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Validity of the Genourob arthrometer in the evaluation of total thickness tears of anterior cruciate ligament

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ABSTRACT

Objective: Our purpose was to evaluate the validity and reliability of the laxity with the GNRB arthrometer in subjects with anterior cruciate ligament injury.
Material and method: A diagnostic study was performed by three operators using the Genourob arthrometer, measuring the displacement of the anterior cruciate ligament. The concordance was assessed by the intraclass correlation coefficient mixed effects model, Lin correlation coefficient and graphic method from Bland-Altman. Using the anterior cruciate ligament tear as a dependent variable and the Genourob measurement as an independent variable, a logistic regression was determined.
Results: Obtaining the complete information of 157 knees. The measurements with the Genourob arthrometer distributed symmetrically, with mean ± standard deviation of knees with anterior cruciate ligament injury: 5.64 ± 1.72 and knees without anterior cruciate ligament injury: 3.29 ± 1.72. The ICCs as well as the LCCs were equal to or greater than 0.99. The BA showed discrepancy for a pair of observations no greater than 7.64%. The odds ratio of the knee displacement measurement for the presence of anterior cruciate ligament injury was 4.04 (95% CI: 2.59–6.32; p-value < .01) with a ROC area of 0.863 (95% CI: 0.789–0.9456). The cut-off point of the anteroposterior knee displacement located at 6.8 mm determined a sensitivity of 74.4% and specificity of 93.8%, with a Youden Index = 0.67.
Conclusion: The Genourob arthrometer is reliable and valid to establish where laxity values correlate with total thickness tears of the anterior cruciate ligament.

1. Introduction

The anterior cruciate ligament (ACL) is one of the most frequently injured structures in the knee joint. It has a critical role in the physiological kinematics of the knee joint, and its alteration eventually causes functional impairment and osteoarthritis.[1]

The clinical evaluation and diagnosis, the lachman test is the most reliable diagnostic test, followed by the anterior drawer test and then the pivot test.[2,3]

Their clinical measurement has been classically indicated to be inaccurate and poorly reproducible, and studies show that the Lachman test retains its reliability only if performed by a single evaluator.[4] In addition, the quantification of the anteroposterior tibial displacement remains inaccurate.[5]

As for imaging, the sensitivity of the magnetic resonance imaging (MRI)for a complete ACL rupture falls within the range of 67%–97%, and the differentiation of a complete rupture from a partial rupture by MRI is much less specific.[6]

Arthroscopy is the gold standard of diagnosis, where partial tears can be distinguished from complete tears with a sensitivity of 80% and a specificity of 100%.[7]

Measurements of knee laxity in an ACL tear can be quantified by instrumented techniques, most commonly by the KT-1000, Rolimeter, Telos, and GNRB.[5,8]

For the evaluation of ACL laxity by arthrometry, many factors influence the results in a clinical setting, including patient position, knee position, muscle tone, degree of muscle relaxation, magnitude, direction and the amplitude of the force applied, with false negative results

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Table 1
Interoperative evaluation of knee anteroposterior displacement measurement by the Genourob arthrometer in 157 knees by 3 examiners E1, E2 and E3. Values are presented as mean ± standard deviation, CI: confidence interval.

Examiner	Uninjured Knee(n = 114) (mm)	Intraclass Correlation Coefficient	95% CI	p-value	Injured Knee(n = 43) (mm)	Intraclass Correlation Coefficient	95% CI	p-value
E1	3.28 ± 0.78	ICC = 0.989 0.986–0.992	0.996–0.997	p < .001	5.59 ± 1.74	ICC = 0.997 0.995–0.998	0.998–0.999	p < .001
E2	3.23 ± 0.76	ICC = 0.989 0.986–0.992	0.996–0.997	p < .001	5.59 ± 1.73	ICC = 0.997 0.995–0.998	0.998–0.999	p < .001
E3	3.29 ± 0.77	ICC = 0.996 0.986–0.992	0.996–0.997	p < .001	5.64 ± 1.69	ICC = 0.997 0.995–0.998	0.998–0.999	p < .001
E1E2E3	3.27 ± 0.77	ICC = 0.99 0.986–0.992	0.996–0.997	p < .001	5.61 ± 1.72	ICC = 0.999 0.998–0.999	0.998–0.999	p < .001

of 28%.[8–10]

In measuring by means of an arthrometer, the knee should be in neutral rotation, since internal rotation reduces the anterior displacement and external rotation increases it as reported in previous the publications.[11,12] For some authors, the high rate of false negatives (up to 50%) should be attributed to the involuntary contraction of the hamstrings.[6]

The KT-1000 is an arthrometer capable of quantifying the anterior laxity of the knee, and most knee laxity measurement studies have used it as a reliable reference. Others report that it is unreliable and poorly reproducible due to the inexperience of the evaluators, with a false negative rate of up to 50%.[10]

Telos is a system that uses stress radiography to measure the differential laxity between injured and uninjured knees, with a false positive rate of 28% and risk of radiation exposure. The study by Jardin et al.[13] concluded the Telos 150 N was more reliable than the KT-1000 in a study of 48 patients operated on for ACL rupture, but its 1-year follow-up revealed no differences. In addition, Telos is an expensive system, with great exposure to radiation.

The Rolimeter is described as easy to operate, but it only allows the recording of the maximum manual traction and has no control of the traction applied, being hardly reproducible and dependent on the examiner.

Finally, the Genourob arthrometer is a computerized system that has pressure and motion sensors for an accurate evaluation of anterior knee laxity that has proven reliable, reproducible and superior to the KT-1000 and other arthrometers internationally.[5,6,8] There are currently no studies published in Chile with the GNRB arthrometer, being an important tool to consider in the diagnosis and follow-up of patients with ligament injuries of the knee.

The purpose of our study was to observe the validity and reliability in the measurement of ACL laxity with the Genourob arthrometer in subjects with ACL injury as compared to the clinical evaluation plus knee MRI as a gold standard.

2. Material and Methods

A cross-sectional study of diagnostic test analysis was carried out incorporating the information of knees of subjects of both sexes between 17 and 60 years of age from March 2018 to December 2018 who were admitted to the Quilin Ambulatory Clinic of the University of Chile due to acute knee trauma and suspected diagnosis of traumatic ACL rupture.

Age, sex, laterality of the injury, trauma mechanism (including sport injuries or accidents) and type of ACL injury (partial or total) confirmed by MRI were recorded for each subject. The clinical evaluation plus the MRI will be the gold standard of comparison in this study.

Between 7 and 35 days after the injury, the ACL laxity in both knees (total thickness tears of ACL knees and uninjured knees) was evaluated by three measurements of anteroposterior knee displacement with 134 N loads that were performed by three trained operators using Genourob equipment.

Patients included high performance athletes and subjects under the age of 17 and over the age of 60. Multi-ligament knee rupture were excluded.

2.1. Measurement technique

The subject was lying on a table in the supine position. The lower limb was placed on an adjustable limb support, with the knee placed at 0° rotation and 20° flexion, thus reproducing the position of the Lachman test.

An electric pressure pad was placed on the upper calf and a pressure load of 134 N was applied. The surface electrodes (EMG) were placed on the back of the thigh to control the muscle relaxation of the hamstrings of the examined knee. A transducer (0.1 mm) recorded the relative displacement of the anterior tibial tuberosity with regard to the patella. The test was repeated on both knees, and the amount of tibial translation was compared between the two extremities. The data was collected on a computer, and three automatic measurements were obtained for each pressure load. The curves obtained for each knee were the anterior tibial translation in mm and the pressure load in N.

The study was approved by the Ethical Committee of the Sotero del Rio Hospital in Santiago, Chile, and in full agreement with the Declaration of Helsinki. All participating subjects accepted and signed informed consent.

2.2. Statistical analysis

A descriptive analysis of the quantitative and ordinal variables was performed reporting measures of central tendency (mean and median) and dispersion using the interquartile range (IQR) and standard deviation (SD).[14] Nominal dichotomous variables are described in terms of proportions with their respective confidence intervals (CIs).[14]

The reproducibility for each observer in the measurement of the articular laxity of the knees was assessed by the coefficient of variation.[14] that was determined in all the knees, as well as in healthy knees and those with a traumatic injury.

Reproducibility among observers for measurements of joint laxity in the total knees observed and also according to the presence of ACL injury was assessed by the intraclass correlation coefficient mixed effects model (ICC) determined in individuals and the average among the observers.[14] In addition, for each pair of observers, reproducibility was assessed in measurements of joint laxity in healthy and injured knees by determining the Lin correlation coefficient (LCC) (10,11) and Bland-Altman (BA) graphical method.[15–17]

Given the hypothesis proposed for this study, a univariate logistic regression was performed, assessing the anteroposterior knee displacement for the presence of ACL rupture. Prior to logistic regression, the anteroposterior displacement of the knee was assessed for compliance with the supposed linearity logit,[11,15,18] using a linear trend test and graphic method.

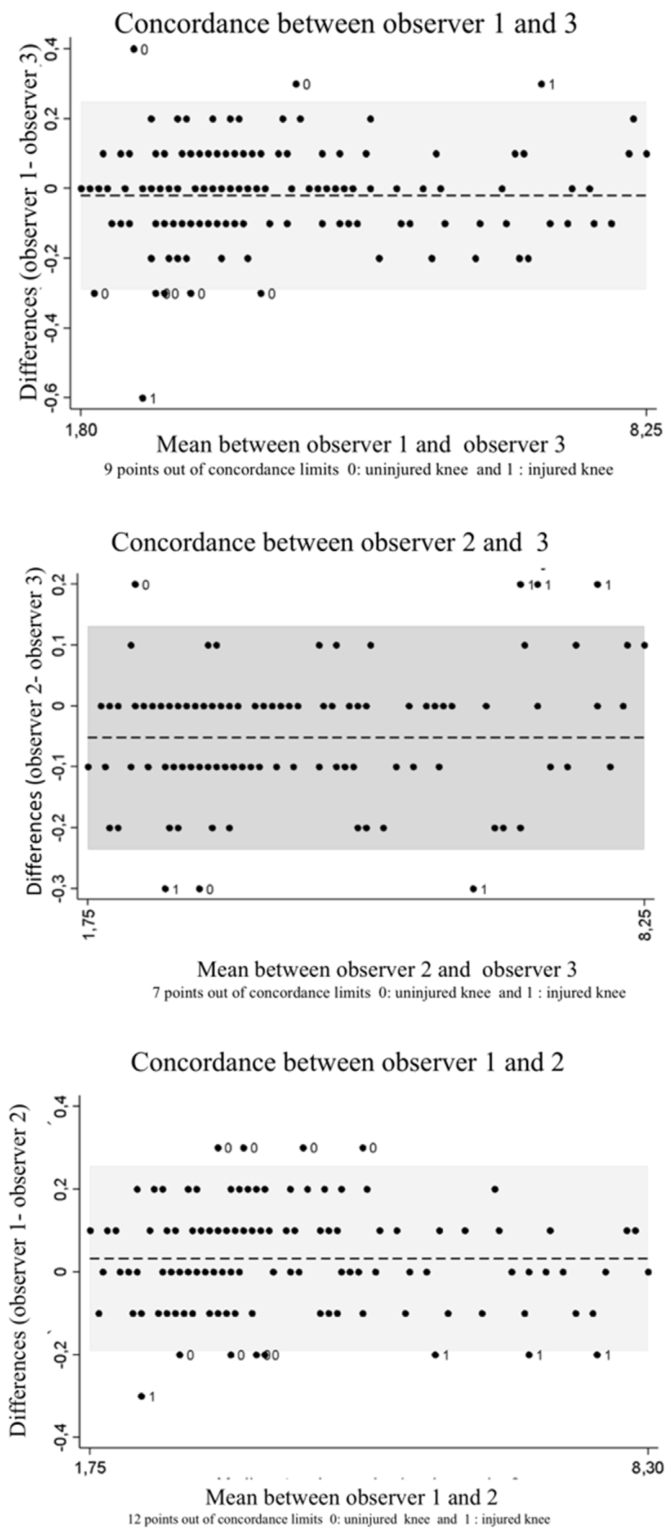

Fig. 1. Concordance between observers in 157 knees of subjects consulting for traumatic rupture of anterior cruciate ligament.

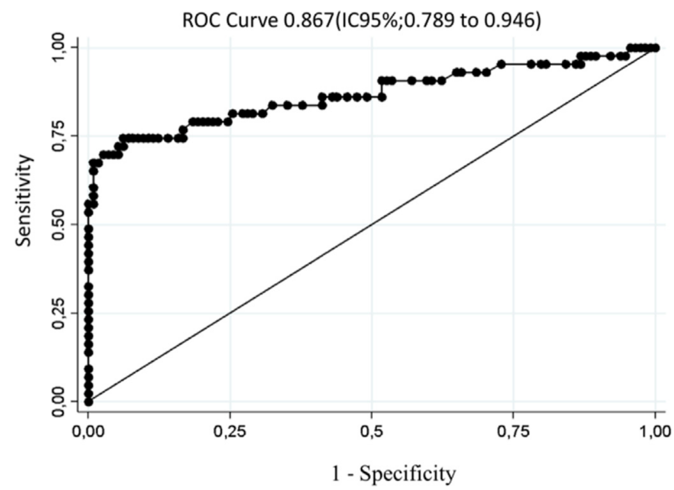

Fig. 2. ROC area for logistic regression model incorporates anteroposterior knee displacement measurement for the presence of anterior cruciate ligament injury in 157 knees of subjects consulting for traumatic rupture of the anterior cruciate ligament.

In the logistic regression model proposed, the Wald test was used to assess the contribution of the independent variable. The Hosmer-Lemeshow test grouped into 10 quantiles was used to assess the quality of the logistic regression adjustment performed.[15,16,18] In addition, to assess the predictive capacity of the logistics model, a "receiver operating characteristic" (ROC) analysis was considered non-parametric.[11]

The analysis was performed using the Stata program (Stata/SE 16.0 for Windows, Copyright 1985–2019 Stata Corp LLC).

3. Results

Of 219 subjects invited to participate, 79 accepted, obtaining the complete information of 157 knees. The age of the incorporated subjects distributed with asymmetry to the right, evidencing a median of 17.5 years with an IQR of 13 years. The minimum and maximum age values were respectively 17 and 60 years old. In all, 90 of the 114 subjects were male (78.95%).

A total of 43 knees had an ACL lesion confirmed through clinical evaluation plus knee MRI, of which 26 were straight (60.47%). Of the 114 uninjured knees, 53 were straight (46.49%) (Chi-square test = 2.4; p-value = .12).

The anteroposterior displacement measurements for each knee made by three different operators, as well as their average, distributed symmetrically, with mean, SD and coefficient of variation values are indicated in Table 1. The knees with ACL injury showed greater means of displacement than those without injury (Mann-Whitney test z = −7.08; p-value < .01) (Table 1).

Regarding the total of knees observed, the ICCs in individuals and average among observers were respectively 0.9970 (95% CI: 0.9961–0.9978, p-value < .01) and 0.9990 (95% CI: 0.9987–0.9993, p-value < .01). The correlation coefficient values per subgroup of healthy and diseased knees are shown in Table 1.

The concordance between observer 1 and 2 showed 12 (7.64%) pairs of discordant observations with a LCC of 0.997 (95% CI: 0.996–0.998). Between observer 1 and 3, there were 9 (5.73%) pairs of discordant observations with a LCC of 0.996 (95% CI: 0.994–0.997). Between observer 2 and 3, there were 7 (4.46%) pairs of discordant observations with a LCC of 0.996 (95% CI: 0.994–0.997). BA graphs for the match between pairs of observers are shown in Fig. 1.

The anteroposterior displacement of the knee for the ACL injury revealed an adequate linearity of the logit in the graph and linear trend test. Anteroposterior knee displacement demonstrated an odds ratio of 4.04 (95% CI: 2.59–6.32; p-value < .01), that is, for every millimetre of displacement (unit used), the probability of detecting ACL breakage is increased 4 times. The usual cut-off point of 3 mm anteroposterior knee displacement delivered a sensitivity of 90.7% and a specificity of 40.3%, with a Youden Index (0.907 + 0.403–1) = 0.31. The cut-off point of the anteroposterior knee displacement located at 6.8 mm determined a higher sensitivity and specificity together for the diagnosis of complete ACL rupture, its sensitivity being 74.4% and specificity

93.8%, with a Youden Index (0.74 + 0.93–1) = 0.67. The global test has an area under the ROC curve of 0.863 (95% CI: 0.789–0.9456) (Fig. 2).

4. Discussion

The main result of this study was to verify that all GNRB diagnostic values have high reproducibility for both uninjured knees and knees with complete ACL tears.

The GNRB reports several advantages in comparison with other arthrometers, such as good control of the positioning of the rotating limbs, electrodes that sense the contraction activity of the hamstrings, greater reproducibility, strength with controlled and constant thrust, precision and automatic measurement recording as compared to the KT-1000. This could be explained by the accuracy of the displacement transducer (0.1 mm).[7] The GNRB can be used in the diagnosis of partial and complete ACL tears and for the clinical monitoring of ACL tears before or after surgery.[5]

These results support what was reported by Robert et al.,[7] specifically the GNRB was reported to have a sensitivity of 80% and a specificity of 87% for partial ACL tears with GNRB 134 N. Likewise, Lefevre et al.[5] reported that the diagnostic value of the GNRB was better than the Telos TM for the diagnosis of partial thickness tears of the ACL with a sensitivity of 84% and specificity of 81%. However, there are reports that warn the results from measurement with the GNRB are affected by the amount of clamping force on the kneecap during the test or that the meniscal and medial collateral ligament damage affects the laxity of the knee causing alterations in the measurements[19,20]

Our limitations were that we did not differentiate partial tears from complete ones by calculating differential laxity, in addition to presenting discordant observations that can be attributed to subjects with partial tears of the ACL and knees with greater hyperlaxity in women and older subjects as compared to the literature may have less muscle strength.[20]

This would guide us to future research where we can differentiate among patients with partial tears versus complete tears, consider the time of injury and other associated injuries, such as those of the menisci and collateral ligaments.

5. Conclusions

The correlation with the GNRB at 134 N was highly significant with adequate agreement, so we can conclude that the GNRB delivers high reproducibility and homogeneous force during the measurement and agrees with the published studies.

Our results confirm our hypothesis regarding the GNRB. It is a valid and reliable instrument for the measurement of laxity in subjects with an ACL injury, directly correlating with the diagnosis of complete ACL tears.

Declaration of competing interest

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.

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