The accuracy of clinical examination of rotational and sagittal laxity of the knee.

by

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BZDCAR004

This study is in partial fulfilment of the requirements for the degree

Master of Medicine in Orthopaedic Surgery

University of Cape Town

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Declaration

I, *Carel Willem Bezuidenhout*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. This work has not been reported or published *prior to registration* for the abovementioned degree.

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Table of content

Title Page 1
Declaration 2
Table of content 3
Abstract 4
Acknowledgements and Contributions 5
List of Tables 6
List of Figures 7
Abbreviations 8
Chapter 1: Introduction and Literature Review 9
- Introduction 9
- Objectives of literature review 9
- Literature search strategy 10
- Summary of the literature 10
- Sagittal Instability 10
- Rotational Instability 12
- Biomechanics of anterolateral structures of the knee 13
- Identification of research gaps 15
- Aims, objectives and hypotheses 15
- References 15

Chapter 2: Publication-ready Manuscript 20
- Abstract 21
- Keywords 22
- Introduction 22
- Methods 23
- Results 25
- Discussion 27
- Conclusion 29
- Conflict of Interest 29
- Authors' Contributions 29
- Acknowledgements 30
- References 30
- Tables and Figures 33

Addenda 38
- Instructions to author for the journal Knee Surgery Sport Traumatology Arthroscopy (KSSTA) 38
- Consent form 51
- Result sheet 53
- Ethics approval letter 55

Abstract

Purpose:

This study evaluates the accuracy and reliability of clinical examination for knee laxity in degrees and millimetres when compared to movement measured by computer-assisted navigation.

Methods:

A cadaver lower limb was connected to a computer assisted knee surgery system (CAS) and calibrated through a mini medial parapatellar arthrotomy. Examiners estimated millimetres of sagittal and degrees of rotational laxity of the knee at 30º and 90º of knee flexion. This examination was done in the ligamentous intact knee and again after sequential release of the anterior cruciate ligament (ACL) and anterolateral ligament (ALL). The clinical assessments were compared with measurements produced by CAS. Intraclass correlation coefficient (ICC), correlation coefficient (CC) and Bland Altman plots were used to compare and summarize the data.

Results:

At least 21 participants assessed the knee after each sequence of ligament sectioning. The reliability of clinical examination when correlated with the CAS measurements was poor for all examination groups. The ICC was poor for sagittal laxity at 30º (R=0.02; p=0.04), rotational laxity at 30º and 90º (R=0.17; p=0.04) (R=0.3; p=0.04) respectively and sagittal laxity at 90º(R=0.47; p=0.04). The correlation coefficients were very weak for sagittal laxity at 30º (R=0.09; p=0.46), weak for rotational laxity at 30º (R=0.24; p=0.06) and 90º (R=0.3; p=0.01) and moderately weak for sagittal

laxity at 90º(R=0.4; p=0.001). Clinical examination was only accurate in the detection of sagittal laxity greater than 11.6mm at 30°, and greater than 9.4mm at 90°. Clinical examination for rotational laxity was only accurate for rotational instability greater than 27.7° at 30°flexion, and 28.9° rotation at 90°.

Conclusions:

There was poor reliability and weak correlation between clinician estimated sagittal and rotational laxity and measurements produced by CAS. This study showed that participants could not accurately estimate laxity in degrees and millimetres and supports the need for accurate objective knee laxity measurements.

Acknowledgements and Contributions

Acknowledgements

The publication of this study was supported by the Harry Crossley Foundation and the South African Orthopaedic Association.

Smith and Nephew Company (Memphis, Tennessee) funded the cadaver, provided the Computer Assisted Surgery (CAS) system, and assisted with the extraction of the raw data from the CAS system.

Authors' contributions

Dr Carel Willem Bezuidenhout was involved in protocol development, study design, data collection, analysis and write-up of the manuscript.

Prof Michael Held supervised the study from its inception and was involved in protocol development, study design, data collection, analysis and write-up of the manuscript.

Dr Juan Kloppers supervised data analysis and interpretation of data.

Dr Richard von Bormann was involved in protocol development, study design

Dr Hayden Hobbs was involved in protocol development

List of Tables

Table 1: Demographics of participants. p33

Table 2: The interrater reliability and correlation between clinical examination and CAS.p33

Table 3: Difference between movements measured by CAS and clinical examination. p34

List of Figures

Figure 1: Bland-Altman plot for sagittal laxity at 30º. p35

Figure 2: Bland-Altman plot for sagittal laxity at 90º. p36

Figure 3: Bland-Altman plot of rotational laxity at 30º. p36

Figure 4: Bland-Altman plot for rotational laxity at 90º. p37

Abbreviations

ACL: Anterior cruciate ligament

ALL: Anterolateral ligament

CAS: Pi Galileo Computer Assisted Surgery System (Smith and Nephew, Memphis, Tennessee)

CC: Correlation coefficient

ICC: Intraclass correlation

ITB: Iliotibial band

LCL: Lateral collateral ligament

SD: Standard deviation

Chapter 1: Introduction and Literature Review

Introduction

A detailed history and clinical examination remains at the core of diagnosing knee ligament injuries in orthopaedic practice[25]. The need for accurate evaluation of knee ligament injuries have come to the front again after the discovery of the Anterolateral ligament (ALL)[10] and the plethora of literature that followed[7, 9, 13, 14, 18, 20, 30-34, 39, 40, 47]. Now the anterior cruciate ligament (ACL) is no longer reconstructed solely for its role as primary restraint of anterior translation (sagittal laxity) of the tibia but also because of the rotational laxity associated an ACL injury[37]. For ACL tears, there is heterogeneity in planes, degrees and diagnostic tests of associated knee laxity. The decision to add an ALL reconstruct to the ACL reconstruction is still controversial as some surgeons base their decision on clinical grounds[8] whereas others rely on instrumented knee laxity testing[3, 4, 26]. An accurate and reproducible assessment of functional deficit is also crucial to report and compare outcomes. For ACL injuries this is only possible if we can accurately quantify the functional laxity in the various planes of movement[23]. For this, most older studies describe specific tests and their respective sensitivity and specificity in diagnosing ligament injuries[2, 5, 15, 25]. In more recent literature the main focus is placed on instrumented knee laxity testing and how the different techniques compare to each other[1, 11, 23, 36, 44, 46].

Objectives of literature review

The objective of this literature review is to review the literature on the accuracy of clinical examination of the knee to evaluate sagittal and rotational laxity in the knee.

Literature search strategy

Medline, Scopus and Web of Science databases were searched. The Medline database was searched using the PubMed search engine. The United States National Library of Medicine maintains the Medline database. The search words were: accuracy, knee, laxity, clinical examination, sagittal, axial, rotational, rotation, Anterior cruciate ligament (ACL), Posterior cruciate ligament (PCL and Anterolateral ligament (ALL). The search term "accuracy AND clinical examination AND knee AND laxity" yielded 45 results on the Medline database. The search words were used in different combinations with the conjunctives "AND" and "OR" to manipulate the results. The abstracts of the search articles were scrutinized to evaluate the relevance to the study question. The full text article for all possible relevant articles were obtained where possible to further evaluate the quality and relevance of these articles. All levels of evidence were included. The level of evidence was taken in to consideration when interpreting the literature. Articles were excluded if they were found not to be relevant to the research question. Animal studies and literature that were not translated into English were excluded.

Summary of the literature

The next section will discuss the various clinical tests commonly used in orthopaedic practice to evaluate laxity of the knee. The discussion will focus on the origin, accuracy and clinical use of sagittal and rotational laxity tests. Furthermore, biomechanical contribution of various capsuloligamentous knee structures are discussed with emphasis on the ACL, iliotibial band (ITB) and ALL biomechanics.

Sagittal Instability

Lachman test

This test was first described by Torg et al[43] who has named it after professor John W Lachman from Temple University. The test is originally described with the patient supine

and the knee flexed to between 0º and 15º. The femur is stabilized with one hand and the tibia is anteriorly translated with the other. The examiner evaluates the knee for anterior translation as well as the character of the endpoint. A soft or "mushy" endpoint and an increase in anterior translation compared to the contralateral side is an indication of an ACL injury[43]. Torg et al described the incidence of specific knee pathologies and correlated it to clinical findings of the Lachman, anterior draw, valgus laxity and rotational instability. Only descriptive statistics were used to summarize the data. No statistical tests were used to compare the different examination methods.

The Lachman test has been described as a sensitive and specific test [2, 35]. The sensitivity can be improved from 0.85 (0.83-0.87) to 0.97(0.93-0.98) when performed under general anaesthesia [2, 15]. It was found to have a strong negative predictive value both in prospective trials [2] as well as a meta-analysis [35].

Anterior Draw test

The origin of the anterior draw test is obscure but it predates the Lachman test as the classic clinical test to diagnose ACL insufficiency[43]. The patient is placed supine with the knee flexed to 90º and an anterior directed force is applied to the proximal tibia. The knee is evaluated for the amount of anterior translation and the quality of the end point[25]. A downside of this test is that at 90º of flexion, the posterior horns of the menisci, the bony contour of the joint, as well as the medial collateral ligament (MCL) may act as secondary restraints to anterior translation. In addition, haemarthrosis, soft tissue swelling, and voluntary hamstring spasms associated with an acute injury often limits its practical use in acute ACL injuries. The diagnostic accuracy of the anterior draw test is inferior to that of the Lachman test. The pooled sensitivity according to a meta-analysis was reported as 0.55 (0.52-0.58) with a specificity of 0.92 (0.90-0.94) in awake patients. Similar to the Lachman test, the sensitivity and specificity improves under anaesthesia to 0.77 (0.75-0.80) and 0.87 (0.82-0.91) respectively.

Pivot shift test

The pivot shift phenomenon have been recognized by many authors but the term was first used by Galway and MacIntosh in 1980[17]. According to them, the pivot shift test has a strong positive predictive value for ACL injuries. The grade of the pivot shift test is also associated with functional outcome scores and the development of osteoarthritis in ACL injuries[42] and is therefore considered an indication for surgery by some authors[22]. Biomechanically the phenomenon is caused by the relocation of an ACL deficient knee as the knee is brought from extension to flexion while internally rotating the tibia and applying a valgus force. The tibia subluxates anteriorly in extension. By applying a valgus stress on the knee the subluxation of the lateral tibia plateau persists and the plateau remains in contact with the lesser curvature of the lateral femoral condyle. As the knee is flexed the lateral tibia plateau impinges on the greater curvature of the lateral femoral condyle. At 30-40º of knee flexion the iliotibial band (ITB) changes from an extensor to a flexor of the knee and reduces the tibia plateau with a palpable clunk[25], which can be subtle. The diagnostic accuracy of the pivot shift ranges widely. According to two separate meta-analysis the pooled sensitivity ranged from 0.18-0.48 with a specificity of 0.96-0.99[2, 35]. Under anaesthesia the specificity improved to 0.99 with 95% confidence interval of (0.96-1)[2]. The pivot shift test is a complex multi-planar phenomenon making it challenging to quantify. The components are translation, rotation and acceleration[42].

Rotational Instability

Rotational instability affects the knee function mostly in flexion. Maximum knee rotation during normal motion occurs at 60-90° flexion[24]. Various tests for rotational instability have been described such as the Slocum test, jerk test of Hughston, Losee test, side lying test of Slocum, flexion rotation draw test, dial test (prone external rotation test), reverse pivot shift test, posterolateral draw test, external rotation recurvatum test and the posterolateral recurvatum test[25].

Rotational instability is considerably more complex to clinically evaluate than sagittal

instability. Sagittal instability is uniplanar compared to rotational instability that can rotate or pivot around a different axis depending on the structures involved. Rotational laxity can be classified as anteromedial, anterolateral, posteromedial or posterolateral rotatory instability depending on the centre of tibia rotation. Anterolateral rotatory instability of the knee is associated with an ACL injury[24, 25] and is the main focus of our study.

Some of these tests evaluate not only rotation but also subluxation and relocation of the knee, which limits adequate measurement and relies on perceived acceleration associated with relocation of the knee, the so-called jerking sensation[19, 25].

Furthermore, the dial test is commonly used to evaluate rotational laxity in varying degrees of knee flexion. It was first described by Cooper et al in 1991[12] and evaluates posterolateral rotatory instability of the knee. The test can be performed in any position but the original authors recommended prone positioning. Both knees are flexed to 30° and both ankles are externally rotated while maintaining neutral ankle dorsiflexion. A side-to-side difference of more than 10° is considered clinically significant and is indicative of a posterolateral corner (PLC) injury of the knee. The test is repeated with the knees flexed to 90°. At 90° knee flexion the posterior cruciate ligament (PCL) acts as a secondary stabilizer of external rotation. If more than 10° external rotation is present at 30° and 90° the test is positive for a PCL and PLC injury[12, 25]. The reliability of the manual dial test in patients with suspected ACL injuries has poor reliability with kappa values <0.4 at 30° and 90° of knee flexion[38] but the combined arc of rotational laxity is more reliable than assessing external rotation laxity in isolation[45].

Biomechanics of anterolateral structures of the knee

The previous paragraphs discussed the availabe clinical tests which are used to detect movement after a ligamentous injury in the knee. With the following section, biomechanical studies are highlighted which aim to measure the actual movement of knee laxity. The effect of an ALL injury on knee stability has been well documented in literature, with the pivot shift, anterior drawer test and Lachman test all being affected[28, 29, 41]. Previous

biomechanical studies have managed to show a statistical significant contribution of the ALL to the stability of the knee as measured by a computer assisted surgery (CAS) navigation system, but in mililmetres and degrees, these movements are potentially not clinically relevant. In a cadaver study, the anteriolateral structures of the knee was evaluated for their respective contribution to resisting sagittal and rotational forces in a ligamentous intact knee as well as an ACL deficient knee[21]. The ACL was the primary restraint to anterior translation of the knee. The iliotibial band (ITB) was the primary restraint to internal rotation in an ACL intact and an ACL deficient knee. The superficial fibres of the ITB resist internal rotation more at higher flexion angles whereas the deep fibres limit internal rotation at lower flexion angles. The ITB resisted 31% and the Anterolateral ligament (ALL) and anterolateral capsule only 4% of the anterior draw force in an ACL deficient knee at 30°. At 90° the superficial layers of the ITB restrained 56% of internal rotation force in an ACL intact and deficient knee. At 30° the deep layers of the ITB restrained 26% and 33% of internal rotaion force in an ACL intact and deficient knee, respectively. The ALL and anterolateral capsule had minimal effect in restraining internal rotation of the knee. "During the pivot-shift test, the ITB provided 72% of the restraint at 45° for the ACL-deficient group. The ACL and other anterolateral structures made only a small contribution in restraining the pivot shift"[21].

An in-vivo ACL injury has been found to generate laxity of a mean of 8.6mm side to side differences when measured with a navigation system[27], but this is reduced to only 4.2mm difference in 90^0 flexion and negligible rotational difference. Similarly, only a 4.2mm difference was found in anterior draw at 30^0 and 90^0 knee flexion, before and after an ACL reconstruction in a different study[6]. The next section will discuss the research gap and the main research questions based on this available knowledge.

Identification of research gaps

The initial perception of laxity during the first physical examination by the clinician is crucial and will likely trigger further investigations, if found to be abnormal. The ideal measurement method should be simple, accurate and reproducible while assessing both anatomy and function in the same assessment[16]. Biomechanical studies have shown a relatively small difference in movement in knees with a deficient ACL and/or ALL. Limited evidence is available on diagnostic accuracy for these measurements during clinical examination of sagittal and rotational knee laxity, as most studies evaluate specific clinical tests in their accuracy to diagnose damage to anatomic structures rather than motion in degrees and millimetres [2, 5, 15, 25].

Aims, objectives and hypotheses

The main aim of this study was therefore to evaluate the accuracy and reliability of the clinical examination of laxity in the knee when compared to objective instrumented knee laxity testing in a cadaver model. Our hypothesis was that clinicians can accurately estimate knee laxity documented in millimetres and degrees.

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Chapter 2: Publication-ready Manuscript

The accuracy of clinical examination of rotational and sagittal laxity of the knee

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Acknowledgements
The publication of this study was supported by the Harry Crossley Foundation and the South African Orthopaedic Association.

The accuracy of clinical examination of rotational and sagittal laxity of the knee.

ABSTRACT

Purpose:

This study evaluates the accuracy and reliability of clinical examination for knee laxity in degrees and millimetres when compared to movement measured by computer assisted navigation.

Methods:

A cadaver lower limb was connected to a computer assisted knee surgery system (CAS) and calibrated through a mini medial parapatellar arthrotomy. Examiners estimated millimetres of the sagittal and degrees of rotational laxity of the knee at 30º and 90º of knee flexion. This examination was done in the ligamentous intact knee and again after sequential release of the anterior cruciate ligament (ACL) and anterolateral ligament (ALL). The clinical assessments were compared with measurements produced by CAS. Intraclass correlation (ICC), correlation coefficient (CC) and Bland Altman plots were used to compare and summarize the data.

Results:

At least 21 participants assessed the knee after each sequence of ligament sectioning. The reliability of clinical examination when correlated with the CAS measurements was poor for all examination groups with (intraclass correlation (ICC) <0.5 (p=0.04). The correlation coefficients were very weak for sagittal laxity at 30º (R=0.09;

p=0.46), weak for rotational laxity at 30º (R=0.24; p=0.06) and 90º (R=0.3; p=0.01) and moderately weak for sagittal laxity at 90º(R=0.4; p=0.001). Clinical examination was only accurate in the detection of sagittal laxity greater than 11.6mm at 30°, and greater than 9.4mm at 90°. Clinical examination for rotational laxity was only accurate for rotational instability greater than 27.7° at 30°flexion, and 28.9° rotation at 90°.

Conclusions:

There was poor reliability and weak correlation between clinician estimated sagittal and rotational laxity and measurements produced by CAS. This study showed that participants could not accurately estimate laxity in degrees and millimetres and supports the need for accurate objective knee laxity measurements.

KEYWORDS

Anterior Cruciate Ligament; Anterolateral Ligament; laxity; stability; Clinical examination; Knee ligament injury

INTRODUCTION

A detailed history and clinical examination remains at the core of an accurate diagnosis of knee injuries,[33] especially for ACL tears which are often associated with damage to other intraarticular structures[18, 48, 49]. This was highlighted once again after the 'discovery' of the ALL[11], which also revived the interest in assessing instability after knee injuries[8, 10, 17, 19, 26, 28, 36, 38-40, 42, 47, 48, 57]. Besides sagittal laxity due to ACL tears, the understanding of rotational laxity is a focus in associated ALL injuries as it might necessitate extra-articular tenodesis in

addition to an ACL reconstruction[48]. An accurate measure of laxity is therefore essential to evaluate knee ligament injury and to guide subsequent management[22]. Despite this, limited evidence is available on diagnostic accuracy for measurements or degrees during clinical examination of sagittal and rotational knee laxity, as most studies evaluate specific clinical tests in their accuracy to diagnose damage to anatomic structures rather than motion in degrees and millimetres [3, 7, 21, 33]. Furthermore, research on knee laxity testing is mostly focused on evaluating various types of laximeters and their performance when compared to each other[2, 14, 31, 44, 53, 55]. Yet, the ideal measurement method should be simple, accurate and reproducible while assessing both anatomy and function in the same assessment[22]. The initial perception of laxity during the first physical examination by the clinician is crucial and will likely trigger further investigations, or not. The main aim of this study was therefore to evaluate the accuracy and reliability of the clinical examination of laxity in the knee when compared to objective instrumented knee laxity testing in a cadaver model. Our hypothesis was that clinicians can accurately estimate knee laxity documented in millimetres and degrees.

METHODS

This cadaver study compared clinicians' findings of knee laxity during clinical examination to a navigation system for computer-assisted surgery (CAS). The PI Galileo navigation system (Smith & Nephew, Memphis, Tennessee) captured movements of the knee during examination by clinicians. Normal knee and hip range of motion and stable collateral and cruciate ligaments in the cadaver were confirmed. The knee dissection was done through a midline skin incision and a mini medial parapatellar arthrotomy.

Participants were recruited from an orthopaedic department of a university hospital. They had various levels of clinical experience ranging from trainee, specialist and knee surgery subspecialist. These participants were asked to examine the cadaver knee and estimate the sagittal and rotational laxity of the knee at 30º and 90º respectively. This was done for the intact knee and after the ACL and ALL were cut sequentially. The ACL was cut under direct vision via the incision. The anterolateral capsule with the ALL was cut from the anterior border of the lateral collateral ligament (LCL) sub-meniscal to the posterior border of the iliotibial band (ITB) at its insertion on Gerdy's tubercle. The knee joint retinaculum and skin were closed after each dissection and participants were blinded to the sectioning.

Ethics

This study protocol was formally approved by the local institutional review board with the reference number 476/2016. Written consent was obtained from all participants.

Statistics

The sample size was calculated for a power of 0.8 using Lin's concordance correlation coefficient power analysis with an alpha value of 0.05. A sample size of 20 yields a power of 0.8 and a sample size of 27 has a power of 0.9.

The normality of the data was determined by drawing a histogram, using a Shapiro-Wilk test and the Levene test. Normal data was summarized with parametric analysis.

Interrater reliability was evaluated using the intraclass correlation (ICC). The specific form of ICC was the two-way mixed effects, absolute agreement and single rater/measurement ICC. ICC values less than 0.5 indicate poor reliability, values

between 0.5 and 0.75 show moderate reliability, values between 0.75 and 0.9 suggest good reliability, and values greater than 0.90 indicate excellent reliability[30].

Pearson correlation coefficient was used to determine the correlation between the examiners and the CAS system for normally distributed data, otherwise Spearman correlation coefficient was used for non-parametric data. The correlation or R-value is a value between -1 and +1 with -1 indicating a perfect negative correlation, zero indicating no correlation and +1 indicating a perfect positive correlation. The strength of the correlation as classified by Evans is very weak for values ±0-0.19, weak from ±0.2-0.39, moderate from ±0.4-0.59, strong for ±0.6-0.79, and very strong from ±0.8-1[23].

The variation in the data set was summarized with Bland-Altman plots. The clinical significance was indicated by 5mm and 10º respective differences in the form of reference lines, which were added in addition to two standard deviation reference lines and represent increments of commonly used clinical grading systems for knee laxity.

RESULTS

Overall, the study showed that there is poor reliability and weak correlation between clinician-estimated laxity and movement measured by CAS. Furthermore, statistical limits calculated in our study did not fall within the ranges proposed by common clinical grading systems of knee laxity.

Demographics of participants

Twenty-four examiners evaluated the intact knee, 22 evaluated the knee after the ACL was cut and 21 evaluated the knee after the ACL and the ALL were cut. The

demographics of the examiners are shown in Table 1. Most examiners had more than four years of experience at various levels of orthopaedic practice.

Reliability and Correlation

The interobserver reliability measured by intraclass correlation (ICC) was poor for all groups (Table 2). The correlation between clinical examination and the CAS system were very weak for sagittal laxity at 30º, weak for rotational laxity at 30º and 90º, and moderately weak for sagittal laxity at 90º (Table 2).

Estimation of knee laxity and clinical limits

Examiners underestimated sagittal and rotational laxity in the ligamentous intact knee at 30º by 2mm and 2º respectively. After the ACL was cut the median sagittal measurements were within 1mm of CAS. However rotational laxity was overestimated at 30º (median 4º) and 90º (median 10º). This was also accompanied by an increase in variation in the examiners' estimations. After the ACL and ALL were cut, the overestimation extended to involve the sagittal plane. The difference between clinical examination findings and CAS are summarized in Table 3. Bland-Altman plots (Figures 1-4) were used to provide a visual representation of the variation in the data sets. The absolute difference between clinical examination and CAS is plotted on the y-axis and the mean difference is plotted on the x-axis. The 1.96 standard deviation (SD) lines represent the limits for 95% of the data points. The clinical significant values proposed by most classification systems of knee laxity (5mm and 10º respectively) are significantly less than the 1.96 SD limits[16, 25].

DISCUSSION

The main findings of this study were poor reliability and weak correlation between clinician estimated laxity and movement measured by CAS. Also, participants initially underestimated laxity in a ligament intact knee and later overestimated the movement with increasing ligament laxity. Additionally, reliable statistical limits for clinical examination in our study did not fall within the ranges proposed by common clinical classifications of knee laxity.

Reliability and Correlation

The reliability and accuracy of estimated knee laxity compared to CAS was poor (Table 2). The sagittal examination at 90º was most reliable (ICC 0.47,p=0.04) whereas the sagittal examination at 30º was least reliable (ICC 0.02, p=0.04). The correlation of clinical examination compared to CAS ranged from moderate (sagittal examination at 90º) to very weak (sagittal examination at 30º). This means that the participants were unable to estimate rotational or sagittal laxity accurately. Similar to our study, poor correlation between rotational laxity measured by CAS and clinical grading was noted previously, although grading of knee laxity during the pivot shift test correlated with CAS in a series of ACL reconstructions[56]. This supports that clinical tests are valuable in diagnosing a knee ligament injury [28, 33, 43] but poor accuracy in estimated laxity might preclude them from being used to grade injuries for clinical or research purposes. In the search of reproducible and objective accuracy, instrumented knee laxity testing has been reported as an accurate objective alternative [1, 5, 13, 22, 34, 37, 50, 53, 55] although its clinical use might be limited by associated costs and logistics in resource constrained environments.

Estimation of knee laxity and clinical limits

Besides poor accuracy, participants initially underestimated laxity in a ligament intact knee and later overestimated the movement with increasing ligament laxity. The most notable difference was the overestimation of rotational laxity as general knee laxity increased. The International Knee Documentation Committee proposes increments of less than 5mm in the sagittal plane. Normal sagittal laxity is considered 0-2mm, near normal as 3-5mm, abnormal is 6-10mm and severely abnormal when laxity is more than 10mm. Rotational measurement limits are not provided[25]. Significant clinical rotational laxity is considered 10º[16]. The statistically calculated limits from the estimates provided by the participants in our study are double of what is considered clinically significant in a sagittal plane and nearly three times of what is considered clinically significant in the rotational plane. This means, the clinicians were unable to accurately estimate the clinical limits provided by common classification systems with the conventional 5mm or 10° increments. The Bland Altman plots (Figure 1-4) visually show how the variation increases and falls outside of the proposed clinically significant limits. Based on these findings, 11.6mm translation at 30°, and 9.4mm translation at 90°, as well as 27.7° rotation at 30°, and 28.9° rotation at 90° should be used as increments to reliably estimate laxity during clinical examination.

Limitations

The nature of a controlled cadaver model for this study has limitations in simulating complex multifaceted injuries of capsular, ligamentous and even bony structures, which are often associated with knee trauma. But our aim was to evaluate the reliability and correlation of clinicians to accurately detect movement, which might not be influenced by these limitations the same way as biomechanical studies[31].

Also, the CAS system is accurate to less than 1mm and 1º respectively[20] but the force used by the respective examiners were not standardized or measured. This can cause variation in the displacement during clinical examination and might influence the perception of laxity. This variation does however reflect the variation in techniques of clinical examination.

Furthermore, although participants were blinded to specific structures being sectioned, the awareness of a sequential sectioning done by the investigators might have influenced participants to initially underestimate and later overestimate laxity.

CONCLUSION

There was poor reliability and weak correlation between clinician estimated laxity in degrees and millimetres and the actual movement measured by CAS. Participants initially underestimated movement in a ligament intact knee and later overestimated the movement with increasing ligament laxity. Increments proposed by conventional systems to grade laxity were not useful. Although clinical examination is valuable to diagnose pathology, it might not accurately grade severity of laxity, limiting its use to guide treatment decisions and assess research related outcomes. Future studies should evaluate these findings in a clinical scenario and should incorporate laximeter testing.

CONFLICT OF INTEREST

The authors have no conflict of interest.

AUTHORS' CONTRIBUTIONS

C.B. was involved in protocol development, study design, data collection, analysis

and write-up of the manuscript.

M.H. supervised the study from its inception and was involved in protocol development, study design, data collection, analysis and write-up of the manuscript.

J.K. supervised data analysis and interpretation of data.

R.B. was involved in protocol development, study design

H.H. was involved in protocol development

ACKNOWLEDGEMENTS

Smith and Nephew Company funded the cadaver, provided the CAS system, and assisted with the extraction of the raw data.

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TABLES AND FIGURES

Table 1. Demographics of participants. This table summarizes the number and level of orthopaedic training of the participants. ACL – anterior cruciate ligament, ALL – anterolateral ligament.

Level of participant	Intact Knee	ACL cut	ACL and ALL cut
Medical officer	3	2	1
Trainee in first two years	4	4	4
Trainee in final two years	10	9	9
Orthopaedic specialists	4	4	4
Knee specialists	3	3	3
Total	24	22	21

Table 2: The interrater reliability and correlation between clinical examination and CAS. The table summarizes the interrater reliability (intraclass correlation - ICC) which is below 0.5 indicating poor reliability. The Spearman correlation coefficient (R-value) has moderate to weak correlation.

Laxity examination	ICC (p-value)	R-value (p-value)
Sagittal laxity 30°	0.02 (0.04)	0.09 (0.46)
Sagittal laxity 90°	0.47 (0.04)	0.4 (0.001)
Rotational laxity 30°	0.17 (0.04)	0.24 (0.06)
Rotational laxity 90°	0.3 (0.04)	0.3 (0.01)

Table 3: Difference between movements measured by CAS and clinical examination. The table summarizes the calculated median difference between the CAS system and clinical examination. Participants initially underestimated laxity in a ligament intact knee and later overestimated the movement with increasing ligament laxity. This is shown by increased differences as more ligaments are sectioned. IQR: interquartile range. ACL – anterior cruciate ligament, ALL – anterolateral ligament. mm – millimetres. Deg – degrees)

Laxity examined	Ligamentous intact Median (IQR)	ACL cut Median (IQR)	ACL and ALL cut Median (IQR)
Sagittal at 30° (mm)	-2 (6)	-1 (9)	3 (7)
Sagittal at 90° (mm)	0 (5)	0 (8)	5 (7)
Rotational at 30° (deg)	-2 (10)	4 (17)	7 (8)
Rotational at 90° (deg)	1 (14)	10 (20)	12 (16)

Figure 1-4: Bland Altman plots. These are scatter plots of the difference between CAS and clinical measurements on the y-axis plotted against the CAS measurements on the x-axis. The 5mm (10°) and -5mm (-10°) reference lines represent the proposed clinically significant difference. The dotted lines represent the mean of the difference between CAS and clinical measurements as well as 1.96 standard deviations (SD). It demonstrates the increase in variation of measurements as more ligaments are sectioned. It also shows a large amount of points outside clinically significant limits. 1: Sagittal laxity at 30º. 2: Sagittal laxity at 90º. 3: Rotational laxity at 30º. 4: Rotational laxity at 90º

Figure 1: Bland-Altman plot for sagittal laxity at 30º.

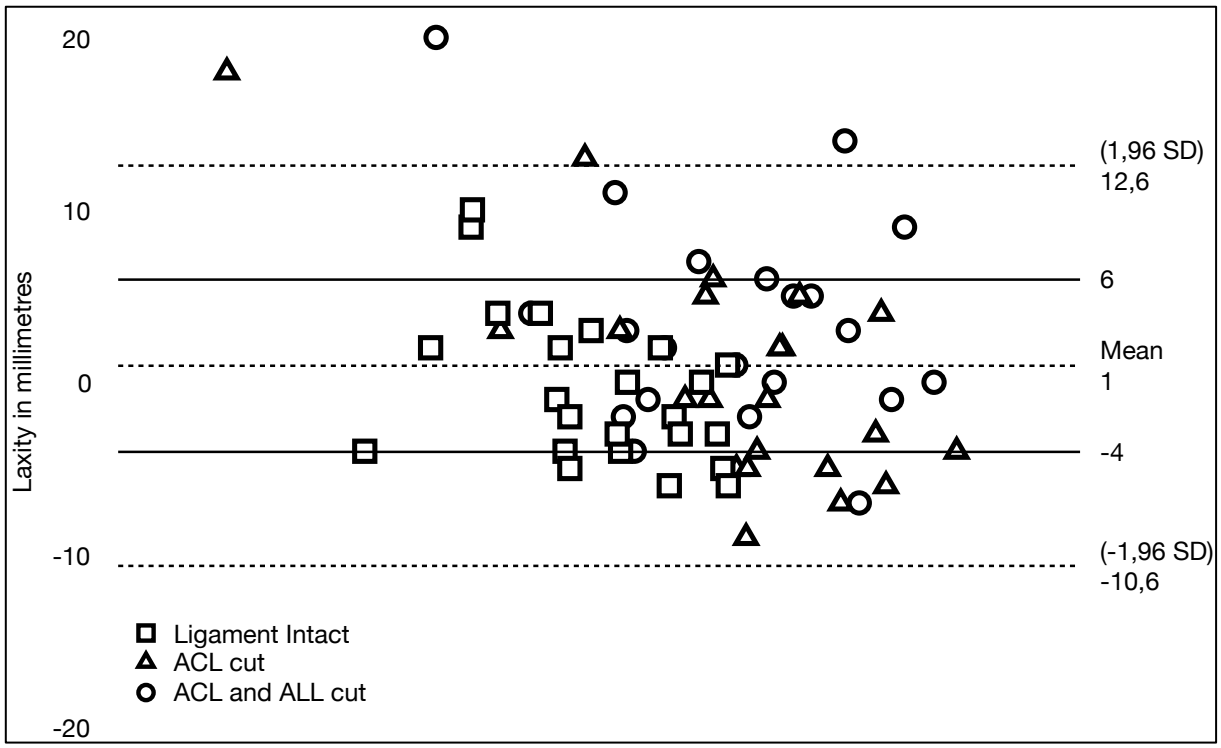


Figure 2: Bland-Altman plot for sagittal laxity at 90º.

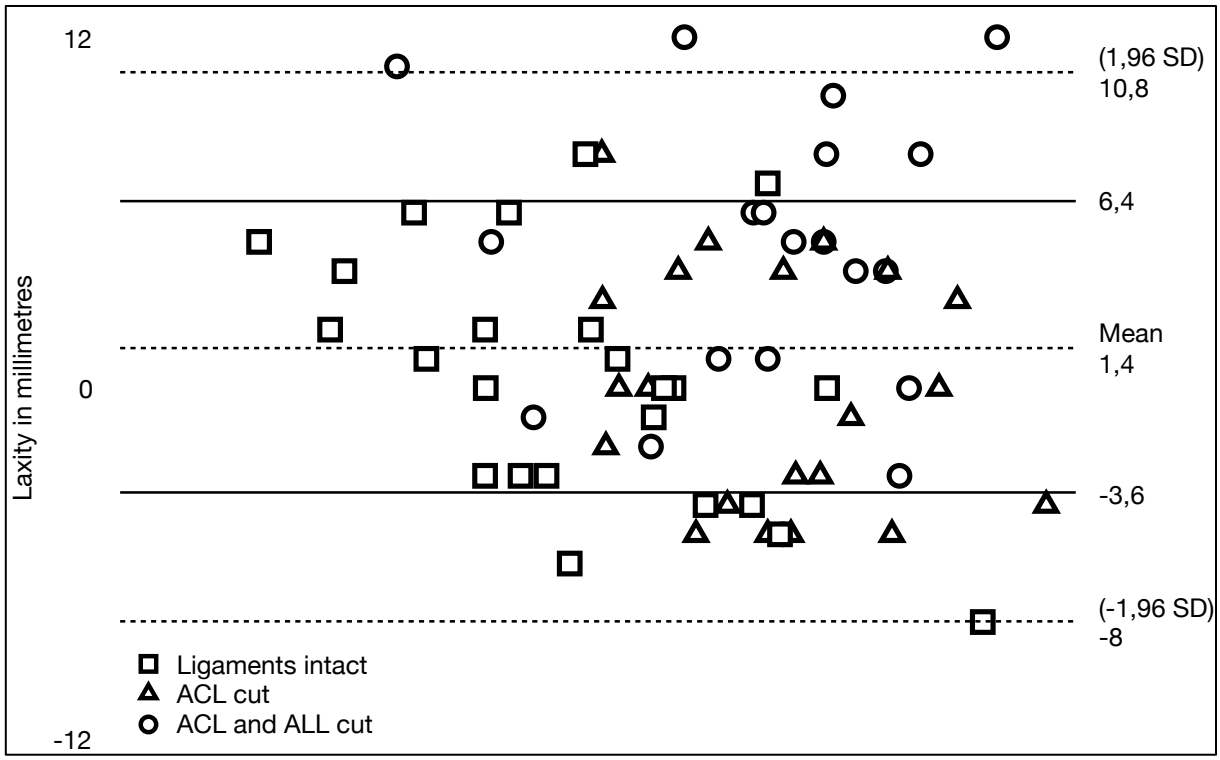


Figure 3: Bland-Altman plot for rotational laxity at 30º.

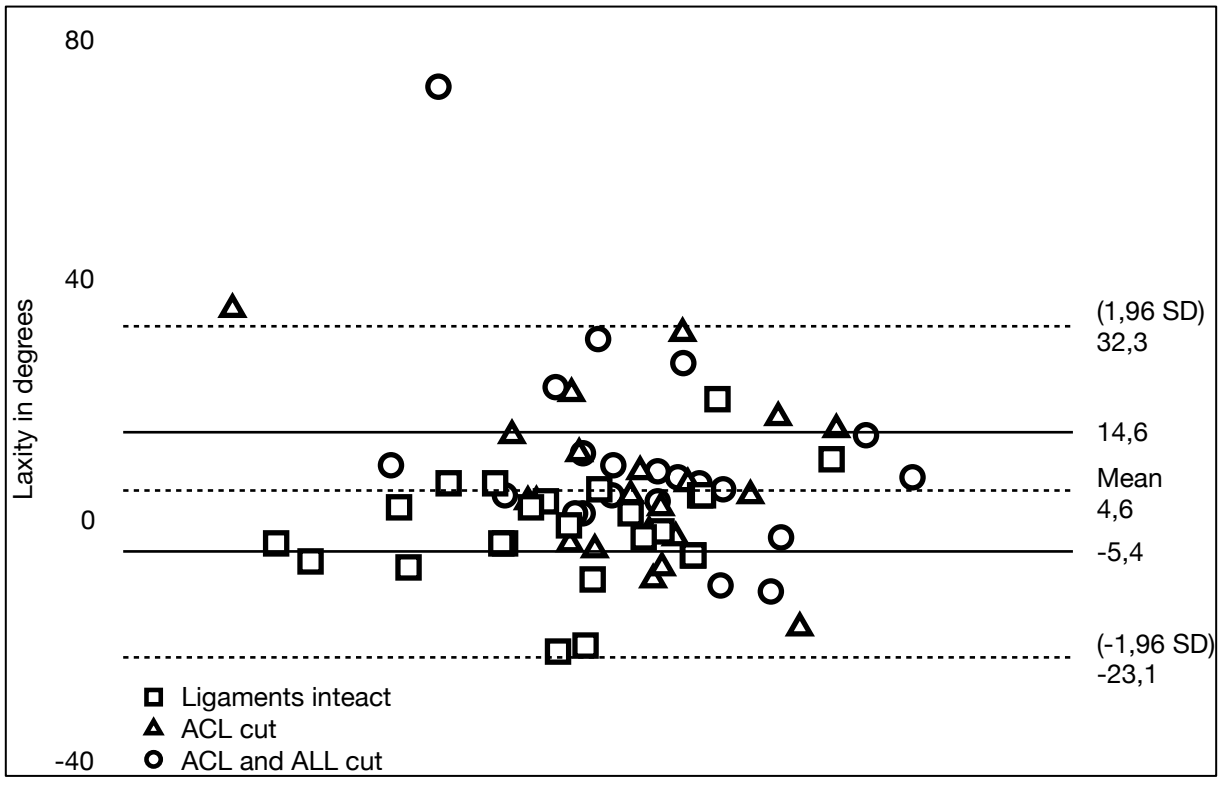
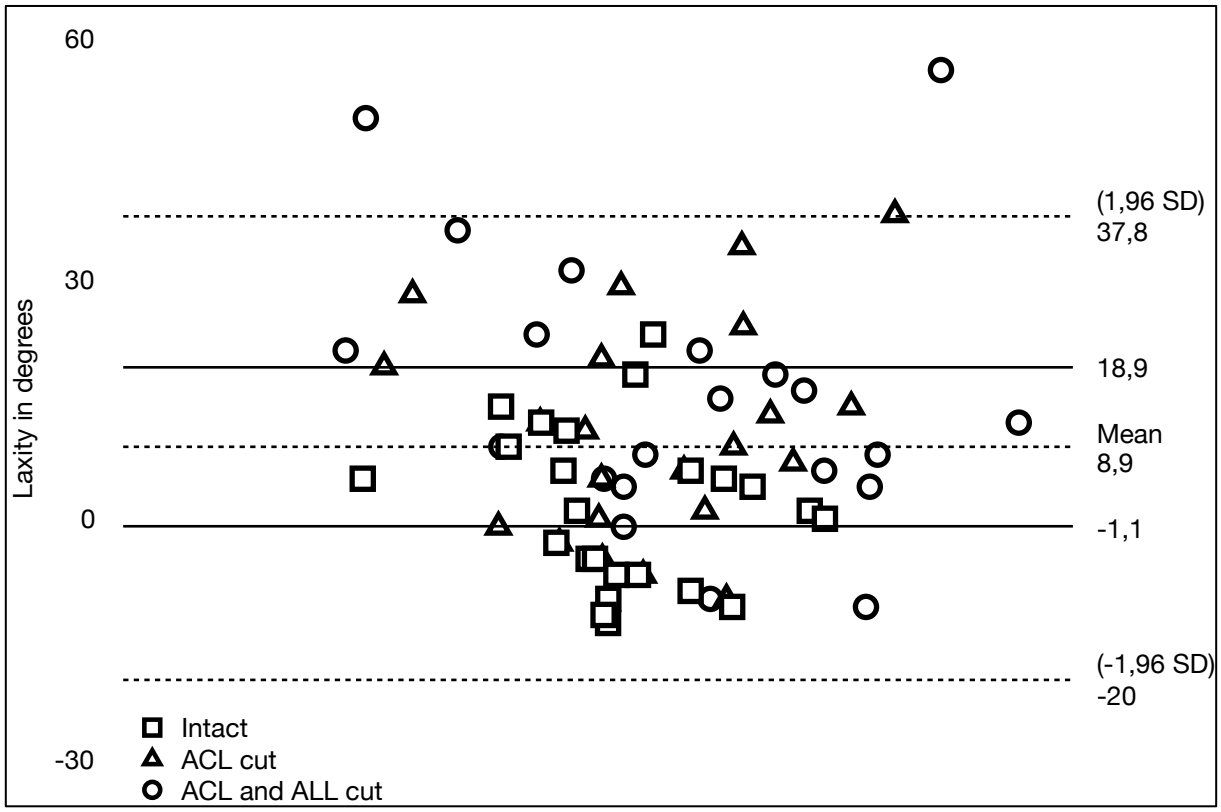


Figure 4: Bland-Altman plot for rotational laxity at 90º.



Addenda

Instructions to author for the journal Knee Surgery Sport Traumatology Arthroscopy (KSSTA)

Original Paper

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- Diagnostic studies evaluate the effectiveness of a diagnostic test or outcome assessment.
- Economic/decision analysis or modelling studies explore costs and alternatives or may even develop or assess the effectiveness of decision models.
- Systematic reviews and meta-analyses are assigned a level of evidence equivalent to the lowest level of evidence used from the manuscripts analysed.
- A prospective study is defined as a study in which the research question was developed (and the statistical analysis for determining power was developed) before data were collected.
- A retrospective study is defined as a study in which the research question was determined after the data were collected (even for studies where the authors collected general data prospectively).

Levels of Evidence for Knee Surgery Sports Traumatology Arthroscopy

Study Type	Question	Level I	Level II	Level III	Level IV	Level V
Diagnostic—Investigating a diagnostic test	Is this (early detection) test worthwhile?	Randomized controlled trial	Prospective[3] cohort[4] study	Retrospective[5] cohort[4] study	Case series	Mechanism-based reasoning
	Is this diagnostic or monitoring test accurate?	Testing of previously developed diagnostic criteria (consecutive patients with consistently applied reference standard and blinding)	Development of diagnostic criteria (consecutive patients with consistently applied reference standard and blinding	Case-control[6] study		
				Nonconsecutive patients	Poor or nonindependent reference standard	Mechanism-based reasoning
				No consistently applied reference standard		
Prognostic—Investigating the effect of a patient characteristic on the outcome of a disease	What is the natural history of the condition?	Inception[3] cohort study (all patients enrolled at an early, uniform point in the course of their disease)	Prospective[3] cohort[4] study (patients enrolled at different points in their disease)	Retrospective[5] cohort[4] study	Case series	Mechanism-based reasoning
			Control arm of randomized trial	Case-control6 study		
Therapeutic—Investigating the results of a treatment	Does this treatment help? What are the harms?7	Randomized controlled trial	Prospective[3] cohort[4] study	Retrospective[5] cohort[4] study	Case series	Mechanism-based reasoning
			Observational study with dramatic effect	Case-control[6] study	istorically controlled study	
Economic	Does the intervention offer good value for € spent?	Computer simulation model (Monte Carlo simulation, Markov model) with inputs derived from Level-I studies, lifetime time duration, outcomes expressed in dollars per quality-adjusted life years (QALYs) and uncertainty examined using probabilistic sensitivity analyses	Computer simulation model (Monte Carlo simulation, Markov model) with inputs derived from Level-II studies, lifetime time duration, outcomes expressed in dollars per QALYs and uncertainty examined using probabilistic sensitivity analyses	Computer simulation model (Markov model) with inputs derived from Level-II studies, relevant time horizon, less than lifetime, outcomes expressed in dollars per QALYs and stochastic multilevel sensitivity analyses	Decision tree over the short time horizon with input data from original Level-II and III studies and uncertainty is examined by univariate sensitivity analyses	Decision tree over the short time horizon with input data informed by prior economic evaluation and uncertainty is examined by univariate sensitivity analyses

1. This chart was adapted from OCEBM Levels of Evidence Working Group, "The Oxford 2011 Levels of Evidence," Oxford Centre for Evidence-Based Medicine, http://www. cebm.net/ocebm-levels-of-evidence/. A glossary of terms can be found here: http://www.cebm.net/glossary/.
2. Level-I through IV studies may be graded downward on the basis of study quality, imprecision, indirectness, or inconsistency between studies or because the effect size is very small; these studies may be graded upward if there is a dramatic effect size. For example, a high-quality randomized controlled trial (RCT) shouldhave‡80% follow-up, blinding, and proper randomization. The Level of Evidence assigned to systematic reviews reflects the ranking of studies included in the review (i.e., a systematic review of Level-II studies is Level II). A complete assessment of the quality of individual studies requires critical appraisal of all aspects of study design.
3. Investigators formulated the study question before the first patient was enrolled.
4. In these studies, "cohort" refers to a nonrandomized comparative study. For therapeutic studies, patients treated one way (e.g., cemented hip prosthesis) are compared with those treated differently (e.g., cementless hip prosthesis).
5. Investigators formulated the study question after the first patient was enrolled.
6. Patients identified for the study on the basis of their outcome (e.g., failed total hip arthroplasty), called "cases," are compared with those who did not have the outcome (e.g., successful total hip arthroplasty), called "controls."
7. Sufficient numbers are required to rule out a common harm (affects >20% of participants). For long-term harms, follow-up duration must be sufficient.

(*Adapted from JBJS Am, with permission: Marx RG, Wilson SM, Swiontkowski MF. Updating the assignment of levels of evidence. J Bone Joint Surg Am. 2015*)

File formats

The following word processor file formats are acceptable for the main manuscript document:

- Microsoft word (DOC, DOCX)
- Rich text format (RTF)
- Portable document format (PDF)
- TeX/LaTeX
- DeVice Independent format (DVI)

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Preparing main manuscript text

General guidelines of the journal's style and language are given below.

Overview of manuscript sections for Original Paper

Manuscripts for should be divided into the following sections (in this order):
Title page
Abstract
Keywords
Introduction
Purpose and Hypothesis
Methods
Results
Discussion
Conclusions
List of abbreviations
Competing interests
Authors' contributions
Authors' information
Acknowledgements
References
EndNote
Preparing illustrations and figures
Formats
Figure legends
Preparing tables
Preparing additional files
Additional file formats
Mini-websites
Style and language
Language editing
Abbreviations
Typography
Units

Title page

The title page should:
provide the title of the article list the full names, institutional addresses and email addresses for all authors indicate the corresponding author

Abstract

The abstract of the manuscript should not exceed 350 words and must be structured into separate sections:

Purpose: the context and purpose of the study; *Methods,* how the study was performed and statistical tests used; *Results,* the main findings; *Conclusions,* brief summary and potential implications.
Please minimise the use of abbreviations and do not cite references in the abstract.

Keywords

Three to 10 keywords representing the main content of the article.
Introduction

Purpose

The purpose and hypothesis section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state —and, if helpful, illustrate — the background to the research and its aims. The hypothesis should be clearly stated. This section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

For studies involving human participants a statement detailing ethical approval (IRB Approval) and consent should be included in the methods section.

This section should always end with information about Statistical analysis, where all statistical methods are clearly explained. Under this subheading, information about sample size calculation (whenever appropriate) must be given. The journal prefers to use (n.s.) for non-significant p-values

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Results

The result section should be formatted in the same manner as the methods section. Please be concise as best as possible. Use tables and figures to shorten the text, DO NOT repeat the same data in the text as already presented in tables and figures! However you may include the most important findings in the text again - highlighting them as the most important findings. It is recommended, if data are normally distributed, to use 95 % confidence interval instead of standard deviation. Present the distribution of the data and the appropriate data format e.g. for non-normally distributed data the median and quartile, percentile or range. For all presented methods, results should also be presented. Statistical significant results might not be clinically significant. If available, present also the clinically significant differences between groups. Results should be presented only up to the accuracy they were collected. For example, height of patients was measured, which is in general done to an accuracy of 1 cm e.g. Mr. X had a height of 187 cm. Thus, the results should not present the

average height of the entire study population as 187.45683 cm. All digits after the decimal have to be deleted.

Discussion

The Discussion section should include discussion about the scientific findings and the authors need to put their findings into context and compare with other relevant studies. The most important findings need to be highlighted, limitations mentioned and clinical relevance discussed towards the end of this section

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations
may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

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A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organisations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. To download this file pleae click HERE. Each author has to fill and sign a form. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

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If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

According to ICMJE guidelines, An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree 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. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the pt. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, a department chair who provided only general support, or those who contributed as part of a large collaboration group.

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Acknowledgements

Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

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References

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References in the text should be presented as numbers in square brackets following the alphabetical order of the reference list. Example: [1] or [4,11,16]

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Reference list entries should be alphabetized by the last names of the first author of each work and numbered consecutively. The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Books and book chapters should not be cited. Ideally, the names of all authors should be provided, but the usage of "et al." in long author lists (above 30) will also be accepted. Always use the standard abbreviation of a journal's name according to the NLM Title Abbreviation list, see http://www.ncbi.nlm.nih.gov/nlmcatalog/journals.

Examples

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1. Smith J, Jones M Jr, Houghton L et al. (1999) Future of health insurance. N Engl J Med 965:325-329
2. Xu Y, Ao YF, Wang JQ, Cui GQ (2014) Prospective randomized comparison of anatomic single- and double-bundle anterior cruciate ligament reconstruction. Knee Surg Sports Traumatol Arthrosc 22(2):308–316

- Journal article (only online published version available) – In this case, the DOI is required.

1. Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine production. J Mol Med. Doi:10.1007/s001090000086

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- Proceedings as a book (in a series and subseries)

1. Zowghi D (1996) A framework for reasoning about requirements in evolution. In: Foo N,

Goebel R (eds) PRICAI'96: topics in artificial intelligence. 4th Pacific Rim conference on artificial intelligence, Cairns, August 1996. Lecture notes in computer science (Lecture notes in artificial intelligence), vol 1114. Springer, Heidelberg, p 157

- Article within conference proceedings with an editor (without a publisher)

1. Aaron M (1999) The future of genomics. In: Williams H (ed) Proceedings of the genomic researchers, Boston, 1999

- Article within conference proceedings without an editor (without a publisher)

1. Chung S-T, Morris RL (1978) Isolation and characterization of plasmid deoxyribonucleic acid from Streptomyces fradiae. In: Abstracts of the 3rd international symposium on the genetics of industrial microorganisms, University of Wisconsin, Madison, 4-9 June 1978

- Study presented at a conference

1. Chung S-T, Morris RL (1978) Isolation and characterization of plasmid deoxyribonucleic acid from Streptomyces fradiae. Paper presented at the 3rd international symposium on the genetics of industrial microorganisms, University of Wisconsin, Madison, 4-9 June 1978

- Patent

1. Norman LO (1998) Lightning rods. US Patent 4,379,752, 9 Sept 1998

- Dissertation

1. Trent JW (1975) Experimental acute renal failure. Dissertation, University of California

- Online document: All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

1. Doe J (1999) Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. Available via DIALOG. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999
2. ISSN International Centre (2006) The ISSN register. http://www.issn.org. Accessed 20 Feb 2007
3. The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 15 Jan 1999

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Each table should be numbered and cited in sequence using Arabic numerals (i.e. Table 1, 2, 3 etc.). Tables should also have a title (above the table) that summarises the whole table; it should be no longer than 15 words. Detailed legends may then follow, but they should be concise. Tables should always be cited in text in consecutive numerical order.

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  - MP4 (MPEG 4)
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Small self-contained websites can be submitted as additional files, in such a way that they will be browsable from within the full text HTML version of the article. In order to do this, please follow these instructions:

Create a folder containing a starting file called index.html (or index.htm) in the root.

Put all files necessary for viewing the mini-website within the folder, or sub-folders.

Ensure that all links are relative (ie "images/picture.jpg" rather than "/images/picture.jpg" or "http://yourdomain.net/images/picture.jpg" or "C:Documents and SettingsusernameMy Documentsmini-websiteimagespicture.jpg") and no link is longer than 255 characters.

Access the index.html file and browse around the mini-website, to ensure that the most commonly used browsers (Internet Explorer and Firefox) are able to view all parts of the mini-website without problems, it is ideal to check this on a different machine.

Compress the folder into a ZIP, check the file size is under 20 MB, ensure that index.html is in the root of the ZIP, and that the file has .zip extension, then submit as an additional file with your article.

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text, otherwise they will be lost during conversion to PDF.

Units

SI units should be used throughout.

Consent form

Why is this study being done?

The ALL has been "rediscovered" in a very public way and the diagnosis, indication for repair and treatment options are a main focus of resent research activity of major international knee centres. The decision to perform an ALL reconstruction is based on clinical grounds. Our study will evaluate the diagnostic accuracy and precision of clinical examination. We want to determine if clinical examination alone is enough to evaluate ALL injuries and rotational instability of the knee.

What is the study about?

The aims of this study are to compare perceived laxity reported after examination of cadaveric knees in which the ACL, ALL and ITB are sectioned, to true measurements recorded via computer assisted surgery (CAS) and to assess the diagnostic accuracy of clinical examination to detect ACL, ALL and ITB tears in a cadaver model.

Who are the principal investigator and the main author?

Principal investigator: Dr M Held
Main author: Dr CW Bezuidenhout

What is expected of you as examiner?

As examiner you will be asked to evaluate the cadaver knees and record your findings on information sheet 1 and 2. On information sheet 1 you must record the perceived sagittal and rotational laxity of the cadaver knees before and after the ACL/ALL/ITB have been cut sequentially. On information sheet 2 you must try and correctly identify which ligaments have been cut in each of the 14 cadavers. Any combination of the 3 ligaments (ACL, ALL and ITB) can be cut. E.g.: ACL; ALL; ITB; ACL+ALL; ACL+ITB; ALL+ITB; ACL+ALL+ITB.

What is the duration of the study?

The study will be concluded in one half-day session of +/- 4 hours.

How many people will take part in the study?

You will be one of 28 participants.

What are the risks and discomforts of this study?

- You will examine fresh cadaver limbs that are not tested for infectious diseases like HIV or Hepatitis. The cadavers will have sutured surgical scars.
- You will however wear protective clothing and will not be asked to handle sharp instruments.

Are there any benefits to you for being in the study?

This study is an opportunity for you to test your clinical skills. You will also help to answer an important scientific question.

What other choices do you have?

You are allowed to decline participation in this study with no consequences to you or your reputation.

Will the results of the research be shared with you?

After conclusion of the study an electronic copy of the results will be available on request by participants of the study.

Will you receive any reward (money or food vouchers) for taking part in this study?

No monetary incentive will be given for participation in this study.

Who will see the information that is collected about you during the study?

- No identifiable information linking the participant to specific test results will be published. Identifiable information will only be available to the principal investigator and the main author.
- Due to the anonymity in the results you run no risk to your reputation.

Who do I speak to (or contact) if I have any questions about the study?

You can contact the main author (Dr Carel Bezuidenhout) on 0845564076 during normal working hours Monday to Friday 8am to 4pm.

Who reviewed or approved this study?

Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town. Please contact the HREC on tel: +27 21 406 6496 with any ethical concerns or questions regarding your rights and welfare as a research participant.

Consent:

I _____(name) give consent that the information obtained in this study be used in academic publications to the discretion of the principal investigator.

Result sheet

Name:
Rank:

☐ Orthopaedic specialist (knee specialist)
☐ Orthopaedic specialist (other than knee specialist)
☐ Orthopaedic registrar (1st or 2nd year)
☐ Orthopaedic registrar (3rd or 4nd year)
☐ Medical officer

Instruction:

Examine the cadaver knee and document anterior translation in millimetres and rotational instability in degrees. After the first examination one of either the ACL, ALL or the ITB will be sectioned in an undisclosed order. After each ligament transection a repeat examination will be done.

Examination: Ligamentous intact

Knee at 30° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

Knee at 90° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

Examination: First ligament cut

Knee at 30° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

Knee at 90° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

What ligament was cut?

ACL □ ALL □ ITB □

Examination: Two ligaments cut

Knee at 30° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

Knee at 90° flexion

AP laxity (mm): _____

Rotational instability measured in degrees: _____

What ligament was cut?

ACL □ ALL □ ITB □

Ethics approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: terry.rossouw@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

03 January 2017

HREC REF: 476/2016

Dr M Held
Orthopaedics
H49, OMB
Groote Schuur Hospital

Dear Dr Held

PROJECT TITLE: THE DIAGNOSTIC ACCURACY AND PRECISION OF CLINICAL EXAMINATION OF THE ANTERIOR CRUCIATE LIGAMENT (ACL) AND ANTEROLATERAL LIGAMENT (ALL) OF THE KNEE (MMed-candidate- Dr C Bezuidenhout)

Thank you for your response to the Faculty of Health Sciences Human Research Ethics Committee comments.

Before formal approval can be given, the investigator must address the issue/s relating to the Informed Consent Form:

1. Please place the Informed Consent form on a UCT letterhead, so that departmental and UCT affiliation is clear.
2. Please include the contact details of the UCT Faculty of Health Sciences Human Research Ethics Committee (HREC), together with a statement that participants may contact the HREC if they have any ethical concerns or questions about their rights or welfare as research participants.
3. Please include the name of the researcher who can be contacted for questions.
4. Please state who the Principal Investigator and Main Author are, who will have access to identifiable information.
5. The consent statement needs to be more comprehensive and must indicate all aspects of consent to research, not just academic publication.

Please quote the HREC REF in all your correspondence.

Please note that no research may occur without formal written HREC approval.

Yours sincerely

pp T Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC REF 476/2016