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Systematic Review

Instrument-based anterolateral rotatory laxity assessment of the knee has a high intra-observer and inter-observer reliability: a systematic review

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ABSTRACT

Importance: A reliable evaluation of anterolateral rotatory instability in the anterior cruciate ligament (ACL) deficient knee is important to help surgeons determine which patients might need concurrent anterolateral augmentation procedures.
Objective: The purpose of this study was to systematically review studies that assess the intra-observer and inter-observer reliability of instruments used to measure anterolateral rotatory laxity of the knee.
Evidence review: A comprehensive literature review was conducted according to the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, using PubMed, Embase, Scopus, and Google Scholar databases for original, English-language studies evaluating the reliability of objective or instrument-based anterolateral rotatory laxity of the knee until October 31, 2022. Reliability data were extracted from text, tables, and figures.
Findings: Twelve studies, with patients between the ages of 14–63 years, were included. The instruments used to measure anterolateral rotatory knee laxity included inertial sensors (n = 9), magnetic resonance imaging (n = 1), and navigation systems (n = 2). The global intra-observer intraclass correlation coefficient for these devices was between 0.63 and 0.97, and the global inter-observer reliability was between 0.63 and 0.99.
Conclusion and relevance: Instrument-based anterolateral rotatory knee laxity assessment has moderate to good intra- and inter-observer reliability. Evaluating anterolateral instability in ACL-deficient knees with these devices could help in decision-making when considering anterolateral augmentation.
Level of Evidence: IV.

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What is already known

- Anterolateral rotatory instability is a key element during the physical examination of an anterior cruciate ligament–deficient knee.
- When evaluating anterolateral rotatory instability, the pivot shift is the main tool during the physical examination; however, it has low inter-observer reliability.
- During the last few years, new instruments have been developed to objectively evaluate the anterolateral rotatory laxity of the knee.

What are the new findings

- There are different instruments available to evaluate the anterolateral rotatory laxity of the knee which use inertial sensors, magnetic resonance, and navigation systems.
- Not only are the instrument-based methods objective but also they are highly reliable for both intra-observer and inter-observer evaluation of the anterolateral rotatory laxity of the knee.
- Magnetic resonance imaging and navigation systems showed the highest intraclass correlation coefficient values.

Introduction

The anterior cruciate ligament (ACL) is the primary restraint for the anterior displacement of the tibia on the femur and a secondary stabilizer for tibial rotation. Therefore, an ACL injury can lead to meniscal injury, functional instability, and early-onset osteoarthritis [1]. After ACL reconstruction (ACLR), approximately 90% of patients achieve normal or near-normal knee function [2]. However, 11–30% still present with recurrent and persistent anterolateral rotational instability [3–5]. Persistent anterolateral instability with a positive pivot shift (PS) test is associated with poor function, progression to osteoarthritis, and inferior clinical outcomes [6–8]. It is important to address this instability in ACL-deficient knees in order to better understand its severity and, based upon this, decide on an anterolateral augmentation that could potentially help prevent ACLR graft failure, re-operation, and further complications [9].

The PS test evaluates anterolateral rotatory instability during physical examination. However, this involves a complex manoeuvre where rotational stress is applied to the tibiofemoral joint during the range of movement. This means that there is no standardization between observers given that not only does the PS may change depending on where you grab it but also the grading is subjective depending on the observer [10]. Objective measurement systems have been described to improve the reliability and accuracy of the anterolateral rotatory instability evaluation [11–13]. These instruments quantify the tibial rotation or acceleration during the PS test using magnetic resonance imaging (MRI), navigation systems, or sensors [10]. These tools not only quantify the anterolateral rotatory instability of the knee in the ACL-deficient knee but also can measure the anterolateral rotatory laxity of a healthy knee. It is important to know how reliable is the assessment performed with these devices among examiners.

The purpose of this study was to systematically review studies that evaluate the intra-observer and inter-observer reliability of instrument-based anterolateral rotatory laxity assessment in the knee. The hypothesis was that both intra-observer and inter-observer reliability would be substantial for these devices.

Methods

Search strategy and study selection

This study was conducted in accordance with the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [14]. A systematic review of the literature regarding the existing evidence for intra-observer and inter-observer reliability of devices assessing anterolateral rotatory laxity of the knee was performed using PubMed (1980–2022), MEDLINE (1980–2022), Scopus, Embase, and Google Scholar databases. No study approval or ethics approval was required.

The queries were performed until October 31, 2022. The literature search strategy included the following: Search ((ACL) AND (pivot shift OR rotational instability OR rotatory instability) AND (assessment OR evaluation) AND (instrumentation OR computer-assisted OR image processing OR acceleration)). Inclusion criteria were as follows: rotatory anterolateral laxity assessment of the knee, English language, human studies, and proper reliability testing. We excluded cadaveric studies, animal studies, biomechanical reports, basic science articles, editorial articles, case reports, literature reviews, surgical technique descriptions, and instructional courses.

Three reviewers (JPM-C, TMF, FF) performed an independent search using the criteria and reviewed the abstracts from all identified articles. Full-text articles were obtained for review, if necessary, to allow for a further assessment of inclusion and exclusion criteria. Additionally, all references from the included studies were reviewed and reconciled to verify that no relevant articles were missing from the systematic review. Duplicates were excluded.

Data extraction and processing

Data were extracted by two reviewers (*blind*). The level of evidence of the studies was assigned according to the classification system specified by Wright et al. [15]. Data were extracted from the full text of all eligible articles using standardized data collection forms. Extracted and recorded data included the year of publication, number of patients, patients' characteristics, type of device, and device characteristics. The intra-observer and inter-observer reliability of the medical device used for the rotational anterolateral laxity assessment of the knee was the variable of interest.

For the reliability evaluation, we aimed for the intraclass correlation coefficient (ICC) as the main outcome (ICC). This is what is meant by proper reliability testing in the inclusion criteria. Data were recorded into a custom spreadsheet using a modified information extraction table [16]. As data from ICCs were reported either as a single value or as a range in the studies, it was extracted and presented in that way.

Methodologic quality assessment

The level of evidence of the studies included was assessed by one reviewer (*blind*) according to the study design. The Methodological Index for Non-Randomized Studies (MINORS) was used to assess the quality of each study and to evaluate the risk of bias. The mean score of the included studies was calculated ranging between 0 (the worst) and 24 (the best) [17].

Results

A total of 725 studies were initially identified, 200 in PubMed, 17 in Scopus, 226 in Embase, and 282 in Google Scholar. A total of 496 duplicate studies were removed, and 229 studies were screened. The three reviewers initially selected 26 studies. Fourteen additional studies were excluded: 4 cadaveric studies [18–21]; 5 without proper reliability testing or ICCs calculation [22–26]; and 5 because they evaluated rotational laxity but not the anterolateral rotatory laxity tested during PS [11, 12,27–29]. In Fig. 1, the PRISMA flow diagram shows the complete search and selection process. Finally, 12 studies fulfilled the eligibility criteria to be included in the systematic review (Table 1). The age of patients from these studies was between 14 and 63 years. The methodological qualitative assessment (Table 2) showed a mean MINORS score of 14.1.

The instrument-based evaluation included studies with devices that used inertial sensors (n = 9), MRI (n = 1), and navigation systems (n = 2). The global intra-observer reliability ICC for these devices was between 0.63 and 0.97. Meanwhile, the global inter-observer reliability ICC was between 0.63 and 0.99. When grouping the results by instrument of measurement (Table 3), MRI and navigation systems had the highest ICC values; however, they also had fewer studies than inertial sensors.

Discussion

This systematic review shows that instrument-based anterolateral rotatory laxity assessment of the knee has moderate to good intra-observer and inter-observer reliability [41]. The ICC showed substantial agreement in the worst scenario and almost total agreement in the best one, for both intra and inter-observer reliability. The studies with inertial sensors devices were the most frequent, especially with the Kinematic Rapid Assessment (KIRA) device (6 studies).

Lopomo et al. [35] and Vaidya et al. [40] studies showed better reliability in ACL-deficient knees than in healthy knees, while Katakura et al. [31] found similar results between them. This could be related to the greater acceleration in ACL-deficient knees; as a knee is more unstable, generating movement, acceleration, or displacement with the PS manoeuvre could be more reliable too. It is interesting that the study by Nakamura et al. [38] found better inter-observer reliability when the reversed PS manoeuvre was performed, in contrast with the conventional manoeuvre. This could be related to a more homogeneous manoeuvre between examiners in the reverse style.

The anterolateral rotatory instability evaluation with the PS test has high variability among observers with only fair or moderate agreement [42–44]. Despite the advantages that instrument-based evaluation may offer over the subjective PS test, there are still some challenges to its worldwide implementation. The use of any device is time-consuming for the patient and health personnel. For instance, navigation systems and MRI showed to have the highest ICCs, but they are also the most difficult to use in the daily clinical setting because they involve complex devices and measurement methods. Anyway, it is not possible to establish direct

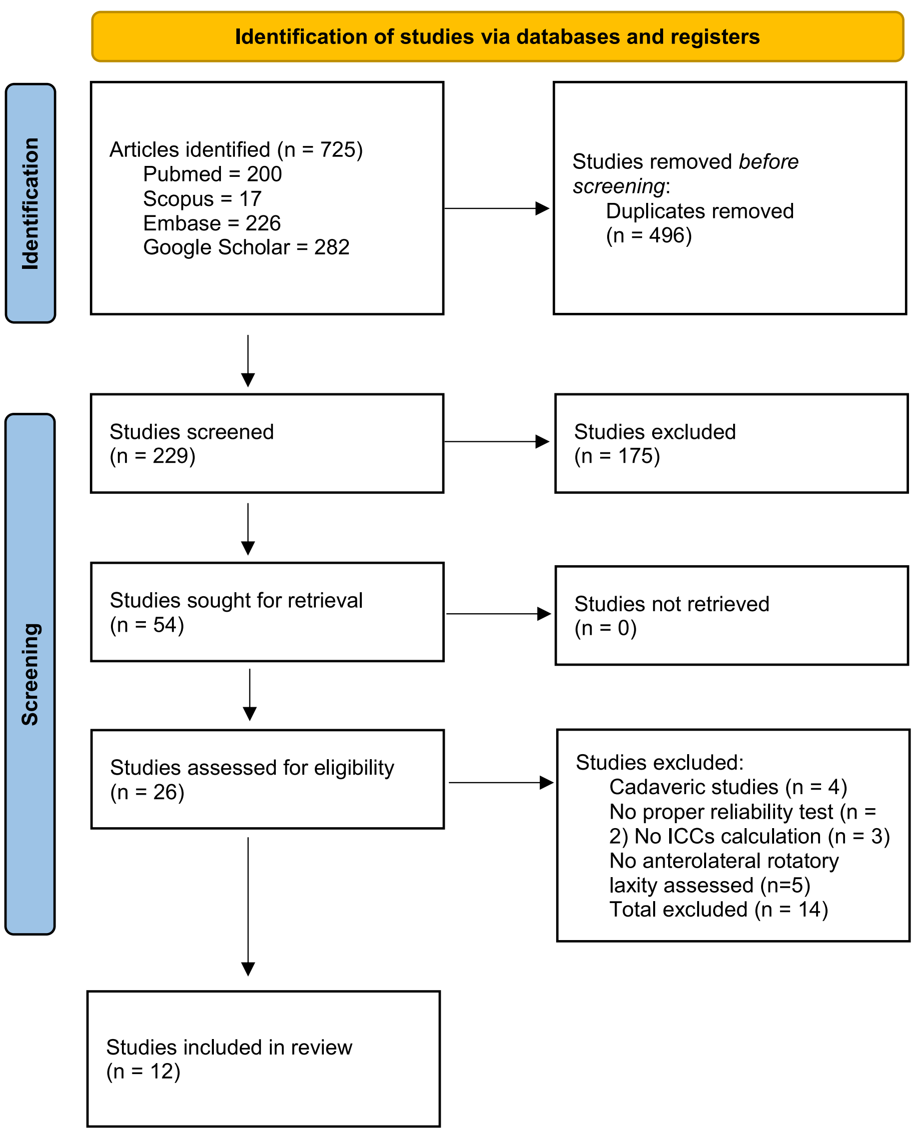

Fig. 1. PRISMA flow diagram of the study selection process. ICC, intraclass correlation coefficient; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Table 1
Studies that fulfilled eligibility criteria and were evaluated in this systematic review of the literature.

Authors	Year	Number of patients	Patient characteristics	Device characteristics	Reliability for anterolateral rotatory laxity
Berruto et al [30]	2013	100	ACL-injured knees: 65 males and 35 females, mean age: 29 ± 9 years (range: 16–45 years)	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Intra-observer reliability (ICC): 0.7–0.9
Hardy et al [13]	2017	43	Healthy knees Mean age: 22.7 ± 1.6 years Male/female: 31/12	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Intra-observer reliability (ICC): 0.86
Katakura et al [31]	2019	41 (82 knees)	41 ACL-deficient knees, 41 healthy knees: median age: 20 years (range: 14–51 years; 13 males and 28 females)	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Intra-observer reliability (ICC): 0.97 Inter-observer reliability (ICC): - ACL-deficient knees: 0.99 - Healthy knees: 0.97
Kawanishi et al [32]	2020	91	ACL-deficient knees: mean age: 20 years old (range: 17–33 years), males 41% and females 59%	Inertial sensor (MVP-RF8-BC; MicroStone) to measure acceleration and external rotational (ER) angular velocity during the pivot shift test	Inter-observer reliability (ICC): 0.65 (acceleration during pivot shift)
Kopf et al [33]	2012	20 (40 knees)	ACL-deficient and healthy knees: mean age: 27.8 years (95% CI: 23.2–32.4), 14 male and 6 female subjects	Six degree of freedom inertial sensors (Razor-IMU, SparkFun Electronics, Boulder, CO, USA).	Intra-observer reliability (ICC): 0.9
Lopomo et al [34]	2010	18	ACL-deficient knees: mean age: 33 years (range 18–45 years)	Surgical navigation system (BLU-IGS; Orthokey, Lewes, DE) with software focused on kinematics acquisition (KLEE; Orthokey).	Inter-observer reliability (ICC): - Pre-Op: 0.88–0.92 - Post-Op: 0.87–0.96
Lopomo et al [35]	2012	51 (102 knees)	ACL-deficient and healthy knees: 40 men and 11 women, mean age: 30.8 years (range: 16–63)	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Intra-observer reliability (ICC): - ACL-deficient: 0.75–0.93 - Healthy: 0.69–0.76
Lopomo et al [36]	2012	15	ACL-deficient knees: 11 men and 4 women, mean age: 35 ± 11 years (range: 17–57)	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Intra-observer Cronbach's alpha = 0.86
Maeda et al [37]	2016	70	ACL-reconstructed knees: 29 men and 41 women, mean age: 23.1 ± 11.4 years	OrthoPilot ACL navigation system, an image-free, wireless system (version 3.0, B. Braun Aesculap, Tuttlingen, Germany)	Intra-observer reliability (ICC): Surface markers: 0.81 Pin-fixed markers: 0.92
Nakamura et al [38]	2017	29 (58 knees)	ACL-deficient and healthy knees: 17 men and 12 women, mean age: 24 years (range: 14–46)	Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)	Inter-observer reliability (ICC): Pivot shift: 0.79 Reverse pivot shift: 0.97
Okazaki et al [39]	2007	14	14 ACL-deficient knees: 8 men and 6 women, mean age: 26.3 ± 6.8 years	Open MRI at 0.4 T (APERTO, Hitachi Medical Corporation, Tokyo, Japan)	Intra-observer reliability (ICC): 0.96 Inter-observer reliability (ICC): 0.91
Vaidya et al [40]	2020	17 (34 knees)	ACL-deficient knees and healthy knees: 14 men and 3 women, mean age: 33 ± 12 years (range: 19–56)	Smartphone (Galaxy S6; Samsung, Seoul, South Korea) with the Sensor Kinetics Pro application (INNOVENTIONS Inc., Houston, TX, USA)	Intra-observer reliability (ICC): 0.63–0.83 in healthy knees and 0.93–0.97 in ACL-deficient knees (longitudinal acceleration) Inter-observer reliability (ICC): 0.63 in healthy knees and 0.95 in ACL-deficient knees (longitudinal acceleration)

ACL, anterior cruciate ligament; CI, confidence interval.

Table 2
Studies included and summary of qualitative evaluation.

Authors	Study design	Level of evidence	MINORS score
Berruto et al [30]	Reliability study	III	13
Hardy et al [13]	Reliability study	III	12
Katakura et al [31]	Reliability study	III	15
Kawanishi et al [32]	Case-control study	III	15
Kopf et al [33]	Reliability study	III	13
Lopomo et al [34]	Reliability study	IV	13
Lopomo et al [35]	Reliability study	II	15
Lopomo et al [36]	Reliability study	III	13
Maeda et al [37]	Case-series	IV	12
Nakamura et al [38]	Reliability study	III	19
Okazaki et al [39]	Reliability study	IV	11
Vaidya et al [40]	Reliability study	II	18

MINORS, Methodological Index for Non-Randomized Studies.

Table 3
Intra-observer and inter-observer reliability by type of device.

Type of device	Intra-observer ICC	Inter-observer ICC
Inertial sensors [13,30–33,35,36,38,40]	0.63–0.97	0.63–0.99
MRI [39]	0.96	0.91
Navigation systems [34,37]	0.81–0.92	0.87–0.96

ICC, intraclass correlation coefficient.

superiority between these instruments as there were no comparative studies between them. Applications with inertial sensors such as KIRA are much easier to use in the office or operating room but require payments for recharging a certain number of tests for the sensor, with costs ranging between 8 and 15 € by case. Additionally, surface markers can be difficult to place in big patients, and they may not necessarily reflect the bone motion. Finally, future studies should aim to establish pathologic thresholds for the anterolateral rotatory laxity measurement of each device.

Evaluating the anterolateral rotatory instability of an ACL-deficient knee is very important for deciding if a patient requires an anterolateral augmentation. Most authors suggest that a high-grade PS (grade II or III) is one of the indications for a concurrent anterolateral augmentation procedure [45,46]. Instrument-based assessment has a very high intra- and inter-observer reliability, and using these devices in ACL-deficient knees can contribute to determine if a patient benefits from an anterolateral reconstruction or a modified Lemaire tenodesis as an augmentation procedure in the ACL reconstruction.

Some limitations were identified in this review. To begin, the level of evidence of the majority of the papers evaluated was II and III, with only two level II studies and no level I study. However, most of these were reliability studies using an objective measurement that makes them less prone to bias. The second limitation is given by the fact that the review grouped different sensors or devices, together as objective or instrument-based tests. These devices have differences in their way of measuring anterolateral rotatory laxity of the knee, and they were grouped together. Nevertheless, the study presents both the intra- and inter-observer reliability of groups according to their type of measurement, as well as the global range between all of them. There is no mention of superiority between devices as no head-to-head studies evaluating this type of reliability were available.

Conclusion

Instrument-based anterolateral rotatory knee laxity assessment has moderate to good intra- and inter-observer reliability. Evaluating anterolateral instability in ACL-deficient knees with these devices could help in decision-making when considering anterolateral augmentation.

Author contributions

All the authors (JPM-C, FF, GV, GM, MAG-S, TMF) have made the following contributions: substantial contributions to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; drafting the manuscript or revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Patient consent for publication

Not required.

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Data availability statement

All data relevant to the study are included in the article.

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