

Methods to diagnose acute anterior cruciate ligament rupture: a meta-analysis of instrumented knee laxity tests

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Abstract

Purpose The aims of this meta-analysis were to determine the sensitivity and specificity of the KT 1000 Arthrometer, Stryker Knee Laxity Tester and Genucom Knee Analysis System for ACL rupture. It was hypothesized that the KT 1000 test is the most sensitive and specific. Secondly, it was hypothesized that the sensitivity and specificity of the KT 1000 arthrometer increase when the amount of Newton force is increased.

Methods An electronic database search was performed using MEDLINE and EMBASE. All cross-sectional and cohort studies comparing one or more instrumented examination tests for diagnosing acute complete ACL rupture in living human subjects to an accepted reference standard such as arthroscopy, arthrotomy and MRI were included.

Results The sensitivity of the KT 1000 Arthrometer with 69 N was 0.54. With 89 N, the sensitivity was 0.78 and the specificity 0.92, and with maximum manual force, the sensitivity was 0.93 and the specificity 0.93. For the Stryker Knee Laxity Tester, the sensitivity was 0.82 and the specificity 0.90. And for the Genucom Knee Analysis System, the sensitivity was 0.74 and the specificity 0.82.

Conclusion The KT Arthrometer performed with maximum manual force has the highest sensitivity, specificity, accuracy and positive predictive value for diagnosing ACL rupture.

Level of evidence Meta-analysis, Level I.

Keywords Anterior cruciate ligament · Instrumented tests · KT 1000 · Stryker knee tester · Genucom

Introduction

The diagnosis of ACL rupture is generally made by physical examination, instrumented tests, imaging and arthroscopy. A number of instrumented tests have been proposed to assess ACL stability and used both to diagnose acute ACL rupture and to assess stability after ACL reconstruction as an objective outcome measure for clinical follow-up [1–5]. The most commonly used instrumented tests are KT 1000 (and 2000) Arthrometer, Stryker Knee Laxity Tester, Genucom Knee Analysis System, Rolimeter, Edixhoven Mechanic Lachman, Telos, Acufex Knee Signature System and the Dyonics Dynamic Cruciate Tester.

Many factors influence the sensitivity and specificity of these instrumented tests. Patients may be guarding due to pain and fear of subluxation. Most of these instrumented tests can be performed with different amounts of force applied; a factor that can certainly influence the sensitivity and specificity of the test. Additionally, concomitant injuries may obstruct the physical examination, such as bucket-handle meniscus tears causing locking of the knee. Lastly, acute injuries usually include reactive synovitis, haemarthrosis and swelling of the knee, while chronic ACL injuries do not [6]. Studies have been performed to investigate the sensitivity and specificity of the various

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instrumented tests for ACL rupture. Recently, a current concept was published to illustrate the proper use and summarize the accuracy and reliability of a variety of different instrumented tests for knee laxity [7]. This review of literature indicated that the KT 1000 Arthrometer and the Rolimeter provide best results when testing anterior laxity at the knee [7]. However, until this data, there has not been a meta-analysis to study the overall sensitivity and specificity of all available instrumented testing devices for ACL injury. This could help guide clinicians in determining which instrumented knee laxity test to use in the setting of ACL rupture and how sensitive and specific the used test is.

The aims of this meta-analysis were (1) to determine the sensitivity and specificity of the KT 1000 Arthrometer, Stryker Knee Laxity Tester, Genucom Knee Analysis System, Rolimeter, Edixhoven Mechanic Lachman, Telos, Acufex Knee Signature System and the Dyonics Dynamic Cruciate Tester for ACL rupture and (2) to determine the sensitivity and specificity KT 1000 with different amounts of Newton force applied. It was hypothesized that the KT 1000 is the most sensitive and specific. Secondly, it was hypothesized that the sensitivity and specificity of the KT 1000 would both increase with a higher amount of Newton in force applied during testing.

Materials and methods

This study was conducted by adhering to the STARD guidelines [8] for reporting on studies on diagnostic accuracy following the Cochrane guidelines [9].

Criteria for considering studies for this review

Types of studies

Cross-sectional and cohort study designs were included, comparing one or more instrumented laxity tests for diagnosing ACL rupture to an accepted reference standard.

Types of participants

Studies enrolling skeletally mature, living individuals suspected of ACL injury were eligible for inclusion. Studies with skeletally immature, congenitally deformed people, patients with degenerative diseases and animals were excluded. If studies had a mixed population of participants of the included and aforementioned excluded participants, they were used only when those groups could be analysed separately.

Index tests

Studies addressing instrumented knee laxity tests to assess ACL injury were included. An instrumented knee test was

defined as a test on patients that is performed manually but with the help of instrumented devices in addition to the hands of the specialist, such as KT 1000 (and 2000) Arthrometer, Stryker Knee Laxity Tester, Genucom Knee Analysis System, Rolimeter, Edixhoven Mechanic Lachman, Telos, Acufex Knee Signature System and the Dyonics Dynamic Cruciate Tester.

Target condition

The target condition was ACL rupture. Acute and chronic injuries were included. Studies dealing exclusively with partial ACL tears were excluded. Studies focusing on combined ligament injuries (i.e. ACL and PCL, LCL, MCL or meniscus) were excluded. If studies included a mixed group of the included and the aforementioned excluded conditions, they were used only when those groups could be analysed separately.

Reference standards

Studies using arthroscopy, arthrotomy or magnetic resonance imaging (MRI) as reference standards were included. MRI was considered a golden standard as recent literature has shown an excellent correlation between MRI and arthroscopic and arthrotomy findings [10].

Search methods for identification of studies

Electronic searches

An electronic database search was performed using MEDLINE via PubMed (1950–July 2011) and EMBASE (1980–July 2011). The following MeSH headings were used: ‘anterior cruciate ligament’, ‘physical examination’, ‘instrumented test’, ‘device’, ‘diagnosis’, ‘diagnostic’ and ‘diagnostic imaging’ (“Appendix”). The database search was performed with the help of a clinical librarian experiences in conducting database searches for systematic reviews and meta-analyses. The reference list of all included studies was reviewed for potentially missed studies that may not be available through an electronic database. There was no restriction in the language for selecting studies for inclusion.

Data collection and analysis

Selection of studies

Two reviewers independently selected relevant studies for inclusion by screening the titles and abstracts of the studies found through the database searches. For every eligible study, the full text was assessed using the aforementioned predefined criteria. Disagreement was resolved by consensus or third-party adjudication.

Data extraction and management

The data were extracted from the included studies by two reviewers independently. Of each study, extracted data included the number of participants, type of test, the applied force, number of true positives, true negatives, false positives and false negatives.

Assessment of methodological quality

Two reviewers independently assessed methodological quality for each study. The quality of the included studies was scored using ‘User’s Guide to the Surgical Literature, how to use an Article about a Diagnostic Test’, by Bhandari et al. [11]. This quality assessment tool evaluates six aspects of methodological quality. Primary guides included (1) if the clinicians faced diagnostic uncertainty and (2) if there was an independent, blind comparison with a reference study. Secondary guides included (1) if the results of the test being evaluated influenced the decision to perform the reference standard and (2) if the methods for performing the tests were described in sufficient detail to permit replication. Regarding the results, it evaluates whether the likelihood ratios are being calculated or the data necessary for this calculation are provided. Lastly, it evaluates whether the results aid in caring for patients in the clinical setting. Disagreement was resolved by consensus or third-party adjudication.

Statistical analysis and data synthesis

For each instrumented laxity test, the sensitivity and specificity were calculated, including the 95 % confidence interval. This was also done for each different force setting of the KT 1000. In addition, accuracy, positive and negative likelihood ratios and positive and negative predictive values were calculated. ROC curves were created for each test. Statistical analysis was performed using RevMan 5 (Review Manager Version 5.1.6 Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011).

Heterogeneity

An attempt was made to reduce clinical heterogeneity by narrowing the patient population to skeletally mature living individuals without deformation and degenerative disease. In all included studies, the instrumented knee laxity tests were used for the diagnosis of acute ACL ruptures, not for post-therapy or post-operative evaluation. Statistical heterogeneity was evaluated using the ROC curves created for each test.

Results

The EMBASE search provided 2044 hits and the PubMed search 1966. From these 4,010 hits, 48 studies were selected based on their title and abstract. Fourteen studies were included based on their full text [1, 2, 12–23]. Screening of the reference list of these included studies provided no additional studies (Fig. 1). A total of 946 patients were included in these studies. The median age of the included subjects was 25 (range 13–42), 67 % was male and 33 % female. There were multiple studies on the KT 1000 Arthrometer, Stryker Knee Laxity Tester and Genucom Knee Analysis System, making pooling of these results possible. The Rolimeter, Edixhoven Mechanic Lachman, Telos, Acufex Knee Signature System and the Dyonics Dynamic Cruciate Tester were only studied in one study each and could, therefore, not be pooled for meta-analysis.

Methodological quality of included studies

The methodological quality of the included studies is presented in Table 1. For the primary guides, in 3 out of the 14 studies, the clinicians did not face diagnostic uncertainty. None of the included studies had an independent, blind

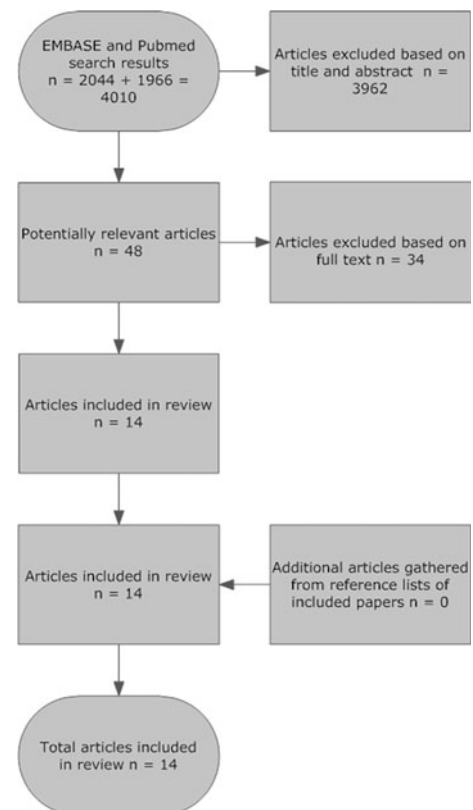


Fig. 1 Flow diagram of the meta-analysis

Table 1 Methodological quality of the included studies

| Guides | Primary guides | | Secondary guides | | Results | Will the results help me in caring for my patients? Will the reproducibility of the test result and its interpretation be satisfactory in my setting? |
|----------------|---|---|---|--|---------|--|
| | Did clinicians face diagnostic uncertainty? | Was there an independent, blind comparison with a reference standard? | Did the results of the test being evaluated influence the decision to perform the reference standard? | Were the methods for performing the test described in sufficient detail to permit replication? | | |
| Anderson [12] | No | No | No | Yes | Yes | Unclear |
| Anderson [1] | No | No | No | Yes | Yes | Unclear |
| Boniface [13] | Yes | No | No | Yes | No | Unclear |
| Boyer [14] | No | No | No | Yes | Yes | Yes |
| Chung [15] | No | No | No | Yes | No | Unclear |
| Daniel [2] | No | No | No | Yes | Yes | Yes |
| Edixhoven [16] | No | No | No | Yes | No | Unclear |
| Ganko [17] | No | No | No | Yes | Yes | Yes |
| Graham [18] | Yes | No | No | No | Yes | Unclear |
| Jonsson [19] | No | No | No | Yes | Yes | Yes |
| Lerat [20] | No | No | No | Yes | Yes | Unclear |
| Liu [21] | No | No | No | Yes | Yes | Yes |
| Rangger [22] | Yes | No | No | Yes | No | Unclear |
| Strand [23] | Yes | No | No | Yes | Yes | Yes |

Fig. 2 Forest plot of the sensitivity and specificity of the KT Arthrometer test at 69 N

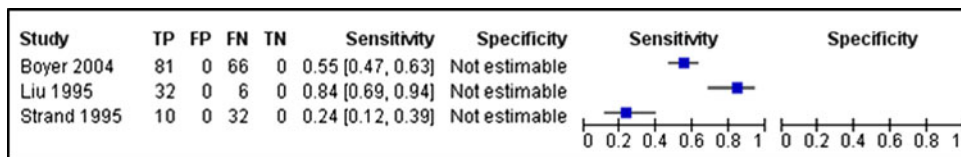
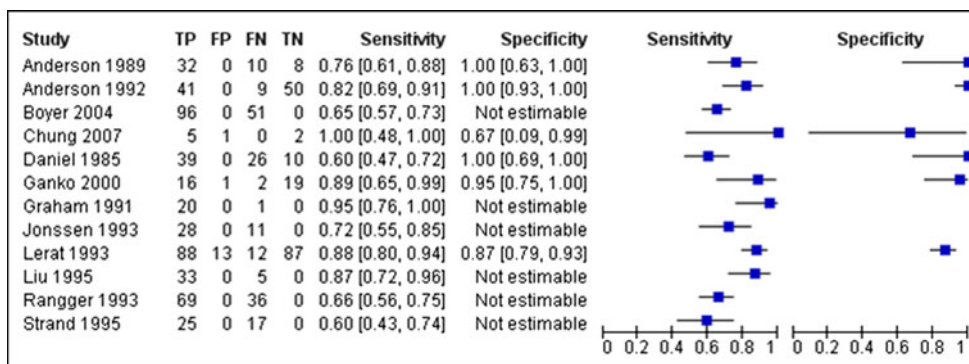


Fig. 3 Forest plot of the sensitivity and specificity of the KT Arthrometer test at 89 N



comparison with the used reference study. Regarding the secondary guides, in none of the included studies did the results of the test being evaluated influence the decision to perform the reference standard. Only 1 study did not

describe the test in sufficient detail to permit replication. Ten studies provided enough data necessary to calculate likelihood ratios or reported those ratios in the paper. Six studies were found to aid in caring for patients in the

Fig. 4 Forest plot of the sensitivity and specificity of the KT Arthrometer test at maximum manual force

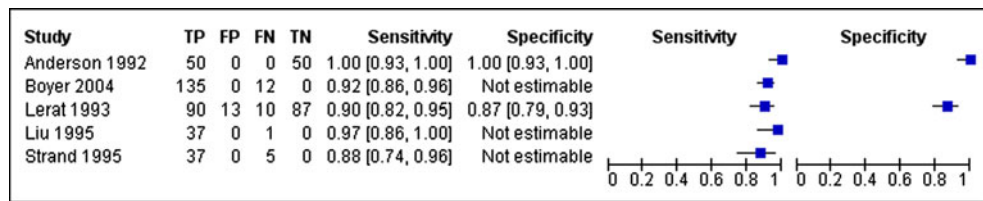


Fig. 5 Forest plot of the sensitivity and specificity of the Stryker Knee Laxity Tester

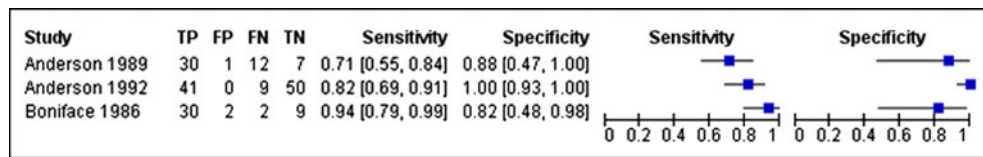


Fig. 6 Forest plot of the sensitivity and specificity of the Genucom Knee Analysis System

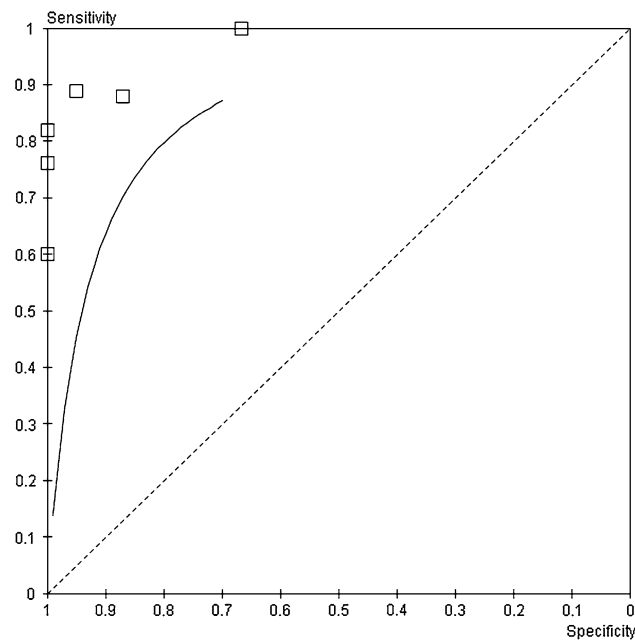
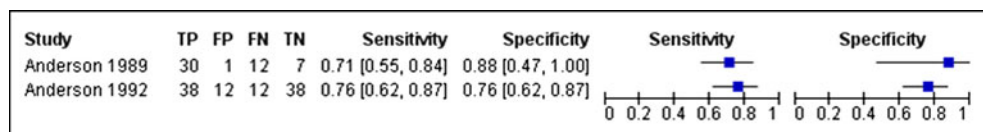


Fig. 7 ROC curve of the sensitivity and specificity of the KT Arthrometer test at 89 N

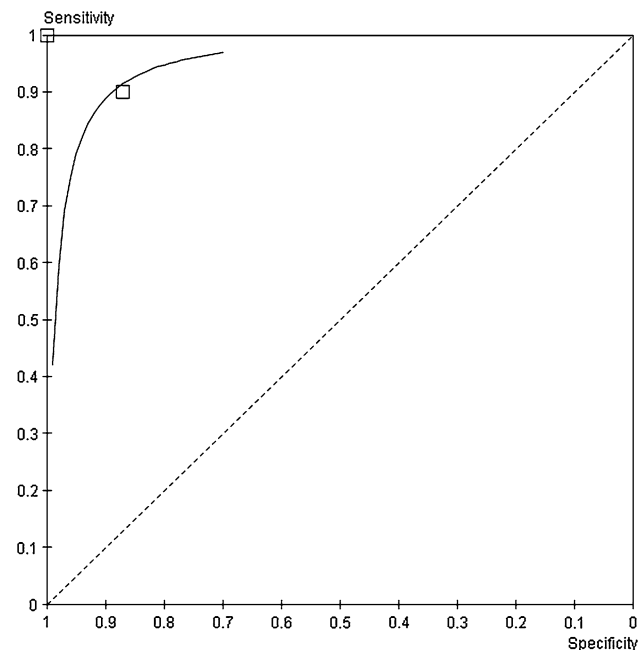


Fig. 8 ROC curve of the sensitivity and specificity of the KT Arthrometer test at maximum manual force

clinical setting, and for the remaining 8 studies, this was unclear.

Findings

The sensitivity and specificity with 95 % confidence interval and forest plots for the KT Arthrometer, Stryker Knee Laxity Tester and Genucom Knee Analysis System are displayed in Figs. 2, 3, 4, 5, 6, for all the included studies. The overall sensitivity of the KT 1000

Arthrometer with 69 N was 0.54, and from the included studies, it was not possible to calculate the specificity (Fig. 2). With 89 N, the sensitivity was 0.78 and the specificity 0.92 (Fig. 3). With maximum manual force, the sensitivity of the KT Arthrometer was 0.93 and the specificity 0.93 (Fig. 4). For the Stryker Knee Laxity Tester, the sensitivity was 0.82 and the specificity 0.90 (Fig. 5). And for the Genucom Knee Analysis System, the sensitivity was 0.74 and the specificity 0.82 (Fig. 6). The ROC curves for the KT Arthrometer, Stryker Knee Laxity

Tester and Genucom Knee Analysis System are displayed in Figs. 7, 8, 9, 10. The overall accuracy, positive and negative likelihood ratios and positive and negative predictive values of the KT Arthrometer, Stryker Knee Laxity Tester and Genucom Knee Analysis System are displayed in Table 2.

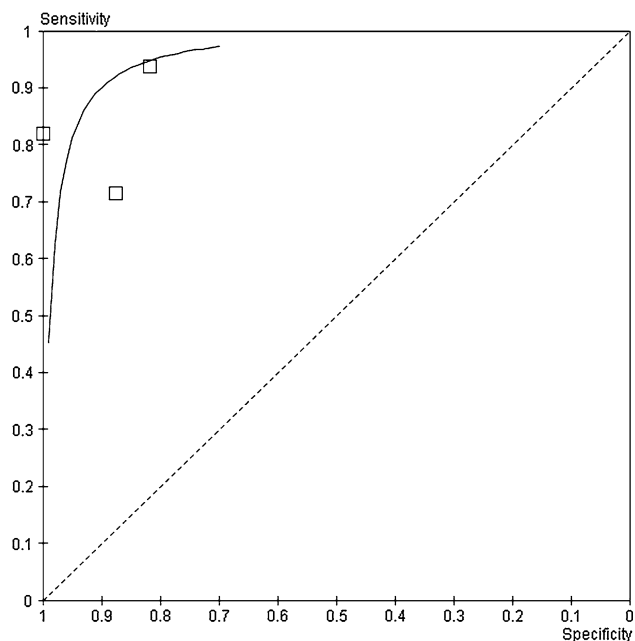


Fig. 9 ROC curve of the sensitivity and specificity of the Stryker Knee Laxity Tester

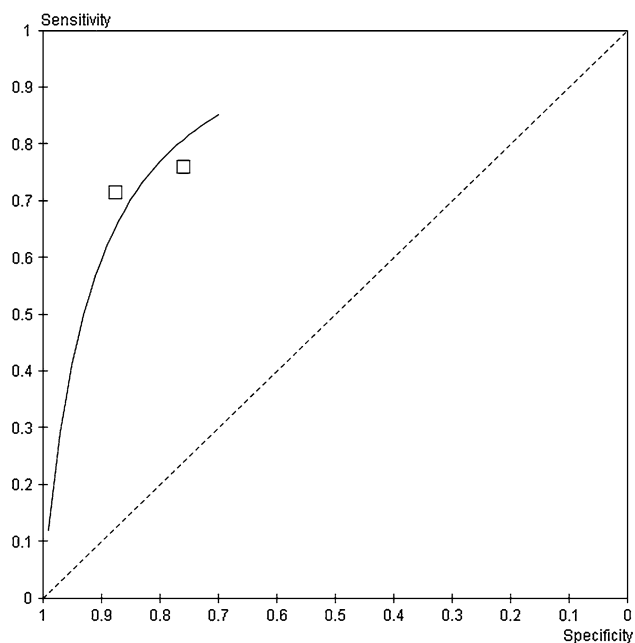


Fig. 10 ROC curve of the sensitivity and specificity of the Genucom Knee Analysis System

Table 2 Average accuracy, likelihood ratio and predictive value of the included mechanical test

| | Accuracy | Positive likelihood ratio | Negative likelihood ratio | Positive predictive value | Negative predictive value |
|---------------------|----------|---------------------------|---------------------------|---------------------------|---------------------------|
| KT 1000 69 N | n/a | n/a | n/a | n/a | n/a |
| KT 1000 89 N | 0.79 | 0.97 | 0.37 | 4.88 | 0.33 |
| KT 1000 Max Manual | 0.93 | 0.97 | 0.38 | 6.9 | 0.06 |
| Stryker Knee Tester | 0.85 | 0.97 | 0.68 | 2.86 | 0.58 |
| Genucom | 0.75 | 0.86 | 0.56 | 4.44 | 0.32 |

n/a: unable to calculate

Discussion

The most important finding of this study was that the KT Arthrometer performed with maximum manual force has the highest sensitivity (0.93), specificity (0.93), accuracy (0.93) and positive predictive value (6.9) for diagnosing an ACL rupture. The KT Arthrometer and the Stryker Knee Laxity Tester both had the highest positive likelihood ratio. The Stryker Knee Laxity Tester had the highest negative likelihood ratio and negative predictive value.

The first aim of this meta-analysis was to determine the sensitivity and specificity of the KT Arthrometer, Stryker Knee Laxity Tester and Genucom Knee Analysis System in diagnosing ACL rupture. It was hypothesized that the KT arthrometer would be the most sensitive and specific. This hypothesis was partially affirmed as this was not true when 69 N or 89 N of force was applied during testing, but it was true when maximum manual force was applied. The second aim was to determine the sensitivity and specificity of the KT 1000 with different amounts of Newton force applied. It was hypothesized that the sensitivity and specificity of the KT 1000 would both increase with a higher amount of Newton in force applied during testing. This hypothesis was affirmed, as both sensitivity and specificity increased when the amount of force in Newton was increased.

This meta-analysis showed that 93 % of people with an ACL rupture will have a positive KT arthrometer test results when maximum manual force was applied. This reduces to 54 and 78 % when 69 and 89 N are used, respectively. Most often KT arthrometer testing in the clinical setting is performed with 89 N. The results of this meta-analysis suggest that to increase the accuracy of the instrumented testing, maximum manual force would be superior. However, this could potentially cause more discomfort of even pain for the patient, especially in the setting of an acute injury. In addition, maximum manual force is largely dependent on the strength of the examiner and

may not produce a reliable measurement. The specificity of a test is defined as the proportion of patients who do not have the conditions and who will test negative for it. The specificity of the KT 1000 with 89 N and maximum manual force was comparable with 92 and 93 %, respectively. For the Stryker Knee Laxity Tester, it was 90 % and Genucom Knee Analysis System the lowest with 82 %. The specificity of the different instrumented knee laxity tests is fairly comparable, suggesting that all are suitable to rule out an ACL injury.

The instrumented knee laxity tests evaluated in this meta-analysis play a very important role in the diagnosis and treatment of ACL injury. They are not only used for diagnosis ACL rupture, but they can also be used to measure the outcome of an ACL reconstruction procedure. Contrary to physical examination test such as the Lachman test, pivot shift test and anterior drawer test, they are objective [24]. Physical examination tests without instruments are largely dependent on the examiner and therefore less reliable [25–30]. A very active issue is the quest for a way to objectify the pivot shift test, as currently no objective evaluation tool exists to measure rotational stability of the knee [31–36]. In recent study, laxity as measured with the pivot shift test has been shown to predict need for late ACL reconstruction in patient managed conservatively [37]. New literature is also focusing on radiographic tools to objectify the relatively subjective physical examination and instrumented knee laxity tests [38]. In addition, more precise methods to implement instrumented knee laxity testing devices are being developed [39].

Regarding the quality of the included studies, for the primary guides of Bhandari et al. [11] in 3 out of the 14 studies, the clinicians did not face diagnostic uncertainty. This can present a source of bias as the diagnosis was already known to the examiner. None of the studies provided an independent, blind comparison with the used reference study. This could have potentially biased the clinician who was performing the instrumented knee laxity examination. Bhandari et al. also proposed two secondary guides for quality. Fortunately, in none of the included studies did the results of the test being evaluated influence the decision to perform the reference standard. All included studies performed the gold standard test on all subjects. This eliminates the risk of missing the diagnosis of an ACL tear because the instrumented knee laxity examination showed a false-negative result. One study did not describe the test in sufficient detail to permit replication, and 4 out of the 14 studies did not provide enough data necessary to calculate likelihood ratios or reported those ratios in the paper. This is a methodological flaw as it does not allow for evaluation of the reliability of the results. The senior authors found that 6 of the included clearly aided in caring for patients in the clinical setting; however, about the 8

remaining papers, they were uncertain about their benefit to clinical practice.

This meta-analysis has limitations. Most of the included studies were not performed recently, and no similar studies have been performed in the last few years. Some of the included studies only had data on sensitivity or specificity, but not both. Furthermore, the initial intent of this meta-analysis was to assess the sensitivity and specificity of the KT 1000 Arthrometer, Stryker Knee Laxity Tester, Genucom Knee Analysis System, Rolimeter, Edixhoven Mechanic Lachman, Telos, Acufex Knee Signature System and the Dyonics Dynamic Cruciate Tester Lastly. However, data were only available for the first three instrumented knee laxity tests. The remaining instruments were only tested in one study, and therefore, pooling of the data was not possible. Lastly, when this study was designed, an attempt was made to reduce clinical heterogeneity by clearly defining a specific patient population, condition and gold standard. However, there are potential sources of heterogeneity, namely: Studies were not in- or excluded based on the activity level of the patient population (i.e. elite athletes vs. weekend warriors vs. sedentary individuals). Furthermore, the large sample of different observers amongst the different studies is a potential source for heterogeneity [3, 26, 27, 29, 40, 41].

Conclusion

The KT 1000 Arthrometer performed with maximum manual force has the highest sensitivity, specificity, accuracy and positive predictive value for diagnosing ACL rupture. The KT 1000 Arthrometer and the Stryker Knee Laxity Tester both had the highest positive likelihood ratio. The Stryker Knee Laxity Tester had the highest negative likelihood ratio and negative predictive value.

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Appendix: Search string (PubMed/Medline)

(((((("Diagnostic Imaging"[Mesh]) ((("physical examination")) AND ((((((diagnosis OR diagnostic) AND ((("Anterior Cruciate Ligament" OR ACL)))) NOT (((("Anthroponotic cutaneous leishmaniasis")) OR ((("Anthroponotic cutaneous leishmaniasis")) OR ((("American cutaneous leishmaniasis")))))) NOT (((anticiardioliipin) OR ((anti-cardiolipin)))))) NOT (((("antiphospholipid syndrome") OR ((("antiphospholipide syndrome"))))))))

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