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Systematic Review

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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; or the acquisition, analysis, or interpretation of data for the work;rafting the work 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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All data relevant to the study are included in the article.

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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 was extracted from text, tables and figures.

Findings: Twelve studies with patients between the ages of 14-63 years old, 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 (ICC) for these devices was between 0.63-0.97 and the global inter-observer reliability between 0.63-0.99.

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 the decision-making when considering anterolateral augmentation.

Level of Evidence: IV.

Word count: 1573
Keywords: Anterior Cruciate Ligament; Knee; Physical Examination; Robotics; Diagnostic Test; Reproducibility of Results.

Text boxes:

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 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, 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 ICC values.
INTRODUCTION

Anterior cruciate ligament (ACL) is the primary restraint for 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. After anterior cruciate ligament reconstruction (ACLR), approximately 90% of patients achieve normal or near normal knee function. However, 11–30% still present with recurrent and persistent anterolateral rotational instability. Persistent anterolateral instability with a positive pivot shift test is associated with poor function, progression to osteoarthritis and inferior clinical outcomes. 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.

The pivot-shift (PS) test evaluates anterolateral rotatory instability during physical examination. However, this involves a complex maneuver where rotational stress is applied to the tibiofemoral joint during range of movement. This means 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. Objective measurement systems have been described to improve the reliability and accuracy of the anterolateral rotatory instability evaluation. These instruments quantify the tibial rotation or acceleration during the PS test using magnetic resonance imaging, navigation systems or sensors. This tools quantify the anterolateral rotatory instability of the knee in the ACL-deficient knee, but can also 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 ((anterior cruciate ligament AND 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 (blinded for review) 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 was 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 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 intraclass correlation coefficient (ICC) as the main outcome (ICC). This is what is meant by proper reliability testing in the inclusion criteria. Data was recorded into a custom spreadsheet using a modified information extraction table.(16) As data from ICCs was reported either as a single value or 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 on 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

725 studies were initially identified, 200 in pubmed, 17 in Scopus, 226 in Embase and 282 in Google Scholar. 496 duplicate studies were removed and 229 studies were screened. The three reviewers initially selected 26 studies. 14 additional studies were excluded; 4 cadaveric studies (18, 19, 20, 21); 5 without proper reliability testing or ICCs calculation (22, 23, 24, 25, 26); and 5 because they evaluated rotational laxity but not the anterolateral rotatory laxity tested during pivot shift (11, 12, 27, 28, 29). In figure 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 old. The methodological qualitative assessment (Table 2) showed a mean MINORS score of 14.1.

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

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Number of patients</th>
<th>Patient characteristics</th>
<th>Device characteristics</th>
<th>Reliability for anterolateral rotatory laxity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berruto et al (30)</td>
<td>2013</td>
<td>100</td>
<td>ACL injured knees: 65 males and 35 females, mean age: 29 ± 9 years (range 16–45 years)</td>
<td>Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)</td>
<td>Intra-observer reliability (ICC): 0.7-0.9</td>
</tr>
<tr>
<td>Hardy et al (13)</td>
<td>2017</td>
<td>43</td>
<td>Healthy knees Mean age: 22.7 ± 1.6 years old Male/female: 31/12</td>
<td>Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)</td>
<td>Intra-observer reliability (ICC): 0.86</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Sample Size</td>
<td>Description</td>
<td>Methodology</td>
<td>Reliability</td>
</tr>
<tr>
<td>------------------------</td>
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<td>-------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Katakura et al (31)</td>
<td>2019</td>
<td>41 (82 knees)</td>
<td>41 ACL-deficient knees, 41 healthy knees: median age: 20 years (range 14–51 years; 13 males and 28 females)</td>
<td>Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)</td>
<td>Intra-observer reliability (ICC): 0.97 Inter-observer reliability (ICC): -ACL-deficient knees: 0.99 -Healthy knees: 0.97</td>
</tr>
<tr>
<td>Kawanishi et al (32)</td>
<td>2020</td>
<td>91</td>
<td>ACL-deficient knees: mean age: 20 years old (range 17-33 years), males 41% and females 59%</td>
<td>Inertial sensor (MVP-RF8-BC; MicroStone) to measure acceleration and external rotational (ER) angular velocity during the pivot-shift test</td>
<td>Inter-observer reliability (ICC): 0.65 (acceleration during pivot shift)</td>
</tr>
<tr>
<td>Kopf et al (33)</td>
<td>2012</td>
<td>20 (40 knees)</td>
<td>ACL-deficient and healthy knees: mean age: 27.8 years (95% CI 23.2–32.4), 14 male and 6 female subjects</td>
<td>Six degree of freedom inertial sensors (Razor-IMU, Sparkfun Electronics, Boulder, CO, USA).</td>
<td>Intra-observer reliability (ICC): 0.9</td>
</tr>
<tr>
<td>Lopomo et al (34)</td>
<td>2010</td>
<td>18</td>
<td>ACL-deficient knees: mean age: 33 years (range 18–45 years)</td>
<td>Surgical navigation system (BLU-IGS; Orthokey, Lewes, DE) with software focused on kinematics acquisition (KLEE; Orthokey).</td>
<td>Inter-observer reliability (ICC): -Pre-Op: 0.88-0.92 -Post-Op: 0.87-0.96</td>
</tr>
<tr>
<td>Lopomo et al (35)</td>
<td>2012</td>
<td>51 (102 knees)</td>
<td>ACL-deficient and healthy knees: 40 men and 11 women, mean age: 30.8 years old (range: 16-63)</td>
<td>Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)</td>
<td>Intra-observer reliability (ICC): -ACL-deficient: 0.75-0.93 -Healthy: 0.69-0.76</td>
</tr>
<tr>
<td>Lopomo et al (36)</td>
<td>2012</td>
<td>15</td>
<td>ACL-deficient knees: 11 men and 4 women, mean age: 35 ± 11 years old (range: 17–57)</td>
<td>Kinematic Rapid Assessment (KiRA) triaxial accelerometer (OrthoKey, Lewes, DE, USA)</td>
<td>Intra-observer Cronbach’s alpha = 0.86</td>
</tr>
<tr>
<td>Maeda et al (37)</td>
<td>2016</td>
<td>70</td>
<td>ACL-reconstructed knees: 29 men and 41</td>
<td>OrthoPilot ACL navigation system,</td>
<td>Intra-observer reliability (ICC):</td>
</tr>
</tbody>
</table>
women, mean age:
23.1 ± 11.4 years old

an image-free, wireless system (version 3.0, B. Braun Aesculap, Tuttlingen, Germany)

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 old (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 old
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 old (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, 0.93-0.97 in ACL-deficient knees
Inter-observer reliability (ICC): 0.63 in healthy knees and 0.95 in ACL-deficient knees
(longitudinal acceleration)

Table 2. Studies included and summary of qualitative evaluation.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study design</th>
<th>Level of evidence</th>
<th>MINORS score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berruto et al(30)</td>
<td>Reliability study</td>
<td>III</td>
<td>13</td>
</tr>
<tr>
<td>Hardy et al(13)</td>
<td>Reliability study</td>
<td>III</td>
<td>12</td>
</tr>
<tr>
<td>Katakura et al(31)</td>
<td>Reliability study</td>
<td>III</td>
<td>15</td>
</tr>
</tbody>
</table>
The instrument-based evaluation included studies with devices that used inertial sensors (n=9), magnetic resonance imaging (n=1) and navigation systems (n=2). The global intra-observer reliability ICC for these devices was between 0.63-0.97. Meanwhile, the global inter-observer reliability ICC was between 0.63-0.99. When grouping the results by instrument of measurement (Table 3), magnetic resonance imaging (MRI) and navigation systems, had the highest ICC values, however they also had fewer studies than inertial sensors.

Table 3. Intra-observer and inter-observer reliability by type of device.
<table>
<thead>
<tr>
<th>Type of device</th>
<th>Intra-observer ICC</th>
<th>Inter-observer ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inertial sensors (13, 30, 31, 32, 33, 35, 36, 38, 40)</td>
<td>0.63-0.97</td>
<td>0.63-0.99</td>
</tr>
<tr>
<td>MRI (39)</td>
<td>0.96</td>
<td>0.91</td>
</tr>
<tr>
<td>Navigation systems (34, 37)</td>
<td>0.81-0.92</td>
<td>0.87-0.96</td>
</tr>
</tbody>
</table>
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. 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 KIRA device (6 studies).

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

The anterolateral rotatory instability evaluation with the pivot shift test has high variability among observers with only fair or moderate agreement. Despite the advantages that instrument-based evaluation may offer over the subjective PS test, there are still some challenges for its worldwide implementation. The use of any device is time consuming for the patient and health personal. 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 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 8-15 € by case. Additionally, surface markers can be difficult to place in big patients and they may not reflect necessarily the bone motion. Finally, future studies should aim to establish pathologic thresholds for the anterolateral rotatory laxity measurement of each device.

Evaluating 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 pivot shift (grade II or III) is one of the indications for concurrent anterolateral augmentation procedure (45, 46). Instrument-based assessment has a very high intra- and inter-observer reliability, 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 where 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 and no level I studies. 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 grouped 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 the decision-making when considering anterolateral augmentation.
Figures legends and tables

**Figure 1.** PRISMA flow diagram of the study selection process.
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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.

☐ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: