High Variability in Outcome Reporting Patterns in High-Impact ACL Literature

Eric C. Makhni, MD, MBA, Ajay S. Padaki, BS, Petros D. Petridis, MS, Michael E. Steinhaus, MD, Christopher S. Ahmad, MD, Brian J. Cole, MD, MBA, and Bernard R. Bach, Jr., MD

Investigation performed at the Columbia University Medical Center, New York, NY

Background: ACL (anterior cruciate ligament) reconstruction is one of the most commonly performed and studied procedures in modern sports medicine. A multitude of objective and subjective patient outcome measures exists; however, nonstandardized reporting patterns of these metrics may create challenges in objectively analyzing pooled results from different studies. The goal of this study was to document the variability in outcome reporting patterns in high-impact orthopaedic studies of ACL reconstruction.

Methods: All clinical studies pertaining to ACL reconstruction in four high-impact-factor orthopaedic journals over a five-year period were reviewed. Biomechanical, basic science, and imaging studies were excluded, as were studies with fewer than fifty patients, yielding 119 studies for review. Incorporation of various objective and subjective outcomes was noted for each study.

Results: Substantial variability in reporting of both objective and subjective measures was noted in the study cohort. Although a majority of studies reported instrumented laxity findings, there was substantial variability in the type and method of laxity reporting. Most other objective outcomes, including range of motion, strength, and complications, were reported in <50% of all studies. Return to pre-injury level of activity was infrequently reported (24% of studies), as were patient satisfaction and pain assessment following surgery (8% and 13%, respectively). Of the patient-reported outcomes, the International Knee Documentation Committee (IKDC), Lysholm, and Tegner scores were most often reported (71%, 63%, and 42%, respectively).

Conclusions: Substantial variability in outcome reporting patterns exists among high-impact studies of ACL reconstruction. Such variability may create challenges in interpreting results and pooling them across different studies.

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ACL (anterior cruciate ligament) reconstruction is one of the most commonly performed—and studied—surgical procedures in modern sports medicine[1]. Patients undergoing ACL reconstruction are typically individuals who regularly participate in athletic and demanding activities; therefore, restoration of functional outcomes to pre-injury levels is of utmost importance. Orthopaedic clinicians must be able to measure postoperative success in a reliable, reproducible fashion in order to improve patient care, communication, and research efforts.

There are multiple methods whereby practitioners can evaluate ACL reconstruction results. These include objective clinical outcomes, such as range of motion, strength, and ligamentous laxity, as well as patient-reported outcomes (PROs). PROs offer many advantages over traditional objective clinical metrics, allowing patients to subjectively assess their knee function with respect to their pre-injury activity level and their desired postoperative activity level. A multitude of these PROs have been developed[2] to specifically measure functional outcome after ACL reconstruction.

A lack of consensus exists among practitioners regarding appropriate utilization of these assessment tools, resulting in high variability in the reporting of clinical outcomes for patients

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TABLE I Objective and Subjective Outcomes Assessed

Objective	Subjective
Range of motion	Return to pre-injury sport/activity
Muscle size	Satisfaction
Quantitative muscle strength	Pain (visual analog scale or qualitative)
Quadriceps (extensor)	Global functional assessment
Hamstring (flexor)	IKDC (International Knee Documentation Committee)
Laxity testing	Lysholm Knee Scale
Anterior drawer test	Tegner Activity Scale
Lachman	KOOS (Knee Injury and Osteoarthritis Outcome Score)
Pivot-shift	SF (Short Form; all variants)
Instrumented laxity (KT, Telos, Rolimeter)	Cincinnati/Noyes Knee Rating System
Functional testing (hop testing)	Marx Activity Scale
Diagnostic/imaging	EQ-5D (EuroQol-5D)
Degenerative joint changes	ACL-QOL (Quality of Life)/Mohtadi
Hardware status	WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)
Tunnel/aperture widening	OAK (Orthopädische Arbeitsgruppe Knie)
Tunnel location/alignment	HSS (Hospital for Special Surgery Knee Scoring System
Graft integrity	KOS-ADLS (Knee Outcome Survey—Activities of Daily Living Scale)
Surgical complications	Irrgang
Revision ACL repair	Larson
Contralateral ACL rupture	KSS (Knee Society Score)

undergoing ACL reconstruction. This variability creates challenges in interpreting results of clinical studies that utilize different clinical assessment tools.

The goal of this study was to objectively quantify the variability in outcome reporting in clinical studies of patients undergoing ACL reconstruction in high-impact orthopaedic journals. We hypothesized that there would be high variability in (1) types of outcomes reported (objective and subjective metrics) and (2) types of validated PROs reported.

Materials and Methods

Study Inclusion

Four orthopaedic journals with high impact factors were selected for review in this study: *The Journal of Bone and Joint Surgery* (American Volume) (JBJS), *Clinical Orthopaedics and Related Research* (CORR), *The American Journal of Sports Medicine* (AJSM), and *Arthroscopy*. These journals have been used in similar prior studies that have reviewed high-quality sports medicine clinical studies[3,4]. For each of these journals, all articles published over a five-year period, from January 2010 through December 2014, were reviewed. Any study involving patients undergoing ACL reconstruction was considered for inclusion. Those studies that reported nonclinical outcomes (i.e., imaging, biomechanical, or basic science studies), as well as studies of skeletally immature patients, were excluded. Additionally, all studies with a small patient cohort size (defined as fewer than fifty patients) were excluded.

There were 119 studies that met our inclusion criteria[5-123]. Each study was reviewed by an orthopaedic surgical chief resident and two dedicated research assistants. Any data collection conflicts were resolved through consensus. For each study, the journal, publication year, level of evidence, country of origin, study type, number of patients followed, and patient characteristics were noted. A variety of clinical outcomes were reported in the included studies: (1) range of motion, (2) strength, (3) laxity measurements, (4) postoperative diagnostic or

TABLE II Study Characteristics*

Level of Evidence	Journal	Year	Study Type
I: 16%	JBJS: 8%	2010: 19%	Prospective RCT: 25%
II: 34%	CORR: 3%	2011: 20%	Prospective, nonrandomized: 33%
III: 28%	AJSM: 46%	2012: 27%	Retrospective: 34%
IV: 22%	Arthroscopy: 43%	2013: 19%	Registry: 4%
		2014: 15%	Cross-sectional: 5%

*N = 119 studies from 2010 to 2014. RCT = randomized clinical trial.

TABLE III Specific Outcome Focus Stated in Study Purposes*

Study Purpose	Studies
Nonspecific clinical outcomes only	47 (39%)
Outcomes in addition to clinical outcomes	
Imaging/characteristics of graft or tunnel	23 (19%)
Stability/laxity	20 (17%)
Progression to degenerative joint disease	16 (13%)
Adverse outcome (reinjury or revision)	11 (9%)
Return to activity/sport level	10 (8%)
Quality of life	5 (4%)

*N = 119 studies.

imaging results, (5) complications (including reporting of ACL rerupture and contralateral ACL rupture), and (6) PROs.

Objective Outcome Reporting

Objective outcomes included range of motion, strength, functional (hop) testing, ligamentous laxity, and postoperative diagnostics or imaging. Studies were noted to report the range of motion if they reported either quantitative outcomes regarding postoperative motion or qualitative outcomes such as the proportion of patients with full range of motion. Studies that reported quantitative measurements of quadriceps (extensor) strength and hamstrings (flexion) strength were noted. Any reporting of qualitative muscle characteristics or size, such as thigh circumference or cross-sectional area on advanced imaging, was also separately noted.

Functional testing included timed or distance testing of the involved extremity. This involved primarily single-leg hop tests but also crossover, timed, and vertical jump tests.

Laxity outcomes were reported with respect to four different clinical maneuvers: the anterior drawer test, Lachman test, pivot-shift test, and instrumented anterior-posterior laxity test. Instrumented testing was further documented with regard to the type of instrument or device used.

Postoperative diagnostic or imaging studies of patients were noted. These included reported findings of (1) postoperative degenerative changes in the knee (or cartilage), (2) hardware status (e.g., resorption and failure rates), (3) tunnel or aperture widening, graft position or alignment, and (4) graft integrity. The modality used to document these findings (radiography, computed tomography [CT], magnetic resonance imaging [MRI], and/or second-look arthroscopy) was also noted.

Finally, reporting of the presence or absence of subsequent ACL ruptures (rerupture of the ipsilateral ACL or rupture of the contralateral ACL) and of surgical complications was also noted for each study included in this review. Examples of complications reported included deep venous thrombosis or pulmonary embolus, superficial or deep (intra-articular) infection, stiffness, and hardware-related complications. Mild loss of terminal flexion or extension was not considered to be a surgical complication. Additionally, if a study indicated that there were no complications, complications were considered to have been reported for the purposes of this investigation.

Subjective Outcome Reporting

Subjective patient outcomes were classified as those involving assessments made by patients using validated or nonvalidated instruments. Nonvalidated patient assessments included reporting of (1) patient satisfaction, (2) return to pre-injury sports or activity, (3) single numerical assessments of knee health, and (4) subjective assessment of global knee function. A number of validated PROs were also measured. A complete list of these metrics, including definitions of their acronyms, is given in Table I. Utilization rates of common, validated PROs were compared with those in a similar series of studies from the preceding five years.

Source of Funding

There was no external funding source used in this investigation.

Results

Included Studies

A total of 119 studies regarding ACL reconstruction met our inclusion criteria (Table II). Of these, nineteen (16%) were

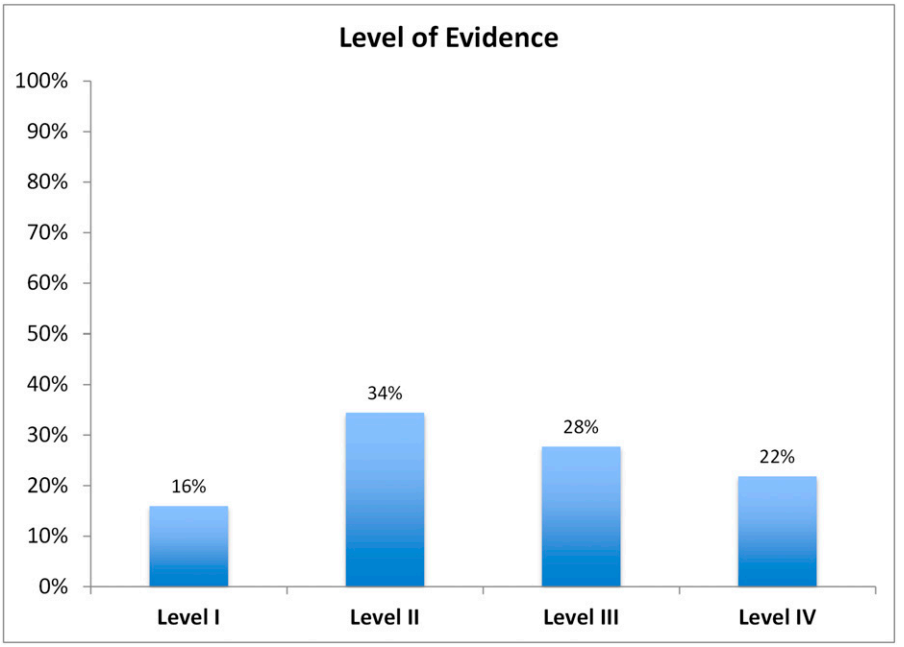

Fig. 1

Level of evidence of the included studies. A majority were either Level-II or III studies.

TABLE IV KT Testing Protocol

	No. of Studies	Percentage of Studies*
Instrument		
KT1000	53	69%
KT2000	22	29%
Unspecified	2	3%
Force		
Maximal manual	31	40%
134 N	27	35%
89 N	2	3%
80 N	1	1%
Unspecified	14	18%
Multiple	2	3%

*Excludes studies that did not utilize a KT instrument.

Level-I studies (Fig. 1), forty-one (34%) were Level II, thirty-three (28%) were Level III, and twenty-six (22%) were Level IV. Thirteen studies (11%) clearly delineated the target patient population, whereas the remainder instead provided descriptive data about the patient population or injury mechanism. The mean patient age was 29.0 years, and the mean duration of follow-up was forty-eight months. Overall, 25% were prospective randomized studies, 33% were prospective cohort studies, and 34% were retrospective studies. All of the included studies reported on the clinical outcomes of patients with ACL injury. Additional target outcome metrics (as indicated in the stated study purpose) are listed in Table III.

Objective Outcome Reporting

Postoperative range of motion (Fig. 2) was reported in forty-eight (40%) of the 119 studies. With regard to quantitative muscle strength testing, seventeen studies (14%) reported hamstring (flexion) strength and twenty studies (17%) reported quadriceps (extension) strength. Eight studies (7%) documented thigh girth or size.

Ninety-six studies (81%) documented at least one of four types of postoperative laxity testing (Fig. 3-A). This included anterior drawer testing in eighteen studies (15%), Lachman testing in fifty-four (45%), pivot-shift testing in seventy-two (61%), and instrumented laxity testing in ninety-one (76%). Of the ninety-one studies reporting instrumented laxity testing outcomes, a majority (seventy-seven studies; 85%) utilized KT instruments (MEDmetric, San Diego, California), whereas the remainder utilized instruments

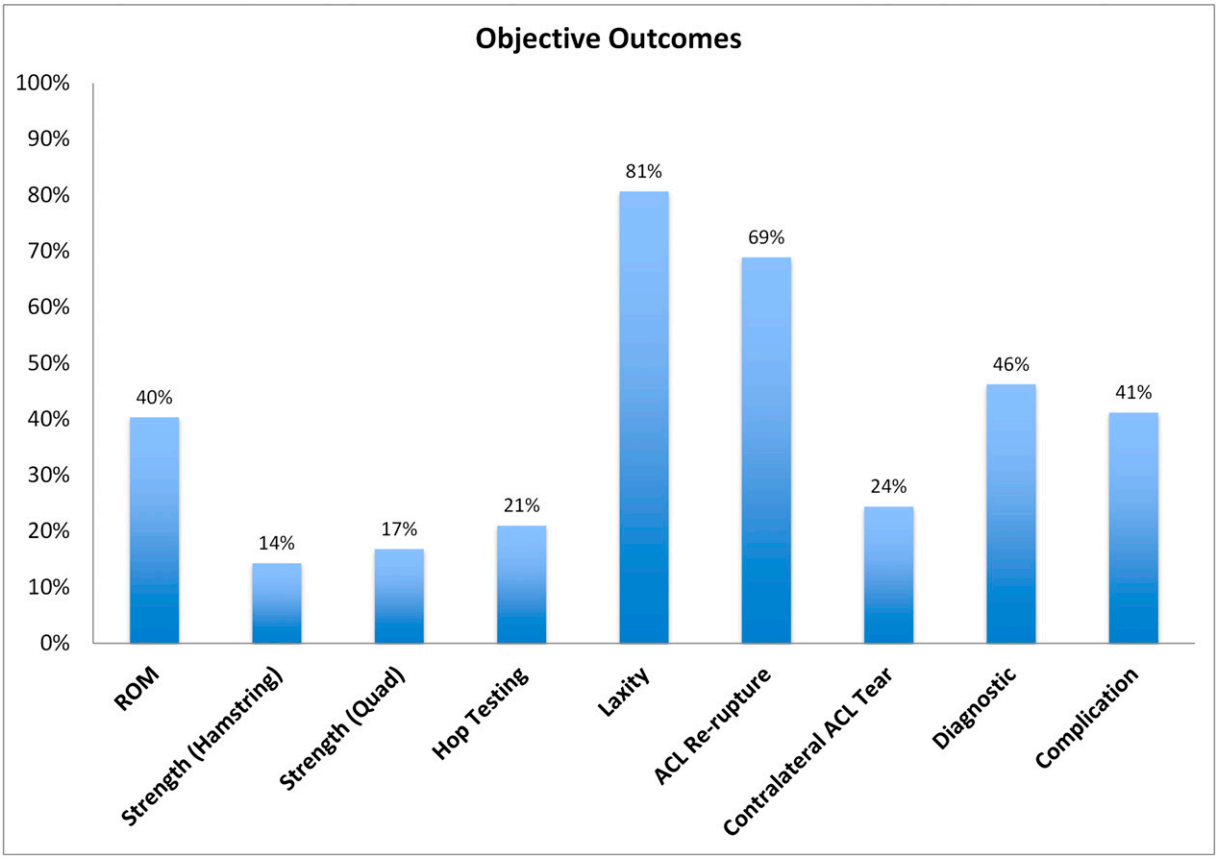

Fig. 2

Objective outcome reporting. Most objective outcome measures were reported in a minority of all studies. ROM = range of motion.

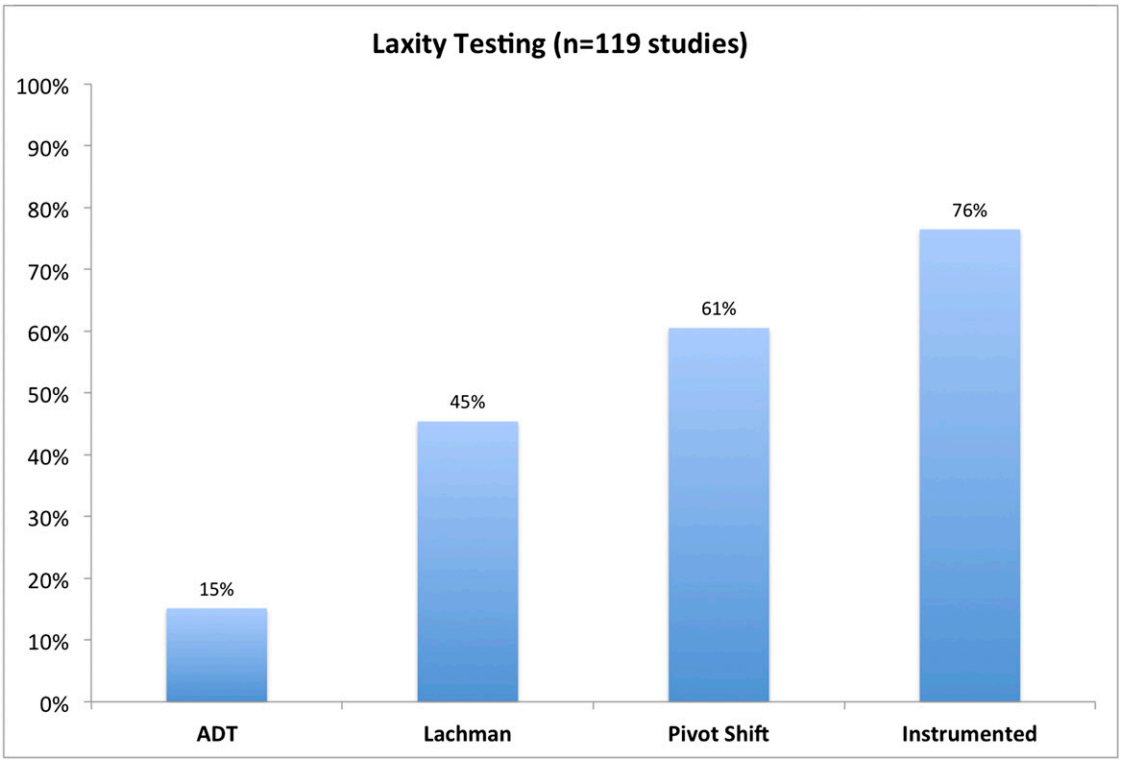

Fig. 3-A

Type of laxity examination reported. Both pivot-shift and instrumented laxity examinations were reported in a majority of studies. ADT = anterior drawer test.

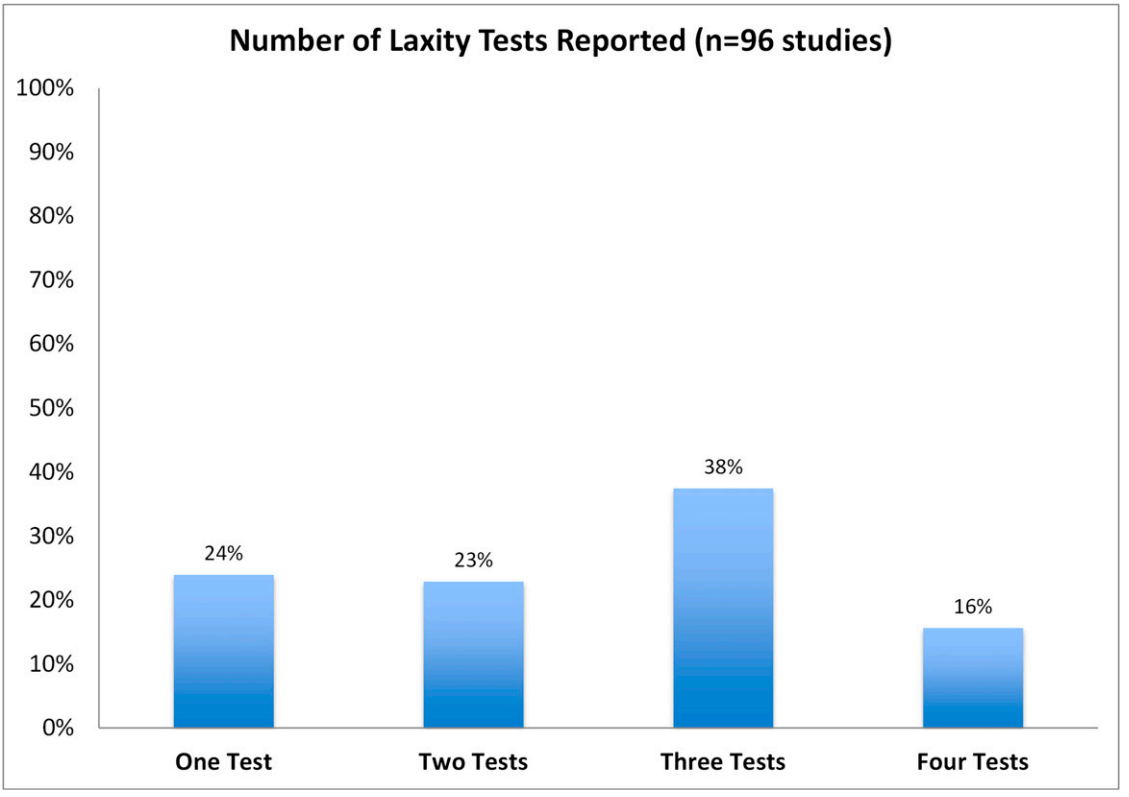

Fig. 3-B

Number of different laxity examinations reported. All four types of laxity examinations were reported in 16% of the studies.

TABLE V Modalities for Assessing Postoperative Diagnostic and Imaging Outcomes

Finding	Total No. of Studies	Modality			
		Radiography	CT	MRI	Second-Look Arthroscopy
Degenerative changes	24	23		2	1
Hardware	5	1	1	4	
Tunnel widening	18	10	5	3	
Graft position	21	12	6	5	
Graft integrity	14			7	9

from Telos (Laubscher, Holstein, Switzerland; n = 10), Aircast (Rolimeter; Boca Raton, Florida; n = 5), or Stryker (Kalamazoo, Michigan; n = 1) or radiostereometric analysis (n = 1). Two studies reported multiple types of instrumented testing. Of the ninety-six studies that reported laxity findings (Fig. 3-B), twenty-three (24%) reported one examination type; twenty-two (23%), two types; thirty-six (38%), three types; and fifteen (16%), all four types. Finally, sixty-nine (58%) of the 119 studies reported both an instrumented laxity finding as well as a pivot-shift result.

Substantial variability was found regarding the precise methodology of KT assessment in the studies that reported this measurement (Table IV). Of these seventy-seven studies, fifty-three (69%) utilized the KT1000 and twenty-two (29%) utilized the KT2000; the exact device was not specified in two studies. With regard to force testing, a majority of these studies used a setting of either maximal manual force (thirty-one studies; 40%) or 134 N (twenty-seven studies; 35%). Of the remainder, 3% used 89 N, 1% used 80 N, and 3% used multiple

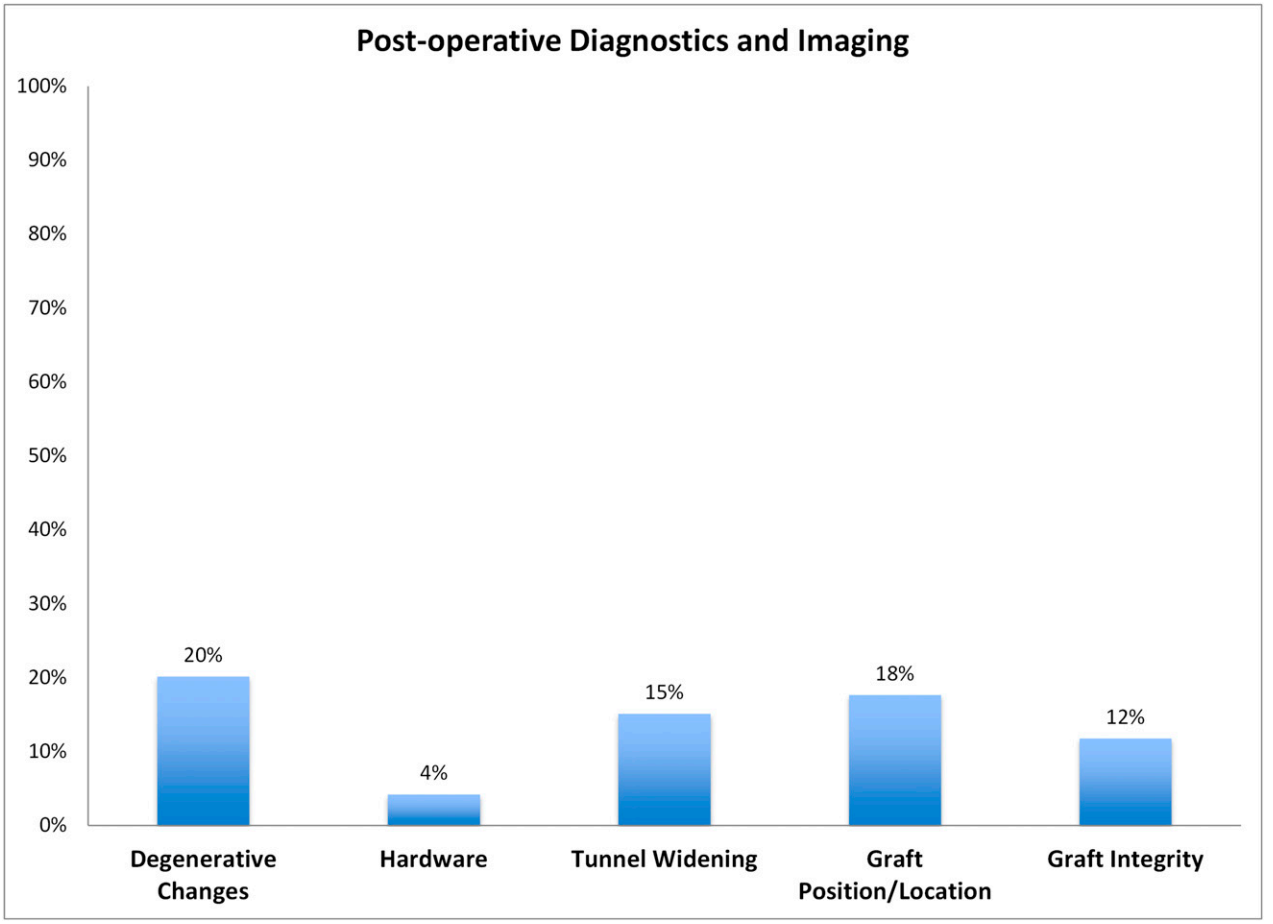

Fig. 4

Postoperative diagnostics and imaging. Documentation of degenerative changes, hardware condition, tunnel or aperture widening, graft position or location, and graft integrity were all reported in a minority of studies.

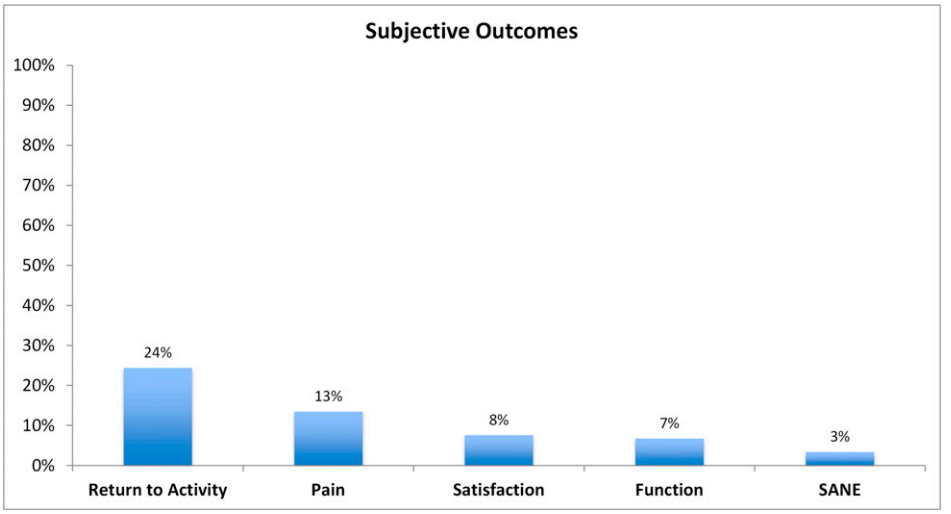

Fig. 5-A

Subjective outcomes reported. All measures were reported in a minority of included studies. SANE = Single Assessment Numeric Evaluation.

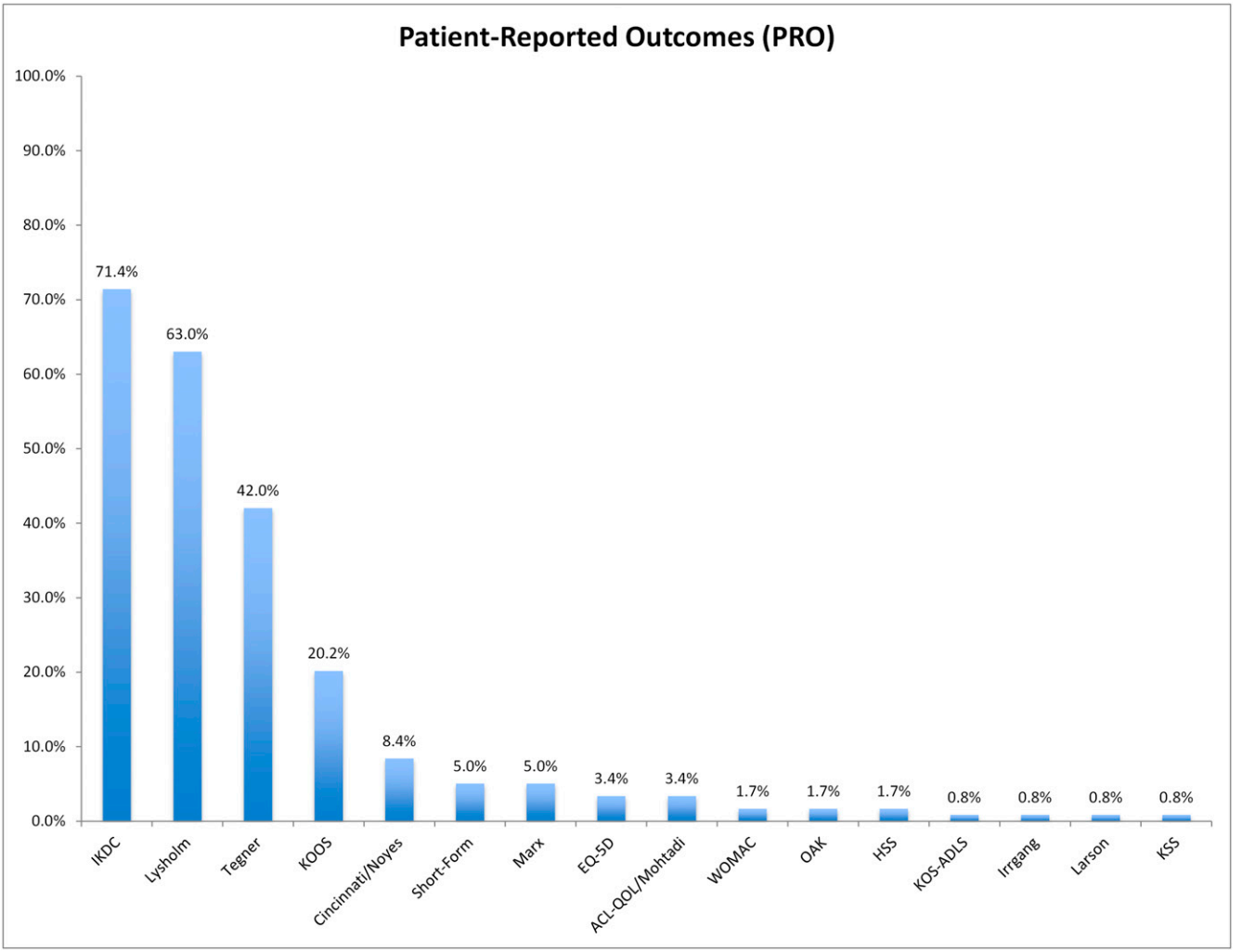

Fig. 5-B

PRO reporting. IKDC and Lysholm scores were reported in >50% of clinical studies. Most metrics were represented in ≤10% of studies.

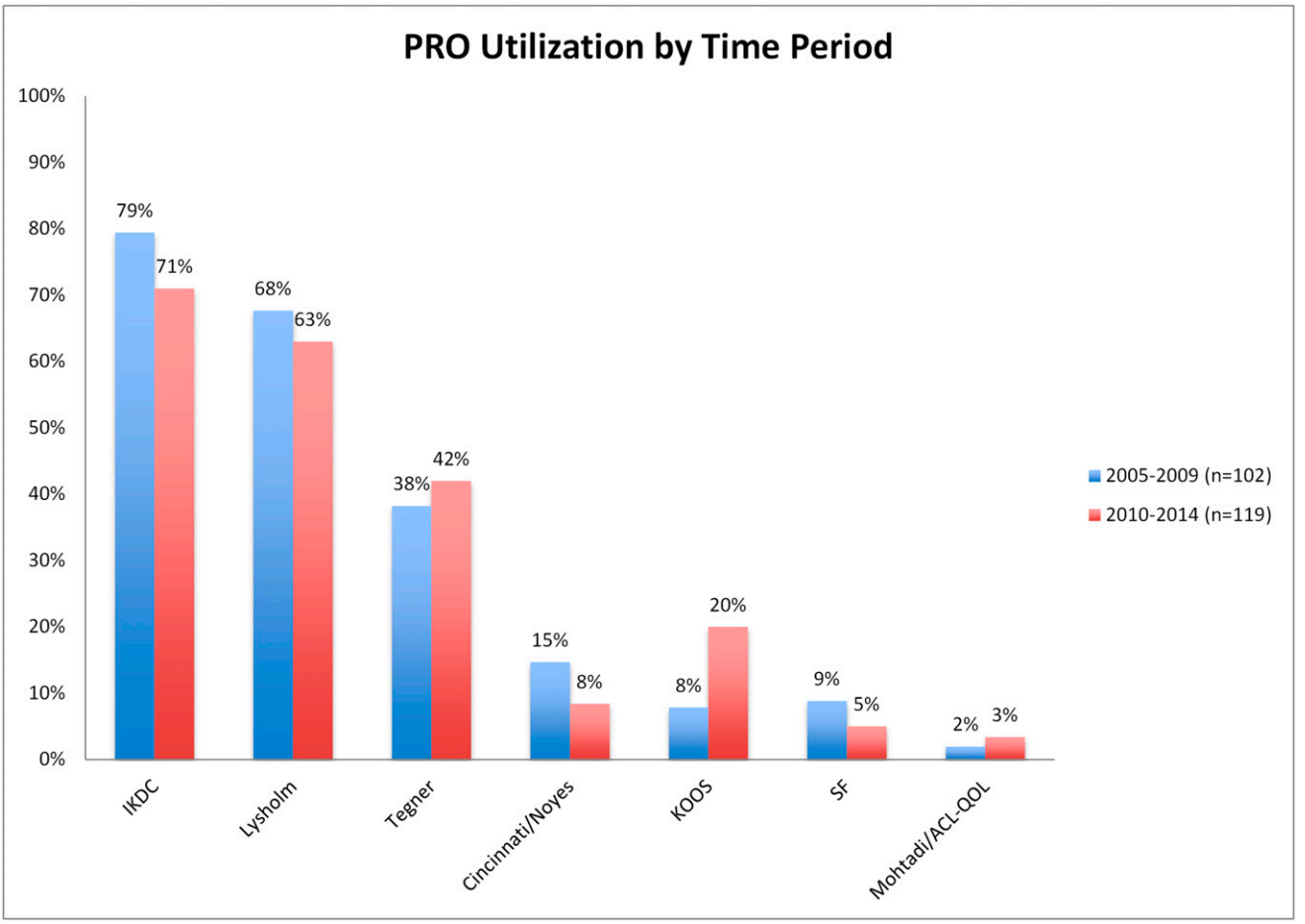

Fig. 6

Utilization of commonly used PROs over time. IKDC, Lysholm, and Tegner utilization rates were similar to those in similarly collected studies in the preceding five-year period.

force settings. In fourteen studies (18%), no precise force setting was identified in the manuscript.

With regard to functional testing, twenty-five studies (21%) reported hop-testing results. Twenty-four studies (20%) reported single-hop testing for distance, and five (4%) reported triple-hop tests. Additionally, crossover, timed, vertical, shuttle, and carioca tests were each reported in three or fewer studies.

Postoperative diagnostics and imaging were used in studies to assess multiple conditions, such as degenerative joint changes, status of implanted hardware, tunnel or aperture widening, graft location or position, and graft integrity. Fifty-five studies (46%) reported on these findings (Fig. 4). Twenty-four studies (20%) reported on postoperative degenerative joint changes, five (4%) documented the status of implanted hardware, eighteen (15%) reported on tunnel or aperture widening, twenty-one (18%) reported on graft location or position, and fourteen (12%) reported on graft integrity. The various imaging modalities used to document these findings are shown in Table V.

Presence or absence of reinjury (ACL rerupture or contralateral rupture) and complication reporting were noted for each study. With regard to reinjury, eighty-two studies (69%) reported the rate of ACL rerupture and twenty-nine (24%) reported the rate of contralateral rupture. There were forty-nine studies (41%) that clearly documented the presence or absence of complications. Seven studies (6%) documented the rate of deep venous thrombosis, and two (2%) documented the rate of pulmonary embolus. With regard to infection, thirteen studies (11%) reported the rate of superficial infection, eighteen (15%) reported the rate of deep (intra-articular) infection, and an additional thirteen studies (11%) reported the rate of infection but did not specify whether the infections were superficial or deep (i.e., intra-articular). Twenty-one studies (18%) reported the complication rate due to hardware, and seven (6%) reported the complication rate due to nerve injury. Finally, ten studies (8%) specifically reported no complications among the study patients.

Subjective Outcome Reporting

Twenty-nine studies (24%) reported on return to pre-injury activity or sports, sixteen (13%) reported on patient pain levels, nine (8%) reported on patient satisfaction, eight (7%) reported on patient-rated subjective knee function, and four (3%) reported a single numerical knee health assessment score (on a scale from 0 to 100) (Fig. 5-A).

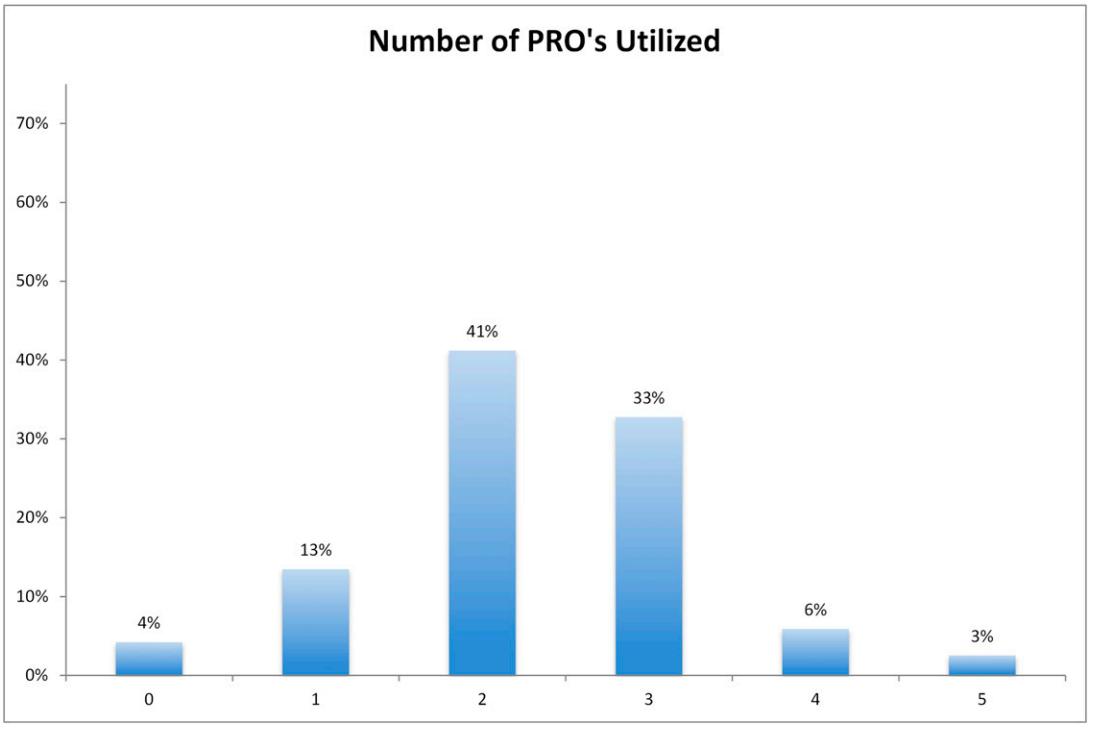

Fig. 7-A

Number of PROs used in each study. A majority of studies reported two or three different PROs.

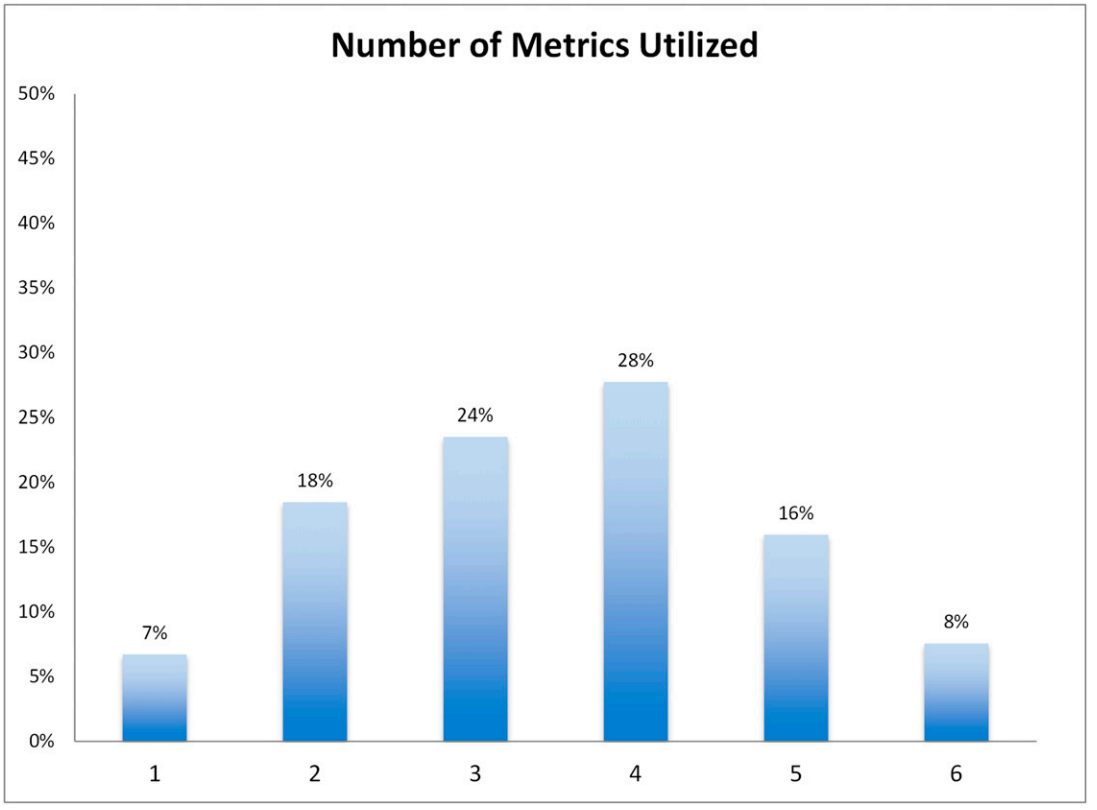

Fig. 7-B

Comprehensiveness of clinical studies. Outcome metric types were classified as objective, laxity, imaging or diagnostic, complication, subjective, and PRO. The majority of studies reported between two and four of these types of metrics.

In addition, sixteen different PROs were reported in the 119 clinical studies that were reviewed. The IKDC score was the most commonly reported PRO (Fig. 5-B) and was utilized in eighty-five studies (71%). The second and third most common were the Lysholm score, in seventy-five studies (63%), and the Tegner score, in fifty (42%). Only two of the sixteen PROs (IKDC and Lysholm) were utilized in ≥50% of the clinical studies, and only four (IKDC, Lysholm, Tegner, and KOOS) were utilized in ≥10% of the studies. Three PROs (WOMAC, OAK, and HSS) were utilized in only two studies (2%) each, and four (Irrgang, Larson, KSS, and KOS-ADLS) were utilized in only one study (1%) each.

Studies that reported IKDC, Lysholm, and/or Tegner outcomes—the three most commonly reported assessments—were analyzed further to determine the frequency of reporting of multiple assessment tools. Of the 119 included studies, 108 (91%) reported one of these three scores. Thirty-three (31%) of those studies reported only one of these scores, 44% reported two, and 25% reported three. The Tegner score was designed to complement the Lysholm score[2,124,125], but forty-one studies (34% of the 119) reported one of these two scores without the other.

Temporal changes in utilization of commonly used PROs that have been validated for use with ACL injury were also studied. Specifically, utilization of the IKDC[126], Lysholm[124], Tegner[124,126], Cincinnati/Noyes[127], KOOS[128,129], Short Form (SF; all variants)[130], and Mohtadi/ACL-QOL[131] were compared between the 119 studies in the current study period (2010 through 2014) and the 102 additional studies in the preceding five-year period (2005 through 2009). Utilization of the IKDC, Lysholm, Cincinnati/Noyes, SF, and Mohtadi/ACL-QOL were similar between the two time periods (Fig. 6). Utilization of the KOOS increased from 8% to 20%, and utilization of the Cincinnati/Noyes decreased from 15% to 8%.

Comprehensiveness of Studies

Each study was assessed for comprehensiveness of inclusion of various clinical outcome metrics. The number of PROs utilized in each study is shown in Figure 7-A. Five studies (4%) reported no PRO, whereas three (3%) reported five different PROs. Most studies reported either two PROs (41%) or three (33%).

Each study was then assessed according to the types of outcomes reported (objective, laxity, imaging or diagnostic, complications, subjective, and PROs). Eight studies (7%) reported one type of outcome from this list (Fig. 7-B), whereas nine studies reported all six of the outcome types (8%). The majority of studies reported between two and four different types of clinical outcomes.

Discussion

The results of this study indicate that there is substantial variability of outcome reporting patterns among high-impact ACL literature. Despite an abundance of available knee outcome instruments, many have not been specifically validated for patients undergoing ACL reconstruction. In a prior literature review, Johnson and Smith[132] reviewed fifty-four different outcome instruments used in assessing patients with ACL injury and found that only a minority of outcome instruments demonstrated adequate reliability and validity testing. Those authors reviewed 197 studies and found that the Lysholm was the most commonly utilized (43%), followed by the Tegner (21%), Cincinnati/Noyes (15%), IKDC (9%), and HSS score (8%). In our study, which reviewed a more recent set of manuscripts published in similarly high-impact journals from 2010 to 2014, we found the IKDC to be the most commonly used score, appearing in >70% of studies, followed by the Lysholm score (63%) and Tegner score (42%). We further found that most of the PROs utilized (twelve of sixteen) were each found in <10% of the studies reviewed. Our study additionally documented rates of inclusion of objective outcomes, as well as inclusion of these metrics in the study purposes (Table III). Even though certain studies referenced target metrics in their stated purposes, the reporting patterns of PROs were still highly variable and independent of these stated purposes.

It is our opinion and experience that return to the pre-injury level of activity and sports is one of the most important outcomes to patients undergoing ACL reconstruction. This notion has been supported by existing literature[133,134]. Although many functional scores (e.g., Tegner and Marx[2]) incorporate activity into their overall score, only 24% of studies in this investigation explicitly stated the likelihood of returning to activity (or the pre-injury level of activity). Therefore, we advocate for increased, and enhanced, reporting of return to pre-injury activity levels from both a patient-care and a research perspective. Moreover, as fear of reinjury has been shown to contribute to unsuccessful return to activity[135,136], postoperative rates of ACL rerupture and contralateral rupture should be regularly reported in clinical studies. Finally, consideration must also be given to the inhomogeneity of patients undergoing ACL reconstruction. For example, a Division-I collegiate football player will have very different demands and expectations following ACL reconstruction than a middle-aged patient with subjective instability would. Therefore, reporting metrics should also be patient-centric.

This study does have several limitations. First, articles in only four different journals were considered for inclusion in this study, and several additional studies that appeared in other journals were therefore not included in the review. However, this omission was intentional, as the goal of this study was to assess outcome reporting variability among the highest-impact orthopaedic journals. It is likely that inclusion of only high-impact-factor journals would actually underestimate the variability in outcome reporting, although this cannot be definitively concluded. Additionally, international journals were not included, in order to minimize the impact of any regional reporting patterns. Second, not every possible outcome was included in this review. However, all attempts were made to include as many objective and subjective metrics as possible. Third, only five years of studies were included, thereby limiting our ability to report on historical trends of outcome reporting. It is unclear how this narrow inclusion window affected the overall variability found in ACL outcome reporting patterns. However, this inclusion window was intentionally chosen in order to allow for reporting of newer outcomes scores that were validated before the study inclusion began.

In conclusion, there is high variability in reporting of most objective and subjective outcomes following ACL reconstruction in high-impact orthopaedic journals. Although a discussion of the validity of each of these individual metrics is beyond the scope of this study, identification of this variability in reporting patterns is necessary to assess whether or not the current state of reporting leads to challenges in comparing or pooling results from different studies. Continued research in identifying the most relevant outcome metrics for assessing recovery following ACL reconstruction may influence future outcome reporting patterns. Moreover, efforts toward establishing registries of ACL outcomes may benefit from including those outcomes that are most meaningful to patients undergoing ACL reconstruction, as opposed to historically popular scores. Further research and consensus development are needed in determining the precise set of outcomes that are considered to be the most important predictors of success following ACL reconstruction, as deemed by patients undergoing the procedure. ■

Eric C. Makhni, MD, MBA
Brian J. Cole, MD, MBA
Bernard R. Bach Jr., MD
Departments of Orthopaedics and Sports Medicine,
Rush University Medical Center,
1611 West Harrison,
Suite 300, Chicago, IL 60612.
E-mail address for E.C. Makhni: ericmakhnimd@gmail.com

Ajay S. Padaki, BS
Petros D. Petridis, MS
Christopher S. Ahmad, MD
Columbia University Medical Center,
622 West 168th Street,
PH-1130, New York, NY 10032

Michael E. Steinhaus, MD
Hospital for Special Surgery,
5353 East 70th Street,
New York, NY 10021

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