Constant score is a valid, reproducible, and relevant assessment tool in the immediate postoperative period. We welcome a thoughtful discussion of this topic with our valued colleagues.

Brian M. Ilfeld, MD, MS
Department of Anesthesiology
University of California San Diego
San Diego, California

Thomas W. Wright, MD
Department of Orthopedics
University of Florida
Gainesville, Florida

Daniel I. Sessler, MD
Department of Anesthesiology
Ohio State University Medical Center
Columbus, Ohio

Terese L. Chmielewski, PhD, PT
Department of Physical Therapy
University of Florida
Gainesville, Florida

REFERENCES


In Response:

Ilfeld et al.1 question the validity of the Constant-Murley assessment2 (CS) for the immediate postoperative
period after open shoulder surgery and whether this scoring system is relevant for hospitalized patients. In our opinion, there are two requirements for validating a new measurement system: the results from a new test can be compared with those obtained from established and reliable predecessors, i.e., a “gold standard,” or the test has to prove its reliability over an extended period of time and numerous applications in clinical trials and (with restrictions) by mathematical and/or statistical controls.

When Constant and Murley developed their score in 1987, standard tests to evaluate shoulder pathology did not exist. However, the CS is now the most frequently used method for assessing shoulder function in orthopedics and trauma surgery. The CS is the only measurement validated in the original paper and, more importantly, validated by comparison with other measurement systems, such as the “Neer-Score.” In addition, the CS is explicitly recommended for use in the postoperative period by the European Society for Surgery of the Shoulder and Elbow (ESSSE). Thus, we believe the CS to be the gold standard for postoperative shoulder testing.

Although some use regional anesthesia for pain control at home, presently, most catheters are removed before the patient leaves the hospital. Therefore, it is important to assess the influence of regional anesthesia on the early postoperative period. Ilfeld et al. have done so themselves. We do not claim the CS to be an ideal measurement tool for this period, and explicitly referred to this limitation in our results and discussion section. However, regarding the remarks of Ilfeld and co-workers on the most important part of the CS testing-active motion may be inadequate as an instrument of early physiotherapy, but could be easily and safely practiced during the short CS testing periods. None of our patients suffered any harm during the study. On the contrary, the risk to damage of the supraspinatus and/or deltoid repairs may even be less than that during passive training, if the patient is in control of his/her movements. As stated—and criticized—by Ilfeld et al., one subsection of the CS is titled “Activity of Daily Life” (ADL). To be “active” as early as possible after surgery today is one of the basic principles of modern patient management. Hospitalized patients nowadays are “out of bed” on the first postoperative day and we see no reason to exclude this point from the Score.

Klaus F. Hofmann-Kiefer, MD
Tim Eiser, MD
Daniel Chappell, MD
Stephan Leuschner, MD
Peter Conzen, MD
Dierk Schwender, MD
University of Munich
Munich, Germany
klaus.hofmann-kiefer@med.uni-muenchen.de

REFERENCES
1. Ilfeld BM, Wright TW, Sessler DI, Chmielewski TL. Valid and relevant outcome measures are critical for objective hypothesis-testing. Anesth Analg 2008;107:722
5. European Society for Surgery of the Shoulder and the Elbow. 2007 Ref Type: Internet Communication: http://www.shoulderdoc.co.uk/education/article.asp

Dr. Paul: Views Through the Piperidine Ring

To the Editor:

Stanley et al. have written an excellent and thorough tribute to Dr. Paul A. J. Janssen. Dr. Janssen’s significant contributions to humanity, anesthesiologists, and their patients are impressive. The many details of his remarkable life with multiple interests are especially interesting. I was unaware that Dr. Janssen spent 6 months in 1948 in the United States and attended a series of lectures given by Carl Pfeiffer, who was Head of Pharmacology at the University of Illinois in Chicago. At that time, I was in medical school at the same university but had no idea that such a future famous man and I were attending the same pharmacology lectures. Pfeiffer’s lectures were accompanied by many chemical formulae and structure-activity relationships. Dr. Janssen must have been influenced by these lectures as were the graduate and medical students in attendance. It is in that spirit I have separated the chemical structures of meperidine and fentanyl and then superimposed meperidine/fentanyl, and fentanyl/morpine. It may help the reader appreciate the elegant chemical relationships of fentanyl and other “tanils” to meperidine as well as to morpine, as seen through the piperidine rings (Figs. 1–3).

Edward F. Domino, MD
Department of Pharmacology
University of Michigan
Ann Arbor, Michigan
efdabcde@umich.edu