

Objective evaluation of anterior knee laxity; comparison of the KT-1000 and GNRB[®] arthrometers

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Abstract

Purpose Accurate measurement of laxity after anterior cruciate ligament (ACL) rupture is usually performed with the KT-1000 arthrometer, and reproducibility and reliability are discussed. A new arthrometer, the GNRB[®], has been recently developed in an attempt to improve intra- and inter-examiner reproducibility. The aim of this diagnostic study was to evaluate the intra- and inter-examiner reproducibility of the GNRB[®] and the KT-1000.

Methods Three protocols were designed to evaluate and compare the two arthrometers. Fifteen physiotherapists conducted tests on 15 subjects with healthy knees. The intra- and inter-reproducibility of the two tests were compared by analysis of variance and the *F*-test.

Results Measure reproducibility was significantly worst with the KT-1000 than with the GNRB[®] (machine effect, $P < 0.001$) regardless of operator experience. There was no significant difference between experienced and inexperienced examiners with the GNRB[®] (no ‘examiners effect’). Regardless of the machine, there was a ‘side effect’ with healthy knees.

Conclusion This clinical study demonstrates the superior intra- and inter-examiner reproducibility of the GNRB[®] over the KT-1000. There appears to be some technological

advantages to using the GNRB[®] including pressure control of the patella, accuracy of the displacement transducer, control of the load on the calf, and control of hamstring activity.

Level of evidence Diagnostic study, Level I.

Keywords Arthrometer · Laximeter · Anterior cruciate ligament rupture · KT-1000 · GNRB

Introduction

Intensive or occasional practice of a sport, especially one involving pivotal movement, carries the risk of rupture of the anterior cruciate ligament (ACL) of the knee. Diagnosis is based mainly on clinical examination (Lachman test, anterior drawer test, and pivot shift test) [22]. These tests have very different sensitivities and specificities depending on the experience of the examiner, the patient’s body type, and the delay between the accident and examination [3, 9]. They do not allow for quantitative comparison between subjects and testers since the results are qualitative.

Because of the subjective nature of the clinical examination, several authors have developed mechanical devices to more consistently quantify the anterior knee laxity by recording the movement of the tibia in relation to the patella, stabilized in the trochlear groove, the knee in 25° of flexion [8, 10, 27]. Among these, the KT-1000 (MED-metric, San Diego, CA, US), developed by Daniel et al. [9] the first and the most popular, is often cited in international publications. Several researchers have found the KT-1000 reliable and valid at 67, 89, and 134 N of force [1, 2, 9, 14, 15, 31]. However, this system has undergone other evaluations and appears to be poorly reproducible [16, 17, 30] and unreliable [7, 19]. Recently, a new arthrometer, the

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GNRB[®] (Genourob, Laval, France) was developed to alleviate the difficulties of using the KT-1000 with partially trained examiners. The arthrometer is powered and incorporates pressure and movement sensors facilitating more accurate measurements. Preliminary results with the GNRB[®] suggest that this device has better inter- and intra-observer reproducibility than the KT-1000 [26].

The aim of the current study was to assess the reliability of the GNRB[®] in comparison with the KT-1000 during tests carried out by examiners with varying levels of experience in an attempt to answer the following two questions: (1) Does the GNRB[®] give reproducible measurements? (2) Is the GNRB[®] examiner dependent?

Materials and methods

Arthrometers

In the KT-1000, the subject lies on their back with their knees kept flexed at approximately 25° by a support 11 cm high placed under the lower end of the thigh. The angle of flexion of the knee is different from one subject to another as it depends on the length of the lower limbs, but the platform ensures that it is identical for both of the subject's knees. A heel rest positions the two feet in external rotation of 15°–20°. This support does not at any time interrupt the automatic internal rotation of the tibia. The force plunger is positioned over the anterior tibial tubercle and secured with Velcro straps. The examiner exerts a steady pull via a force-sensing handle at three levels (67, 89, 134 Newtons (N)) indicated by an audio tone signal. At each stage, the relative anterior translation in millimetres is read on a dial [8]. According to the manufacturer, the accuracy of the KT-1000 is estimated to be 0.5 mm [9].

The GNRB[®] system is shown in 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 single thermoformed support, which does not pose any problem for the installation of different sized adult patients or variation in the positioning of the support. The knee is in neutral rotation so that the patella is facing anteriorly. The knee should be placed so that the inferior pole of the patella is covered by the lower border of the patellar support. This support exerts a symmetric pressure on the patella during the test, checked by a pressure control. The joint line is palpated and should be located between the thigh support above and the calf support below. An electric actuator (Linak, Nordborg, Denmark) exerts slowly (11 mm/s) increasing loads according to the examiner: 67, 89, 134, 150, or 250 N on the upper aspect of the calf. Surface (EMG) electrodes are

placed on the posterior aspect of the thigh to control hamstring muscle relaxation of the tested knee (feedback effect). In the case of hamstring activity, an alert appears on the screen and the operator can either keep or delete the record. If the knee is not painful, the load pressure does not provoke an abnormal reaction of the hamstrings, but if the knee is painful, the test is not done. A displacement transducer (the accuracy given by the company is 0.1 mm) (FGP sensor, Global Headquarters, Hampton, VA, US) records the relative displacement of the anterior tibial tubercle with respect to the patella. Testing is repeated on both knees, and the amount of tibial translation is compared between the 2 limbs. Motion data obtained from the displacement transducer produce a force–displacement curve. The displacement is plotted along the *X* axis and the *Y* axis for the force. The slope ($\mu\text{m}/\text{N}$) of the curve obtained determines the ligamentous elasticity of the patient's ACL. All the data are collected on a remote computer. A laxity file is built up for each patient including measurement conditions (pressure applied to the thigh, load forces) and results (the displacement–load curve, the side-to-side difference in mm and the slope in $\mu\text{m}/\text{N}$) [16].

Our testing procedure required three consecutive trials on each knee with an anterior force at each test up to 134 N, with both devices. The mean and standard deviation (SD) were calculated for the three trials.

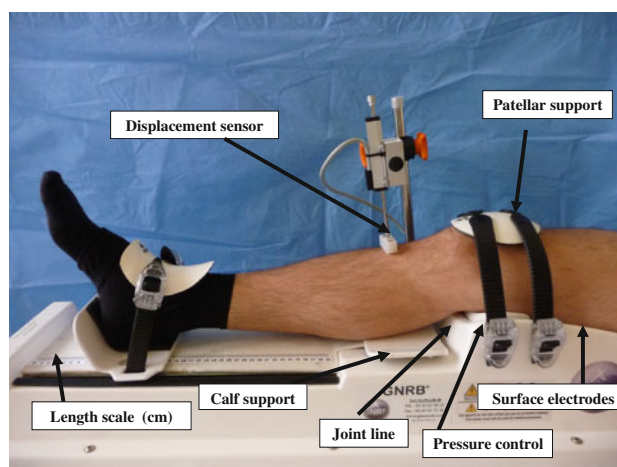


Fig. 1 The lower limb is placed in a single thermoformed support. The knee is in neutral rotation, so that the patella is facing anteriorly. The knee should be placed, so that the inferior pole of the patella is covered by the lower border of the patellar support. This support exerts a symmetric pressure on the patella during the test, checked by a pressure control. The joint line is palpated and should be located between the thigh support above and the calf support below. An electric actuator exerts increasing loads according to the examiner: 67, 89, 134, 150, or 250 N on the upper aspect of the calf. Surface (EMG) electrodes are placed on the posterior aspect of the thigh to control hamstring muscle relaxation of the tested knee (feedback effect). A displacement sensor records the relative displacement of the anterior tibial tubercle with respect to the patella

Examiners

Fifteen physiotherapists participated in the study. Prior to the study, all examiners attended an oral presentation and watched a demonstration of each device (positioning of the limb, and device starting procedure). “Experienced examiners” had used both instruments for more than 6 months on many different patients before the study. “Inexperienced examiners” did not practice before with both devices but attended the presentations and validated the procedure on both knees of 3 subjects, before starting. All the fifteen physiotherapists had validated their training.

Study participants

Fifteen young (19–27 years) students in physiotherapy volunteered as subjects, with healthy, pain free knees, and without history of present or previous knee injuries or surgery and were tested. All had a side-to-side anterior laxity inferior to 3 mm.

Study protocols

Three protocols were used to compare the intra- and inter-observer reproducibility of the two systems. All tests were performed during February 2009, in a room provided for the purpose in the physiotherapy centre at the hospital.

Protocol 1

Two experienced examiners E1 and E2 carried out multiple sessions using both devices. These sessions consisted of 3 consecutive trials every day for 10 consecutive days, on one subject (22-year-old man with healthy knees). Mean and standard deviations for each knee were calculated.

Protocol 2

Fifteen examiners performed one test session on a healthy 24-year-old man, using both devices. Seven of them were experienced, E1 to E7, and eight, E8 to E15, were not.

Protocol 3

Two examiners E3 and E8, (E3— experienced examiner with both devices and E8— inexperienced examiner with both devices) performed one test session on 15 healthy subjects (mean age 24 years) with the two devices.

All participants gave their informed consent, and the protocol was approved by the Establishment’s Ethics Committee. Each measurement of anterior displacement of the tibia from the patella (in mm) was made at a force of 134 N for each instrument.

Between each measurement, the patient and the device were checked to ensure that they were properly installed. Three tests were carried out on each knee, and the patient was repositioned exactly at the start of each new test. All patients moved from the table and performed five knee flexions between each test.

Statistical analysis

The factors of our statistical model were device, examiner, and side. The variations in measurements in different configurations (device, examiner, side) were studied through estimated residual variances in analysis of variance (ANOVA) taking into account the repetitions by adjustment. An “examiner effect” is an observed difference in results between 2 examiners when one knee is tested with the same device. A “side effect” is an observed difference in results between the 2 knees of the same subject tested by the same device. A “device effect” is an observed difference in results between the 2 devices testing the same knee by the same examiner. The tests focused on a comparison of residual variances of the models in pairs (e.g. comparison KT-1000 examiner E1 vs. KT-1000 examiner E2 for the “examiner effect” on KT-1000, comparison KT-1000 examiner E1 vs. GNRB[®] examiner E1 for the “device effect”, comparison of right and left side with examiner E1 for the “side effect”). A low scatter of measurements represents good reproducibility. The F-test was used to determine the degree of significance, with the threshold set at $P < 0.05$.

Results

No test had to be stopped due to pain. Among all the subjects examined, the side-to-side anterior laxity was inferior to 3 mm, whatever the device used, confirming that all knees were free from ACL rupture (Tables 1, 2, 3).

Protocol 1 (Table 1)

In a healthy subject, there was significantly less scatter of measurements ($P < 0.001$) with the GNRB[®] than with the

Table 1 Protocol 1 shows the results (mean \pm SD) of laxity measurements on a healthy subject by 2 experienced examiners E1 and E2 with the GNRB[®] and the KT-1000, on day 1 to day 10

| Examiner | Device | Right knee (mean \pm SD) (mm) | Left knee (mean \pm SD) (mm) |
|----------|-------------------|------------------------------------|-----------------------------------|
| E1 | GNRB [®] | 2.1 \pm 0.1 | 2.5 \pm 0.3 |
| E1 | KT-1000 | 2.3 \pm 0.3 | 2.7 \pm 0.4 |
| E2 | GNRB [®] | 3 \pm 0.5 | 2.4 \pm 0.4 |
| E2 | KT-1000 | 5.3 \pm 0.9 | 3 \pm 0.5 |

Table 2 Protocol 2 shows the results (mean \pm SD) of laxity measurements made by 15 different examiners (half were experienced E1 to E7 and half E8 to E15 were not) on the same healthy subject with the GNRB[®] and the KT-1000

| Examiner | Device | Right knee (mean SD) (mm) | Left knee (mean SD) (mm) |
|-----------|-------------------|------------------------------|-----------------------------|
| E1 to E7 | GNRB [®] | 0.6 \pm 0.3 | 0.6 \pm 0.2 |
| E8 to E15 | GNRB [®] | 0.8 \pm 0.3 | 1 \pm 0.3 |
| E1 to E7 | KT-1000 | 1 \pm 0.7 | 1.1 \pm 0.7 |
| E8 to E15 | KT-1000 | 2.4 \pm 0.7 | 2.2 \pm 0.5 |

Table 3 Protocol 3 shows the results (mean \pm SD) of laxity measurements made by an experienced examiner E1 and by an inexperienced examiner E8 on 15 different healthy subjects (S1 to S15) with the GNRB[®] and the KT-1000

| Examiner | Device | Right knee (mean SD) (mm) | Left knee (mean SD) (mm) |
|----------|-------------------|------------------------------|-----------------------------|
| E1 | GNRB [®] | 2.5 \pm 0.9 | 2.1 \pm 0.8 |
| E1 | KT-1000 | 2.6 \pm 0.8 | 3.7 \pm 1 |
| E8 | GNRB [®] | 2.8 \pm 1.3 | 2.3 \pm 0.7 |
| E8 | KT-1000 | 3.8 \pm 1.5 | 3.7 \pm 1.7 |

KT-1000, regardless of the examiner (E1 or E2), demonstrating the “device effect”. An “examiner effect” was observed on the scatter of measurements with the KT-1000 ($P < 0.05$) but not with the GNRB[®]. There was also less variation in measurements with the GNRB[®] ($P < 0.001$) irrespective of the side. A “side effect” was observed on the scatter of measurements with both devices, but this was less with the GNRB[®] ($P < 0.001$) than with the KT-1000 ($P = 0.04$).

Protocol 2 (Table 2)

There was significantly less variation in measurements obtained by the 15 examiners with the GNRB[®] than with the KT-1000 ($P < 0.001$). There was no “examiner effect” with the GNRB[®], but it was observed with the KT-1000.

Protocol 3 (Table 3)

Irrespective of the examiner, the measurements with the GNRB[®] were more reproducible. A significant “examiner effect” was observed with the KT-1000 ($P = 0.04$) but not with the GNRB[®]. In particular, the KT-1000 was less reproducible in the hands of an inexperienced examiner (E8) than with an experienced examiner (E1).

Discussion

The most important finding of the present study was that the GNRB[®], compared with the KT-1000, gave more

reproducible intra- and inter-examiner results over the 10-day testing period, regardless of examiner experience. The scatter of results around the mean was more significant with the KT-1000, and a “device effect” was observed with the KT-1000 but not with the GNRB[®]. A poor inter-tester reliability may result in false-negative tests because the difference between examiners can be greater than the patient side-to-side difference. Thus, it appears that the GNRB[®] can be used by any physiotherapist, subject to them having read the instruction manual, being assisted in setting up the device, and having completed a minimum of 3 tests under supervision, with no “examiner effect”. Both devices used the patella and the tibial tuberosity as reference points, and the patella has to be firmly attached, like in the GNRB[®] with a specific support. Our hypotheses regarding the GNRB[®] were confirmed: (1) the GNRB[®] gives reproducible measurements and (2) the GNRB[®] is not examiner dependent.

Our results in absolute value of the anterior laxity with both devices are inferior in this series in relation to other publications, but the side-to-side differences are similar with GNRB[®] and different with KT-1000 [15, 24]. Wroble et al. [31] found that to achieve optimal results, the KT-1000 should record paired differences as opposed to individual knee measurements. Myrer et al. [24] found a high anterior laxity intraclass correlation coefficient between tester (0.81–0.86) and within tester experienced or not (0.92–0.95). Several other studies concluded that good reproducibility was possible only if a well-trained examiner took the measurements [2, 4–7, 26, 28]. KT-1000 provides reproducible results when tests have been achieved by an experienced examiner and if the device is accurately positioned over the joint line. The KT-1000 remains a good screening tool for complete and chronic ACL rupture, but not for partial ACL tears [8, 11].

In healthy subjects, a “side effect” was observed with both the KT-1000 and GNRB[®], but better reproducibility was observed with the GNRB[®]. The “side effect” with the KT-1000 might be explained by a difference in traction force between the dominant and weaker side of the examiner [28].

For many authors, several factors have been reported to introduce measurement error in the use of the the KT-1000 [3, 8, 10, 14, 24]. It seems difficult to position the knee in an identical way in rotation between two examiners, and this may explain the poor inter-examiner reproducibility observed in this study. Controlling the amount of rotation of the foot has been suggested to improve the accuracy and reliability of the measures with the KT-1000. Mayr et al. [23] have developed a laximeter combining the KT-1000 with a device that exerts a torque of 2 Nm on the lower leg, either internally or externally. Thus, the rotation is imposed and identical for each test on the same subject but different

between 2 subjects. With KT-1000, the clamping of the leg, the amount of pressure on the patellar pad, and the direction in which and rate at which the force is applied are uncontrolled [8, 14]. Furthermore, the possible contraction of the hamstring makes for very variable elements from one measurement to the next, depending on the side, the day, and the examiner. Hamstring muscle activity that can decrease anterior translation is not controlled when using KT-1000. For some authors, the high false-negative rate (up to 50%) for detecting ACL rupture should be attributed to involuntary contraction of the hamstring tendons [8, 12]. The KT-2000 uses the same components as the KT-1000 with added feature of graphic documentation via an X–Y plotter [25]. No comparative trials have been undertaken to assess any advantage to the addition of the X–Y plotter [25]. Both devices KT-1000 and GNRB[®] require rigorous, symmetrical, and standardized positioning of the limb to ensure good reproducibility. The knee must be in neutral rotation since internal rotation reduces the anterior displacement and external rotation increases it [13, 26]. With the GNRB[®], the patellar clamp has to be positioned accurately; if too proximal the pressure will produce larger anterior translation, if too distal, translation will be smaller. Symmetric pressure on each patella controlled by a pressure sensor and identical length positioning of each limb controlled by a scale (Fig. 1) are both verified. The hamstrings muscles should be relaxed as revealed by inactivity of the surface sensors, if not the data are eliminated. There seem to be some technological advancements and clinical advantages to using the GNRB[®]: pressure control of the patella, accuracy of the displacement transducer, control of the load on the calf, and control of hamstring activity.

A number of other laximeters have also been developed. The Rolimeter is similar to the KT-1000 in its design and performance, but only allows recording of manual maximum traction, which is poorly reproducible. It is small, portable, simple to use but the displacements are measured at the end point of the tibial motion with relatively low resolution (± 1 mm). The Telos is widely used in Europe, but its accuracy is 0.5 mm, the false-negative rate at 250 N was 28% [7], and its repeated use post-operatively is impossible due to increasing exposure of the patient to radiation levels. Lerat et al. [21] have developed stress radiography for the anterior translation of the knee through a comparative lateral X-ray with 9 kg of passive constraint on the thigh. The differential displacement of the tibia with respect to the femoral condyles is measured. The threshold of pathologic laxity or “cut-off point” is 6 mm for the medial compartment, with a sensitivity of 87% and a specificity of 90%. Radiological methods are very useful pre-operatively and can guide the surgical procedure [21], but are costly, irradiating and the line traces on each X-ray are not reproducible. Electromagnetic systems rely on

sensors attached to tightly fitting splints on the thigh and leg where movements are recorded by a camera. This method is very accurate (0.1 mm), but its reproducibility is no better than the KT-1000, and it requires a metal-free environment and the routine presence of an engineer [5]. All these systems are highly dependent on the quality of limb installation, relaxation of the subject, and the experience of the examiner. Radiostereometric analysis (RSA) allows measurement of tibial micromobility relative to the femur in the laboratory but is invasive (Tantalum beads implanted in the cortices of the tibia and the femur) and clinically difficult to apply in order to compare the 2 knees [18, 20]. Recorded tibial translational measurements are lower than those obtained with the KT-1000 as they are inter bone and independent of soft tissue [29].

One limitation of these two devices is that they only measure translational displacement neglecting internal rotation (coupled rotation).

This study demonstrates the superior intra- and inter-examiner reproducibility of the GNRB[®] over the KT-1000 by a better control of the magnitude, direction and rate of force application, and the hamstring activity. Furthermore, the results are shown as a nonlinear displacement–force curve (elasticity) with the slope ($\mu\text{mm/N}$) related to the quality of the ACL (ACL healthy, incomplete or complete rupture) [26]. The price of each device with data output (KT-2000 and GNRB[®]) advertised on the Internet shows no significant difference.

Based on these results, it appears that the new GNRB[®] system can be used not only for diagnosis and monitoring complete and partial tears of the ACL, but also in the assessment of ACL reconstruction.

Conclusion

This clinical study demonstrates the superior intra- and inter-examiner reproducibility of the GNRB[®] over the KT-1000. Additionally, the GNRB[®] is not examiner dependent.

Conflict of interest The authors have no potential conflict of interest.

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