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ORIGINAL ARTICLE

A new knee arthrometer, the GNRB[®]: Experience in ACL complete and partial tears

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KEYWORDS

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disruption

Summary

Introduction. – Clinical diagnosis of anterior cruciate ligament (ACL) tears (Lachman test and Pivot shift test in valgus and internal rotation) is reliable in case of complete ACL tear but reveals elusive in case of partial tears. Quantitative assessment of anterior tibial translation proves to be imprecise, subjective and poorly reproducible especially with the KT-1000 arthrometer. We developed the GNRB[®], an alternative original anterior knee laxity measurement device. The lower limb is placed in a rigid support with the knee at 0° of rotation, the restraining power being recorded. A 0–250 N thrust force is transmitted by a jack to the upper segment of the calf. This force is only applied in the absence of hamstring muscles contraction. Displacement of the anterior tibial tubercle is recorded using a sensor with a 0.1 mm precision.

Hypothesis. – We hypothesize that this knee laxity measurement device is more reliable and reproducible than other currently available arthrometers.

Material and methods. – During a first validation study, the GNRB[®] was compared to the KT-1000 arthrometer, in 20 pairs of healthy knees, measurements being performed by two investigators. Variance analyses were carried out at 134 N. In a second clinical study, 21 complete ACL tears (the notch is devoid of ACL) and 24 partial ACL tears (anterior or posterior bundle tear and cicatricial ACL remnant in continuity) were tested with these arthrometers to exact a differential laxity threshold value between both knees at 250 N. Statistical analysis was subsequently performed using variance and ROC curves analysis.

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Results. — The GNRB[®] arthrometer reveals to be significantly more reproducible than the KT-1000, irrespectively of the tester's experience level. Moreover, unlike the KT-1000, the achieved measurement is independent from the uninvolved side. Reproducibility of laximetry proves to be significantly better with the GNRB[®] than with the KT-1000, wherever the examiner's experience stands and whatever the evaluated side condition could be. When differential laxity threshold value was 3 mm in complete ACL tears, sensitivity was 70% and specificity 99% at 134 N. Using a 1.5 mm threshold value in ACL partial tears, the arthrometer sensitivity was 80% and specificity was 87% at 134 N.

Discussion. — Reproducibility of laximetry was significantly better with the GNRB[®] than the KT-1000 device, wherever the examiner's experience stands and whatever the evaluated side-condition could be. The GNRB[®] reports various supplementary advantages compared with other available laximeters. Good control of the investigated limb position in rotation, recording of translation in the absence of hamstring muscles contraction and in direct comparison with the KT-1000: reproducibility, constant pressure, arthrometry improved accuracy and automated measurements recording. The GNRB[®] might be used for diagnosis of partial and complete ACL tears and during follow-up of reconstructed or not ACL tears.

Level of evidence: type II. Prospective comparative study

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Introduction

Clinical diagnosis of anterior cruciate ligament (ACL) tears (Lachman test and Pivot shift test in valgus and internal rotation) is reliable in case of complete ACL tear but reveals elusive in case of partial tears. Quantitative assessment of anterior tibial translation proves to be imprecise, subjective and poorly reproducible [1,2]. Over the past 30 years, various authors have shown great interest in measuring tibial translation in relation to the femur in order to assess ACL function in anteroposterior, frontal and rotational stability of the knee [3–5]. It clearly appeared that a 20° of knee flexion, which corresponds to the Lachman test position, was more relevant in evaluating the anterior tibial displacement. Today, measurements are commonly obtained using the KT-1000 laximeter (Medmetric, San Diego, CA, USA) first introduced in the early 80s by Daniel et al. [5], the Rolimeter (Aircast, Summit, NJ, USA) developed by Roland Jacob [7] or even stress radiography with the Telos (GmbH, Hungen/Obbornhafen, Germany) in clinical settings. The KT-1000 arthrometer is the most widely used knee ligament testing system because it is an easy-to-use device and still remains a reference instrument in the many published scientific papers, even the most recent ones [8,9]. All these measurement devices are operator-dependent with approximately 1 mm increments of precision. None of these requires standardization of limb position during measurements and do not take into account muscular relaxation of the patient's thigh thus likely to induce false negative results [10,11] and poor reproducibility [12,13]. Considering all these elements, we thus developed in 2005 the GNRB[®] a new testing apparatus for measurement of anteroposterior knee laxity.

The purposes of this study were:

- to compare the GNRB[®] with the KT-1000, healthy knees with intact ACL were tested by two operators at 134 N.
- to determine the threshold value of complete and partial ACL tears with the GNRB[®] at 134 N.

Material and methods

The GNRB[®]

The GNRB[®] is a knee laxity testing device for measurement of anteroposterior tibial translation at 20° of knee flexion thus reproducing the Lachman test position (Fig. 1). The patient is lying on a standard examination table in the supine position with the arms placed along the body, each knee being comparatively tested, the healthy knees are investigated first. The lower limb is placed in a rigid adjustable leg support, with the knee placed at 0° of rotation. The knee should be placed so that the inferior pole of the patella corresponds to the lower border of the patellar support, the joint line is palpated and should be located between the support and the jack. A linear jack (a 24 V power supply) exerts gradually increasing thrust forces according to the examiner: 67, 89, 134, 150 or 250 N on the upper section of the calf. Surface electrodes are placed on the posterior aspect of the thigh to control hamstring relaxation of the tested knee (feedback effect). A displacement transducer (0.1 mm precision) records the relative displacement of the anterior tibial tubercle with respect to the femur. Motion data obtained from the displacement transducer produce a force–displacement curve whose slope determines



Figure 1 Presentation of the GNRB[®].

the ligamentous elasticity. Data are collected on a distant PC. A laxity file is built up for each patient including measurement conditions (pressure applied to the thigh, thrust forces) and results (ligamentous elasticity curve, differential laxity). The whole device is microcalculator-driven in order to ensure measurement consistency and precision. In October 2007, we filed an international patent application to patent the GNRB[®].

Method

For GNRB[®] validation, a 134 N force was applied as for the KT-1000, but for study of ACL clinical ruptures, a maximum of 250 N force was applied, considering that a threshold value of 200 N was necessary to obtain a good measurement reproducibility for the injured knees [3,4].

Data collection

Between November 2006 and March 2007, two trained examiners (operator 1 with more than 15 years of experience with KT-1000, operator 2 with a 1-year experience) performed knee laxity measurements on 20 volunteer engineers aged 19–22 years with intact ACL or free of pain using the GNRB[®] and the KT-1000 arthrometers, laximeter and tested sides were selected randomly. A 67, 89 and 134 N force was applied with both devices. Measurements were repeated on several occasions (left and right sides were assessed on each occasion) by both examiners. Therefore, 308 pairs of measurements were recorded in 17 males and three females (series 1).

During 2007, the operator 1 evaluated a series of 21 chronic complete ACL disruptions (series 2a). Each knee was evaluated at least three times from an applied 0 to 250 N force, 143 measurements were thus analyzed. Fifteen males and six females of average age 26 years (range: 16 to 36 years) were included in this study group. All patients showed a soft-end-point Lachman test with a true positive pivot shift test and were operated on. Arthroscopically, ACL had completely disappeared from the intercondylar notch. During the same period, 24 partial ACL tears (series 2b), secondarily operated on, were studied following the same protocol. Each knee was evaluated at least three times by operator 1, 98 measurements were thus analyzed. Nineteen males and five females of average age 31 years (range: 15 to 59 years) were included in this study group. All patients showed a delayed firm-end-point Lachman test and an absent (seven cases) or mild (17 cases) pivot shift test. During operation, an isolated tear of the anterior bundle was observed in seven cases, an isolated tear of the posterior bundle in three cases and a slack cicatricial ACL in 14 cases. Meniscal lesions involved the medial meniscus in nine cases and the lateral one in four cases.

Statistics

In series 1, analysis of variance (the square of the standard deviation) was performed for each operator (1 or 2), measurement device (KT-1000 and GNRB[®]) and tested side (right or left). Interindividual residual variances (measure of the degree of data spread relative to the mean value) were compared in two using F-tests in order to evaluate differences in precision obtained for each configuration. In series

Table 1 Variance analysis of tibial translation measured with KT-1000 and GNRB at 134 N. Dispersion of the results is smaller with the GNRB[®] than with the KT-1000.

	KT-1000 variance (df)	GNRB [®] variance (df)	p _{method}
Operator 1	88.96 (135)	69.16 (130)	0.07
Operator 2	173.98 (143)	59.29 (144)	< 0.001
p _{operator}	< 0.001	< 0.17	

Variance: intraindividual residual variance i.e. residual sum of squares in analysis of variance. df: degree of freedom: number of degrees of freedom in the analysis of variance. p_{method}: significance of the method with fixed operator. p_{operator}: significance of the operator with fixed method.

2a and 2b, ROC curves were used and analyzed to define a "threshold value" for differential laxity between normal and injured knees at 134 N. The threshold value was chosen to provide a maximum sensitivity and specificity value, by including the greatest number of subjects.

Results

Series 1. Normal knees

Operator effect

A significant "operator effect" was observed at 134 N with the KT-1000 but not with GNRB[®], revealing a poor dispersion of values around the central tendency with GNRB[®] thus showing a good inter- and intraobserver reproducibility (Table 1). None of the operators could find similar measures with the KT-1000 arthrometer thus revealing a high dispersion of results and a poor reproducibility.

Method effect

A significant "method effect" (KT-1000 or GNRB[®]) was observed at 134 N with operator 2, the less trained operator (p < 0.001). For operator 1, the most experienced one, the method effect was at the limit for significance (p = 0.07) (Table 1). Data dispersion around the central tendency was thus lower with a trained operator for both methods but still remained inferior with the GNRB[®].

Side-effect

A "side-effect" (right or left knee) was observed at 134 N with the KT-1000 but not with the GNRB[®], whatever the operator (Tables 2 and 3). Results were side-dependent with the KT-1000, unlike the GNRB[®].

Mean differential displacement

Mean differential displacement between right and left knees, at 134 N was 0.8 mm (IC at 95%: 0.7–0.94 mm) for the GNRB[®] and 1.34 mm (IC at 95%: 1.1–1.56 mm) for the KT-1000 (p = 0.0001).

Series 2a. Complete ACL ruptures

A nonlinear elasticity curve was obtained which showed that cruciate ligaments exhibit a viscoelastic behavior (Fig. 2).

Table 2 Comparative analysis of variance for right/left knee translation under 134 N, measured with KT-1000. Dispersion of the measurements is high between both knees, whatever the operator.

	Right knee Variance (df)	Left knee Variance (df)	p_{side}
Operator 1	98.01 (60)	42.07 (60)	< 0.001
Operator 2	193.85 (63)	50.25 (62)	< 0.001
$p_{operator}$	0.004	0.25	

Variance: intraindividual residual variance i.e. residual sum of squares in analysis of variance. df: degree of freedom: number of degrees of freedom in the analysis of variance. p_{side} : significance of the method with fixed operator. $p_{operator}$: significance of the operator with fixed method.

Table 3 Comparative analysis of variance for right/left knee translation under 134 N, measured with GNRB®. Dispersion of the measurements is similar and nonsignificant, whatever the operator and the side.

	Right knee variance (ddl)	Left knee variance (ddl)	p_{side}
Operator 1	64.76 (57)	64.36 (57)	0.72
Operator 2	55.78 (68)	62.30 (59)	0.45
$p_{operator}$	0.49	0.33	

Variance: intraindividual residual variance i.e. residual sum of squares in analysis of variance. Ddl: number of degrees of freedom in the analysis of variance. p_{side} : significativity of the method with fixed operator. $p_{operator}$: significativity of the operator with fixed method.

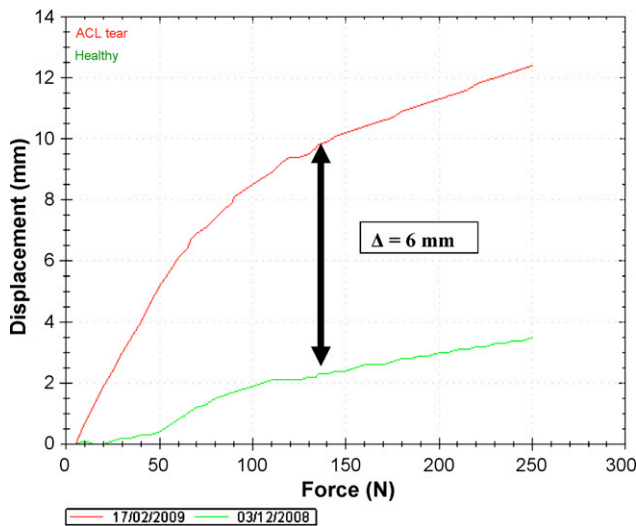


Figure 2 Complete ACL tear measured with the GNRB®. The green curve corresponds to the normal knee and the red one to the injured knee, differential laxity is 6 mm.

The diagnosis of complete tear could be confirmed if differential tibial translation at 134 N was at least of 3 mm with a sensitivity of 70% and a specificity of 99%, this threshold resulted in 88% of good-grade patients (Fig. 3).

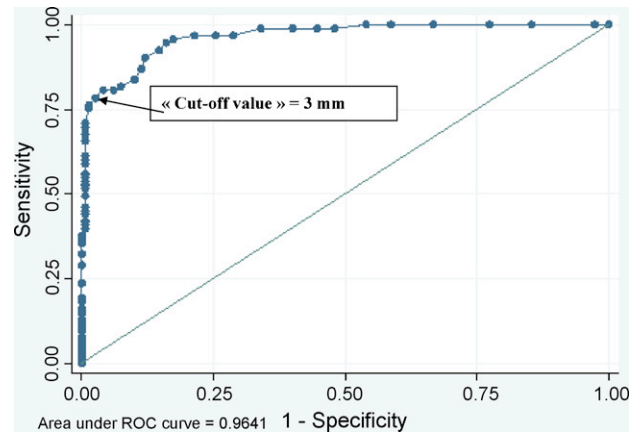


Figure 3 ROC curves for specificity and sensitivity of the GNRB® arthrometer in diagnosis of complete ruptures. The threshold level is 3 mm at 134 N (series 2a).

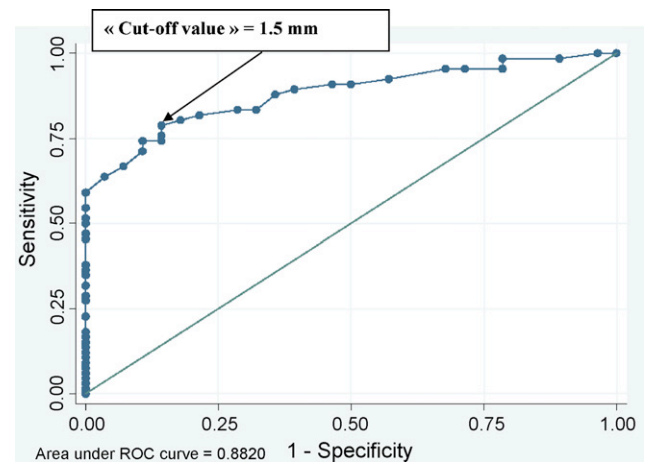


Figure 4 ROC curves for specificity and sensitivity of the GNRB® arthrometer in diagnosis of partial ruptures. The threshold level is 1,5 mm at 134 N (series 2b).

Series 2b. Partial ACL ruptures.

In partial ACL tears, a 1.5 mm differential laxity threshold value at 134 N providing a sensitivity of 80% and a specificity of 87% was retained as it permitted to include 81% of patients (Fig. 4). Fig. 5 illustrates comparative measurements of an isolated AM bundle tear and a normal knee.

Discussion

The Lachman test is a reliable clinical test for diagnosis of ACL rupture but quantification of anteroposterior tibial displacement still remains inaccurate [2]. It is only possible using a mechanical, radiographic or electromagnetic system. The KT-1000 arthrometer is probably the most widely used laximeter in the world and for that reason it was chosen for comparison with the GNRB®. Laximetry reproducibility is significantly better with the GNRB® than with the KT-1000 whatever the examiner’s experience. Arthrometric evaluation with KT-1000 instrumentation has been described in the literature to be highly reproducible with a 3 mm threshold

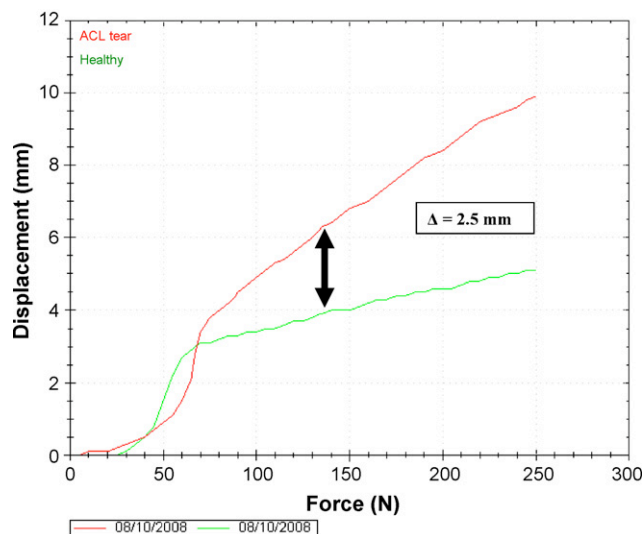


Figure 5 Partial ACL rupture (injury to the anteromedial bundle) measured with the GNRB[®]. The green curve reflects the normal ACL behavior and the red one the injured ACL. Differential laxity is 2.5 mm.

value at 134 N when used by an expert rater [5,10,14], but appears poorly reproducible with a novice rater [11]. The degree of error is equally due to both the subject relaxation condition and the quality of patient's positioning [16]. We have reported a poor KT-1000 reproducibility according to the tested side which correlates Sernert et al. [15] and Wiertsema et al. [2] results. The differences in translation between both normal knees of a single subject are related to the dominant arm of the examiner. The use of the KT-1000 may result in up to 50% of false negative results in some authors [17], mainly due to the subject involuntary or defensive hamstring contraction [5,18]. Daniel et al. have suggested that laxity measurements could be performed under general anesthesia [5]. When using the GNRB[®], there is a feedback control of the jack by the muscular activity and a lack of thrust force when the subject activity exceeds the threshold value of resting activity. Contrary to what some authors advocate [5,18], we believe that the patient's confidence is unreliable and insufficient particularly when a 250 N force is applied on a painful knee [19]. Electrically evaluated tibial translation during hamstring relaxation significantly increases the displacement value on either healthy or injured knees [16]. Knee positioning in neutral rotation is well standardized with the GNRB[®], malposition in internal rotation influences the KT-1000 results [1,20]. Hemarthrosis may induce false positive results with the KT-1000 and its evacuation is also advocated when using the GNRB[®] [21].

Our results demonstrate good reproducibility of the GNRB[®] measurements, whatever the operator's experience and the tested side which might be explained by the displacement transducer precision (0.1 mm) higher than that of the KT-1000 (1 mm), the rigorous patient positioning (neutral rotation of the knee, good control of the thigh pressure) and the muscular feedback control. Patient positioning and measurement takes approximately 2 to 3 min. The Rolimeter device is a laximeter which displays similar features and performances to the KT-1000 but can only provide a linear

measure using maximal manual force which we believe to be poorly reproducible [6].

The Telos device is widely used in Europe but provides a 0.5 mm precision, reports a false negative rate of 28% at 250 N [10], and its postoperative repeated use is not possible. Lerat et al. [22] has developed a static measurement device of anterior knee laxity using a comparative profile radiograph with a 9 kg load applied on the thigh. The differential displacement between the tibial plateau and the condyle of each compartment is measured. The threshold value for global pathological laxity or "cut-off point" is 6 mm for the medial compartment with an 87% sensitivity and a 90% specificity. Radiographic methods prove to be very useful preoperatively and help guide the surgical procedure [22] but appear irradiating, expensive and traces of each radiograph are poorly reproducible.

Electromagnetic measurement devices feature motion sensors positioned on a splint which is moulded to fit the contours of the thigh and leg, displacements being videotaped [1]. This is a very precise method (0.1 mm) in which reproducibility is similar to that of the KT-1000. All these systems are very dependent on the quality of patient's positioning and relaxation and the examiner's experience. Radiostereometric analysis (RSA) is used to determine the tibial relative microdisplacements with respect to the femur in laboratory but appears to be a quite invasive and noncomparative method in the clinical setting [17,23]. The recorded tibial translation measurements are inferior to that obtained with the KT-1000 arthrometer as it involves interosseous measures, independent from soft tissues [24].

Anterior displacement, when measured with the GNRB[®], takes into account the potential initial position in spontaneous posterior translation (absence of posterior cruciate ligament rupture), since we are unaware of the true neutral position of the tested knee. This reference position is supposed to be identical in both knees except in case of posterior cruciate ligament tear, and we analyse the difference in translation between the patient's injured and uninjured knees. The measured displacement in 0° of rotation is considered as an intermediate displacement between that of each medial and lateral compartment. Unlike the Lerat radiographic system, we are not capable of evaluating each compartment's specific displacement [22].

According to the findings of Markolf et al. [3], the "cut-off point" is at least 3 mm, with the knee at 20° of knee flexion and an applied force of 100 N. Therefore, sensitivity is 82% and specificity 88%. The differential laxity threshold value at 250 N was determined to be 3 mm for complete ruptures (sensitivity of 70% and specificity of 99%) and 1.5 mm for partial tears (80% sensitivity and 87% specificity). Bercovy and Weber [4], have determined the threshold value to be of 3 mm at 134 N with a sensitivity of 97% and a specificity of 80% using a radiolaximetry method. When considering a differential laxity threshold value of 3 mm at 134 N, Rangger et al. report a sensitivity of 100% for diagnosis of complete chronic ruptures using the KT-1000 [25], while Boyer et al. report a rate of 72% [10] and Isberg et al. a 50% rate [17]. As far as we know, we are the first to report a 1.5 mm threshold value for partial tears with an 87% specificity. These clinically assessed injuries (Lachman test with hard-end-point and pivot shift graded as absent or glide) are confirmed with the GNRB[®]. Accurate diagnosis of a torn ACL is of great

importance to provide the patient with comprehensive information and appropriately adapted care. Surgically treated patients presented with an isolated anterior bundle rupture (seven cases), a posterior bundle rupture (three cases) or a slack cicatrized ACL, nonanatomically reattached into the notch or to the posterior cruciate ligament. These injuries are considered as partial ruptures, especially on MRI reports, and might be symptomatic in pivot sports and associated with meniscal and chondral lesions. Their accurate diagnosis has fundamental implications for proper conservative or surgical treatment selection. Adachi et al. have suggested an ACL augmentation, by only repairing the torn bundle. Their results seem encouraging [26].

Conclusion

We have developed the GNRB[®], a new anterior knee laxity measurement device. The GNRB[®] reports various advantages compared with other currently available laximeters. Good control of limb positioning in rotation, recording of translation in the absence of hamstring contraction and compared with the KT-1000 arthrometer: reproducibility, constant thrust force, accuracy and automatic recording of measurements. The GNRB[®] might be used in diagnosis of partial and complete ACL tears and for clinical follow-up of operated or not ACL tears.

Conflicts of interest

I.R. and S.N. are co-inventors of the GNRB[®].

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