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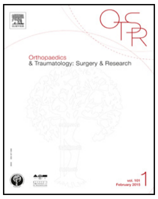

Original article

Comparative reproducibility of TELOS^{TM} and GNRB$^{®}$ for instrumental measurement of anterior tibial translation in normal knees

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ABSTRACT

Background: TELOS^{TM} is among the reference tools for the instrumental measurement of anterior tibial translation during the initial work-up and follow-up of patients with injuries to the anterior cruciate ligament (ACL). GNRB$^{®}$ is a non-irradiating but recently developed tool for which only limited data are available.
Hypothesis: The GNRB$^{®}$ offers better reproducibility than TELOS^{TM} for measuring anterior tibial translation without rotation in normal knees.
Material and methods: We retrospectively evaluated instrumental laxity measurements in normal knees. Data were available for 60 TELOS^{TM} measurements (9 kg load) and 57 GNRB$^{®}$ measurements (89 N and 134 N loads). For each instrument, we compared the absolute variation in anterior tibial translation between two measurements performed 6 months apart. For each GNRB$^{®}$ measurement, patellar pressure was recorded.
Results: No significant differences were found between mean (± SD) variations in translation between the two instruments. A greater than 2.5 mm variation between the two measurements was significantly more common with TELOS^{TM} than with GNRB$^{®}$ ($P < 0.05$, Chi^2 test). GNRB$^{®}$ translation values did not correlate with patellar pressure.
Discussion: The GNRB$^{®}$ device offers greater reproducibility than TELOS^{TM} when used to quantitate anterior tibial translation. The limited sample size may have prevented the detection of a significant difference between mean values. In addition, disadvantages of the TELOS^{TM} include radiation exposure of the patient, operator-dependency of measurements made on the radiographs, and absence of a biofeedback system to limit hamstring contraction. GNRB$^{®}$ does have hamstring contraction biofeedback control but uses another parameter, namely, patellar pressure, for which the optimal value is unknown. Quadriceps and hamstring co-contraction induced by excessive patellar pressure may influence anterior tibial translation. The optimal patellar pressure value needs to be determined.
Level of evidence: IV, retrospective study.

1. Introduction

Manual assessment of anterior tibial translation, although simple, is subjective and lacks precision [1,2]. The decision to perform reconstruction of the anterior cruciate ligament (ACL) rests not only on the presence of function-impairing knee instability, but also on age, the nature and level of sporting activities, time since injury, degree of laxity, whether the menisci or cartilage are damaged, and each patient's social and occupational requirements [3]. Thus, laximetry instruments are not sufficient to make surgical decisions. Nevertheless, they serve as a complementary decision aid, and instrumental measurement of anterior tibial translation is a major component of the initial evaluation and follow-up of cruciate ligament injuries. Laximetry serves three purposes: diagnostic, therapeutic, and prognostic. [4,5]. TELOS^{TM} (Telos GmbH, Laubscher, Holstein, Switzerland) has gained widespread acceptance for obtaining stress radiographs but requires patient exposure to radiation. GNRB$^{®}$ (Genourob, Laval, France) is a non-irradiating device that was developed more recently and has therefore been less extensively studied. We are not aware of any studies comparing the GNRB$^{®}$ and TELOS^{TM} devices for measuring normal knee laxity.

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Our objective here was to compare the reproducibility of the GNRB® and TELOS™ devices for measuring anterior tibial translation without rotation in normal knees. Our working hypothesis was that the GNRB® offered better reproducibility than the TELOS™. As the optimal patellar pressure for GNRB® measurements in unknown, we assessed potential correlations between translation and patellar pressure values.

2. Materials and method

We conducted a retrospective clinical study of two patient cohorts assessed sequentially, 60 using the TELOS™ and 57 using the GNRB®. All measurements were made on normal knees, at the orthopaedic department of the sports medicine centre in Bordeaux-Mérignac (Mérignac, France). As part of the pre-operative work-up before ACL reconstruction, instrumental measurements were obtained for both the injured knee and the normal knee of each patient. The measurements were repeated 6 months post-operatively to assess the effectiveness of surgery in controlling knee laxity. Thus, for the normal knee in each patient, we had a pre-operative value (T1) and a post-operative value (T2). An at least 6-month interval between the T1 and T2 measurements was required. We excluded patients with a past history of surgery or trauma or with abnormal laxity of the uninjured knee; patients with patellar pressure values lower than 30 N at T1 and/or T2; and patients with a greater than 40 N difference between the T1 and T2 measurements. Thus, 11 patients were excluded from the analysis.

The 60 pairs of TELOS™ measurements were obtained in patients who underwent surgery between March and July 2010. The patient was lying on the side with the knee flexed at 20°. Two lines were defined: the line tangent to the posterior edge of the medial femoral condyle and perpendicular to the line tangent to the medial tibial plateau; and the line tangent to the posterior edge of the medial tibial plateau and perpendicular to the line tangent to the medial tibial plateau [5–7]. The distance between these two lines was measured by a single observer (NB), with 0.1mm precision, using Carestream® software (Carestream Health, Rochester, NY, USA), with a 9 kg (88.2 N) posterior-anterior thrust force applied to the tibia.

The 57 pairs of GNRB® measurements were from patients who had surgery between March and September. The patient was supine with the knee flexed at 20°. Thrust forces of 89 N and 134 N were applied gradually, and anterior translation of the anterior tibial tubercle was measured. The mean translation values were computed for each thrust force value. For each measurement, the pressure applied by the GNRB® to the patella was recorded in N. The patellar pad was positioned as recommended by the manufacturer to immobilise the patella while allowing tibial translation. The biofeedback electrode available to encourage hamstring relaxation was not activated. The normal knee was assessed before the injured knee. Measurements were obtained by the same independent observer, who used the GNRB® device daily.

For each patient, we recorded the following data: side of the normal knee, age, gender, body weight, height, and body mass index (BMI). These data were compared between the two cohorts.

2.1. Statistical analysis

All variables were normally distributed (Kolmogorov Smirnov test), and parametric tests were therefore chosen. Student's *t* test for paired data was used to compare the two cohorts and the two series of measurements (T1 and T2) obtained with each device. To compare the mean absolute variations from T1 to T2 between the two devices, we used the multiple Student's *t* test with Bonferroni's correction, which set the *P* level for statistically significant differences at 0.0163.

Table 1
Mean anterior tibial translation values in mm.

	T1	T2	*P* value
TELOS™	−1.76 ± 0.33	−1.79 ± 0.4	NS
GNRB® 89 N	3.43 ± 0.19	3.97 ± 0.2	0.007
GNRB® 134 N	4.86 ± 0.23	5.67 ± 0.25	0.002

T1: pre-operative measurement; T2: measurement at least 6 months after surgery; NS: non-significant.

To detect a difference ≥ 0.3 with 80% power, 60 patients were required in each group. Absolute differences between two measurements ≥ 2.5 mm were considered excessive. We therefore dichotomised the absolute difference based on this value (< 2.5 mm and ≥ 2.5 mm). The percentages of values ≥ 2.5 mm obtained with each device were compared using the Chi^2 test. Linear correlation analysis was performed between patellar pressure with the GNRB® and anterior tibial translation.

Statistical analyses were performed using JMP 7.0.1 software (SAS Institute, Cary, NC, USA). Values of $P \leq 0.05$ were considered significant.

3. Results

3.1. Characteristics of the two cohorts

The 60 patients in the TELOS™ cohort had a mean age of 31.9 ± 11.1, a mean body weight of 71.7 ± 12.9 kg, a mean height of 174.6 ± 8 cm, and a mean BMI of 23.4 ± 2.9 kg/m^2; 68% were male, and in 52% the normal knee was on the right side.

The 57 patients evaluated using the GNRB® device had a mean age of 29.8 ± 10.6 years, a mean body weight of 73.6 ± 12.5 kg, a mean height of 174.7 ± 9.7 cm, and a mean BMI of 24 ± 2.6 kg/m^2; 72% were male and 51% had a normal right knee.

No statistically significant differences were found between the two cohorts for any of these variables.

3.2. Comparison of mean values at T1 and T2 with each device

Mean values obtained at T1 and T2 were not significantly different with the TELOS™ device (Table 1). With the GNRB® device, the mean values recorded at T2 were significantly higher with thrust forces of both 89 N ($P < 0.01$) and 134 N ($P < 0.01$) (Table 1).

3.3. Comparison of absolute variations from T1 to T2 between the two devices

With the TELOS™, the mean absolute T1-to-T2 variation in translation values for normal knees was 1.68 ± 0.2 mm (range, −6 to +4 mm). Corresponding values with the GNRB® were 1.25 ± 0.14 mm (range, −2.4 to +4.3 mm) for a force of 89 N and 1.62 ± 0.19 (range, −2.8 to +4.5 mm) for a force of 134 N. These mean absolute variations were not significantly different between the two devices: TELOS™ vs. GNRB® 89 N, $P = 0.08$; and TELOS™ vs. GNRB® 134 N, $P = 0.82$. Neither was there a significant difference between the two GNRB® forces: 89 N vs. 134 N, $P = 0.07$.

3.4. Proportion of absolute T1-to-T2 variations ≥ 2.5 mm

A difference greater than 2.5 mm between the T1 and T2 measurements was significantly more common with TELOS™ (17/60, 28.3%) than with GRNB® 89 N (3/57, 5.3%) ($P = 0.0022$) (Table 2, Fig. 1).

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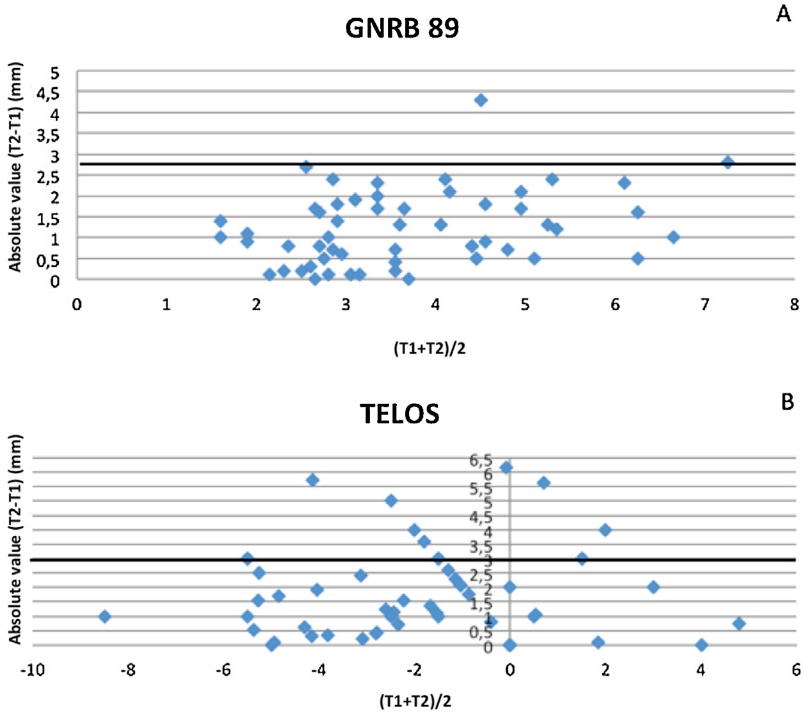

Fig. 1. Bland and Altman plot of the absolute variation from T1 to T2 against the mean of T1 and T2 values (panel A, GNRB® 89 N; and panel B, TELOS™). The probability of having a greater than 2.5mm difference between the T1 and T2 measurements was significantly greater with TELOS™.

Table 2
Numbers of patients with anterior tibial translation ≥ 2.5 mm and < 2.5 mm.

Device	≥ 2.5 mm	< 2.5 mm	Total (number of patients)
TELOS™	17	43	60
GNRB® 89 N	3	54	57

3.5. *Linear correlation analysis between anterior translation and patellar pressure with GNRB®*

No significant correlation was evidenced between patellar pressure and the T1-to-T2 variation in measured anterior translation ($P > 0.05$) (Fig. 2).

4. Discussion

We compared the reproducibility of anterior knee laxity measurements obtained in normal knees using the TELOS™ and GNRB®. We did not evaluate the diagnostic usefulness of these two devices.

With a posterior-anterior thrust force of 89 N, the risk of having a variation ≥ 2.5 mm between pre-operative and 6-month post-operative evaluations was significantly greater with the TELOS™ than with the GNRB®. However, the mean absolute variations from T1 to T2 were not significantly different between the two devices.

Beldame et al. [5] compared the GNRB®, TELOS™, and radiological technique described by Lerat but focussed on the side-to-side difference in tibial translation. Lefèvre et al. [8] compared the GNRB® to the TELOS™ but also used the difference between the injured and uninjured knees as their endpoint. Jenny et al. compared pre-operative GNRB® and stress radiographs to intra-operative computer-assisted navigation measurements of injured knees [9]. Studies of normal knees have compared the GNRB® to the KT-1000™ [10,11]. In a comparison of both normal knees of healthy volunteers, Collette et al. demonstrated better reproducibility with the GNRB® than with the KT-1000 [10] but used the mean values for all data from each knee. Bercovy and Weber [12] assessed the reproducibility of fluoroscopic laximetry with a dynamometer, by obtaining at least two measurements for each knee at a 9-month interval. However, they did not compare their findings to those obtained using non-radiological laximetry methods. Vauhnik et al. reported poor inter-observer reproducibility with the GNRB® and suggested that the reason might be difficulty in replicating patient position from one measurement to the next and to poor control of rotation during anterior tibial translation [13,14]. Thus, our work is original, as we found no published studies comparing GNRB® and TELOS™ on normal knees. All data were stored electronically and we had no missing data for any patient.

A limitation of our study is the small sample size, which may have precluded the detection of a significant difference between mean absolute variations. However, our sample size is in line with earlier studies of laximetry devices [15–18]. The variables used to compare the two populations also had similar values to those in earlier reports [13] and the two cohorts were statistically comparable. We obtained measurements of the uninjured knee, after excluding patients with a past history of knee abnormalities on that side, under the hypothesis that the physiological laxity of the tested knee would not change between the two measurement sessions, at T1 and T2. This hypothesis was not expected to be completely borne out, as ACL elasticity increases with physical activity and decreases with rest [19]. These changes are minimal and we therefore considered that our hypothesis was acceptable. The normal knee was tested before the injured knee, although we could have tested the two knees in random order.

We chose 2.5 mm as the cut-off for dichotomising the results. Lefèvre et al. [8] reported that a 2.5mm difference with the GNRB® suggested a partial ACL tear with 84% sensitivity and 81% specificity. Although validated in this study [8] for a thrust force of 250 N, a 2.5mm error might result in a false-positive diagnosis of partial ACL tear. With the TELOS™, Hyder et al. [16] found a difference of about 2.5 mm between the injured and uninjured knees.

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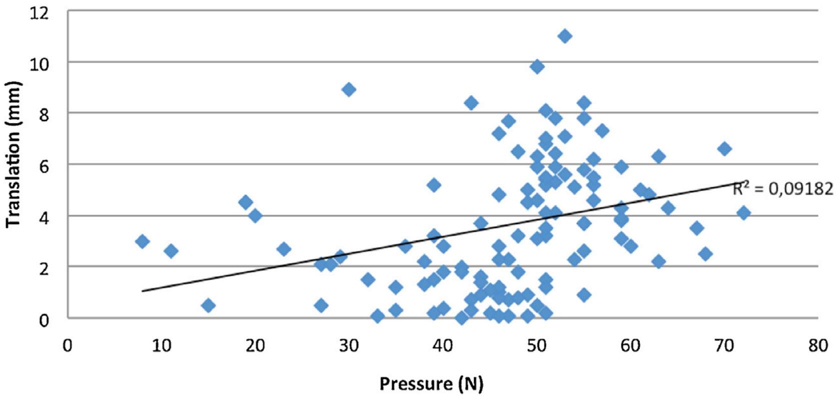

Fig. 2. Linear correlation analysis of patellar pressure and anterior tibial translation. The two variables showed no correlation ($P > 0.05$).

Comparing our results to previously published data is difficult, since studies comparing GNRB® to another laximetry system in normal knees by obtaining repeated measurements [10,11] pooled all the values for each knee and analysed the means. With the TELOS™ and 250 N to obtain two measurements of normal knees, Boyer et al. [4] reported that the variation was ≤ 1 mm in 25% of patients and ≤ 5 mm in 90% of patients. In our study, 72% of patients had variations < 2.5 mm.

The TELOS™ and GNRB® are fully independent from the operator regarding the execution of the test (which is not the case with KT-1000™, for instance [20]). The TELOS™ avoids the approximation related to the soft tissues [2,21] but exposes the patient to radiation and requires operator-dependent measurements on the radiographs. Thus, we measured the distance between the posterior aspect of the condyles and the posterior edge of the medial plateau [5,12], but the landmarks used have been described in many different ways [5] and may therefore vary across operators in everyday practice. In addition, minimal rotation of the femur may bias the analysis and the measurement of distances in millimetres on a radiograph exposed to magnification error.

The TELOS™ and GNRB® share with all laximetry devices a dependency on possible co-contraction of the quadriceps and hamstrings (which may decrease tibial translation) and on the degree of quadriceps tension [22]. TELOS™ has no biofeedback system for limiting hamstring contraction. GNRB® does have such a system, which can be left inactivated. Feller et al. reported that a biofeedback system to encourage hamstring relaxation increased the amount of anterior tibial translation (in normal, unstable, and stabilised knees), thereby improving measurement sensitivity, but did not affect the ratio of translations on the normal side and stabilised side [23]. We were unable to confirm this result, as we used the GNRB® without activating the biofeedback system.

The optimal patellar pressure when using GNRB® is unknown, and no recommendations are available for this parameter. We therefore arbitrarily chose a minimum value and a difference cutoff for patellar pressure. Excessive patellar pressure can induce either quadriceps and hamstring co-contraction or reflex or pain-induced quadriceps contraction. However, in our study, patellar pressure was not significantly correlated to anterior tibial translation. Studies are needed to determine the optimal patellar pressure value and the largest acceptable difference between two measurements.

We measured translation in response to similar thrust forces with the two devices: 9 kg with the TELOS™ and 89 N with the GNRB®. Lerat et al. also compared the KT 1000™ at 89 N to stress radiographs with a 9 kg load [24]. Hyder et al. compared the KT 1000™ at 89 N to the TELOS™ at 95 N [16]. In a study of the KT 1000™, Ranger et al. also used a thrust force of 89 N [22]. This value of 89 N may thus be the lowest possible force for using a laximetry system to diagnose ACL injuries [25]. Bercovy and Weber [12] stated that a thrust force greater than 180 N was needed to make a definite diagnosis of ACL tear but that 100 N was sufficient to detect a significant difference between the injured and uninjured sides. We could have used 150 or even 250 N [4,12,13,26]. However, a stronger thrust force is associated with a higher risk of reflex muscle contraction, which may be subclinical. As pointed out by Feller et al., anterior tibial translation during instrumental measurements may be influenced by operator-dependent factors (degree of knee flexion, knee/device alignment, and patellar stabilisation) and patient-dependent factors, such as muscle relaxation [23]. Increasing the thrust force decreases the false-negative rate (by increasing translation) while preventing reflex muscle contraction. Paradoxically, the increase in force is designed to overcome defence mechanisms (reflex contraction) but increases patient discomfort [4]. In their study of the GNRB®, Beldame et al. [5] were able to reach 250 N in only 133 of 157 (84%) patients because some patients reported unacceptable pain before reaching this value. Collette et al. reported no instances of GNRB® protocol discontinuation due to induced pain [10]. As our goal was to assess reproducibility, as opposed to diagnostic usefulness, we chose a value of 89 N. However, this value may be considered low and may, therefore, have prevented the detection of a significant difference, a fact that is among the limitations of our study. We obtained negative mean values with the TELOS™. The lateral decubitus position used for the TELOS™ assessment requires that the translation be maintained while the radiograph is taken. This causes greater patient discomfort, which may lead to uncontrolled co-contraction or reflex contraction, explaining the negative translation values.

Finally, with the GNRB®, we found greater translation at T2 than at T1. A single study, by Feller et al., showed that a first test measurement increased the amount of translation, although the difference was not statistically significant [23]. They did not believe that a learning effect on the patient influenced the translation values. However, we suggest that our findings may be ascribable to a learning effect and to a decrease in patient apprehension. To minimise any bias related to a learning effect, the effect of a non-recorded test measurement with thrust force values of up to 250 N performed on both knees before the first visit would have to be evaluated.

In conclusion, the GNRB® offers greater reproducibility than the TELOS™, requires no radiation exposure, allows the use of increasing thrust forces, and can be coupled with a biofeedback system to encourage hamstring relaxation. The GNRB® is thus a useful tool for the initial evaluation and follow-up of patients with ACL injuries. However, studies designed to determine the optimal device settings would be helpful. Special attention should be directed to the position of the knee and GNRB® during the assessments. We chose

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a thrust force of 89 N to decrease and limit the influence of reflex contraction, and our conclusions therefore apply only to this value.

Confirmation of our findings would require a prospective study comparing GNRB® and TELOS™ measurements on healthy knees with the GNRB® biofeedback system activated and a full series of test measurements at gradually increasing thrust forces when the patient first uses the device. Given that knee stability has not only an antero-posterior component, but also a rotational component, clinical knee testing remains crucial, and the development of systems for measuring rotational stability will add information to that obtained by instrumental analysis of anterior translation.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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