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Anterior knee translation measurements after ACL reconstruction are influenced by the type of laximeter used

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Abstract

Purpose Laximeters were designed to diagnose an anterior cruciate ligament (ACL) deficient knee, but their use has now focused on providing an objective assessment of the anterior translation (AT) of an intact and ACL-reconstructed knee. In this study we report the introduction and direct comparison of an automated and computerized AT measurement device, GNRB, with the device previously established by the institute and as the current literature standard, the KT1000.

Methods A prospective data collection was commenced upon introduction of the GNRB. The measurements of AT in each patient were performed by the same investigator with each device using 134 N applied to both knees, giving a side-to-side difference. The investigators were a sport scientist, a biomechanical engineer and a physiotherapist. Increased AT was defined as a difference > 3 mm.

Results Three investigators performed the measurements in 122 patients, 9.8 ($\pm$ 1.8) months after ACL reconstruction. Mean AT of the healthy knee was 5.7 mm with KT1000 and 4.4 mm with GNRB ($p = 0.002$). Mean AT of the ACL reconstructed knee was 7.0 mm with the KT1000 and 5.3 mm with the GNRB ($p = 0.037$). The KT1000 had a higher variance of results than the GNRB ($p < 0.001$). There were 25 patients with increased AT measured by KT1000 compared with 12 patients using the GNRB ($p < 0.016$), with only 5 on both devices.

Conclusions GNRB has better consistency of results when compared to the KT1000. Both devices lack comparability for detecting increased AT, with the KT1000 recording a side-to-side difference of more than 3 mm in twice as many patients as the GNRB.

Level of evidence II.

Keywords Anterior cruciate ligament · Knee · Laxity · Laximetry · Laximeter · KT1000 · GNRB

Introduction

Rupture of the anterior cruciate ligament (ACL) is one of the most frequent injuries in sport and the most common knee ligament injury [6]. Historically, laximeters were introduced to diagnose ACL disruptions [5]. Since their introduction

in the 1980′s, KT1000 (Medmetric, San Diego, CA, USA) became the most commonly used laximeter. Its indication has evolved to become the main objective measurement of anterior tibial translation, to assess knee laxity after an ACL reconstruction (ACLR) [23]. Some authors still regard it as the "gold standard" [17], whilst others find it to be less reliable than a Lachman test [27] or even claim that the device is inaccurate. This questions its use as an accurate objective measure of anterior tibial translation [7].

In 2009 an alternative to KT1000 called GNRB (Genourob, Laval, France) had its first clinical validation study [16]. The main criticisms of KT1000 were the induction of false negative results due to muscular relaxation of the patient's thigh and poor reproducibility [16]. In a validation study [16], the GNRB outperformed KT1000 in inter- and intra-observer reproducibility and overall showed significantly less variance in results in the analysis of an intact or

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chronically ruptured ACL. Even in a setting with different examiner experience with GNRB and KT1000, GNRB has been reported to have more consistent results [4]. GNRB has also shown more reliable results compared to stress radiography [8] and navigation [9]. A recent study has compared four laximeters and has shown KT1000 and GNRB to be comparable for quantifying anterior tibial translation in patients with a ruptured ACL [15]. Current literature on GNRB is limited to healthy knee [4, 9, 16], ruptured ACL [9, 11] or ACLR at time zero [8].

The purpose of this study was to compare the results of the KT1000 and GNRB over an extended time period in a clinical setting with patients who have undergone ACLR. Given the current literature, it was hypothesised that the GNRB would show less variance in measurements. This is the first study where these two devices were directly compared in a clinical setting as a part of a return to sport assessment.

Materials and methods

Surgical information and rehabilitation

Ethical approval for the prospective data collection was obtained from the North Sydney Local Health District (HREC/17/HAWKE/140). All ACL reconstructions were performed by one of three knee fellowship trained surgeons. International Knee Documentation Committee (IKDC) score was collected preoperatively and at follow-up. Two surgeons were using adjustable suspensory fixation for femur and the tibia using a semitendinosus graft. One surgeon was using suspensory fixation on the femur and a bioresorbable screw and sheath for the tibial fixation with a semitendinosus and gracilis graft. All patients underwent the same postoperative rehabilitation protocol, Online Appendix 1. Any issues that might have occurred during the rehabilitation were reported to the practice. The patients underwent a comprehensive return to sports (RTS) assessment at 9 months, during which the measurements were taken. Before the RTS assessment, the patients were examined by the consulting orthopaedic surgeon. If deemed clinically stable and if no issues occurred during the rehabilitation period, the patient underwent the RTS assessment. The results of the RTS assessment were then discussed with the patient by the operation surgeon.

The devices and measurements

The KT1000 (Fig. 1) was introduced to the Institute in September 2002 as a part of the pre- and postoperative assessment of patients undergoing ACLR, with an additional unit added in 2010. The GNRB (Fig. 2) was introduced in December 2017. On-site training for the GNRB
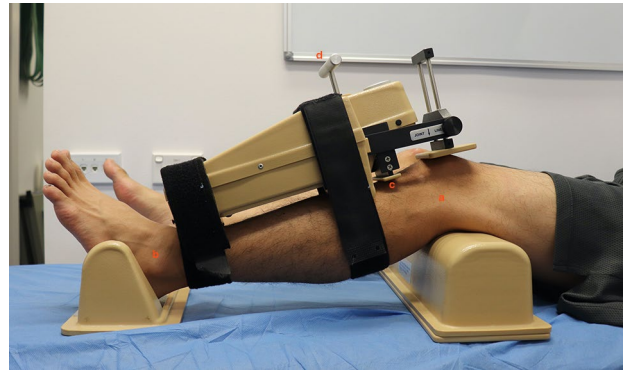

Fig. 1 The KT1000 measurement set-up. The knees were flexed to 30° (**a**), the ankle was internally rotated to 15° (**b**), the force plunger was seated on the tibial tubercle (**c**) and lever arm used to exert the correct force (**d**)

Fig. 2 The GNRB measurement set-up. All straps were securely fastened (**a**), the sensor was placed perpendicular to the tibia (**b**) and the sequence was run

was performed for all investigators by the manufacturer. As a new institute instrument, the GNRB required validation in this clinical setting against the well-established KT1000 [10], and by comparison against historical related literature. During the study period, the investigators were research assistants with a higher degree in sports science, biomechanical engineering in 2 instances and a physiotherapist.

Initial examination measured and recorded the range of motion of each leg, including the ability to normally hyperextend both knees symmetrically.

Regarding the KT1000, the measurements were performed following the manufacturer's instructions and a verified protocol [2] with the patient supine, with both knees flexed to 30°, verified with a goniometer. The ankles were held in external rotation of 15°–20°. The force plunger was positioned over the anterior tibial tubercle and secured with Velcro straps. The KT1000 was recalibrated to zero before force application. The investigator exerted a steady pull via a force-sensing handle at 134 Newtons (N) indicated by an

audio tone signal. At each stage, the anterior tibial translation in millimetres was read on a dial and documented. Each force level was repeated three times and a mean was taken as the final value. Measurements were repeated if it was felt that a patient demonstrated muscle contraction.

Regarding the GNRB, the measurements were taken according to the manufacturer's guidelines. The knee was placed in the centre of the support with the patella secured and the foot placed on the adjustable foot-rest. A pen was used to mark the position of the patella and the tibial tuberosity. After adjusting the height of the patella in the centre of the rotula and the foot in the footrest, the buckles were fastened. The support-foot base-foot distance measurements were taken and recorded. The sensor was then placed perpendicular to the tibia at the height of the marked tibial tuberosity and fixed into place. The aimed patellar pressure was minimum of 60 N. Finally, after all of the buckles were fastened the measuring sequence was run. The sequence for measurements was 1 and 3 pushes at 134 N. The average of the second 134 N sequence was documented.

The difference between the healthy and the injured leg was calculated. The threshold was set at 3 mm as this value has been previously used as a clinically significant amount of increased anterior laxity [16, 23].

Patient enrollment

Patients performing RTS after ACLR commencing January 2018 were prospectively enrolled and eligible for the study (Fig. 3). Measurements were routinely taken for the healthy leg first and then for the ACLR leg. Exclusion criteria were measurements taken by an investigator performing less than 10 measurements in the first year, and patients with bilateral ACL injuries or reconstructions.
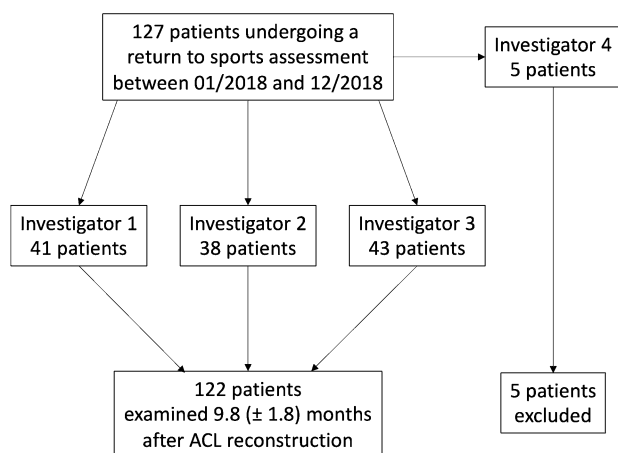

Fig. 3 Patient flow chart

Statistical analysis

Based on the results from a comparison by Colette et al. [4], 22 measurements per investigator would be sufficient to achieve a 0.9 beta with an alpha of 0.05. The post-hoc power analysis, calculated based on the results of this study, found 36 patients investigated with both devices to be sufficient to achieve a 0.9 beta with an alpha of 0.05. Comparison pairs were the healthy leg and the reconstructed leg, measured with both machines set at 134 N. The measurements were compared using analysis of variance. Bland–Altman plots were created for testing the agreement between machines. The consistency between the measurements was calculated using Pearson correlation. Each device's ability to detect a 3 mm side-to-side difference was compared using Fisher's Exact Test. The IKDC scores were compared using independent t test and the correlation between IKDC scores and measurements using Pearson correlation. Statistical significance was set at $p < 0.05$. Statistical analysis was performed in SPSS 24 (IBM, Armonk, NY, USA).

Results

A total of 127 patients were eligible for the study. After clinical examination, all patients were deemed clinically fit for the RTS assessment. The RTS assessment was performed after a mean of 9.8 (± 1.8) months after ACL reconstruction. The measurements were performed by 4 investigators. Investigator 1 performed measurements in 41 patients, Investigator 2 in 38 patients, Investigator 3 in 43 patients and Investigator 4 in 5 patients. Measurements taken by Investigator 4 were excluded giving 122 sets of measurements. Mean patient age was 27.4 years (± 10.0). Mean BMI was 24.0 (± 4.5). There were 53 women and 69 men. Mean preoperative IKDC score was 46.2 (± 15.1). Mean IKDC score at follow-up was 80.9 (± 10.6), with the improvement being significant ($p < 0.001$).

Mean laxity of the healthy leg was 5.7 mm (± 1.8) measured with the KT1000 and 4.4 mm (± 1.7) measured with the GNRB ($p = 0.002$), shown as scatter plots in Fig. 4. Mean laxity of the ACLR leg was 7.0 mm (± 2.0) with the KT-1000 and 5.3 mm (± 1.7) with the GNRB ($p = 0.037$), shown as scatter plots in Fig. 5. The variance of the KT1000 measurements was higher than of those with the GNRB ($p < 0.001$). The Pearson correlation coefficients between the two machines were 0.378 for the healthy and 0.373 for the ACLR leg. The Bland–Altman plots of the healthy and the ACLR legs are shown in Figs. 6 and 7. Even with wide confidence intervals, there are differences between measurements that are outside of this interval, rendering any comparison between the devices virtually impossible.

Fig. 4 Scatter plot of healthy leg anterior laxity measurements, absolute GNRB values in mm in blue and KT1000 values in green. Notice the higher scattering of GNRB values on the lower end of the scale
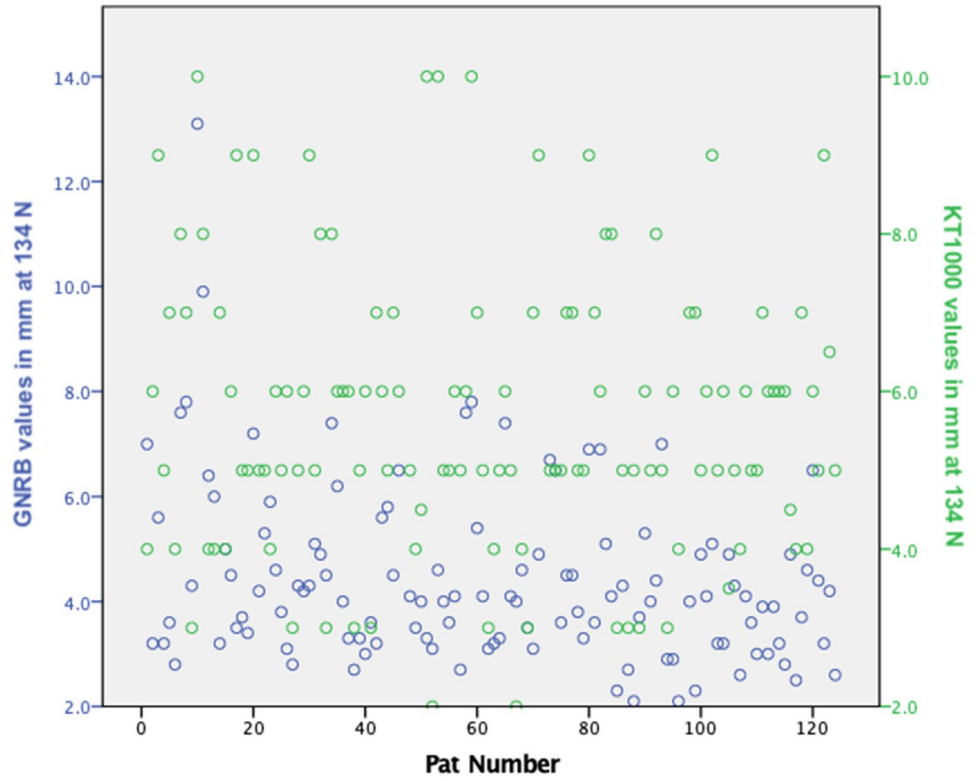
Fig. 5 Scatter plot of injured leg anterior laxity measurements, absolute GNRB values in mm in blue and KT1000 values in green
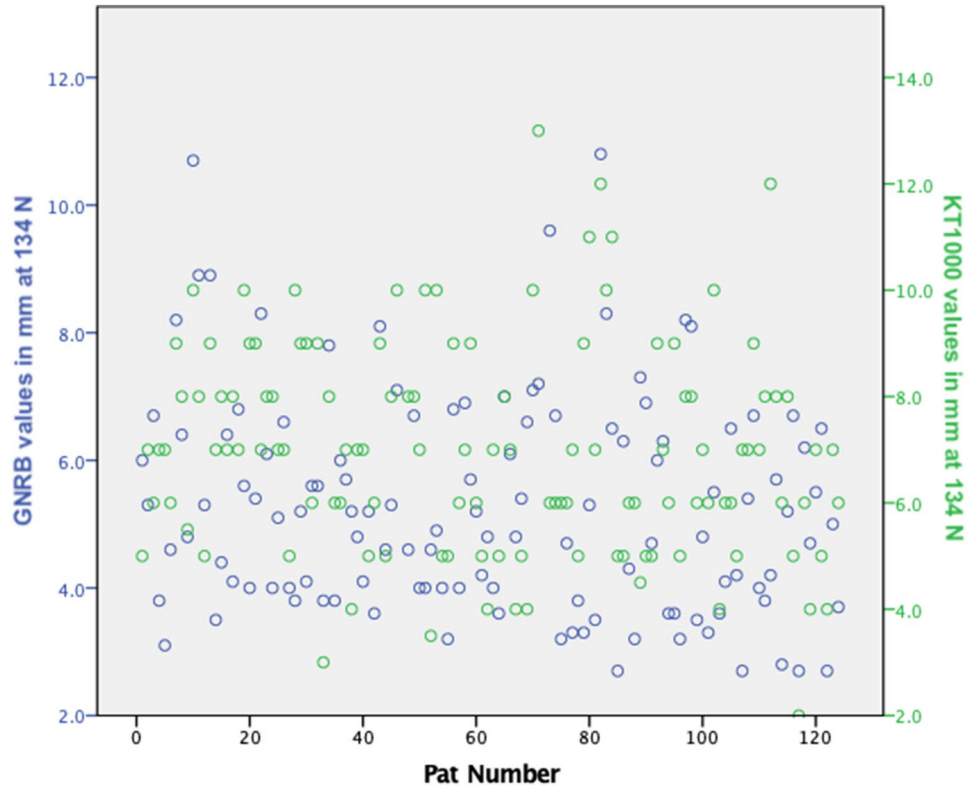
Fig. 6 Bland–Altman plot of healthy leg laxity measurements. The solid line is the mean difference between measurements performed with each, for a single patient. The area between the dotted lines is the confidence interval of the difference between measurements
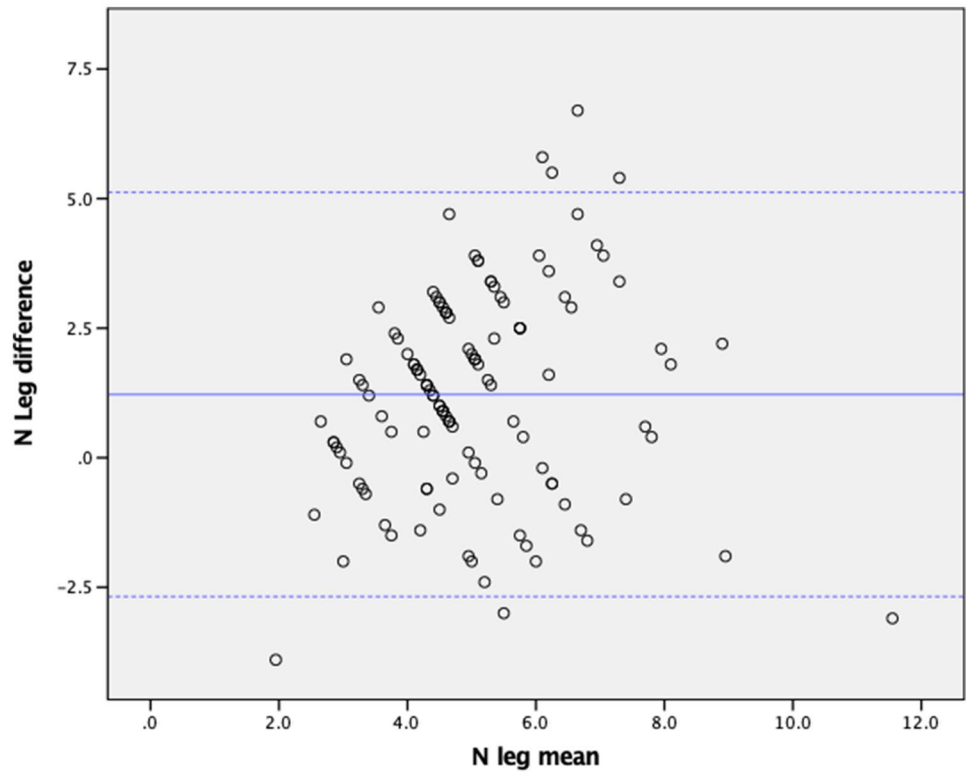

Fig. 7 Bland–Altman plot of injured leg laxity measurements. The solid line is the mean difference between measurements performed with each, for a single patient. The area between the dotted lines is the confidence interval of the difference between measurements
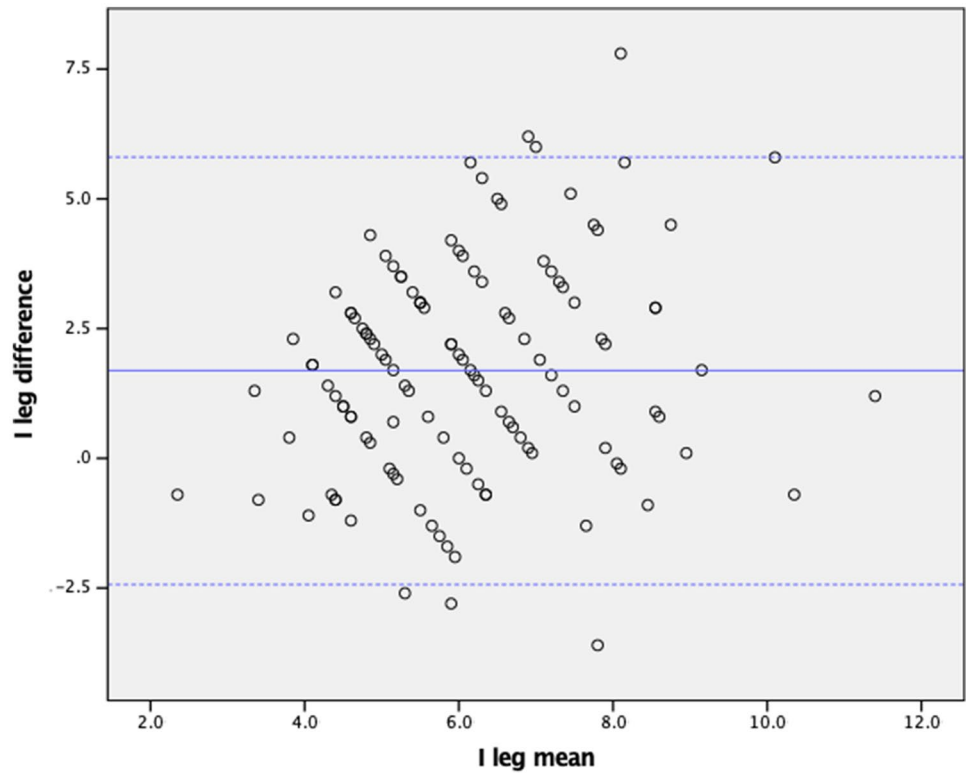

There were 25 patients (20.5%) diagnosed with a side-to-side difference > 3 mm using the KT1000, compared with 12 patients (9.8%) with the GNRB ($p < 0.016$). Only 5 patients (4.0%) had a > 3 mm side-to-side difference detected by both devices. IKDC at follow-up had no correlation to the measurements with the KT1000 (ns).

Discussion

The most important findings of the present study are higher readings in both the healthy and the injured leg, higher variance between readings, and twice as many patients with increased anterior laxity measured with the KT1000, when compared to the GNRB. There was a low level of agreement between KT1000 and the GNRB in measuring anterior translation after ACL reconstruction.

Even though the KT1000 was primarily designed for diagnosing an ACL rupture [5], and some studies are still validating laximeters as a diagnostic tool for ACL tears [1, 11, 12, 16, 18], the role of these devices for diagnosis alongside modern techniques such as MRI is diminishing [9, 22].

The clinical role of these devices in ACL reconstructed knees in some studies used a threshold of > 3 mm difference between the healthy and the reconstructed knee as a clinically significant amount of increased anterior laxity [16, 23]. More recent studies used these devices as an additional tool to measure the difference as a continuous variable [3, 19, 21, 26, 28]. A threshold was not used. The means and standard deviations vary greatly, and again cannot be compared between the studies even when using the same laximeter.

A comparison between KT1000 and GNRB has been performed previously. Collette et al. recruited 15 physiotherapists to perform measurements on 15 healthy individuals [4]. Over a 10-day study period, the GNRB delivered more consistent inter- and intra-examiner results than the KT1000. After reading the instruction manual, receiving assistance with the set-up and performing 3 tests under supervision, the authors observed no variation in measurements for the same individual by other examiners, the "examiner effect". This study was specifically designed only to perform a set of measurements with the two devices with multiple trials per day but for 10 days only. The role of the spacing effect in this setting is unclear [20]. However, these measurements were not taken in a typical clinical setting. It is more valid to take measurements at a useful time point in patients who have had an ACLR and want to return to sport, and this clinical environment also allows a direct comparison with the healthy knee.

Murgier et al. [15] accounted for some of these limitations comparing four different devices on injured individuals. The authors found the highest comparability between KT1000 and GNRB, with the other two devices being Telos (Telos GmbH, Laubscher, Hölstein, Switzerland) and Rolimeter (Aircast Europa, Neubeuern, Germany). The authors state that equal forces were used, 200 N for GNRB, 25 kPa for Telos and maximum manual force applied by one surgeon for KT1000. Since it has been

shown that one hand pull strength for men is on average around 300 N [13], this comparison raises some questions as this threshold cannot be reached in some injured patients [25]. Klouche et al. demonstrated that applying 250 N does not seem to be useful [11] at least for diagnosing an ACL rupture, and Vauhnik et al. performed a study on 27 patients with 250 N also finding the inter-rater reliability to be low [24]. Contrary to this, Lefevre et al. [12] found the best results for diagnosing a rupture was with GNRB set at 250 N and recommended a difference of 2.5 mm as a threshold.

Two recent studies from the same authors compared GNRB to a navigation system as a reference [8, 9]. In this cadaveric study, the amount of anterior tibial translation measured by the GNRB using 4 forces was compared to the measurements with navigation without a statistically significant difference, and good correlation [9]. This demonstrated that the GNRB accurately measures the anterior tibial translation in a controlled setting. In the second study, when comparing patients under general anaesthesia, GNRB at 250 N was compared to stress radiographs where the force was calibrated with the KT2000 (Medmetric, San Diego, CA, USA), an updated KT1000 which has the additional option of printing results, and found no difference [8]. The GNRB and KT2000 were then compared to a navigation system where force was manually applied and not controlled for. The authors conclude that the GNRB is as reliable as stress radiography. It is unclear why the KT2000 values were not reported, given the fact that it was used to exert force for anterior translation.

Robert et al. [16] found the GNRB to be more reproducible, irrespective of the examiner's experience level for both the healthy and torn ACL. Vauhnik et al. [25] performed a study on 13 individuals and found the relative reliability of the GNRB to be 2–3 mm. Their normative data on 23 patients, which was the second part of this study, at 134 N are higher than in our study's healthy leg population. Even for an automated arthrometer, that controls more variables than a purely manual arthrometer, there still seems to be some variability in the set-up since the baseline characteristics of our demographics and that from Vauhnik et al. and other studies are similar. One of the potential explanations for this is the fact that different patellar pressures during measurements significantly affect the translation measurements. Mouarbes et al. [14] overall had lower translation measurements than our study. They tested the measurements with 2 pulling forces using the GNRB (134 N and 200 N) and different patellar pressures (75–90 and > 90) and found the change in patellar pressure to powerfully impact the measurements. They conclude that reproducibility, even in optimal testing conditions, with one examiner, is poor. The study did not perform a correlation analysis of patellar force and laxity measurements, but higher patellar force had lower

readings. As we aimed for a consistent patellar pressure of 60 N, this lower force could explain the higher laxity measurements observed in our study.

One of the more important applications of these devices is the ability to detect a side to side difference with a certain threshold [23]. When the results of these two devices in this study were reviewed, not only was there a difference in the number of patients with anterior laxity but also a different mix of patients. With only 5 of the 25 patients with anterior laxity in the KT1000 also being confirmed with the GNRB, and an additional 7 patients with anterior laxity in the GNRB that wasn't detected with the KT1000. These results demonstrate that the two devices used in this clinical setting are not comparable. They currently provide the best objective measure of anterior laxity but given these findings, their use as a single outcome measure should be guarded and should be recorded in combination with other outcome measures. It should also be noted that the sagittal linear anterior stability is not the only goal in ACLR. Restoration of anterolateral rotational stability plays an additional key role due to its association with optimal patient outcome [29].

Some limitations need to be noted. Intra-observer reliability was not performed since each patient received only one set of measurements. Consistency of measurements with the GNRB is therefore not yet possible in our setting. Muscle contraction, which could influence the translation results, were not controlled for using surface electromyography. In an ideal setting, this would be a part of the measurement, but this is not standard practice in any of the validated protocols and is not the manufacturer requirement.

Conclusions

This study demonstrates better consistency of results with the GNRB when compared to the KT1000. Both devices lack comparability for detecting increased anterior laxity, with the KT1000 recording a side to side difference of more than 3 mm in twice as many patients as the GNRB.

Compliance with ethical standards

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