Western University
Scholarship@Western

Bone and Joint Institute

8-1-2020

Clinical outcomes after anterior cruciate ligament injury: panther symposium ACL injury clinical outcomes consensus group

Eleonor Svantesson
Göteborg University, Sahlgrenska Academy

Eric Hamrin Senorski
Gothenburg Sports and Trauma Research Center

Kate E. Webster
La Trobe University

Jón Karlsson
Göteborg University, Sahlgrenska Academy

Theresa Diermeier
Klinikum rechts der Isar der Technischen Universität München

See next page for additional authors
Follow this and additional works at: https://ir.lib.uwo.ca/boneandjointpub

Part of the Medicine and Health Sciences Commons

Citation of this paper:

Svantesson, Eleonor; Hamrin Senorski, Eric; Webster, Kate E.; Karlsson, Jón; Diermeier, Theresa; Rothrauff, Benjamin B.; Meredith, Sean J.; Rauer, Thomas; Irrgang, James J.; Spindler, Kurt P.; Ma, C. Benjamin; Musahl, Volker; Fu, Freddie H.; Ayeni, Olufemi R.; Della Villa, Francesco; Della Villa, Stefano; Dye, Scott; Ferretti, Mario; Getgood, Alan; Järvelä, Timo; Kaeding, Christopher C.; Kuroda, Ryosuke; Lesniak, Bryson; Marx, Robert G.; Maletis, Gregory B.; Pinczewski, Leo; Ranawat, Anil; Reider, Bruce; Seil, Romain; van Eck, Carola; Wolf, Brian R.; Yung, Patrick; and Zaffagnini, Stefano, "Clinical outcomes after anterior cruciate ligament injury: panther symposium ACL injury clinical outcomes consensus group" (2020). *Bone and Joint Institute*. 1477.
https://ir.lib.uwo.ca/boneandjointpub/1477

Authors

Eleonor Svantesson, Eric Hamrin Senorski, Kate E. Webster, Jón Karlsson, Theresa Diermeier, Benjamin B. Rothrauff, Sean J. Meredith, Thomas Rauer, James J. Irrgang, Kurt P. Spindler, C. Benjamin Ma, Volker Musahl, Freddie H. Fu, Olufemi R. Ayeni, Francesco Della Villa, Stefano Della Villa, Scott Dye, Mario Ferretti, Alan Getgood, Timo Järvelä, Christopher C. Kaeding, Ryosuke Kuroda, Bryson Lesniak, Robert G. Marx, Gregory B. Maletis, Leo Pinczewski, Anil Ranawat, Bruce Reider, Romain Seil, Carola van Eck, Brian R. Wolf, Patrick Yung, and Stefano Zaffagnini

This article is available at Scholarship@Western: https://ir.lib.uwo.ca/boneandjointpub/1477

Check for updates

Clinical Outcomes After Anterior Cruciate Ligament Injury

Panther Symposium ACL Injury Clinical Outcomes Consensus Group

Eleonor Svantesson,* MD, Eric Hamrin Senorski, PT, PhD, Kate E. Webster, PhD, Jón Karlsson, MD, PhD, Theresa Diermeier, MD, Benjamin B. Rothrauff, MD, Sean J. Meredith, MD, Thomas Rauer, MD, James J. Irrgang, PT, PhD, FAPTA, Kurt P. Spindler, MD, C. Benjamin Ma, MD, Volker Musahl, MD, and the Panther Symposium ACL Injury Clinical Outcomes Consensus Group

Investigation performed at UPMC Freddie Fu Sports Medicine Center, Pittsburgh, Pennsylvania, USA

A stringent outcome assessment is a key aspect of establishing evidence-based clinical guidelines for anterior cruciate ligament (ACL) injury treatment. To establish a standardized assessment of clinical outcome after ACL treatment, a consensus meeting including a multidisciplinary group of ACL experts was held at the ACL Consensus Meeting Panther Symposium, Pittsburgh, Pennsylvania, USA, in June 2019. The aim was to establish a consensus on what data should be reported when conducting an ACL outcome study, what specific outcome measurements should be used, and at what follow-up time those outcomes should be assessed. The group reached consensus on 9 statements by using a modified Delphi method. In general, outcomes after ACL treatment can be divided into 4 robust categories: early adverse events, patient-reported outcomes (PROs), ACL graft failure/recurrent ligament disruption, and clinical measures of knee function and structure. A comprehensive assessment after ACL treatment should aim to provide a complete overview of the treatment result, optimally including the various aspects of outcome categories. For most research questions, a minimum follow-up of 2 years with an optimal follow-up rate of 80% is necessary to achieve a comprehensive assessment. This should include clinical examination, any sustained reinjuries, validated knee-specific PROs, and health-related quality of life questionnaires. In the midterm to long-term follow-up, the presence of osteoarthritis should be evaluated. This consensus paper provides practical guidelines for how the aforementioned entities of outcomes should be reported and suggests the preferred tools for a reliable and valid assessment of outcome after ACL treatment.

Keywords: reconstruction; patient-reported outcome; laxity; osteoarthritis; consensus statement

The evolution of evidence-based medicine is considered one of the most important paradigm shifts in modern medicine,[28,104] for which conduction of high-quality research is fundamental. Anterior cruciate ligament (ACL) injuries are among the most studied in the field of orthopaedics and sports medicine, with over 25,000 publications available in the PubMed database up to mid-2019. Despite ongoing research and advancements in treatment regimens for ACL injuries over the past decades, the goal of restored knee function and preserved long-term knee-related health remains a challenge. Reinjury rates are high, especially among the young and active,[117,120] and the high rate of subsequent development of posttraumatic osteoarthritis (OA) is worrying.[1,21,81,86] In the best interest of our patients, a deepened understanding of how to optimize an individualized approach to ACL injury treatment is needed. One important part of this process is to strive for a standardized and homogeneous research methodology of clinical outcome assessment after ACL treatment.

A rigorous outcome assessment after ACL injury is a key aspect for determining the clinical efficacy and effectiveness of treatment. It can also identify modifiable and nonmodifiable predictors of good and poor outcome, which provide valuable insights for the patient's prognosis and should be discussed in the context of shared decision making for the treatment choice after ACL injury. Moreover, a standardized outcome assessment and reporting of data are required for comparisons between studies and for

The Orthopaedic Journal of Sports Medicine, 8(7), 2325967120934751
DOI: 10.1177/2325967120934751
© The Author(s) 2020

This open-access article is published and distributed under the Creative Commons Attribution - NonCommercial - No Derivatives License (https://creativecommons.org/licenses/by-nc-nd/4.0/), which permits the noncommercial use, distribution, and reproduction of the article in any medium, provided the original author and source are credited. You may not alter, transform, or build upon this article without the permission of the Author(s). For article reuse guidelines, please visit SAGE's website at http://www.sagepub.com/journals-permissions.

pooling of data in meta-analyses to provide the highest level of evidence-based medicine. Current literature related to ACL treatment is limited by the fact that no consensus exists on how to assess and report clinical outcome. There is a wide range of validated outcome assessment tools for ACL treatment. Although each of these outcome measures may offer certain advantages and the patient's perspective of outcome should always be evaluated, caution must be taken to ensure that outcome measures accurately capture patient-centered and clinically relevant outcomes for an ACL-injured patient. Another debated area in ACL outcome assessment is the use of ACL graft failure as an endpoint for research. This is highly relevant to the patient; however, there is no universally accepted definition of graft failure utilized in the literature. Moreover, the lack of a consistent approach as to the timing of when outcomes should be measured after treatment and how such measures are reported makes appraisal of the current literature challenging, which limits the recommendations for the patient's best possible care.

As the body of evidence on ACL treatment grows, there is an urgent need to reach consensus on how clinical outcome should be assessed and reported. Surgeons and researchers should strive to create optimal conditions for appraisal of the cumulative evidence regarding ACL treatment, thereby promoting an evidence-based approach by using outcome measures that are reliable, valid, responsive over time, and comparable. Therefore, a multidisciplinary group of experts was assembled for an international consensus meeting aiming to establish a standardized approach to clinical outcome assessment for patients receiving ACL treatment, that is, both operative and nonoperative treatment.[79] The purpose of this article is to provide the results from the consensus meeting in terms of what outcomes should be reported when conducting an ACL outcome study, the recommended outcome measurements, and at which follow-up time points those measurements should be used.

METHODS

A multidisciplinary panel of national and international experts in ACL injury, including orthopaedic surgeons, physical medicine and rehabilitation physicians, physical therapists, and scientists, was convened in a 1-year consensus-building effort, which culminated in the ACL Consensus Meeting Panther Symposium held at the University of Pittsburgh and University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania, USA, in June 2019. The symposium included delegates from 18 countries encompassing 6 continents. The working group of this topic consisted of 25 participants.

A list of 13 statements on clinical outcomes was drafted by the steering committee of the meeting based on current literature and controversies in clinical outcome assessment. The consensus group members completed an online survey addressing the 13 statements before the consensus meeting. The initial statements and corresponding responses are found in the supplementary material (Appendix).

A modified Delphi consensus discussion for each of the 13 statements was subsequently held at the in-person consensus meeting. The session was moderated by 2 senior researchers (K.E.W. and J.K.). Each statement was discussed and revised by the working group, after which a vote on agreement with the statement was performed. No count was held on the number of roundtables, but discussion was continued until consensus was met for each statement. A majority of 80% agreement was determined a priori as being a satisfactory level of consensus. Opposing views were documented, and it was determined that those statements for which 80% agreement was not achieved should be discussed in the paper, noting the percentage of agreement and accompanied with the discussion held during the meeting. Statements that the panel determined as irrelevant, redundant, or overlapping with another statement were either excluded or combined with the overlapping statement. Statement 2 in this consensus paper was

*Address correspondence to Eleonor Svantesson, MD, Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, SE-431 80 Mölndal, Sweden (email: eleonor.svantesson@outlook.com).

All authors are listed in the Authors section at the end of this article.

This article has been copublished in *Knee Surgery, Sports Traumatology, Arthroscopy* and *Journal of ISAKOS*. Minor differences exist between this version and others to be consistent with *OJSM* editorial style.

Final revision submitted April 28, 2020; accepted May 12, 2020.

One or more of the authors has declared the following potential conflict of interest or source of funding: The ACL Consensus Meeting Panther Symposium at the University of Pittsburgh Medical Center (UPMC) was sponsored by Smith & Nephew, the UPMC, Elizur, Arthrex, Conmed, DJO, Mid-Atlantic Surgical Systems, RTI Surgical, and BlackRhino Medical. K.S. has received consulting fees from the National Football League, Service Excellence, Mitek, Flexion Therapeutics, Samumed, and NovoPedics and royalties from nPhase. C.B.M. has received consulting fees from Linvatec, Medacta, Stryker, Wright Medical, and Zimmer Biomet. V.M. has received educational grants, consulting fees, and speaking fees from Smith & Nephew and educational grants from Arthrex. O.R.A. has received speaking fees from Conmed and honoraria from DJO. S.D. has received personal fees from Zimmer Biomet. A.G. has received grants and personal fees from Smith & Nephew and Ossur and personal fees from Graymont and Olympus. C.C.K. has received grant support from DJO, educational support from CDC Medical, consulting fees from Zimmer Biomet, and nonconsulting fees from Arthrex. R.K. has received grants from Smith & Nephew, Zimmer Biomet, Stryker, and Johnson & Johnson; consulting fees from Medacta, Arthrex, Japan Tissue Engineering, and Hirosaki Life Science Innovation; and speaking fees from Arthrex, Smith & Nephew, Zimmer Biomet, Johnson & Johnson, and Japan Tissue Engineering. B.L. has received royalties from Wolters Kluwer Health–Lippincott Williams & Wilkins. R.G.M. has received stock/stock options from MEND Nutrition and royalties from Springer and Demos Health. L.P. has received research support from the Australian Orthopaedic Association, Friends of the Mater Foundation, and Smith & Nephew; has received speaking fees from Smith & Nephew; has received royalties from Australian Biotechnologies and Signature Orthopaedics; has stock/stock options in Australian Biotechnologies; and has patents with Hip Developments, Smith & Nephew, and Surgical Apps. A.R. has received other support from Enhatch, Conformis, Stryker, Smith & Nephew, Arthrex, Anika Therapeutics, and Bodycad. B.R. has received fellowship support from Smith & Nephew, has received royalties from Elsevier, has stock in Johnson & Johnson and Merck, and is the Editor-in-Chief of *The Orthopaedic Journal of Sports Medicine*. B.R.W. has received educational support from Wardlow Enterprises, consulting fees from Linvatec, and faculty/speaking fees from Linvatec. M.Z. is the founder of and has stock in Orthocell. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

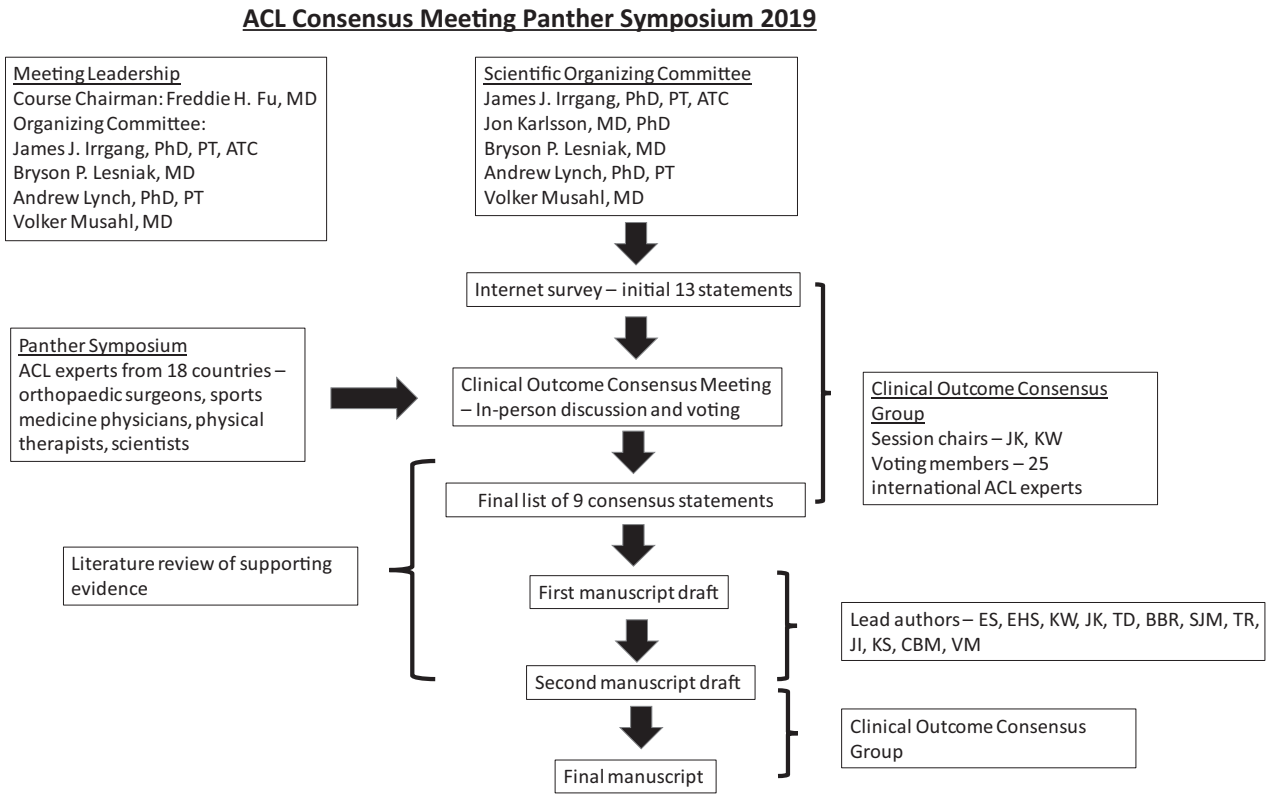

Figure 1. The process of the consensus project. ACL, anterior cruciate ligament.

combined from 2 original statements (originally statements 10 and 11 in the online survey [Appendix]) because these were considered as overlapping. There was 100% agreement for the original statement 10, and when proceeding to discussion and voting on the original statement 11, the panel instead agreed to combine statements 10 and 11 into one. However, no formal voting was undertaken for the finalized combination of the two. Thus, the percentage of agreement for statement 2 in this consensus paper could not be reported.

This working group was assigned 2 liaisons (E.S. and E.H.S.), who were responsible for amending each statement as requested over the course of the discussion. Liaisons transcribed the discussion, performed data analyses, and subsequently completed a MEDLINE literature review for each finalized statement. To reduce the potential for bias in the data analysis and/or literature review, liaisons did not submit answers to the online questionnaire, nor did they partake in the voting process. A description of the consensus process is presented in Figure 1, and a list of definitions used at the consensus meeting for the specific statements is provided in Table 1.

TABLE 1
Operational Definitions[a]

Chronic ACL injury	A nonoperatively treated ACL injury with persistent complaints of instability more than 6 months after initial injury.
Acute ACL reconstruction	An ACL reconstruction taking place within 3 months from injury.
Delayed ACL reconstruction	An ACL injury that is planned to be treated with reconstruction and take place after 6 months from injury, or an ACL reconstruction that takes place after nonoperative treatment has been tried without a satisfactory outcome.
Instability	A patient's perception of the knee not feeling stable.
Laxity	The passive displacement of the knee joint when an external force or torque is applied.

[a]ACL, anterior cruciate ligament.

CONSENSUS STATEMENTS AND DISCUSSION

Of the 13 statements discussed by the working group, 9 achieved consensus, and 4 were excluded because these were considered to include information similar to ≥1 of the other statements. Thus, some of the 9 statements achieving consensus were slightly modified to include aspects from the 4 excluded statements. The 9 final statements, with supporting literature review, are presented below. These statements are presented in 3 main sections for readability purposes: (1) planning for outcome assessment, (2) clinical outcome assessment, and (3) patient-reported outcome (PRO). An overview of the consensus statements is presented in Table 2.

TABLE 2
Summary of the Consensus Statements for Clinical Outcome Assessment After ACL Injury[a]

Planning for outcome assessment
- A priori power calculation of sample size in relation to the primary endpoint must be performed and reported to avoid underpowered studies.
- Improvement from pretreatment status is the outcome of interest. Minimum description of pretreatment status should include demographic data, validated knee-specific PRO assessment, HRQoL, and measure of type and level of preinjury sport/activity.

Clinical outcome assessment
- Minimal length of follow-up when reporting outcomes depends on the outcome being assessed and should optimally include 80% of the entire cohort.
- Comprehensive assessment after ACL surgery (minimum 2 years) should include adverse events, clinical measures of knee function and structure, PRO, activity level, and recurrent ligament disruption.
- Comprehensive assessment after ACL surgery in the medium to long term (≥5 years) should also include measures of posttraumatic OA.
- Clinical assessment of ACL injury treatment should include measures of AP and rotatory knee laxity.

PRO
- Assessment of PRO should optimally include at least 1 knee-specific outcome tool, 1 activity rating scale, and 1 measure of HRQoL.
- The IKDC-SKF is the recommended knee-related outcome measure for ACL injury and treatment.
- Measurement of the PASS is valuable in the assessment of outcome of ACL injury and treatment.

[a]ACL, anterior cruciate ligament; AP, anteroposterior; HRQoL, health-related quality of life; IKDC-SKF, International Knee Documentation Committee Subjective Knee Form; OA, osteoarthritis; PASS, Patient Acceptable Symptom State; PRO, patient-reported outcome.

Section 1: Planning for Outcome Assessment

1. A priori power calculation of sample size in relation to the primary endpoint must be performed and reported to avoid underpowered studies (25/25; 100% agreement).

"Sample size is key to avoiding underpowered studies. We should always try to perform high-quality research, and power calculation is part of this."

A critical point when evaluating a study outcome is to ensure that the sample size is large enough to detect a difference when a true difference in fact exists. Otherwise, the study may be underpowered and subject to beta error (type II error). This can have serious consequences on clinical practice if no difference in outcome is concluded to exist between, for example, 2 interventions, even though one of the interventions is truly inferior, or superior, compared with the other. Ultimately, underpowered studies fail to identify the best possible care for our patients. Approximately two-thirds of randomized controlled trials related to ACL reconstruction failed to report an a priori sample size calculation.[4,94] Although a more recent assessment of the literature shows that these numbers have substantially improved since 2009,[54] improvements can be made. A study should have a power of at least 80% (1 – β), which means that the risk of a type II error, or false negative result, is 20%. A priori power calculation helps to ensure that the sample size will be large enough to minimize the risk of type II error. The power calculation should be determined for the primary patient-centered endpoint, meaning that if an endpoint is chosen that has a low event rate, the study sample size will need to be larger than if one expects that many patients will reach the endpoint. The sample size calculation therefore aids in the determination of feasibility and will help reduce the rate of incomplete studies and wasted resources. It is also an ethical responsibility to perform a sample size calculation because it is unethical to include substantially more patients than necessary. In relation to large registry studies, a power calculation may be redundant, but this can depend on the outcome. It is therefore recommended that a statement on power always should be included. A sample size calculation should be performed whenever possible before the start of the study. However, a post hoc power calculation to test the validity of the study results can be an acceptable method under certain conditions, for instance, in the case of a retrospective study, but caution must be given to the high risk of overestimating power.[38,116]

CONCLUSION. Researchers must report the power of the study to ensure that the sample size is sufficient to detect a difference if one truly existed and to give readers of the paper an understanding of the strength and generalizability of the results.

2. Improvement from pretreatment status is the outcome of interest. Minimum description of pretreatment status should include demographic data, validated knee-specific PRO assessment, HRQoL, and measure of type and level of preinjury sport/activity.

"We must know where we started to determine whether the treatment was effective."

The goal of all available treatments for an ACL injury is to improve the outcome from the pretreatment status. Hence, without assessment of the pretreatment status, the relative improvement cannot be measured and reported. Assessment of the pretreatment status is also important to identify baseline variables that may confound or explain a given study result. When comparative trials are conducted, variables known to influence the outcome of interest should be equally distributed between the groups or otherwise adjusted for by using appropriate statistical methods. Adjustments can be planned a priori based on previous studies or assessed by adjusting for variables that correlate with both the predictor and the outcome. Researchers should thoroughly plan data collection before the study start while considering their study population and their research question.

The demographic data should give an overview of the characteristics of the investigated population, which aids

to determine the generalizability of the study results. Demographic data should at a minimum include patient sex, age, anthropometric data, relevant medical history, and prior knee joint injuries. Family history of ACL injuries may also be relevant because a heritable component of ACL injuries appears to exist.[18,118] Moreover, the type and level of preinjury sport or activity should be reported to determine whether the treatment successfully returned the patients to their preinjury activity level. The recommended tool for sport and activity assessment is the Marx activity scale,[66] which has been validated and has high reliability. The Marx activity scale enables an evaluation of both the type of activity and the exposure time, which are both crucial aspects when reporting on activity. In this aspect, it differs from other measures of activity, for example, the Tegner activity scale,[105] which enables grading of activity level but does not account for activity exposure. Other validated tools for activity include, for example, the International Knee Documentation Committee Subjective Knee Form (IKDC-SKF),[50] which includes 1 item (item 8) related to the activity level that the patient performs on a regular basis. The item is answered by choosing 1 of 5 responses ranging from *very strenuous activity* to *unable to perform light activities*. Classification of activity and sports participation can also be rated according to level I to IV activity, which was included in the original version of the IKDC Knee Ligament Standard Evaluation Form[45] and is still frequently used in ACL research.[30,39,70] Another example of a tool for activity assessment is the Cincinnati sports activity scale.[9] The tools for activity assessment are presented in Table 3. It is of importance to further distinguish between preinjury and presurgery activity level. Because a presurgery activity level has a risk of being representative of the patient's activity while injured, preinjury activity should always be reported.

Pretreatment assessment of PROs is particularly valuable for patients with chronic ACL injuries or as a presurgical treatment baseline for patients undergoing delayed ACL reconstruction. This is because patients with chronic ACL injury may have had the time to live with and try to cope with the potential limitations of their ACL-deficient status as opposed to the acutely injured patients who are impaired because of injury-related factors (eg, pain and hemarthrosis). There is, however, no strict definition for what should be regarded as early and delayed ACL reconstruction, and the timing of ACL reconstruction varies considerably between geographical regions.[87] Surgery within 3 weeks has been defined as an early ACL reconstruction,[33,101] although this definition is not consistent, and a recent literature review found that the definition of early ACL reconstruction ranged from 2 days to 7 months among the included trials.[2] For correct interpretation of the pretreatment assessment, it is important that the time from injury to pretreatment assessment is always reported, as outcomes may be very different for a patient who is completing such an assessment soon after injury compared with a patient who was injured many years previously.

The impact of the ACL injury on the patient's overall well-being and quality of life before treatment should also be measured.[72,85] A health-related quality of life (HRQoL) measure covers a larger picture of how an ACL injury affects a patient in terms of physical, social, and emotional health, which must not be overlooked among patients sustaining an ACL injury.[34] Pretreatment assessment of HRQoL allows for evaluation of health status over time and whether the treatment restores the patient to better, similar, or worse health. Most measures of HRQoL also have the advantage of providing the possibility to determine utilities that are used in estimating the economic impact of the injury and allow for comparison between many other conditions and treatments. A list of HRQoL measures is provided in Table 4.

CONCLUSION. Description of the sample in terms of demographic characteristics, preinjury activity level, and pretreatment PROs is necessary to interpret the results of treatment and generalizability of the study.

Section 2: Clinical Outcome Assessment

3. Minimal length of follow-up when reporting outcomes depends on the outcome being assessed and should optimally include 80% of the entire cohort (25/25; 100% agreement).

> *"An ≥80% follow-up rate is optimal. Follow-up time should reflect the primary outcome, be based upon the purpose of the study, and be stated a priori."*

The follow-up time of a study should be defined depending on what is relevant in relation to the primary investigated outcome. In general, outcomes after ACL treatment can be divided into 4 categories: early adverse events, PROs, ACL failure/recurrent ligament disruption, and clinical measures of knee function and structure (Table 5), all of which could be further stratified in specific outcomes, necessitating different considerations for follow-up time as exemplified in Table 6.

Evidence provided by previous research as well as clinical experience is the foundation to determine what a relevant follow-up time is. For example, the rates of ACL rerupture and ACL revision peak at 1 to 2 years after an ACL reconstruction and with return to sport (RTS).[32,40,61,82,118] Therefore, a study with a shorter follow-up than this is not relevant if the primary outcome is rerupture or ACL revision, and a study aiming to make conclusions about ACL treatment failure should not have a follow-up time of less than 2 years and should report RTS as a proxy of risk exposure. In contrast, the outcome of septic arthritis or hardware failure can manifest soon after an ACL reconstruction,[99,114] and a follow-up time of ≤6 months is sufficient to collect data that will represent a true estimation of such outcomes. Thus, it is important that the follow-up time is defined and based upon the study aims and outcomes.

In most studies, especially with increasing length of follow-up time, a certain degree of patients lost to follow-up is inevitable. Even a small proportion of patients lost to follow-up can lead to considerable study bias,[16] although a common opinion is that a dropout rate of more than 20% is associated with a serious threat to the internal and external validity and power of the study.[93] A study is therefore recommended to optimally include at least an 80% follow-up rate. However, the possibility of dropout/retention bias should

TABLE 3
Tools for Activity Assessment[a]

Assessment Tool	Description
IKDC-SKF[50]	4: Very strenuous activities like jumping or pivoting as in basketball or soccer 3: Strenuous activities like heavy physical work, skiing, or tennis 2: Moderate activities like moderate physical work, running, or jogging 1: Light activities like walking, housework, or yard work 0: Unable to perform any of the above activities because of knee
Tegner activity scale[105]	Level 10 competitive sports: soccer, football, rugby (national elite) Level 9 competitive sports: soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball Level 8 competitive sports: racquetball or bandy, squash or badminton, track and field athletics (jumping, etc), downhill skiing Level 7 competitive sports: tennis, running, motorcar speedway, handball; recreational sports: soccer, football, rugby, bandy, ice hockey, basketball, squash, racquetball, running Level 6 recreational sports: tennis and badminton, handball, racquetball, downhill skiing, jogging at least 5 times per week Level 5 work: heavy labor (construction, etc); competitive sports: cycling, cross-country skiing; recreational sports: jogging on uneven ground at least twice weekly Level 4 work: moderately heavy labor (eg, truck driving, etc) Level 3 work: light labor (nursing, etc) Level 2 work: light labor; recreational sports: walking on uneven ground possible but impossible to backpack or hike Level 1 work: sedentary (secretarial, etc) Level 0: sick leave or disability pension because of knee problems
Marx activity scale[66]	Patient is asked how often the activities running, cutting, deceleration, and pivoting have been performed during the last year in his/her healthiest and most active state. Each activity is scored on a 0-4 scale as follows: 0: <1 time in a month 1: 1 time in a month 2: 1 time in a week 3: 2-3 times in a week 4: ≥4 times in a week
Cincinnati sports activity scale[9]	Divided into 4 major levels with subcategories Level I: participates 4-7 d/wk Level II: participates 1-3 d/wk Level III: participates 1-3 times/mo Level IV: no sports Subcategories for level I-III (5-point decline for every step downward, starting from 100 points): Jumping, hard pivoting, cutting (basketball, volleyball, football, gymnastics, soccer) Running, twisting, turning (tennis, racquetball, handball, ice hockey, field hockey, skiing, wrestling) No running, twisting, jumping (cycling, swimming) Level IV with the following subcategories and points for each: 40: Activities of daily living without problems 20: Moderate problems with activities of daily living 0: Severe problems with activities of daily living, on crutches, full disability
IKDC Knee Ligament Standard Evaluation Form[45]	Level I: jumping, pivoting, hard cutting, football, soccer Level II: heavy manual work, skiing, tennis Level III: light manual work, jogging, running Level IV: activities of daily living, sedentary work

[a]IKDC-SKF, International Knee Documentation Committee Subjective Knee Form.

always be considered when patients are lost to follow-up. Data should be presented such that the dropout rate is accurately reported. A strict adherence to the use of checklists is encouraged to facilitate complete data reporting, such as the CONSORT (Consolidated Standards of Reporting Trials) statement[97] for randomized controlled trials and the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) statement[113] for cohort studies. Clear step-by-step flowcharts are encouraged. Whenever dropouts are present, the authors are recommended to perform a dropout sensitivity analysis to enable interpretation of the possible dropout effects. This should include a comparison of the baseline characteristics of those who completed versus those who did not complete the study.

TABLE 4
Health-Related Quality of Life Outcome Measures[a]

Instrument	Developer	No. of Items	Response Options
KOOS	Roos et al[91]	42 items, of which 5 are related to quality of life	Each item scored 0-4
ACL-QoL	Mohtadi[69]	32 items	A 100-mm visual analog scale for each item
SF-8[17]	Quality Metric	8 items	Each item scored on a 6-point scale
EQ-5D[31]	EuroQoL	6 items	Item specific
SF-36	Ware and Sherbourne[115]	36 items	Item specific
SIP	Bergner et al[15]	136 items	Yes/no
QWB	Anderson et al[3]	71 items	Via interview

[a]ACL-QoL, Quality of Life Outcome Measure for Chronic Anterior Cruciate Ligament Deficiency; EQ-5D, European Quality of Life–5 Dimensions; KOOS, Knee injury and Osteoarthritis Outcome Score; QWB, Quality of Well-Being; SF-8/SF-36, Short Form Health Survey; SIP, Sickness Impact Profile.

TABLE 5
4 Robust Outcome Categories After ACL Injury Treatment[a]

Adverse events
PRO measurements
ACL failure or recurrent ligament disruption
Clinical measures of knee function and structure

[a]ACL, anterior cruciate ligament; PRO, patient-reported outcome.

It should be emphasized that there can be circumstances where an acceptable follow-up rate for a study is determined by weighing the disadvantages of loss to follow-up against certain advantages, for example, a long-term follow-up or a considerable amount of data in a study. In such cases, a lower threshold for follow-up rate is acceptable. Large registry studies can be used to exemplify this, where the patient response rates to PROs are a challenge.[43] Registries comprise data on large numbers of patients and include multiple follow-up occasions, sometimes over more than a decade.[43,103] Hence, they are important sources for determining the effectiveness of ACL treatment and for providing hypotheses-generating results.[104] Nonetheless, a large dropout rate increases the importance of a stringent data reporting, and a statistical analysis of patients lost to follow-up also needs to be considered.

CONCLUSION. Follow-up time should be determined by the purpose of the study and primary outcome and should be stated a priori. The follow-up rate should optimally exceed 80%, and data must be reported so that the possible effects of patients lost to follow-up can be considered.

4. Comprehensive assessment after ACL surgery (minimum 2 years) should include adverse events, clinical measures of knee function and structure, PRO, activity level, and recurrent ligament disruption (25/25; 100% agreement).

"The comprehensive assessment needs to cover both clinical assessment and the patient's perspective and should optimally also include RTS."

A comprehensive assessment after ACL reconstruction should aim to provide a complete picture of outcome related to different dimensions of limitations, which involves numerous aspects of knee-related health and function, objective assessment of hard endpoints (Table 6), and technical aspects of the surgery (graft choice, fixation, tunnel placement, meniscus/cartilage assessment, and treatment). A minimum follow-up of 2 years is likely necessary to enable a comprehensive assessment. Multiple follow-ups during the first 2 years could certainly fulfill the purpose of evaluating, for example, the progress such as in the early, middle, and end state of the rehabilitation. However, the final assessment should be withheld until 2 years postoperatively because a substantial number of outcomes require that this time has been given for the ACL reconstruction to completely heal[47,83,112,123] and for the patient to complete rehabilitation and progress to testing the knee in more demanding activities including full participation in sport or activity. A follow-up of 2 years should allow for determining the patient's capability of a successful RTS,[6] and importantly, it will include a period when patients are participating at high-risk exposure for ACL failures and reinjuries.[32,40,61,82,118] An optimal 2-year outcome assessment should therefore include reporting of the rate and time of RTS. A consensus statement related to assessment and reporting of RTS was similarly reached at the ACL Consensus Meeting Panther Symposium 2019 and is provided in a separate publication.[67]

A comprehensive assessment also implies that the contralateral knee should be examined and assessed for each outcome. Outcome tools such as the IKDC Knee Ligament Standard Evaluation Form[45] require a comparison with the contralateral knee for the standardized reporting. The uninjured contralateral knee serves as a reference for the ACL-injured knee in terms of range of motion, laxity, and functional performance,[119] which helps to account for differences between patients. It should also be noted that the contralateral limb/leg/knee might also be affected by an ACL injury such as altered kinematics[53,68] and a decrease in muscle strength,[119] which underscores the importance to ensure that the function of the contralateral limb is optimized before allowing the patient to return to knee-strenuous activities by assessing it likewise. It is therefore recommended that the standard practice is to assess the contralateral knee and report such data, which ultimately will contribute to increased knowledge of risk factors for a patient sustaining a subsequent contralateral ACL injury.

TABLE 6
Examples of Outcome Measurements and Considerations for Follow-up Time[a]

Outcome Category	Example of Specific Outcome	Comment
Adverse events	Intraoperative complications Surgery- or device-related complications Infections Venous thromboembolism Reoperation	Usually less than 1-year follow-up required to detect these outcomes. When identifying adverse events, these should be reported as soon as possible, regardless of the minimum time lapsed from treatment start.
PRO	Validated knee-specific outcome scores Psychological measures HRQoL Activity level RTS	Depending on study purpose, population, and the specific outcome tool used. Generally, at least 1-year follow-up is required to obtain meaningful measures for interpretation of treatment effect, preferably 2 years. However, for the IKDC-SKF and the KOOS, the 1- and 2-year results have been reported equivalent.[80,95] Patients could be followed over several years to detect changes over time and to compare short-term, midterm, and long-term results.
ACL failure and recurrent ligament disruption	Graft rupture/failure ACL revision Contralateral ACL injury	The follow-up time must allow for sufficient time to detect events such as rerupture and ACL revision. These events tend to occur after the patient returns to knee-strenuous activities, which means that a 2-year follow-up should be a minimum.
Clinical measures of knee function and structure	Strength testing Hop testing Performance testing Knee joint laxity Range of motion Imaging OA Concomitant knee joint injuries	Largely depending on the specific outcome and the study purpose. However, care should be taken not to draw conclusion about the short-term treatment result until a 2-year follow-up is obtained. Functional performance tests, knee joint laxity, and range of motion assessments are preferably performed in multiple follow-ups before the 2-year follow-up for changes over time. OA assessment should have at least 5-year follow-up. Concomitant knee joint injuries should be reported whenever identified.

[a]ACL, anterior cruciate ligament; HRQoL, health-related quality of life; IKDC-SKF, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee injury and Osteoarthritis Outcome Score; OA, osteoarthritis; PRO, patient-reported outcome; RTS, return to sport.

Failure of ACL reconstruction is a nonspecific term that is commonly used without a stringent definition in the literature. It is therefore recommended that well-defined outcome assessments are used and that the authors, if choosing to use the term *failure*, report an a priori definition of what a failure is in detail. To define failure as reoperation is verifiable and clear; however, it introduces a risk of underestimating the true failure rate. Other examples of definitions for ACL graft failure include recurrent/persistent instability, pathological anterior or rotatory laxity, or evidence of graft failure assessed by magnetic resonance imaging (MRI) or arthroscopic surgery. In overall terms, reasons for ACL failure may be classified as traumatic (eg, reinjury), technical (eg, surgical errors), and patient related (eg, compliance to rehabilitation, recovery of neuromuscular function, or generalized hyperlaxity). Technical errors account for a great amount of all graft failures, with femoral tunnel malposition being a common cause.[71,106] It has also been reported that previous tibial tunnel malposition is a significant predictor for worse 2-year PROs after ACL revision.[122] It is therefore recommended that reporting of ACL reconstruction failure is complemented by reporting of details with regard to the surgical technique. A useful tool is the Anatomic ACL Reconstruction Scoring Checklist (AARSC),[107] which enables grading of surgical variables that define ACL tunnel position in an anatomic manner.

CONCLUSION. A minimum of 2-year follow-up is necessary for a comprehensive and reliable determination of outcome. The comprehensive assessment should include outcomes provided by clinical examination, PROs, activity level, and verified reinjuries.

5. *Comprehensive assessment after ACL surgery in the medium to long term (≥5 years) should also include measures of posttraumatic OA (25/25; 100% agreement).*

"A common methodology of outcome assessment for OA is needed and should be included in midterm to long-term follow-up studies."

It is well known that sustaining an ACL injury entails a high risk of developing posttraumatic OA in the midterm to long term, especially if concomitant intra-articular injuries are present.[1,21,81,86] Reducing the risk of OA is a clinical priority, which means that the midterm to long-term follow-up assessment should include measures of OA to monitor and evaluate the degenerative changes in the knee joint. This is necessary for developing therapeutic interventions aiming to counter the high rate of OA after an ACL injury.

Measures of OA may include clinical examination, PROs, and imaging modalities. Clinical examination findings that may indicate OA are joint-line tenderness or crepitus, which previously have been found to be strong predictors for OA.[96] Good interobserver reliability for

joint-line tenderness and crepitus has been reported when a standardized approach is used.[65] The IKDC Knee Ligament Standard Evaluation Form includes a grading system for such an examination and should be used for standardized reporting.[45]

The use of PROs is valuable to capture the patients' perception of impairments caused by OA. Questionnaires specifically developed and validated for assessment of OA are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[13] and the Knee injury and Osteoarthritis Outcome Score (KOOS).[91] However, the WOMAC was developed for evaluation of established OA; as such, the KOOS may be a more appropriate assessment for patients after ACL injury. This is because the KOOS is more likely to detect early development of OA compared with WOMAC, as the KOOS was developed to cover a broader spectrum from knee injury to manifest OA.[91,92]

Imaging modalities still provide the most sensitive assessment of OA, although not without limitations. One should remember that radiographic findings of OA are not necessarily accompanied by symptomatic OA,[5,84] and other intra-articular abnormalities may give similar symptoms as OA. It is therefore recommended to combine radiographic imaging assessment with PROs for decision making when it comes to symptomatic OA. Radiographic findings should be described in a standardized manner using validated tools, where the Kellgren-Lawrence perhaps is the most commonly used tool, taking into account osteophyte formation, sclerosis, joint space narrowing, and bone deformity.[55] Although plain radiography has long been the established method for imaging of OA, it must be acknowledged that the modality has a limited capacity to visualize early stages of OA and to grade OA progression.[63]

The rapid evolution of MRI techniques enables a much more comprehensive assessment of knee joint structure, such as early morphological and biochemical changes of articular and periarticular structures. Quantitative measurements of cartilage thickness on MRI have a higher sensitivity for knee OA compared with traditional radiological measures.[121] In addition, MRI detects characteristic OA signs earlier and with a greater sensitivity compared with radiography.[41] Structural intra-articular changes are indicative for OA and can be seen as early as 2 years after an ACL reconstruction with MRI, which is earlier than these changes can be seen on radiographs.[19,108] In addition, MRI can also rule out other intra-articular injuries that may explain symptoms perceived by patients. Thus, although plain radiography has an established role in assessment of OA and is favorable from an availability and cost perspective, its main role is to assess the development of OA in the long term and for already established OA. For early or midterm assessment of OA, attempts should be made to include MRI to detect early changes with greater validity and sensitivity.[41]

It is not known when clinically relevant posttraumatic OA occurs or when in this process the structural changes of the knee joint start to appear. With advancement in imaging techniques, there is a risk of overdiagnosis of OA because structural changes without clinical significance might be detected. Future research will hopefully provide a clearer picture of this as well as methods to distinguish between what are pathological changes and what changes are related to normal aging.[64] Until then, an assessment of knee OA should always be made in relation to a "control knee" to provide a reference for such variables. A synthesis of current literature shows that the contralateral knee is most commonly used for this purpose, followed by using an age- and sex-matched control group.[86] The latter methodology, using a separate comparison group, is the preferred method because degeneration can occur in the contralateral knee, although it was not part of the original injury. Some studies have used baseline imaging of the acute ACL-injured knee as the control,[1] which cannot be recommended because this method does not take into account the impact of natural aging occurring between the injury and the long-term follow-up.

CONCLUSION. Outcome assessment of OA should include clinical examination, PROs, and imaging modalities, for which MRI is the preferred modality for increased accuracy. Imaging findings should always be set in context with the patient's perception and the clinical examination for decision making. Hence, these outcome assessments are equally important for determining the outcome of OA.

6. Clinical assessment of ACL injury treatment should include measures of anteroposterior and rotatory knee laxity (25/25; 100% agreement).

> *"Evaluation of knee joint laxity is a cornerstone for evaluating the outcome of ACL treatment. Quantitative measures of knee joint laxity increase the reliability and validity."*

The anatomic properties of the ACL make it a primary passive restraint to both anteroposterior (AP) and rotatory forces of the knee joint.[46] Valid assessment of knee joint laxity is therefore key in the evaluation of the outcome of surgical treatment after ACL injury, preferably at multiple follow-ups to detect any changes over time. Failure to eliminate knee joint laxity with ACL reconstruction could indicate treatment failure, while patients undergoing nonoperative treatment should be assessed for excessive laxity or propagation of knee joint laxity. The latter scenario might be an indication for subsequent operative treatment, although the term *laxity* should be distinguished from instability or stability. Knee joint laxity is defined as the passive response of the knee joint when an external force or torque is applied, while instability is the patient's perception of symptoms during functional movement independent of laxity.[78] Hence, knee joint laxity can be reliably measured and reported, which makes it the preferred metric for clinical outcome assessment. To minimize the risk of bias, every attempt should be made to blind the assessors, and all participating assessors should be trained in using a standardized execution technique of the laxity test.

Laxity assessment consists of static and dynamic examinations, and methods for both grading by the examiner and quantification of laxity have been developed. Laxity assessments should always include a side-to-side comparison with the contralateral knee. Static AP knee laxity tests consider a single degree of freedom of motion and include application of a

Figure 2. The KiRA inertial sensor system for quantifying lateral tibial acceleration during the pivot-shift test.

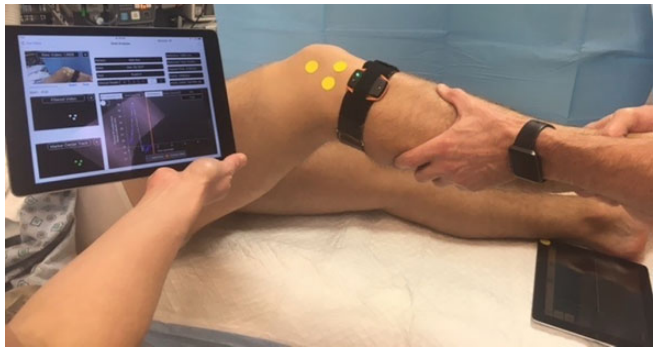

Figure 3. Image analysis system on iPad for quantifying lateral tibial translation during the pivot-shift test.

unidirectional force in a single plane, such as the Lachman test and the anterior drawer test. The IKDC Knee Ligament Standard Evaluation Form provides a standardized classification of the degree of AP translation.[45] For instrumented quantitative assessment of AP laxity, the KT-1000/2000 arthrometer (MEDmetric Corp)[27] and the Rolimeter (Aircast)[8] provide among the most accurate measurements, although the intraclass correlation coefficient is variable according to the literature, and the results are examiner dependent.[88] Another instrument is the GNRB (Genourob), which is a robotic arthrometer developed to alleviate the difficulties with examiner-dependent measurements. The patient's leg is placed in the robotic system, and a predefined force is applied to the proximal calf, while the relative displacement of the anterior tibial tubercle with respect to the patella is recorded by a displacement sensor. The GNRB also offers the advantage of using electromyography sensors to record hamstring activity to detect incomplete hamstring relaxation that affects the result.[89] Static AP measurements do not necessarily correlate with clinical outcome and function,[7,57,58] which indicates that laxity assessment should not solely rely on static AP translation because it fails to capture the more complex knee kinematics.

The pivot-shift (PS) test is considered to simulate a more physiological multiaxial loading of the knee joint because it is a dynamic test of laxity that evaluates both AP and rotatory laxity.[48] It has been reported as the most specific test for ACL deficiency.[14] On the other hand, the PS is characterized by a large variability in execution techniques,[60,77] which may lead to a variation in clinical grading between examiners. To overcome this, a standardized PS test has been described, which has led to an improved accuracy of the test.[77] Moreover, user-friendly devices for noninvasive quantitative PS have been developed and determined to be valid for objective assessment of the PS.[76] Such devices may include an inertial sensor system (KiRA; Orthokey)[124,125] to quantify the tibial acceleration during the PS and an image analysis system,[74] which enables a quantification of the lateral tibial translation during the PS. Both devices have been shown be able to validly detect differences between clinically high- and low-grade PS (Figures 2 and 3).[76] Examples of devices for quantitative AP and rotatory knee laxity that are easily applicable in the clinical setting are summarized in Table 7.

CONCLUSION. Knee joint laxity should be assessed after ACL treatment and reported in a standardized manner using the IKDC Knee Ligament Standard Evaluation Form when clinical grading is used. The use of quantitative measures is encouraged to increase the reliability and validity of the assessment.

Section 3: Patient-Reported Outcome

7. Assessment of PRO should optimally include at least 1 knee-specific outcome tool, 1 activity rating scale, and 1 measure of HRQoL (25/25; 100% agreement).

"There is a fine balance between multiple outcome assessments and the responder burden in clinical outcome assessment."

The use of PROs has become a cornerstone for researchers to understand the patients' perspective of the impact of ACL injury and treatment. During recent decades, technical development has facilitated the use of PROs, as patients can report and researchers can collect responses electronically. The time-efficient collection has tempted researchers to burden patients with more PROs in studies. Responder burden is an important term in research and is defined as the time to complete items as well as the physical energy and cognitive demands placed on those responding. In addition, all clinical testing of patients is part of the burden placed on our patients. Because of the risk of excessive responder burden, which threatens the validity of a patient's responses and thus their score, researchers are advised to wisely choose PROs specific for the study purpose.

Similar to statement number 2 of this consensus paper on baseline information to collect, it is recommended to use at least 1 knee-specific tool, 1 HRQoL tool, and 1 activity rating scale. This provides the researcher with a comprehensive picture of the patients' perception of outcome after treatment.

CONCLUSION. To give a comprehensive assessment of the patients' perception of the impact of ACL injury and outcome of treatment, validated knee-specific PRO assessment, HRQoL, and measure of type and level of preinjury

TABLE 7
Devices for Quantitative Assessment of Knee Joint Laxity[a]

Device	Accuracy	Comment
KT-1000/2000 arthrometer	The majority of studies show at least a fair reproducibility (intertester ICC range, 0.14-0.92; intratester ICC range, 0.47-0.95).[88]	Measure anterior tibial displacement in millimeters. Different reliability depending on examiner experience.[88] Dependent on dominant hand of the examiner.[100] The maximal manual force testing is the most reliable.[88]
Rolimeter	The literature shows an intertester correlation ranging between 0.39 and 0.89 and intratester correlation ranging between 0.55 and 1.00.[73,98]	Measure anterior tibial displacement in millimeters. Not as crucial with examiner experience compared with the KT-1000 arthrometer.[73] Might be easier to apply in the clinical setting compared with the KT-1000 arthrometer because of the lighter design. At least as reliable as the KT-1000 arthrometer.[88]
GNRB	Sensitivity and specificity for an ACL tear ranging between 62% to 92% and 76% to 99%, respectively.[11,56,89] The intertester ICC has been reported ranging between 0.220 and 0.424.[110]	Measure anterior tibial displacement in millimeters. Robotic testing meaning a less examiner-dependent measurement. Several studies reporting the GNRB as reliable as or superior to other arthrometers.[90] Possible to account for patient guarding with hamstring activation.[89]
Pivot App	Excellent intertester and intratester reliability reported. Intertester ICC of 0.95 (95% CI, 0.54-1.00) and intratester ICC ranging between 0.91 and 0.99 (95% CI, 0.319-1.000).[74]	Lateral tibial translation during the PS test is calculated (in mm) by a software program analyzing the movement of 3 markers placed on the skin during video recording of the PS test using a commercial tablet. Been proved valid to detect differences between clinically high- and low-grade PS.[76]
KiRA	Mean intrarater ICC of 0.79. Reproducibility is good to excellent across all different parameters being quantified (minimum, maximum, and range of tibial acceleration).[62]	An inertial sensor system quantifies the tibial acceleration (m/s^2) during the PS test. An elastic strap is used to position the sensor on the patient's leg when executing the PS test. Has been proved to be valid to detect differences between clinically high- and low-grade PS.[76]

[a]ACL, anterior cruciate ligament; ICC, intraclass correlation coefficient; PS, pivot shift.

sport/activity should be collected before and after treatment.

8. The IKDC-SKF is the recommended knee-related outcome measure for ACL injury and treatment (24/25; 96% agreement).

"It is important to find a universal metric. The IKDC-SKF is currently the optimal scale, but we should be careful not to neglect the other scores."

The evaluation of treatment outcome started historically with use of objective measurements as proxies for what clinicians and patients really cared about. For instance, both rating scales and measures of range of motion, strength, and laxity were frequently used; however, these measures are limited by interrater and intrarater variability and alone failed to determine symptoms and limitations perceived important by the patient. Failure to report and quantify the patients' perspective of treatment outcome after ACL injury led to the development of knee-related PROs during the late 1990s and early 2000s. The 2 most commonly used PROs after ACL injury are the KOOS and the IKDC-SKF, which were both developed during this time period. Measurement properties of the IKDC-SKF and KOOS are presented in Table 8.

These PROs have advantages and disadvantages, and when choosing between them, one should evaluate what the population is and what it is that you want to capture. Most importantly, measurements should consist of those that are relevant to the patient and capture the full range of symptoms, activity limitations, and participation restrictions to increase the relevance and validity in results attained from PROs.[23] It is essential that the PROs have undergone rigorous validation to the target condition to be able to differentiate better from worse treatment outcome. The inappropriate use of a PRO can distort results from a study and cause difficulties to detect differences, as items may not be relevant for the given population. This can be the case when a questionnaire aimed to assess outcome in patients with OA is used to assess patients with an ACL injury.

The KOOS is an extension of the WOMAC[12] (covers the subscales of Pain, Symptoms, and limitations in Activities of Daily Living) and was validated for patients with OA of the knee. The initial idea of the KOOS was to develop a region-specific outcome to capture the progression of knee-related symptoms across the life span of a patient from knee injury to the development of OA. Despite the inclusion of the Sport and Recreation and Quality of Life subscales, the KOOS has

TABLE 8
Psychometric Properties of the IKDC-SKF and the KOOS[37a]

	IKDC-SKF	KOOS
PASS	75.9	Pain = 88.9 Symptoms = 57.1 ADL = 100.0 Sport = 75.0 QoL = 62.5
MCID	11.5	N/A
MIC	10.9	Pain = 2.5 Symptoms = –1.2 ADL = 2.4 Sport = 12.1 QoL = 18.3
MDC	11.5	Pain = 6.0 to 6.1 Symptoms = 5.0 to 8.5 ADL = 7.0 to 8.0 Sport = 5.8 to 12.0 QoL = 7.0 to 7.2
Content validity	Poor	No evidence
Structural validity	No evidence	No evidence
Internal consistency	0.77 to 0.97	Pain = 0.84 to 0.91 Symptoms = 0.25 to 0.75 ADL = 0.94 to 0.96 Sport = 0.85 to 0.89 QoL = 0.64 to 0.90
Measurement error	3.2 to 5.6	Pain = 2.2 to 10.1 Symptoms = 3.1 to 9.0 ADL = 2.9 to 11.7 Sport = 2.1 to 24.6 QoL = 2.6 to 10.8
Test-retest reliability	0.85 to 0.99	Pain = 0.85 to 0.93 Symptoms = 0.83 to 0.95 ADL = 0.75 to 0.91 Sport = 0.61 to 0.89 QoL = 0.83 to 0.95
Responsiveness	Good	Poor
Cross-cultural validity	Fair	No evidence

[a]ADL, Activities of Daily Living; IKDC-SKF, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; MDC, minimum detectable change; MIC, minimally important change; N/A, not available; PASS, Patient Acceptable Symptom State; QoL, Quality of Life.

limited measurement properties in the 3 original WOMAC subscales when used for patients after ACL reconstruction.[23,59] It is also worth mentioning that the hybrid version of the KOOS, the $KOOS_4$ (a modified version in which the items related to activities of daily living have been excluded to avoid ceiling effects)[36] has not undergone a validation.[22,23] This is problematic, as the ability to detect differences between treatments will be limited with the KOOS used in patients with an ACL injury.[59] Using PRO measurements that include items that are not relevant or do not cover important limitations of the target condition is not optimal. Using such PROs entails a potential washout of treatment effects, inadequate measurement properties, and risk of false negative findings.[23,95,102] In terms of the KOOS, several questions are at risk for a ceiling effect when used in patients after ACL reconstruction; that is, the item is too "easy" for the patient. In addition, the KOOS does not include specific items relating to instability, which is one of the most common symptoms and one of the strongest indications for an ACL reconstruction. The KOOS consists of 42 items entailing higher responder burden compared with other outcomes such as the IKDC-SKF. Awareness of the limitations of the KOOS for the patients after an ACL injury or reconstruction is important to avoid missing the effects of treatment results.

The IKDC-SKF was developed as a region-specific outcome relevant for a variety of conditions including ligament and intra-articular abnormalities.[50] This PRO underwent rigorous testing during its development including a reduction from 42 to 18 items and an exploratory factor analysis, suggesting that it was reasonable to combine the items into a single overall score. To test the relevance of the IKDC-SKF for patients with an ACL injury, Rasch analysis was performed separately for patients with and without knee ligament injury.[50,109] The analysis supported the premise that the items of the IKDC performed similarly in terms of difficulty for individuals with or without a ligament injury. The results from the primary testing of the IKDC-SKF also indicated that the IKDC-SKF items performed the same, regardless of age, sex, and a variety of diagnoses including ligament, meniscal, and articular cartilage injury and patellofemoral pain.[29,50]

The IKDC-SKF is recommended as the knee-related PRO to use for patients after ACL reconstruction because of its quick-to-use 18 items.[50] The IKDC-SKF shows adequate internal consistency and has no floor or ceiling effects across mixed groups of patients with knee conditions.[29] It also has high levels of test-retest reliability, construct validity, and responsiveness. Moreover, normative data have been determined, which is valuable for comparisons as well as cutoffs for what the patients consider an acceptable symptom state.[52]

There are also other promising PROs used to cover different aspects of recovery after ACL reconstruction, including the Quality of Life Outcome Measure for Chronic Anterior Cruciate Ligament Deficiency (ACL-QoL)[69] and the Knee Numeric-Entity Evaluation Score (KNEES-ACL).[24] The ACL-QoL is used to determine the effectiveness of ACL reconstruction, or any other treatment, and is a 32-item condition-specific quality of life scale for patients with ACL deficiency.[69] The KNEES-ACL was developed in 2013,[24] and the thorough development process and dimensionality assessment resulted in 42 items across 7 latent constructs. There is strong positive evidence given to content validity.[24,25]

The ACL-QoL and the KNEES-ACL are promising outcome measurements and likely will help us to better understand patients who have sustained an ACL injury. However, these PROs have mainly been used in comparative studies and are yet to be compared with the established IKDC-SKF and KOOS to prove their respective strengths of constructs.

CONCLUSION. The IKDC-SKF is the recommended knee-related outcome measure for ACL injury and treatment.

9. *Measurement of the patient acceptable symptom state (PASS) is valuable in the assessment of outcome of ACL injury and treatment (25/25; 100% agreement).*

"One question can carry the advantage of giving the patient the opportunity to tell the story."

As researchers and clinicians of today, we are equipped with a great variety of PROs. However, the development and use of these PROs means little if the results are not interpreted in a clinically meaningful manner. The use of numeric scores poses a risk that researchers focus myopically at numbers and statistically significant findings without reflecting over whether such findings really are impactful from the patient's perspective. For many such PROs, the same score can be achieved, despite that patients respond differently to the items that comprise the PRO measure. The question of whether the patient perceives an acceptable symptom state is a priority for all clinicians, and the use of the PASS in PRO assessment is important. The PASS considers a single-item question and aims to determine a threshold beyond which the patients consider themselves "well."[75] Thresholds for the PASS have been established for the KOOS and the IKDC-SKF by asking the question "Taking account of all the activity you have during your daily life, your level of pain, and also your activity limitations and participation restrictions, do you consider the current state of your knee satisfactory?" alongside the administered PRO.[75] Several studies have since then applied the PASS values for the KOOS and IKDC-SKF when reporting on outcome after ACL treatment.[26,42,44,111]

A single-item outcome like the PASS summarizes the patient's perception and allows the patient to make an overall statement through a binary answer: "yes" or "no." A numeric scale might have its advantages; however, it is associated with difficulties of interpretation for both patients and researchers. That is, what is considered as a good and poor outcome, respectively? The PASS reference value at which a majority of the patients feel well is valuable for determining this important question, and its use is warranted to overcome limitations with numeric PROs such as ceiling effects and poor responsiveness.[49,72]

In addition, the evidence to support the interpretation and use of a PRO should include the minimum detectable change (MDC) score and the minimal clinically important difference (MCID) score. These scores collectively describe the responsiveness of the PRO, which is the ability to detect a clinically important change in outcome for the metric. The MDC is the amount of change that is needed to confidently state that the change is beyond measurement error.[10] Thus, if a study finds a difference that is smaller than the MDC for the chosen PRO, one should be careful to draw any conclusions because the observed difference is within the range of measurement error for the PRO. On the other hand, if the change in outcome is larger than the MDC, it still remains unknown whether this change is clinically relevant. This is where the MCID becomes valuable. If a change in outcome exceeds the value of the MCID for the PRO, the difference is likely to be perceived as important by most patients.[51]

CONCLUSION. The PASS is a valuable complement to numeric PROs and should be used to facilitate interpretation of PROs. Researchers should also consider the MDC and MCID for the PRO when reporting and discussing their study findings.

FUTURE DIRECTIONS

Reaching consensus for clinical outcome assessment after ACL treatment is an important step toward refining and improving the quality of ACL research. Further efforts should be made to develop methods for outcome assessment that provide the most relevant and valid data for patients receiving ACL treatment. A focus is to improve the PRO assessment. The collection of PROs has become increasingly important among health care professions. Not only is it a valuable asset for a clinician to understand a patient's perception of health and results of treatment, it has also gained importance for policy makers in determining health care quality and developing a value-based health care.[72] Commonly used PROs in ACL research are limited by a format of fixed-length surveys that many times include items of questionable relevance for the young and active population sustaining ACL injuries, leading to ceiling effects and potentially survey fatigue. Therefore, a current priority is to decrease the responder burden for patients in PRO assessment.

Improved PRO data collection may be achieved through the use of the item response theory (IRT),[20,35] which has enabled the introduction of computer adaptive testing (CAT). The underlying premise of IRT is that the way a patient responds to an item (question) is based on the difficulty of the question and the ability of the patient. When administered as a CAT, a mathematical algorithm is utilized to select items that are matched to the ability of the patient. For example, if a patient responds to an item that he/she is unable to walk a mile, the computer algorithm will bypass "harder" items such as running a mile and select an easier item such as ability to walk a block. This means that only items that are relevant about the patient's ability level are administered, which substantially reduces the time and burden associated with administration of PROs. Efforts are under way to convert the IKDC-SKF to a CAT format that is based on IRT.

Although computer-aided PRO assessment likely is the future, further research for optimization of currently used PROs is needed. Research should focus on determining the most responsive items of current PROs to condense the surveys to include only the most responsive questions. This is important when considering the already collected PRO data for tens of thousands of patients in large registries and national databases. Such data might need to be reanalyzed using the condensed PROs and thereby provide results with a greater precision on clinically relevant outcomes.

Other important aspects for further research are outcome measures on activity and RTS after ACL treatment. Optimally, a tool that is able to quantify sports participation in terms of level, volume, and intensity should be developed and implemented as a standardized tool used

across studies. With the rapid evolution of technology, the future will likely also hold easily accessible use of quantitative instruments for quantitatively measuring patient activity, for example, the use of Global Positioning System and motion detectors during sports participation, measurements of joint function, and measurements of heart rate and speed to estimate intensity.

CONCLUSION

Clinical outcome assessment after ACL injury can be divided in 4 robust categories: early adverse events, PROs, ACL failure/recurrent ligament disruption, and clinical measures of knee function and structure. A minimum of 2-year follow-up is necessary for a comprehensive and reliable determination of outcome, which should include outcomes provided by clinical examination, PROs, and verified reinjuries. The PRO assessment is a cornerstone in evaluating outcome after ACL injury, where validated knee-specific PRO assessment, HRQoL, and measure of type and level of sport/activity should be collected. The IKDC-SKF is the recommended knee-related PRO measure for ACL treatment, and the use of PASS is encouraged to facilitate interpretation of PROs.

AUTHORS

Eleonor Svantesson, MD (Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; Gothenburg Sports and Trauma Research Center, Gothenburg, Sweden); Eric Hamrin Senorski, PT, PhD (Gothenburg Sports and Trauma Research Center, Gothenburg, Sweden; Department of Rehabilitation and Health, Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden); Kate E. Webster, PhD (School of Allied Health, Human Services and Sport, La Trobe University, Melbourne, Victoria, Australia); Jón Karlsson, MD, PhD (Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; Gothenburg Sports and Trauma Research Center, Gothenburg, Sweden; Department of Orthopaedics, Sahlgrenska University Hospital, Gothenburg, Sweden); Theresa Diermeier, MD (Department of Sports Orthopedics, Klinikum Rechts der Isar, Technical University of Munich, Munich, Germany); Benjamin B. Rothrauff, MD (UPMC Freddie Fu Sports Medicine Center, Department of Orthopaedic Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania, USA); Sean J. Meredith, MD (UPMC Freddie Fu Sports Medicine Center, Department of Orthopaedic Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania, USA; Department of Orthopaedics, University of Maryland School of Medicine, Baltimore, Maryland, USA); Thomas Rauer, MD (UPMC Freddie Fu Sports Medicine Center, Department of Orthopaedic Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania, USA; Department of Trauma Surgery, University Hospital Zurich, Zurich, Switzerland); James J. Irrgang, PT, PhD, FAPTA (Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA; Department of Physical Therapy, University of Pittsburgh, Pittsburgh, Pennsylvania, USA); Kurt P. Spindler, MD (Sports Health Center, Cleveland Clinic, Garfield Heights, Ohio, USA); C. Benjamin Ma, MD (Department of Orthopaedic Surgery, University of California, San Francisco, San Francisco, California, USA); Volker Musahl, MD (Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA); and the Panther Symposium ACL Injury Clinical Outcomes Consensus Group: Freddie H. Fu, MD (Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA); Olufemi R. Ayeni, MD, PhD, FRCSC (Division of Orthopaedic Surgery, McMaster University, Hamilton, Ontario, Canada); Francesco Della Villa, MD (Education and Research Department, Isokinetic Medical Group, Bologna, Italy); Stefano Della Villa, MD (FIFA Medical Centre of Excellence, Bologna, Italy); Scott Dye, MD (Department of Orthopaedic Surgery, University of California, San Francisco); Mario Ferretti, MD, PhD (Federal University of Sao Paulo, Sao Paulo, Brazil); Alan Getgood, MD, FRCS (Tr&Orth), DipSEM (Fowler Kennedy Sport Medicine Clinic London, London, Ontario, Canada); Timo Järvelä, MD, PhD (Arthroscopic and Sports Medicine Center, Pohjola Hospital, Helsinki, Finland); Christopher C. Kaeding, MD (The Ohio State University, Columbus, Ohio, USA); Ryosuke Kuroda, MD, PhD (Kobe University Graduate School of Medicine, Kobe, Hyogo, Japan); Bryson Lesniak, MD (Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA); Robert G. Marx, MD, MSc, FRCSC (Medicine Institute, Hospital for Special Surgery, New York, USA); Gregory B. Maletis, MD (Southern California Permanente Medical Group, Baldwin Park, California, USA); Leo Pinczewski, MD (North Sydney Orthopaedic & Sports Medicine Centre, Sydney, Australia); Anil Ranawat, MD (Center for Hip Pain and Preservation, Hospital for Special Surgery, New York, New York, USA); Bruce Reider, MD (University of Chicago, Section of Orthopaedics and Rehabilitation Medicine, Department of Surgery, Chicago, Illinois, USA); Romain Seil, MD, PhD (Department of Orthopaedic Surgery, Clinique d'Eich-Centre Hospitalier de Luxembourg, Luxembourg); Carola van Eck, MD, PhD (Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA); Brian R. Wolf, MD, MS (UI Sports Medicine, Iowa City, IA, USA); Patrick Yung, MD (Department of Orthopaedics and Traumatology, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China); Stefano Zaffagnini, MD (Istituto Ortopedico Rizzoli, Bologna, Italy); and Ming Hao Zheng, MD, PhD, FRCPath (Centre for Orthopaedic Translational Research, School of Surgery, University of Western Australia, Perth, Western Australia, Australia).

REFERENCES

1. Ajuied A, Wong F, Smith C, et al. Anterior cruciate ligament injury and radiologic progression of knee osteoarthritis: a systematic review and meta-analysis. *Am J Sports Med*. 2014;42(9):2242-2252.

2. Andernord D, Karlsson J, Musahl V, et al. Timing of surgery of the anterior cruciate ligament. *Arthroscopy*. 2013;29(11):1863-1871.
3. Anderson JP, Kaplan RM, Berry CC, Bush JW, Rumbaut RG. Interday reliability of function assessment for a health status measure: the Quality of Well-Being scale. *Med Care*. 1989;27(11):1076-1083.
4. Andersson D, Samuelsson K, Karlsson J. Treatment of anterior cruciate ligament injuries with special reference to surgical technique and rehabilitation: an assessment of randomized controlled trials. *Arthroscopy*. 2009;25(6):653-685.
5. Andersson Molina H, Karlsson H, Rockborn P. Arthroscopic partial and total meniscectomy: a long-term follow-up study with matched controls. *Arthroscopy*. 2002;18(2):183-189.
6. Ardern CL, Taylor NF, Feller JA, Whitehead TS, Webster KE. Sports participation 2 years after anterior cruciate ligament reconstruction in athletes who had not returned to sport at 1 year: a prospective follow-up of physical function and psychological factors in 122 athletes. *Am J Sports Med*. 2015;43(4):848-856.
7. Ayeni OR, Chahal M, Tran MN, Sprague S. Pivot shift as an outcome measure for ACL reconstruction: a systematic review. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(4):767-777.
8. Balasch H, Schiller M, Friebel H, Hoffmann F. Evaluation of anterior knee joint instability with the Rolimeter: a test in comparison with manual assessment and measuring with the KT-1000 arthrometer. *Knee Surg Sports Traumatol Arthrosc*. 1999;7(4):204-208.
9. Barber-Westin SD, Noyes FR, McCloskey JW. Rigorous statistical reliability, validity, and responsiveness testing of the Cincinnati Knee Rating System in 350 subjects with uninjured, injured, or anterior cruciate ligament-reconstructed knees. *Am J Sports Med*. 1999;27(4):402-416.
10. Beaton DE, Bombardier C, Katz JN, Wright JG. A taxonomy for responsiveness. *J Clin Epidemiol*. 2001;54(12):1204-1217.
11. Beldame J, Mouchel S, Bertiaux S, et al. Anterior knee laxity measurement: comparison of passive stress radiographs Telos® and "Lerat", and GNRB® arthrometer. *Orthop Traumatol Surg Res*. 2012;98(7):744-750.
12. Bellamy N, Buchanan WW. A preliminary evaluation of the dimensionality and clinical importance of pain and disability in osteoarthritis of the hip and knee. *Clin Rheumatol*. 1986;5(2):231-241.
13. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988;15(12):1833-1840.
14. Benjaminse A, Gokeler A, van der Schans CP. Clinical diagnosis of an anterior cruciate ligament rupture: a meta-analysis. *J Orthop Sports Phys Ther*. 2006;36(5):267-288.
15. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. *Med Care*. 1981;19(8):787-805.
16. Bhandari M, Guyatt GH, Swiontkowski MF. User's guide to the orthopaedic literature: how to use an article about a surgical therapy. *J Bone Joint Surg Am*. 2001;83(6):916-926.
17. Bost JE, Williams BA, Bottegal MT, Dang Q, Rubio DM. The 8-item Short-Form Health Survey and the physical comfort composite score of the quality of recovery 40-item scale provide the most responsive assessments of pain, physical function, and mental function during the first 4 days after ambulatory knee surgery with regional anesthesia. *Anesth Analg*. 2007;105(6):1693-1700, table of contents.
18. Bourke HE, Salmon LJ, Waller A, Patterson V, Pinczewski LA. Survival of the anterior cruciate ligament graft and the contralateral ACL at a minimum of 15 years. *Am J Sports Med*. 2012;40(9):1985-1992.
19. Bowes MA, Lohmander LS, Wolstenholme CBH, et al. Marked and rapid change of bone shape in acutely ACL injured knees: an exploratory analysis of the Kanon trial. *Osteoarthritis Cartilage*. 2019;27(4):638-645.
20. Brodke DJ, Hung M, Bozic KJ. Item response theory and computerized adaptive testing for orthopaedic outcomes measures. *J Am Acad Orthop Surg*. 2016;24(11):750-754.
21. Claes S, Hermie L, Verdonk R, Bellemans J, Verdonk P. Is osteoarthritis an inevitable consequence of anterior cruciate ligament reconstruction? A meta-analysis. *Knee Surg Sports Traumatol Arthrosc.* 2013;21(9):1967-1976.
22. Comins J, Brodersen J, Krogsgaard M. Treatment for acute anterior cruciate ligament tear. *N Engl J Med*. 2010;363(19):1871, author reply 1872-1873.
23. Comins J, Brodersen J, Krogsgaard M, Beyer N. Rasch analysis of the Knee injury and Osteoarthritis Outcome Score (KOOS): a statistical re-evaluation. *Scand J Med Sci Sports*. 2008;18(3):336-345.
24. Comins JD, Krogsgaard MR, Brodersen J. Development of the Knee Numeric-Entity Evaluation Score (KNEES-ACL): a condition-specific questionnaire. *Scand J Med Sci Sports*. 2013;23(5):e293-e301.
25. Comins JD, Krogsgaard MR, Kreiner S, Brodersen J. Dimensionality of the Knee Numeric-Entity Evaluation Score (KNEES-ACL): a condition-specific questionnaire. *Scand J Med Sci Sports*. 2013;23(5):e302-e312.
26. Cristiani R, Mikkelsen C, Edman G, et al. Age, gender, quadriceps strength and hop test performance are the most important factors affecting the achievement of a patient-acceptable symptom state after ACL reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2020;28(2):369-380.
27. Daniel DM, Malcom LL, Losse G, et al. Instrumented measurement of anterior laxity of the knee. *J Bone Joint Surg Am*. 1985;67(5):720-726.
28. Djulbegovic B, Guyatt GH. Progress in evidence-based medicine: a quarter century on. *Lancet*. 2017;390(10092):415-423.
29. Ebrahimzadeh MH, Makhmalbaf H, Golhasani-Keshtan F, Rabani S, Birjandinejad A. The International Knee Documentation Committee (IKDC) Subjective Short Form: a validity and reliability study. *Knee Surg Sports Traumatol Arthrosc*. 2015;23(11):3163-3167.
30. Eitzen I, Moksnes H, Snyder-Mackler L, Risberg MA. A progressive 5-week exercise therapy program leads to significant improvement in knee function early after anterior cruciate ligament injury. *J Orthop Sports Phys Ther*. 2010;40(11):705-721.
31. EuroQol Group. EuroQol: a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199-208.
32. Faltstrom A, Hagglund M, Magnusson H, Forssblad M, Kvist J. Predictors for additional anterior cruciate ligament reconstruction: data from the Swedish national ACL register. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(3):885-894.
33. Ferguson D, Palmer A, Khan S, Oduoza U, Atkinson H. Early or delayed anterior cruciate ligament reconstruction: is one superior? A systematic review and meta-analysis. *Eur J Orthop Surg Traumatol.* 2019;29(6):1277-1289.
34. Filbay SR, Culvenor AG, Ackerman IN, Russell TG, Crossley KM. Quality of life in anterior cruciate ligament-deficient individuals: a systematic review and meta-analysis. *Br J Sports Med*. 2015;49(16):1033-1041.
35. Fries JF, Bruce B, Cella D. The promise of PROMIS: using item response theory to improve assessment of patient-reported outcomes. *Clin Exp Rheumatol*. 2005;23(5)(suppl 39):S53-S57.
36. Frobell RB, Roos EM, Roos HP, Ranstam J, Lohmander LS. A randomized trial of treatment for acute anterior cruciate ligament tears. *N Engl J Med*. 2010;363(4):331-342.
37. Gagnier JJ, Shen Y, Huang H. Psychometric properties of patient-reported outcome measures for use in patients with anterior cruciate ligament injuries: a systematic review. *JBJS Rev*. 2018;6(4):e5.
38. Gelman A. Don't calculate post-hoc power using observed estimate of effect size. *Ann Surg*. 2019;269(1):e9-e10.
39. Grindem H, Eitzen I, Moksnes H, Snyder-Mackler L, Risberg MA. A pair-matched comparison of return to pivoting sports at 1 year in anterior cruciate ligament-injured patients after a nonoperative versus an operative treatment course. *Am J Sports Med*. 2012;40(11):2509-2516.
40. Grindem H, Snyder-Mackler L, Moksnes H, Engebretsen L, Risberg MA. Simple decision rules can reduce reinjury risk by 84% after ACL reconstruction: the Delaware-Oslo ACL Cohort Study. *Br J Sports Med*. 2016;50(13):804-808.

41. Guermazi A, Niu J, Hayashi D, et al. Prevalence of abnormalities in knees detected by MRI in adults without knee osteoarthritis: population based observational study (Framingham Osteoarthritis Study). *BMJ*. 2012;345:e5339.
42. Hamrin Senorski E, Sundemo D, Svantesson E, et al. Preoperative and intraoperative predictors of long-term acceptable knee function and osteoarthritis after anterior cruciate ligament reconstruction: an analysis based on 2 randomized controlled trials. *Arthroscopy*. 2019; 35(2):489-499.
43. Hamrin Senorski E, Svantesson E, Baldari A, et al. Factors that affect patient reported outcome after anterior cruciate ligament reconstruction: a systematic review of the Scandinavian Knee Ligament Registers. *Br J Sports Med*. 2019;53(7):410-417.
44. Hamrin Senorski E, Svantesson E, Beischer S, et al. Factors affecting the achievement of a patient-acceptable symptom state 1 year after anterior cruciate ligament reconstruction: a cohort study of 343 patients from 2 registries. *Orthop J Sports Med*. 2018;6(4): 2325967118764317.
45. Hefti F, Muller W, Jakob RP, Staubli HU. Evaluation of knee ligament injuries with the IKDC form. *Knee Surg Sports Traumatol Arthrosc*. 1993;1(3-4):226-234.
46. Hirschmann MT, Muller W. Complex function of the knee joint: the current understanding of the knee. *Knee Surg Sports Traumatol Arthrosc*. 2015;23(10):2780-2788.
47. Hofbauer M, Soldati F, Szomolanyi P, et al. Hamstring tendon autografts do not show complete graft maturity 6 months postoperatively after anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):130-136.
48. Hoshino Y, Kuroda R, Nagamune K, et al. In vivo measurement of the pivot-shift test in the anterior cruciate ligament-deficient knee using an electromagnetic device. *Am J Sports Med*. 2007;35(7): 1098-1104.
49. Ingelsrud LH, Terwee CB, Terluin B, et al. Meaningful change scores in the Knee injury and Osteoarthritis Outcome Score in patients undergoing anterior cruciate ligament reconstruction. *Am J Sports Med*. 2018;46(5):1120-1128.
50. Irrgang JJ, Anderson AF, Boland AL, et al. Development and validation of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2001;29(5):600-613.
51. Jaeschke R, Singer J, Guyatt GH. Measurement of health status: ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407-415.
52. Kanakamedala AC, Anderson AF, Irrgang JJ. IKDC Subjective Knee Form and Marx Activity Rating Scale are suitable to evaluate all orthopaedic sports medicine knee conditions: a systematic review. *J ISAKOS*. 2016;1(1):25.
53. Kaur M, Ribeiro DC, Theis JC, Webster KE, Sole G. Movement patterns of the knee during gait following ACL reconstruction: a systematic review and meta-analysis. *Sports Med*. 2016;46(12):1869-1895.
54. Kay J, Memon M, Sa D, et al. A historical analysis of randomized controlled trials in anterior cruciate ligament surgery. *J Bone Joint Surg Am*. 2017;99(24):2062-2068.
55. Kellgren JH, Lawrence JS. Radiological assessment of osteoarthrosis. *Ann Rheum Dis*. 1957;16(4):494-502.
56. Klouche S, Lefevre N, Cascua S, et al. Diagnostic value of the GNRB® in relation to pressure load for complete ACL tears: a prospective case-control study of 118 subjects. *Orthop Traumatol Surg Res*. 2015;101(3):297-300.
57. Kocher MS, Steadman JR, Briggs K, et al. Determinants of patient satisfaction with outcome after anterior cruciate ligament reconstruction. *J Bone Joint Surg Am*. 2002;84(9):1560-1572.
58. Kocher MS, Steadman JR, Briggs KK, Sterett WI, Hawkins RJ. Relationships between objective assessment of ligament stability and subjective assessment of symptoms and function after anterior cruciate ligament reconstruction. *Am J Sports Med*. 2004;32(3):629-634.
59. Krogsgaard MR, Brodersen J, Comins J. A scientific approach to optimal treatment of cruciate ligament injuries. *Acta Orthop*. 2011; 82(3):389-390, discussion 390-392.
60. Kuroda R, Hoshino Y, Kubo S, et al. Similarities and differences of diagnostic manual tests for anterior cruciate ligament insufficiency: a global survey and kinematics assessment. *Am J Sports Med*. 2012; 40(1):91-99.
61. Kyritsis P, Bahr R, Landreau P, Miladi R, Witvrouw E. Likelihood of ACL graft rupture: not meeting six clinical discharge criteria before return to sport is associated with a four times greater risk of rupture. *Br J Sports Med*. 2016;50(15):946-951.
62. Lopomo N, Zaffagnini S, Signorelli C, et al. An original clinical methodology for non-invasive assessment of pivot-shift test. *Comput Methods Biomech Biomed Engin*. 2012;15(12):1323-1328.
63. Madry H, Kon E, Condello V, et al. Early osteoarthritis of the knee. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(6):1753-1762.
64. Magnusson K, Kumm J, Turkiewicz A, Englund M. A naturally aging knee, or development of early knee osteoarthritis? *Osteoarthritis Cartilage*. 2018;26(11):1447-1452.
65. Maricar N, Callaghan MJ, Parkes MJ, Felson DT, O'Neill TW. Interobserver and intraobserver reliability of clinical assessments in knee osteoarthritis. *J Rheumatol*. 2016;43(12):2171-2178.
66. Marx RG, Stump TJ, Jones EC, Wickiewicz TL, Warren RF. Development and evaluation of an activity rating scale for disorders of the knee. *Am J Sports Med*. 2001;29(2):213-218.
67. Meredith SJ, Rauer T, Chmielewski TL, et al. Return to sport after anterior cruciate ligament injury: Panther Symposium ACL Injury Return to Sport Consensus Group. *Orthop J Sports Med*. 2020;8(6): 2325967120930829.
68. Mirkov DM, Knezevic OM, Maffiuletti NA, et al. Contralateral limb deficit after ACL-reconstruction: an analysis of early and late phase of rate of force development. *J Sports Sci*. 2017;35(5):435-440.
69. Mohtadi N. Development and validation of the quality of life outcome measure (questionnaire) for chronic anterior cruciate ligament deficiency. *Am J Sports Med*. 1998;26(3):350-359.
70. Moksnes H, Snyder-Mackler L, Risberg MA. Individuals with an anterior cruciate ligament-deficient knee classified as noncopers may be candidates for nonsurgical rehabilitation. *J Orthop Sports Phys Ther*. 2008;38(10):586-595.
71. Morgan JA, Dahm D, Levy B, Stuart MJ. Femoral tunnel malposition in ACL revision reconstruction. *J Knee Surg*. 2012;25(5):361-368.
72. MOTION Group. Patient-reported outcomes in orthopaedics. *J Bone Joint Surg Am*. 2018;100(5):436-442.
73. Muellner T, Bugge W, Johansen S, Holtan C, Engebretsen L. Inter- and intratester comparison of the Rolimeter knee tester: effect of tester's experience and the examination technique. *Knee Surg Sports Traumatol Arthrosc*. 2001;9(5):302-306.
74. Muller B, Hofbauer M, Rahnemai-Azar AA, et al. Development of computer tablet software for clinical quantification of lateral knee compartment translation during the pivot shift test. *Comput Methods Biomech Biomed Engin*. 2016;19(2):217-228.
75. Muller B, Yabroudi MA, Lynch A, et al. Defining thresholds for the patient acceptable symptom state for the IKDC Subjective Knee Form and KOOS for patients who underwent ACL reconstruction. *Am J Sports Med*. 2016;44(11):2820-2826.
76. Musahl V, Griffith C, Irrgang JJ, et al. Validation of quantitative measures of rotatory knee laxity. *Am J Sports Med*. 2016;44(9): 2393-2398.
77. Musahl V, Hoshino Y, Ahlden M, et al. The pivot shift: a global user guide. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(4):724-731.
78. Musahl V, Hoshino Y, Becker R, Karlsson J. Rotatory knee laxity and the pivot shift. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(4): 601-602.
79. Musahl V, Karlsson J. Anterior cruciate ligament tear. *N Engl J Med*. 2019;380(24):2341-2348.
80. Nguyen J, Rodeo SA. No clinically relevant change between 1 and 2 year outcomes following ACL reconstruction. *Orthop J Sports Med*. 2017;5(7)(suppl 6):2325967117S2325900258.
81. Oiestad BE, Engebretsen L, Storheim K, Risberg MA. Knee osteoarthritis after anterior cruciate ligament injury: a systematic review. *Am J Sports Med*. 2009;37(7):1434-1443.

82. Paterno MV, Rauh MJ, Schmitt LC, Ford KR, Hewett TE. Incidence of contralateral and ipsilateral anterior cruciate ligament (ACL) injury after primary ACL reconstruction and return to sport. *Clin J Sport Med*. 2012;22(2):116-121.
83. Pauzenberger L, Syre S, Schurz M. "Ligamentization" in hamstring tendon grafts after anterior cruciate ligament reconstruction: a systematic review of the literature and a glimpse into the future. *Arthroscopy*. 2013;29(10):1712-1721.
84. Petty CA, Lubowitz JH. Does arthroscopic partial meniscectomy result in knee osteoarthritis? A systematic review with a minimum of 8 years' follow-up. *Arthroscopy*. 2011;27(3):419-424.
85. Poolman RW, Swiontkowski MF, Fairbank JC, et al. Outcome instruments: rationale for their use. *J Bone Joint Surg Am*. 2009;91(suppl 3):41-49.
86. Poulsen E, Goncalves GH, Bricca A, et al. Knee osteoarthritis risk is increased 4-6 fold after knee injury: a systematic review and meta-analysis. *Br J Sports Med*. 2019;53(23):1454-1463.
87. Prentice HA, Lind M, Mouton C, et al. Patient demographic and surgical characteristics in anterior cruciate ligament reconstruction: a description of registries from six countries. *Br J Sports Med*. 2018; 52(11):716-722.
88. Pugh L, Mascarenhas R, Arneja S, Chin PY, Leith JM. Current concepts in instrumented knee-laxity testing. *Am J Sports Med*. 2009; 37(1):199-210.
89. Robert H, Nouveau S, Gageot S, Gagniere B. A new knee arthrometer, the GNRB: experience in ACL complete and partial tears. *Orthop Traumatol Surg Res*. 2009;95(3):171-176.
90. Rohman EM, Macalena JA. Anterior cruciate ligament assessment using arthrometry and stress imaging. *Curr Rev Musculoskelet Med*. 2016;9(2):130-138.
91. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee injury and Osteoarthritis Outcome Score (KOOS): development of a self-administered outcome measure. *J Orthop Sports Phys Ther*. 1998;28(2):88-96.
92. Roos EM, Toksvig-Larsen S. Knee injury and Osteoarthritis Outcome Score (KOOS): validation and comparison to the WOMAC in total knee replacement. *Health Qual Life Outcomes*. 2003;1:17.
93. Sackett DL. *Evidence-Based Medicine: How to Practice and Teach EBM*. Churchill Livingstone; 1997.
94. Samuelsson K, Andersson D, Karlsson J. Treatment of anterior cruciate ligament injuries with special reference to graft type and surgical technique: an assessment of randomized controlled trials. *Arthroscopy*. 2009;25(10):1139-1174.
95. Samuelsson K, Magnussen RA, Alentorn-Geli E, et al. Equivalent Knee injury and Osteoarthritis Outcome Scores 12 and 24 months after anterior cruciate ligament reconstruction: results from the Swedish National Knee Ligament Register. *Am J Sports Med*. 2017;45(9):2085-2091.
96. Schiphof D, van Middelkoop M, de Klerk BM, et al. Crepitus is a first indication of patellofemoral osteoarthritis (and not of tibiofemoral osteoarthritis). *Osteoarthritis Cartilage*. 2014;22(5):631-638.
97. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:C332.
98. Schuster AJ, McNicholas MJ, Wachtl SW, McGurty DW, Jakob RP. A new mechanical testing device for measuring anteroposterior knee laxity. *Am J Sports Med*. 2004;32(7):1731-1735.
99. Schuster P, Schulz M, Immendoerfer M, et al. Septic arthritis after arthroscopic anterior cruciate ligament reconstruction: evaluation of an arthroscopic graft-retaining treatment protocol. *Am J Sports Med*. 2015;43(12):3005-3012.
100. Sernert N, Helmers J, Kartus C, Ejerhed L, Kartus J. Knee-laxity measurements examined by a left-hand- and a right-hand-dominant physiotherapist, in patients with anterior cruciate ligament injuries and healthy controls. *Knee Surg Sports Traumatol Arthrosc*. 2007;15(10):1181-1186.
101. Smith TO, Davies L, Hing CB. Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis. *Knee Surg Sports Traumatol Arthrosc*. 2010;18(3): 304-311.
102. Spindler KP, Huston LJ, Chagin KM, et al. Ten-year outcomes and risk factors after anterior cruciate ligament reconstruction: a MOON longitudinal prospective cohort study. *Am J Sports Med*. 2018;46(4): 815-825.
103. Svantesson E, Hamrin Senorski E, Baldari A, et al. Factors associated with additional anterior cruciate ligament reconstruction and register comparison: a systematic review on the Scandinavian Knee Ligament Registers. *Br J Sports Med*. 2019;53(7):418-425.
104. Svantesson E, Hamrin Senorski E, Spindler KP, et al. While modern medicine evolves continuously, evidence-based research methodology remains: how register studies should be interpreted and appreciated. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(8): 2305-2308.
105. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res*. 1985;198:43-49.
106. Trojani C, Sbihi A, Djian P, et al. Causes for failure of ACL reconstruction and influence of meniscectomies after revision. *Knee Surg Sports Traumatol Arthrosc*. 2011;19(2):196-201.
107. van Eck CF, Gravare-Silbernagel K, Samuelsson K, et al. Evidence to support the interpretation and use of the Anatomic Anterior Cruciate Ligament Reconstruction Checklist. *J Bone Joint Surg Am*. 2013; 95(20):e153.
108. Van Ginckel A, Verdonk P, Witvrouw E. Cartilage adaptation after anterior cruciate ligament injury and reconstruction: implications for clinical management and research? A systematic review of longitudinal MRI studies. *Osteoarthritis Cartilage.* 2013;21(8):1009-1024.
109. van Meer BL, Meuffels DE, Vissers MM, et al. Knee injury and Osteoarthritis Outcome Score or International Knee Documentation Committee Subjective Knee Form: which questionnaire is most useful to monitor patients with an anterior cruciate ligament rupture in the short term? *Arthroscopy*. 2013;29(4):701-715.
110. Vauhnik R, Morrissey MC, Perme MP, Sevsek F, Rugelj D. Inter-rater reliability of the GNRB® knee arthrometer. *Knee*. 2014;21(2):541-543.
111. Vega JF, Jacobs CA, Strnad GJ, et al. Prospective evaluation of the Patient Acceptable Symptom State to identify clinically successful anterior cruciate ligament reconstruction. *Am J Sports Med*. 2019; 47(5):1159-1167.
112. Vogl TJ, Schmitt J, Lubrich J, et al. Reconstructed anterior cruciate ligaments using patellar tendon ligament grafts: diagnostic value of contrast-enhanced MRI in a 2-year follow-up regimen. *Eur Radiol*. 2001;11(8):1450-1456.
113. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet*. 2007; 370(9596):1453-1457.
114. Wang C, Lee YH, Siebold R. Recommendations for the management of septic arthritis after ACL reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2014;22(9):2136-2144.
115. Ware JE Jr, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36), I: conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.
116. Wasserstein RL, Lazar NA. The ASA's statement on p-values: context, process, and purpose. *Am Stat*. 2016;70(2):129-133.
117. Webster KE, Feller JA. Exploring the high reinjury rate in younger patients undergoing anterior cruciate ligament reconstruction. *Am J Sports Med*. 2016;44(11):2827-2832.
118. Webster KE, Feller JA, Leigh WB, Richmond AK. Younger patients are at increased risk for graft rupture and contralateral injury after anterior cruciate ligament reconstruction. *Am J Sports Med*. 2014; 42(3):641-647.
119. Wellsandt E, Failla MJ, Snyder-Mackler L. Limb symmetry indexes can overestimate knee function after anterior cruciate ligament injury. *J Orthop Sports Phys Ther*. 2017;47(5):334-338.
120. Wiggins AJ, Grandhi RK, Schneider DK, et al. Risk of secondary injury in younger athletes after anterior cruciate ligament reconstruction: a systematic review and meta-analysis. *Am J Sports Med*. 2016;44(7):1861-1876.

121. Wirth W, Duryea J, Hellio Le Graverand MP, et al. Direct comparison of fixed flexion, radiography and MRI in knee osteoarthritis: responsiveness data from the Osteoarthritis Initiative. *Osteoarthritis Cartilage*. 2013;21(1):117-125.
122. Wright RW, Huston LJ, Haas AK, et al. Predictors of patient-reported outcomes at 2 years after revision anterior cruciate ligament reconstruction. *Am J Sports Med*. 2019;47(10):2394-2401.
123. Zaffagnini S, De Pasquale V, Marchesini Reggiani L, et al. Neoligamentization process of BTPB used for ACL graft: histological evaluation from 6 months to 10 years. *Knee*. 2007; 14(2):87-93.
124. Zaffagnini S, Lopomo N, Signorelli C, et al. Innovative technology for knee laxity evaluation: clinical applicability and reliability of inertial sensors for quantitative analysis of the pivot-shift test. *Clin Sports Med*. 2013;32(1):61-70.
125. Zaffagnini S, Signorelli C, Grassi A, et al. Assessment of the pivot shift using inertial sensors. *Curr Rev Musculoskelet Med*. 2016;9(2): 160-163.

APPENDIX

Panther Consensus 2 Outcomes: Initial Survey Data

Answer choices: *strongly agree*, *somewhat agree*, *neither agree nor disagree*, *somewhat disagree*, *strongly disagree*

Q1. Short-term outcome assessment should include a minimum 2 years and 80% follow-up of the entire cohort.
78% strongly agree
17% somewhat agree
5% somewhat disagree

Q2. Medium-term outcome assessment should include a minimum 5 years and 80% follow-up of the entire cohort.
70% strongly agree
30% somewhat agree

Q3. Assessment of patient-reported outcome (PRO) should include one knee-specific outcome tool, one activity rating scale, and one measure of health-related quality of life (HRQoL).
50% strongly agree
50% somewhat agree

Q4. The International Knee Documentation Committee Subjective Knee Form (IKDC-SKF) is the accepted knee-related outcome measure for anterior cruciate ligament (ACL) injury and surgery.
61% strongly agree
22% somewhat agree
13% neither agree nor disagree
4% strongly disagree

Q5. A single numerical measure is sufficient for assessing overall outcome after ACL injury/surgery.
13% strongly agree
8% somewhat agree
29% neither agree nor disagree
25% somewhat disagree
25% strongly disagree

Q6. The evidence to support the interpretation and use of a PRO for the knee should include:
- The minimum detectable change (MDC) score
- The minimal clinically important difference (MCID) score
- The patient acceptable symptom state (PASS) score
- Normative data from a large and representative sample

52% strongly agree
35% somewhat agree
13% neither agree nor disagree

Q7. After ACL surgery, short-term outcome assessment ($\geq$2 years) should include PRO, return to play, and graft failure/reinjury.
82% strongly agree
18% somewhat agree

Q8. After ACL surgery, medium- to long-term outcome assessment ($\geq$5 years) should include osteoarthritis (OA) progression, PRO, and graft failure/reinjury.
64% strongly agree
36% somewhat agree

Q9. Rotatory knee laxity outcome should be assessed as an outcome after ACL reconstruction.
33% strongly agree
54% somewhat agree
8% neither agree nor disagree
4% somewhat disagree

Q10. For acute injury, final functional status is the outcome of interest, and minimum preoperative outcome reporting must include demographic information and recording of type and frequency of preinjury activity and participation.
50% strongly agree
46% somewhat agree
4% strongly disagree

Q11. For chronic injury, improvement from presurgery status is the outcome of interest, and minimum preoperative outcome reporting must include full PRO assessment (demographic, knee specific, activity level, HRQoL).
48% strongly agree
52% somewhat agree

Q12. For medium- to long-term outcome assessment ($\geq$5 years), OA progression is the outcome of interest, and baseline radiographic status of the ipsilateral knee and

concurrent radiographic status of the contralateral knee must be reported.

38% strongly agree
42% somewhat agree
4% neither agree nor disagree
13% somewhat disagree
4% strongly disagree

Q13. Sample sizes of 400 to 500 are required for studies assessing absolute reinjury risk reduction of 10% in high-risk patients.

25% strongly agree
42% somewhat agree
29% neither agree nor disagree
4% somewhat disagree